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The Litigation Jolting Health & Life Sciences In 2023's 2nd Half

By **Jeff Overley**

Law360 (July 21, 2023, 11:44 PM EDT) -- A head-spinning spree of rulings and new lawsuits in 2023's first half is reverberating across the health care industry and auguring a dizzying denouement in the year's final months that may well upend assumptions about drug prices and approvals, the False Claims Act and the powers of federal regulators.

The frenetic first half featured abundant action at the U.S. Supreme Court involving the FCA, an abortion drug's approval and a conservative-led quest to weaken the so-called administrative state. Recent weeks have also seen a spate of suits from Big Pharma and big business targeting Medicare's new authority to negotiate prescription drug prices.

Here, Law360 shares details and expert insights on what to watch as these cases evolve and accelerate throughout the rest of 2023.

Landmark Drug Pricing Law Confronts Surge of Suits

Drugmakers, starting with Merck & Co., and business groups, including the U.S. Chamber of Commerce, filed an average of one lawsuit a week from early June to mid-July against drug price negotiations in Medicare. The negotiations were a central component of the Inflation Reduction Act that Democrats approved in 2022.

Six suits have been brought, and all contend that the negotiation framework is unconstitutional. The cases are playing out in federal courts in Illinois, New Jersey, Ohio, Texas and Washington, D.C., upping the odds of a circuit split that will result in the Supreme Court having the last word.

While some of the cases contemplate several months of briefing, an early ruling on the framework's legality is possible. The Chamber, for instance, has moved to quickly enjoin implementation, arguing that looming deadlines — Sept. 1 for the selection of drugs subject to negotiations and Oct. 1 for negotiation agreements — mean that "the constitutional harm [its] members face is certain and impending."

The Biden administration has denounced the challenges but not yet detailed its legal defenses. A key issue to watch, according to experts, is whether the Centers for Medicare & Medicaid Services can convince courts that negotiations are akin to other conditions that companies must accept when billing taxpayer-funded programs.

"One of the most significant hurdles … is whether the plaintiffs can successfully challenge the long-

standing argument by the government that CMS is properly regulating the Medicare program as a voluntary program," Wendy C. Chow, of counsel at Morrison Foerster LLP, told Law360.

After the challenges began, CMS announced streamlined procedures for drugmakers to exit Medicare if they refuse to negotiate. But challengers might still portray the enormous cost of sacrificing Medicare reimbursement as unduly coercive. Merck, for example, has cited a 2012 ruling in which the Supreme Court said that states could not be forced to choose between expanding or discontinuing Medicaid. That ultimatum was tantamount to "a gun to the head," the high court found.

"Drug companies rightfully point out that removing products from the Medicare program is a complicated and drawn-out process that would also affect millions of Medicare patients who could be left without medications," Chow said. "How the courts may address this question with a long history of precedent will be one point to watch."

The cases are Merck & Co. Inc. v. Becerra et al., case number 1:23-cv-01615, in the U.S. District Court for the District of Columbia; Dayton Area Chamber of Commerce et al. v. Becerra et al., case number 3:23-cv-00156, in the U.S. District Court for the Southern District of Ohio; Astellas Pharma U.S. Inc. v. HHS et al., case number 1:23-cv-04578, in the U.S. District Court for the Northern District of Illinois; National Infusion Center Association et al. v. Becerra et al., case number 1:23-cv-00707, in the U.S. District Court for the Western District of Texas; and Janssen Pharmaceuticals Inc. v. Becerra et al., 3:23-cv-03818, and Bristol-Myers Squibb Co. v. Becerra et al., case number 3:23-cv-03335, each in the U.S. District Court for the District of New Jersey.

Clock Ticking on FCA Rebound After Dismal Year

One of the biggest trial verdicts in the False Claims Act's modern history occurred earlier this year when a Minnesota jury agreed with the government's kickback case against an ophthalmology distributor, triggering almost $500 million in damages and penalties.

