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A Blockbuster Year Ahead For Health, Life Sciences Litigation

By **Jeff Overley**

Law360 (January 3, 2022, 12:03 PM EST) -- Health care and life sciences litigation is already red hot as 2022 begins and appears all but certain to intensify throughout the year as the clock ticks on time-sensitive lawsuits, the U.S. Supreme Court nears the end of its current term and opioid cases generate more trials and fresh drama. Here, Law360 explores five key litigation areas to watch.

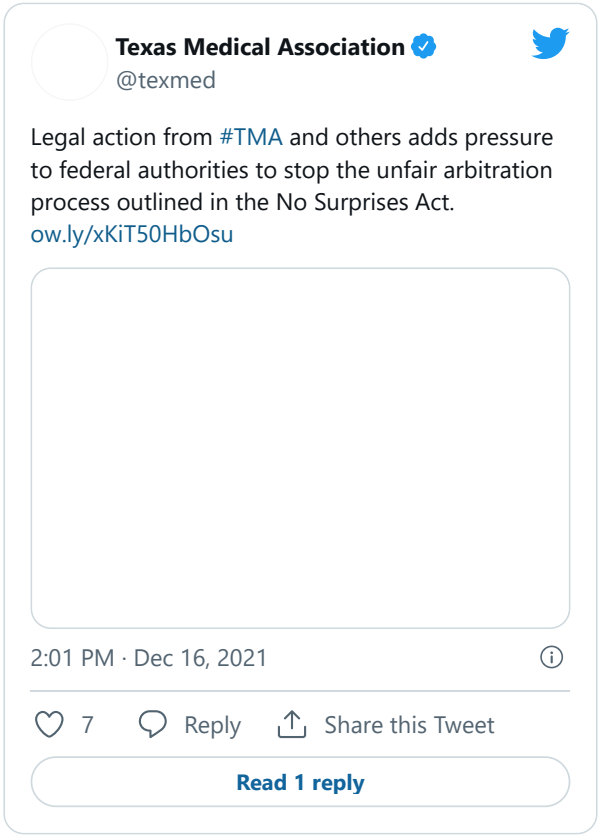
Make-Or-Break Rulings Imminent For No Surprises Act

National and state lobbying groups for health care providers are entering 2022 having just commenced litigation challenging the mechanics of a high-profile arbitration system that debuted on New Year's Day, about one year after its creation by Congress as part of the No Surprises Act.

The system will apply when patients are shielded from "surprise medical bills" for services unexpectedly performed by out-of-network providers. In those situations, if providers and health insurance payors can't agree on reimbursement, they'll each submit their preferred payment amount to an arbitrator, who will select one of the two amounts.

Three lawsuits — including one from the American Medical Association and the American Hospital Association — have accused regulators of stacking the deck against providers by telling arbitrators to presume that insurers' median rates for services reflect appropriate payment.

The Association of Air Medical Services, for example, said in one lawsuit that federal agencies have constructed an "indefensibly one-sided scheme" that is "rigged" in favor of insurers and will "cripple the air ambulance industry."



In another lawsuit, the Texas Medical Association averred that No Surprises Act regulations are "manifestly unlawful and will unfairly skew [arbitration] results in payors' favor, granting them a windfall they were unable to obtain in the legislative process."

And in a third suit, the AMA and the AHA argued that regulators are "severely tilting the scales" in favor of insurers, adding that the alleged imbalance "will harm patients" by giving insurers incentives to eschew higher-cost specialty

providers.

A distinctly different description has been offered by the trade group America's Health Insurance Plans, which recently said that the Biden administration's approach to No Surprises Act rulemaking "signals a strong commitment to consumer affordability" and contains "the right approach" to arbitration.

The U.S. Department of Health and Human Services and other agencies have agreed to expedited briefing that is expected to produce decisions by early spring, when payment disputes are first expected to make their way to No Surprises Act arbitration.

"I think the state of some of the core provisions of the [regulations] is going to be decided in the February-March-April time frame," McDermott Will & Emery LLP partner Brian R. Stimson, counsel for the Association of Air Medical Services, told Law360. "And those decisions will have pretty significant consequences for both health care payors and health care providers."

The cases are Texas Medical Association et al. v. United States Department of Health and Human Services et al., case number 6:21-cv-00425, in the U.S. District Court for the Eastern District of Texas, and Association of Air Medical Services v. U.S. Department of Health and Human Services et al., case number 1:21-cv-03031, and American Medical Association et al. v. U.S. Department of Health and Human Services et al., 1:21-cv-03231, in the U.S. District Court for the District of Columbia.

