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Health Care Antitrust Weekly: FTC Takes Aim at NC Hospital Merger; Advocates Criticize Senate White Paper for Not Targeting GPO Fees; Senators Seek Updates on FTC's PBM Investigation

Antitrust Agency Health Care Agenda

FTC Health Care Division calendars for December 2023. Calendars for FTC Health Care Division Acting Assistant Director Bradley Albert; Deputy Assistant Director Kara Monahan; and Acting Deputy Assistant Director Lauren Peay for December can be found at the following link.

Some highlights of the calendars:

- All three officials attended meetings on December 7 and December 14 related to "Pharma Bro" Martin Shkreli, who was banned from the drugmaking industry in 2022 after a court sided with the agency and found that he illegally prolonged a monopoly on the toxoplasmosis treatment Daraprim. The FTC on January 20 asked a federal judge to hold Shkreli in contempt for failing to provide information related to whether he's complying with the ban.

- Albert also attended a meeting on December 12 regarding *FTC v. Vyera,* the agency's case against the company at the center of Shkreli's alleged scheme. Philip Levitz, senior assistant solicitor general in the New York attorney general's office, signed on to the case.

- Albert participated in a meeting on December 1 with Megan Hansen, senior advisory attorney at the U.S. Department of Labor.

FTC sues to block Novant Health's purchase of two hospitals in North Carolina. The agency's January 25 administrative complaint and accompanying lawsuit filed in federal court seek to prevent Novant Heal, a provider that has a significant presence in several local markets in North Carolina, from acquiring Community Health Systems' Lake Norman Regional Medical Center and Davis Regional Medical Center, in addition to other assets. The $320 million deal would increase concentration in the general acute care market, eliminate price competition in the Eastern Lake Norman area and end the head-to-head rivalry between Lake Norman Regional Medical Center and a nearby Novant hospital, Huntersville Medical Center, the FTC said.

"Hospital consolidations often lead to worse outcomes for nurses and doctors, result in higher prices, and can have life and death consequences for patients," Henry Liu, director of the agency's Bureau of Competition, said in a statement. "There is overwhelming evidence that Novant's deal with Community Health Systems will be detrimental to patients in the Eastern Lake Norman Area, including leading to higher out-of-pocket costs for critical health care services."

The agency said the deal would give Novant almost 65% of the inpatient general acute care market in the Eastern Lake Norman area, which is north of Charlotte. The transaction would allow the health system to charge higher prices, according to the FTC.

"[I]f the Proposed Transaction is allowed to close, Novant would be able to leverage its control of an even greater proportion of the Eastern Lake Norman Area's hospitals when negotiating rates for Lake Norman Regional," the complaint said. "The Proposed Transaction is likely to substantially reduce the need to offer attractive rates at Lake Norman Regional to persuade insurers to include the hospital in their provider networks."

The agency also alleged that the transaction would violate Section 7 of the Clayton Act and Section 5 of the FTC Act.

A Novant Health spokesperson said in a statement to *The Capitol Forum* that the company would fight the suit*:* "As a nationally recognized leader in quality and patient safety, Novant Health is committed to delivering the highest-quality, patient-centered, physician-directed care to the communities served by Lake Norman and Davis Regional Medical Centers. We will pursue available legal responses to the FTC's flawed position and vigorously defend our commitment in court. We remain confident that Novant Health can bring exceptional care, leading-edge innovation and long-term stability to Lake Norman and Davis Regional Medical Centers for these reasons."

The other hospitals didn't respond to requests for comment.

DOJ investigating AI in health care. DOJ is taking a closer look at whether the integration of artificial intelligence algorithms into electronic health records can be used to steer doctors toward certain treatments, potentially in violation of anti-kickback and false claims laws, according to reporting from Bloomberg.

DOJ took aim at this issue in a criminal case against Purdue Pharma and electronic health record contractor Practice Fusion that subsequently settled. Purdue pled guilty in 2020 to federal prosecutors' allegations that the companies used pop-up messages embedded in Practice Fusion's software to push doctors to prescribe Purdue's opioids.

DOJ has over the past several years subpoenaed information about electronic medical records from major drugmakers including Merck, GSK and AstraZeneca, according to Bloomberg.

"GSK is cooperating with the United States Department of Justice," a company spokesperson told *The Capitol Forum,* declining to comment further because "the investigation is in its early stages."

DOJ, Merck and AstraZeneca didn't respond to a request for comment on the investigation.

Pharma Supply Chain Developments

GPO reform advocates criticize Senate Finance Committee white paper on drug shortages. Senate Finance Committee Chair Ron Wyden (D-OR) and Ranking Member Mike Crapo (R-ID) released a white paper on Thursday with policy ideas for tackling ongoing generic drug shortages—and some advocates for health care reform aren't impressed.

As *The Capitol Forum* reported, critics point to group purchasing organizations (GPOs), consolidated middlemen that manage contracts between buyers and suppliers, as one of the root causes of drug shortages. Critics argue that GPOs destabilize the drug supply chain and lessen incentives for generic drug production by charging drugmakers high fees and using restrictive contracting.

Wyden referred to consolidation among health care middlemen at a December 5 Senate Finance Committee hearing on the drug shortage crisis. The recent white paper, however, omitted any mention of consolidation.

Instead, the lawmakers in the paper suggested the drug shortages could be resolved in part with an adjustment to Medicare payments for generic sterile injectable drugs (GSIs) "coupled with policies that create incentives for providers and their business partners (e.g., GPOs, wholesalers) to contract with GSI manufacturers at sustainable prices." In the white paper, the senators also floated the idea of rewarding hospitals based on "contract features between hospitals and/or GPOs and GSI manufacturers."

