# Legal Lens

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## CDC SIGNS OFF ON UPDATED COVID-19 BOOSTERS

Brenda Goodman, *CNN*, September 1, 2022. https://www.cnn.com/2022/09/01/health/acip-cdc-updated-covid-booster/index.html

In early September, Dr. Rochelle Walensky, director of the CDC, approved an independent vaccine adviser's recommendation in favor of updated Covid-19 booster vaccines from Pfizer/BioNTech and Moderna. The updated boosters have been formulated to better protect against more recent variants of Covid-19 and may, "help restore protection that has waned since previous vaccination." The CDC emphasized that the decision followed a comprehensive scientific evaluation and, "robust scientific discussion." Pfizer/BioNTech's updated vaccine is a 30-microgram dose authorized for people 12 and older. Moderna's updated vaccine is a 50-microgram dose authorized for people 18 and older. An individual is eligible for the updated booster if they have completed all primary doses in the recommended vaccine series. Analyses of the cost-effectiveness of the boosters suggest potential savings of over $63 billion between August 2022 and March 2023 if as many people get these boosters as got flu shots during the 2021-22 season. At the time of publication, nearly two-thirds of the total U.S. population was vaccinated against Covid-19, though less than half with the initial series has also gotten a booster.

## JUUL TO PAY $438.5 MILLION IN SETTLEMENT WITH DOZENS OF STATES OVER MARKETING TO UNDERAGE PEOPLE

Jen Christensen. *CNN*, September 6, 2022. https://www.cnn.com/2022/09/06/health/juul-settlement-marketing/index.html

The e-cigarette manufacturer will pay over $438 million to 34 states and territories following a finding that the company deliberately marketed to young people, even though cigarette sales to children are illegal. The company marketed to young people by offering free samples, utilizing social media campaigns, and casting young actors in advertising campaigns. In addition to paying out the settlement, Juul's sales and marketing abilities will be restricted regarding people under 35. Additionally, in-store displays, as well as online and retail sales will be limited. Prior to this settlement, the FDA rebuked Juul for its marketing practices and ultimately ordered the company to stop selling its products, though a court blocked that ban. As the company works through the FDA's administrative appeals process, it continues to sell its products, though subject to the restrictions as described in the multi-state settlement. The states and territories involved in the settlement include: Alabama, Arkansas, Connecticut, Delaware, Georgia, Hawaii, Idaho, Indiana, Kansas, Kentucky, Maryland, Maine,

Mississippi, Montana, North Dakota, Nebraska, New Hampshire, New Jersey, Nevada, Ohio, Oklahoma, Oregon, Puerto Rico, Rhode Island, South Carolina, South Dakota, Tennessee, Utah, Virginia, Vermont, Wisconsin, and Wyoming.

## BIOTECH CO-FOUNDER, FACING MURDER-FOR-HIRE CHARGES, ACCUSED OF FABRICATING DATA

Joseph Walker, *The Wall Street Journal*, October 24, 2022. https://www.wsj.com/articles/biotech-co-founder-facing-murder-for-hire-charges-accused-of-fabricating-data-11666634272?page=1

Enochian BioSciences Inc. has sued co-founder Serhat Gumrukcu and his husband, Anderson Wittekind, for contractual fraud. Enochian claims that the company has suffered a substantial loss due to Gumrukcu providing them with altered and fabricated scientific data and is seeking $25 million in damages. The complaint alleges that Mr. Gumrukcu repeatedly gave the company falsified data for experiments related to research agreements to develop gene therapies for certain viruses, including hepatitis B and Covid-19. Allegedly, Gumrukcu sent the company data from lab experiments showing promising results of his drugs in mice. An internal review showed that he had given Enochian data showing his drug reduced hepatitis B DNA levels by 98.6% in mice, but original experiment data showed only a 25.1% reduction. Additionally, the suit states that Gumrukcu presented data to Enochian's board showing that his gene therapy prevented Covid-19 infection in mice, but the experiment had not been conducted at the time of Gumrukcu's presentation. The data triggered a series of milestone payments totaling $25 million, and allegedly Gumrukcu and Wittekind used the funds to help purchase an $18 million property in Los Angeles last year. An attorney for Gumrukcu did not respond to a request for comment about the lawsuit, and Wittekind denies the allegations, holding that the purchase was for commercial buildings used to support biotech and medical research.

## WITH PROMISE OF LEGALIZATION, PSYCHEDELIC COMPANIES JOUST OVER FUTURE PROFITS

Andrew Jacobs, *The New York Times*, October 25, 2022. https://www.nytimes.com/2022/10/25/health/psychedelic-drug-therapy-patents.html

With the increased interest in the potential of psychedelic medicine, there is a growing crowd of psychedelic medicine companies seeking to gain a financial edge through a blizzard of patent claims. One psychedelic medicine company valued at $450 million, Compass Pathways, is part of this fray. Being aggressive with its intellectual property filings, the company has filed over 100 patent claims asserting that the company's patent strategy was necessary to ensure that psilocybin therapy would one day be available to people across the globe. Compass Pathways claims it must raise hundreds of millions of dollars to conduct clinical trials at 150 sites in Europe and North America to accomplish this goal. This will convince private and government insurers to cover psychedelic therapies and that patents are often necessary to protect a company's investment in that process. However, scientists and patient advocates are scoffing patent claims like this by Compass Pathways and other companies, warning that trying to profit from psychedelic drugs like psilocybin, LSD, and ecstasy could deter academic research and

prevent public access to new therapies. With the potential to, "revolutionize the treatment of depression, substance abuse, post-traumatic stress disorder, and other mental health conditions," the debate about psychedelic-related intellectual property seems valuable. But, Robin Feldman, an expert on pharmaceutical intellectual property at the University of California Hastings College of Law, said this conflict is indicative of larger problems in our patent system, including some of the highest prescription drug prices in the world. She says, "With psychedelics, what we're seeing is a clash of cultures between the altruism of those who want to use existing compounds in new and exciting ways crashing up against the realities of the patent system."

