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## Editor's Report

In this edition of the *Chronicle*, we are pleased to offer four articles covering a range of antitrust issues relating to the health care and pharmaceutical industries:

- In our first article, **Douglas Ross and Ryan Gist of Davis Wright Tremaine** analyze the FTC's litigation victory in its recent challenge to St. Luke's Health System's acquisition of Saltzer Medical Group.
- In our second article, **Joseph Adamson of Weil, Gotshal & Manges** provides an in-depth look at the Massachusetts Health Policy Commission's report and recommendation to the Office of the Attorney General to review and potentially challenge Partners' proposed acquisition of South Shore Hospital.
- In our third article, **Valentina Rucker and Roisin Comerford of Wilson Sonsini** break down the antitrust issues and policy considerations for follow-on biologics in a discussion of the FTC's recent workshop on this emerging area.
- In our fourth article, **Spencer Graf of Charles River Associates** provides a profile of the DOJ Antitrust Division's Chief Economist, Aviv Nevo, and an analysis of his research and writings in the health care industry.

As you know, we are always interested in hearing from our Committee members. If there is a topic that you would like to see covered in a Committee program or if you have any other suggestions, please contact the Committee Co-Chairs, Jeff Brennan ([jbrennan@mwe.com](mailto:jbrennan@mwe.com)) or Philip Nelson ([nelson.p@east.ei.com](mailto:nelson.p@east.ei.com)).

If you are interested in writing an article for the *Chronicle*, please contact the Executive Editors, Jeff White ([jeff.white@weil.com](mailto:jeff.white@weil.com)), Leigh Oliver ([leigh.oliver@hoganlovells.com](mailto:leigh.oliver@hoganlovells.com)), or Gus Chiarello ([gchiarello@ftc.gov](mailto:gchiarello@ftc.gov)).

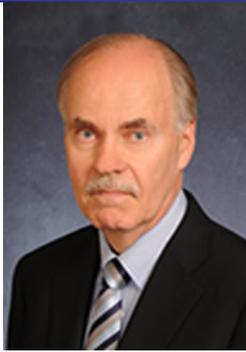
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## St. Luke's Litigation

*By Douglas Ross and Ryan Gist  
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The Federal Trade Commission (“FTC”) won a significant victory in January when a federal judge determined that St. Luke’s Health System’s acquisition of a large multi-specialty physician group in Idaho violated federal and state merger laws.<sup>1</sup> The case represents the first litigation through trial of an FTC challenge to a physician acquisition by a health system.

Although a final decision in the case probably is months or even years away—St. Luke’s has appealed to the Ninth Circuit<sup>2</sup>—given the rapid pace at which hospitals and health systems continue to acquire physician practices across the country it is not too soon to examine the litigation and draw preliminary lessons. The case provides guidance on the competitive theories that the FTC uses when examining hospital-physician transactions, the role of the

Affordable Care Act in a merger case, the weight given to claimed efficiencies (including the claim that hiring physicians permits health systems to better integrate care), the continuing importance of “hot” documents in merger enforcement, remedies the FTC and courts will consider when faced with a completed anticompetitive physician acquisition, and strategies parties should—or, perhaps, should not—consider when negotiating a deal under the full glare of an antitrust investigation.

The most important lesson health care providers should take from the litigation, however, is a simple one: hospital-physician transactions will be judged by traditional antitrust standards. This is true despite the financial, regulatory and governmental pressures that may drive hospitals to acquire physicians and the industry perception that health care is different and competition should not be its polestar. The court in *St. Luke’s* sympathized with these views, finding the transaction was motivated, in part at least, by a desire to improve quality of care. The court suggested that in a world “not governed by the Clayton Act, the best result might be to approve the Acquisition” and monitor the results.<sup>3</sup> But, the court concluded, “the Clayton Act is in full force, and . . . does not give the Court discretion to set it aside to conduct a health care experiment.”<sup>4</sup>

<sup>1</sup> Saint Alphonsus Medical Center-Nampa and Fed. Trade Comm’n, et al. v. St. Luke’s Health System and Saltzer Medical Group, No. 1:12-CV-00560-BLW (Jan. 24, 2014) (Memorandum and Decision, *available at* [www.ftc.gov/sites/default/files/documents/cases/140124stlukememodo.pdf](http://www.ftc.gov/sites/default/files/documents/cases/140124stlukememodo.pdf)) and (Findings of Fact and Conclusions of Law, *available at* [www.ftc.gov/system/files/documents/cases/140124stlukesfindings.pdf](http://www.ftc.gov/system/files/documents/cases/140124stlukesfindings.pdf)). Individual findings and conclusions hereafter are referred to as either “Finding of Fact” or “Conclusion of Law,” followed by the number assigned by the court.

<sup>2</sup> St. Luke’s filed its appeal March 4, 2014, less than a week after the final judgment was entered on February 28. See *St. Luke’s*, Notice of Appeal, Dkt. No. 472, (March 4, 2014).

<sup>3</sup> Conclusion of Law, *supra* note 1, at 76.

<sup>4</sup> Conclusion of Law, *supra* note 1, at 77.



## Background

### *Increasing Employment of Physicians by Hospitals and Health Systems*

The transaction that sparked the *St. Luke's* litigation is part of a much larger national trend of hospitals and health systems acquiring physician practices and employing doctors. For many years physicians prized their independence. Hospitals did little more than provide facilities where independent physicians could hospitalize and treat their patients. But times have changed. Several factors explain the desire, shared by hospitals and physicians alike, to join forces.

Hospitals are under unrelenting financial pressure. Over the last three decades, inpatient hospital days at traditional hospitals (short-term, acute-care facilities) fell by one-third, despite the substantial increase and aging of the population during these years.<sup>5</sup> As medical care improves and technology advances, lengths of stay shorten and many procedures formerly performed in a hospital migrate to outpatient settings.<sup>6</sup> Alternative institutions, including long-term acute care hospitals and skilled nursing facilities, provide care to patients who otherwise would have received care in short-term, acute-care hospitals. Medicare reimbursement for hospitals has been under constant pressure—and the Affordable Care Act has taken another whack at this source of funding.<sup>7</sup> As a result of these pressures, 15 percent of the nation's hospitals have closed

over the last 30 years; the only surprise is that the figure is not larger. Hospital bond ratings also reflect the financial difficulties under which hospitals labor—fewer than one in five hospitals rated by Moody's receive a high grade for their debt.<sup>8</sup>

One response to these pressures has been for hospitals to consolidate horizontally, through mergers, acquisitions and other affiliations.<sup>9</sup> A second and growing response has been to integrate vertically by acquiring physician practices and employing physicians.<sup>10</sup> Employing physicians allows hospitals to diversify their revenue streams, so that not all eggs are in the inpatient basket. It stands to reason that physicians likely will admit their patients to the hospitals that employ them. The court in *St. Luke's* made this point, finding that as a result of the acquisition, "it is virtually certain" that referrals from the acquired group to *St. Luke's* "will increase."<sup>11</sup> These new admissions generate additional revenue for hospitals that employ doctors. But there is a second reason to employ physicians that goes beyond additional referrals—physician behavior has a substantial impact on the costs hospitals

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<sup>8</sup> *Id.* at 1965.

<sup>9</sup> See Margaret Guerin-Calvert & Jen Maki, *Hospital Realignment: Mergers Offer Significant Patient and Community Benefits*, CTR. FOR HEALTHCARE ECONS. & POL'Y, at 7 (Jan. 23, 2014), available at [http://fahpolicy.org/wp-content/uploads/2014/01/FTI\\_Hospital-Realignment-Mergers-Offer-Significant-Patient-and-Community-Benefits\\_Report.pdf](http://fahpolicy.org/wp-content/uploads/2014/01/FTI_Hospital-Realignment-Mergers-Offer-Significant-Patient-and-Community-Benefits_Report.pdf).

<sup>10</sup> Sometimes physicians are directly employed, other times hospitals and health systems enter into professional service agreements with them. As the court noted in *St. Luke's*, a "PSA arrangement creates a relationship functionally equivalent to employment," and so the difference is of no consequence in an antitrust analysis. Finding of Fact, *supra* note 1, at 12 & n.1.

<sup>11</sup> Finding of Fact, *supra* note 1, at 140.

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<sup>5</sup> David M. Cutler, Fiona Scott Morton, *Hospitals, Market Share, and Consolidation*, 310 J. OF THE AMERICAN MEDICAL ASS'N 1964, 1965 & Fig. 1 (Nov. 13, 2013), available at [http://scholar.harvard.edu/files/cutler/files/jsc130008\\_hospitals\\_market\\_share\\_and\\_consolidation.pdf](http://scholar.harvard.edu/files/cutler/files/jsc130008_hospitals_market_share_and_consolidation.pdf).

<sup>6</sup> *Id.* at 1966.

<sup>7</sup> *Id.* at 1967 & n.13.



incur to treat patients. Decisions by physicians to discharge (or not discharge) patients or to order (or not order) particular tests and procedures have serious financial ramifications for hospitals.<sup>12</sup> When physicians are independent members of a hospital's medical staff, but otherwise are unaligned with the hospital, the hospital has little ability to influence these decisions. When a hospital employs physicians the dynamic changes and it may be better positioned to influence physician decisions that can result in unnecessary costs. Government payers such as Medicare and Medicaid (and increasingly commercial payers) reimburse hospitals on a diagnosis-related group basis, where the amount paid for a patient is fixed and does not vary based on services provided. As a result, physician decisions to extend patient stays or to order unnecessary tests and procedures drive up hospital costs without concomitant increases in revenue.

