

# Legal Lens

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## COLLEGES' OPENING FUELED 3,000 COVID CASES A DAY, RESEARCHERS SAY

Researchers from the University of North Carolina-Greensboro, Indiana University, the University of Washington, and Davidson College, have looked at the effects of colleges that opened in the fall amidst the COVID-19 pandemic. The study assessed reopening programs for 1,400 colleges, cross referencing with county infection rates from July 15 to September 13, 2020. The study found that classes taught in person were associated with a 2.4 rise in daily cases. Many schools experienced a fear of spikes in cases similar to the situation at the University of Illinois where 2,0000 cases were reported on campus in the first month students returned. However, the researchers are quick not to blame the school reopening plans or student behavior, but want to continue research and figure out the best practices regarding how to respond. The study will examine whether the surge is related to students arriving at campus with COVID-19 versus contracting it at school, and look at how responses at different schools have decreased the spread. Also, the researchers plan to assess the study's estimate of an increase of 3,000 in daily cases from schools opening to

see the true linkage between case rise and colleges to become better prepared for the spring semester, and present some best practices on how schools may mitigate the spread.

Michael McAuliff, *Kaiser Health News*, Sept. 23, 2020, <https://khn.org/news/colleges-opening-fueled-3000-covid-cases-a-day-researchers-say/>

## JUDGE HALTS TRUMP'S ROLLBACK OF TRANSGENDER HEALTH PROTECTIONS

U.S. District Court Judge Frederic Block halted Trump's policy to rollback Obama-era anti-discrimination protections for transgender patients just one day before it was to take effect due to the recent Supreme Court ruling in June 2020 that LGBTQ are protected against discrimination in the workplace for their sexual orientation under the Civil Rights Act of 1964. In his opinion, Block stated the decision came three days after the health department finalized these rollbacks, yet the HHS was not sensible enough to reflect on how this decision may impact their policy. There have already been five lawsuits against the new Trump rule, and Block claims plaintiffs challenging this rule are likely to succeed. Advocacy groups are relieved for the halt in policy, as they fear it would create new challenges for transgender patients amongst the COVID-19 pandemic. It should be noted that the Obama rules have also been stalled in court for a separate litigation, so this decision to halt Trump's policy will change little at this time.

Susannah Luthi, *Politico*, Aug. 17, 2020, <https://www.politico.com/news/2020/08/17/judge-trump-rollback-transgender-health-397332>

## FDA WILL ALLOW STATES TO IMPORT DRUGS FROM CANADA

The Trump administration released a rule allowing states, as well as some pharmacists or wholesale distributors, to import some prescription drugs from Canada. The requirements state the plan does not pose any additional safety risks and must save consumers money. Under the rule, the Food and Drug Administration must approve each plan. It should be noted that imported drugs will not be subject to Medicaid rebates. There is a question whether importing drugs would save states significantly compared to the rebates given from the Medicaid Rebate program. The FDA has issued guidance to assist companies with importing approved prescription drugs from Canada. Once published on the Federal Register, this rule would go into effect after 60 days.

Michael Brady, *Modern Healthcare*, Sept. 24, 2020, <https://www.modernhealthcare.com/policy/fda-will-allow-states-import-drugs-canada>

## CORONAVIRUS TESTS ARE SUPPOSED TO BE FREE. THE SURPRISE BILLS COME ANYWAY.

Amidst the COVID-19 pandemic, people worried about the cost of testing for the virus and Congress attempted to address that worry by enacting two laws. *The Families First Coronavirus Response Act* states that insurers could not charge co-payments or apply deductibles to the tests and other services during the doctor's visit. The *CARES Act* added to the previous requirements by claiming that insurers' out-of-network coronavirus tests must be covered at no cost to the patient. However, these laws are not doing what they promised. People are still hit with

unexpected fees or denied claims for testing. About 2.4 percent of tests billed to insurers are still being held at the patient's expense, which is a lot considering the 77 million tests performed thus far. While this seems like insurance companies are violating the law, companies blame it on medical billing. If the hospitals or doctor's offices do not place the right billing codes, the insurance company cannot flag the items to be covered under the new laws. However, it is more than that. Insurance companies are attempting to find loopholes in the laws. For example, it is silent on how much an insurer must pay to an out-of-network facility or whether they must cover other tests related to obtaining the coronavirus test. Currently, there is a call to create clear federal guidance, so insurers aren't left interpreting what is covered and patients aren't left receiving unexpected bills.

