

Legal Lens

Students from the Saint Louis University School of Law Center for Health Law Studies contributed the following items to this column. Amy N. Sanders, associate director, supervised contributions by Jessie Bekker (J.D., M.P.H. anticipated 2023) and Darian Diepholz M.B.A., M.P.H., (J.D. anticipated 2022).

FLORIDA TELEMARKETER CONVICTED IN GENETIC TESTING FRAUD SCHEME

A telemarketing call center owner in Florida was convicted after his agency made fraudulent calls to Medicare beneficiaries, claiming Medicare covered genetic testing to detect cancer risk. Ivan A. Scott, who owned Scott Global, was convicted January 8 on counts of conspiracy, health-care fraud, and paying and receiving kickbacks, the Department of Justice said, for his involvement in the \$2.8 million scam. After Medicare beneficiaries agreed to genetic testing, Scott sent bribes and kickbacks to telemedicine doctors who authorized tests for patients they never treated. Scott then sent doctors' orders disguised as marketing services to laboratories, also in exchange for kickbacks. Labs submitted \$2.8 million in fraudulent Medicare claims between November 2018 and May 2019, of which Medicare reimbursed more than \$880,000. Scott pocketed \$180,000. Genetic testing, which can cost up to \$6,000, is generally only reimbursed by Medicare for patients with a history of cancer.

Christopher Brown, *Bloomberg Law News*, Jan. 11, 2021, https://www.bloomberglaw.com/document/XDDQCOBS000000?bna_news_filter=health-law-and-business&jcsearch=BNA%252000000176f33ad345a777f33a32bf0001#jcite

SOME COVID SURVIVORS HAUNTED BY LOSS OF SMELL AND TASTE

Some COVID-19 survivors lose their senses of smell and taste. For a portion of those patients, those senses have yet to return. A *New York Times* piece on January 2, 2021 chronicled the struggles of some patients with anosmia, the scientific term for loss of smell, who are hindered from partaking in daily activities. Katherine Hansen, a Seattle, Wash. realtor, lost her sense of smell and taste in March, at the beginning of the pandemic, and still can't even bear the feeling of chewing food. Others like her have consequently worsening mental health, reporting diminished quality of life due to an inability to enjoy food and related pleasure, along with feelings of isolation, anxiety and depression. A short-term side effect may be nutritional deficiency and weight loss. Still others have experienced unpleasant phantom smells. Until COVID-19 started impacting olfactory senses, research in the field received little attention. Now, scientists are struggling to cure anosmia in COVID-19 patients and worry some may lose their senses of smell and taste permanently.

Rony Caryn Rabin, *The New York Times*, Jan. 2, 2021 <https://www.nytimes.com/2021/01/02/health/coronavirus-smell-taste.html>

IN MINORITY COMMUNITIES, DOCTORS ARE CHANGING MINDS ABOUT VACCINATION

Among those most resistant to the COVID-19 vaccine are Black and Hispanic Americans, who are also hardest hit by the pandemic. To help persuade them to vaccinate when the time comes, Black and Hispanic doctors are educating their families, friends and communities about the benefits of vaccination and dispelling myths. Dr. Zanthia Wiley, an infectious disease expert at Emory University in Atlanta, has traveled to her Alabama hometown to sit down with community members and discuss vaccination with those who worry vaccine efforts may be borne out of the government's historical experimentation on Black people. Wiley, however, says Black Americans like her should be among the first to receive vaccination. In addition to her hometown visits, Wiley is sharing messages on social media and through video chat. Dr. Valeria Daniela Lucio Cantos, also an infectious disease specialist at Emory, conducts virtual town halls, which she thinks are effective not just because she speaks Spanish, but because she is an immigrant. "Culturally, they have someone they can relate to," Cantos told the *New York Times*. Along with dispelling myths and misinformation, doctors are explaining the importance of vaccination on returning to normal living. Wiley said she believes conversations with experts may be key in shifting away from vaccination hesitancy among Black and Hispanic Americans.

Gina Kolata, *The New York Times*, Dec. 31, 2020, <https://www.nytimes.com/2020/12/31/health/coronavirus-black-hispanic-vaccination.html>.

