

CPI Antitrust Chronicle

Sep 2014 (2)

The Evolution of Efficiencies
and Treatment of Quality of
Care Defenses in Light of
Changing Health Care Industry
Dynamics

Dionne Lomax & Helen Kim

Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, P.C.

The Evolution of Efficiencies and Treatment of Quality of Care Defenses in Light of Changing Health Care Industry Dynamics

Dionne Lomax & Helen Kim¹

I. INTRODUCTION

The consolidation of health care markets and the impact of this consolidation on prices, costs, and quality, has been a hotly debated topic in the health care industry. Hospitals across the country are merging and acquiring physician practices faster than they have in decades. These dynamic changes in the nation's health care delivery systems have been prompted, in part, by the implementation of the Patient Protection and Affordable Care Act² ("ACA"), which seeks, among other things, to promote higher quality, lower cost health care by encouraging increased coordination of care among health care providers through the creation of Accountable Care Organizations ("ACOs").³

One premise of the ACA is that the restructuring of the health care industry through coordinated care and integration should enable providers to cut costs and improve quality in ways that benefit patients. However, antitrust enforcement officials are quick to remind providers that the ACA does not change the fact that provider collaborations remain subject to the antitrust laws. Thus, providers must ensure that their new health care delivery systems do not enhance or create market power or otherwise harm consumers.

Efficiencies are frequently a significant part of the business rationale for hospital mergers and other provider collaborations and are an area of increased focus in health care antitrust litigation. However, receiving credit for the efficiency-enhancing aspects of a combination in a merger review is often difficult. By the Federal Trade Commission's ("FTC") own account, "efficiencies are most likely to make a difference in merger analysis when likely adverse competitive effects, absent the efficiencies, are not great."⁴ Moreover, in a recent speech, Debbie Feinstein, Director of the FTC's Bureau of Competition, made clear that although the FTC will consider merger-specific efficiencies to balance concerns of market power, the agency is increasingly taking a more stringent approach to how these defenses outweigh competitive harm.

This is particularly evident when analyzing the FTC's treatment of quality improvement claims in some of its most recent cases. As noted by Director Feinstein, while the agencies

¹ Dionne Lomax is a member, and Helen Kim is an associate, in Mintz Levin's antitrust and trade regulation practice in Washington, D.C.

² See Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119 (2010).

³ A network of doctors, hospitals, and other health care providers who come together to provide coordinated high-quality care to a group of patients and are held accountable for the cost and quality of the full continuum of care delivered to those patients.

⁴ See U.S. Dep't of Justice & Fed. Trade Comm'n, Horizontal Merger Guidelines § 5.3 (2010), *available at* <http://ftc.gov/os/2010/08/100819hmg.pdf>.

“expect and encourage parties to provide ... concrete evidence to support quality claims,”⁵ there is an outstanding question regarding the extent to which quality improvement claims can be demonstrated with the specificity required to satisfy the FTC’s efficiencies standard as they weigh the competitive implications of a transaction. Indeed, the FTC acknowledges the complexities involved in assessing quality improvement claims, stating:

[I]t is more difficult to determine how best to balance a possible price increase on the one hand and a quality improvement on the other hand. To date, however, that is not something we have found necessary to do. In the handful of transactions we have challenged, we have determined that the quality improvements were speculative, not substantiated and/or the merger was not necessary to achieve them.⁶

As such, merging parties have had difficulty prevailing on quality improvement defenses. The most recent debate in this regard is the FTC and Idaho Attorney General’s 2013 challenge of St. Luke Health System’s (“St. Luke’s”) acquisition of Saltzer Medical Group (“Saltzer”), where efficiencies are a significant component of the parties’ defense.

II. FTC V. ST. LUKE’S HEALTH SYSTEM

In *FTC v. St. Luke’s Health System*, the first fully litigated challenge by the FTC to a hospital acquisition of physician practices,⁷ the parties claimed that St. Luke’s acquisition of Saltzer would generate substantial efficiencies. They argued that factors such as—(1) shared use of St. Luke’s information technology, including electronic medical records; (2) aligned incentives to enable clinically integrated, value-based patient care; (3) expansion of access for the poor and uninsured; and (4) management of population health—were consistent with the objectives of federal health reform legislation.

