

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.H.A. anticipated 2023) and Darian Diepholz (M.B.A., M.P.H., (J.D. anticipated 2022)).

BIDEN PATENT OFFICE PICK WILL SHAPE FIGHT OVER HIGH DRUG PRICES

The next director of the U.S. Patent and Trademark Office (PTO) could influence the future of drug pricing, and drug companies are sharing their opinions as President Biden makes his selection. While generic drug manufacturers are calling for patent invalidation in hopes it lowers drug costs, backers of patent protections argue that stronger protections will lead to greater innovation. The Patent Trial and Appeal Board, which reviews approved drug patents, has been reviewing fewer patents annually since fiscal year 2015 — down from 130 that year, to twenty in fiscal year 2020. Industry experts argue those proceedings help differentiate novel ideas from monopolies. The conversation comes at a pivotal point in the national drug debate, as government officials work to increase access to COVID-19 treatments. Biden has shown support for lowering drug prices, including by way of an executive order issued in July. A new PTO director could be especially influential in removing barriers to invalidating “secondary

patents,” patents which cover production methods and drug formulations when a drug’s original patent has expired, thereby extending the drug’s patent and keeping generics off the market. Some lawyers, meanwhile, are hoping for an improved patent approval process, which they argue would give examiners more time to review patent applications to sort out the good from the bad.

Ian Lopez, *Bloomberg Law News*, July 30, 2021.
https://www.bloomberglaw.com/product/health/bloomberglawnews/health-law-and-business/XF9TUHIS000000?bc=W1siU2VhcmNoICYgQnJvd3NlliwiaHR0cHM6Ly93d3cuYmxvb21iZXJnbGF3LmNvbS9wcm9kdWN0L2hiYWx0aC9zZWYy2gvcmlVzdWx0cy8wZDVmZTE5ODE5ZTFiYjM1ODBiNjE4MjA1NzQxYmJlZiJdXQ-2090a116df81dc2b6fb1452720f3056b0fec694c&bna_news_filter=health-law-and-business&criteria_id=0d5fe19819e1bb3580b618205741bbef

PHARMA GETS FDA CLARITY ON ‘INTENDED USES’ OF APPROVED PRODUCTS

The Food and Drug Administration has issued a new rule which defines how drug companies can market products for off-label uses. FDA rule RIN 0910-AI47 states that the agency can reference “any relevant source of evidence” in determining whether a product is used as intended. The rule, while intended to clarify how drug makers can communicate about off-label uses to consumers, does not require

changes to labeling. It does, however, allow manufacturers to sell their products without including language on product labels if used for an “unapproved purpose.” The rule allows manufacturers to sell drugs and medical devices without approval for a new “intended use” designation.

Ian Lopez, *Bloomberg Law News*, July 30, 2021.
https://www.bloomberglaw.com/product/health/bloomberglawnews/health-law-and-business/X86HNVBS000000?bc=W1siU2VhcmNoICYgQnJvd3NlIiwiaHR0cHM6Ly93d3cuYmxvb21iZXJnbGF3LmNvbS9wcm9kdWN0L2h1YWx0aC9zZWFiY2gvcmlvZdWxOcy8wZDZmZTE5ODE5ZTFiYjM1ODBiNjE4MjA1NzQxYmJlZiJdXQ-2090a116df81dc2b6fb1452720f3056b0fec694c&bna_news_filter=health-law-and-business&criteria_id=0d5fe19819e1bb3580b618205741bbef

A CALIFORNIA BILL WOULD LIMIT PROTESTS AT VACCINATION SITES. DOES IT VIOLATE THE FIRST AMENDMENT?