"Heavy Use" Of New Kickback Law Seen As Overdoses Surge

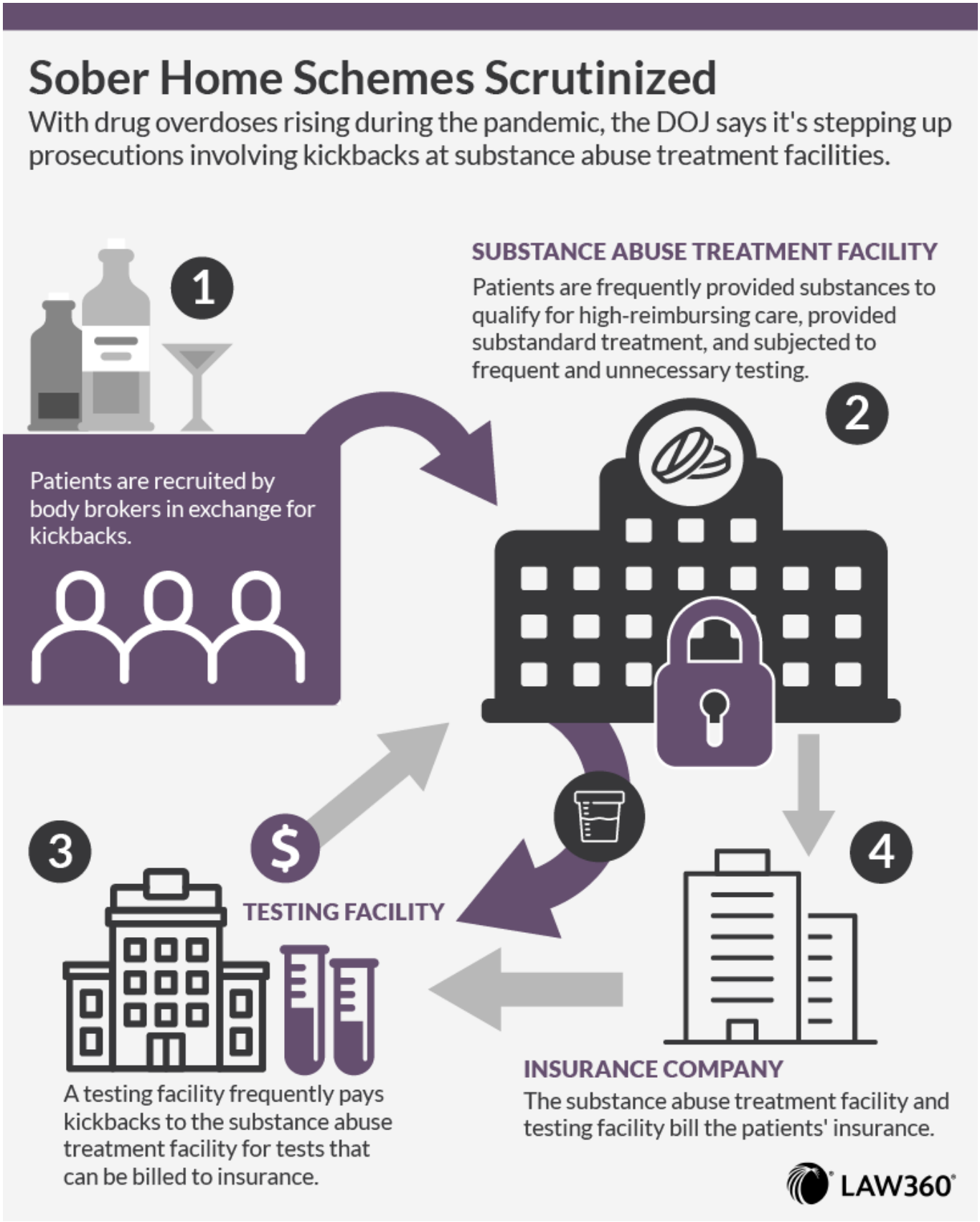
COVID-19 has killed more than 800,000 Americans, but the coronavirus pandemic has an indirect death toll that includes fatal drug overdoses. The most recent federal data projects that 100,000 drug deaths occurred during the pandemic's first year in the U.S., up almost 30% from the prior yearlong period.

