

[The World's Best-Selling Drug Just Lost a Key Patent Battle](#)



Fortune [is reporting](#) that AbbVie's Humira, the best-selling drug on the planet with a staggering \$14 billion in 2016 sales, has lost a key patent battle with a prospective rival product by the small biotech Coherus Biosciences.

Reporter [Sy Mukherjee](#) explains that "The rheumatoid arthritis and psoriasis medicine has recently been a target of biopharma companies that are trying to make generic Humira copycats called 'biosimilars.' That's not surprising given both Humira's market reach and the steep price of the brand name medication – which has a list price of about \$4,500 for a set of two syringes before discounts and rebates, making it a prime target for cheaper alternatives."

Humira sales make up more than 60 percent of AbbVie's revenues.

[Read the Fortune article.](#)

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[U.S. Accuses UnitedHealth of Medicare Advantage Fraud](#)

The U.S. Justice Department has accused UnitedHealth Group Inc. of obtaining inflated payments from the government based on inaccurate information about the health status of patients enrolled in its largest Medicare Advantage Plan, [Reuters is reporting](#).

The accusation against the company is the latest, following separate lawsuits in two separate whistleblower lawsuits against the country's largest health insurer.

"Medicare Advantage, an alternative to the standard fee-for-service Medicare in which private insurers manage health benefits, is the fastest growing form of government healthcare, with enrollment of 18 million people last year," writes reporter [Nate Raymond](#).

A UnitedHealth spokesman said the company rejects the claims and will contest them vigorously.

[Read the Reuters article.](#)

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[Big Law Widow Awarded \\$3M in GlaxoSmithKline Case](#)

The widow of a partner at the Reed Smith law firm won a \$3 million verdict Thursday in a lawsuit against a pharmaceutical company that she blamed for her husband's suicide, reports [The Chicago Tribune](#).

"Wendy Dolin's husband, Stewart, stepped in front of a CTA Blue Line train in the Loop on July 15, 2010. He had been taking paroxetine, a drug for depression and anxiety, and his widow claimed in her lawsuit that GlaxoSmithKline failed to warn her husband's doctor of the drug's increased risk of suicidal behavior, leading to his death," writes reporter [Grace Wong](#).

GlaxoSmithKline's defense was that Dolin was taking a generic version of Paxil, manufactured by another company. But the judge hearing the case released the maker of the generic, saying it had no control of the drug's label.

[Read the Tribune article.](#)

[Health Law: Is Your](#)

Arbitration Agreement Enforceable?

A recent decision of the Arizona Court of Appeals provides guidance for evaluation of the enforceability of arbitration agreements in the health care field, reports Snell & Wilmer in its [Health Law Checkup](#) blog.

[Andrew Sniegowski](#) explains that *Gullett v. Kindred Nursing Centers West, LLC* arose out of the plaintiff's claims that a rehabilitation center had abused and neglected his father, who lived there for the last month of his life. The plaintiff argued that the arbitration agreement was substantively and procedurally unconscionable.

The court determined that the agreement was substantively valid, but it remanded the case for further proceedings in the trial court limited to the issue of procedural unconscionability.

[Read the article.](#)

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How States Are Using the Law

to Bring Drug Executives to Heel



Image by
[Images Money](#)

The generic drug industry has come under fire the last couple of years because of staggering price increases, but now generic drug executives can expect to face tougher legal repercussions, [reports MedCity News](#).

The efforts come in the wake of a 500 percent hike in the generic price of the EpiPen and the 5,400 percent jump in the price of Daraprim for the treatment of potentially deadly parasite infections, writes [Johanna Mayer](#).

In November 2016, Heritage Pharmaceuticals Inc. sued two of its former executives, Jeffrey Glazer and Jason Malek, using the Racketeer Influenced and Corrupt Organizations Act (RICO). And in December 20 states sued six companies, including Heritage, after a major antitrust investigation by the state of Connecticut.

“Experts predict that these diverse types of lawsuits could ignite a legal domino effect,” Mayer writes. “They also suspect that, as cases like these develop, they’ll expand to touch multiple prongs of the pharmaceutical industry, such as wholesale manufacturers and pharmacies.”

