I. ANTITRUST
(Updated January 2022)

A. M&A

1. Provider Merger Enforcement
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a. Hackensack Meridian Health/Englewood Healthcare Foundation

- In December 2020, the FTC sued to block Hackensack Meridian Health's ("HMH") acquisition of Englewood Healthcare Foundation ("Englewood").[1]
  - HMH is the largest healthcare system in New Jersey, operating 12 general acute care ("GAC") hospitals, two children's hospitals, two rehabilitation hospitals, and one behavioral health hospital; and employing more than 7,000 physicians. In Bergen County, HMH operates two of the six hospitals located there, including a 781-bed flagship facility.
  - Englewood is one of very few remaining independent hospitals in Northern New Jersey. In addition to Englewood Hospital and Medical Center (531 licensed beds), it also operates Englewood Physician Network (over 500 physicians providing care at more than 100 locations across six counties in New Jersey and New York), and the Englewood Healthcare Foundation.
  - The FTC defined the relevant geographic market as no broader than Bergen County (the main area of competition for HMH, Englewood, and Pascack Valley Medical Center, which HMH partially owns).
  - Post-transaction, HMH would be one of only three GAC providers in Bergen County. The complaint alleges that the transaction would increase concentration in the relevant market to a presumptively unlawful level: post-transaction, the Herfindahl-Hirschman Index ("HHI") would increase by approximately 900 to almost 3,000, well beyond the post-acquisition market concentration level of 2,500 points and an increase of 200 points that is the threshold for presumptive illegality under the 2010 Horizontal Merger Guidelines.[2]
- In a sealed opinion, Judge John Michael Vazquez of the United States District Court for the District of New Jersey granted the FTC's request for a preliminary injunction on August 4, 2021. HMH and Englewood appealed the preliminary injunction to the

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[1] Complaint, In the Matter of Hackensack Meridian Health, Inc./Englewood Healthcare Foundation, Docket No. 9399 (Dec. 3, 2020), *available at* https://www.ftc.gov/enforcement/cases-proceedings/2010044/hackensack-meridian-health-inc-englewood-healthcare-foundation.

[2] *See* U.S. DEP'T OF JUSTICE & FED. TRADE COMM'N, HORIZONTAL MERGER GUIDELINES (2010), *available at* https://www.ftc.gov/sites/default/files/attachments/merger-review/100819hmg.pdf.

Third Circuit Court of Appeals on August 26, 2021.

- On appeal, the merging parties advance a number of arguments in support of the transaction, including:

  - That Bergen County is an inappropriate geographic market due to robust evidence that commercial health plans and employers do not treat Bergen County as a distinct market, and do not view HUMC and Englewood as substitutable facilities for networks or plans.

  - That the FTC has not demonstrated "price discrimination" to customers as required to establish anticompetitive harm under the FTC's Horizontal Merger Guidelines. According to defendants, managed care plans negotiate their contracts on a regional basis (e.g., northeastern New Jersey), thereby disallowing the prospect of discriminatorily high rates for Bergen County subscribers. Because the FTC cannot establish price discrimination as the result of the transaction, the defendants argue, its prima facie case of anticompetitive effects fails.

  - That the lower court committed error by using patients' willingness to pay for the economic analysis, which allegedly has no bearing on insurers' willingness to pay and therefore is the incorrect metric to use.

- In its reply brief, the FTC argues:

  - That the element of price discrimination is applicable only in the context of a traditional supplier-customer relationship, whereas health care markets are multi-dimensional, involving suppliers (hospitals), insurers, and those covered by insurers.

  - That insurers would experience higher prices from HMH/Englewood, which in turn would be passed onto their members in the form of higher premiums – an indirect form of price discrimination for Bergen County residents who prefer to use local hospitals. In support of this argument, the FTC cites testimony and other evidence that insurers would be compelled to agree to post-merger price increases because they would not be able to offer a marketable network without the participation of HMH/Englewood.

  - That the FTC's economist expert analyzed the geographic market from a "hospital-based" perspective (i.e., the area where hospitals within Bergen County or contiguous counties derive their patients). Hospital-based methodology does not require a showing of price discrimination under the Guidelines (which the merging parties acknowledge in their own briefing).

- Nine amicus briefs have been filed by national trade organizations, including the American Hospital Association and Association of American Medical Colleges, in support of the transaction.