The impetus to employ physicians does not come from health systems alone. Over the last several years, physicians graduating from medical school and training programs increasingly have been interested in employment, eschewing entrepreneurial private practice.<sup>13</sup> As a result of all these factors,

employment of physicians has risen sharply. One report suggests hospital employment of specialists rose from five percent in 2000, to 25 percent in 2012, while hospital employment of primary care physicians more than doubled during the same period, to about 40 percent.<sup>14</sup> Other reports indicate the percentage of employed physicians may be even greater.<sup>15</sup> All sources appear to agree, however, that the trend of hospital employment will continue. If so, antitrust scrutiny of hospital-physician deals likely will increase.

### ***A Brief History of Government Enforcement Actions Against Provider Mergers***

#### **Hospital Mergers**

The Federal Trade Commission long has had an active program of attacking hospital mergers and acquisitions that the agency believes to be anticompetitive. There have been roughly three phases of modern hospital merger enforcement history that span the last three decades. In the 1980s and early 1990s, the FTC, together with the Department of Justice's Antitrust Division, brought various cases to enjoin hospital mergers and won most while losing some.<sup>16</sup> But then the

<sup>12</sup> "The most expensive piece of medical equipment, as the saying goes, is a doctor's pen. And, as a rule, hospital executives don't own the pen caps. Doctors do." Atul Gawande, *The Cost Conundrum: What a Texas town can teach us about health care*, THE NEW YORKER (June 1, 2009), available at [www.newyorker.com/reporting/2009/06/01/090601fa\\_fact\\_gawande?currentPage=all](http://www.newyorker.com/reporting/2009/06/01/090601fa_fact_gawande?currentPage=all).

<sup>13</sup> Elisabeth Rosenthal, *Apprehensive, Many Doctors Shift to Jobs With Salaries*, N.Y. TIMES (Feb. 13, 2014), available at [www.nytimes.com/2014/02/14/us/salaried-doctors-may-not-lead-to-cheaper-health-care.html](http://www.nytimes.com/2014/02/14/us/salaried-doctors-may-not-lead-to-cheaper-health-care.html); *Filling the Void: 2013 Physician Employment and Practice Trends*, JACKSON HEALTHCARE, available at [www.jacksonhealthcare.com/media/191888/2013physician-trends-void\\_ebk0513.pdf](http://www.jacksonhealthcare.com/media/191888/2013physician-trends-void_ebk0513.pdf).

<sup>14</sup> Anna Wilde Mathews, *Doctor, Hospital Deals Probed*, WALL ST. J. (Sept. 13, 2012), available at <http://online.wsj.com/news/articles/SB1000087239639044433504577649523985288422> (subscription required). Another study indicated that in 2011, almost half of all physician groups were owned by hospitals. Cutler & Morton, *supra* note 5.

<sup>15</sup> *Apprehensive, Many Doctors Shift to Jobs With Salaries*, N.Y. TIMES (reporting that one leading physician placement firm is placing two of every three new doctors in an employed position and expects the ratio to be three in four within two years—while the comparable figure ten years ago was just 11 percent).

<sup>16</sup> Government wins include: *FTC v. University Health*, 938 F.2d 1206 (11th Cir. 1991); *U.S. v. Rockford Mem'l Corp.*, 898 F.2d 1278 (7th Cir. 1990); *Hosp. Corp. of Am. v. FTC*, 807 F.2d 1381, 1390 (7th Cir. 1986); and *FTC v. Columbia Hospital Corp.*, 1993-1 Trade Cas. (CCH)



tide turned. Between 1994 and 1999, the federal agencies lost six hospital merger challenges in a row.<sup>17</sup> The government losing streak was capped at seven when a state, California, lost a hospital merger challenge of its own in 2000.<sup>18</sup> The Antitrust Division responded to these results by exiting the hospital merger business. The FTC reacted differently. The Commission retrenched, conducting a widely-publicized retrospective study to determine what went wrong in the litigated losses.<sup>19</sup> Then, in 2004, the modern era of hospital challenges began when the Commission challenged the already consummated Evanston/Northwestern merger in

Chicago's northern suburbs.<sup>20</sup> The agency won that litigation<sup>21</sup> and followed it up with challenges to hospital mergers in northern Virginia;<sup>22</sup> Toledo, Ohio;<sup>23</sup> Albany, Georgia;<sup>24</sup> Rockford, Illinois;<sup>25</sup> and Reading, Pennsylvania.<sup>26</sup> The FTC obtained favorable results (either after litigation or through a consent order) in all these cases, though one,

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¶ 70,209 (M.D. Fla. 1994). Losses include *Adventist Health Sys./West*, 117 F.T.C. 224 (1994) and *U.S. v. Carillion Health System*, 707 F. Supp. 840 (W.D. Va. 1989), *aff'd*, 892 F.2d 1042 (4th Cir. 1989).

<sup>17</sup> The FTC and DOJ lost six litigated hospital merger cases between 1994 and 1999, without a countervailing success. The FTC lost in *Hosp. Bd. of Directors of Lee County*, 38 F.3d 1184 (11th Cir. 1994), *FTC v. Freeman Hospital*, 69 F.3d 260 (8th Cir. 1995), *FTC v. Butterworth Health Corp.*, 946 F. Supp. 1285 (W.D. Mich. 1996), *aff'd mem.*, 121 F.3d 708 (6th Cir. 1997) and *FTC v. Tenet Healthcare Corp.*, 186 F.3d 1045 (8th Cir. 1999). DOJ accumulated losses in *United States v. Mercy Health Servs.*, 902 F. Supp. 968 (N.D. Iowa 1995), *vacated as moot*, 107 F.3d 632 (8th Cir. 1997) and *United States v. Long Island Jewish Medical Center*, 983 F. Supp. 121 (E.D.N.Y. 1997).

<sup>18</sup> *State of California v. Sutter Health System*, 84 F. Supp. 2d 1057 (N.D. Cal. 2000), *aff'd*, 217 F.3d 846 (9th Cir. 2000), *amended by*, 130 F. Supp. 2d 1137 (N.D. Cal. 2001).

<sup>19</sup> The FTC's retrospective review of hospital mergers was discussed in a 2002 speech by former Chairman Muris. See *Everything Old is New Again: Health Care and Competition in the 21st Century*, Prepared Remarks of Timothy J. Muris before the 7th Annual Competition in Health Care Forum (Nov. 7, 2002), available at [www.ftc.gov/sites/default/files/documents/public\\_statements/everything-old-new-again-health-care-and-competition-21st-century/murishealthcarespeech0211.pdf](http://www.ftc.gov/sites/default/files/documents/public_statements/everything-old-new-again-health-care-and-competition-21st-century/murishealthcarespeech0211.pdf).

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<sup>20</sup> Complaint, *Evanston Northwestern Healthcare Corp.*, FTC Dkt. No. 9315 (2004), available at [www.ftc.gov/sites/default/files/documents/cases/2004/02/040210emhcomplaint.pdf](http://www.ftc.gov/sites/default/files/documents/cases/2004/02/040210emhcomplaint.pdf).

<sup>21</sup> The final decision, issued in 2008, and other pertinent decisions and filings, can be accessed here: [www.ftc.gov/enforcement/cases-proceedings/0110234/evanston-northwestern-healthcare-corporation-enh-medical-group](http://www.ftc.gov/enforcement/cases-proceedings/0110234/evanston-northwestern-healthcare-corporation-enh-medical-group).

<sup>22</sup> In the Matter of *Inova Health System Foundation and Prince William Health System, Inc.*, FTC Dkt. 9326, order dismissing complaint (2008) available here: [www.ftc.gov/sites/default/files/documents/cases/2008/06/080617orderdismisscmpt.pdf](http://www.ftc.gov/sites/default/files/documents/cases/2008/06/080617orderdismisscmpt.pdf); pertinent filings here: [www.ftc.gov/enforcement/cases-proceedings/061-0166/inova-health-systems-foundation-prince-william-health-system](http://www.ftc.gov/enforcement/cases-proceedings/061-0166/inova-health-systems-foundation-prince-william-health-system).

<sup>23</sup> In the Matter of *ProMedica Health System, Inc.*, FTC Dkt. 9346, opinion (2012) and other pertinent filings here: [www.ftc.gov/enforcement/cases-proceedings/101-0167/promedica-health-system-inc-corporation-matter](http://www.ftc.gov/enforcement/cases-proceedings/101-0167/promedica-health-system-inc-corporation-matter).

<sup>24</sup> *FTC v. Phoebe Putney Health System, Inc.*, 133 S. Ct. 1003, 185 L. Ed. 2d 43 (2013); see also In the Matter of *Phoebe Putney Health System, Inc.*, et al., FTC Dkt. 9348, available at [www.ftc.gov/enforcement/cases-proceedings/111-0067/phoebe-putney-health-system-inc-phoebe-putney-memorial](http://www.ftc.gov/enforcement/cases-proceedings/111-0067/phoebe-putney-health-system-inc-phoebe-putney-memorial)

<sup>25</sup> *FTC v. OSF Healthcare System and Rockford Health System*, No. 3:11-cv-50344 (N.D. Ill. 2012), available at [www.ftc.gov/sites/default/files/documents/cases/2012/04/120505rockfordmemo.pdf](http://www.ftc.gov/sites/default/files/documents/cases/2012/04/120505rockfordmemo.pdf).

<sup>26</sup> *Reading Health System and Surgical Institute of Reading*, FTC Dkt. 9353 (2012), pertinent filings available at [www.ftc.gov/enforcement/cases-proceedings/121-0155/reading-health-system-surgical-institute-reading-matter](http://www.ftc.gov/enforcement/cases-proceedings/121-0155/reading-health-system-surgical-institute-reading-matter).