Amid that surge, counselors specializing in substance abuse and mental health are seeing greater demand "due to the toll of the COVID-19 pandemic on many individuals' mental health," and counseling employment is poised to grow "much faster than the average for all occupations," according to the U.S. Department of Labor.

"As more money flows to programs to address this part of the crisis, we can expect to see fraud," Goldberg Kohn Ltd. litigator Roger A. Lewis told Law360. "Unscrupulous mental health and addiction centers will be under the microscope."

There are already signs of such scrutiny. In particular, the U.S. Department of Justice has begun wielding the Eliminating Kickbacks in Recovery Act, which became law in late 2018 amid the already severe opioid crisis.

"DOJ is making heavy use of EKRA in the context of criminal prosecutions involving sober living homes," Davis Wright Tremaine LLP partner Alexander F. Porter, a former federal prosecutor specializing in health care fraud, told Law360.



(Source: U.S. Department of Justice)

When the DOJ in September announced the results of a national health fraud sweep, kickbacks at sober living homes were one of the main schemes it spotlighted. Additionally, the DOJ on Dec. 16 revealed kickback charges filed over the prior 10 months against individuals working with drug treatment centers in Southern California.

EKRA covers "recovery homes, clinical treatment facilities and laboratories" — even if they don't bill government health care programs — and generally bars them from paying for patient referrals. A single violation carries the threat of a

$200,000 fine and a 10-year prison sentence.

Although EKRA is primarily aimed at the drug rehab sector, prosecutors in 2022 might deploy it more widely. Porter told Law360 that enforcers "have started to make use of EKRA outside of the sober living home space in the areas of genetic testing and COVID testing."

"It will be interesting to see what new areas DOJ will venture into with EKRA," he said.

Roe V. Wade Decision Carries Daubert Significance

By the end of June, the U.S. Supreme Court will decide the fate of a Mississippi statute — H.B. 1510, or the Gestational Age Act — that would prohibit most abortions after 15 weeks of pregnancy. That restriction conflicts with the high court's landmark rulings in Roe v. Wade and Planned Parenthood v. Casey; those rulings recognized women's constitutional right to abortion before a fetus is viable outside the womb, which can first happen around 22 weeks of pregnancy.

In addition to directly affecting abortion rights, the outcome carries implications for the circumstances in which the Supreme Court will overturn its past rulings. That's an especially salient issue nowadays because high court conservatives have demonstrated a willingness **to break with important precedent**.

When doing so, the justices often claim to be motivated by significant factual changes; examples include weakening campaign finance limits in Citizens United v. Federal Election Commission because of "rapid changes in technology," and reducing federal oversight of voting rights in Shelby County v. Holder because states are no longer "blatantly discriminatory."

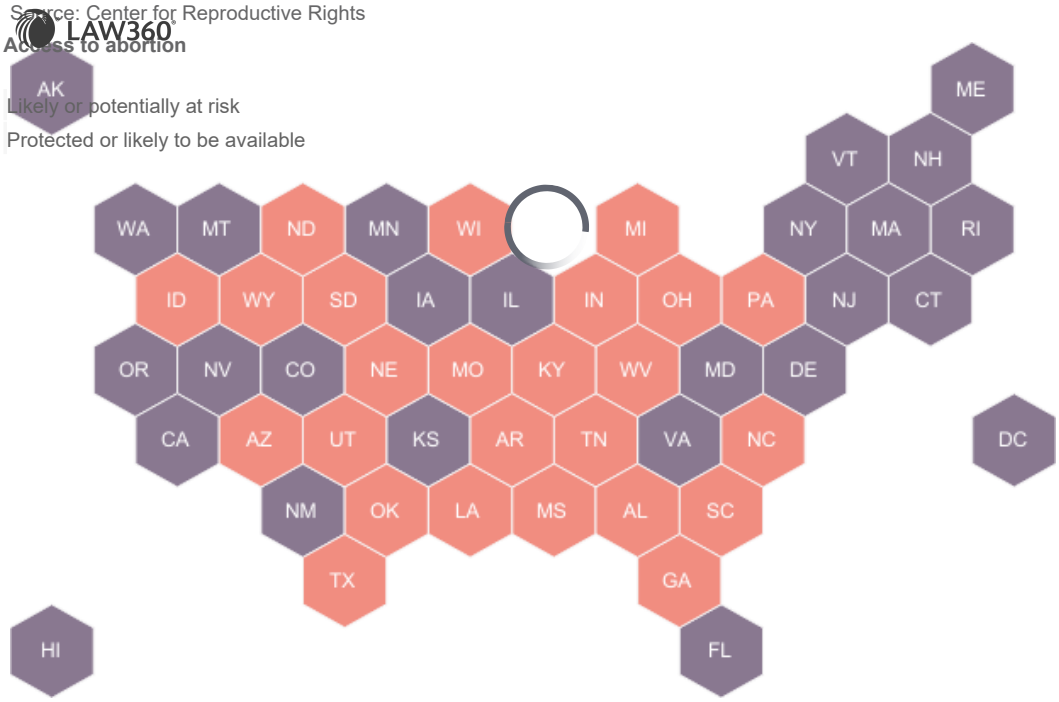
Mississippi has contended that "Roe and Casey shackle states to a view of the facts that is decades out of date," and at oral arguments last month, Mississippi Solicitor General Scott G. Stewart pointed to "an advancement in knowledge and concern about such things as fetal pain."

