Antitrust Life Sciences Quarterly Update 2025 Q1

 While M&A activity slowed in the first quarter of 2025, including in life sciences, there have been plenty of noteworthy developments in the antitrust space in the first 100 days of the Trump administration. The Federal Trade Commission (FTC) under new Chairman Andrew Ferguson has already launched its first merger challenge while also signaling a more deal-friendly approach by reinstituting the "early termination" process, whereby the FTC uses its discretion to terminate a Hart-Scott-Rodino (HSR) review prior to the expiration of the statutory review period in instances in which the transaction does not present any competitive issues.

Whether or not it is indicative of a more permissive approach to life sciences merger enforcement, the obesity therapeutics space remains a hotbed of M&A activity. While a variety of players have aggressively expanded their weight-loss drug portfolios through acquisitions, licensing agreements, and partnerships, these deals have thus far avoided significant antitrust agency scrutiny. This remains an area to watch, as a long list of sponsors strive to improve on (and compete with) the blockbuster Wegovy and Zepbound franchises through a multitude of Mechanisms of Action and combinations.

In the litigation realm, exclusive dealing claims remain a focus of plaintiffs, with increasing scrutiny of contracting strategies involving pharmacy benefit managers (PBMs). These claims have gained momentum in recent years as PBMs have become increasingly vertically integrated with health insurers. A recent summary judgment decision in the *Regeneron v. Amgen* antitrust lawsuit highlights a growing litigation trend involving rebate bundling and alleged formulary exclusivity agreements with PBMs.

On the government enforcement front, California continues to remain a key battleground state for life sciences antitrust litigation, with a ruling striking down California's controversial "pay for delay" statute targeting patent settlements and a new proposed bill seeking to add civil antitrust penalties for violations of California's Cartwright Act.

Read the full Antitrust Life Sciences Quarterly Update for Q1 2025 written by Antitrust lawyers **Arman Oruc**, **Andrew Lacy**, **Elliot Silver**, **Alexandra Russell**, and **Nick Pellow** **here**.

Boston Forum: Merger Control & Competition in Life Sciences

Arman Oruc, **Andy Lacy**, **Sarah Jordan**, and **Stephen Mavroghenis** are excited to invite you to join Goodwin for an in-person, engaging discussion on antitrust in life sciences transactions, navigating global merger control investigations and what to do when your deal hits a regulatory brick wall. We'll cover the latest trends in early-stage deals, strategies for surviving antitrust scrutiny, and stories from deals that didn't make it through. Special guests Abbas Kazimi, Chief Executive Officer at Nimbus Therapeutics, Jana Gold, Principal at JanaGold Law (former General Counsel of Maze Therapeutics), and Jeff Stoll, Partner, Deal Advisory & Strategy at KPMG, will join to speak on the fireside chat and panel discussion. Don't miss this chance to gain practical insights, ask the tough questions, and discuss what's to come over cocktails!

CLE credit will be offered for CA, NY, NJ, and PA (pending approval).

Please RSVP **here** to join us.

Antitrust and Competition Life Sciences Year in Review 2024

The last year (and particularly the last few months) of the Biden Administration brought a flurry of activity from the Federal Trade Commission (FTC) in the life sciences space, continuing a yearslong pattern of close scrutiny and culminating most notably in the issuance of a complaint against the leading pharmacy benefit managers (PBMs). It was not all bad news, however, as 2024 still featured several notable deal clearances, including the long-awaited approval of the Novo Holdings / Catalent deal and clearances of multiple transactions involving radiopharmaceutical, neurology, and obesity/diabetes assets.

Looking forward in the United States, the return of a Republican-led FTC likely signals a return to an enforcement regime and enforcement priorities that more closely resemble the pre-Lina Khan period. While the FTC under new Chairman Andrew Ferguson may be more predictable, we expect continued scrutiny of life sciences transactions and commercialization practices, particularly to the extent those areas dovetail with President Trump's broader domestic policy agenda.