ProMedica, remains on appeal before the Sixth Circuit.<sup>27</sup>

### Physician Mergers Before *St. Luke's*

Despite active hospital merger enforcement, until two years ago neither of the federal enforcement agencies had filed a single case challenging a physician practice merger or a hospital acquisition of a physician practice.<sup>28</sup>

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<sup>27</sup> Calling *FTC v. Phoebe Putney* a win for the FTC is a matter of opinion; both the Commission and the hospital can legitimately claim to have won that litigation. The agency challenged Phoebe Putney's proposed acquisition of Palmyra Park Hospital in 2011. The FTC tried, but failed, to obtain a preliminary injunction and the hospitals closed their deal while the litigation continued. The case went to the Supreme Court on the hospitals' claim (backed by the Eleventh Circuit) that the transaction was immunized by the state action doctrine. The Supreme Court disagreed, finding the transaction was not immune, and sent the case back for further proceedings. The FTC justifiably saw this as a major win for its enforcement program, particularly as to its efforts to limit the scope of state action immunity defense. See Statement of FTC Chairman Jon Leibowitz on the U.S. Supreme Court Ruling in Favor of the Commission in the Phoebe Putney/Palmyra Park Hospital Case (Feb. 19, 2013), available at [www.ftc.gov/news-events/press-releases/2013/02/statement-ftc-chairman-jon-leibowitz-us-supreme-court-ruling](http://www.ftc.gov/news-events/press-releases/2013/02/statement-ftc-chairman-jon-leibowitz-us-supreme-court-ruling). Following remand to the lower courts, however, the FTC discovered a major snag in its plan to force the divestiture of Palmyra Park. If the hospital was divested it would have to obtain a certificate of need to operate separately from Phoebe Putney. But Georgia authorities administering the state's certificate of need program stated that the area in which Palmyra Park operates is overbedded. The authorities indicated they would deny Palmyra Park a certificate of need if it were to seek one—which would force the hospital to close following divestiture. Because meaningful relief was rendered impractical by the CON regime, the FTC gave up its challenge and entered a consent order that did not unwind the deal. See Analysis of Proposed Agreement Containing Consent Order to Aid Public Comment (August 22, 2013), available at [www.ftc.gov/sites/default/files/documents/cases/2013/08/130822phoebeputneyanal.pdf](http://www.ftc.gov/sites/default/files/documents/cases/2013/08/130822phoebeputneyanal.pdf).

<sup>28</sup> Both federal enforcement agencies, and especially the FTC, have filed many cases against physicians and other

Twenty years ago the federal agencies issued a few business review letters indicating some very small physician mergers might be anticompetitive,<sup>29</sup> but no enforcement actions were filed. Although all was quiet on the federal front, the occasional state took action against physician mergers viewed as anticompetitive.<sup>30</sup>

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practitioners for formation of loosely integrated organizations that sought to negotiate collectively on behalf of their providers. See Overview of FTC Antitrust Actions in Health Care Services and Products (March 2013), available at [www.ftc.gov/sites/default/files/attachments/competition-policy-guidance/hcupdate.pdf](http://www.ftc.gov/sites/default/files/attachments/competition-policy-guidance/hcupdate.pdf), for examples. While some of the challenged transactions were seen by their proponents as involving sufficient integration to permit review under the more balanced standard of Section 7 of the Clayton Act, rather than the per se prohibitions of Section 1, see, e.g., Surgical Specialists of Yakima, 136 F.T.C 840 (consent order) (2003) available at [www.ftc.gov/enforcement/cases-proceedings/commission-decision-volumes/volume-136](http://www.ftc.gov/enforcement/cases-proceedings/commission-decision-volumes/volume-136), the agencies did not see them that way.

<sup>29</sup> See, e.g., DOJ Business Review Re: Gastroenterologists in Allentown, Pennsylvania (July 7, 1997) (three groups of four gastroenterologists each in Allentown were informed by DOJ that it "cannot say at this time that it would not take enforcement action" against their proposed merger; only two other gastroenterologists were located in Allentown). More frequently, the agencies issued advice indicating they would not oppose proposed physician mergers. See, e.g., DOJ Business Review Letter Re: Itasca Clinic and Grand Rapids Medical Associates (March 19, 1996) (merger of two clinics with 15 to 25 percent each of the primary care physicians and with one-third of the general surgeons between them permitted when no payer raised concerns); DOJ Business Review Letter Re: Albuquerque pulmonologists (Oct. 31, 1994) (DOJ indicated that they would not oppose merger of two groups of five pulmonologists each in Albuquerque, N.M., where two other groups with 12 pulmonologists between them existed in area and non-pulmonologists competed to provide many of the same services).

<sup>30</sup> See, e.g., *Maine v. Maine Heart Surgical Associates* (1996). The Maine Attorney General filed an antitrust complaint when nine of the ten cardiothoracic surgeons in



Inaction by the federal enforcement agencies came to an end in 2011, when the Bureau of Competition issued a statement announcing the closing of a previously-undisclosed FTC investigation into a health system's proposed acquisition of two cardiology groups in Spokane, Washington.<sup>31</sup> According to the statement, Commission staff had "expressed serious concerns to the parties regarding possible anticompetitive effects of the transactions."<sup>32</sup> After the health system abandoned the acquisition of one group (it proceeded with the acquisition of the other) the Commission closed its investigation. In the statement, Bureau Director Richard Feinstein noted that "physicians across the country are exploring a variety of new business arrangements as part of an effort to achieve cost containment and quality objectives," including "consolidating with other same specialty or multi-specialty physician groups, entering into employment arrangements with hospitals, and

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Portland combined their four separate practices into one entity. The state and surgeons entered into a consent order permitting the merger so as to take advantage of promised efficiencies, but agreed to a rate cap to managed care payers.

<sup>31</sup> See *Statement of Bureau of Competition Director Richard Feinstein on the Abandonment by Providence Health & Services of its Plan to Acquire Spokane Cardiology and Heart Clinics Northwest in Spokane, Washington* (March 21, 2011), available at [www.ftc.gov/sites/default/files/documents/closing\\_letters/providence-health-services/spokane-cardiology-and-hearts-clinic-northwest/110321providencstatement.pdf](http://www.ftc.gov/sites/default/files/documents/closing_letters/providence-health-services/spokane-cardiology-and-hearts-clinic-northwest/110321providencstatement.pdf); see also the press release and closing letters in connection with Providence Health & Services/Spokane Cardiology and Hearts Clinics Northwest, all available at: [www.ftc.gov/enforcement/cases-proceedings/closing-letters-and-other-public-statements/commission-closing-letters?title=&field\\_matter\\_number\\_value=&field\\_document\\_description=&date\\_filter\[min\]=&date\\_filter\[max\]=&page=2](http://www.ftc.gov/enforcement/cases-proceedings/closing-letters-and-other-public-statements/commission-closing-letters?title=&field_matter_number_value=&field_document_description=&date_filter[min]=&date_filter[max]=&page=2).

<sup>32</sup> *Id.*

forming other affiliations."<sup>33</sup> Feinstein recognized that these "arrangements have the potential to generate cost savings and quality benefits for patients," but warned, "in some cases, such arrangements can create highly concentrated markets that may harm consumers through higher prices or lower quality of care."<sup>34</sup>

The FTC filed its first action alleging a health system's acquisition of a physician group was anticompetitive the very next year.<sup>35</sup> In a situation that resembled the situation in Spokane, the Commission asserted that Renown Health, the largest hospital system in Reno, Nevada, acted anticompetitively when it acquired two cardiology groups in the area. Renown had acquired one group of 15 cardiologists in early 2011, and another group, of 16 cardiologists, a few months later. When the acquisitions were over, only one independent cardiologist remained in town. Renown's initial post-acquisition market share of 97 percent declined slightly when some cardiologists left its employ and others entered the market, but when the FTC and state of Nevada filed their action Renown's share of cardiology still was substantial, at 88 percent.

The complaint attacked the acquisition of the second cardiology group on horizontal grounds, asserting the consolidation of cardiology

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<sup>33</sup> *Id.*

<sup>34</sup> *Id.*

<sup>35</sup> In the Matter of Renown Health, FTC File No. 1110101 (Decision and Order, Dec. 4, 2012), available at: [www.ftc.gov/enforcement/cases-proceedings/1110101/renown-health-matter](http://www.ftc.gov/enforcement/cases-proceedings/1110101/renown-health-matter). Note that in 2011, the FTC challenged OSF Healthcare's acquisition of Rockford Memorial Hospital in Illinois, which included an allegation that the transaction would increase concentration in a market for primary care services. *FTC v. OSF Healthcare System and Rockford Health System*, No. 3:11-cv-50344 (N.D. Ill. 2012).



services under Renown's umbrella would lead to higher prices. Simultaneously, the FTC entered into a consent order with the system. Renown agreed to release up to ten of its cardiologists from non-competes all doctors had signed when they joined the system.<sup>36</sup> The non-competes had barred employed cardiologists from competing within a 50-mile area for two years after termination of their employment.

While the FTC was busy in Reno, the state of Maine investigated a health system acquisition of competing physician groups. MaineHealth, which owns and operates hospitals, proposed to acquire two groups of cardiologists. The state entered into a complex consent decree that, among other things, limits increases in the cardiologists' rates, regulates cardiology margins for a period of time, guarantees access by all payers to the cardiologists, and forbids non-competes.<sup>37</sup>

### *The St. Luke's Case*

#### **Initial Investigation and Initiation of Private Litigation**

Boise lies in an area of Idaho known as the Treasure Valley. Twenty miles to the west of Boise sits the smaller city of Nampa. An interstate highway and other roads link the two. Small communities dot the landscape between and to the north of Boise and Nampa.