Several longtime advocates for GPO reform said that the white paper missed the mark in part by not addressing the administrative fees that these entities charge to drug manufacturers. Critics allege that these fees, protected by the Anti-Kickback Statute (AKS) safe harbor, create a "pay to play" marketplace, as we've reported.

"I read and re-read it several times and found no mention of the AKS safe harbor, and no mention of the fact that the generic drugmakers and other suppliers pay 'legalized' kickbacks to GPOs and that the GPOs in turn pay 'share backs' to CEOs of major GPO member hospitals for enforcing compliance with their exclusive contracts," Phillip Zweig, executive director of Physicians against Drug Shortages, said. "GPO prices are not real prices. They're rigged prices. Normal markets don't operate the way they're described in this paper. The GPOs (and PBMs) have undermined the law of supply and demand that governs virtually every other industry."

Zweig said that Medicare Part B reimbursements are based on the average sales price (ASP) of a drug, which excludes "bona fide service fees"—including those paid by manufacturers to GPOs. For its part, in 2011, the Department of Health and Human Services decided that increasing ASP wouldn't necessarily remedy drug shortages because of the role played by GPOs and other intermediaries in the drug supply chain.

"In theory, the drugmakers can charge whatever they want," Zweig said. "But the GPOs are extorting whatever they want from the drugmakers."

The Senate Finance Committee declined to comment. The Healthcare Supply Chain Association, which lobbies on behalf of hospital GPOs, didn't respond to a request for comment.

Senators request update on FTC's 18-month PBM inquiry; CEOs of Merck, J&J agree to testify on drug prices after Sanders threatens subpoenas. In a letter to FTC Chair Lina Khan last week**,** Senators Chuck Grassley (R-IA) and Maria Cantwell (D-WA), along with 12 of their colleagues, sought a progress report on the agency's 6(b) inquiry into pharmacy benefit managers (PBMs), launched in June 2022. The senators noted political momentum for PBM reform and requested the agency provide an update to inform their efforts and complete the investigation promptly.

"A commitment to a timely study and interim progress report will provide transparency, insight about possible competitive harms, and inform the responsiveness and cooperation of impacted parties," the senators wrote. "We appreciate the FTC's commitment on this matter to patients and taxpayers."

An FTC spokesperson declined to comment on the senators' letter or the PBM inquiry's status.

Following a threat to issue the Senate Health, Education, Labor and Pensions (HELP) Committee's first subpoenas in decades, the CEOs of Merck and Johnson & Johnson have agreed to testify in a hearing on what panel Chair Bernie Sanders (I-VT) called "outrageously high" U.S. drug prices. Merck CEO Robert Davis and J&J CEO Joaquin Duato had previously ignored requests to testify, but "reconsidered their positions" late last week, according to a press release from Sanders.

Davis and Duato are scheduled to appear at the February 8 hearing with Bristol Myers Squibb CEO Chris Boerner, who had already agreed to testify.

"We have accepted the Senate HELP Committee's invitation for Johnson & Johnson's Chairman and CEO to participate in a hearing and look forward to building an understanding of our

longstanding efforts to improve affordability and access to medicines," Johnson & Johnson said in a statement to *The Capitol Forum*.

Neither Merck nor BMS responded to requests for comment.

The HELP committee also recently launched an investigation into the high prices of inhalers marketed by AstraZeneca, Boehringer Ingelheim, Teva and GSK.

Updates in Copaxone litigation: Judge denies most of Teva's motion to dismiss; opinion could affect other related lawsuits. Blue Cross Blue Shield of Vermont's lawsuit alleging it overpaid for Teva's multiple sclerosis treatment Copaxone (glatiramer acetate) due to an anticompetitive scheme has survived Teva's motion to dismiss. Judge Geoffrey Crawford of the U.S. District Court for the District of Vermont recently issued an opinion and order denying most of Teva's motion to dismiss the case. The order did grant a handful of dismissals related to particular state laws and exemptions.

Teva's alleged conduct to extend its monopoly over this type of multiple sclerosis treatment was detailed last spring in our "Exclusive Drug Dealing" series.

Crawford rejected Teva's arguments that sham patent litigation and FDA citizen petitions couldn't have delayed approval of generic Abbreviated New Drug Applications (ANDA) and concluded that Noerr-Pennington immunity shouldn't apply at this stage of the case. The immunity provision shields from antitrust enforcement companies petitioning the government to adopt laws or rules that may be anticompetitive.

Although Teva's strategy to convert patients to a new form of Copaxone couldn't be considered a true "product hop" because the older product remained on the market, the court found the behavior sufficiently coercive to deny the motion to dismiss without addressing the allegations of the company's conduct following the entry of rival generic drugs.

"The combination of pricing the new 40 mg drug below the legacy 20 mg version, threatening to withhold rebates for the 20 mg version, and pressing prescribers to exclude new generic entrants from their orders is sufficient to constitute a claim of coercive conduct," Judge Crawford wrote.

Teva didn't respond to a request for comment.

Blue Cross Blue Shield of Vermont's case is just one of several ongoing lawsuits related to Teva's conduct with Copaxone. The opinion could provide clues as to how other courts may view similar cases. In *Mylan v. Teva* (2:21-cv-13087), Mylan's counsel summarized the highlights of Crawford's

opinion in a letter, noting that "though the court partially granted and partially denied the motion, it denied it as to all aspects of the motion that are relevant to Mylan's case."

The allegations in both complaints are "nearly identical" with the Vermont insurer "borrowing heavily from Mylan's complaint," according to the letter from the company's counsel. The company is facing a similar motion to dismiss from Teva, and the letter indicates that Mylan is hoping for an opinion similar to Crawford from the New Jersey District Court, which is where Mylan filed the case. Mylan's attorneys noted that concluding one component of a scheme is anticompetitive is sufficient for the entire scheme claim to survive the motion to dismiss.