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POLICY BRIEF

Antitrust and Innovation in Life Sciences: A Market-Oriented Law and Economics Perspective

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Few industries illustrate the limits and promise of antitrust more clearly than the life sciences industry does. Medical-device and drug markets can generate enormous benefits for patients, yet these markets also involve concentrated purchasing, expensive research, regulatory bottlenecks, patent disputes, and contractual arrangements that are difficult for outsiders to evaluate. The resulting policy challenge is not simply to decide whether antitrust enforcement should be more aggressive or more restrained. It is to determine which rules and institutions best preserve a competitive process that discovers, finances, tests, approves, manufactures, distributes, and improves therapies.

That process is unusually dynamic. A company that appears to be a small or distant competitor today may be the source of tomorrow's breakthrough. A merger that removes duplicative research may also provide capital, trial expertise, manufacturing capacity, regulatory knowledge, and global distribution that make a promising therapy more likely to reach patients. Conversely, a contract or regulatory filing that appears technical may delay entry or make it harder for a rival to compete. Antitrust must therefore be vigorous where conduct is demonstrably exclusionary, but humble about claims that rest on speculation, political salience, or a dislike of successful scale.

A useful way to express the principle is through error costs. False negatives allow genuinely anticompetitive conduct to persist. False positives condemn conduct that may have lowered costs, improved quality, or expanded innovation. In life sciences, the second kind of error, false positives, can be especially costly because a lost research program, clinical trial, or commercialization opportunity may not be recreated. The objective should be to minimize the expected social cost of both errors, not to maximize the number of cases, remedies, or officials with authority.[1]

This brief describes major developments in US and foreign life-sciences competition policy and draws lessons for a more disciplined, evidence-based approach to antitrust enforcement. The

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ideal is not to attain antitrust-free medical-device and pharmaceutical sectors. Antitrust enforcers, including the Department of Justice (DOJ) Antitrust Division and the Federal Trade Commission (FTC), as well as regulators within the Department of Health and Human Services (HHS), including the Food and Drug Administration (FDA) and National Institutes of Health (NIH), can help shape an enforcement system guided by four principles of market-based law and economics: identifying concrete competitive harm, recognizing transaction-specific efficiencies, accounting for innovation and investment, and respecting the limits of agencies that are charged with enforcing law rather than designing an industry. As the following developments show, that distinction matters in mergers, pharmacy benefit manager (PBM) contracting, patent and regulatory disputes, collaborations, and public research licensing.

Mergers and Acquisitions: Innovation and the Value of Scale

The US merger picture in 2025 and the first half of 2026 was active but not indiscriminately permissive. Large transactions involving later-stage assets and established pharmaceutical firms generally obtained clearance, including Sun Pharma and Organon, AbbVie and Apogee, and GSK and Nuvalent. The broader record suggests that many transactions can be cleared after an initial review, while pipeline and emerging-therapy transactions continue to require a detailed competitive narrative.[2]

The clearance of these large transactions shows an important lesson: not that transaction size is irrelevant to assessing competitive harm but that size alone is a poor proxy for competitive harm in an industry where an acquirer may supply complementary assets that the target cannot readily obtain on its own. A transaction can eliminate duplicative research, but it can also increase the probability that a promising therapy is developed and commercialized.

The relevant question in merger review is what the parties are likely to do with the assets and what credible alternatives exist, based on evidence available at the time of the transaction. In addressing this question, the nature of the merger being assessed is key. Some transactions have relatively straightforward likely competitive effects, and the question is readily addressed. Other transactions, however, require more complex assessments of future competition. The cases discussed below illustrate the importance of an evidence-based approach, as well as ways procedural requirements and regulatory uncertainty can affect transactions.