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<sup>36</sup> The Nevada Attorney General filed a similar complaint in federal court along with an identical settlement and final judgment. The Attorney General's settlement required Renown pay the state \$550,000 in fees.

<sup>37</sup> State of Maine v. MaineHealth, No. BCD-CV-11-08 (Me. B.C.D.), Order Approving Consent Decree (Jan. 3, 2012) available at [www.courts.state.me.us/opinions\\_orders/bcd/CV%20Orders/CV-11-08/2012-1-3%20Order%20CV-11-08.pdf](http://www.courts.state.me.us/opinions_orders/bcd/CV%20Orders/CV-11-08/2012-1-3%20Order%20CV-11-08.pdf); Consent Decree available at [www.maine.gov/tools/whatsnew/attach.php?id=310574&an=1](http://www.maine.gov/tools/whatsnew/attach.php?id=310574&an=1).

Mountains and national forest lie to the east and south of Boise.

Two integrated health systems compete in the Treasure Valley. St. Luke's Health System operates two hospitals in the valley, one in Boise and the other in Meridian, a hamlet west of Boise on the road to Nampa. The St. Luke's Clinic, a multi-specialty physician group wholly controlled by St. Luke's has three locations in the valley: in Boise, Meridian and Nampa. Saint Alphonsus Health System, the other integrated health system in the valley, operates hospitals in Boise and Nampa. The Saint Alphonsus Medical Group employs physicians in Boise, Nampa, and two communities to the north, Eagle and Caldwell.

Several years ago St. Luke's began acquiring physicians in the Treasure Valley, and elsewhere in Idaho where the system operates hospitals. Between 2007 and 2012, the St. Luke's Clinic grew to employ (or have professional service agreements with) approximately 500 physicians in Idaho (and eastern Oregon). In early 2012, news broke that St. Luke's was negotiating to acquire Idaho's largest independent physician group, the Saltzer Medical Group—and that the antitrust authorities were reviewing the possible deal.<sup>38</sup> Saltzer's 41 physicians, all in the Treasure Valley, were clustered in Nampa, Meridian and Caldwell.

The Idaho Attorney General wrote to St. Luke's in February 2012, asking that the health system delay its acquisition of Saltzer until the state and the FTC could conclude ongoing investigations

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<sup>38</sup> Audrey Dutton, *Acquisitions by Idaho's St. Luke's Health System under antitrust review*, IDAHO STATESMAN (March 16, 2012), available at [www.idahostatesman.com/2012/03/16/2038698/idahos-st-lukes-health-system.html#storylink=cpy](http://www.idahostatesman.com/2012/03/16/2038698/idahos-st-lukes-health-system.html#storylink=cpy).



into St. Luke's acquisitions.<sup>39</sup> In November, the Idaho Attorney General wrote St. Luke's again, asking again that it hold off closing the Saltzer acquisition until the investigations were complete.<sup>40</sup> To do otherwise, the Attorney General asserted in the November letter, would be "counter-productive. Indeed, such a strategy would appear designed to invite litigation."<sup>41</sup> Four days later, after St. Luke's still had not provided the requested assurances, Saint Alphonsus apparently decided not to wait for a *fait accompli* and filed its own suit, requesting injunctive relief.<sup>42</sup>

Saint Alphonsus complained that the acquisition by St. Luke's of the Saltzer group, and in particular of the Saltzer physicians in Nampa, would deprive Saint Alphonsus of patients the group traditionally admitted to Saint Alphonsus, and in particular to its Nampa hospital.<sup>43</sup> This vertical foreclosure, Saint Alphonsus argued, would weaken its Nampa hospital and thus damage competition among general, acute-care hospitals in the Boise-Nampa area. Saint Alphonsus alleged also that the acquisition, if completed, would reduce competition for

primary care physician services in Nampa, general pediatric services in Nampa, and outpatient surgery services in the Boise area.

Saint Alphonsus moved to enjoin the acquisition pending trial. In late December 2012, the district court denied the requested preliminary injunction, finding no threat of imminent harm to Saint Alphonsus.<sup>44</sup> The court did not reach the merits of plaintiff's claims. It set the case for an expedited trial and warned the merging parties that if Saint Alphonsus were to prevail on its antitrust claims, "[t]he acquisition can be unwound and divestiture ordered."<sup>45</sup>

### The Completion of the Acquisition

Soon after the injunction was denied, on the last day of 2012, the deal closed. St. Luke's paid "an amount not to exceed" \$16 million to acquire the assets of the Saltzer Medical Group—\$9 million of which does not have to be paid back even if the transaction ultimately is undone. All doctors in the Saltzer group were required to enter into five-year professional service agreements with St. Luke's. Physicians were guaranteed compensation no lower than that received in the three years preceding the deal. Physicians were to be paid for production (on a work relative value unit basis), although a quality component was added later that could affect up to 20 percent of their income. Each physician had an exclusivity provision included in the professional services agreement that lasted for the life of the agreement; this was simply a non-compete by another name. No

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<sup>39</sup> See Letter from Attorney General Lawrence Wasden to General Counsel Christine Neuhoff (Feb. 24, 2012), available at [www.idahopress.com/letter-from-attorney-general-to-st-luke-s/pdf\\_a41ca640-7091-11e1-9ee2-0019bb2963f4.html](http://www.idahopress.com/letter-from-attorney-general-to-st-luke-s/pdf_a41ca640-7091-11e1-9ee2-0019bb2963f4.html).

<sup>40</sup> The letter is quoted in the Complaint Saint Alphonsus filed November 12, 2012. Saint Alphonsus Medical Center, Nampa – Inc., Treasure Valley Hospital Limited Partnerships et al. v. St. Luke's Health System, No. 1:12-cv-00560-CWD (D. Id.) at 4, available at <http://media.idahostatesman.com/smedia/2014/02/07/17/27/kG6JO.S0.36.pdf> (hereafter "Saint Alphonsus Complaint").

<sup>41</sup> Saint Alphonsus Complaint.

<sup>42</sup> *Id.* Treasure Valley Hospital, a physician-owned, nine-bed hospital in Boise with limited services, but offering a full range of imaging services, joined as a plaintiff.

<sup>43</sup> *Id.*

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<sup>44</sup> Saint Alphonsus Medical Center-Nampa, Inc. v. St. Luke's Health System, No. 1:12-cv-00560-CWD (D. Id. December 20, 2012), 2012-2 TRADE CASES ¶78,194, available at [http://scholar.google.com/scholar\\_case?q=saint+alphonsus&hl=en&as\\_sdt=4,143&case=16927439041896881093&scilh=0](http://scholar.google.com/scholar_case?q=saint+alphonsus&hl=en&as_sdt=4,143&case=16927439041896881093&scilh=0).

<sup>45</sup> *Id.*



Saltzer physician was precluded from having privileges at Saint Alphonsus, or any other hospital.

### **The FTC and Idaho Sue to Undo the Acquisition**

In March 2013, the FTC and the State of Idaho finally entered the fray, filing their own complaint in federal court in Boise. Like Saint Alphonsus before them, the agencies claimed the transaction was anticompetitive and asked the court to undo the deal.<sup>46</sup> The agencies did not adopt the vertical foreclosure theory advanced by Saint Alphonsus, however, sticking instead to a traditional theory of horizontal harm. Their complaint asserted the transaction would lessen competition in the market for adult primary care physician services in an area that consisted of 5-counties including Nampa and Caldwell by creating a dominant provider with almost 60 percent of that relevant market.

### **The Trial and the Decision**

The trial began in Boise federal court in September 2012, and lasted five weeks. In late January, Judge B. Lynn Winmill released a short opinion<sup>47</sup> and separately entered extensive

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<sup>46</sup> FTC and Idaho v. St. Luke's Health System and Saltzer Medical Group, No. 13-cv-116-BLW (D. Id. 2013), available at [www.ftc.gov/sites/default/files/documents/cases/2013/03/130312stlukescmpt.pdf](http://www.ftc.gov/sites/default/files/documents/cases/2013/03/130312stlukescmpt.pdf). Additional FTC documents in the case can be found here: [www.ftc.gov/os/caselist/1210069/130312stlukescmpt.pdf](http://www.ftc.gov/os/caselist/1210069/130312stlukescmpt.pdf). An excellent resource for those interested in the trial is maintained by the *Idaho Statesman*, here: [www.idahostatesman.com/2014/02/05/3010489/st-lukes-lawsuit-news-documents.html#othermedia](http://www.idahostatesman.com/2014/02/05/3010489/st-lukes-lawsuit-news-documents.html#othermedia). The Idaho Attorney General's Office has pertinent documents here: [www.ag.idaho.gov/consumerProtection/pendingActions/stLukes.html](http://www.ag.idaho.gov/consumerProtection/pendingActions/stLukes.html).

<sup>47</sup> Available at [www.ftc.gov/sites/default/files/documents/cases/140124stlukememodo.pdf](http://www.ftc.gov/sites/default/files/documents/cases/140124stlukememodo.pdf).

findings of fact and conclusions of law,<sup>48</sup> holding the acquisition unlawful. The court focused on the market for the provision of adult primary care physician services in Nampa. St. Luke's acquisition of the Saltzer group gave it 80 percent of the primary care physicians in Nampa alone. This share made St. Luke's the "dominant provider in Nampa for primary care" and conferred "significant bargaining leverage over health insurance plans."<sup>49</sup> Although the court found St. Luke's and Saltzer entered into their deal "primarily to improve patient outcomes," it was "highly likely that health care costs will rise as the combined entity obtains a dominant market position."<sup>50</sup> Accordingly, the court found the acquisition unlawful and ordered divestiture of Saltzer.

