

Health Care Cases To Watch In 2020

By Jeff Overley

Law360 (January 1, 2020, 12:04 PM EST) -- Health care litigation in the 2020s is poised for a roaring start as opioid suits head to trial, defense attorneys trumpet a U.S. Supreme Court decision on Medicare rulemaking, the Affordable Care Act faces another life-or-death legal showdown and conservative justices consider curtailing abortion rights. Here, Law360 explains key cases to watch as the new decade gets underway.

Opioid Litigation Wave Rises Higher

Several drug companies, including Amneal Pharmaceuticals Inc., Johnson & Johnson, Teva Pharmaceuticals, Mallinckrodt PLC, McKesson Corp. and AmerisourceBergen Corp., disclosed in recent months that they had received subpoenas from the U.S. attorney's office in Brooklyn regarding sales of narcotic painkillers. The demands for information may herald an eye-popping escalation of opioid enforcement.

The subpoenas apparently relate to the Controlled Substances Act obligations of drug companies to closely track opioid sales in order to minimize diversion for illicit use. In a disclosure echoed by several other companies, Teva said in a quarterly report that its subpoena appears to be "part of a broader investigation."

It's not clear whether any indictments will materialize. But the subpoenas emerged against the backdrop of criminal opioid cases that the U.S. Department of Justice has pursued against drugmaker Insys Therapeutics, drug distributors Miami-Luken Inc. and Rochester Drug Co-Operative Inc., and dozens of doctors in the Appalachian region. Those cases are widely seen as a reflection of changing DOJ prerogatives.

"Traditionally, DOJ has not believed it could prosecute its way out of the nation's health care fraud problem, but this appears to be an effort to do just that — to prosecute the opioid crisis into submission," Thompson Hine LLP senior counsel Sarah M. Hall, a former DOJ health fraud prosecutor, told Law360.

In civil litigation, a wave of suits blaming pharmaceutical companies for a devastating epidemic of opioid abuse is barreling full steam ahead into 2020 despite increasingly earnest efforts to broker nationwide settlements. Across the country, states and local governments are collectively seeking tens of billions of dollars to fund health care and law enforcement services that have been strained by rampant addiction and related crime.

New York state and two Long Island counties are poised to go to trial starting March 20 against a fleet of major drug manufacturers and distributors, including J&J and McKesson, all of which have denied wrongdoing.

In an amended complaint filed in June, New York assailed the companies generally as "unrepentant culprits" that were legally obligated to help prevent opioid abuse but instead "deliberately betrayed those duties through a persistent course of fraudulent and illegal misconduct."

Elsewhere, more than 2,500 cities and counties are pursuing damages in multidistrict litigation centralized in Cleveland federal court. A trial testing the allegations of two Ohio counties against pharmacies including CVS Health Corp., Walgreen Co. and Walmart Inc. has been set for Oct. 13. It could be the first opioid-crisis trial against retail drug dispensers, which unlike manufacturers and distributors haven't reached any major settlements in the opioid-litigation wave.

Several other cases in the MDL have also been handpicked for bellwether trials in federal courts around the country, including California, Florida, Illinois, Michigan, Oklahoma and West Virginia; trial dates haven't yet been set.

Allina Reverberates Across Health Litigation Landscape

A decision in June by the Supreme Court in *Azar v. Allina Health Services* has quickly become a potent weapon for lawyers in numerous cases to contest the government's views of appropriate Medicare billing.

The Allina decision found that the U.S. Department of Health and Human Services erred by not soliciting public input before changing a Medicare reimbursement policy. The ruling has broad implications, casting doubt on the viability of numerous payment policies that HHS has adopted without notice-and-comment rulemaking. More specifically, attorneys have new ammunition to battle False Claims Act cases and launch proactive legal challenges against Medicare reimbursement guidance.

In October, a California federal judge in *Agendia v. Azar* cited Allina when ruling that Medicare payment policies for clinical laboratory tests "were unlawfully promulgated without notice-and-comment." In November, a Pennsylvania federal judge in *Polansky v. Executive Health Resources* cited Allina when ruling in a False Claims Act case that "there can be no FCA liability" for certain hospital billing practices because HHS "did not go through the notice-and-comment process."

In 2020, health care providers will likely defend against enforcement actions, particularly False Claims

Act cases, "by challenging guidance as invalid under Allina," Reed Smith LLP partner Selina Coleman told Law360.

And in response, the government may "seek to formalize some of its guidance through notice-and-comment rulemaking [that] would provide independent support for enforcement actions," Coleman said.

In an internal memo first reported by Law360, HHS attorneys recently acknowledged that Allina would complicate the department's billing enforcement and discussed plans to reissue some guidance documents via notice-and-comment rulemaking.

ACA Outcome Will Affect 'Almost Everyone'

When it comes to individual cases to watch, few if any can match the stakes of *Texas v. U.S.*, a Republican-led challenge to the ACA's constitutionality. In a surprise move, the Fifth Circuit on Dec. 18 told a Texas federal judge to better explain his decision invalidating the entire ACA and consider less drastic action.