The Federal Trade Commission's challenge to Edwards Lifesciences Corp.'s (Edwards) proposed acquisition of JenaValve Technology, Inc. (JenaValve) illustrates why innovation markets deserve serious, but careful, analysis. The FTC alleged that because Edwards had already acquired the other leading US transcatheter aortic valve replacement device (TAVR-AR device) developer, JC Medical, the proposed transaction would combine the only two companies with ongoing US clinical trials for a less-invasive treatment for aortic regurgitation. A federal district court granted a preliminary injunction in January 2026, and Edwards later abandoned the deal. In this case

the FTC's analysis treated products still in clinical development as potential competitors and examined how barriers to FDA approval, competition from foreign products, evidence of ongoing innovation, and the companies' development plans affected the likelihood that the two therapies would compete.[3]

The Edwards matter also shows how procedural rules can become substantive deal risks. In July 2026, the FTC announced a $12 million settlement concerning allegations that Edwards acquired JC Medical without making a Hart–Scott–Rodino (HSR) filing, which requires companies to notify federal antitrust authorities of certain proposed mergers and acquisitions before completing them. The agency contended that a $115 million payment and a contemporaneous $25 million investment should be viewed together rather than as a below-threshold transaction. The settlement imposed notice and compliance obligations relating to future TAVR-AR device acquisitions. Whatever the merits of the agency's theory, the episode demonstrates that transaction planning, disclosure, and valuation can affect the competitive feasibility of a deal before a conventional merits inquiry is complete.[4]

The FTC's Aurobindo–Lannett action shows a different competitive concern: concentration among suppliers of existing generic drugs, rather than potential competition between therapies still in development. The $250 million acquisition of Lannett Company Inc. by Aurobindo Pharma Limited could proceed only with divestiture of four of Aurobindo's generic products. The agency alleged that the parties were among a small number of significant suppliers of those four generic products and that the deal could permit unilateral price increases or coordinated interaction regarding those products. Generic markets can be concentrated at the molecule, formulation, dosage, or strength level even when a broad pharmaceutical market appears populated. That is a legitimate reason to examine the details, but it is not a reason to presume that every small generic transaction is harmful.[5]

Finally, the Pfizer–Metsera bidding contest in 2025 demonstrates that antitrust risk has an economic value that can affect which bid is superior. Novo Nordisk's proposed two-part structure would have transferred substantial economic value before traditional HSR review. Pfizer argued that the structure created procedural and substantive risk, and the FTC contacted the target about HSR concerns. The board ultimately selected Pfizer after Pfizer matched the economics, and the transaction closed. The episode is a reminder that uncertainty can reduce the value of an asset and may deter transactions that would otherwise bring useful capital and expertise to a research program.[6]

Taken together, these cases illustrate why life-sciences mergers require careful, evidence-based analysis. Rather than being concerned with a transaction's size, antitrust enforcers should focus on the particular competitive effects of a merger. As such, even relatively small acquisitions may provoke challenges if enforcers identify likely postmerger harm in narrowly defined markets. Furthermore, products still in the development pipeline may raise enforcement concerns if they

TABLE 1. Life-sciences merger cases: competitive concerns and policy lessons

Case	Central issue	Policy significance
Edwards–JenaValve	Potential competition between therapies still in clinical development	Merger review must assess likely future competition, not just existing products.
Edwards–JC Medical	Premerger filing requirements and transaction valuation	Procedural compliance and regulatory uncertainty can affect transaction feasibility.
Aurobindo–Lannett	Concentration among suppliers of four generic products	Even smaller acquisitions can raise competitive concerns in narrowly defined markets.
Pfizer–Metsera	Hart–Scott–Rodino review concerns and competing bid structures	Regulatory uncertainty can influence transaction value and bidding decisions.

are likely to compete in future product markets. Finally, potential merger partners should ensure that they comply with premerger reporting requirements to avoid possible future complications (including potential fines) when dealing with enforcers.

PBMs: Bundled Rebates and Vertical Integration

Beyond mergers and acquisitions, the practices of pharmacy benefit managers, or PBMs, remain the most politically visible antitrust issue in US drug distribution. PBMs administer formularies, negotiate with manufacturers, manage pharmacy networks, and process claims for health plans. Those activities can create purchasing power and lower transaction costs, but they can also create conflicts over rebates, list prices, affiliated pharmacies, and the distribution of savings. The policy problem is therefore not whether PBMs are good or bad in the abstract. It is whether a particular practice produces measurable foreclosure of effective competition by restricting competitors' access to customers or markets, excludes rivals, or harms consumers, and whether the proposed remedy improves the overall system.

