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The Hottest Topics For Health Attys In 2022's Homestretch

By **Jeff Overley**

Law360 (September 2, 2022, 10:55 PM EDT) -- A torrid 2022 for health care litigation is entering a red-hot homestretch featuring fallout from the U.S. Supreme Court's explosive repudiation of abortion rights, the potential for three False Claims Act clashes at the high court, and the increasingly likely prospect of a funding fiasco for the U.S. Food and Drug Administration.

Lawyers for doctors, hospitals, pharmacies, drugmakers and medical device developers forecasted a tumultuous trip around the sun when 2022 began, and those predictions have been borne out during the past eight months.

Abortion is no longer a constitutional right, Medicare has been empowered to negotiate drug prices, physicians have been equipped with stronger defenses in opioid crisis prosecutions, and legal challenges to health regulations are suddenly surrounded by **a** redesigned doctrine of administrative law, to name just a few highlights.

The health care and life sciences industries — massive and heavily regulated sectors with wide-ranging legal needs — are now facing an autumn of additional upheaval. That's partly because of aftershocks from seismic Supreme Court rulings in recent months and partly because of separate policy endeavors and court cases that have been quietly gathering steam.

Here, Law360 shares perspectives from health and life sciences lawyers in varied practice areas about the sizzling stretch they expect as the year wraps up.

'Three-Ring Circus' of FCA Litigation at Supreme Court

Attorneys widely agree that the next few months could produce profound movement in the False Claims Act space, where the Supreme Court is eyeing a trio of hotly contested legal issues.

The high court has already agreed to examine one of those issues: the murky boundaries of the federal government's power to torpedo disfavored FCA complaints filed by whistleblowers. Justices have also expressed interest in two other issues: a circuit split over the amount of detail required in FCA lawsuits, and the idea that an incorrect yet "objectively reasonable" approach to regulatory compliance negates FCA liability.

"As it pertains to False Claims Act litigation, the final quarter of 2022 is poised to be a veritable three-ring circus," Nichols Liu LLP partner Bob Rhoad told Law360.

All three issues carry relevance for FCA enforcement in virtually any industry. But the three issues are all arising at the Supreme Court in the context of medical treatments and prescription drugs, and the FCA nowadays is overwhelmingly wielded against bogus billing in Medicare and Medicaid, so the significance for health and life sciences is crystal clear.

"Today's False Claims Act is now primarily a health care fraud enforcement law," Arnold & Porter partner Murad Hussain noted. "It's no surprise that the Supreme Court recently singled out three Medicare-related FCA cases as vehicles for potentially clarifying the FCA's scope."

Although the justices haven't formally accepted cases involving two of the three issues, they have repeatedly requested the U.S. solicitor general's views on the issues; those requests are often precursors to acceptance of a case.

It's also true that the high court has frequently accepted FCA cases during the past quarter-century. In that time period, the Supreme Court's FCA opinions overall have tended to benefit the defense bar, but some individual decisions have been mixed bags or victories for FCA plaintiffs. With that in mind, it's tough to predict how one or more FCA cases in the upcoming term might ultimately affect health and life sciences companies.

"Whether anticipated decisions will favor enforcement, or curb overreach, is yet to be seen," Rhoad said. "But they are certain to significantly alter the FCA [and] health care fraud enforcement landscape for years to come."

'Badly Needed Reforms' in FDA Realm Face Pivotal Moment

While the calendar year is only a few months from completion, the federal government's fiscal year is mere weeks from its Sept. 30 finish line. That's especially important in 2022, because time is running out for Congress to renew a five-year authorization — last granted in 2017 — of billions of dollars in fees that bankroll FDA approvals and inspections for drugs and devices.

For much of this year, lawmakers looked like they were gliding toward a bipartisan accord on fees and a potpourri of provisions involving accelerated drug approvals, medical device cybersecurity, dietary supplement labeling, off-label promotion, the safety of personal cosmetics and oversight of diagnostic devices known as laboratory developed tests, among other things.