Although the district court credited the defendants’ efficiencies defenses, acknowledging that the merging parties entered into the transaction “primarily to improve patient outcomes” and health care quality, and even stated the merger “would have that effect if left intact,” it ultimately concluded that the efficiencies were not “merger-specific” and that St. Luke’s could achieve the same efficiencies without fully merging with Saltzer and employing its physicians.⁸ The district court held that employment is not necessary to achieve the claimed efficiencies, citing examples of other health systems that had achieved high-quality, low-cost care using independent physician practices. The court also noted that the promised benefits of integration were in an “experimental stage” with the payback, if any, a decade away. As a result, the court ordered St. Luke’s to divest the Saltzer assets and permanently enjoined the acquisition.⁹

⁵ Deborah L. Feinstein, Director, Bureau of Competition, Fed. Trade Comm’n, Remarks at the Fifth National Accountable Care Organization Summit, *Antitrust Enforcement in Health Care: Proscription, Not Prescription*, June 19, 2014.

⁶ *Id.* at 11.

⁷ *St. Alphonsus Medical Center – Nampa, Inc. v. St. Luke’s Health System, Ltd.*, Findings of Fact and Conclusions of Law, No. 12-0560, Dkt. No. 464 (D. Idaho Jan. 24, 2014), appeal dktd., No. 14-35173 (9th Cir. filed Mar. 7, 2014).

⁸ *Id.* at 3.

⁹ The court found that St. Luke’s efficiencies defense could not overcome the presumption of illegality created by its dominant market share, a figure the court determined to be 80 percent of the primary care physicians in the

On appeal to the Ninth Circuit,¹⁰ St. Luke's contended that the FTC placed an "impossible" burden on merging parties to prove efficiencies, and argued that the district court wrongly decided that the parties could have raised the quality of health care without an affiliation.¹¹ Appellants dismissed the FTC's examples of where benefits of integrated care were achieved without a tight affiliation of physicians and instances of improved healthcare without employed physicians, arguing that such other arrangements did not answer the question relevant to the St. Luke's case: "The facts in *this* case do not support the notion that *these parties* could achieve these benefits in the *same timeframe* by some other means."¹² Appellants pointed to the court's finding that previous attempts at a looser affiliation by Saltzer physicians had failed, and asserted that "[o]nly this transaction—which allowed St. Luke's and Saltzer to share technological infrastructure, sophisticated analytics, all patient information, resources for community outreach, and both upside and downside accountability for patient outcomes—could achieve those benefits."¹³

The FTC argued that the district court correctly held that the deal would have anticompetitive effects. Noting that the Ninth Circuit "has not yet accepted a claim that a presumptively unlawful acquisition can be justified because it allows greater efficiency of operation,"¹⁴ the FTC rejected St. Luke's argument that the merger would create efficiencies in health care and thus reduce prices and improve care. They said that those effects could just as easily be achieved through competition, and thus argued that the case was a "poor candidate" for validating an efficiency defense under the Clayton Act.

According to the FTC, appellants' asserted efficiencies cannot "salvage an acquisition held to be anticompetitive...If the Court considers St. Luke's efficiency defense, it should affirm the district court's application of the strict, two-part analysis that the D.C. Circuit used in *Heinz*,"¹⁵ meaning the court must first "undertake a rigorous analysis of the kinds of efficiencies being urged... in order to ensure that those 'efficiencies' represent more than mere speculation and promises about post-merger behavior." The court must then assess whether the asserted efficiencies are merger-specific. The FTC sought strong appellate support for the district court's conclusions that the efficiencies advanced by St. Luke's—a) enabling the parties to move away from "fee-from-service" toward "risk-based care;" b) allowing the parties to provide "integrated" rather than "fragmented" care, thus improving the quality of care; and c) allowing the better use of electronic medical records and data analytical tools—were not merger-specific.

relevant area, and that no court has found (without being reversed) that efficiencies were enough to save an otherwise illegal merger.

¹⁰ The Ninth Circuit stayed the District Court's order of divestiture and the appeal is on an expedited schedule. *St. Alphonsus Medical Center – Nampa, Inc. v. St. Luke's Health System, Ltd.*, Order Granting Motion to Stay, No. 12-0560, Dkt. No. 510 (D. Idaho Jun. 25, 2014).

¹¹ *Alphonsus Medical Center – Nampa, Inc. v. St. Luke's Health System, Ltd.*, Reply Brief of Appellants St. Luke's Health System, Ltd, et al., No. 14-35173 (9th Cir. Sep. 2, 2014), at 26.

