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Health Care Antitrust Weekly: Klobuchar Presses Drugmakers to De-list FTC-Disputed Patents by End of Month; FTC Responds to Motions to Dismiss in Case Against U.S. Anesthesia Partners and Welsh Carson; Updates on Encompass Health, iRythm, Corcept

Klobuchar presses defiant drugmakers to de-list FTC-disputed patents by end of month. While the FTC "discusses next steps" for dealing with manufacturers who refused to remove patent listings disputed as improper, Senator Amy Klobuchar (D-MN) warned drugmakers last week to withdraw the listings. AbbVie (ABBV), AstraZeneca (AZN), Boehringer Ingelheim, GlaxoSmithKline (GSK), Mylan-Viatris (VTRS) and Teva (TEVA) have until the end of the month to delist all patents identified by the FTC or provide Klobuchar with a written explanation defending the listings.

Klobuchar noted that "at least three warning letter recipients" had taken steps to remove listings disputed by the FTC as improper, and gave GSK and its subsidiary GlaxoGroup some credit for having removed most of their disputed patents in the letters.

"While your inventions that benefit consumers deserve strong patent protections, those patents should not be used to box out generic drug competition long after legitimate patent protections have expired. I urge you to remove all remaining patents identified in the FTC's November 7 letter as quickly as possible," Klobuchar wrote to the companies.

Boehringer Ingelheim, AstraZeneca and GSK responded to a request for comment on Klobuchar's warning letters with general statements regarding their disputed patent listings; None addressed Klobuchar's requests specifically. AbbVie, Mylan-Viatris and Teva did not respond.

Drugmakers who refuse to remove improperly listed patents face legal risks beyond federal enforcement, as we've previously reported, and the issue is already making an appearance in ongoing private litigation. In a federal antitrust lawsuit alleging Teva abused the Orange Book to deter competition for its QVAR product line of inhalers, Plaintiffs' counsel recently asked the Court to take "judicial notice" of Teva's defiance of the FTC and a recent HELP Committee investigation of the company's inhaler products.

FTC defends antitrust claims against anesthesiology group, says Welsh Carson is still on the hook. The agency reasserted its allegations that physician group U.S. Anesthesia Partners (USAP) and private equity backer Welsh, Carson, Anderson and Stowe "rolled up" anesthesiology practices in Texas, stifling competition and forcing insurance plan sponsors and patients to pay higher prices. In responses filed last week, the FTC opposed both Welsh Carson's and USAP's motions to dismiss.

As *The Capitol Forum* reported last November, Welsh Carson argued that the suit against it should be dropped because the company could not be held liable for USAP's actions. However, the FTC argued in its opposition to Welsh Carsons' motion to dismiss that Welsh Carson and USAP acted as a single enterprise—and even if they didn't, the FTC said, the complaint still plausibly establishes Welsh Carson's involvement as anticompetitive.

"Unable to engage on the merits of the FTC's claims, Welsh Carson instead raises a series of tangential arguments about corporate law and the FTC's statutory and Constitutional authority," the FTC wrote. "None of them, however, entitle Welsh Carson to evade responsibility for its unlawful conduct."

The FTC also opposed USAP's motion to dismiss, using similar arguments to those used against Welsh Carson. USAP, like Welsh Carson, had challenged the FTC's authority to bring the case. USAP, like its co-defendant, argued that Section 13(b) prevented the FTC from seeking injunctive relief in the absence of parallel administrative proceedings.

The FTC pushed back against this claim, writing that USAP had misunderstood Congress' intents in establishing the FTC's powers and that USAP's arguments weren't clear.

"If USAP were correct that the FTC must always file an administrative complaint seeking a cease-and-desist order (contrary to every court's interpretation of Section 13(b)), it is unclear what purpose would be served by also using Section 13(b) to 'seek . . . a permanent injunction' from a district court for the same violation," the FTC wrote.

Neither FTC nor WCAS responded to a request for comment on the FTC's recent court filings by press time.

PBM critics discuss "revolving door" in Congress. The former legislative director for Rep. Tom Cole (R-OK) recently left Cole's office to serve as vice president of federal affairs at America's Health Insurance Plans (AHIP). The lobbying group, which represents the parent organizations and affiliates of two of the "Big Three" PBMs, has received media attention for defending the PBM industry amid mounting concerns about PBMs' impact on drug pricing and affordability.

Dr. Ge Bai, professor of accounting at Johns Hopkins Carey Business School and professor of health policy and management at Johns Hopkins Bloomberg School of Public Health, described this personnel change as a "typical revolving door episode."