Antitrust + Competition lawyers **Arman Oruc**, **Andrew Lacy**, **Sarah Jordan**, **Elliot Silver**, **Eram Khan**, **Charlotte Brunsdon**, **Anuj Ghai**, **Sophie Entwisle**, and **Danielle Fong** discuss transaction developments and predictions in the **Antitrust and Competition Life Sciences Year in Review 2024**.

How the Trump Administration Could Reshape Regulation in the Life Sciences Sector

Based on recent policy signals and statements from incoming administration officials, a picture of potential regulatory and policy changes that could affect biotech, pharmaceutical, and medical device companies in coming months and years is emerging.

Anticipated changes span multiple regulatory fronts: a revamped approach to antitrust review at the Federal Trade Commission (FTC), continued momentum on biosecurity measures, and a fundamental rethinking of agency regulation to streamline "red tape" and accelerate patient access to innovative treatments. The Trump administration's stated focus on "making America healthy again" suggests a broader transformation in how healthcare is delivered and regulated, with emphasis on nutrition, prevention, longevity, enhanced physician autonomy, and a more holistic approach to health to reduce the burdens of chronic disease.

While some changes may create opportunities for innovation and growth, others could pose compliance and operational challenges. Understanding these emerging dynamics will be crucial for industry stakeholders as they position themselves for success under the new administration.

The following six sections are based on discussions from a regulatory panel held on January 15 at the **Goodwin + KPMG 6th Annual Symposium**, which was held during the 2025 JPM Healthcare Conference.

Read the full insight **here**.

Antitrust and Competition Life Sciences Quarterly Update Q2 2024

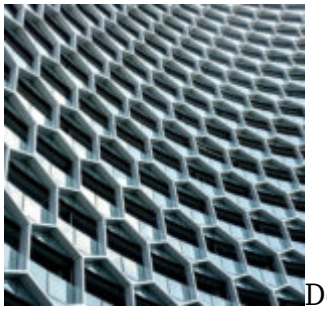
 To date, 2024 has not yet seen the type of mega-merger (Pfizer/Seagen) or level of agency enforcement (Sanofi/Maze or Amgen/Horizon) as 2023. But two notable investigations — one still active — show the Federal Trade Commission (FTC) is continuing to closely examine life sciences transactions for both horizontal and vertical concerns. The agency also continues to put the life sciences industry under the regulatory microscope, including through investigations regarding alleged "junk" patents in the Food and Drug Administration's (FDA's) Approved Drug Products with Therapeutic Equivalence Evaluations (commonly known as the Orange Book) and the release of its interim staff report on pharmacy benefit managers (PBMs).

In the EU, the European Commission (EC) opened its first abuse-of-dominance probe related to the shelving of a novel pipeline therapy in the veterinary medicine space (Zoetis).

That said, deals are still getting done, as evidenced by the flurry of deals in the radiopharmaceutical and obesity/diabetes spaces that were cleared without any publicly known investigations.

Read the full Antitrust & Competition Healthcare Quarterly Update for Q2 2024 written by Antitrust + Competition lawyers **Arman Oruc**, **Andrew Lacy**, **Sarah Jordan**, **Elliot Silver**, **Charlotte Brundson**, and **Charlie Stewart** **here**.

Antitrust & Competition Life Sciences Year in Review 2023

 Despite increasingly aggressive rhetoric from the agencies, 2022 was largely characterized as “business as usual” in the antitrust world. In contrast, 2023 featured a significant step up in enforcement activity, including multiple challenged transactions and lengthy investigations in the life sciences space. As notable, many of these enforcement activities involved more “novel” theories of harm — such as bundling, potential competition, and harm to research, development, and innovation — displaying a willingness by the Federal Trade Commission (FTC) to put its rhetoric into action. At the same time, the novel theories pursued by both the FTC and Department of Justice (DOJ) have generally (though not uniformly) been met by skepticism in federal court.