¹² *Id.* at 22-24.

¹³ *Id.* at 23.

¹⁴ *Alphonsus Medical Center – Nampa, Inc. v. St. Luke's Health System, Ltd.*, Answering Brief for Plaintiffs Federal Trade Commission and the State of Idaho, No. 14-35173 (9th Cir. Aug. 13, 2014), at 4.

¹⁵ *Id.* at 47-48.

The St. Luke's case raises a number of interesting issues and questions in the minds of antitrust practitioners. Some argue that the FTC's merger challenge is misguided because this case is precisely the type of provider collaboration the ACA promotes and that such consolidation is precisely what the industry needs in order to provide a higher level of care to patients and combat rising health care costs. In addition, the FTC is attempting to persuade the Ninth Circuit to adopt the very stringent efficiency defense standard articulated in *Heinz*, where the D.C. Circuit held that the high market concentration levels in the case required, "in rebuttal, proof of extraordinary efficiencies."¹⁶

This approach to the efficiencies analysis and treatment of the parties' quality of care defense leaves some unanswered questions regarding the type of quality of care defenses the FTC would find acceptable. The D.C. Circuit did not define the term "extraordinary" so it remains unclear what level of efficiencies satisfy that standard. If this more restrictive efficiencies defense standard is applied to future transactions, what type of quality of care efficiencies would be viewed as "extraordinary" and more importantly, how can parties demonstrate such efficiencies with the precision required to satisfy the standard?

If the FTC prevails, it will be the first time on the appellate level in the health care context that the very stringent efficiency defense standard articulated in *Heinz* is adopted. However, this strict efficiency defense standard is one that the Commission previously embraced when assessing quality of care defenses in the *Evanston* case.

III. IN THE MATTER OF EVANSTON NORTHWESTERN HEALTHCARE CORPORATION

The FTC's case challenging Evanston Northwestern Healthcare's ("Evanston") acquisition of Highland Park Hospital ("Highland Park") was a result of the FTC's retrospective review of hospital mergers announced by then-FTC Commissioner Tim Muris in 2002. Two years after the retrospective review was initiated, and four years after the transaction closed, the FTC issued a three-count administrative complaint alleging that Evanston's acquisition of Highland Park violated the antitrust laws.

ENH argued that the merger produced significant quality improvements and presented evidence that it spent over \$120 million post-merger to make improvements and expand services at Highland Park in 16 areas. The Commission disagreed, stating that Evanston failed to rebut complaint counsel's showing of anticompetitive effects,¹⁷ and finding that the quality improvements asserted by ENH should not be credited as benefits of the merger because Highland Park could have made similar improvements without a merger. It cited evidence that Highland Park had plans in place to improve its quality and had already begun to make a number of the improvements that ENH attributed to the merger (e.g., developing a cardiac surgery program in affiliation with Evanston or another hospital). Further, "ENH produced little verifiable evidence that the changes it made at Highland Park improved quality of care,"¹⁸ such as

¹⁶ *FTC v. H.J. Heinz Co. and Milnot Holding Corp.*, 246 F.3d 708, 720 (D.C. Cir. 2001) (finding that the claimed efficiencies in a merger between two of the only three baby food producers were not large enough to meet the standard when measured across the merged firm's total output and cost structure).

¹⁷ *In the Matter of Evanston Nw. Healthcare Corp.*, Opinion of the Commission at 83, FTC Docket No. 9315 (Aug. 6, 2007), available at <http://www.ftc.gov/os/adjpro/d9315/070806opinion.pdf>.

¹⁸ *Id.*

failing to “produce data to substantiate its assessments of quality at Highland Park, even though the record shows that ENH routinely tracks numerous quality indicators as part of its quality improvement program.”¹⁹ According to the Commission:

Given the particular circumstances of this case—the fact that the merger has already been consummated, many of the claimed improvements were implemented years ago, and ENH routinely tracks numerous quality indicators—ENH could have produced more concrete evidence than it did to substantiate its claims that the changes it made at Highland Park improved the quality of care. As the court emphasized in *Heinz*, “a rigorous analysis” is required to ensure that defendant’s claims of offsetting procompetitive benefits “represent more than mere speculation.” The dearth of verifiable evidence here is all the more reason for us to find that ENH has failed to satisfy its burden to prove “extraordinary” procompetitive benefits, offsetting complaint counsel’s showing of competitive harm.”²⁰

