

# Novel Antitrust Theories in Healthcare and Life Sciences Matters

**Monday, June 30**

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*2025 AHILA Annual Meeting*



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## Motivation

- 2023 DOJ/FTC Merger Guidelines
- Federal enforcement
- State level enforcement

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## Agenda

1. Serial Acquisitions
2. Allegations of Algorithmic Collusion
3. Drug Patent Listings as Alleged Means of Delaying Generic Entry
4. Life Sciences M&A as Alleged Means of Stifling Innovation
5. Takeaways

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## Serial Acquisitions in Healthcare: Legal Theories of Harm

- **Section 7 of the Clayton Act: Substantial Lessening of Competition**
  - Agency theory is that even if no single acquisition creates a dominant player, a series of acquisitions can cumulatively reduce competition in a geographic or service market
  - *JAB Consumer Partners/National Veterinary Associates*
- **Section 5 of the FTC Act: Unfair Methods of Competition**
  - The FTC can challenge conduct that doesn't rise to a full-blown Section 7 violation but nevertheless still undermines competition
  - *FTC v. U.S. Anesthesia Partners, Inc. & Welsh Carson Anderson & Stowe*
  - *JAB Consumer Partners/National Veterinary Associates*
- **Section 2 of the Sherman Act: Attempted Monopolization**
  - Should a single firm pursue a roll up strategy when it hasn't monopolized the market yet but is allegedly taking steps to do so
  - *FTC v. U.S. Anesthesia Partners, Inc. & Welsh Carson Anderson & Stowe*
- **Section 2 of the Sherman Act: Conspiracy to Monopolize**
  - This requires an agreement with two or more actors
  - *FTC v. U.S. Anesthesia Partners, Inc. & Welsh Carson Anderson & Stowe*

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## Serial Acquisitions in Healthcare: Economics Issues

- Despite their prevalence in the industry, serial acquisitions in healthcare have not been sufficiently studied by economists
- Their potential economic impacts are not well understood
  - How do serial acquisitions impact prices?
  - How do serial acquisitions affect medical care quality?
- Some economic studies have found that serial acquisitions can lead to industry consolidation in certain specialties and be accompanied by price increases
- At the same time, many serial acquisitions are multi-specialty acquisitions involving purchases of complementary rather than substitutable firms
- The price impacts of such acquisitions are more complex and require analysis of factors such
  - How does overall intensity/utilization of care change?
  - How does the patient mix change?

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## Serial Acquisitions in Healthcare: Economics Issues

- Beyond pricing, economists have studied the impact of serial acquisitions on medical quality and innovation and found mixed results
- For example, studies have shown that
  - Chain/private equity acquisitions can improve quality in IVF clinics
  - Notification exempt mergers in the dialysis industry can reduce quality
  - Physician management companies can change acquired physician groups' practice styles and clinical goals
- Although different studies find different results in different contexts, there is economic evidence that it matters a lot who the acquirer is
  - If firms which offer high medical quality and innovate are serial acquirers, we would expect to see medical quality increase as a result of serial acquisitions
  - The opposite would be true if serial acquirers are firms which offer low medical quality and do not innovate

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## Serial Acquisitions in Healthcare: Economics Issues

- Economists have also recently started analyzing the interplay between serial acquisitions and the emergence of large healthcare platforms
- Many large healthcare companies nowadays combine a variety of healthcare services such as
  - Health insurer
  - Pharmacy benefit manager
  - Physician practice
  - Home health agency
  - Data analytics firm
- Economic analysis of the impact of such conglomerate companies on healthcare prices and quality is complex; it requires analysis of issues such as
  - Does such conglomeration help deliver more integrated and better coordinated care?
  - Are there increased incentives to steer patients to other parts of a large conglomerate and what are the implications of such steering?

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## Allegations of Algorithmic Collusion in Healthcare: Legal Theories of Harm in *In Re MultiPlan Litigation*

- **Algorithmic collusion across sectors was a major focus of the Biden DOJ**
  - As an example, the Biden DOJ sued RealPage for an Algorithmic Pricing scheme that allegedly increased the cost of rent for Americans
  - The DOJ alleged that RealPage allowed competing landlords who share with RealPage competitively sensitive price information to benefit from the tacit collusion of resulting recommended rental pricing and terms, thus keeping costs high for renters
- **Algorithmic collusion in healthcare**
  - The DOJ submitted a statement of interest in the multi-district litigation *In re MultiPlan Health Insurance Provider Litigation* clarifying that algorithmic collusion may violate Section 1 of the Sherman Act
  - The case alleges that MultiPlan, now known as Claritev, conspired with health insurers to underpay doctors and other out of network providers for healthcare