- A number of professors, economists, industry experts as well as twenty-six state attorneys general, including Pennsylvania, New York and California, have filed briefs in support of the FTC urging the Third Circuit to affirm the district court decision.

- In 2020, the state of New Jersey approved the disposition of Englewood's charitable assets pursuant to the transaction, but has not otherwise taken a stance for or against the transaction.

- Oral arguments related to the appeal took place on December 8, 2021 with a decision expected in early 2022.

b. Vazquez v. Indiana University Health Inc.

- In June 2021, an independent vascular surgeon practicing in southern Indiana ("Plaintiff") sued Indiana University Health, Inc., Indiana University Health Bloomington, Inc., IU Health Bloomington Hospital (collectively "IU Health"), and IU Health's Chief Medical Officer over allegations of monopolization, anticompetitive conduct and merging, breach of contract, and defamation.[3]
    - IU Health operates 14 hospitals throughout Indiana including Bloomington Hospital. Patients are often transferred to Bloomington Hospital because they retain the only Level III Trauma center, the only Level I Heart Attack center, and the only Stroke Center in the region.[4]
    - The Plaintiff is a vascular surgeon who previously retained admitting privileges at multiple IU Health facilities. As part of the recent acquisitions by IU Health, the plaintiff remained the only independent vascular surgeon in the area.[5]
    - IU Health is alleged to control 92.5% of inpatient discharges in the Bloomington area and 97% of primary care physicians because of anticompetitive acquisitions. As a result of these acquisitions, the Plaintiff alleges that this has led to localized healthcare costs and decreased quality of care.[6]

- In November 2021, the U.S. District Court for the Southern District of Indiana dismissed the Plaintiff's claims under Section 2 of the Sherman Act and Section 18 of the Clayton Act with prejudice. The state law claims for violations of Ind. Code § 24-1-2-2 and Ind. Code § 24-1-2-7, breach of contract, and defamation were dismissed

[3] Heebink, Kendall, *Surgeon Sues Indiana University Health, Alleging Monopolization*, News Health Healthcare (June 14, 2021).
[4] Order, *Vasquez v. Indiana University Health, Inc.*, Case No. 1:21-cv-01693-JMS-MG (S.D. Ind.) (Nov. 5, 2021).
[5] *Id*.
[6] Complaint, *Vasquez v. Indiana University Health, Inc.*, Case No. 1:21-cv-01693-JMS-MG (S.D. Ind.) (June 11, 2021).

without prejudice.[7]

- o In granting the defendant's motion to dismiss, the Court considered several issues:

  - ▪ Plaintiff's geographic market definitions were viewed as "sufficiently contradictory to render them implausible" because he alleged patients traveled several hours to receive care in Bloomington and yet the geographic market should be limited to the immediate Bloomington area.

  - ▪ The Court also scrutinized when the Plaintiff's claim accrued and thus the statute of limitations began to run. Generally, there is a four-year statute of limitations on damages under the Clayton Act. The statute begins to run "as soon as the acquisition takes place." However, where a merger only produces anticompetitive effects post-merger, the statute begins to run at the time the injury occurred. The plaintiff alleged in his complaint that the injury took place in 2017, around the time that IU Health acquired Premier Healthcare; not two years later when his admitting privileges were revoked.

  - ▪ Finally, the Court considered whether it must exercise supplemental jurisdiction over the state law claims. The Court determined that judicial economy considerations, convenience, and fairness and comity warranted dismissal of the complaints without prejudice.

- In November 2021, the plaintiff filed an appeal to the U.S. Court of Appeals for the Seventh Circuit.

c. Marion HealthCare, LLC v. Southern Illinois Hospital Services

- In July 2021, Marion HealthCare ("Plaintiff"), a multispecialty surgery center, sued to enjoin the combination of Southern Illinois Hospital Services ("SIHS") and Harrisburg Medical Center ("Harrisburg") (collectively, the "Defendants") alleging that the transaction would "substantially reduce competition in an already highly concentrated market, would harm the public and would cause antitrust injury."[8]

  - o SIHS is an Illinois not-for-profit corporation that owns and operates two acute care general hospitals, a critical access hospital, outpatient ambulatory surgery centers, and numerous physician practices and primary and specialty care clinics throughout southern Illinois.[9]