"Since health care is heavily regulated and subsidized by the government, government experience becomes very valuable to industries aiming to enhance bottom lines," Bai said. "The lucrative options they offer are usually difficult to refuse as a post-Hill career choice."

Dr. Marion Mass, pediatrician and co-chair of the advocacy organization Practicing Physicians of America, agreed: "It's no surprise to the public to know there is brisk traffic in the revolving door between congressional offices and lobby groups," Mass told *The Capitol Forum*. "The medical care sector relies upon public trust for functionality; it's been rapidly eroding, for a myriad of reasons, not the least of which is the outsized influence of large corporations that put profits over patient needs as the center of their model."

According to Dr. Madelaine Feldman, immediate past president of the Coalition of State Rheumatology Organizations, "many members of the House and Senate see moving to a lobbying firm after retirement, as a 'golden egg' laid by the 'goose' named Congress."

AHIP logged $134,500 in lobbying in its mid-year report for 2023, distributed across 25 senators and House members—though Cole, who chairs the House Committee on Rules, wasn't included in that list. Congress has proposed and advanced a number of laws aimed at PBM reform, including a legislative package that passed the Senate Finance Committee last November. However, no sweeping PBM reform has been enshrined into law.

The Capitol Forum reached out to the former legislative director, AHIP, the House Rules Committee, and Rep. Cole's office with questions about the so-called "revolving door" between PBM lobbyists and Congress. We did not receive any statements.

Medical Care Market Developments

Rising Medicare Advantage costs could place additional pressure on third-party facilities. Over the past few weeks, several large insurers participating in the Medicare Advantage program, such as Humana (HUM) and UnitedHealthcare (UHC), have disclosed higher-than-expected medical payouts to beneficiaries.

In a regulatory filing, Humana noted that the trend would likely be sustained, as it "anticipated the higher level of medical utilization experienced during the third quarter in its Medicare Advantage business would continue for the remainder of the year." Humana highlighted higher than anticipated in-patient utilization as well as "physicians, outpatient surgeries, and supplemental benefits" as drivers of these rising costs.

These increased costs could cause Medicare Advantage insurers to further scrutinize high-cost, third-party healthcare providers that work with the programs, such as skilled nursing facilities and inpatient rehabilitation hospitals.

The Capitol Forum has previously reported that inpatient rehabilitation facilities run by Encompass Health (EHC) engaged in certain practices to admit patients in their facilities that may not have qualified for admission.

The rise of Medicare Advantage already poses a problem for the company, as *The Capitol Forum* previously reported. Recently, a former controller at a rehabilitation hospital run by the company explained to *The Capitol Forum* how Medicare Advantage plans already have high rates of denial in order to lower the cost of care.

According to the former controller, admitting patients on a Medicare Advantage plan was far harder than admitting patients on traditional Medicare.

"I always tell people to sign up for regular Medicare rather than Advantage," the former controller said, "Medicare Advantage plans are very restrictive by design when it comes to things like outpatient rehabilitation."

For those programs, the controller explained, Medicare Advantage plans are not only more restrictive in admissions, but also often negotiate lower payment rates.

"For Medicare Advantage, the whole pitch is that it is saving Medicare money. At the same time, the Medicare Advantage contractor also has to make money on the program, so there's less money going in, while more is being diverted away to the contract holder. That leaves a lot of facilities with a lot less payment."

As plans seek to lower costs, those restrictive admissions policies and low payment rates may become more stringent.

Reports of iRhythm algorithm issues tripled in December. Reports of iRhythm's (IRTC) Zio AT heart monitor failing to warn doctors of patient arrythmias because of a "potential algorithm sensitivity issue" more than tripled from November to December, according to a *Capitol Forum* analysis of the FDA's Manufacturer and User Device Experience (MAUDE) database. As *The Capitol Forum* previously reported, November was the first month in which the algorithm issue began appearing in reports to the database, with eight reports citing the problem.

In December, that number grew to 27 reports; an additional two reports appear to have been added to the November tally since *The Capitol Forum* reported the initial figures, bringing the current number of reports in November to ten.

This new issue could further add to the problems that the company has faced with its Zio AT device. As *The Capitol Forum* reported, the Department of Justice is likely investigating iRhythm's marketing of the Zio AT as a mobile cardiac telemetry monitor, which garners significantly more reimbursement than a typical electrocardiograph monitor.

In a lengthy warning letter to the company, the FDA found deficiencies with the Zio AT that prevented it from alerting doctors to cardiac events in their patient, including a 500-transmission limit. That limit was cited in the narratives of several injuries and deaths of patients wearing the Zio AT that were reported to the FDA.

iRhythm did not respond to a request for comment.

