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Annual Checkup from the ABA Antitrust in Healthcare Conference

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The American Bar Association's recent Antitrust in Healthcare Conference brought together enforcers, academic researchers, economists, and members of the bar for a lively, wide-ranging discussion of issues at the intersection of antitrust and healthcare. Three topics came up across multiple panels: (i) markets for products in pre-commercial development; (ii) the process for searching for a buyer of distressed assets; and (iii) merger enforcement under a "cross market" theory.

Market Definition for Products in Development

Edwards/JenaValve involved a successful FTC challenge to Edwards Lifesciences' proposed acquisitions of two companies engaged in their own clinical trials for medical devices that would compete if and when they are brought to market. At the time the FTC brought the case, the only treatment for aortic regurgitation approved by the Food and Drug Administration was open-heart surgery. But two companies—JenaValve Technology and JC Medical—were engaged in clinical trials for transcatheter aortic valve replacement devices used to treat aortic regurgitation ("TAVR-AR devices"), which make it possible to replace a diseased aortic valve through a catheter without open-heart surgery. Edwards Lifesciences Corporation planned to separately acquire both JenaValve Technology and JC Medical.

Several panelists at the conference described the district court decision blocking the merger as a potential turning point for product market definition case law. At the time of the decision, no TAVR-AR device had received premarket approval from the FDA, and the devices accordingly were not yet available for sale or use in the United States outside the clinical trial setting. The district court credited the FTC's asserted "TAVR-AR device market" despite the merging parties' urging to reject such a "novel, pre-commercial market."

Enforcers, members of the private bar, and economists all agreed that it is highly likely the *Edwards/JenaValve* decision will embolden the antitrust agencies to challenge other mergers involving products that are still in development and not yet commercially available. Rohan Pai, Acting Assistant Director of Mergers IV, suggested enforcers could use the court's reasoning to challenge a merger involving in-development products even where the structural presumption (i.e., combined share over 30%) is not met, although he acknowledged the agencies would likely only do so under the right factual circumstances.

Adequate Search for a Buyer in Failing Firm Cases

The "failing firm" defense in the FTC and DOJ's 2023 Merger Guidelines not only requires that a firm face the grave probability of business failure and that its prospects of reorganization are dim, but also that the company seeking to acquire the failing firm is the only available purchaser. The question of what passes for an adequate search process for a buyer of distressed healthcare assets and how that will be investigated was a focus of discussion about the failing firm defense at the conference. Since *Novant/Community Health Systems*, the FTC has focused attention on the sale process record from a back-pocket litigation argument to a gating issue in the merger review. In that case, the district court accepted the parties' position that CHS had conducted an adequate sales process and that no alternative buyer for Lake Norman Regional Hospital had emerged. The FTC appealed the decision, but the parties abandoned the deal after the Fourth Circuit granted a stay of the district court's order while the FTC pursued its appeal.

At the conference, the FTC's Pai suggested that Duke Health's later acquisition of Lake Norman Regional—after Novant abandoned the deal—was practical confirmation that CHS's initial search for a buyer was not adequate. Pai noted that the FTC has seen a number of non-public transactions in the past two years involving sellers facing significant financial hardship that have raised the failing firm defense to justify a transaction. He provided several insights about how the FTC approaches its assessment of whether there may be a better alternative acquirer. Pai explained that FTC staff have begun to independently contact realistic alternative purchasers early in the Second Request process. At these meetings, staff will "frequently" hear third parties report that they did not know the asset was available, which undermines the parties' reliance on the failing firm defense. In some of those matters, Pai noted the FTC has "incentivized" the merging parties to reopen the sales process and consider other options to avoid the high costs of substantially complying with a Second Request and defending a potential lawsuit. In cases where the FTC makes such a request, buyers will need to weigh the risk of forgoing exclusivity if the seller reopens the sales process versus the benefits of proving this aspect of the failing firm defense.

For healthcare companies anticipating a possible sale, the most important takeaway is that the sales process record and the antitrust record must be built together. Distressed sellers should cast a wide net at the outset and document the rationale for exclusion of any buyer or type of

buyer. Buyers, for their part, should conduct their own diligence on the seller's sales process to determine who was approached, when, and why each candidate fell out before signing.

"Cross Market" Theories of Antitrust Enforcement

Cross-market theories of antitrust harm were another hot topic at the conference. Roughly half of all hospital mergers in the United States involve hospitals that are located far enough away from one another that they would not typically be considered part of the same geographic market from the perspective of patients seeking care or as alternatives for inclusion in a payor's network. While these cross-market mergers have not historically been a focus of antitrust enforcers, several enforcer and economist panelists observed that, as healthcare prices continue to rise, enforcers are increasingly considering whether cross-market mergers may play a role in reducing competition and increasing prices.

Panelists noted that the FTC has investigated cross-market issues in hospital transactions but to date has not brought an enforcement action under this theory of harm. State enforcer panelists were, however, quick to note that states are taking action in this area. They referenced California imposing conditions on three different hospital mergers in recent years based on cross-market concerns: Cedars-Sinai/Huntington (2020), Acadia/Adventist Health Vallejo (2021), and USC Health System/Methodist (2022). To assuage California's concerns, the hospitals involved in these mergers agreed to price and conduct conditions intended to address cross-market harm. Among these were commitments that merging hospitals would continue to engage in separate negotiations with payors (with a firewall between the negotiating teams), limit price increases in payor contract renewals for five years, and refrain from "all or nothing" contracting (pressuring or requiring payors to agree to contract with all hospitals in the merging parties' system, or none at all). Panelists also flagged that Oregon recently conducted a months-long review of a healthcare transaction even though there were no overlaps between the merging parties in the state given the buyer had no presence there. Given rising healthcare costs continue to be a key issue for voters, state enforcer panelists suggested that they will continue to take a close look at cross-market healthcare mergers. While neither DOJ nor the FTC has so far pursued a cross-market enforcement action, they would likely be open to doing so if presented with the right set of facts. The takeaway for healthcare companies is that absence of a traditional geographic overlap may not be enough to escape scrutiny.

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