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Health Care & Life Sciences Litigation To Watch In 2023

By **Jeff Overley**

Law360 (January 2, 2023, 12:03 PM EST) -- Before the New Year's Eve confetti has even been swept up, lawyers specializing in health care and life sciences already have enough litigation to keep them busy for much of 2023, which is kicking off with federal courts eyeing suits that carry sweeping significance for administrative law, the False Claims Act, drug approvals, the opioid crisis and abortion rights.

Here, Law360 summarizes key details of consequential cases in the coming year for doctors and hospitals, drug and device makers, laboratories and clinics, and other players in the nation's vast health care system.

High Court's 'Major Questions Doctrine' to Reverberate Widely

In the final six months of 2022, the U.S. Supreme Court's half-year-old "major questions doctrine" became a focal point of administrative law litigation, much of which relates to health care policymaking. The doctrine demands "clear congressional authorization" for executive branch endeavors with immense "economic and political significance," and numerous courts in 2023 are poised to clarify its parameters.

After the high court in June delineated the doctrine, experts told Law360 that corporations would increasingly attempt to portray disfavored policies as major issues. And the litigation landscape — in health care and many other sectors — has borne out that prediction, with the doctrine becoming central to cases involving casinos, minimum wages and smoking in public housing, among other things.

Near the end of 2022, the Fifth Circuit issued one of the most important interpretations of the doctrine, finding that it applies generally to presidential actions — not just agency actions — and specifically to a coronavirus vaccine mandate for federal contractors.

"The pandemic … does not justify such an enormous and transformative expansion of presidential authority," according to the Fifth Circuit majority, which raised the specter of presidential directives forcing contract workers to "take daily vitamins, live in smoke-free homes, exercise three times a week or even … take birth control."

Even more significantly, the doctrine will return to the Supreme Court spotlight in February when the justices hear arguments over the U.S. Department of Education's $400 billion plan for student debt relief. The arguments will occur in a pair of comparable cases. In one of those cases, a Texas federal judge rejected the DOE's plan after concluding that "because [it] is an agency action of vast economic

and political significance, the major questions doctrine applies."

In advance of February's arguments, briefing at the high court has explored implications that reach far beyond student loans. As one example, the American Federation of Teachers wrote in an amicus brief that the dispute's importance extends to "critical public sector industries like health care."

In another amicus brief, a group of law professors — including Dean Erwin Chemerinsky of the University of California, Berkeley School of Law — averred that "it's not just the Department of Education's regular activity that would be disrupted" if multibillion-dollar initiatives inherently present "major questions." The professors pointed to a multibillion-dollar regulation involving health insurance transparency as one example of a policy that could suddenly require unmistakable approval from Congress.

The student debt cases are U.S. Department of Education et al. v. Brown et al., case number 22-535, and Biden et al. v. Nebraska et al., case number 22-506, before the Supreme Court of the United States.

FCA Battle at Supreme Court Portends 'Seismic Impact'

Lawyers are forecasting fireworks in False Claims Act litigation this year on numerous fronts, including the Supreme Court, which has already taken up one FCA case and is closely eyeing another. In one case, the justices are handling a climactic clash over the U.S. Department of Justice's authority to end FCA suits — most of which involve billing of Medicare and Medicaid — despite objections from whistleblower plaintiffs.

Amid an enormous FCA caseload, the DOJ in recent years began sinking suits at an unprecedented pace. Its campaign stoked congressional ire, splintered circuit courts and culminated in a Supreme Court case, Polansky v. Executive Health Resources, that was argued in early December and appears unlikely to sharply curtail the DOJ's dismissal discretion.

Troutman Pepper partner Miranda Hooker, a former DOJ health fraud prosecutor, told Law360 that "all False Claims Act practitioners will be watching the Polansky case," even though the weighty questions about government powers probably won't produce a game-changing decision.

"The outcome may not have a significant practical impact on FCA litigation," but "it is nonetheless a case that practitioners are watching to determine where the Supreme Court will come out on the government's authority," Hooker said.

Practitioners are also watching a different FCA case that's been gaining momentum in its bid for Supreme Court review. The case involves the Seventh Circuit's conclusion that the billing practices of grocery-and-pharmacy chain SuperValu Inc. reflected an "objectively reasonable" interpretation of regulations, and that FCA liability therefore isn't permissible. There wouldn't be liability even if SuperValu never believed its interpretation was correct and had been told by its lawyers that another interpretation was better, the Seventh Circuit wrote in its controversial opinion, which sparked a fiery dissent.