  - o SIHS announced its intent to buy Harrisburg and create a four-hospital system serving a 16-county region. This purchase would leave only one non-SIHS

[7] *See*, Final Judgement Pursuant to Fed. R. Civ. P. 58, *Vasquez v. Indiana University Health, Inc.*, Case No. 1:21-cv-01693-JMS-MG (S.D. Ind.) (Nov. 5, 2021).
[8] Paavola, Alia, *Illinois hospitals sued over plan to create 4-hospital system*, Becker's Healthcare (Aug. 2, 2021).
[9] Complaint, *Marion HealthCare, LLC v. Southern Illinois Hospital Services et al*, Case No. 3:21-cv-00873 (S.D. Ill.) (July 7, 2021)

affiliated acute care general hospitals in the relevant market.

- Plaintiff alleges that this merger would violate Section 7 of the Clayton Act, Section 2 of the Sherman Act, and Sections 3(2) and (3) of the Illinois Antitrust Act (740 ILCS 3).[10] In doing so, Plaintiff invoked public policy promulgated by the Biden Administration which, in part, seeks to "enforce the antitrust laws to combat the excessive concentration of industry, the abuses of market power, and the harmful effects of monopoly and monopsony – especially as these issues arise in…healthcare markets…"[11]
    - Plaintiff also alleges that the relevant geographic market consists of a seven-county area including the Illinois counties of Jackson, Williamson, Franklin, Johnson, Perry, Saline, and Union. Currently, SIHS's pre-merger market share of inpatient acute care general hospital services is 71.1%, resulting in a "highly concentrated" market under the Herfindahl-Hirschman Index (HHI). The Plaintiff alleges that as a result of the merger, SIHS' HHI would increase 445 points, more than twice the amount necessary to presume anticompetitive effects.

- In October 2021, the Defendants filed a motion to dismiss for lack of subject matter jurisdiction and for failure to state a claim.[12] Broadly, the Defendant's argue that:
    - Plaintiff did not plausibly plead any injury in fact. Instead, the Plaintiff pled to speculative injury and not "actual or imminent" injury citing "potentially" raised costs to patients, preventing the "possibl[e] acquisition of Harrisburg by Plaintiff, future disruption of established referral patterns, and enhancement of Defendant's ability to attract and retain surgeons who might otherwise join Plaintiff.
    - Plaintiff did not allege any injury to itself or to competition.
    - Plaintiff failed to allege proximate cause. Instead, the Plaintiff's complaint alleges injury that is "too remote and too attenuated to support proximate cause."
    - Because no amendment can save the complaint, the Court should dismiss the complaint with prejudice.

d. Colucci v. Health First

- In April 2021, three plaintiffs alleged that Health First, Inc. engaged in "pervasive and long-term exclusionary conduct" as a means of maintaining a monopoly in the

[10] *Id*.
[11] Complaint, *Marion HealthCare, LLC v. Southern Illinois Hospital Services et al*, Case No. 3:21-cv-00873 (S.D. Ill.) (July 7, 2021).
[12] Defendant's Motion and Memorandum of Law in Support of Their Motion to Dismiss Pursuant to Federal Rules of Civil Procedure 12(b)(1) and 12(b)(6), *Marion HealthCare, LLC v. Southern Illinois Hospital Services et al*, Case No. 3:21-cv-00873 (S.D. Ill.) (Oct. 1, 2021).

market for acute care in Florida.[13]

- Health First was formed in 1995 by the joining of Holmes Regional Medical Center and Palm Bay Hospital and Cape Canaveral Hospital. At this time, Health First because the sole provider in Southern Brevard County because it controlled the only two acute care hospitals in the county. Since then, the only other acute care hospital to enter the market was Wuesthoff-Melbourne in 2002.

- Health First was initially sued for anticompetitive conduct in *Omni Healthcare Inc. v. Health First*, No. 6:13-cv-1509-Orl-37DAB (filed Sept. 27, 2013). Physician competitors of Health First sued the system for anticompetitive conduct. On August 16, 2016, Health First settled the case which was subsequently voluntarily dismissed.[14] The complaint alleges that Health First was "unchastised" by the settlement and continued efforts to maintain and strengthen its monopoly in violation of Sections 1 and 2 of the Sherman Act.

- The plaintiffs allege:

  - Monopolization of the acute care market in violation of Section 2 of the Sherman Act resulting in reduced competition and higher-than-competitive fees paid to Health First. Plaintiffs allege this has reduced quality of care to patients far below competitive standards.