The FTC's 2025 interim report alleged that the three largest PBMs—Caremark, Express Scripts, and OptumRx—used affiliated pharmacies, engaged in spread pricing by charging health plans more for drugs than they reimbursed pharmacies and keeping the difference, and tied compensation to rebates in ways that produced very large markups on specialty generic drugs. The agency reported more than $7.3 billion in dispensing revenue above estimated acquisition cost for the specialty generics examined over 2017–2022, plus an estimated $1.4 billion from spread pricing. These are important allegations, but determining whether the reported markups reflect anticompetitive conduct requires accounting for services provided, risk borne, negotiated discounts, plan design, and how costs are distributed across patients, employers, insurers, and public programs.[7]

The FTC's insulin case against the three major PBMs presented a more specific theory. The FTC alleged that compensation tied to rebates encouraged PBMs to prefer insulin products with high list prices and large rebates over lower-list-price alternatives, increasing costs for patients whose copays or coinsurance were tied to list prices. Express Scripts settled in February 2026, and Caremark settled in July. The settlements require standard offerings that delink fees from list prices, pass rebates through at the point of sale, provide more transparency, and permit acquisition-cost-plus reimbursement options for community pharmacies. The FTC projected substantial 10-year patient savings from the settlements.[8]

The potential gains for some patients should not end the analysis. Economist and legal scholar Satya Marar has noted that moving rebates to the point of sale can redistribute costs, potentially increasing premiums or public-program spending even while lowering costs for patients who face list-price-based copays. More broadly, the legal-economic case for changing an industry's contracting model should not be inferred from the existence of high list prices or politically salient intermediaries. It should be tested against the actual mechanics of bargaining, pass-through, formulary design, and entry.[9]

Beyond their economic effects, such remedies also raise questions about the proper scope of antitrust enforcement. DOJ Deputy Assistant Attorney General Nicole Sarrine has emphasized that the Antitrust Division is a law enforcer, not a lawmaker or regulator. That observation is especially important in healthcare, where a remedy that dictates the terms of contracting may become a form of market design. Enforcers should challenge practices that violate the antitrust laws, but they should be cautious about converting antitrust into a general authority to restructure complex relationships whenever an alternative arrangement appears more attractive.[10]

At the same time, the need to distinguish anticompetitive practices from legitimate business arrangements extends to private antitrust litigation. In *Regeneron v. Amgen*, a Delaware jury awarded Regeneron $406.8 million after finding that Amgen used bundled rebates involving Repatha and its blockbuster immunology product Enbrel to obtain preferred or exclusive formulary placement and foreclose Regeneron's Praluent. The case turned on foreclosure, formulary structure, and spillover effects, in which discounts on one product affect competition for another. It also involved the discount-attribution test, which assesses whether an equally efficient competitor could match the bundled discount. Portfolio-wide bundles can raise serious concerns when a rival cannot match the discount because it lacks a second product, but the same facts must be distinguished from ordinary discounts that reduce costs and benefit patients.[11]

The practical policy lesson is straightforward. A bundle or exclusive arrangement should be evaluated by asking what demand is realistically foreclosed, whether an equally efficient rival could match the discount, whether switching costs and contract duration make it impractical for customers to move to competing products, and whether there is a documented safety, quality, or

cost justification. Those questions direct attention to competitive effects rather than to the mere existence of vertical integration or a complicated contract.

Patents: Orange Book Listings and the Antitrust Boundary

Patent rights are central to competition in life sciences because they provide a temporary reward for risky innovation and constitute tradable assets that can be licensed, financed, or acquired. The patent and regulatory framework can, however, delay entry when a patent is improperly listed or when a regulatory procedure is used for a purpose unrelated to protecting a valid right. The challenge for antitrust enforcement is to distinguish misuse of patent rights and regulatory procedures from legitimate investment in intellectual property.