Another blockbuster payout became public Friday evening, when the DOJ announced that Booz Allen Hamilton Holding Corp. would pay nearly $380 million in "one of the largest procurement fraud settlements in history."

FCA cases have now netted about $2 billion during the 2023 fiscal year, according to Law360's reporting and statistics compiled by Arnold & Porter. With roughly 10 weeks left in the fiscal year, it's looking like the total haul may eclipse last year's $2.2 billion. But that was the smallest annual sum since 2008, and it fell far short of the $5.7 billion recovered in 2021.

"The stats at this point don't lie. Like '22, FCA settlements will likely lag behind the historic 2021 recoveries," Wiggin and Dana LLP partner Jolie Apicella said.

Apicella, a former health fraud chief at the U.S. Attorney's Office for the Eastern District of New York, stressed that the DOJ in recent years has been bringing far more cases than usual. Most of that uptick relates to pandemic relief funding, and recoveries have mostly been small. But the increase nonetheless creates fodder for big payouts, and in any event, it reflects important safeguarding of taxpayer resources.

"This does not mean that FCA enforcement is slowing overall," Apicella said. "We are still talking about billions in recoveries and thousands of new matters."

Abortion Pill Decision Looms

One of the most dramatic litigation chapters in 2023 so far occurred in a case brought by anti-abortion groups aiming to invalidate the U.S. Food and Drug Administration's decades-old approval of mifepristone, a drug used in most medication abortions.

The drama, which unfolded during a two-week stretch in April, started when a Texas federal judge effectively ordered mifepristone off the market. A few days later, the Fifth Circuit stayed that order, while leaving intact the judge's reinstatement of FDA restrictions on access to mifepristone. The Supreme Court then blocked the judge's order entirely and sent the matter back to the Fifth Circuit.

The circuit court heard arguments in mid-May, and a decision could come down any day. Regardless of how the Fifth Circuit rules, it's expected that the matter will quickly return to the high court, where conservatives in 2022 overturned the constitutional right to abortion and thereby made mifepristone more important, since anti-abortion states cannot easily prevent residents from ordering abortion pills by mail.

The case is Alliance for Hippocratic Medicine et al. v. FDA et al., case number 23-10362, in the U.S. Circuit Court of Appeals for the Fifth Circuit.

Chevron Deference Hurtles Toward Moment of Truth

One of the biggest litigation developments in the first half of 2023 was the Supreme Court's announcement in May that it would revisit its 1984 decision in Chevron v. Natural Resources Defense Council. The landmark decision birthed so-called Chevron deference, a two-step framework that tells judges to decide if laws are ambiguous and, if so, to defer to reasonable agency interpretations.

The revisitation is huge for health care because the U.S. Department of Health and Human Services generates thousands of pages of regulations annually and attracts countless lawsuits in the process. Many of those lawsuits turn on the Chevron doctrine. The doctrine's supporters say it appropriately credits agency expertise; detractors say it empowers regulators to play fast and loose with laws enacted by elected officials.

Supporters tend to be liberal, and detractors tend to be conservative. Because the Supreme Court has a conservative supermajority and has chipped away at deference for years, it's widely expected to side with the doctrine's challengers. But even in that scenario, it's possible that the justices might merely modify the doctrine instead of scrapping it entirely.

The government's opening brief is due by Sept. 15. A date for oral arguments has not yet been publicly set.

The case is Loper Bright Enterprises et al. v. Raimondo et al., number 22-451, before the Supreme Court of the United States.

Justices Open Door to Resumption of DOJ Dismissals

The Supreme Court's decision last month in Polansky v. Executive Health Resources — one of two FCA decisions from the high court in 2023's first half — has ignited chatter about the future of a

controversial DOJ initiative.

In its decision, the high court gave the government wide berth to unilaterally terminate FCA whistleblower suits. Questions about the termination powers emerged when the DOJ began scuttling suits with unusual frequency after the issuance of its so-called Granston memo. The 2018 memo told government lawyers to torpedo cases that presented certain problems, such as burdensome discovery on federal agencies, misguided fraud theories or the potential to generate unhelpful precedent.