Morgan Lewis & Bockius LLP partner Kathleen McDermott, a former DOJ health fraud coordinator, told Law360 that the issue carries profound importance for companies that bill Medicare and Medicaid, because those programs are "governed by a maze of duplicative and inconsistent federal and state regulations."

"This will be a closely watched legal issue this year and of potential seismic impact," McDermott said.

The case has seemingly been gathering steam for many months. After whistleblowers petitioned the high court last year, Sen. Chuck Grassley, R-Iowa, the modern FCA's architect, chimed in to offer his official support. The justices then sought input from the government, which hasn't formally intervened in the case. In December, the U.S. solicitor general made a splash by urging review — "usually signifying that such review is imminent," Goldberg Kohn principal Roger A. Lewis told Law360.

The cases are U.S. ex rel. Polansky v. Executive Health Resources Inc. et al., case number 21-1052, and U.S. ex rel. Schutte et al. v. SuperValu Inc. et al., case number 21-1326, both before the Supreme Court of the United States.

IP Suits Carry 'Wide-Ranging Implications' for Drug Approvals

The pharmaceutical industry enters 2023 awash in uncertainty as recent and pending cases raise intriguing questions about intellectual property protections at the heart of product launches. Perhaps most notably, Supreme Court justices might soon wade into a high-stakes showdown over "skinny labels" — generic-drug labels that are bowdlerized to omit patent-protected indications.

At issue is a Federal Circuit decision that rejected a skinny label used by Teva Pharmaceuticals, leaving the generic-drug giant liable for induced infringement and $235 million in damages. The decision created "complete unpredictability" and "competition-killing uncertainty" around skinny labels, Teva wrote in a petition at the Supreme Court, which in October called for the views of the U.S. solicitor general — a common precursor to a cert grant.

A separate Federal Circuit skirmish that's just getting started will explore patent listings in the U.S. Food and Drug Administration's so-called Orange Book. Those listings can temporarily block approval of copycat products, and after a Delaware federal judge recently ordered the delisting of a Jazz Pharmaceuticals patent, the Federal Circuit intervened, leaving the listing in place at least until a February hearing.

In yet another closely watched area, confusion suddenly surrounds so-called orphan drug exclusivity — a temporary monopoly for certain uses of rare-disease drugs. The confusion stems from the Eleventh Circuit's rejection of FDA approval for pediatric use of an orphan drug that was already approved for adults. The circuit court's decision in Catalyst Pharmaceuticals v. Becerra remains intact because of a subsequent settlement.

In a Dec. 21 statement, an FDA spokesperson told Law360 that "the circuit court's decision in Catalyst potentially has far-reaching implications" for orphan-drug exclusivity, "raises several novel questions" and "has caused uncertainty for rare-disease drug development." The decision means drugmakers can "seek approval and exclusivity for a drug by focusing on the smallest, easiest-to-study populations, and such exclusivity would block the drug for the entire disease," the spokesperson said.

The spokesperson added that the outcome "could adversely affect children — particularly the youngest pediatric populations — and other populations that are typically studied later in drug development," and confirmed that the agency has temporarily stopped finalizing orphan-drug exclusivity determinations while it analyzes the issue.

Morrison Foerster LLP partner Stacy Cline Amin told Law360 — without commenting on specific cases — that disputes over skinny labels, the Orange Book and orphan exclusivity are "the most interesting litigation" to watch in 2023 for the life sciences sector.

"Litigation over these issues will have wide-ranging implications for product development and approvals," Amin said.

The cases are Teva Pharmaceuticals USA Inc. v. GlaxoSmithKline LLC et al., case number 22-37, before the Supreme Court of the United States; Jazz Pharmaceuticals v. Avadel CNS Pharmaceuticals, case number 23-1186, in the U.S. Court of Appeals for the Federal Circuit; and Catalyst Pharmaceuticals Inc. v. Becerra et al., case number 20-13922, in the U.S. Court of Appeals for the Eleventh Circuit.

Post-Roe Fallout Still Spreading Nationwide

After Supreme Court conservatives in June erased the constitutional right to abortion, a whirlwind of legal challenges emerged, and while the storm has subsided somewhat, reproductive rights litigation is far from calm as 2023 commences.