### **The Relevant Market**

The parties did not dispute that adult primary care physician services sold to commercially insured patients was a relevant product market. The court adopted this as the relevant product market, ignoring the separate product markets Saint Alphonsus had advanced in its complaint.<sup>51</sup>

The scope of the relevant geographic market was contested, however. Judge Winmill sided squarely with the FTC on this issue, finding Nampa was the relevant market and rejecting the notion that the market extends to Boise. In

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<sup>48</sup> Available at [www.ftc.gov/system/files/documents/cases/140124stlukesfindings.pdf](http://www.ftc.gov/system/files/documents/cases/140124stlukesfindings.pdf).

<sup>49</sup> Findings of Fact and Conclusions of Law, *supra* note 1, at 3.

<sup>50</sup> *Id.*

<sup>51</sup> The court wrote it "need not resolve the issues raised by the private plaintiffs because the Acquisition is being unwound due to its effects in the Nampa market for primary physician services." Conclusion of Law, *supra* note 1, at 64.



reaching this result the judge relied heavily on testimony from Northwestern University economist David Dranove, who was retained as an expert by the FTC. Dranove showed that 68 percent of Nampa residents stayed in Nampa for primary care. Although 15 percent of Nampa's residents obtained primary care in Boise, they did so because they worked there. In Dranove's view, this "basically confirm[ed] that patients like to get their medical care close to home."<sup>52</sup> Dranove testified that commercial insurers needed to have Nampa primary care physicians in their networks to have a viable product to sell in Nampa. Along the same lines, evidence showed that Blue Cross of Idaho, the state's largest commercial insurer, offers primary care physicians in every zip code in Idaho where it has enrollees; it does not require any enrollee to travel outside his zip code to get care. Finally, the St. Luke's director of payer contracting testified that a "Select Medical Network" created by St. Luke's in partnership with other providers, "decided it should include Saltzer in the network because it needed providers in Nampa in order to market itself to employers."<sup>53</sup>

Based on these facts, the court concluded Nampa primary care physicians have "leverage with health plan networks to profitably impose" a small, but significant and nontransitory price increase in Nampa (a SSNIP in the jargon of the Horizontal Merger Guidelines<sup>54</sup>). As a result, the city, in the court's view, was the relevant geographic market.<sup>55</sup>

<sup>52</sup> Finding of Fact, *supra* note 1, at 67.

<sup>53</sup> *Id.* at 63.

<sup>54</sup> Federal Trade Commission & Department of Justice, Horizontal Merger Guidelines, Section 4.1.1 (2010), available at [www.ftc.gov/sites/default/files/attachments/merger-review/100819hmg.pdf](http://www.ftc.gov/sites/default/files/attachments/merger-review/100819hmg.pdf).

<sup>55</sup> Finding of Fact, *supra* note 1, at 73.

## Market Power

To determine whether the acquisition would give St. Luke's market power in the relevant market the court first looked to market shares and market structure. In doing so, Judge Winmill relied squarely on the structural presumption, articulated 50 years ago in *Philadelphia National Bank*,<sup>56</sup> that mergers of a certain size in markets with a certain concentration are presumptively unlawful. In *Philadelphia National Bank*, the Supreme Court held that a merger of two banks with a combined market share of 30 percent, in a market where the top four firms had a 60 percent share, was presumptively unlawful. Judge Winmill found that Saltzer and St. Luke's together accounted for nearly 80 percent of the primary care physician services in Nampa (measured by visits). As a result of the acquisition, the HHI rose 1,607 points, to a post-merger total of 6,219. The HHI measures were "well above the thresholds for a presumptively anticompetitive merger," the judge wrote, holding the acquisition "is therefore presumptively anticompetitive under § 7 of the Clayton Act."<sup>57</sup>

Judge Winmill did not rely entirely on market shares and HHIs to support his conclusion that the acquisition was anticompetitive. Saltzer and

<sup>56</sup> 374 U.S. 321, 363 (1963). Ironically, the week the St. Luke's trial began, one of the FTC Commissioners gave a speech in which he urged that "the Commission should encourage courts to abandon the use of the structural presumption—first announced by the Supreme Court in *Philadelphia National Bank*. Such a change would considerably improve courts' analysis of mergers, and better reflect modern economic thinking and empirical evidence." See Remarks of Joshua D. Wright, Commissioner, *The FTC's Role in Shaping Antitrust Doctrine: Recent Successes and Future Targets*, at the 2013 Georgetown Global Antitrust Symposium Dinner (Sept. 24, 2013).

<sup>57</sup> Finding of Fact, *supra* note 1, at 81.



St. Luke's were the two largest providers of primary care physician services in the Nampa area and each was the other's closest substitute: half of St. Luke's patients in Nampa would choose to go to Saltzer if St. Luke's were not available, while one-third of Saltzer's patients in Nampa would see a St. Luke's physician if Saltzer's Nampa physicians were unavailable. In the judge's view, health plans negotiating with St. Luke's before the merger considered Saltzer to be the best alternative – and vice versa. After the merger, the second best alternative was foreclosed, so health plans seeking an alternative to the merged group in Nampa would have to settle for “their third best option. That is not an attractive option for a health plan trying to market that network to patients who live in Nampa.”<sup>58</sup>

As has become common in recent merger cases,<sup>59</sup> the FTC introduced documents authored by the parties that talked in terms of “clout,” and “leverage,” and “dominance.”<sup>60</sup> The court found these persuasive on the existence of market power post-merger. One document showed the chair of Saltzer's contracting committee commenting that if Saltzer

completed the deal with St. Luke's it could go to Blue Cross and use “the clout of the entire network” to gain higher payments.<sup>61</sup> St. Luke's, for its part, had internal documents that argued “market share in primary care is a key success factor ... to sustaining a strong position relative to payer contracting.”<sup>62</sup>

The court also relied on past conduct of St. Luke's in other markets to support the conclusion that the combined St. Luke's and Saltzer entity would have market power in Nampa. St. Luke's had a hospital and medical group in Twin Falls, Idaho (a city far from Nampa). For a number of years, Blue Cross did not contract with the St. Luke's medical group in Twin Falls, believing its rates were too high. The insurer relied on the existence of other primary care physicians within 15 to 30 miles of Twin Falls. “But patients did not want to drive that distance for primary care,” Judge Winmill wrote, so Blue Cross found itself with an unmarketable product.<sup>63</sup> “Eventually, the St. Luke's negotiators had such leverage that [Blue Cross] had no choice but to concede to their pricing proposal.”<sup>64</sup>

There is one curious use of evidence marshaled by the court to support its finding that the combined entity's market power would lead to increased prices. When a patient undergoes an outpatient procedure in a hospital facility, Medicare may pay more for the procedure (by paying a facility fee, in addition to the professional fee) than it would pay if the procedure were performed in an independent physician's office. The theory is that hospitals have higher costs than doctors' offices and

<sup>58</sup> Finding of Fact, *supra* note 1, at 110.

<sup>59</sup> The FTC notably used the parties' documents against them in both *Evanston/Northwestern* and *ProMedica*. FTC and DOJ enforcement challenges outside of health care also routinely use the parties' documents. *See, e.g.*, *FTC v. Whole Foods Market, Inc.*, 548 F.3d 1028 (2008); *see also* *United States v. BazaarVoice*, Case No. 13-cv-00133-WHO (N.D. Cal. Jan. 8, 2014), available at [www.justice.gov/atr/cases/bazaarvoice.html](http://www.justice.gov/atr/cases/bazaarvoice.html) (documents included slide decks showing B-52s bombers dropping bombs, ostensibly on the competition).

<sup>60</sup> Slides from the opening and closing statements highlight some of these documents. The opening is here: [www.ag.idaho.gov/consumerProtection/pendingActions/StLukesFTCOpeningStatement.pdf](http://www.ag.idaho.gov/consumerProtection/pendingActions/StLukesFTCOpeningStatement.pdf). The closing is here: [www.ag.idaho.gov/consumerProtection/pendingActions/StLukesFTCAAndOAGClosingStatements\\_FINAL-PUBLIC.pdf](http://www.ag.idaho.gov/consumerProtection/pendingActions/StLukesFTCAAndOAGClosingStatements_FINAL-PUBLIC.pdf).

<sup>61</sup> Finding of Fact, *supra* note 1, at 113.

<sup>62</sup> *Id.* at 116.

<sup>63</sup> *Id.* at 119.

<sup>64</sup> *Id.* at 120.



should be reimbursed for these costs. A hospital facility where such “provider-based” rates may be charged does not have to be physically joined to the hospital, under Medicare rules, so long as it is licensed as part of the hospital and meets other criteria.<sup>65</sup> Notably, Medicare’s provider-based rates are an artifact of a system of administered prices and not the result of hospital bargaining power in a particular market.

Many insurers also follow the Medicare convention in their private reimbursement arrangements with hospitals. Blue Cross of Idaho apparently is one of these. The insurer testified at trial that if St. Luke’s, after the acquisition, were to bill for procedures done at Saltzer locations using provider-based rates, Blue Cross’s commercial contract costs would increase by one-third. Internal analysis done by St. Luke’s confirmed that the health system expected to earn additional revenue through provider-based billing after the Saltzer acquisition, though it is not clear from the opinion whether St. Luke’s projected this purely as a result of Medicare paying more or because it thought it could force higher payments from commercial insurers as well. The distinction is important. Medicare pays more because those are its rules, but Medicare pays more to any provider that implements provider-based billing at a location, regardless of the provider’s market power. If St. Luke’s could extract additional reimbursement from commercial insurers, however, whether through provider-based billing increases that the insurer could not negotiate around or directly through higher rates, this could be suggestive of market power. But the court didn’t examine that issue. It simply wrote that “leverage gained by the Acquisition would give St. Luke’s the ability to

make these higher rates ‘stick’ in future contract negotiations” with Blue Cross. It left unexplained how the existence of provider-based contracting contributed anything to the critical conclusion that St. Luke’s could raise rates as a result of the acquisition.