A new California bill would make it illegal to harass, intimidate, obstruct, or injure people waiting to get vaccines of any kind outside a vaccination site. The bill, written by Sen. Richard Pan (D-Sacramento), a pediatrician, would make the offense punishable by up to \$1,000 and/or six months in jail. Pan himself has been subject to harassment by anti-vaccine protesters and wants to protect patients from the same. The bill passed in the state Senate and will head to vote in another committee before the state Assembly reviews it. First Amendment proponents say the bill goes too far in defining harassment to include protest or distribution of materials within 30 feet of a patient. UCLA law professor Eugene Volokh called it “clearly

unconstitutional,” arguing that a court would strike down a 30-foot buffer. Volokh also argued that banning specifically anti-vaccine content would violate First Amendment protections. The American Civil Liberties Union has said it supports the bill as written.

Rachel Bluth, *Kaiser Health News*, August 9, 2021.
<https://khn.org/news/article/a-california-bill-would-limit-protests-at-vaccination-sites-does-it-violate-the-first-amendment/>

CALIFORNIA LAWMAKERS PUSH FEDS TO ALLOW A THERAPY THAT PAYS METH USERS TO ABSTAIN

California’s Senate unanimously passed a bill which authorizes Medicaid funding for contingency management, a program which pays people for their sobriety. The tool, used consistently by the Department of Veterans Affairs, is backed by research but rarely used by providers, who fear they’ll violate anti-kickback laws by paying their patients. California’s bill would treat 1,000 individuals for the price tag of \$179,000 annually. Medi-Cal, California’s Medicaid program, would need federal approval to operate the therapy. Over a dozen organizations have lobbied the Department of Health and Human Services (HHS) to waive anti-kickback regulations as it relates to the program. A spokesperson for the HHS Office of the Inspector General said contingency management programs would be evaluated case-by-case. The VA is virtually immune from the rule, because it pays for the therapy from its departmental budget. The therapy works best for those dependent on stimulants,

including methamphetamines and cocaine. No two organization might approach it the same way — at the VA, participants choose slips out of a fishbowl, where over 200 slips are worth \$1, and one slip is worth \$100. At a program in San Francisco, participants are given gift cards worth \$300 to \$400 for participating in the program for 12 weeks.

Mark Kreidler, *Kaiser Health News*, July 2, 2021.
<https://khn.org/news/article/california-lawmakers-push-feds-to-allow-a-therapy-that-pays-meth-users-to-abstain/>

THE HEALTH 202: TEXAS IS CUTTING RED TAPE FOR DOCTORS AND PATIENTS

A new Texas law will strip prior authorization requirements for doctors with a history of insurance approvals. The law, which takes effect September 1, allows doctors to skip the approval process for providing a medication or procedure if ninety percent of their orders were granted by insurers in the last six months. It is a change welcomed by physicians, who have battled with insurers to give their patients timely treatment. According to the American Medical Association, ninety-four percent of physicians report delays in patient care due to prior authorization, and another thirty percent say the requirement has led to adverse effects on patient health and safety. Meanwhile, insurers fear the new law is a gateway to fraud. The Texas Association of Health Plans argued that physicians should have to meet approval requirements for more than ninety percent of orders before being able to bypass prior authorization requirements. Insurance advocates also worry the law will put patient safety at risk, as prior authorization requirements operate as stopgaps to opioid

overprescribing. There is limited research to show whether prior authorization requirements impact health care spending.

Alexandra Ellerbeck and Paige Winfield Cunningham, *The Washington Post*, July 26, 2021.
<https://www.washingtonpost.com/politics/2021/07/26/health-202-texas-is-cutting-red-tape-doctors-patients/>

