

# Register for the Healthcare Enforcement Compliance Institute



The Healthcare Compliance Institute is scheduled for Oct. 29-Nov. 1 in Washington, DC.

The event will give participants the opportunity to go beyond legal analysis, learn how to implement systems that ensure the law is followed, and gain practical advice from experts in a one-of-a-kind forum where lawyers and compliance officers work together, according to the Health Care Compliance Association.

Some of the topics to be covered include:

- Are We Ineffective at Assessing Compliance Program Effectiveness or Are Industry and Government Using Different Standards?
- Handling a Criminal Healthcare Fraud Case
- Tips and Tools for Mitigating CMS Enforcement Actions
- Using Data and Statistics to Defend Against Health Care Enforcement
- Your Company Has Been Served with a Civil Investigative Demand: Now What?
- Managed Care Fraud Enforcement & Compliance

[Register or get more information.](#)

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# Massive California Verdict Expands J&J's Talc Battlefield



Image by [Open Grid Scheduler / Grid Engine](#)

Reuters [is reporting](#) that a massive California verdict in a lawsuit alleging Johnson & Johnson's talc-based products cause cancer has opened a new front in the litigation.

"The \$417 million award by California jury to a California resident suggested so-called forum-shopping, in which parties seek to file cases in whichever jurisdictions seem most favorable, may not be the main problem facing J&J as it wrestles with some 4,800 outstanding talc lawsuits," according to reporter [Tina Bellon](#).

Previous talc cases, all tried in the same state court in St. Louis and involving out-of-state plaintiffs, totaled \$307 million.

[Read the Reuters article.](#)

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## [Big Pharma's Tobacco Moment as Star Lawyers Push Opioid Suits](#)

Big Pharma is having a Big Tobacco moment as litigation over opioids attract star lawyers and a growing list of states and local governments seeking their own multibillion-dollar payout to deal with costs of a burgeoning drug epidemic, reports [Bloomberg Law](#).

Six states have sued opioid makers, alleging they have created a public health crisis.

“Plaintiffs’ lawyer Joe Rice, a plaintiff lawyer who helped negotiate a \$246 billion settlement with the tobacco industry in 1998, suggests states are laying the groundwork to force a resolution that provides billions of dollars to cover the costs of an epidemic blamed for 62 deaths per day,” explain Jef Feeley and Jared S. Hopkins.

[Read the Bloomberg article.](#)

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# Defense Lawyer: Shkreli Would Lose \$65 Million If Convicted



Image by [OversightandReform](#)

A defense lawyer says former pharmaceutical CEO Martin Shkreli would lose a \$65 million stake in a drug company he founded if he's convicted at his securities fraud trial, reports the Associated Press through [ABC News](#).

The lawyer told jurors that a drug company official who testified against Shkreli was biased because the company would benefit financially if Shkreli is convicted of a felony.

"Shkreli is best known for raising the price of a life-saving drug by 5,000 percent and trolling his critics," the AP reports.

[Read the article.](#)

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# Buchalter Adds Three New Health Care Litigators in Los Angeles

Buchalter announces that Andrew “Andy” Selesnick, Damaris L. Medina, and Suzanne Cate Jones have joined as shareholders in the Health Care Practice Group in Los Angeles. Selesnick and Medina joined the firm from Nixon Peabody, and Jones joined from Theodora Oringer.

A release from the firm continues:

Selesnick and Medina have successfully litigated a number of high-profile health care cases, many in the health care reimbursement arena. Their clients range from physicians and physician groups to hospitals and urgent care centers, pharmacies, dentists, and elective surgery centers. Selesnick and Medina also defend providers in government investigations for fraud and abuse, and routinely represent health care providers in complex business disputes. Both Selesnick and Medina were recipients of a California Lawyer of the Year (“CLAY”) award earlier this year for their California Supreme Court victory in *Centinela Freeman Emergency Medical Associates v. Health Net of California, Inc.* (2016) 1 Cal. 5th 994 where they successfully argued that Health Plans may be liable to providers of emergency services for negligently delegating their financial responsibility to IPAs.