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## Allegations of Algorithmic Collusion in Healthcare: Economic Issues in *MultiPlan*

- Plaintiffs allege that MultiPlan's algorithm is a vehicle for cartel behavior among health insurers
- There are a variety of empirical tests that economists can conduct to examine whether the use of the algorithm and associated outcomes are consistent with allegations of algorithmic collusion
  - Are the algorithmic recommendations driven by competitively sensitive data or are they based on anonymized, aggregate data?
  - Do different insurers employ the same rules for the algorithm?
  - How much do insurers customize the methodology? What is the extent of variation in the algorithm configurations?
  - Does the use of the algorithm depress provider prices relative to the prices insurers charged before the use of the algorithm?
  - Do insurers act on the algorithm's recommendation?
  - How often do insurers adjust the recommendation? How often do they reject the recommendation?

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## Allegations of Algorithmic Collusion in Healthcare: Economic Issues in *MultiPlan*

- Are there procompetitive effects of MultiPlan's algorithm and how do they compare with the alleged anticompetitive effects?
- Is the algorithm akin to a survey that gives access to aggregate, anonymized data?
- Information sharing is different from price coordination and can be procompetitive
  - Can MultiPlan's algorithm help insurers and providers by streamlining reimbursement and reduce negotiating time?
  - Can MultiPlan's algorithm improve insurer competition?
  - Can MultiPlan's algorithm benefit self-funded employers by lowering payments to providers and thereby reducing healthcare expenditures?
  - Can MultiPlan's algorithm benefit patients by lowering premiums or increasing other health benefits?
- More generally, algorithms are widely used in healthcare as they can have many benefits including lower costs and lower error rates and can lead to more-informed decision-making

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## Drug Patent Listings as Alleged Means of Delaying Drug Entry: FTC Theories of Harm

- Hatch-Waxman: Brand drug manufacturers submit information to the FDA for patents to appear in the "Orange Book," a listing of approved drug products with therapeutic equivalence evaluations
- Drug companies that seek to market a follow-on version apply to be certified, usually resulting in an automatic 30-month stay of any approval
- 2023 FTC:
  - Orange Book warning letters to ten major pharmaceutical manufacturers challenging over 100 "Improperly Listed" patents
  - Improper listings disincentivize investments in competing products and increase the risk of delayed entry, reducing access and increasing costs
- 2024 FTC:
  - Orange Book warning letters to ten major pharmaceutical manufacturers challenging over 300 "Junk Listing" patents
  - Amicus brief in D.N.J. asthma inhaler patent dispute, *Teva Pharma. v. Amneal Pharma.*

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## Drug Patent Listings as Alleged Means of Delaying Drug Entry: FTC Theories of Harm

- 2025 FTC:
  - Orange Book warning letters to major pharmaceutical manufacturers challenging over 200 "Improper Patent Listings"
  - "FTC will continue to vigorously pursue firms using practices that harm competition"

**"The FTC's renewed challenges come after the U.S. Court of Appeals for the Federal Circuit upheld a District Court's order to pharmaceutical maker Teva to delist several asthma inhaler patents from the FDA's Orange Book. The Federal Circuit affirmed a finding that the patents were improperly listed, consistent with an amicus brief filed by the FTC. The FTC previously challenged the Teva asthma inhaler patents at issue in that case via the FDA's Orange Book dispute process. The Federal Circuit ruling confirmed the basis underlying the FTC's prior Orange Book disputes."**

- No Section 5 language

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## Drug Patent Listings as Alleged Means of Delaying Generic Entry: Economic Issues

- Does a brand manufacturer listing a drug patent in the Orange Book necessarily lead to delayed entry by generic competitors?
- Can generic manufacturers design around a drug patent such as a method-of-use patent?
- Even if a generic manufacturer can design around, is it always economically rational to do so?
  - As a threshold matter, earlier market entry is not always more profitable
  - Generic manufacturers balance the time value of money with expectations about future sales of the brand drug and entry of other generic competitors
  - Earlier Section viii entry may open the pathway for many other generic competitors
  - Later Paragraph IV entry may be accompanied by a 180-day Hatch-Waxman exclusivity

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## Drug Patent Listings as Alleged Means of Delaying Generic Entry: Economic Issues