### Efficiencies

After finding that plaintiffs had made a prima facie case the acquisition would confer market power on the combined St. Luke’s/Saltzer entity, Judge Winmill considered St. Luke’s arguments “that the merger will create efficiencies that will far outweigh any anticompetitive effects.”<sup>66</sup> Before examining specific claimed efficiencies, however, the judge reviewed well-known criticisms that health care in the U.S. costs too much and delivers too little. “In Idaho,” he wrote, things are even worse: “health care costs are above even the already-high national average.”<sup>67</sup> As a result, Blue Cross of Idaho pays “considerably more” than the national average for health care.<sup>68</sup>

One significant cause of waste in the U.S. health care system, Judge Winmill asserted, is fee-for-service reimbursement in a fragmented health care system. Health care could be organized better, the judge opined, if providers were to integrate their services and be reimbursed on a capitated or other risk basis, where the incentive is not to provide more services, but to provide needed care efficiently and effectively.<sup>69</sup> St.

<sup>66</sup> Finding of Fact, *supra* note 1, at 147.

<sup>67</sup> *Id.* at 156.

<sup>68</sup> *Id.* at 157.

<sup>69</sup> Judge Posner provided another view on the incentives provided by capitated payments in his decision in *Blue Cross & Blue Shield United of Wisconsin v. Marshfield Clinic*, 65 F.3d 1406, 1412 (7th Cir. 1995) in which he wrote, “From a short-term financial standpoint—which we do not suggest is the only standpoint that an HMO is

<sup>65</sup> 42 C.F.R. § 413.65, available at [www.gpo.gov/fdsys/pkg/CFR-2011-title42-vol2/pdf/CFR-2011-title42-vol2-sec413-65.pdf](http://www.gpo.gov/fdsys/pkg/CFR-2011-title42-vol2/pdf/CFR-2011-title42-vol2-sec413-65.pdf).



Luke's claimed the transaction created significant efficiencies because by employing physicians the system could better position itself to deliver integrated care. Judge Winmill disagreed. Based on testimony from an expert witness, he found that "physicians are committed to improving the quality of health care, and lowering its cost, whether they are employed or independent."<sup>70</sup> Judge Winmill also held, based on the testimony of a Blue Cross executive, that risk contracting does not require a sizeable number of physicians, because health plans "manage the level of risk proportionate to the level of the provider organization."<sup>71</sup> Both findings are significant to those in the health care industry who believe they are at odds with their experience.

The court next considered the claim that the combined entity would implement a common electronic health record (in this case, the Epic system) across all St. Luke's Clinic and Saltzer physicians, thereby permitting more integrated and efficient care. Judge Winmill acknowledged that a common health record is a good thing. But St. Luke's was in the process of rolling out the Epic system to physicians unaffiliated with either the St. Luke's Clinic or Saltzer. "These circumstances demonstrate," the judge wrote, "the efficiencies resulting from the use of Epic do not require the employment of physicians and hence are not merger-specific."<sup>72</sup>

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likely to have—the HMO's incentive is to keep you healthy if it can but if you get very sick, and are unlikely to recover to a healthy state involving few medical expenses, to let you die as quickly and cheaply as possible. HMOs compensate for these perceived drawbacks by charging a lower price than fee-for-service plans."

<sup>70</sup> Finding of Fact, *supra* note 1, at 180.

<sup>71</sup> *Id.* at 182.

<sup>72</sup> *Id.* at 204.

## Entry

Finally, the court turned to the argument that other physicians could enter the Nampa market, "thereby mitigating any anticompetitive effects" of the acquisition. Borrowing from the language of the Horizontal Merger Guidelines, Judge Winmill held "St. Luke's must show that entry by competitors will be 'timely, likely, and sufficient in its magnitude, character and scope to deter or counteract the competitive effects' of the proposed transaction."<sup>73</sup>

But the evidence did not support a claim that entry is likely on the required scale. It has been difficult to recruit primary care physicians to the Nampa area. In particular, the Saint Alphonsus Medical Group was unable to recruit any family practitioners in 2013 to Nampa and has been unable to recruit general internists to that area for two years.

## Vertical Foreclosure?

Although the court entered no conclusions on Saint Alphonsus's claim of vertical foreclosure, it entered factual findings that are supportive of the claim. Saint Alphonsus, as noted above, expressed concern that after the acquisition Saltzer physicians no longer would refer their patients to the Saint Alphonsus hospital in Nampa but would direct them instead to a St. Luke's facility. St. Luke's pointed to the professional service agreements the Saltzer physicians signed as evidence that doctors have complete autonomy to decide where to send their patients. While acknowledging that the agreements did not restrict physician referrals, Judge Winmill found it highly likely that referral patterns would shift once Saltzer physicians became affiliated with St. Luke's. Evidence showed that after earlier purchases of specialty practices by St. Luke's the amount of

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<sup>73</sup> *Id.* at 208.



business those physicians referred to St. Luke's increased dramatically, and the amount of business they referred to Saint Alphonsus decreased similarly. The judge had no trouble concluding that this "trend" is likely to occur here, unless the transaction is reversed, and will result in Saltzer referrals switching from Saint Alphonsus to St. Luke's.<sup>74</sup>

It is unclear what significance the court attached to this finding. Judge Winmill examined the effect of the acquisition on competition in only one market: the market for adult primary care in Nampa. The loss of referrals that Saint Alphonsus would suffer is not relevant to that analysis. It would be highly relevant to an analysis of a claim of anticompetitive vertical foreclosure—but the judge did not consider that claim.

### **Remedy: Divestiture, not Separate Bargaining Teams**

When the court denied Saint Alphonsus's motion for a preliminary injunction in late 2012, it warned St. Luke's and Saltzer that if, after trial, it found their transaction anticompetitive it could order divestiture. St. Luke's had represented to the court, at the hearing on the preliminary injunction, that it would not oppose divestiture on grounds that divestiture could not be accomplished or that it would be costly or burdensome.<sup>75</sup>

Nonetheless, at trial St. Luke's did argue that divestiture should not be ordered, claiming that the departure of seven surgeons from Saltzer to Saint Alphonsus after the St. Luke's deal was announced caused an unforeseen financial hardship to Saltzer that ought to preclude divestiture. Judge Winmill was not sympathetic. The representations St. Luke's

made at the earlier hearing probably doomed the plea, but the judge made an additional observation: St. Luke's had agreed with Saltzer that \$9 million of the acquisition price did not have to be paid back in the event the acquisition was undone. Given this windfall, Judge Winmill commented, Saltzer could not very well claim hardship from the loss of seven practitioners.

Finally, the court rejected the remedy proposed by St. Luke's that it and Saltzer maintain two separate teams to negotiate contracts with payers. The Commission itself had ordered such a remedy in the wake of the *Evanston/Northwestern* retrospective merger challenge.<sup>76</sup> The FTC made clear in the later *ProMedica* merger challenge, however, that it considered the *Evanston/Northwestern* remedy to be unique.<sup>77</sup> The Commission (over staff's objection) permitted separate negotiating teams in *Evanston* because the FTC attacked the merger long after it was completed—seven years had passed by the time the remedy was ordered and by then the two organizations were thoroughly enmeshed. The court in *ProMedica* (a consummated merger in which the parties agreed to hold separate pending the FTC investigation, followed by a court-ordered hold separate) declined to adopt the *Evanston*

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<sup>76</sup> *Evanston Northwestern Healthcare Corporation*, Opinion of the Commission on Remedy, FTC Docket No. 9315 (April 28, 2008), available at [www.ftc.gov/opa/2008/04/evanston.shtm](http://www.ftc.gov/opa/2008/04/evanston.shtm).

<sup>77</sup> See *ProMedica Health System, Inc.*, FTC Docket No. 9346 (March 28, 2012) available at [www.ftc.gov/os/adjpro/d9346/120328promedicabrillopini.on.pdf](http://www.ftc.gov/os/adjpro/d9346/120328promedicabrillopini.on.pdf) (rejecting ProMedica's argument that separate negotiating teams should be allowed because they had been earlier in the *Evanston* case; a conduct remedy was appropriate in *Evanston* only because the parties had merged seven years before the FTC's final decision and unscrambling the eggs would be nearly impossible).

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<sup>74</sup> *Id.* at 140.

<sup>75</sup> Conclusion of Law, *supra* note 1, at 53.



remedy, ordering divestiture instead, and the Judge Winmill followed suit in *St. Luke's*.<sup>78</sup>

### Lessons from the *St. Luke's* Litigation

The government has won hospital merger cases at trial before, only to see the results reversed on appeal.<sup>79</sup> Accordingly, the lessons to be drawn in the wake of the district court's decision can only be tentative ones, subject to revision when any appeal has run its course. But this much, at this juncture, is apparent:

- The FTC continues to believe that the best challenge to a health care merger or acquisition is on grounds the transaction lessens horizontal competition. The agency was given a vertical theory on a platter by Saint Alphonsus, which it chose largely to ignore.
- When litigating, FTC staff will use the tools at hand. This means that so long as *Philadelphia National Bank* remains good law, FTC staff will rely in litigation on the case's structural presumption—even if this approach is criticized by many, including one of the FTC's own commissioners. Using the tools at hand means also that the FTC will not hesitate to use the parties' own

words in pre-merger documents against them. If providers want to put an end to the use of “hot” documents in merger cases they should choose their words carefully and focus on the patient benefits of proposed transactions—and excise “clout,” “leverage” and “dominance” from their vocabularies while they're at it.