[Read the MedCity News article.](#)

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[Veteran Healthcare Lawyer Joins Barnes & Thornburg in South Bend](#)

[Robert A. Wade](#), who has counseled healthcare institutions for more than 25 years, has joined [Barnes & Thornburg LLP](#)'s South Bend office as a partner in the Healthcare Department.

Wade represents large health systems, hospitals, ambulatory surgical centers, physician groups, physicians and other medical providers on a variety of legal issues.

"We are excited to have Bob join Barnes & Thornburg, as he brings a tremendous wealth of experience," said Laura Seng, chair of the firm's healthcare department. "The healthcare industry has undergone numerous changes in recent years and will continue to evolve. Bob's addition to our healthcare team will provide clients with important counsel on critical issues they face."

Wade has experience with matters involving the Stark Law, Anti-Kickback Statute, False Claims Act, and Emergency Medical Treatment and Active Labor Act, the firm said in a news release. Additionally, he counsels clients in developing, monitoring and documenting effective healthcare compliance programs. He also represents healthcare clients being investigated by the U.S. Department of Justice and the Office

of Inspector General. Currently, he serves as Compliance Expert to the Board of Commissioners of Halifax Health, a hospital system in Daytona Beach, Florida, advising on all aspects of their Corporate Integrity Agreement.

The release continues:

Wade joins the firm's national healthcare group that advises all types of providers on complex regulatory issues related to Medicare and Medicaid compliance, adherence to state and federal licensure regulations, and the impact of the Affordable Care Act, among other issues.

He is a frequent speaker at national and regional healthcare legal, compliance and regulatory conferences. He has been recognized on The Best Lawyers in America and Indiana Super Lawyers lists for his work in healthcare law since 2009. He serves on the editorial advisory boards for Strategies for Health Care Compliance and for the Report on Medicare Compliance.

Wade earned his J.D., summa cum laude, from The Ohio State University Moritz College of Law, where he served as the managing editor for The Ohio State University Law Journal and was a member of the Order of the Coif and Omicron Delta Kappa. He received his bachelor's degree, summa cum laude, from Bowling Green State University.

Federal Appeals Court Sides

With Physicians in 'Docs vs. Glocks' Case



The 11th U.S. Circuit Court of Appeals ruled Thursday that Florida's so-called "Docs and Glocks" law, which prohibited doctors from asking patients about guns in the home, violated a physician's free speech rights, reports [The Atlanta Journal-Constitution](#).

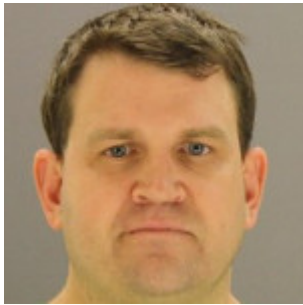
"The 10-1 decision said the other three elements of Florida's 2011 Firearms Owners' Privacy Act were unconstitutional: the ban on asking patients about guns in the home, writing down their answers, and harassing patients," writes [Rhonda Cook](#).

"In an effort to prevent and reduce firearm-related deaths and injuries, particularly to children, the American Medical Association 'encourages its members to inquire as to the presence of household firearms as a part of childproofing the home and to educate patients to the dangers of firearms to children,'" the ruling said.

[Read the *Journal-Constitution* article.](#)

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Doctor Guilty of Felony for Botched Surgery; Prosecutors Said His Hands Were Deadly Weapons



A day after a Dallas jury found a neurosurgeon guilty of intentionally crippling an elderly woman he operated on, a string of his former patients and co-workers testified in his sentencing trial, [reports *The Dallas Morning News*](#).

Christopher Duntsch of Colorado has been in jail since his arrest in July 2015, charged with five aggravated assault charges after four of his patients were maimed and two died between July 2012 and June 2013, reports [Claire Ballor](#).

“His trial focused only on a first-degree felony charge: injury to an elderly person. Mary Efurd was 74 years old in 2012 when Duntsch promised to fix her back pain but instead damaged her spinal cord and amputated part of a nerve,” writes Ballor.

[Read the *Dallas News* article.](#)

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Bill in Texas Legislature Would Give Nurse Practitioners More Power



A bill in the Texas House seeks to end regulations that require nurse practitioners to contract with doctors in order to treat and write prescriptions. The proposal, HB1415, would give nurse practitioners (NPs) in Texas the freedom and flexibility they have been seeking for decades, reports [Androvett Legal](#)

[Media & Marketing](#).