IV. IN THE MATTER OF OSF HEALTHCARE SYSTEM AND ROCKFORD HEALTH SYSTEM:

In a 2012 case involving Illinois health systems, the FTC’s complaint alleged that OSF Healthcare’s proposed acquisition of Rockford Health System would substantially reduce competition among hospitals and primary care physicians in Rockford, Illinois.²¹ In opposition to the FTC’s request for a preliminary injunction, the defendants argued that the proposed merger would lead to improved quality of care and provide other benefits to the Rockford community, such as allowing the merged entity to develop “Centers of Excellence”²² and increasing defendants’ ability to attract and recruit specialists and subspecialists. The FTC contested defendants’ claims, arguing that they were unsubstantiated, speculative, and not merger-specific.²³

The court agreed. Granting the FTC’s request for a preliminary injunction, the court held that the claimed efficiencies failed to outweigh the potential harm to consumers from the presumptively anticompetitive merger. The court explained that proof of “extraordinary efficiencies” would be required in the face of high concentration levels and observed that: (1) conflicting evidence from experts made it unclear whether increased quantity of procedures would lead to improved quality of care; (2) it was unclear that defendants would be able to develop “Centers of Excellence” as a result of the merger and possible that the designation could be achieved independent of the merger; and (3) the argument that the merger would enable the parties to recruit specialists and subspecialists was belied by their history of successfully recruiting specialty physicians.

V. A FRAMEWORK FOR QUALITY IMPROVEMENT CLAIMS

As these decisions highlight, the FTC and the courts require parties to provide evidence of quality improvement efficiencies that are significant, detailed, and merger-specific in order to rebut a presumption of anticompetitive effects from a transaction. These cases also demonstrate

¹⁹ *Id.* at 84.

²⁰ *Id.* at 85 (citations omitted) (emphasis added).

²¹ *In the Matter of OSF Healthcare Sys. and Rockford Health Sys.*, FTC Docket No. 9349 (Apr. 13, 2012).

²² *FTC v. OSF Healthcare Sys.*, 852 F. Supp. 2d 1069, 1088 (D. Ill. 2012).

²³ *Id.* at 1089.

that providing such clinical quality evidence to the government's satisfaction is often an uphill battle for merging parties. It is clear that the FTC is skeptical of a hospital merger's ability to reduce costs and improve quality. In fact, in a recent interview, Director Feinstein stated that when providers seek to merge, their goal is not only to improve care and reduce costs, but also to "get increased leverage" in negotiations with health plans and employers.²⁴

In the face of an agency that appears predisposed to assume a transaction is unlikely to yield significant pro-competitive benefits, citing health care reform and the desire to meet its cost reduction and quality improvement goals as the impetus for a transaction cannot be relied on as the primary defense to what may be viewed as an otherwise unlawful transaction. Rather, parties must provide concrete facts and evidence that substantiate their ability to realize significant quality improvements.

There is a conceptual framework that parties can apply when presenting quality improvement claims that may help parties demonstrate that their efficiency claims are credible, merger-specific, and likely to occur. These include, but are not limited to, the following:

- Analyze the potential for clinical quality improvements as soon as practicable and in as much detail as permissible under the antitrust laws. Develop and solidify concrete steps for the implementation of as many of the quality improvement plans as possible and adopt the plans as part of the deal analysis.²⁵ When efficiencies are not considered or used by the parties' boards as part of discussions regarding proposed transactions, the agencies and the courts do not view them as credible evidence of legitimate efficiencies.
- Provide evidence regarding the comparative quality of the merging parties and demonstrate that the clinically superior party is able to transfer its clinical expertise to the acquired entity with specific details explaining precisely how the acquiring entity will improve the quality metrics of the acquired party and how the new methods will benefit patients through improved quality of care. According to the FTC economists who analyzed the quality metrics in the *Evanston* matter, the likelihood of realizing "an improvement as a result of clinical superiority is greater if there are specific quality-improving measures that have been adopted by the acquiring system and for which there are concrete, documented plans to export them following the merger."²⁶
- Provide evidence that the acquiring firm has a track record of increasing clinical quality by showing the firm has successfully improved quality after previous acquisitions. Such evidence could help persuade the government that clinical quality is likely to improve post-merger in the pending transaction. According to Commissioner Maureen

²⁴ Robert Pear, *FTC Wary of Mergers by Hospitals*, N.Y. TIMES, Sep. 17, 2014, available at <http://www.nytimes.com/2014/09/18/business/ftc-wary-of-mergers-by-hospitals-.html>? ("They say they need better rates, so they will have more money to invest in their facilities... When you strip that down, it's basically just saying, 'We want a price increase.'")