## EMPLOYERS ARE CONCERNED ABOUT COVERING WORKERS' MENTAL HEALTH NEEDS, SURVEY FINDS

Michell Andrews, *Kaiser Health News*, October 27, 2022.
https://khn.org/news/article/kff-employer-health-insurance-survey/

In the wake of the Covid-19 pandemic, employers are grappling with a new "normal" where demand for mental health services has increased. In a survey of large employers — those with at least 200 workers — employers report a growing share of employees using mental health services. This increase includes use of services related to substance use, and requests for leave related to mental health conditions under the Family and Medical Leave Act. Employers have also reported high telemedicine usage among their employees. Recognizing this trend, many large employers have added mental health care providers to their plan's network, either in person or through telemedicine. Premium costs, however, have been "remarkably" stable; employers and economists speculate that the stability in premium costs is the "calm before the storm" of inflation and larger premium increases.

## CLOCK RUNS OUT ON EFFORTS TO MAKE DAYLIGHT SAVING TIME PERMANENT

Dan Diamond, *The Washington Post*, November 4, 2022.
https://www.washingtonpost.com/health/2022/11/04/permanent-daylight-saving-time/

The Sunshine Protection Act aims to, "permanently 'spring forward,'" but remains stalled in Congress after seven months as support remains staunchly divided. House officials say they have experienced an influx of split opinions from stakeholders like voters and sleep specialists over the nearly century-old practice. Congressman Frank Pallone, Chair of the House Energy and Commerce Committee, is wary of a "hasty change" followed by an equally hasty reversal. Stakeholders are divided on the issue. The "Big Sleep" lobby opposes the change, claiming it would disrupt entrenched sleep cycles; they are supported by the American Academy of Sleep Medicine who, in recent years, has significantly bolstered its lobbying spending. Jewish religious groups also oppose the change, claiming it would prevent them from conducting morning prayers after the sun rises and still get to work or school on time. Floridians, however, support the change because it would maximize sunshine for residents in the winter months. The White House has avoided taking a stance on this divided issue but conceded its influence on "matters of trade and health".

## HOSPITAL GIANT HCA FENDS OFF ACCUSATIONS OF QUESTIONABLE INPATIENT ADMISSIONS

Blake Farmer. *Kaiser Health News*, Novermber 4, 2022. https://www.washingtonpost.com/health/2022/01/30/nurses-fake-vaccination-cards-long-island/

U.S. Rep. Bill Pascrell and the Service Employees International Union have been pressing the Department of Health and Human Services to investigate allegations against HCA for potential Medicare fraud. The Centers for Medicare & Medicaid Services have said they are reviewing a letter from Pascrell that details the claims that HCA forced doctors to meet unofficial quotas, or targets, for the number of patients admitted to the hospital. A previously sealed whistleblower case is shedding new light on such internal policies. Pascrell's concerns stem from a 58-page investigative report from the SEIU published in February, estimating HCA overcharged the Medicare program at least $1.8 billion over roughly a decade through excessive admissions, according to the report. Dr. Camilo Ruiz, a whistleblower at a 400-bed HCA hospital in suburban Miami, accused the health system of threatening his job if he didn't admit more patients, instead of sending them home from the ER. Ruiz's attorneys used publicly available Medicare data to show that HCA hospitals nationwide routinely admitted patients for low-level illnesses such as abdominal pain, lower respiratory problems, dizziness, and nausea. Meanwhile, non-HCA hospitals sent patients with the same conditions home. At the 41 HCA hospitals with the highest admission rates, the attorneys found that from 2013 through 2016, 84% of Medicare patients were admitted for eight common diagnoses, compared with 55% at non-HCA hospitals. An HCA spokesperson refuted the accusations saying that the HCA, "categorically reject[s] any allegation that physicians admit patients to our hospitals based on anything other than their independent medical judgment and their patients' conditions and medical needs."

## MEDICARE ADVANTAGE OR JUST MEDICARE?

Paula Span, *The New York Times*, November 5, 2022. https://www.nytimes.com/2022/11/05/health/medicare-seniors-health.html?searchResultPosition=1

Researchers have found that Medicare Advantage plans performed better than fee-for-service Medicare on a few measures. Beneficiaries are more likely to use preventive services and vaccinations and to say they had "a usual source of care." Advantage plans provide numerous different plans to find the best individual coverage without need for a separate supplemental policy. Medicare Advantage may appear less expensive due to low or no monthly premiums and capping out-of-pocket expenses. Traditional Medicare beneficiaries experienced fewer affordability problems if they had supplementary Medigap policies and were more likely to use high-quality hospitals and nursing homes. In addition, there are no networks -- you can see any doctor that accepts Medicare and use any hospital or clinic while avoiding the delays and frustrations of "prior authorization." Consumers can switch between Medicare Advantage plans easily but switching from traditional Medicare to Advantage requires caution. Consumers using traditional Medicare typically also use Medigap policies, to cover the uncapped out-of-pocket expenses. Beneficiaries who have moved from

traditional Medicare with Medigap to Medicare Advantage and then seek to move back to traditional Medicare may not be eligible for another Medigap policy. "Determining the best Medicare plan, including a Part D drug plan, can be challenging. The best allies, along with Medicare's website and its toll-free 1-800-MEDICARE number, are the federally funded State Health Insurance Assistance Programs, whose trained volunteers can help people assess Medicare and drug plans."