The FTC's 2025 challenge to more than 200 Orange Book listings illustrates a targeted intervention. The Orange Book identifies patents that a brand manufacturer asserts cover a drug. When a generic applicant challenges a listed patent through a Paragraph IV certification—a formal assertion that the patent is invalid or will not be infringed—the patent-holder's timely infringement lawsuit can trigger an automatic stay of FDA approval for up to 30 months under the Hatch–Waxman Act. If a patent does not meet the statutory requirements for listing, its inclusion in the Orange Book can therefore create a regulatory bottleneck that delays generic competition. The FTC relied on the Federal Circuit's decision in *Teva v. Amneal*, and Teva subsequently requested delisting of more than 200 challenged entries. This targeted challenge to improper patent listings is materially different from treating ordinary patenting, patent enforcement, or a large patent portfolio as presumptively anticompetitive.[12]

A more novel antitrust question concerns whether the acquisition of patent rights can itself be challenged based on how those rights are later used. In *CareFirst of Maryland v. Johnson and Johnson*, the plaintiffs allege that Johnson and Johnson acquired four patent applications as part of a much larger Momenta portfolio and later used patents covering cell-culture media to delay Stelara biosimilar competition. In a related matter involving Amgen and Enbrel, the FTC filed an August 2026 amicus brief arguing that a commercial acquisition of pending patent applications can be subject to scrutiny under section 2 of the Sherman Act, which prohibits monopolization. The FTC argued that such an acquisition is not shielded from antitrust scrutiny merely because the buyer subsequently pursued the patent applications before the Patent and Trademark Office or enforced the issued patents in court.[13]

A market-oriented analysis should distinguish objectively exclusionary conduct from ordinary investment in intellectual property. Section 2 does not require proof that a company specifically intended to exclude competitors, but it does require exclusionary conduct and the willful acquisition or maintenance of monopoly power. If a company's later use of a patent automatically makes its earlier acquisition unlawful, dominant firms could face a form of retrospective merger review, in which an acquisition is judged based on developments that were not foreseeable when the

transaction occurred. That risk is especially costly in research-intensive markets, where portfolios contain hundreds of assets whose value and applications are uncertain at closing. The sounder approach is to ask what the patent or other acquired asset could realistically do based on information available at the time of acquisition, while preserving separate claims for sham litigation, fraud, or later exclusionary conduct.[14]

Bayh–Dole and Public Research Licensing

The relationship between public research and private commercialization also illustrates why antitrust should not be separated from regulatory design. The Bayh–Dole Act, enacted in 1980, generally allows universities, nonprofit institutions, and small businesses that receive federal research funding to retain ownership of inventions made with that funding, subject to specified government rights and obligations. In practical terms, the statute was designed to help turn laboratory discoveries into commercially available products by permitting institutions to patent, license, and attract private capital for development. It also preserves safeguards such as government march-in authority, which allows federal agencies, under specified circumstances, to require licensing of federally funded inventions to other parties.[15]

That framework matters because federally funded discoveries usually require substantial private investment before they become approved medicines or useful technologies. NIH licensing policies that require detailed plans for ensuring the availability, affordability, acceptability, and sustainability of licensed technologies may pursue legitimate public goals. But if administrators use those conditions to second-guess private pricing or commercialization decisions beyond what the Bayh—Dole Act authorizes, they could effectively impose price controls through patent licensing. Such a condition may discourage the formation of startups, licensing agreements, and investment in discoveries that otherwise would reach patients. The competitive question is not whether public research should ever carry public obligations. It is whether a new administrative condition increases or decreases the expected supply of future therapies.[16]

Collaboration, Licensing, and AI-Enabled Life Sciences

The FTC and DOJ's February 2026 request for public comment on new guidance for competitor collaborations is particularly relevant to life sciences, where firms frequently share resources and expertise to develop new therapies. The agencies withdrew the 2000 Collaboration Guidelines in December 2024 and now seek public input on joint licensing, conditional dealing, information sharing, algorithmic pricing, and new technologies. The agencies have recognized that many collaborations can lower costs, enable investment, and drive innovation.[17] Clear guidance is therefore important to distinguish collaborations that promote innovation from those that restrict competition.