WHY THE AMAZON, JPMORGAN CHASE, BERKSHIRE VENTURE COLLAPSED: "HEALTH CARE WAS TOO BIG A PROBLEM"

A joint health care venture between Amazon.com Inc., JPMorgan Chase & Co., and Berkshire Hathaway, Inc. will end February after three years of challenges. Named Haven, the joint venture sought to reduce health care costs for the three companies' combined 1.5 million employees. However, the \$100 million project struggled from the start with obtaining data and battled staff turnover and competition. For example, Haven struggled to estimate and establish explanations for their employees' medical costs, a major roadblock and one not unfamiliar in health care. A person from within Haven told *The Wall Street Journal* that "health care was too big a problem for us to solve." Others from within Haven said the three companies realized their goals would be better managed internally than through a partnership unless more companies or government agencies cooperated with the venture's goals. The venture also lacked bargaining power with health insurers and providers. JPMorgan CEO Jamie Dimon, whose idea it was to embark on the joint venture, was reported to be the only executive who actively participated in projects. While Haven employees worked to establish the venture, including setting up a virtual primary care service called Starfield, it faced competition from its own partners -- namely, Amazon set up a similar service called AmazonCare for its Seattle employees. Haven eventually shut down Starfield, the venture's head and Harvard University professor Dr. Atul Gawande stepped down. Lacking direction, Haven employees left their jobs or were laid off. Ultimately, industry experts and former staff say the three

companies, with their sprawling geographical reach and disparate corporate structures, were “an odd fit.”

Sebastian Herrera and David Benoit, *The Wall Street Journal*, Jan. 7, 2021,
<https://www.wsj.com/articles/why-the-amazon-jpmorgan-berkshire-venture-collapsed-health-care-was-too-big-a-problem-11610039485>

ILLINOIS IS FIRST IN THE NATION TO EXTEND HEALTH COVERAGE TO UNDOCUMENTED SENIORS

Illinois will allow low-income, noncitizen seniors to access publicly provided health insurance, the first state in the nation to offer public health insurance to undocumented seniors. Experts are hopeful Illinois’ decision will set the stage for other states to follow suit. The move is especially important during the COVID-19 pandemic, as uninsured immigrants often forgo health care for lack of coverage. The newly insured include undocumented legal permanent residents -- people who have had green cards for less than five years, who are typically left out of health insurance programs. Those recipients must fall below the federal poverty line and must be over 65. Illinois already covers organ transplants for undocumented immigrants and covers undocumented children, while California covers undocumented, low-income people 26 and younger. Federal law prohibits Medicare, nonemergency Medicaid, and Affordable Care Act marketplace coverage for undocumented people; states with coverage for the undocumented must cover services using state funding. The Illinois Department of Healthcare and Family Services estimates up to 4,600 seniors will gain coverage under the expansion.

Giles Bruce, *Kaiser Health News*, Jan. 7, 2021,
<https://khn.org/news/article/illinois-is-first-in-the-nation-to-extend-health-coverage-to-undocumented-seniors/>

HOW MIGHT A MASK MANDATE PLAY OUT? LOOK TO THE BATTLE OVER SEAT BELT LAWS

Advocates for mask mandates are looking to the past battles over seat belt and helmet laws, as well as failed mask mandates to decide how to move forward during the COVID-19 pandemic. In the 1950s, campaigns began for the U.S. to adopt legislation to enforce seat belt usage. Seat belt advocates were met with pushback from the car industry, who did not wish to have people focus on issues of safety in their products, and from fellow citizens who claimed these laws were attempting to “nanny” the people of the U.S. It took years of advocating before President Johnson signed legislation in 1966 to require seat belts in passenger cars. Beginning in 1984, states began passing seat belt mandates and the federal government provided extra highway funding to those with strict laws. Since then, seat belt usage has risen to 91% nationally as of 2019. The U.S. tried a similar route with motorcycle helmet laws, by requiring helmets in order to receive federal highway construction funds. However, in 1976 Congress dropped the requirement to receive funding and half the states reversed their helmet laws. Even with striking research on the benefits to safety, still only half of the U.S. have helmet mandates. These factors play into how the U.S. may attempt to create a mask mandate. In 1918, there was a mask mandate during the influenza epidemic, but with little research on its protective qualities, the mandate failed. Now, research shows masks reduce transmission of the virus. Currently, 33 states and D.C.

have mandates, but there is slow progress for mandates in other states that believe it is a personal responsibility and should not be a law. President-elect Joe Biden has spoken of his plan to speak with each state's officials about creating mask mandates, but researchers wonder if an act by Congress to regulate funds like the passing of seat belt laws will be needed. A study projected universal mask-wearing could save 130,000 lives in the U.S. by the end of February, showing the importance masks bring.