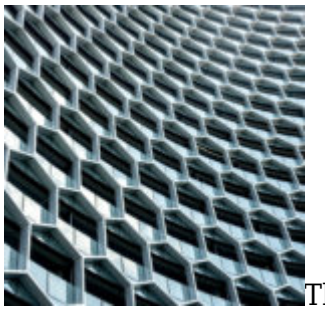
Antitrust + Competition lawyers **Arman Oruc**, **Andrew Lacy**, **Elliot Silver**, and **Charlie Stewart** discuss transaction developments and predictions in the **Antitrust & Competition Life Sciences Year in Review 2023**.

United States: Trends of Agency Scrutiny on Pharmaceutical Transactions Expected to Shift Amid Rise in Deal Activity (GCR)

 Despite the threatening rhetoric, the early years of the Biden Administration largely followed previous regimes with respect to antitrust enforcement in the life sciences space. Pharmaceutical transactions in particular encounters the expected amount of agency scrutiny, with most proceeding without an extended investigation and, in contrast to deals in the tech space, did not become testing grounds for more novel theories of competitive harm. This trend might be changing just as deal activity icked up in early 2023. **Antitrust & Competition** co-chairs **Arman Oruc** and **Andrew Lacy**, partner **Elliot Silver**, and associate **Charlie Stewart** explain more in **GCR’s The Guide to Life Sciences**.

Read the in the press highlight **here**.

Antitrust & Competition Life Sciences Quarterly Update Q3 2023

 The third quarter in the life sciences space saw notable developments in significant agency enforcement actions:

- The FTC abandoned its pursuit of a novel theory and settled its Amgen/Horizon lawsuit 10 days before the scheduled preliminary injunction hearing. As detailed below, the settlement is fairly modest in scope and embraces the sort of behavioral remedy that current agency leadership (as well as recent administrations) has publicly dismissed as insufficient to resolve merger-related concerns.

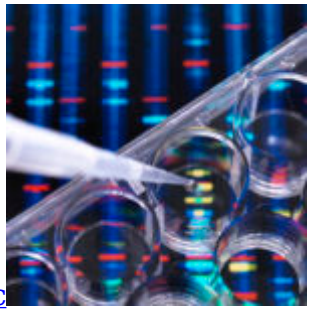
- The FTC continues to explore other novel theories in its ongoing investigation of the Pfizer/Seagen transaction.

- The FTC remains concerned with "killer acquisitions" — transactions where Big Pharma with a commercial or late-stage asset acquire a clinical- or preclinical-stage asset allegedly with the purpose of eliminating or avoiding future competition. Although the agency has not challenged any transaction based on such a theory, it appears to be using the HSR process to screen therapeutics transactions for such a fact pattern.

- Finally, we also saw the creation of an industry trade group specifically focused on the FTC's life science antitrust enforcement.

Read the full Antitrust & Competition Healthcare Quarterly Update for Q3 2023 written by Antitrust + Competition lawyers **Arman Oruc**, **Andrew Lacy**, **Sarah Jordan**, **Elliot Silver**, and **Charlie Stewart** **here**.

Bloomberg Intelligence – Arman Oruc's Perspective on the FTC and Pharma and Biotech Industry M&A Impact


Arman Oruc joined the **Bloomberg Intelligence** podcast to share his views on the FTC, and its impact on M&A for the pharma and biotech industry.

Listen to the podcast **here**.

Antitrust & Competition Life Sciences Quarterly Update Q2 2023


The second quarter saw significant enforcement and dealmaking in the life sciences space. The Federal Trade Commission (FTC) announced its attempt to block Amgen/Horizon, the first such challenge to a life science transaction since 2009, and issued a second request in Pfizer's proposed $43 billion acquisition of Seagen. In contrast, however, several sizable deals announced and closed within the normal waiting period, while the status of others is unknown at the time of publication.

Read the full Antitrust & Competition Healthcare Quarterly Update for Q2 2023 written by Antitrust + Competition lawyers **Arman Oruc**, **Andrew Lacy**, **Sarah Jordan**, **Elliot Silver**, and **Charlie Stewart** **here**.