Sarah Kliff, *The New York Times*, Sept. 9, 2020, <https://www.nytimes.com/2020/09/09/upshot/coronavirus-surprise-test-fees.html>

## A CORONAVIRUS VACCINE WON'T CHANGE THE WORLD RIGHT AWAY

The quest for a vaccine for COVID-19 is not a get-out-of-jail free card. Health researchers claim that the vaccine will not create an off switch to take us back to the times before the pandemic. Politicians and companies seem to be giving the population an unrealistic belief of how the vaccine will affect our lives. It should be noted that it takes weeks for the immune system to build up antibodies after a vaccination. Therefore, people cannot immediately take off their masks after leaving the doctor's office. However, companies are worried about a loss in belief once the vaccine rolls out. There may be people who still get sick and this could

create a false impression it does not work. A successful vaccine does not mean it must vanquish the virus but may decrease the severity of symptoms, both of which are positive outcomes. Professionals compare COVID-19 vaccination to HIV/AIDS, where the first generation of medications was mediocre. Similar to phases of reopening, vaccines must occur in gradual phases to be safe and could go back steps before going forward, as we learn more. Another example is the polio vaccine, where cases dropped 80% over two years, but the outbreak continued for several more years after. It must be understood that it may take years to vaccinate enough people to make the world safe. Currently, the U.S. regulators require the COVID-19 vaccine to be 50% effective before it can be released, as decided by the estimate needed to establish herd immunity. The population needs to understand as we move forward not to lose hope of a vaccine helping but be realistic about the time and effort that will be needed to decrease the spread. Adequate research, development, and time for the vaccine can allow us to create herd immunity and slowly move past this pandemic.

Carolyn Y. Johnson, *The Washington Post*, Aug. 2, 2020, <https://www.washingtonpost.com/health/2020/08/02/covid-vaccine/>

### COVID VACCINE TRIALS MUST WEIGH EFFECTS ON BOTH MEN AND WOMEN, RESEARCHERS SAY

Biotechnology companies researching a COVID-19 vaccine are not segregating adverse effects data by sex, which at least one biochemist says will keep doctors from knowing whether men and women respond to vaccine dosages differently. Early research shows COVID-19 symptoms differ by sex — men die at higher

rates than women — while women respond better to the annual flu vaccine. “I don’t want to make this a women’s health issue — it benefits all people if we analyze data by sex,” biochemist Nicole Woitowich said. Conversely, some infectious disease experts argue such data segregation likely will not show a sex-related difference in vaccine effects, and such data segregation rarely occurs, though that trend may be rooted in research biases toward Caucasian men, others argued. The National Institutes of Health, which is funding the vaccine trial by biotechnology company Moderna, said testing was in Phase 1, and such data segregation would likely occur during Phase 3 testing, when the sample size is larger.

*Modern Healthcare*, Aug. 1, 2020, <https://www.modernhealthcare.com/safety-quality/covid-vaccine-trials-must-weigh-effects-both-men-women-researchers-say>

### SCAM ALERT: THINGS A COVID CONTRACT TRACER WOULDN’T SAY

Scammers are now posing as COVID-19 contact tracers looking to obtain bank and credit card information, state and federal officials say. The Montana Attorney General warned that scammers typically say, “I’m calling from your local health department to let you know that you have been in contact with someone who has COVID-19” before seeking payment information. Officials warn that contact tracers will not request such information. Instead, contact tracers seek the names of those with whom a COVID-19 patient has been in contact, including friends and neighbors, to request the patient and their contacts quarantine themselves. Contact tracers generally ask for identify verification to protect health information and may send a text message prior to making a phone call. Most

contract tracers work for health departments. Public health experts also advised consumers to take down a name and phone number for the caller and call back after researching that information.

Julie Appleby, *Kaiser Health News*, Aug. 20, 2020, <https://khn.org/news/scam-alert-things-a-covid-contact-tracer-wouldnt-say/>

### **PREMERA BLUE CROSS TO PAY SECOND-LARGEST HIPAA FINE TO OCR**

Premera Blue Cross will owe a \$6.85 million fine to the Office of Civil Rights (OCR) for a HIPAA violation, the second-largest in history. Premera Blue Cross, a Washington-based insurer, will have to pay for a 2014 data breach in which hackers, using a phishing email, installed malware on the company's information

system, compromising the data of 10.4 million people. Premera did not notice the attack for nine months until January 2015 and reported it in March 2015 to OCR, an agency within the Department of Health and Human Services. A subsequent investigation showed the company did not institute risk management and audit procedures. HHS will monitor Premera's HIPAA compliance for two years and Premera must create a corrective action plan. The settlement is second only to one paid by Anthem in 2018 for \$16 million stemming from a data breach that impacted 79 million people.

*Modern Healthcare*, Sept. 25, 2020, <https://www.modernhealthcare.com/cybersecurity/prem-era-blue-cross-pay-second-largest-hipaa-fine-ocr>