²⁵ Jeffrey Perry & Richard Cunningham, *Effective Defenses of Hospital Mergers in Concentrated Markets*, 27 (2) ANTITRUST 43 (Spring 2013) (noting that the existence of an implementation plan adopted as part of the deal analysis helps to reinforce quality claims).

²⁶ Patrick Romano & David Balan, *A Retrospective Analysis of the Clinical Quality Effects of the Acquisition of Highland Park Hospital by Evanston Northwestern Healthcare*, 18(1) INT'L J. OF THE ECON. OF BUSINESS, 60 [hereinafter "Romano & Balan"].

Ohlhausen, “[o]ne of the things we fear most is that parties will offer these potential efficiencies and then we go back and look at previous acquisitions or integrations and the promised quality failed to materialize.”²⁷

- Analyze quality improvement plans previously considered by the acquired entity and explain how the proposed transaction will provide more robust results. This should also include providing an explanation as to why any previous plans contemplated by the acquired firm could not have been successfully implemented absent the proposed transaction and/or could not have achieved the level of quality that would only be possible through the merger.
- Demonstrate that certain quality-improving investments that may not have been made at the acquired entity pre-merger are now worthwhile given the acquiring party’s new lower cost of capital that will be realized from the transaction (e.g., the merger may make additional investment in quality-improving pieces of equipment with high fixed costs more feasible for a larger health system than for an independent hospital or smaller health system).²⁸
- Demonstrate the ability to improve clinical outcomes for certain surgical procedures that exhibit a volume-outcome relationship in which repetition of the procedure generates better clinical outcomes. By consolidating such procedures at fewer hospitals, or by sending experienced personnel from one hospital to another, a system can theoretically extend the benefits of scale enjoyed by a high-volume acquiring hospital to the acquired hospital.²⁹
- Provide evidence that demonstrates how the merger will enhance the parties’ incentives to innovate and improve the quality of care.
- Use contemporaneous ordinary course documents from the merging parties to demonstrate the likelihood of improving quality and to show that the key drivers of the deal include the desire to improve clinical quality and reduce the cost of health care.

VI. CONCLUSION

Substantiating quality of care efficiencies will remain critically important for merging parties in future transactions, but the FTC’s rather stringent approach to assessing quality of care defenses creates uncertainties regarding the type and magnitude of quality of care efficiencies that the FTC will find acceptable.

In a recent speech, the Director of the Bureau of Economics, Martin Gaynor, acknowledged the challenges presented in evaluating efficiency claims in health care, “both because efficiency is multi-faceted (because of the importance of quality), and because there’s so much activity and ferment in health care organizations.”³⁰ According to Gaynor, health care

²⁷ See, *A Discussion with FTC Commissioner Maureen K. Ohlhausen*, ANTITRUST HEALTH CARE CHRON., 3 (Nov. 2013).

²⁸ Romano & Balan, *supra* note 26 at 48.

²⁹ *Id.*

³⁰ Martin Gaynor, Director, Bureau of Economics, Federal Trade Comm’n, Remarks, *Efficiencies Analysis: False Dichotomies, Modeling and Applications to Health Care*, Aug. 3, 2014, available at

provides the FTC with the opportunity to advance its modeling and measurement of efficiencies, because “there are a lot of data in health care, and there is a great deal of work being done to develop new and better measures of quality and to try to understand organizational factors.”³¹ As the FTC continues to develop new ways to measure and assess quality, hopefully their analyses of clinical quality efficiencies will evolve in a way that helps parties gain greater acceptance for their quality claims to the benefit of all interested parties.

http://www.ftc.gov/system/files/documents/public_statements/574751/140619efficienciesanalysis.pdf (“health care provides us with the challenge and the opportunity to advance our modeling and measurement of efficiencies, but most importantly our understanding of how to assess and incorporate them into economic analysis of antitrust issues.”)

³¹ *Id.*