It also would cut costs for both patients and providers, according to attorney [Bill Hopkins](#) of the Austin office of [Shackelford, Bowen, McKinley & Norton, LLP](#).

“From the start, there has been a fundamental tension between their role and the role of the physician in the health care setting,” says Hopkins, who advises both individual and institutional health care providers on matters involving administrative law, regulatory defense and litigation. “No one has ever questioned that the physician is at the top of the pyramid. But over the years there has been some question as to whether there was some room at the top for the nurse practitioner who can drastically improve access to care.”

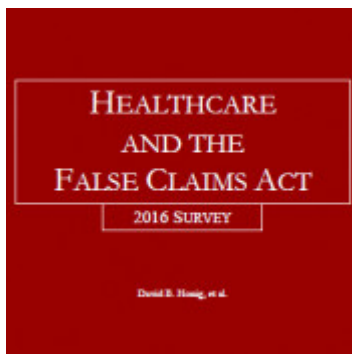
Currently NPs must complete four years of nursing school and two years in a graduate-level training program. Although they are regulated by both the Texas Board of Nursing and the Texas Medical Board, regulations require a doctor to supervise – even if the physician is not physically present and does not even see the patient, says Hopkins. Similar regulations have been rolled back in other states, with no evidence of increased safety issues, he says, adding that in some studies,

nurse practitioner safety has ranked as high or higher than doctor care.

“For many years, NPs have argued that their knowledge, ability and training were more than sufficient to allow them to practice independently, care for patients and ensure safety,” he says. “The justification for charging NPs for this ‘supervision’ traditionally has been that it is a necessary cost to ensure patient safety. But thanks to the Affordable Care Act, there are more people with insurance than ever before and access has become a primary concern. With the safety argument becoming less relevant and calls for better access getting louder, it looks like this may be the time for NPs to finally get the independence that they have sought.”

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[Healthcare and the False Claims Act, 2016 Survey](#)



Healthlaw Publishing announces the upcoming release of [Healthcare and the False Claims Act, 2016 Survey](#). Registration is available now for free downloading of the survey report.

Healthcare and the False Claims Act, 2016 Survey summarizes

the important laws, regulations, pronouncements, and cases of the past year, to inform healthcare providers and healthcare attorneys on this crucial statute in the healthcare industry.

On Dec. 14, 2016, the United States Department of Justice announced the recovery of more than \$4.7 billion in False Claims Act (“FCA”) settlements and judgments. It was the third-highest total in history, and more than \$2.5 billion came from the healthcare industry. During the eight years of the Obama Administration, the Department of Justice recovered more than \$31 billion in FCA settlements and judgments, taking more than \$19.3 billion from healthcare providers and other participants in the healthcare industry.

2016 was a pivotal year for the FCA. It was the year of a tremendously important Supreme Court decision that could expose healthcare providers to whole new areas of FCA liability based upon state and federal regulations. The penalties were more than doubled to a minimum of more than \$11,000 per claim and a maximum of more than \$22,000 per claim, massively increasing both the risk of litigation and the likelihood of settling FCA cases even in the absence of wrongdoing. And it saw a new focus on the investigation and even the criminal indictment of individuals involved with entities sued under the FCA. 2016 also saw new regulations and new court interpretations of laws first put in place in 2009 and 2010 to turbocharge the FCA and encourage greater participation by whistleblowers.

[Download the survey report.](#)

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[Judge Blocks \\$54 Billion Anthem-Cigna Health Insurance Merger](#)

A federal judge blocked the \$54 billion merger between health insurance giants Anthem and Cigna, saying the deal would increase prices and reduce competition, according to a report by [The Washington Post](#).

[Carolyn Y. Johnson](#) reports that this ruling is the second recent court decision to uphold the Justice Department's opposition to deals that would have consolidated the five largest insurers in the United States into three companies.

"The evidence has also shown that the merger is likely to result in higher prices, and that it will have other anticompetitive effects: it will eliminate the two firms' vigorous competition against each other for national accounts, reduce the number of national carriers available to respond to solicitations in the future, and diminish the prospects for innovation in the market," U.S. District Judge Amy Berman Jackson wrote in a 12-page order.