CONTROVERSY FLARES OVER INFORMING RESEARCH SUBJECTS ABOUT 'INCIDENTAL' GENETIC FINDINGS

A recent study published by the National Institutes of Health (NIH) suggests research participants should be informed of incidental findings that uncover genetic risks for conditions that can be prevented or treated. Incidental findings are unrelated disease mutations that turn up in sequence data that researchers were testing, such as genes that boost cancer risk. In current studies, participants must opt-in to receive results on incidental findings. In a large NIH study, an initial 83 participants (only 1.9% of total participants) refused to receive incidental findings, but 41 changed their mind after learning they would only receive results that raised the risk of serious conditions that were preventable or treatable. Based on the number of participants who wished to know the incidental findings, some have suggested that studies should change to an opt-out system, with initial informed consent given to receive results and allow active refusal. These results could be lifesaving, causing one to take preventative steps. However, there is more that must be analyzed before an opt-out system can be in place. The NIH study found Black

participants were significantly more likely than others to refuse results. Researchers have called for more research to be completed on “why participants refused and how we use information from the study to figure out an ethically informed way to handle secondary findings.” Others have stated that automatic return could be “a bridge too far.” At this time, the bioethical analysis of the opt-out system continues as more studies are beginning to provide incidental findings.

Meredith Wadman, *Science*, August 2, 2021.
<https://www.sciencemag.org/news/2021/08/controversy-flares-over-informing-research-subjects-about-incidental-genetic-findings>

V.A. ISSUES VACCINE MANDATE FOR HEALTH CARE WORKERS, A FIRST FOR A FEDERAL AGENCY

The Department of Veteran Affairs (VA) will be the first federal agency to mandate employee vaccination for Covid-19, as 115,000 frontline health care workers must be vaccinated in the next two months. The Secretary of the VA states he is doing this because “it’s the best way to keep our veterans safe.” The mandate requires workers who are “the most patient-facing,” such as doctors and nurses, be vaccinated or face penalties. While over 70 percent of workers in VA health care centers are vaccinated, that is not enough to ensure the risk of danger to veterans is gone. VA workers will be able to appeal the mandate for medical or religious reasons. The trend towards vaccination requirements goes beyond the VA as New York municipal workers must be vaccinated by the time school reopens, and California state employees and on-site public and private health care workers are also

mandated to be vaccinated. Further, recent court decisions have supported employers' right to mandate vaccines.

Jennifer Steinhauer, *The New York Times*, July 26, 2021.
<https://www.nytimes.com/2021/07/26/us/politics/veterans-affairs-coronavirus-covid-19.html>

THE HEALTH 202: OKLAHOMA IS THE FIRST STATE TO POCKET EXTRA NEW MEDICAID DOLLARS

It has been one year since Oklahomans voted to amend the state constitution to expand Medicaid, making it the 39th state to expand. The American Rescue Plan, signed by President Biden, allows states in return for expanding Medicaid, to receive an additional 5 percent increase in federal payments for Medicaid enrollees. This means Oklahoma will get an increase of \$860 million in federal funds for the next two years. Oklahoma will be the first to start benefit from this incentive. Missouri could receive even more money (\$1.15 billion).

Paige Winfield Cunningham and Alexandra Ellerback, *The Washington Post*, July 1, 2021.
<https://www.washingtonpost.com/politics/2021/07/01/health-202-oklahoma-is-first-state-pocket-extra-new-medicare-dollars/>

COLORADO MAKES DOXXING PUBLIC HEALTH WORKERS ILLEGAL

Doxxing is the practice of sharing a person’s information, like physical address or phone number. Due to increased harassment during the pandemic, Colorado has made it illegal to dox public health workers and their families. This act has been commonly used among law

enforcement personnel, but recently health care workers have had their property vandalized or received death threats and harassing phone calls after information was posted online. The bill's sponsors found it imperative that healthcare workers be able focus on their work and not dealing with threats amidst the pandemic. Now, violators can receive up to 18 months in jail and a \$5,000 fine. Doxxing is not a federal crime, but states have taken similar steps to prohibit this act against law

enforcement offices or judges and prosecutors. Some states have discussed bills that would completely prohibit doxxing against anyone. While there is support for these new protections, some remind authorities the process of identifying perpetrators and hold people accountable will be difficult.

Anna Schaverien, *The New York Times*, May 19, 2021.
<https://www.nytimes.com/2021/05/19/us/colorado-doxing-law.html?searchResultPosition=9>