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SEAL THE VALVE, BUT NOT THE DEAL: COURT BLOCKS EDWARDS LIFESCIENCES' PRE COMMERCIAL MERGER

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SUMMARY

A recent federal district court decision in *FTC v. Edwards Lifesciences* adds another win to U.S. enforcers' efforts to apply traditional antitrust principles to mergers involving early-stage or pre-commercial products. In granting the FTC a preliminary injunction blocking Edwards' acquisition of JenaValve, the court endorsed an expansive "pre-commercial innovation market" theory—accepting that the two companies were actively competing not in a traditional commercial market, but in the research, development, and anticipated commercialization of next-generation transcatheter aortic valve replacement (TAVR-AR) devices.[1] Although no TAVR-AR device is yet FDA-approved for commercial sale in the United States, the court found that the companies' efforts to progress through FDA trials constituted meaningful competitive interaction.[2] Relying on the 2023 Merger Guidelines, the ruling underscores the growing institutional acceptance of research and development-based theories of harm. For clients, *Edwards Lifesciences* represents a helpful reminder of the import of antitrust counsel advising on potential transactions and reviewing deal terms as early as possible in the process, even when there is no present commercial competition between an acquirer and a target, so long as there is specific evidence of competition in innovation or R&D.

The deal at issue was part of an effort by Edwards Lifesciences, a medical device manufacturer focused on structural heart technologies such as transcatheter valve replacement systems, to acquire two companies in short succession, JC Medical and JenaValve Technology. Both companies were developing a next-generation transcatheter device to treat a specific heart valve condition. JenaValve and JC Medical were the only two companies with TAVR-AR devices in U.S. clinical trials. Edwards Lifesciences had successfully acquired JC Medical in a deal that fell below the Hart–Scott–Rodino (HSR) reporting threshold shortly before entering into a separate, reportable agreement to acquire JenaValve. Together, the transactions would have placed the only two TAVR-AR development programs under Edwards Lifesciences' control. The FTC challenged the

JenaValve transaction under Section 7 of the Clayton Act, and Judge Contreras of the district court for the District of Columbia granted the agency's request for a preliminary injunction.

The district court's opinion highlights the enforcement risk associated with deal structures that may be designed to fall below HSR reporting thresholds. The court pointed to testimony suggesting that Edwards Lifescience's earlier acquisition of the smaller target (JC Medical) was deliberately priced below the then-applicable HSR threshold and timed so that the later, larger transaction (JenaValve) would clear before the smaller one closed.[3] This sequencing resulted in two simultaneous acquisitions of competing technologies without either target being aware of the other's impending sale.[4] While such structuring may comply with formal HSR requirements, the court in *Edwards Lifesciences* viewed the surrounding circumstances as relevant to assessing competitive effects—providing a reminder that sub-HSR-threshold and non-reportable transactions can still attract significant enforcement interest, particularly when they involve concentrated innovation pipelines or serial acquisition patterns.

The ruling also underscores the continued vitality of the 2023 Merger Guidelines. Though the current administration has sought to move away from some antitrust priorities of the previous administration, the current Merger Guidelines represent a significant exception to that trend. *Edwards Lifesciences* specifically found the Merger Guidelines to be persuasive and relied on the Merger Guidelines stricter concentration thresholds without qualification, in contrast to other decisions that have occasionally used both the modern thresholds and those from previous versions of the Guidelines. The decision in many ways validates both the prior administration's decision to update the Guidelines and the current administration's decision to maintain them, as they provide predictability and clarity to the business community. Nonetheless, companies that engage in strategic M&A activities will benefit from experienced antitrust counsel closely monitoring how the Guidelines are implemented by enforcers and interpreted by the courts.

For life sciences and medical device companies, the decision reinforces that antitrust scrutiny increasingly extends beyond current commercial sales to include parallel R&D efforts, ongoing FDA trials, and competition to innovate. As illustrated by the government's longstanding approach in pharmaceutical matters and the FTC's recent success enjoining a vertical merger involving the development of cancer detection studies, agencies are focused on whether a transaction would eliminate pipeline-to-pipeline rivalry or otherwise reduce incentives to bring differentiated products to market. *Edwards Lifesciences* cited evidence concerning the firms' respective clinical trial stages, projected FDA approval timelines, and differentiated device features, concluding that the merger would dampen innovation incentives.[5] The court also rejected arguments that uncertainty around future FDA approvals rendered the FTC's theory too speculative, emphasizing Section 7's focus on probabilities, not certainties.[6] Based on evidence showing that high-risk medical devices typically take nearly a decade to complete the premarket approval process—and that no other TAVR-AR competitor had initiated U.S. clinical trials—the court found new entry unlikely to be sufficiently timely to counteract the merger's harms.[7]

Given these developments, companies contemplating acquisitions in highly regulated, innovation-driven sectors should involve antitrust counsel early—regardless of deal size or whether the parties have launched commercial products. Early analysis can help identify innovation market risks, anticipate regulatory scrutiny, and evaluate whether deal timing, structure, or disclosures may raise concerns even where no HSR filing is required. *Edwards Lifesciences* signals a willingness by the courts to recognize innovation-focused theories of harm and to intervene at the pre-commercial stage, making proactive antitrust risk assessment more important than ever.

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[1] *Fed. Trade Comm'n v. Edwards Lifesciences Corp.*, No. 1:25-cv-02569 (D.D.C. Aug. 6, 2025) (ECF No. 178), at 27 (defining the relevant market as "the research, development, and commercialization of TAVR-AR devices in the United States"); *id.* at 41–42 (recognizing a market composed entirely of pre-commercial products).

[2] *Id.* at 54–57.

[3] *Id.* at 20–22.

[4] *Id.* at 21–22.

[5] *Id.* at 57–63.

[6] *Id.* at 72–75.

[7] *Id.* at 76–81.

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