In the merger agreement, Anthem had agreed to pay Cigna a \$1.85 billion termination fee if the deal is blocked because of regulatory interference.

[Read the Washington Post article.](#)

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Painful Verdicts for Johnson & Johnson



In 2016, two federal juries in Dallas delivered significant verdicts on behalf of the victims of serious medical complications caused by defective metal-on-metal hip implants made by Johnson & Johnson and its subsidiary DePuy Orthopaedics Inc., [according to a post](#) by the plaintiffs' legal counsel, [The Lanier Law Firm](#).

Although the court has reduced the amount of punitive damages awarded by the juries in each case, and those judgments are under appeal by The Lanier Law Firm, the two verdicts still total almost \$700 million in actual and punitive damages assessed against Johnson & Johnson and DePuy.

In the post, the firm said these verdicts marked the second and third bellwether trials among thousands of similar lawsuits nationwide that have been consolidated in multidistrict litigation (*MDL 3:11-md-0244*) in the U.S. District Court for the Northern District of Texas. A bellwether trial is one that is typically representative of all the issues involved in the litigation of a mass tort case.

[Read the article.](#)

2016 HIPAA Year in Review: Audits, Fines, and Enforcement Trends

The logo features the word "HIPAA" in a large, bold, blue sans-serif font. Below it, the text "Health Insurance Portability and Accountability Act" is written in a smaller, lighter blue font.

Health Insurance Portability
and Accountability Act

Compliancy Group will present a [complimentary webinar](#) examining the major breaches and fines that made 2016 the most expensive year on record for HIPAA fines and enforcement.

The event will be Wednesday, Jan. 25, at 2 p.m. Eastern time.

HIPAA experts at Compliancy Group will analyze the causes of these breaches, the reasons for these substantial fines (almost \$24 million in total), trends in compliance, and what to expect from OCR investigations in 2017.

[Register for the webinar.](#)

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Obamacare Repeal: 18 Million Lose Insurance, Premiums Soar: Report



Image by [LaDawna Howard](#)

[NBC News is reporting](#) that about 18 million people would lose or drop their health insurance in the first year after Obamacare is repealed, the Congressional Budget Office reported Tuesday.

“The nonpartisan federal agency also found that health insurance premiums would spike another 20 to 25 percent, according to the new report. Within 10 years, 32 million more people would be without health insurance, the CBO projects,” writes Maggie Fox.

The report’s projections are based on the repeal law passed in the House of Representatives last year, using a budget-based process called reconciliation, the same process that Congress is working on now.

[Read the NBC article.](#)

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[A Chicago GC's Journey From Mortgages to Medical Marijuana](#)

It turns out a law degree is just as helpful in launching a medical marijuana business as it is dealing with mortgages, according to a report in [The Chicago Tribune](#).

Charlie Bachtell, CEO and co-founder of medical marijuana company Cresco Labs, was general counsel at Chicago-based mortgage company Guaranteed Rate before he moved into the legal cannabis business, reports [Ally Marotti](#).

In a question-and-answer session, he discusses how he decided to switch fields, the stigma that can be attached to his new business, securing financing, and growing the business.

[Read the Chicago Tribune article.](#)

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[Trial Lawyer Jay Old Joins](#)

Texas-based Hicks Thomas LLP



Veteran trial lawyer Jay Old has joined commercial litigation firm [Hicks Thomas LLP](#) where he will continue to represent construction, insurance, petrochemical and health care companies as part of his client portfolio.

Old's addition will add offices in Austin and Beaumont. Old joined the firm effective Jan. 1.

"We are thrilled to be adding Jay and his team. He's an exceptional lawyer with an outstanding track record," said John B. Thomas, name partner and firm co-founder. "Many of us have known Jay for years, dating back to our days together at Andrews Kurth."

Old's clients include refineries, construction contractors, manufacturers, hospital systems and insurers. Joining him is labor and employment lawyer Jim Henges, along with four other lawyers from Old's firm.

"I like to say I represent the job creators," Old said. "I'm very excited to be joining the Hicks Thomas team, and hope to add to its reputation as a premier trial firm."

Old is a frequent speaker at continuing education programs for lawyers across the country. He also is a former president of the Texas Association of Defense Counsel and has chaired the Construction Law Section of the State Bar of Texas.