- Are there procompetitive benefits of drug patent listings? How should we weigh them against the alleged anticompetitive effects?
- Can a drug patent listing in fact lead to earlier rather than later generic entry?
  - Generic entry is often the result of licensed entry negotiated through a patent settlement between a brand and a generic manufacturer
  - A generic manufacturer eligible for 180-day exclusivity under Paragraph IV may have a stronger bargaining position than a manufacturer attempting to enter under Section viii
  - A stronger bargaining position for a generic is likely to lead to earlier rather than later licensed entry
- If a drug patent listing is less likely to lead to at-risk generic entry, this can also be procompetitive
  - At-risk generic entry that increases uncertainty in a brand manufacturer's cash flows can lead to lower level and less efficient R&D
- Generic entry via a "skinny" label can lead to consumer confusion and safety concerns

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## Life Sciences M&A as Alleged Means of Stifling Innovation: Economic Issues

- Economic research has documented a variety of theoretical mechanisms through which M&A activity in the life sciences industry can affect innovation
- Some mechanisms are positive, e.g., a merger can stimulate rather than stifle innovation if it
  - creates economics of scale and scope,
  - enhances asset complementarity
  - improves funding access
- Other mechanisms are negative, e.g., a merger can stifle innovation if
  - a stronger market position reduces innovation incentives of the merging parties
  - it forecloses future competition by stifling innovation of other companies
- Relative to the large body of theoretical literature studying the various possible mechanisms at play, empirical studies measuring the impact of M&A on innovation are scarce

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## Life Sciences M&A as Alleged Means of Stifling Innovation: Economic Issues

- Existing empirical studies have produced mixed results due to important differences in how different studies measure innovation and the time horizon of analysis
- Most studies measure innovation in terms of patent counts, R&D investments, new drug applications, i.e., metrics that capture innovation *input* but not necessarily innovation *output*
- Relatedly, many studies also have a relatively short-term horizon, i.e., examine a merger's impact on innovation only a few years after a merger is completed
- Both of these features are problematic given that pharmaceutical innovation is a very long and risky process
  - It takes more than a decade for a new drug compound to complete clinical development
  - Less than 12 percent of drugs that enter clinical development ever obtain marketing approval
- Although existing empirical research is limited, available evidence indicates positive impacts of M&A are likely to be more dominant

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## Life Sciences M&A as Alleged Means of Stifling Innovation: Recent Challenges

- **Recent Challenges**
  - *FTC v. Amgen-Horizon Therapeutics*
  - *FTC v. Illumina Grail*
  - *FTC v. Sanofi-Maze Therapeutics*
- **Agency Pharma Workshop and Revised Merger Guidelines**
  - On June 1, 2023, the FTC and DOJ released a summary of a workshop jointly held by the agencies in June 2022 titled “Future of Pharmaceuticals: Examining the Analysis of Pharmaceutical Mergers.”
  - The revised Merger Guidelines more broadly consider a merger’s potential effect on innovation. This would include scrutinizing competition at all stages of innovation, including analyzing the potential loss of innovation competition separately from any specific product or pipeline overlaps
  - In response, a coalition of major pharmaceutical companies, including Amgen, Merck, and Gilead, formed the Partnership for the U.S. Life Science Ecosystem (PULSE). The coalition argues that the new guidelines could deter pro-innovation M&A, which is vital for bringing new treatments to market. PULSE emphasizes that mergers often enable smaller biotech firms to access the resources necessary for successful drug development.

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## Takeaways

- **Serial acquisitions**
  - Involving economists early in the analysis of a potential set of serial acquisitions may be valuable given there is little existing economic research that can be relied upon
  - Analysis of serial acquisitions involving conglomerate healthcare companies is likely to be particularly complex
- **Alleged algorithmic collusion**
  - Determine what algorithmic pricing platforms your clients are using, terms of the agreements, whether they or other users are contributing competitively sensitive information, and how the outputs of the platforms are being used by the business so that you are able to counsel regarding antitrust risk
  - Economists have a variety of empirical tests they can apply to establish whether the use of a given algorithm is associated with anticompetitive effects
  - Full analysis would also require examination of potential procompetitive impacts, particularly whether algorithm use can lead to fewer errors and better decisions

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## Takeaways

- **Drug patent listings**
  - FTC continues warning letters and coordination with FDA administrative enforcement—no Section 5 assertion
  - Whether a given drug patent listing can delay generic entry requires analysis of the alternative market entry pathways available to a generic manufacturer and the benefits and costs from pursuing them
  - A drug patent listing can in fact lead to earlier rather than later generic entry as can be demonstrated by analysis of the bargaining positions of brand and generic manufacturers
- **Life sciences M&A and innovation**
  - Given the many theoretical mechanisms through which life sciences M&As can affect drug innovation, careful empirical work is required to understand which particular mechanism is likely to dominate in a given transaction

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