Jones regularly advises and represents hospitals, medical staffs, and health systems in litigation involving a range of health care areas, including medical staff and peer

review, antitrust, medical privacy/security breach, complex business and commercial contracting disputes, health regulatory issues, business torts, and the Federal False Claims Act. Jones also has successfully litigated and resolved health care related class action matters on behalf of hospital clients, including in the areas of medical privacy/security breach and unfair business practices, and is experienced in defending other types of putative class action lawsuits brought against corporate clients, including in the areas of wage/hour, consumer credit reporting, product liability and antitrust.

“Expanding our Health Care Practice is, and has been a priority for our firm. Andy, Damaris, and Suzanne are not only well-known and accomplished litigators, but also valuable assets to both our Health Care and Litigation Practices,” said Adam J. Bass, President and Chief Executive Officer of Buchalter.

Selesnick is currently a member of the California Society for Healthcare Attorneys, Health Care Law Section of the Los Angeles County Bar Association, and the American Cancer Society Race for the Cure. He earned his J.D., at the University of San Diego School of Law, and his B.A. at the University of California, Santa Barbara.

Medina serves as the Treasurer and on the Board of Directors for the Urgent Care Association of America, serves on the Board for the California Urgent Care Association, and is a member of the Los Angeles County Bar Association, Health Care Law Section, and the California Society for Health Care Attorneys. She earned her J.D., cum laude, at Suffolk University Law School where she earned a certificate in International Law, with distinction, and was also a member of Phi Delta Phi International Legal Honor Society. She earned her B.A. from Tufts University.

Jones has served on the board of the Health Law Committee

for the California State Bar. She is also a member of the American Health Lawyers Association; American Bar Association, Health Law Group; and the Los Angeles County Bar Association, Litigation, and Health Care Law Sections. She earned her J.D. from Loyola Law School, Los Angeles where she was an editor of the International and Comparative Law Journal, her B.A. in History, Certificate in Russian Studies from the University of Southern California, and completed Russian Studies at the Pushkin Institute in Moscow, Russia.

“The addition of Andy, Damaris, and Suzanne is very complimentary to the transactional health care and life sciences work we are known for,” added Carol Lucas, Chair of Buchalter’s Health Care Practice Group. “We are thrilled to welcome the newest members of our team, and delighted to offer their impressive capabilities to our clients.”

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## [Pharmaceutical Company Celgene Settles Suit for \\$280 Million](#)

The [Associated Press](#) is reporting that Celgene Corp. has agreed to pay \$280 million to settle a whistleblower lawsuit alleging the pharmaceutical company committed fraud promoting

a drug with a notorious history that was re-purposed to treat leprosy and another therapy for unapproved cancer treatments.

The agreement, announced by federal prosecutors, came out of a lawsuit filed by a former Celgene saleswoman who said Celgene submitted false claims to Medicare and health care programs in 28 states and Washington, D.C.

“The lawsuit filed by Beverly Brown was brought on behalf of the U.S. government under a federal whistleblower law. She could receive as much as \$84 million as her share of the settlement,” writes Brian Melley.

[Read the AP article.](#)

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## [After N.F.L. Concussion Settlement, Feeding Frenzy of Lawyers and Lender](#)

Some former NFL players are receiving pitches for legal help in receiving checks from the league’s legal sports history aimed at retirees who sued for lying about the dangers of concussions suffered by the players.

[Ken Belson](#) of [The New York Times](#) writes, “Some players may get very little, but others with severe neurological diseases may



receive as much as \$5 million. Now lawyers, lenders and would-be advisers are circling, pitching their services and trying to get a cut of the money.”

Some of the ex-players with severe neurological disorders are cognitively impaired and may not understand the terms used by the lawyers who make the pitches.

[Read the NYT article.](#)

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## [Potential Medicaid Cuts Put Savings of Middle-Class Elderly at Risk](#)

The health care bill the U.S. Senate is fine-tuning could have profound effects on elderly people who rely on nursing home care, says Houston-area elder law attorney [Kelley Bentley](#) of [Roberts Markel Weinberg Butler Hailey PC](#). Bentley is board certified in estate planning and probate law by the Texas Board of Legal Specialization.