In response, Justice Sonia Sotomayor called that knowledge "not well-founded in science at all" and held only by "a small fringe of doctors," and she specifically invoked the Daubert standard that judges use when determining whether expert testimony is credible.

Keker Van Nest & Peters LLP attorney Anjali Srinivasan, counsel for economists who filed an amicus brief opposing Mississippi's ban, told Law360 that Justice Sotomayor's comments underscored how the case may reverberate beyond the abortion context.

"It sort of sounded to me like, 'Say what you will about abortion. … But if you believe in Daubert, if you believe in the way our court gatekeeps evidence, you need to think critically before you accept the views espoused by the state of Mississippi here," Srinivasan said.

As for the impact on abortion rights, most of the Supreme Court's six conservatives **seemed receptive** at December's arguments to wiping out Roe and Casey. In that scenario, more than 20 states have existing laws or constitutional amendments that "make them certain to attempt to ban abortion as quickly as possible," according to the Guttmacher Institute, a research group that supports abortion rights.



But the arguments also explored the possibility of upholding Mississippi's law without paving the way for states to enact near-total bans on abortion.

"I'd like to focus on the 15-week ban, because that's not a dramatic departure from viability," Chief Justice John G. Roberts Jr. said at one point.

None of the other justices seemed as interested in a middle-ground ruling. But related comments came from Justice Elena Kagan, who inquired about the idea of "intermediate positions" where "the viability line was discarded"; Justice Neil Gorsuch, who asked about an "alternative line" before viability; and Justice Amy Coney Barrett, who asked a lawyer to discuss "the viability line and … if that's the right line to draw."

The case is Dobbs et al. v. Jackson Women's Health Organization et al., case number 19-1392, in the Supreme Court of the United States.

Justices Eye Updates Of Chevron Deference "Guardrails"

The question of whether the Supreme Court should overturn one of its landmark rulings is also attracting attention in a pending case involving Medicare reimbursement for hospitals in the so-called 340B drug discount program.

During oral arguments in late November, multiple justices asked whether they should **jettison the high court's 1984 decision** in Chevron v. Natural Resources Defense Council. The decision requires judicial deference to reasonable agency interpretations of ambiguous statutes and has become a bête noire of big business and right-leaning legal minds.

"The court should squarely overrule Chevron here and now," an amicus brief from the Americans for Prosperity Foundation asserted in advance of November's arguments, echoing other filings from pro-industry amici.

The distaste is partly a reflection of the fact that Chevron v. NRDC gives the federal government considerable regulatory power over corporate America. Conservatives who advocate a strict "textualist" approach to statutory interpretation also contend that judges are often too lenient about agreeing that a statute is ambiguous and granting deference.

Although the high court might nullify Chevron deference, another option would be to create what some observers call "Chevron-lite." That overhaul would likely stress that judges must make every practical effort to discern a statute's meaning.

"It seems unlikely to me that the court is going to overturn Chevron. It seems more plausible to me that the court is

going to restate and strengthen the existing guardrails for applying Chevron," McDermott Will & Emery's Stimson told Law360.

Discussion of Chevron deference also arose recently during Supreme Court arguments in a case involving Medicare reimbursement for hospitals serving relatively large numbers of poor patients. The government has conceded that the rulemaking process for that reimbursement wasn't smooth, and **the arguments featured debate** about when courts should withhold Chevron deference because of procedural mistakes.

"A decision that addresses the implications of procedural snafus and irregularities on the level of deference could be really significant for the health care industry," Ropes & Gray LLP partner Stephanie A. Webster said in an interview.