He has defended national clients in statewide and regional mass tort litigation, in toxic torts, construction and product liability cases. He also successfully defended insurance companies in a series of high-profile trials involving hailstorm claims in Galveston and elsewhere.

Old is Board Certified in Personal Injury Trial Law by the Texas Board of Legal Specialization and has been recognized on the Texas Super Lawyers list every year since 2005. A native of Beaumont, he is a graduate of Texas A&M University and the Texas Tech University School of Law.

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[Obamacare Replacement May Look Like Existing Law, Without Mandate](#)

It's hard to predict exactly what President-elect Donald Trump wants in a new health care law, but a repeal of the Affordable Care Act (ACA) is rapidly on track in Congress, according to a report published on the website of [Androvett Legal Media & Marketing](#). Dallas health care lawyer [Jeff Drummond](#) of [Jackson Walker LLP](#), who represents doctors, hospitals and other health care facilities, has some predictions about what to expect:

“Repeal is almost entirely certain, and will be near immediate with the new Congress. It will be done using the same reconciliation technique that allowed ACA to pass in the first place, thus avoiding the filibuster and the need for 60 votes in the Senate.

“The changes likely will be phased in over time, with very few, if any, immediately repealed. That will allow the new Congress time to fashion replacement parts. And those

replacement parts will mostly resemble the old law.

“For example, the new law will allow insured parents to keep their children on their policies until age 26. It also will likely preserve the ban on lifetime limits.

“The new law will drop the individual mandate to buy health insurance. But coverage for pre-existing conditions will be more like the portability requirement under the Health Insurance Portability and Accountability Act (HIPAA). That law requires insurers to accept people with existing health problems only when they previously had coverage, such as from their current or former employer. So people with pre-existing health conditions now covered under individual policies through the ACA would be eligible for coverage under the new law, but individuals who did not previously have coverage would be subject to potential exclusion for pre-existing conditions.”

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[**Judge Halves Jury's \\$1 Billion Punitive Damages Award in J&J Hip Implant Case**](#)

Johnson & Johnson won a ruling cutting almost in half a \$1.04 billion jury award to patients who accused the company of hiding defects in its Pinnacle artificial hips that had to be surgically removed, [reports Insurance Journal](#).

The jury's finding that officials of J&J and its DePuy unit failed to properly warn doctors and patients about the artificial hips' flaws is intact. But U.S. District Judge Ed Kinkeade in Dallas found the panel's punitive-damage awards to six patients were excessive and should be reduced, according to court filings.

"J&J still faces almost 9,000 lawsuits accusing the company of illegally marketing the flawed metal-on-metal hips. J&J stopped selling the devices in 2013 after the U.S. Food and Drug Administration toughened artificial-hip regulations," according to reporter [Jef Feeley](#).

[Read the *Insurance Journal* article.](#)

[If Republicans Repeal Health Law, Paying For A Replacement Could Be Tough](#)



Leading Republicans in Congress have vowed that even if they repeal most of the Affordable Care Act early in 2017, a replacement won't hurt those now receiving benefits, [reports NPR](#).

Reporter Julie Rovner writes that Republicans will seek to ensure that "no one is worse off," quoting House Speaker Paul

Ryan. “The purpose here is to bring relief to people who are suffering from Obamacare so that they can get something better.”

“But that may be difficult for one big reason: Republicans have also pledged to repeal the taxes that Democrats used to pay for their health law. Without that money, Republicans will have far less to spend on whatever they opt for as a replacement.” writes Rovner.

[Read the NPR article.](#)

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[Nation's Largest Freestanding ER operator Shedding Executives](#)

The president and chief operating officer of Texas-based Adeptus Health is the latest executive out the door at the nation's largest operator of freestanding emergency facilities, [reports *The Dallas Morning News*](#).

Graham Cherrington is the second executive to leave the embattled company suddenly in recent months, following a disappointing \$11.7 million loss in third quarter. He follows longtime chief executive officer Thomas Hall, whose retirement was accelerated to November, writes reporter [Sabriya Rice](#).

“The company went public with its freestanding emergency room

model in June 2014, and now operates more than 90 facilities across the United States. In 2015 it generated \$365 million in revenue," she writes. "Shares plummeted in November following the disappointing loss and an unexpected request to secure \$27.5 million in emergency financing from investors."

[Read the *Dallas News* article.](#)