*“The bill proposes large cuts to federal Medicaid support over several years with reliance on states to decide funding in the future. In Texas, nearly 70 percent of nursing home residents are enrolled in Medicaid.*

*“While many people may assume the program pays solely for health care for the poor, it also fills a gap for long-term care, including at-home and nursing home care for the elderly*

population. The cost of long-term care in the U.S. can be substantial and a serious drain on an individual's assets. That includes middle-class retirees who sometimes have managed to save substantial assets. Some people simply outlive their savings for long-term care.

“Older people should take a hard look at their savings long before any health problems. Consider a long-term care savings plan or long-term care insurance and also talk to a lawyer about how to organize and protect assets. In Texas, long-term care Medicaid programs can provide a wide range of care, including nursing home, assisted living and at-home programs. The secret is to start to plan early, before the need arises as there are more options available for the preservation of assets. The goal is not necessarily to preserve assets for future generations, but to ensure that an individual (or married couple) has sufficient assets to cover any future long-term care needs.”

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## [Ex-WellCare General Counsel Pleads Guilty in Florida Medicaid Case](#)

Reuters [is reporting](#) that an ex-general counsel of insurer WellCare Health Plans Inc. pleaded guilty on Wednesday in federal court in Tampa to having made a false statement to

Florida's Medicaid program, prosecutors said, the latest former executive to be convicted in the case.

Thaddeus Bereday, indicted along with four other former WellCare executives in 2011, faces a maximum of five years in prison.

"Bereday's plea came after the U.S. Supreme Court in April declined to hear an appeal by former WellCare Chief Executive Todd Farha of his fraud conviction for his role in a scheme to cheat the Medicaid health insurance program for the poor," writes reporter [Nate Raymond](#).

[Read the Reuters article.](#)

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## [HIPAA 101: The 30-Minute Guide to Understanding Compliance](#)



Compliance Group will present a free webinar on HIPAA compliance, titled "[The 30-Minute Guide to Understanding Compliance.](#)"

The event will be Tuesday, June 27, at 2 p.m. EDT.

In this webinar, the goal is to break down HIPAA compliance by walking you through the Regulation since the moment it was enacted in 1996, Compliancy Group says on its website.

“Through the years HIPAA regulation has undergone significant change, and the need to understand the Regulation has as well.

“Though it was once just another regulation, HIPAA has become a cultural issue for health care organizations of all kinds, affecting how to run a practice and the means of doing business. Join us through this timeline of HIPAA compliance and a how it pertains to you as a Covered Entity or Business Associate,” the site adds.

[Register for the webinar.](#)

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## [More States Likely to Sue over Opioid Epidemic](#)



Texas lawyer [Kent Sullivan](#), who helped build a potent state health care fraud unit as the No. 2 lawyer in the Texas Attorney General’s office, is convinced that more states will follow Mississippi and Ohio in suing to recover damages related to the opioid epidemic, reports a post on the website of

[Androvett Legal Media & Marketing](#). Sullivan, now a partner in the Austin office of [Jackson Walker LLP](#), says states wield “a huge hammer” over defendants through their tough anti-fraud laws.

*“I expect a national trend, a significant wave of lawsuits against the companies and organizations connected with the spread of these powerful prescription drugs. States will be very tempted by the significant potential damages that may be awarded in court to try to recoup some of the costs of treatment.*

*“There is, of course, a way to successfully defend these cases, but at the beginning, state governments have a huge advantage under Medicaid fraud and consumer protection statutes. There is an easier burden of proof and enhanced damages available under these laws. Intent or negligence often is not required to prove liability. You have a huge hammer over these companies’ heads, and they can be at risk of losing more than actual damages. The damages are often multiplied if you’re found liable, and the states can often recover attorneys’ fees.*

*“As government health care has expanded, so have anti-fraud actions by states. These lawsuits are not part of the traditional private party litigation framework, where the burden of proof is higher. In many cases, the defendants consider settlement to avoid the significant risk and high cost of litigation. It is fairly unusual for these cases to go to trial but, as I often tell clients, the way to obtain the best settlement is to be totally ready for trial.”*

Sullivan, a former appeals court judge, was chief deputy AG to then-Attorney General Greg Abbott and ramped up the state’s Civil Medicaid Fraud Division from four lawyers to over 40. In 2012, Texas won a \$158 million settlement from Johnson & Johnson over its improper marketing of the anti-psychotic drug

Risperdal to patients on Medicaid from 1994-2008. It was the largest Medicaid settlement in Texas history and is believed to be the first settlement paid at that time to any state in the nationwide litigation over Risperdal.

