

# Legal Lens

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## DEMOCRATIC WIN AND THE RELENTLESS BACKING OF THE ACA

House Democrats passed legislation with flying colors on May 9th - a vote of 230 to 183 - to reverse the Trump Administration's October 2018 regulation that loosened waiver eligibility requirements, allowing for the creation of health plans with more limited coverage; plans that did not comply with the Affordable Care Act (ACA) provisions mandating coverage of pre-existing conditions. This was a big win for Democrats in the House, but they didn't stop there -- they had a total of 12 bills to be voted on over the next 2 weeks of May; all measures that represent Speaker Nancy Pelosi's policy agenda as she aims to improve our current system, as opposed to making more sweeping proposals such as the single-payer "Medicare for all" plan supported by others in the Democratic party. There is a political purpose behind all of this action, as Democrats push to capitalize on the issues surrounding healthcare policy with the 2020 election looming in the not-so-far-off future, and also to possibly divide congressional Republicans, who continue to back the preservation of protecting those with pre-existing conditions or chronic disease despite the actions of the Administration. The other measures up for a vote are intended to

build on the ACA system, which include funding to make signing up for coverage more accessible, several measures to decrease drug costs and increase access to biologics, new disclosure requirements for prescription drug rebate programs, and new reinsurance payments to offset expensive insurance claims and lower health care premiums. More specifically, one of these bills would eliminate the Trump Administration's rule that expanded the 3-month time limit to 3 years for short-term limited-duration insurance (SLDI) plans - plans intended for gaps in coverage, not as a long-term plan. Despite the lack of state waiver applications, this rule still serves as a major threat to the functionality of the ACA as an estimated 1.6 million health care consumers could opt out of the marketplace in exchange for the SLDI plans. In the grapple between affordability of coverage and sustainability of the marketplace, it will be interesting to see how Americans with pre-existing conditions are protected moving into election season with the Trump Administration making its opposition to the ACA clear earlier this month in Texas Federal Court of Appeals and with Democrats disagreeing internally on pushing for "Medicare for all" versus improving the ACA.

Glenn Thrush, *The New York Times*, May 9, 2019  
<https://www.nytimes.com/2019/05/09/us/politics/democrats-health-trump.html>

## BIPARTISAN EFFORTS TO ELIMINATE SURPRISE PATIENT BILLS

In an effort to lower healthcare costs, Senators Lamar Alexander (R-Tenn.) and Patty Murray (D-Wash) released the details of a massive piece of legislation, which they anticipate moving through the health committee in June, and hopefully into law by the end of July. This legislation would impact nearly every area of the healthcare industry, including billing, prescription drugs, transparency, public health, and health information. One of the big takeaways is the plan to eliminate surprise medical bills: bills that are received following a patient being treated outside of their insurance network; bills that are also often unexpected and pricey. The Senators' idea behind this is to mandate an "in-network guarantee," which means that a hospital considered "in-network" must ensure that all those that work there are also in-network – this includes all doctors and the lab and/or diagnostic testing services. This portion of their proposal sits alongside a number of efforts to end surprise billing in the House; however, this legislation also addresses other important issues. It tackles the prescription drug pricing by focusing on patent protections instead of attempting to regulate prices – making it more difficult for brand name drugs to maintain exclusive patents long-term, allowing for generics to more easily enter the market. It also addresses the transparency of pharmacy benefit managers (PBMs) by proposing they be assigned reporting requirements, especially in regards to information about rebates (discounts drugmakers offer to PBMs in exchange for their drug being covered under a health plan) and then all discount information must be available to consumers. The size and breadth of this legislation will make it a challenge to pass,

but it carries with it some weight – being a bipartisan package created by a chairman and a ranking member of the Health, Education, Labor and Pensions Committee.

Rachel Bluth, *Kaiser Health News*, May 23, 2019  
<https://khn.org/news/sen-alexander-releases-bipartisan-plan-to-lower-health-costs-end-surprise-bills/>

## THE FIRST OF MANY OPIOID TRIALS BEGINS IN OKLAHOMA

Johnson & Johnson (J&J) is the sole target of the nation's first opioid-liability trial, with Oklahoma Attorney General, Mike Hunter, claiming their 'illegal' marketing campaigns and 'greed for more sales' aided in creating the deadly epidemic now facing the state. Specifically, Hunter is accusing the company, through its Janssen unit, of convincing doctors to overprescribe their products – a fentanyl-based patch and opioid pain-killing pill - for unapproved ailments, and targeted at youths, then contributing to the wave of addictions and fatal overdoses. Hunter has linked more than 4,600 Oklahoma resident deaths occurring between 2007 and 2017 to J&J's illegal marketing, while J&J's lawyer claims these allegations are both false and misleading being that their products only accounted for 1% of the state market. Although Oklahoma's lawsuit is the first to go to trial, it is one of more than 1,600 that have been filed by U.S. government bodies against drugmakers and distributors. Each lawsuit is claiming company responsibility and seeking damages in order to address the outlay of tax dollars spent on dealing with this public-health crisis. Oklahoma will most likely be asking for approximately \$13 billion in damages and penalties in order to cover the 20 years of J&J's impact; the outcome of this case

and the damages reached will likely impact other claims and settlement talks all over the countries.