The cases are American Hospital Association et al. v. Becerra et al., case number 20-1114, and Becerra v. Empire Health Foundation, case number 20-1312, in the Supreme Court of the United States.

Opioid Drama Surrounds Purdue, Cherokees, Trials

Opioid crisis litigation pitting state and local governments against pharmaceutical companies kicked into high gear in 2021, generating multiple trials and verdicts, and it's expected to continue full speed ahead in 2022.

One of the most complicated and consequential issues in 2022 will likely be fallout from **the implosion** in December of a Chapter 11 plan for Purdue Pharma LP. The OxyContin seller was a prime target from the outset of opioid litigation, and roughly two years after seeking bankruptcy protection, Purdue retained a presence in the names of opioid cases that went to trial in 2021: State of New York v. Purdue Pharma et al., County of Suffolk v. Purdue Pharma et al., County of Nassau v. Purdue Pharma et al., People of the State of California v. Purdue Pharma et al., County of Lake v. Purdue Pharma et al. and County of Trumbull v. Purdue Pharma et al.

New York Attorney General Letitia James — who had sued not only Purdue but also its Sackler family owners — in late December flagged the bankruptcy plan's collapse to the judge overseeing jury deliberations in an opioid trial against other drug companies.

"The state expects that there will be additional significant developments relating to the Sackler and Purdue defendants in 2022 and will inform this court of such developments affecting this action, including when proceedings herein are no longer stayed by operation of law or related court order," James wrote.

Separately, there's also likely to be fallout in 2022 from the Oklahoma Supreme Court's recent **erasure of a $465 million opioid verdict** against Johnson & Johnson. The Sooner State's high court held that the "public nuisance" theory undergirding most opioid cases can't be used in Oklahoma. Its conclusion casts doubt on the Cherokee Nation's tribal bellwether case in multidistrict opioid litigation, which is based in Oklahoma federal court and scheduled for trial in September.

"That holding squarely forecloses the nation's attempt to hold defendants liable under Oklahoma public nuisance law for selling prescription opioids," pharmacy giants Walmart Inc., Walgreens and CVS Pharmacy said in a mid-December motion for judgment.

They added that the Oklahoma Supreme Court's decision on the public nuisance theory also dooms the rest of the Cherokee Nation's claims, which include negligence, unjust enrichment and civil conspiracy.

Tyler Ulrich of Boies Schiller Flexner LLP, counsel for the Cherokees, noted in an interview that a judge previously refused to dismiss any of the tribe's claims against the pharmacies.

"We would expect the same result on all of the claims that were not addressed in the [Oklahoma Supreme Court's] decision … which relates only to public nuisance," Ulrich said.

But is it possible that a new tribal bellwether will be selected if the Cherokees' case is thrown out?

"That's not going to happen, because we don't think the case is going anywhere," Ulrich replied.

Other key opioid cases in 2022 are expected to include **an ongoing trial** pitting Washington state against the nation's largest drug distributors; a multidistrict litigation bellwether case brought by San Francisco against various drug companies; a damages trial in May following **a jury verdict** finding Walmart, Walgreens and CVS liable for opioid woes in two Ohio counties; and trials tentatively scheduled to begin in various state courts, including in Texas, Florida and West Virginia.

The cases include In re: Opioid Litigation, case number 400000/2017, County of Suffolk v. Purdue Pharma LP et al., case number 400001/2017, County of Nassau v. Purdue Pharma LP et al., case number 400008/2017, and State of New York v. Purdue Pharma LP et al., case number 400016/2018, all in the Supreme Court of the State of New York, County of Suffolk;

Cherokee Nation v. CVS Pharmacy Inc. et al., case number 6:18-cv-00056, in the U.S. District Court for the Eastern District of Oklahoma;

County of Lake v. Purdue Pharma LP et al., case number 1:18-op-45032, County of Trumbull v. Purdue Pharma LP et al.,

case number 1:18-op-45079, and In re: National Prescription Opiate Litigation, case number 1:17-md-02804, in the U.S. District Court for the Northern District of Ohio;

State of Washington v. McKesson Corp. et al., case number 19-2-06975-9, in the Superior Court of the State of Washington, County of King;

City and County of San Francisco et al. v. Purdue Pharma LP et al., case number 3:18-cv-07591, in U.S. District Court for the Northern District of California.

--Editing by Robert Rudinger.