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Health Care Antitrust Weekly: Health Care Antitrust Under Trump; DOJ Sues to Block UnitedHealth/Amedisys; Update on Private Inhaler Antitrust Suit Against Teva; Mississippi Pharmacy Board Finds Optum Underpaid Independent Pharmacies

This article has been updated with a comment from an Amedisys spokesperson.

Experts weigh in on health care antitrust under Trump; PBM scrutiny is likely, but enforcers may be more lenient on health care roll-ups, health insurance deals. While the future of antitrust enforcement depends largely on who's appointed to key positions at the Federal Trade Commission and Justice Department, experts offered some clues into how the new administration might approach health care competition issues.

Under the Biden Administration, the FTC and DOJ have taken a relatively aggressive approach to health care—attacking private equity roll-ups, pharmacy benefit managers (PBMs), vertical integration in the insurance industry, and patent gamesmanship that delays generic competition for prescription drugs.

In a Nov. 12 speech, Assistant Attorney General Jonathan Kanter described the current administration's evolving approach to antitrust as compared to establishment antitrust, which he dubbed "Healthcare Tetris"—where enforcers "looked at whether simplistic blocks line up to create discrete horizontal or vertical lines."

"Unfortunately, these simple Tetris-like paradigms bear little resemblance to the emerging, but complex, ecosystem we confront as patients, health care practitioners, and employers," Kanter said. "In the world of Healthcare Tetris, we all agreed that horizontal consolidation raises concerns but did not look behind the two-dimensional geometry to see how vertical and horizontal business relationships intersect."

Experts predicted that a Republican-led FTC might take some different approaches. "The expected shift away from the Biden Administration's novel antitrust theories and new areas of focus like labor will undoubtedly have an impact in health care deals, but I don't expect any significant lessening of antitrust enforcement in the health care space," Daniel Powers, antitrust partner at McDermott, told *The Capitol Forum.*

Powers said that "[w]hile there are many areas where the new administration can be expected to shift direction from the current administration—e.g., abandoning the attempted revival of Robinson-Patman enforcement, scaling back the aggressive interpretation of the FTC's Section 5 unfair methods of competition authority, etc.—health care antitrust may see less significant changes."

Experts predicted that under Trump, the FTC will continue to target PBMs, health care middlemen that, according to critics, drive up drug prices so they can pocket large rebates from manufacturers. This could mean continuing the FTC's ongoing lawsuit against the "Big Three" PBMs for their alleged role in driving up insulin prices. There's distinct bipartisan support for an overhaul of the PBM business model.

"I could see a continued strong focus on PBMs because they tend to be a popular scapegoat for high drug prices that might allow the Trump Administration to say they're doing something to lower drug prices without actually harming drug manufacturers," Loren Adler, fellow and associate director at the Center on Health Policy at Brookings, told *The Capitol Forum*.

If it's any indication of how the incoming administration will approach PBMs, the previous Trump administration finalized a rule, going into effect in 2032, to remove the safe harbor for PBM rebates under the federal anti-kickback statute.

A robust approach to health care competition issues would fit with "some of the rulemaking during the Trump-Pence administration," including that PBM rule, and with "the economic populism they campaigned on," said Emma Freer, senior policy analyst for health care at the American Economic Liberties Project. Freer told *The Capitol Forum* that any efforts by Trump to favor large corporations over everyday citizens "will be met with loud and strong resistance from AELP and the American public."

But looking beyond PBMs, sources said it's likely the incoming administration will be less aggressive on challenging mergers and acquisitions, especially those that "go beyond textbook antitrust concerns surrounding horizontal consolidation," in Adler's words.

For example, private equity roll-ups in health care will, on the whole, face less antitrust scrutiny, sources said. Current FTC leadership, for its part, has expressed concerns about the effects of serial acquisitions on prices and patient care. The FTC sued a private equity-backed anesthesia group last year.

Lawyers and policy experts consulted by *The Capitol Forum* disagreed on the extent to which the Trump administration will continue scrutinizing vertical integration in the health insurance industry—the subject of a current DOJ probe into UnitedHealth Group (UNH) as well as DOJ's recent suit to block UnitedHealth from acquiring home health provider Amedisys (AMED). But several agreed that mergers between insurers will be more likely to go unchallenged.

While the agencies under Trump will be more merger-friendly overall, experts said hospital merger enforcement might be only modestly less aggressive as Republicans shift away from establishment antitrust politics.

"I think the enforcement would be more selective by the Trump administration with respect to hospital mergers," Bob Threlkeld, a partner in Morris, Manning & Martin's health care group, told *The Capitol Forum*. Threlkeld noted that a Trump-led FTC may not have sued to block Novant Health's acquisition of Community Health System in North Carolina, a deal *The Capitol Forum* covered closely.

"But if you have a proposed merger that will have a significant concentration of market power, then yes, I think there will be continued efforts by the Trump administration to enforce the Clayton Act or other laws," Threlkeld added.

Experts cautioned that the future of health care antitrust is still up in the air and depends on key staffing decisions and the extent of turnover at the agencies.

Notably, the Heritage Foundation's Project 2025—a massive policy document that came under attack by Democrats throughout the election—has a section on the Federal Trade Commission. It urges a Republican-led FTC to create a role in the Chair's office specifically for coordinating cooperation with state attorneys general.