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## [Webinar: HIPAA and the Compliance Officer](#)

MentorHealth will present a webinar, [HIPAA and the Compliance Officer](#), addressing how practice/business managers (or compliance officers) need to get their HIPAA house in order before the imminent audits occur.

The 90-minute event will be Wednesday, August 9, 2017, 10 a.m. PDT (1 p.m. EDT).

The webinar also will address major changes under the Omnibus Rule and any other applicable updates for 2017. Areas also covered will be texting, email, encryption, medical messaging, voice data and risk factors as they relate to IT.

On its website, [MentorHealth](#) says the primary goal is to ensure everyone is well educated on what is myth and what is reality with this law.

“I will uncover myths versus reality as it relates to this very enigmatic law based on over 1000 risk assessments performed as well as years of experience in dealing directly

with the Office of Civil Rights HIPAA auditors,” says instructor [Brian Tuttle](#). “I will also speak to real life litigated cases I have worked where HIPAA is being used to justify state cases of negligence -THIS IS BECOMING A HUGE RISK! In addition, this course will cover the highest risk factors for being sued as well as being audited (these two items tend to go hand in hand).”

Topics will include:

- Do you have an affective HIPAA compliance program?
- New laws and funding mean increased risk for both business associates and covered entities
- HIPAA Omnibus – Do you know what’s involved and what you need to do?
- What does Omnibus mean for covered entities and business associates?
- Why should you be concerned?
- Court cases that are changing the landscape of HIPAA and patient’s ability to sue

“It is important to understand the new changes going on at Health and Human Services as it relates to enforcement of HIPAA for both covered entities and business associates as it relates to what we need to do as compliance officers,” according to Tuttle. “You need to know how to avoid being low hanging fruit in terms of audit risk as well as being sued by individuals who have had their PHI wrongfully discloses due to bad IT or internal administrative practices.”

### **Speaker Profile**

Brian L Tuttle, CPHIT, CHP, CBRA, Net+, A+, CCNA, MCP is a Certified Professional in Health IT (CPHIT), Certified HIPAA Professional (CHP), Certified Business Resilience Auditor (CBRA) with over 15 years’ experience in Health IT and Compliance Consulting.

[Register for the webinar.](#)

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## [Healthcare Developer Fined \\$155 Million for Lying About Compliance](#)

Health records software developer eClinicalWorks has agreed to pay a \$155 million to the federal government for civil fraud and kickback charges, according to [HIT Consultant](#).

“Both the government and the whistleblower alleged that eClinicalWorks falsely represented to customers that its EHR [electronic health record] system complied with Meaningful Use requirements,” the publication says. “The settlement marks the first time an EHR vendor is being charged for the truthfulness and accuracy of representations made when seeking government certification of its EHR system and the government applying the federal Anti-Kickback Statute (AKS) law to the promotion and sale of EHR systems.”

The whistleblower alleged the company modified its software to pass testing, without being fully functional. The lawsuit listed several allegations against the company, such as kickbacks for recommendations, and failure to test its software adequately before releasing it.

[Read the HIT Consultant article.](#)



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## [CVS's Omnicare to Pay \\$23 Million to Resolve U.S. Kickback Case](#)

Reuters [is reporting](#) CVS Health Corp's Omnicare unit has agreed to pay \$23 million to resolve a whistleblower lawsuit alleging that it took kickbacks from a drugmaker to promote two antidepressants, according to settlement papers.

The agreement comes out of a 2007 lawsuit against the pharmacy operator by two former employees of drugmaker Organon USA Inc on behalf of the federal government and various states.

"The lawsuit claimed that from 1999 to 2005, Omnicare and certain pharmacies it acquired sought and received kickbacks from Organon in the form of discounts in exchange for promoting the antidepressants Remeron and Remeron SolTabs," writes [Nate Raymond](#).

Former Organon employees Richard Templin and James Banigan filed the suit, which reached a related \$31 million settlement in 2014.

[Read the Reuters article.](#)

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# [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.](#)

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[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.