All eyes are now on whether the U.S. Supreme Court takes up the case without waiting for do-overs at the district and circuit court levels. If the high court holds off, the case could drag on well past 2020.

Under the ACA, more than 20 million Americans have obtained free or subsidized health coverage via Medicaid or individual insurance policies. The law also dramatically expanded consumer protections — such as a ban on higher insurance prices for preexisting conditions — and greenlighted less-pricey versions of brand-name biologic drugs, which usually cost thousands of dollars per month.

"Ultimately, the outcome of this case could affect almost everyone in the country," said Covington & Burling LLP attorney Anna Kraus, who called *Texas v. U.S.* "by far the most important case to watch in 2020."

The ACA's uncertain future is likely to be a flash point in the 2020 race for the White House. President Donald Trump supports totally scrapping the law and hasn't articulated a replacement; the top Democratic candidates universally oppose the anti-ACA case and have advanced a variety of plans for expanding health insurance access.

The case is *Texas et al. v. U.S. et al.*, case number 4:18-cv-00167, in the U.S. District Court for the Northern District of Texas.

Abortion Rights in High Court Crosshairs

Another case with unmistakable political implications is a Supreme Court sequel to an abortion rights case, *Whole Woman's Health v. Hellerstedt*, that the high court decided three years ago — before President Donald Trump added two justices and solidified the court's conservative majority.

The prospect of a revamped court reviewing an abortion case for the first time is notable by itself. But the case also involves a Louisiana admitting-privileges law that's practically identical to the Texas law that the Supreme Court rejected in *Whole Woman's Health*.

The move to quickly revisit the admitting-privileges issue is shining a spotlight on the conservative majority's willingness to overturn liberal precedent. In an amicus brief, constitutional law scholars quoted from the Supreme Court's landmark abortion ruling in *Planned Parenthood v. Casey*, which cautioned that overruling major precedent without a compelling reason could "subvert the court's legitimacy."

Amicus briefs filed by other parties, including the American Bar Association and former federal judges, have added that the Fifth Circuit's decision to uphold Louisiana's law presents a threat to "the rule of law."

Some observers doubt the conservative justices will completely scrap the constitutional right to abortion, while also predicting that they may nonetheless create new leeway for states to restrict abortion access.

"*Roe v. Wade* is well entrenched," Epstein Becker Green member Stuart Gerson said, adding that there is, however, a "substantial probability that a conservative majority will uphold the Louisiana restrictive law this time around."

Arguments are set for March 4, and a decision is expected by late June, right when the presidential campaigns will likely be kicking into high gear.

The cases are *June Medical Services LLC et al. v. Rebekah Gee*, case number 18-1323, and *Rebekah Gee v. June Medical Services LLC*, case number 18-1460, in the Supreme Court of the United States.

Drama Continues in Epic FCA Saga

One of the most fascinating False Claims Act cases in recent memory is poised for yet another captivating chapter as the U.S. Department of Justice seeks to salvage eight years of effort to punish alleged fraud by hospice chain AseraCare Inc.

Although the Eleventh Circuit in September revived the DOJ's case, U.S. District Judge Karon Bowdre on Dec. 4 rejected a government bid to reopen discovery to supplement its evidence.

"Without significant additional evidence, the case will be an uphill battle at trial," Foley & Lardner LLP partner Lisa Noller told Law360.

In fact, a trial may never happen; Judge Bowdre is weighing whether to award summary judgment to AseraCare, which she previously awarded in 2016 and is now revisiting after the Eleventh Circuit told her to look at evidence more broadly.

The DOJ's predicament stems from its heavy reliance on an expert who said that the medical records of AseraCare patients didn't support hospice eligibility. That allowed AseraCare to successfully argue that one expert's disputed view of medical necessity couldn't sustain an FCA case.

Regardless of the outcome, health care providers facing similar FCA cases with "inherently subjective" diagnoses will now be pondering how they can "align those scenarios to the AseraCare case," Foley & Lardner partner Christopher Donovan said.

The DOJ intervened in the case against AseraCare in 2012. The case has made headlines because of Judge Bowdre's apparently unprecedented move to split an FCA trial into two parts; sanctions against the DOJ that were later erased; an unsuccessful effort to disqualify a plaintiffs attorney for speaking with Law360; and the judge's unilateral decision to grant summary judgment to AseraCare after a jury found it had submitted false claims.

The DOJ's lead trial counsel in the case was Jeffrey Wertkin; he joined Akin Gump Strauss Hauer & Feld LLP in early 2016 and shortly afterward was arrested and sentenced to prison for trying to sell a sealed FCA suit while wearing a wig-and-sunglasses disguise.

The case is U.S. ex rel. Paradies v. AseraCare Inc. et al., case number 2:12-cv-00245, in the U.S. District Court for the Northern District of Alabama.

--Editing by Brian Baresch and Orlando Lorenzo.