DOJ and four states sue to block UnitedHealth's planned Amedisys takeover. After a more than year-long review, the department, joined by four states, sued yesterday to block the $3.3 billion deal, alleging that the tie-up would overly concentrate home health and hospice services in hundreds of local markets across the country.

If the merger were completed, DOJ said UnitedHealth would control at least 30% of those services in eight states. Nurses providing the services also would lose the benefit of UnitedHealth's LHC unit and Amedisys competing to employ them, according to the complaint, which was filed in federal court in Maryland.

"Home health and hospice nurses can play UnitedHealth and Amedisys off each other during hiring negotiations, resulting in higher pay or better conditions of employment," according to the complaint.

In the suit, DOJ details how UnitedHealth and Amedisys compete with each other in regional Medicare Advantage markets. The two parties try to outdo the other in Medicare Star Ratings, a

measurement of quality set by the Centers for Medicare & Medicaid Services. The two also compete on price, according to the complaint.

To address DOJ's concerns, the companies proposed divesting locations to a smaller rival. VitalCaring Group. However, that would still leave more than 100 communities will too few competitors, according to DOJ, that serve at least 200,000 patients and are covered by at least 4,000 nurses.

As for VitalCaring, it "is an unproven company with only three years of operational experience, poor financial performance, and potentially catastrophic legal exposure," the complaint says.

In a statement, UnitedHealth Group's Optum unit said: "The Amedisys combination with Optum would be pro-competitive and further innovation, leading to improved patient outcomes and greater access to quality care. We will vigorously defend against the DOJ's overreaching interpretation of the antitrust laws."

An Amedisys spokesperson gave the following statement: "We remain committed to the transaction, which we believe will create more opportunities to deliver quality, compassionate and value-based care to patients and their families. We look forward to supporting Optum in presenting our case."

Antitrust Agency Health Care Agenda

In private inhaler antitrust case, judge agrees with Teva that plaintiffs can't prove pay-for-delay. A U.S. district judge scrapped claims that drugmaker Teva (TEVA) unlawfully delayed generic competition for its QVAR inhaler by paying a would-be competitor, Amneal (AMRX), to stay off the market. Other antitrust claims in the case remain.

According to the antitrust suit, filed in 2023 by the Iron Workers District Council of New England Health and Welfare Fund, Teva's "pay-for-delay" agreement was anticompetitive and forced patients and health plans to continue to pay high brand-name prices. The lawsuit also accused Teva of warding off generic competition by listing bogus patents on its inhalers, filing sham litigation based on those patents, and "hopping" patients to new inhaler products simply to extend patent protections.

The FTC disputed Teva's patents on the QVAR inhaler last November, arguing that they were improper because they don't claim an active drug ingredient. Teva hasn't delisted any of the FTC-disputed patents and faces legal scrutiny from the agency.

But the judge's recent ruling in the private antitrust suit against Teva, rejecting the pay-for-delay allegations, shows how difficult it is to demonstrate that a company has paid a competitor to stay off the market.

In its complaint, the health and welfare fund argued that because Teva didn't sue Amneal, the first generic challenger for QVAR, for patent infringement, Teva likely paid Amneal to delay market entry. There's evidence in Amneal's earnings calls that the company has mapped out plans to launch a QVAR generic.

The judge, however, described the plaintiffs' argument as "pure conjecture."

The judge also found that Teva's explanation for its failure to sue was meaty enough to render the plaintiff's arguments implausible. In a response to the complaint, Teva said the company was barred by a 2016 divestiture order from the FTC—part of Teva's acquisition of drugmaker Allergan's generic business—from suing the acquirers of certain products, including off-brand QVAR. Specifically, Teva said the order prevented it from suing Impax Labs, Amneal's predecessor, over the drug.

The plaintiffs argued in return that it's not clear whether the order applied to Amneal and that Teva's responses don't rule out the possibility of pay-for delay.

Further details of the order are heavily redacted in court filings. Still, the judge wasn't convinced that the plaintiffs had offered enough evidence to suggest that a pay-for-delay agreement ever happened.

Teva's arguments about the FTC order may have helped to quash other cases against the company. Private plaintiffs filed two copycat QVAR antitrust suits, but both were dismissed in June.

Details of the Teva case aside, it's notoriously difficult to prove the existence of pay-for-delay agreements. Drugmakers must report certain agreements to the FTC, but the agency doesn't necessarily share details on specific deals. Academics have raised concerns that more nuanced pay-for-delay arrangements often fall under the radar.

Pharma Supply Chain Developments

UnitedHealth Group's PBM Optum reimbursed Mississippi independent pharmacies at lower rates than chain and UHG-affiliated pharmacies, state pharmacy board audit finds. In Mississippi, PBMs are prohibited from under-reimbursing independent pharmacies compared to affiliated pharmacies.

The state's board will host an administrative hearing in late December to discuss the audit's findings. PBMs' self-preferencing of their own subsidiaries—which may include under-reimbursements to unaffiliated pharmacies—was a central focus of the Federal Trade Commission's interim report on the PBM industry.

Separate from the Optum audit, the state's pharmacy board is set to hold administrative proceedings with Cigna's (CI) Express Scripts and CVS Caremark (CVS) on November 21.

UnitedHealth Group didn't respond to a request for comment.