But serious disagreements spilled into public view over the summer and have cast doubt on the timing and scope of a reauthorization package. Sen. Richard Burr, R-N.C., ranking member on the Senate health committee, in mid-July denounced "anti-innovation" amendments to a 400-page draft bill and released an alternative 70-page bill that he described as a "clean reauthorization."

Morrison Foerster LLP partner Stacy Cline Amin, who served as the FDA's chief counsel during the Trump administration, told Law360 that "one of the biggest sticking points" for Burr appears to be a rider that would essentially overrule the Eleventh Circuit's controversial decision in Catalyst Pharmaceuticals v. Becerra. The decision dramatically widened market exclusivity for so-called orphan drugs that treat rare diseases.

"I understand his concern about tacking such an important piece of legislation onto the bill at the last minute," Amin said. "But I think his concern is misplaced in this instance. The Catalyst fix would clarify

the interpretation of orphan exclusivity that Congress meant when it originally enacted the provision."

It's virtually certain that lawmakers will eventually reauthorize the fees. What's unknown is whether they'll find common ground on the sizable suite of tagalong provisions involving supplements, cosmetics and lab tests.

"These are three huge industries that are largely unregulated today," Amin said. "It's important that Congress get the balance right in regulating these industries, but if they don't attach to the user fee [legislation], it might be years or decades before we see badly needed reforms."

'Often-Conflicting' Laws Complicate Abortion Drug Access

More than two months have passed since Supreme Court conservatives overruled Roe v. Wade, clearing the way for near-total abortion bans that are in effect, or looming, in states throughout much of the South, the Midwest and the Great Plains.

Widespread litigation and policy pronouncements have ensued, and some of the most prominent battles thus far have pitted the Biden administration against Republican-led states in tests of the federal government's ability to preserve abortion access in limited circumstances.

One of the top unanswered questions centers on access to abortion-inducing drugs, including drugs that have other medical uses unrelated to pregnancy. Reports of pharmacists refusing to fill certain prescriptions — sometimes because of personal opposition and sometimes because of concerns about potential legal exposure — have prompted admonitions from the U.S. Department of Health and Human Services and Democratic state attorneys general.

"Pharmacy providers now face a patchwork of often-conflicting state and federal laws," Quarles & Brady LLP associate Richie Davis told Law360, adding that the issue "is particularly acute for mail-order pharmacies that ship medications across all 50 states" and must ensure that individual prescriptions comport with laws in multiple jurisdictions.

Additional questions have arisen surrounding circumstances in which emergency contraception can be dispensed without running afoul of state laws that are backed up by criminal penalties. To steer clear of legal jeopardy, pharmacies should be diligently monitoring laws and guidance that are changing by the day, and they should also be "closely reviewing diagnosis codes on prescriptions to ensure the drugs are dispensed for a lawful purpose," Davis said.

The issue is made even more salient by the fact that medication has become the dominant method of terminating a pregnancy, accounting for 54% of abortions in 2020, according to the nonprofit Guttmacher Institute, which supports abortion access.

Medication abortion typically utilizes the drug mifepristone, which won approval more than two decades ago. Since then, "states have taken steps to restrict access to the drug," and after the end of Roe's guarantee of abortion access, "these efforts are likely to intensify," Rachel L. Sher, a partner in the Manatt Health practice at Manatt Phelps & Phillips LLP, told Law360.

On the same day that the Supreme Court struck down Roe in Dobbs v. Jackson Women's Health Organization, U.S. Attorney General Merrick Garland warned that "states may not ban mifepristone based on disagreement with the FDA's expert judgment about its safety and efficacy. "

That warning was premised on the supremacy of federal law, and Sher said that "courts will be faced with determining whether a state-based ban of mifepristone violates the Supremacy Clause and is therefore preempted."