- The FTC will investigate and bring small cases.<sup>80</sup> The \$16 million purchase price *St. Luke's* paid for Saltzer was far below the 2013 notification threshold of \$70.9 million.<sup>81</sup> Moreover, the overlap that doomed the *St. Luke's/Saltzer* transaction involves very few physicians: Saltzer has 16 primary care physicians in Nampa; *St. Luke's* has just eight.<sup>82</sup>

<sup>78</sup> Conclusions of Law 60-62. *St. Luke's* filed a motion in early March 2014 asking that divestiture be stayed pending resolution of its appeal, filed the same day. *St. Luke's*, Motion for Stay, Dkt. No. 473, (March 4, 2014). *St. Luke's* argues that divestiture likely would lead to the loss of physicians from Saltzer, “and its elimination as an effective competitor” while a delay of divestiture pending appeal would have no adverse effect because “there is no evidence that *St. Luke's* has engaged in any anticompetitive pricing during the period of more than a year since the affiliation was effectuated, and nothing in the findings of fact of this Court supports a conclusion that any anticompetitive effects from the affiliation are imminent.” *Id.* at 1.

<sup>79</sup> See, e.g., *FTC v. Healthcare Corp.*, 17 F. Supp. 2d 937 (1998), *rev'd*, 186 F.3d 1045 (8th Cir. 1999).

<sup>80</sup> Events in 2012 and 2013 at the FTC should have alerted practitioners that when it comes to health care, no case is too small for the agency. In January 2012, press reports indicated the agency had investigated the acquisition of a 26-bed hospital in Roswell, New Mexico. The deal was abandoned because the cost of responding to the agency's inquiries was too great. *Community Health Systems calls off Roswell hospital purchase*, ALBUQUERQUE BUSINESS FIRST (Jan. 11, 2012), available at [www.bizjournals.com/albuquerque/news/2012/01/11/community-health-systems-calls-off.html](http://www.bizjournals.com/albuquerque/news/2012/01/11/community-health-systems-calls-off.html). And in late 2012, the agency announced it would oppose a merger involving a 15-bed hospital. *Reading Health System and Surgical Institute of Reading*, *supra* note 26. These two hospital matters call into question the FTC's ongoing commitment to the 100-bed safety zone established for hospital mergers in Statement 1 of the 1996 *Statements of Antitrust Enforcement Policy in Health Care*, available at [www.ftc.gov/sites/default/files/attachments/competition-policy-guidance/statements\\_of\\_antitrust\\_enforcement\\_policy\\_in\\_health\\_care\\_august\\_1996.pdf](http://www.ftc.gov/sites/default/files/attachments/competition-policy-guidance/statements_of_antitrust_enforcement_policy_in_health_care_august_1996.pdf).

<sup>81</sup> *FTC Announces Revised Thresholds for Clayton Act Antitrust Reviews for 2013* (Jan. 10, 2013), available at [www.ftc.gov/news-events/press-releases/2013/01/ftc-announces-revised-thresholds-clayton-act-antitrust-reviews](http://www.ftc.gov/news-events/press-releases/2013/01/ftc-announces-revised-thresholds-clayton-act-antitrust-reviews).

<sup>82</sup> Findings of Fact, *supra* note 1, at 14, 16, 17, 19. The relatively small number of physicians involved in Nampa



- The FTC is skeptical of the claim that employment of physicians helps integrate doctors and hospitals and leads to better and more efficient care. This is an issue for health care researchers and others to consider carefully as it will have an impact on future transactions.
- The FTC does not believe that the goals of the Affordable Care Act and the antitrust laws are incompatible. Commissioner Brill (among others) has made this clear in other contexts<sup>83</sup> and the FTC litigation team made the point forcefully at the *St. Luke's* trial. In response to Saint Alphonsus's preliminary injunction motion, St. Luke's had argued that "the procompetitiveness of the Saltzer transaction is underscored by the fact that it accords with, and carries out, the federal policy, reflected in the ... Affordable Care Act ... of encouraging large clinically-integrated physician-hospital networks

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raises an intriguing question. St. Luke's acquired its Nampa primary care physicians only in 2011, when seven primary care physicians employed by Saint Alphonsus left to join St. Luke's. (The eighth physician joined later.) If St. Luke's were to spin off its Nampa group, could it then argue that the entire competitive problem has been taken care of and it now should be permitted to complete the acquisition of the Saltzer group?

<sup>83</sup> FTC Commissioner Julie Brill, *Promoting Healthy Competition in Health Care Markets: Antitrust, the ACA, and ACOs*, Keynote Address before the 2013 National Summit on Provider Market Power, at 3 (June 11, 2013), available at

[www.ftc.gov/sites/default/files/documents/public\\_statements/promoting-healthy-competition-health-care-markets-antitrust-aca-and-acos/130611cprspeech.pdf](http://www.ftc.gov/sites/default/files/documents/public_statements/promoting-healthy-competition-health-care-markets-antitrust-aca-and-acos/130611cprspeech.pdf) ("parties and their counsel complain that the federal government is 'speaking out of both sides of its mouth,' with the Medicare program encouraging providers to come together and create organizations that will enable greater collaboration, while the antitrust agencies challenge them. These contentions are creative, but misguided. Indeed, the goals of the ACA and antitrust enforcement are aligned and compatible.").

designed to reduce the overall cost of health care."<sup>84</sup> The FTC responded to this in its opening presentation with a slide entitled, "The 'Healthcare Reform' Defense is Contradicted by the Affordable Care Act."<sup>85</sup>

- The remedy permitted in *Evanston* was a one-time event. The argument that in the wake of a finding that a merger is unlawful the parties should be permitted to continue their combination so long as they negotiate managed care contracts separately falls on deaf ears at the FTC—and, as *ProMedica* and now *St. Luke's* illustrate, at the courts as well.
- In transactions not subject to the Hart-Scott-Rodino reporting and waiting periods, parties under investigation by the FTC should think long and hard before deciding to close their deal during the pendency of an FTC investigation. As both *Renown* and now *St. Luke's* have learned, closing the deal does not deter the FTC from filing suit, and undoing a merger is more painful and expensive than abandoning it in the wake of a loss at trial. Admittedly, consummating the transaction will force the FTC to litigate in court rather than in a Part III proceeding, and some practitioners consider a federal court preferable to an administrative forum. Practitioners may wish to reconsider the validity of this view in light of the outcomes in recent hospital merger challenges, including *OSF*, *ProMedica*, and now *St. Luke's*.

The final lesson is one well-known to antitrust lawyers but which physicians and hospitals, dedicated as they are to patients, sometimes

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<sup>84</sup> FTC Opening Statement, Slide 73, available at [www.ag.idaho.gov/consumerProtection/pendingActions/StLukesFTCOpeningStatement.pdf](http://www.ag.idaho.gov/consumerProtection/pendingActions/StLukesFTCOpeningStatement.pdf).

<sup>85</sup> *Id.* at 74.



have difficulty absorbing: provider combinations are subject to the same merger standards that apply in other industries. Good motives are commendable, but alone are not enough. Judge Winmill wrote:

The Acquisition was intended by St. Luke's and Saltzer primarily to improve patient outcomes. The Court is convinced that it would have that effect if left intact, and St. Luke's is to be applauded for its efforts to improve the delivery of health care in the Treasure Valley. But there are other ways to achieve the same effect that do not run afoul of the antitrust laws and do not run such a risk of increased costs. For all of these reasons, the Acquisition must be unwound.



## The Massachusetts Health Policy Commission's Review of the Partners-South Shore Hospital Merger

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### Introduction

On December 18, 2013, the Massachusetts Health Policy Commission (“HPC”) issued a preliminary report on its review of Partners HealthCare System’s (“Partners”) proposed acquisition of South Shore Hospital (“SSH”) and Harbor Medical Associates (“Harbor”).<sup>2</sup> The HPC’s Preliminary Report strongly criticized the proposed acquisition on the grounds that it would likely “increase health care spending, likely reduce market competition, and result in increased premiums for employers and consumers.”<sup>3</sup> It further found that the increased costs and decreased competition would not be offset by efficiency benefits or quality improvements that might result from the transaction.<sup>4</sup>

A rebuttal report from Partners and SSH after a 30-day comment period strongly criticized the

HPC’s report, emphasizing that its analyses of the competitive effects of the transaction were incomplete and inherently flawed.<sup>5</sup> The HPC issued its final report on February 19, 2014, adopting much of the analysis of its preliminary report and recommending that the Office of the Attorney General review the transaction.<sup>6</sup>

### The Massachusetts Health Policy Commission

The HPC was established in 2012 by the state’s health care cost containment law. The HPC is intended to, among other goals, “foster innovative health care delivery and payment models that lower health care cost growth while improving the quality of patient care” and “monitor and review the impact of changes within the health care marketplace.”<sup>7</sup> Although

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<sup>2</sup> COMMW. MASS. HEALTH POL’Y COMM’N, REVIEW OF PARTNERS HEALTHCARE SYSTEM’S PROPOSED ACQUISITIONS OF SOUTH SHORE HOSPITAL AND HARBOR MEDICAL ASSOCIATES: PRELIMINARY REPORT (Dec. 18, 2013) [hereinafter *Preliminary Report*], at <http://www.mass.gov/anf/docs/hpc/hpc-preliminary-review-of-phs-ssh-harbor-12-18-2013.pdf>.

<sup>3</sup> *Id.* at 2.