Joanne Silberner, *STAT*, Nov. 10, 2020,
https://www.statnews.com/2020/11/10/covid19-masks-mandate-seatbelt-laws/?fbclid=IwAR1eBct9ZBsDzbS9C30u0BYK8RCVQ5wZTq2r4o8K_JP2fYAJRmBeQdmy-iv

“EVERY DAY IS AN EMERGENCY”: THE PANDEMIC IS WORSENING PSYCHIATRIC BED SHORTAGES NATIONWIDE

In the U.S., 40% of adults have mental health conditions. A study completed in June 2020 found nearly 11% of adults surveyed had considered suicide in the last 30 days. Even with these numbers, the COVID-19 pandemic has decreased the availability of inpatient psychiatric beds across the country as facilities comply with social distancing or use beds for COVID-19 patients. States do not have the beds to help all those in need. Over the years, funding and beds have slowly decreased. A CEO for a Massachusetts behavioral network estimated the state had lost 300 psychiatric beds this past year. COVID-19 has only worsened the mental health problems already occurring. For example, governors are stopping admission to psychiatric hospitals, temporarily shutting them down when an employee tests positive for COVID-19. In addition, many hospitals have had to shut down their inpatient mental health units due to financial loss. This

backup has led to prolonged stays in the emergency room while staff attempt to place a patient in a psychiatric bed, some staying for longer than three days. Beyond beds, state governments have considered cutting mental health budgets during the pandemic, but the public's disapproval has halted any progress thus far. Researchers state many legislators are only looking at the virus and should pay attention to the mental health problems increasing during the pandemic that could cause major long-term effects. These researchers suggest this rise in mental health conditions should be treated as a part of the response to the COVID-19 pandemic and receive better funding for more beds and facilities to stay open.

Roger Rapoport, *STAT*, Dec. 23, 2020,
<https://www.statnews.com/2020/12/23/mental-health-covid19-psychiatric-beds/>

CHANNEL TO RESOLVE DRUG DISCOUNT DISPUTES UNDER EXECUTIVE REVIEW

Low-income health centers often rely on the federal drug discount program, 340B, to continue providing affordable health care to their patients. Under 340B, drug companies have to sell discounted products to these centers or be at risk for fines or their product being pulled from Medicare and Medicaid programs. However, 340B does not allow centers to sue companies if they feel they have been overcharged. Plus, companies state under the current rule they are not required to give discounts to pharmacies that are partnered with the centers. Now, there is a rule up for review with the White House's Office of Management and Budget that would provide a formal channel for centers to challenge drug charges. This rule was created after legal

demands from health centers were taken against the Department of Health and Human Services (HHS) for neglecting to add a dispute process to 340B. The issue is how to create a remedy. In 2016, HHS published a rule for a dispute process but was pulled after complaints it wasn't fair to companies. Thus, simply reviving the old proposal would not work. Further, another suit has been filed requesting that 340B entities be allowed to buy and distribute 340B drugs through their chosen pharmacies to settle the issue with companies not providing discounts to pharmacies associated with health centers. Thus, the dispute rule currently up for review is a good start to addressing the discount program, but it is unknown how this will affect the current lawsuits and address issues health centers are facing.

Jacquie Lee, *Bloomberg Law News*, Nov. 18, 2020, https://www.bloomberglaw.com/product/health/document/XFR0CR6G000000?criteria_id=d7733c3ad614beb9ced66554d13b2b68&searchGuid=73610411-641b-4adf-b320-a23138320918&bna_news_filter=health-law-and-business

PURDUE WINS APPROVAL OF \$8.3 BILLION U.S. OPIOID SETTLEMENT

In November 2020, a bankruptcy judge approved the settlement between Purdue Pharma and the Justice Department for \$8.34 billion. The settlement required Purdue to plead guilty to three felonies over their marketing

and distribution of OxyContin. The judge also approved a \$225 million payment to the Justice Department from the Sackler Family, who owns Purdue, for civil charges. This settlement was opposed by many, including almost 24 states. The judge urged Purdue and states that opposed to go through mediation for the next month to resolve any open issues over Purdue's claims against the Sacklers and Purdue's plans for restructuring once the company emerges from Chapter 11. Purdue's intent is to come out a public-benefit company, including a resolution from the case that ensures Purdue takes action towards combating the opioid crisis. Purdue will end up only paying a fraction of the \$8 billion settlement, with fines and penalties being paid off at less than 1 cent on the dollar. At the hearing, the federal government agreed to a substantial discount, meaning states and local governments throughout the country will be able to get a bulk of Purdue's assets instead of the Justice Department. Purdue is currently trying for a broad framework that will settle thousands of claims from states and more for their role in fueling the opioid crisis. The Sacklers have offered to cede the company to creditors while paying another \$3 billion. This proposal requires court approval.

Jonathan Randles, *The Wall Street Journal*, Nov. 17, 2020, <https://www.wsj.com/articles/purdue-gets-chapter-11-approval-of-justice-department-opioid-settlement-11605655666>