  - Agreements in restraint of trade in violation of Section 1 of the Sherman Act by entering into exclusive-dealing agreements with physicians, and by organizing a group boycott of competing hospitals.

  - Violation of the Florida Antitrust Act through anticompetitive conduct. Specifically, Health First's alleged agreements with physicians and organization of a group boycott in violation of Fl. Stat. § 542.18 which prohibits "[e]very contract, combination, or conspiracy in restraint of trade or commerce in [the] state." Secondly, plaintiffs allege that Health First is in violation of Fl. Stat. § 542.19 which makes it "unlawful for any person to monopolize, attempt to monopolize, or combine or conspire with any other person or persons to monopolize…"

- Plaintiffs seek to enjoin the anticompetitive conduct and claim treble damages for the class.

- In August 2021, plaintiffs amended the complaint twice to include additional causes action including horizontal market division in restraint of trade and exclusive dealing in restraint of trade.[15] This was made necessary by the U.S. Dist. Ct. for the Middle

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[13] Rizzi, Corrado, *Health First Hit with Antitrust Class Action in Florida*, Newswire (Apr. 20, 2021).
[14] Complaint, *Colucci v. Health First, Inc.,* Case No. 6:21-cv-00681 (M.D. Fla.) (Apr. 19, 2021).
[15] Second Amended Class Action Complaint, *Colucci v. Health First, Inc.,* Case No. 6:21-cv-00681 (M.D. Fla.) (Aug. 25, 2021).

Dist. of Florida dismissing the original complaint without prejudice for being a "shotgun" complaint containing multiple counts where each count adopts the allegations of all preceding counts.

e. Board of Dental Examiners of Alabama Settles Teledentistry Charges

- In October 2021, the Federal Trade Commission ("FTC") filed a complaint alleging the Board of Dental Examiners of Alabama ("Dental Board") excluded emerging competition from new and innovative teledentistry platforms.[16] As a result of this complaint, the Dental Board agreed to stop requiring on-site supervision by licensed dentists of alignment scans of prospective patients' mouths seeking to address misaligned teeth or gaps between teeth.[17]

- The Dental Board consists of six licensed dentists and one licensed dental hygienist who administer dental licensing in Alabama. In September 2018, the Dental Board sent a letter to new companies such as SmileDirectClub, Candid Co., and SmileLove, LLC (collectively, the "Companies") demanding they stop using non-dentist personnel to take scans of patients' mouths. As a result, SmileDirectClub abandoned plans to open additional locations in Alabama.

- The Companies created a new treatment model in which patients are fitted for clear aligners following a visit to a storefront location where a digital scan is performed by a dental assistant. The scan is reviewed by a dentist working remotely and is "substantially less expensive than traditional treatments."[18] In response, the Dental Board amended Alabama Admin. Code 270-X-3.10(o)(2) to prohibit non-dentists from performing digital scans without on-site dentist supervision.

- The complaint alleges that the Dental Board's actions have "unreasonably restrained competition for the treatment of malocclusion in Alabama."[19]

    - Additionally, the complaint alleges that the amendment offers no procompetitive benefits sufficient to justify the harmful effect on competition. As a result, the alleged acts by the Dental Board "constitute unfair methods of competition in violation of Section 5 of the Federal Trade Commission Act, 15 U.S.C. § 45.

    - According to the complaint, state regulatory boards comprised of active market participants (such as licensed dentists continuing to practice as is the case here)

[16] *See,* Complaint, In the Matter of Board of Dental Examiners of Alabama, *available at* https://www.ftc.gov/system/files/documents/cases/1910153_alabama_bd_dental_examiners_complaint.pdf

[17] *Alabama Board of Dental Examiners Agrees to Settle FTC Charges that it Unreasonably Excluded Lower Cost Online and Teledentistry Providers from Competition,* Federal Trade Commission (Sept. 28, 2021), *available at* https://www.ftc.gov/news-events/press-releases/2021/09/alabama-board-dental-examiners-agrees-settle-ftc-charges-it?utm_source=govdelivery

[18] *See,* Complaint, In the Matter of Board of Dental Examiners of Alabama, *available at* https://www.ftc.gov/system/files/documents/cases/1910153_alabama_bd_dental_examiners_complaint.pdf