Life-sciences firms increasingly share research platforms, clinical-trial infrastructure, manufacturing capacity, safety data, regulatory expertise, and commercialization rights. AI-assisted drug

discovery adds model training, access to computing resources, shared data for evaluating models, privacy, cybersecurity, and validation to that list. A collaboration can be procompetitive if it pools complementary assets, reduces duplicative research, creates interoperability, or permits a smaller firm to reach clinical development. It can be harmful if it coordinates prices, allocates research territories or customers, unnecessarily exchanges competitively sensitive information, or forecloses downstream competitors' access to resources or markets.

The agencies should provide practical safe harbors—clear conditions under which certain arrangements are generally treated as lawful—for bona fide research and development collaborations, infrastructure projects, standards and safety testing, interoperability, and privacy-enhancing information sharing. Such safe harbors would not immunize cartels. They would reduce uncertainty for arrangements whose principal purpose is to create new capacity or improve quality. Comments submitted by Alden F. Abbott and the International Center for Law and Economics emphasize that mistakenly condemning beneficial collaborations can be especially costly in innovation markets: A lost trial, manufacturing platform, or safety standard may never be recreated.[18]

The right compliance approach is concrete rather than formulaic. Firms should define the project and its legitimate objective; limit information exchange to what the project requires; use clean teams (groups of designated individuals who handle competitively sensitive information under restrictions designed to prevent inappropriate sharing), aggregation, anonymization, or access controls where appropriate; preserve independent downstream decision-making; and ensure that any exclusivity is reasonably necessary to achieve the collaboration's legitimate objectives. Agreements should explain how the arrangement expands capacity or accelerates innovation, rather than merely asserting that it does.

Regulation Can Open Markets or Become a Competitive Bottleneck

The regulatory environment is part of the competitive environment. Drug-pricing executive orders, PBM reforms and proposed fee-disclosure rules, Medicare drug-price negotiations, FDA listing policies, and NIH licensing policies affect entry, bargaining, and the returns to innovation. The DOJ's 2025 listening sessions grouped anticompetitive conduct with regulatory barriers and rent seeking, while its 2026 healthcare remarks emphasized that government rules can create opportunities for rent extraction—for firms to obtain economic benefits without creating corresponding value—when incentives and information are misaligned.[19]

A procompetitive regulatory agenda should reduce artificial barriers: faster and clearer generic and biosimilar pathways, reliable FDA standards, transparent and nondiscriminatory reimbursement rules, and removal of duplicative rules or rules that firms can exploit to delay competitors' entry. But regulation that dictates business models can displace competition with centralized judgment. A policy intended to lower prices can reduce negotiation, investment, or the supply of future therapies if it ignores the mechanisms that finance innovation. This is why antitrust and

regulatory policy should be evaluated together, while still respecting the different institutional roles of enforcement and legislation.

Europe and China Show the Cost of Broadening Competition Policy

Developments in Europe and China illustrate how different approaches to competition enforcement can affect innovation, investment, and regulatory uncertainty. The European Commission continues to treat pharmaceuticals and healthcare as priority areas, but its tools reflect a broader conception of competition. In July 2025, the Commission fined Alchem for a cartel involving SNBB, an active pharmaceutical ingredient used in Buscopan and generic versions. In October 2025, the Court of Justice upheld the Commission's Teva and Cephalon pay-for-delay decision concerning modafinil, involving an agreement to compensate a potential competitor for delaying entry into the market, reinforcing the principle that a value transfer paired with nonentry or nonchallenge obligations can be a restriction by object—conduct considered inherently harmful to competition under EU law. Price fixing, quota allocation, and pay-for-delay agreements are appropriate subjects for serious enforcement because the theory of harm is direct.[20]

Other matters illustrate the risk of turning competition policy into a broad instrument for controlling communications or business models. The Commission closed an investigation into Edwards Lifesciences after Edwards withdrew a global anticopycatting policy that allegedly limited physicians' participation in competitors' clinical and educational activities; the closure was not a finding of infringement. In June 2026, the Commission opened a formal investigation into Sanofi's promotion of Efluelda, alleging that communications to healthcare professionals disparaged a competing vaccine. These matters bring medical, regulatory, and marketing communications within the scope of antitrust scrutiny in concentrated therapeutic areas, potentially creating uncertainty for firms when the line between scientific disagreement and exclusionary conduct is difficult to draw.[21]