By most accounts, the DOJ dialed back its dismissal campaign around the time that Supreme Court review started to seem realistic. But that timing also coincided with the installation of new DOJ leadership under the Biden administration. It's not clear whether the slowdown was a temporary reflection of the Supreme Court situation or a permanent reflection of the new political situation.

Hogan Lovells partner Gejaa T. Gobena, who left the DOJ's criminal fraud section in 2016, noted in an interview that the Granston memo was followed in 2018 by the so-called Brand memo. The Brand memo warned prosecutors against bringing FCA cases premised on nonbinding guidance, and the Biden administration rescinded it in 2021.

"The fact that the Granston memo activity diminished while this [Polansky] was pending — I don't know if that was necessarily a reflection of waiting for this decision to come out, as much as perhaps there being even less of an appetite in the new administration to be proactive on the dismissal side," Gobena said.

FCA defendants have pressured the DOJ to use its dismissal authority, sometimes with explicit advocacy, and perhaps sometimes with demands for voluminous discovery. That pressure is likely to continue, because the Polansky decision "gives defendants more ammo to push the government," Apicella said.

"But I imagine it will still be the rare case that the government decides to seek dismissal," she added.

The case is U.S. ex rel. Polansky v. Executive Health Resources Inc. et al., case number 21-1052, before the Supreme Court of the United States.

Fraud Law's Future Suddenly Shrouded in Uncertainty

In addition to prompting questions about the future of DOJ dismissals, the Polansky decision surprisingly sparked speculation about the future of the FCA itself. That's because Justice Clarence Thomas penned a dissent that said "there is good reason to suspect" that FCA whistleblower suits, also known as qui tams, are unconstitutional.

In a concurring opinion, Justices Brett Kavanaugh and Amy Coney Barrett said they agreed that "there are substantial arguments that the qui tam device is inconsistent" with the executive branch's constitutional powers. The two justices wrote that the high court "should consider the competing arguments on the [constitutional] issue in an appropriate case."

It won't be long before the defense bar starts trying to capitalize on those constitutional concerns, several attorneys told Law360. "We're going to start seeing more constitutional challenges to qui tam lawsuits," Jay Dewald, head of health care investigations at Norton Rose Fulbright, said in an interview. "When you have three of the nine saying it's an issue, we're going to see that pop up."

Troutman Pepper partner Michael S. Lowe echoed that prediction, saying there was "an open invitation from the dissenting and concurring justices in Polansky to raise the issue of the constitutionality of the False Claims Act."

"I expect defense counsel will raise this issue in the district courts regardless of the circuit in which their cases are pending," Lowe said. "There appears to be little to no downside to doing so in order to, at a minimum, preserve the issue."

"Real Risk" as Defendants Mull Waiver of Attorney-Client Privilege

The Supreme Court's other FCA decision this year occurred on June 1 in Schutte v. SuperValu. Much like the Polansky decision, its meaning and implications will be a dominant theme on the FCA landscape for the rest of 2023.

In SuperValu, the justices found that the FCA's standard for scienter, or knowingly false billing, refers to someone's "subjective beliefs" about their billing practices, not whether the practices seemed "objectively reasonable." That finding will force defendants to demonstrate that they genuinely believed their billing satisfied compliance obligations. And because corporations rely on legal counsel to gauge those obligations, the SuperValu decision is likely to raise thorny questions about confidentiality.

"The downside of saying we're going to ignore whether the actions taken were objectively reasonable, we're always going to allow subjective intent, guarantees … you're going to have to weigh the attorney-client privilege in every single case," Sidley Austin LLP partner Carter G. Phillips, defense counsel in the case, said at oral arguments in April. "That seems to me not something Congress would have wanted."

Phillips' lament didn't sway the justices, and the high court's ruling has engendered "a real risk and a real concern" for companies in heavily regulated industries, Gobena of Hogan Lovells told Law360.