"There is little precedent on these questions and therefore limited guidance on how courts are likely to rule," she said.

Deference Decisions Mean 'Sea Change in Health Care Law'

At the end of the Supreme Court's term, several decisions seemed to dilute so-called Chevron deference, the landmark doctrine that requires judicial deference to reasonable agency views of ambiguous laws.

One of those decisions indicated that the Chevron framework doesn't apply to "major questions" with hugely significant economic or political implications. Two other cases, both of which involved Medicare reimbursement, ended up being decided without use of Chevron, even though the doctrine was extensively discussed during briefing and oral arguments.

"The court made clear that 'major' assertions of agency authority are not to be evaluated under Chevron," and "the court may be diminishing Chevron ... by simply ignoring it," Hunton Andrews Kurth LLP partner Elbert Lin told Law360.

Chevron deference had already been watered down in recent years amid conservative complaints about judges being too deferential, and the doctrine's diminution is likely to prove helpful for lawsuits alleging overreach by regulators.

"These decisions reflect a potential sea change in health care law and for administrative litigation more generally," Arnold & Porter partner Allon Kedem told Law360.

The Supreme Court has been eyeing several petitions related to firearm regulations and could accept one of those cases soon, creating an opportunity for the justices to explicitly overrule the Chevron doctrine. Reed Smith partner James F. Segroves, who has been tracking those petitions, told Law360 that a definitive end to Chevron deference could mean that courts will largely stop considering the context surrounding the passage of federal laws, resulting in narrower analyses of statutes during litigation.

"There are some who would omit from that analysis legislative history altogether — they would say, 'Focus on the plain language of the statute,'" Segroves said.

Some observers are skeptical, however, that the weakening of Chevron will deal a big blow to agencies within HHS, given that health care rules and regulations often involve intricate factual issues.

"Judges don't want to wade into scientific areas they don't know about," Brown Rudnick LLP partner Neil P. DiSpirito said.

Amin, the MoFo partner, echoed that observation, telling Law360 that the so-called major questions doctrine is unlikely to have profound consequences for FDA rulemaking.

"I guess I'm a contrarian in that I think most FDA actions are well within the agency's statutory authority, and courts tend to give deference to FDA when it's exercising its expert or scientific judgment," she said.

DOJ Tasks 'Much More Difficult' After CSA Decision

In one of the last decisions of its recently concluded term, the Supreme Court in Ruan v. U.S. interpreted the Controlled Substances Act to require proof beyond a reasonable doubt in criminal cases that medical professionals "knowingly or intentionally" doled out narcotic painkillers in an unauthorized manner.

There have already been signs that the interpretation spells trouble for the U.S. Department of Justice. For example, the DOJ dropped a major opioid case against a drug distributor last month and several individuals, and defense counsel have said that the Ruan decision was a factor.

As another example, retail giant Walmart Inc. has been touting the Ruan decision in a civil opioid case brought by the DOJ. In one recent filing, Walmart averred that the DOJ had failed to identify "new factual allegations or legal theories it intends to assert in an amended complaint in an effort to shore up ... deficiencies following the Ruan decision."

The final months of 2022 are likely to generate clarity about Ruan's impact on pending cases and past convictions, as briefs hit court dockets across the country. In the longer term, the decision's emphasis on the need to prove intentional wrongdoing could elevate the importance of compliance advice.

"Doctors [who] wish to violate the law will take all the wrong lessons from Ruan and attempt to create a willfulness defense while committing violations of the Controlled Substances Act," Hunton Andrews Kurth counsel Sean O'Connell told Law360.

As a result, O'Connell added, the DOJ "will likely have a much more difficult time drawing the line between health care professionals that attempt to rely in good faith on the advice of compliance professionals, but mistakenly fall short, versus those that know they are illegally distributing controlled substances and hire compliance professionals to cover up their crimes."

--Editing by Jay Jackson Jr. and Emily Kokoll.