Pharma Supply Chain Developments

Teva appears to launch first generic competitor for Corcept's sole product Korlym. With the appearance of 300mg mifepristone tablets on its website last week, Teva seems to be gearing up to launch its generic competitor for Korlym "at-risk" after defeating Corcept Therapuetics' ANDA litigation in late December.

While Corcept appealed, Teva can begin marketing its product before the appeal is resolved, knowing it could be on the hook for hefty damages if Corcept manages to get the ruling thrown out. Firms are often hesitant to launch "at-risk," since damages in patent litigation are based on the harm to plaintiffs—meaning the amount would be calculated using the price of Corcept's product rather than Teva's discounted version.

As detailed in previous reporting, generic competition for Korlym poses significant material risk to Corcept because it's the company's sole approved product and revenue generator. Appealing is another attempt by Corcept to stall Teva's entry, though the Israeli drugmaker appears unfazed.

According to Teva's website, the generic has launched in the U.S., though it may not be commercially available yet due to a variety of supply chain and logistical factors. Teva's online catalog lists a "launch date" of January 19, 2024 and includes links to documents with "launch materials" in the URL. Pricing information also became available on at least one industry pricing compendia website, listing Teva's product at a 13% discount off Korlym. The drug's packager is Teva subsidiary Actavis Pharma, according to the National Drug Code listed in Teva's catalog.

It's not yet clear when Teva's generic will reach pharmacy shelves—or which pharmacies' shelves it will fill. Due to the medication's risks, Corcept uses a "limited distribution network" with a single specialty pharmacy dispensing all Korlym prescriptions—but that wasn't required by the FDA, and there is no indication in Teva's approval letter that a similar program would be necessary. Distribution of other mifepristone products used in medication abortions are subject to Risk Evaluation & Mitigation Strategy (REMS) requirements from the FDA, though even this program has more distribution channels than Corcept's. The FDA does not require REMS for Korlym.

The catalog also already has information on a copay assistance card for Teva's generic, which offers up to $2500 per 14 tablets of Mifepristone 300mg in assistance for commercially-insured patients. "Commercially insured patients could pay as low as $0 for their prescription" according to Teva's website.

The copay assistance card suggests Teva will make the drug available through more pharmacies: When *The Capitol Forum* asked Teva's mifepristone copay assistance program—operated by Mercalis—for participating pharmacies in Washington, D.C., the representative identified numerous retail pharmacy locations including smaller, local pharmacies and multiple CVS locations. Though these stores are part of Teva's copay card network, *The Capitol Forum* was unable to confirm current availability of generic Mifepristone 300mg at any pharmacy.

CVS could face fine, probation for "a period of years" due to ongoing staffing, safety issues at Ohio pharmacy locations. As the hearing regarding issues discovered during inspection at a CVS pharmacy location in Canton, Ohio in 2021 nears conclusion, the state's Board of Pharmacy is expected to decide next month which penalties, if any, to impose on CVS store #2063. Principal Deputy Assistant Attorney General Henry Appel—who is representing the Board in the hearing—recommended that CVS be fined and the Canton store put on probation for "a period of years" due to the safety violations.

At its January meeting, the Board heard from CVS' expert witness Dennis McAllister who argued that the issues in the pharmacy inspection report were systemic in the industry rather than the result of actions by CVS. McAllister, who previously served on the Arizona State Board of Pharmacy for decades, argued that all pharmacies have experienced challenges due to the pandemic and labor shortages.

But the Board members, all but one of whom are pharmacists themselves, have expressed skepticism of CVS' arguments during the hearings. At the January hearing, one board member noted that the Canton CVS store did not appropriately increase pharmacists' hours after they absorbed the prescriptions of two other pharmacies that had closed.

How harshly the state body responds could be an indication of whether the Board considers the violations as isolated to individual stores, or view the issues as part of a broader trend at CVS in the state. The Board has issued citations against at least 15 CVS locations across the state since July. The Ohio Board of Pharmacy did not respond to a request for comment by press time.

A spokesperson for CVS provided the following statement to *The Capitol Forum*:

"We work with the Board of Pharmacy to resolve any allegation raised from inspections at CVS Pharmacy locations and have policies and procedures in place to support prescription safety and security.

"Regarding staffing, it's well known that there's an industry-wide shortage of health care providers, including pharmacists, and we're committed to ensuring there are appropriate levels of staffing and resources at our pharmacies. In response to feedback from our pharmacy teams, we're making targeted investments to address their key concerns, including enabling teams to schedule additional support as needed, enhancing pharmacist and technician recruitment and hiring and strengthening pharmacy technician training. These changes began in November and will continue to be introduced throughout 2024."