In merger review, meanwhile, the Commission's April 2026 draft revised Merger Guidelines would give more explicit weight to innovation, investment, resilience, and scale and would introduce an Innovation Shield for some transactions involving small innovative firms. The draft also formalizes attention to dynamic harm, pipeline products, killer acquisitions, and efficiencies. Its four-stage innovation analysis shows why parties must prepare a granular evidence record. The strongest defense is not that innovation is important in the abstract, but that a transaction increases the probability, speed, quality, or scope of development and commercialization.[22]

China presents a different but equally important warning about jurisdictional and regulatory risk. A recent enforcement action illustrates how transactions that do not trigger ordinary notification requirements may nevertheless face antitrust intervention after completion. The State Administration for Market Regulation (SAMR) is China's primary ministerial-level agency for market supervision, consumer protection, and antitrust enforcement. In July 2025, SAMR ordered the unwinding of Wuhan Yongtong Pharmaceutical's 2019 acquisition of Shandong PKU High

Tech Huatai Pharmaceutical, even though the parties reportedly did not meet the filing thresholds. The transaction vertically integrated an active pharmaceutical ingredient (API) distributor with an injectable-drug producer, and SAMR found that the upstream firm controlled 80 to 95 percent of the relevant API supply. China's pharmaceutical antimonopoly guidelines and related cases signal that below-threshold deals, vertical contracts, APIs, and individual executive conduct may all receive scrutiny when a product is medically important or politically sensitive.[23]

Taken together, these developments illustrate the importance of distinguishing enforcement against demonstrably anticompetitive conduct from broader regulatory intervention that may create uncertainty for firms. Competition authorities should address genuine competitive harm while considering how expansive enforcement theories and unpredictable procedures may affect investment and innovation.

A Sounder Policy Direction

The developments described above point toward a more disciplined, evidence-based approach to life-sciences antitrust enforcement.

First, life-sciences enforcement should remain vigorous against cartels, sham regulatory tactics, improper patent listings, and exclusionary contracts supported by evidence of foreclosure or consumer harm.

Second, agencies should examine innovation and efficiencies as part of the competitive inquiry, not as afterthoughts or presumptions to be overcome.

Third, public officials should distinguish enforcement from market design. A remedy that dictates how an entire industry must contract or price may produce unintended effects that are more difficult to correct than the original conduct.

Fourth, agencies should improve guidance for lawful collaboration and provide earned safe harbors for research, infrastructure, safety, interoperability, and privacy-enhancing information sharing.

Fifth, lawmakers and regulators should focus on removing bottlenecks that shelter incumbents, including unnecessary filing uncertainty, opaque reimbursement rules, strategically exploitable procedures, and licensing conditions that deter commercialization.

Sixth, federal and state enforcers should coordinate their reviews and provide clear, consistent guidance so that firms receive reasoned decisions rather than a sequence of conflicting vetoes.

These recommendations do not assume that markets are perfect. They recognize that public institutions also face information limits, error costs, and incentives that can produce rent seeking.

The best overall prediction is continued sector-specific scrutiny coupled with selective openness to transactions and collaborations that can be explained in ordinary economic terms. The most durable cases will be those that connect conduct to foreclosure or exclusion with evidence. The most durable policies will be those that preserve the incentive to invest in the next therapy. Life-sciences antitrust should therefore move toward a market-based law-and-economics approach: Protect the competitive process, test claims against facts, account for dynamic innovation, and intervene with humility when the evidence is uncertain. That is not a plea for inaction. It is a recognition that patients ultimately depend not only on lower prices today, but also on the discovery and delivery of better treatments tomorrow.

About the Author

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Notes

An earlier version of this paper inspired remarks by the author at the Life Sciences Law USA Conference, October 20, 2026, in Boston, Massachusetts.

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