Jef Feeley, *Bloomberg*, May 28, 2019  
<https://www.bloomberg.com/news/articles/2019-05-28/j-j-s-greed-helped-spawn-opioid-epidemic-in-oklahoma-ag-argues>

### IMMUNIZATION LAWS CONTINUE TO FACE PARENTAL RESISTANCE

The argument over infringing on individual liberties vs. protecting population health echoed in the Washington state legislator after 71 of its residents had fallen ill to measles earlier this year, most of them being unvaccinated children. State Representative, Paul Harris (R) sponsored a measure to limit exemptions for vaccinations – claiming many people are misinformed in regard to their safety and the number of actual injuries resulting from vaccines. Specifically, the measure would only allow medical exemptions to vaccination instead of the current medical, philosophical or personal, and religious exemptions. This was met with strong resistance from groups claiming it to be an attack on their parental rights and religious freedom. This year, New York and Maine have been the only states to successfully outlaw all exemptions except medical ones, which have also been met with public protest – even in New York where 80% of the nation’s measles cases are concentrated. The Washington legislator ended up only passing the elimination of the personal beliefs’ exemptions, not religious due to the political pushback. The U.S. is currently faced with the worst measles outbreak in 25 years, with over 1,00 confirmed cases spreading across 28 states. There is consensus among medical experts and

a majority of Americans that supports routine childhood vaccinations and agrees that vaccines prevent epidemics, save lives, and are very safe – with complications only occurring in rare cases. Where the problem lies is within the individual communities that use these vaccination exemptions – unvaccinated children are concentrated here, making them more susceptible to an outbreak.

Roni Caryn Rabin, *The New York Times*, June 14, 2019  
<https://www.nytimes.com/2019/06/14/health/vaccine-exemption-health.html>

### THE REGULATORY ACCOUNTABILITY ACT OF 2017 IMPOSES SUBSTANTIAL REQUIREMENTS ON RULE MAKING

The proposed Regulatory Accountability Act of 2017 would substantially revise the 1946 Administrative Procedure Act, a law that established rules for federal agency regulation, to impose onerous requirements on rule making. The proposed bill increases procedural requirements for rulemaking by expanding the extent to which businesses or other interested parties could intervene in the rulemaking process and imposes prohibitions on agencies from explaining how new regulations are beneficial. The bill promotes “formal rulemaking,” an expensive and cumbersome procedure, where anyone could petition the agency to conduct a trial-like hearing for proposed major or high-impact rules, which include most health and safety regulations. While the proponents of the bill claim that it will minimize unnecessary regulatory burdens that harm the economy, it is likely that this Act will make rule-making time-consuming and costly, inhibit agencies from responding to emergencies and new scientific evidence,

and deprive the public from formal guidance on rules.

Jonathan J. Darrow, Erin C. Fuse Brown, and Aaron S. Kesselheim, *New England Journal of Medicine*, Dec. 20, 2017, <https://www.nejm.org/doi/full/10.1056/NEJMp1711643#t=article>

### MISSOURI'S ONLY ABORTION CLINIC CAN STAY OPEN—FOR NOW.

A total of 58 new abortion restrictions have been signed into law this year – the most covered ones being in Alabama, Georgia, and Missouri – among the seven states, banning the procedure in very early stages of pregnancy, often too early for a woman to know she's pregnant. Abortion has become an extremely contentious issue around the nation with many states approving stricter limits and abortion-opponents discussing the reversal of *Roe v. Wade* more rigorously, since the U.S. Supreme Court maintains a more conservative tilt. Missouri's law bans abortion after 8 weeks of pregnancy, with no exceptions for rape or incest, has stood without legal challenge, and is scheduled to take effect August 28<sup>th</sup>. Paired with Missouri's new abortion ban is their attempt to shut down the state's only abortion clinic, Planned Parenthood. The Missouri state health department has been in a licensing dispute with the clinic, but legal protection was extended both in state court and by an official in the Administrative Hearing Commission, allowing the clinic to stay open with another hearing set for August 1<sup>st</sup>. The health department is claiming deficiencies in clinical outcomes, citing evidence of a procedural complications, while the clinic has stated that their complication rate is less than 1%, in line with the national average. Although the clinic is

currently open, its future remains an uncertainty – and if it were to be closed, Missouri would be the first state in 45 years to completely lack access to abortion services for women.

Sabrina Tavernise & Timothy Williams, *The New York Times*, June 28, 2019 <https://www.nytimes.com/2019/06/28/us/missouri-abortion-clinic.html>