[19] *Id*.

can violate antitrust law by publicizing and enforcing rules that harm competition in the industry in which board members participate.[20]

- The FTC voted 5-0 to issue the complaint and accept the proposed consent order for public comment. The consent order requires the Dental Board to:
  - Cease and desist from requiring on-site supervision by dentists when non-dentists perform intraoral scans on prospective patients
  - Cease and desist from requiring non-dentists affiliated with clear aligner platforms to maintain on-site dentist supervision when performing intraoral scanning
  - Provide notice of the proposed order to board members and employees, and to certain dentists and clear aligner platforms
  - Notify the commission of any changes to its rules related to intraoral scanning or clear aligner platforms.

f. Taro, Sandoz, and Apotex DOJ Civil Settlements

- In October 2021, Taro Pharmaceuticals USA, Inc. ("Taro"), Sandoz Inc. ("Sandoz") and Apotex Corporation ("Apotex"), three generic pharmaceutical manufacturers, agreed to pay a total of $447.2 million to resolve alleged violations of the False Claims Act.[21]

- The Anti-Kickback Statute ("AKS") prohibits companies from receiving or making payments in return for arranging the sale or purchase of items for which payment may be made by a federal health care program. The False Claims Act ensures that the United States is fully compensated when it is the victim of kickbacks paid to further anticompetitive conduct.

- The Department of Justice alleged that between 2013 and 2015, all three companies paid and received compensation prohibited by the AKS by making arrangements with other pharmaceutical manufacturers to control price, supply, and allocation of generic drugs. The result of such a scheme was to "increase costs both to federal health care programs and beneficiaries."[22]

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[20] *Alabama Board of Dental Examiners Agrees to Settle FTC Charges that it Unreasonably Excluded Lower Cost Online and Teledentistry Providers from Competition,* Federal Trade Commission (Sept. 28, 2021), *available at* https://www.ftc.gov/news-events/press-releases/2021/09/alabama-board-dental-examiners-agrees-settle-ftc-charges-it?utm_source=govdelivery

[21] *Pharmaceutical Companies Pay Over $400 Million to Resolve Alleged False Claims Act Liability for Price-Fixing of Generic Drugs,* Department of Justice Office of Public Affairs (Oct. 1, 2021) *available at* https://www.justice.gov/opa/pr/pharmaceutical-companies-pay-over-400-million-resolve-alleged-false-claims-act-liability

[22] *Id*.

- Taro manufactures etodolac, a NSAID, and nystatin-triamcinolone cream, an antifungal medicine. As a result of the allegations and settlement, Taro agreed to pay $213.2 million.

- Sandoz manufactures benazepril, used to treat hypertension, and clobetasol, a corticosteroid. As a result of the allegations and settlement, Sandoz agreed to pay $185 million.

- Apotex manufactures pravastatin, a drug used to treat high cholesterol. As a result of the allegations and settlement, Apotex agreed to pay $49 million.

- Each company is also subject to a 5-year Corporate Integrity Agreement ("CIA") in order to "promote transparency and accountability by requiring the companies to report price-related information to OIG and mandating individual certifications by key executives involved in pricing and contracting functions."[23] In addition to the internal monitoring and price transparency provisions, the CIAs "also require the companies to implement compliance measures including risk assessment programs, executive recoupment provisions and compliance-related certifications from company executives and board members."[24]

- Prior to the payment of civil penalties and implementation of CIAs, each company entered into deferred prosecution agreements with the Antitrust Division to resolve corresponding criminal charges. Taro paid an additional criminal penalty of $205.6 million, Sandoz paid $195 million, and Apotex paid $24.1 million. Each of these deferred prosecution agreements also included an admission of guilt for price fixing.

- In a press release, the United States Attorney for the Eastern District of Pennsylvania made clear that the office "will continue to aggressively pursue these violations of the Anti-Kickback Statute and the False Claims Act and obtain significant recoveries."[25]

[23] *Pharmaceutical Companies Pay Over $400 Million to Resolve Alleged False Claims Act Liability for Price-Fixing of Generic Drugs,* Department of Justice Office of Public Affairs (Oct. 1, 2021) *available at* https://www.justice.gov/opa/pr/pharmaceutical-companies-pay-over-400-million-resolve-alleged-false-claims-act-liability
[24] *Id*.
[25] *Id*.