"This decision can potentially put companies in a tough position where they're going to have to strongly consider waiving attorney-client privilege to show that they didn't have the requisite scienter with respect to their view on a regulation or statute," Gobena said.

The high court cases are U.S. ex rel. Proctor v. Safeway Inc., case number 22-111, and U.S. ex rel. Schutte et al. v. SuperValu Inc. et al., case number 21-1326, each before the Supreme Court of the United States.

SuperValu Adds Wrinkle to Anti-Kickback Statute Split

Another emerging debate in SuperValu's aftermath is its possible impact on the Anti-Kickback Statute, or AKS, which covers quid pro quo payments in health care and frequently triggers FCA liability. At issue is a circuit split over FCA liability for billing claims "resulting from" kickbacks. The Third Circuit has held that there must be "some connection" between claims and kickbacks, while the Sixth and Eighth circuits have ruled that there must be a direct link.

SuperValu is relevant because it refused to import the Fair Credit Reporting Act's standard for scienter into the FCA. The DOJ has seized on that refusal, noting that the Sixth and Eighth circuits imported the Controlled Substances Act's standard for "resulting from" into the FCA context.

"SuperValu cautions against interpreting different standards for scienter. In other words, don't rely on the FCRA in interpreting the FCA," Apicella, the Wiggin and Dana partner, told Law360. "If the Supreme

Court, in a future term, reviews AKS causation and applies its own caution ... that puts the [Sixth and Eighth circuits'] interpretation at risk."

Defendants have pooh-poohed the DOJ's invocation of SuperValu in the AKS context. Teva Pharmaceuticals, for example, recently derided "the government's strained attempt," saying it ignores "the plain text of the AKS." But a Massachusetts federal judge this month sided with the government, finding that "a sufficient causal connection between an AKS violation and a claim" is enough.

The circuit split is immensely important, Norton Rose's Dewald said, because there's a wide gulf between requiring a mere connection and requiring a direct link. "There's a big difference there," he said, "and this thing is heading to the Supreme Court, I think."

"Three-Part Test" Fuels Clashes in Courts Across the Country

SuperValu also held that the FCA's standard for reckless disregard — one form of scienter — includes being "conscious of a substantial and unjustifiable risk" that billing violates government rules. That holding is virtually certain to fuel widespread wrangling in 2023's second half.

Law360 **recently reported** that some defendants have broken down those seven words into several parts. The drugmaker Indivior Inc., for example, wrote last month that SuperValu "clarified that the FCA's reckless-disregard standard 'captures defendants who are [1] conscious of a [2] substantial and [3] unjustifiable risk that their claims are false, but submit them anyway.'"

Gobena, who represents Indivior, told Law360 in an interview for this story that "we certainly think that [SuperValu's] formulation of reckless disregard really creates a three-part test."

"I definitely think that defendants are going to be advocating that view," Gobena said. "I'm sure, depending on the judge and what their perspective is on the False Claims Act … you're going to see some differences showing up there. And we'll see whether or not that leads to yet another circuit split."

K&L Gates LLP partner John Lawrence sees matters playing out the same way in the coming months. Even though SuperValu was a win for whistleblowers, it "created some areas of daylight for defense counsels, particularly surrounding what is required to demonstrate reckless disregard," Lawrence said.

"As we have seen already, citing the opinion, defense counsels are arguing the creation of new standards and multipart tests," Lawrence said. "Lower courts across the country will have to address and rule on such arguments," and "this will inevitably create potentially fertile ground for emerging circuit splits"

The FCA has three routes for showing scienter: actual knowledge, deliberate ignorance and reckless disregard. The latter is often the simplest, making the existence of a three-part test especially significant.

"Without a doubt, this is the area upon which liability is likely to turn in a good percentage of FCA cases," Troutman Pepper's Lowe said.

--Editing by Jill Coffey and Emily Kokoll.