Roughly a dozen states have prohibited abortion almost entirely since the high court overturned Roe v. Wade, and major decisions are expected this year regarding attempts to enforce restrictions elsewhere. Some of the biggest decisions are expected in Georgia and Ohio, where courts are reviewing bans on abortion after six weeks of pregnancy — a point at which women might not even know they're pregnant.

In the Buckeye State, abortion is legal until 22 weeks of pregnancy because a preliminary injunction blocked a six-week ban and an appeals court in mid-December declined to intervene until there's a final order. The American Civil Liberties Union, Planned Parenthood and lawyers at WilmerHale in 2023 will "continue the litigation in trial court to obtain a permanent injunction on behalf of Ohio abortion providers," the ACLU said in a recent statement.

In the Peach State, the Georgia Supreme Court in November preliminarily reinstated a six-week ban, which a trial court judge had invalidated, and is set to review the ban in 2023. The reinstatement was a win for Georgia Gov. Brian Kemp, who had argued "that court should stay the lower court's decision now, without waiting to overrule it months down the line, while untold numbers of unborn children suffer the permanent consequences."

More broadly, a pending suit in the U.S. District Court for the Northern District of Texas is challenging the FDA's decades-old approvals of the abortion drugs mifepristone and misoprostol. A response from the FDA is due in January.

The case is being heard by Judge Matthew J. Kacsmaryk, who won confirmation during the Trump administration and hears virtually all cases in the district's Amarillo division. Judge Kacsmaryk was a lightning rod for liberals even prior to his confirmation, and he has issued a number of controversial decisions, including a December decision in favor of "state laws requiring parental consent or notification before distributing contraceptive drugs or devices to minors" in the Title X family planning program.

In the U.S. District Court for the Western District of Texas, reproductive rights advocates have launched litigation aimed at stopping Lone Star State prosecutors from targeting Texas women who obtain

abortions in other states. The case attracted extra attention amid efforts to compel testimony from Texas Attorney General Ken Paxton, who ran away from a process server in his front yard. A motion to dismiss is pending.

The cases include Preterm-Cleveland et al. v. Yost et al., case number A 2203203, in the Hamilton County Court of Common Pleas; State of Georgia v. SisterSong Women of Color Reproductive Justice Collective et al., case number S23M0358, in the Supreme Court of Georgia; Alliance for Hippocratic Medicine et al. v. U.S. Food and Drug Administration et al., case number 2:22-cv-00223, in the U.S. District Court for the Northern District of Texas; and Fund Texas Choice et al. v. Paxton et al., case number 1:22-cv-00859, in the U.S. District Court for the Western District of Texas.

'Decisions Have to Be Made' in Big Opioid Cases

After five years of knock-down-drag-out litigation, a nationwide legal clash over the opioid crisis reached an inflection point in late 2022 when the nation's largest pharmacy retailers floated multibillion-dollar settlements. Those offers meant that multidistrict opioid litigation had worked its way through the largest defendants, which also included drugmakers and wholesale distributors.

Appeals are still pending in two major cases — a pharmacy case, now at the Sixth Circuit, that produced a $650 million verdict for Ohio local governments and a distributor case, now at the Fourth Circuit, that produced a defense win over West Virginia local governments. But generally speaking, attention is turning in opioid litigation to a handful of supermarket chains with drugstore divisions, such as Albertsons Cos. and The Kroger Co. The MDL has bellwether pharmacy trials teed up if settlement talks with those regional pharmacies aren't fruitful.

Fifty manufacturers and distributors have also managed to stay on the MDL's sidelines until now. There's considerable variation in the companies' market shares and financial wherewithal to fund sizable settlements, and it's not publicly known whether many of them have an appetite for litigation.

Spangenberg Shibley & Liber LLP lawyer Peter H. Weinberger, plaintiffs liaison counsel in the MDL, told Law360 in mid-December that the parties were seeking to decide in the coming months whether they could strike deals to resolve the outstanding suits.

"The judge has identified 50 defendants that are manufacturers or distributors that were not part of any bellwether, and decisions have to be made," Weinberger said.

The MDL is In re: National Prescription Opiate Litigation, case number 1:17-md-02804, in the U.S. District Court for the Northern District of Ohio.

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