<sup>4</sup> *Id.*

<sup>5</sup> Partners Healthcare et al., *Partners HealthCare, Brigham and Women’s Hospital, and South Shore Hospital’s Response to the Health Policy Commission’s Preliminary CMIR Report dated December 18, 2013* (Jan. 17, 2014) [hereinafter *Response*], at 1-2, at <http://www.connectwithpartners.org/wp-content/uploads/2014/01/PHS-BWH-SSH-CMIR-Response.pdf>.

<sup>6</sup> COMMW. MASS. HEALTH POL’Y COMM’N, REVIEW OF PARTNERS HEALTHCARE SYSTEM’S PROPOSED ACQUISITIONS OF SOUTH SHORE HOSPITAL AND HARBOR MEDICAL ASSOCIATES: FINAL REPORT (Feb. 19, 2014) [hereinafter *Final Report*], at <http://www.mass.gov/anf/docs/hpc/20140219-final-cmir-report-phs-ssh-hmc.pdf>.

<sup>7</sup> Massachusetts General Laws Chapter 6D §5.



the HPC does not have authority on its own to challenge a merger, transactions under review by the HPC may not be finalized until the HPC issues its final report.<sup>8</sup> The HPC's report is intended to support the analysis of other agencies, including the Massachusetts Attorney General's Office, in reviewing the acquisition, and may identify key issues for the Attorney General or other state agencies to investigate in a review of the acquisition.

One of the HPC's duties in carrying out these goals is to review material changes to the structure of health care providers or provider organizations, including mergers and other transactions between health care providers. The law establishing the HPC directs it to initiate a cost and market impact review of such material changes to include assessments of various measures of cost and quality in the health care market, such as: size and market share within an organization's primary service area; the impact on competing options for health care within the primary service area and in areas of potential entry; various measures of provider quality and cost, including cost trends; effects on access to health care services, including access to at-risk or underserved populations; and any other factors that may be in the public interest.<sup>9</sup>

The HPC's report on the proposed acquisition is the "first time any state has authorized a policy-oriented, prospective review of the impact of health care transactions that is distinct from an administrative determination of need or law enforcement review of antitrust or consumer protection concerns."<sup>10</sup> In keeping with the HPC's mission to conduct a cost and market impact review of the proposed acquisition, however, the HPC included an analysis of

antitrust principles. The HPC report analyzed the competitive effects of the acquisition on the local market for health care services, including a calculation of the Herfindahl–Hirschman Index ("HHI") before and after the proposed acquisition.

As discussed in detail below, Partners and Harbor both strongly objected to the HPC's antitrust analysis in the report. They pointed to the HPC's own admission that the analysis was truncated as a result of the short, 30-day window in which it could produce its report. They further noted that the HPC's analysis made a number of key assumptions about the market for which evidence was lacking, or which were contradicted by the evidence in the marketplace. As a result, they requested that the HPC strike all portions of its report including this antitrust analysis.

### The Proposed Acquisition

On December 21, 2012, Partners and SSH entered into an Affiliation Agreement for Partners to acquire SSH and make it a member of the Partners system.<sup>11</sup> Their agreement included a plan to integrate physician and care systems to support Population Health Management ("PHM") efforts. Partners and SSH have stated that full physician and facility integration is a key to the successful implementation of PHM.<sup>12</sup>

On July 19, 2013, Brigham and Women's Physician Organization, a subsidiary of Partners, executed a Memorandum of Understanding to acquire Harbor Medical Associates, which is the largest local practice group within the South Shore Physician Hospital Organization ("SSPHO"). SSPHO is the managed care contracting organization for

<sup>8</sup> Massachusetts General Laws Chapter 6D §13(f).

<sup>9</sup> Massachusetts General Laws Chapter 6D §13(d).

<sup>10</sup> *Preliminary Report*, *supra* note 2, at Introduction.

<sup>11</sup> *Id.* at 1.

<sup>12</sup> *Id.*



SSH and certain other physicians in SSH's region. Partners intends to integrate SSPHO into its Brigham and Women's unit, with the stated goal of improving PHM and controlling health care costs in the SSH region.<sup>13</sup>

Partners and SSH have stated the importance of aligning existing Partners- and SSH-affiliated physicians to assist the integration of acute and post-acute care. The Partners system is the largest provider in Massachusetts, and was created in 1994 by an affiliation of Massachusetts General Hospital and Brigham and Women's Hospital.<sup>14</sup> In addition to a network of hospitals containing 2,793 acute care beds, Partners's managed care network includes approximately 6,500 physicians and specialists.<sup>15</sup> SSH is a 900-bed hospital located in Southeastern Massachusetts. SSPHO is a managed care organization for SSH including approximately 400 physicians and specialists, approximately 65 of which are affiliated with the Harbor medical group.<sup>16</sup>

### The HPC Report on the Proposed Acquisition

The HPC's Preliminary Report strongly criticized the proposed acquisition, finding that it would likely increase total medical spending by \$23 - \$26 million each year as a result of increases in the Harbor/SSPHO physician prices and by increased utilization of Partners and SSH facilities.<sup>17</sup> It also found that the combined entity would have the power to negotiate more favorable contract terms and higher prices in negotiations with commercial payers, causing

consumers and employers to pay higher premiums.<sup>18</sup> The cost impact of the increased negotiating power was not included in the estimate of total medical spending.

Importantly, the HPC noted in its analysis that historically, state and federal agencies with expertise in antitrust law typically analyze the competitive effects of mergers. The HPC did not attempt to complete all steps of the econometric modeling typical in a full antitrust analysis, but tried to "mirror many of the initial steps that would likely be included in an antitrust investigation to provide a public analysis of the likely nature of a transaction's competitive effects, so that transactions may be referred to appropriate agencies for further review as needed."<sup>19</sup>

To analyze the effect of the proposed acquisition on the market, the HPC began by determining the relevant market, including both the product and geographic markets. The HPC determined that the relevant product market was for inpatient general acute care services.<sup>20</sup> The HPC then applied two methods for determining the geographic market, the hospitals' Primary Service Areas ("PSAs"). First, the HPC used its standard method, which focused on the contiguous zip codes closest to the hospital from which the hospital draws 75 percent of its commercial discharges. Second, the HPC used SSH's method for defining its primary and secondary service areas, respectively representing 75 percent and 90 percent of SSH's total commercial and non-commercial discharges.<sup>21</sup>

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<sup>13</sup> *Id.*

<sup>14</sup> *Id.* at 7.

<sup>15</sup> *Id.* at 7-8.

<sup>16</sup> *Id.* at 8.

<sup>17</sup> *Id.* at 49.

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<sup>18</sup> *Id.* at 43.

<sup>19</sup> *Id.* at 36 n.107.

<sup>20</sup> *Id.* at 36.

<sup>21</sup> *Id.* at 36-37.



The HPC noted that its definition of a relevant geographic market reflects “key concepts that would be considered in a full antitrust analysis,” but that in antitrust litigation the definition of a relevant geographic market is data and time sensitive. The HPC stated that its analysis would provide the type of focused analysis intended by the Legislature when it granted the HPC 30 days to review such a transaction, but that it may not align precisely with a “relevant geographic market” used by an antitrust enforcement agency in its analysis.<sup>22</sup> The HPC’s definition focused on whether (1) the hospital is an important provider for the geographic area and (2) whether the geographic area is important to the hospital, providing a significant proportion of the hospital’s discharges. The HPC noted that the methodology to assess a PSA based on the area comprising 75 percent of the hospital’s discharges mirrors the guidelines used by the FTC and DOJ, and was based on the methods of analyzing PSAs used by hospitals and care organizations throughout Massachusetts.<sup>23</sup>

The HPC’s analysis determined that Partners and SSH combined account for approximately 50 percent of the commercial discharges in the SSH PSA, and that Partners and SSH are each other’s closest competitors as a result of the cost and quality outcome profiles of the two hospital systems. Because the HPC found that Partners and SSH are close competitors with similar market profiles, it concluded that:

[T]he merger of close competitors can reduce choices available to payers and employers building desirable provider networks and, as such, enhance the ability of the merging parties to negotiate higher prices and more

favorable contract terms. Thus, the merger of these top two providers is anticipated to lessen competition and could have substantial implications for health care costs.<sup>24</sup>

The HPC further analyzed the proposed acquisition comparing pre- and post-acquisition HHIs. The HPC found that in the SSH PSA, the pre-acquisition HHI of 2,847 would increase to 4,131 following the merger, for a change of 1,284, and found a similarly drastic increase for market concentration in SSH’s secondary service area. The HPC also noted that the *DOJ and FTC Horizontal Merger Guidelines* define a “highly concentrated” market as one with a HHI over 2,500, with a post-merger HHI change of more than 200 being “presumed to be likely to enhance market power.” The HPC determined that the increase in HHI “would be well over DOJ/FTC thresholds at which mergers are presumed likely to enhance market power.”<sup>25</sup>

The HPC also reviewed Partners’ and SSH’s statements to that date, in which the parties claimed that the proposed acquisition would be unlikely to have anti-competitive effects. The HPC specifically addressed three main claims made by the parties: (1) that SSH faces many competitors in the South Shore region; (2) that competitor hospitals have excess capacity that would constrain the parties’ market power; and (3) that payers have the ability to market limited and tiered network products.

First, the HPC found that Partners and SSH were each other’s main competitors in the SSH region. It found that other hospitals in the region only account for a small percent of market share, and found that Partners and SSH

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<sup>22</sup> *Id.* at 36-37 n.109.

<sup>23</sup> *Id.* at 37 n.111.

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<sup>24</sup> *Id.* at 39.

<sup>25</sup> *Id.* at 40.



combine to have a 62 percent market share in SSH's primary service area.<sup>26</sup>

Second, the HPC found that Partners and SSH are already among the highest-priced hospitals in the state and region, and are currently unconstrained by the lower prices charged by other hospitals in the region.<sup>27</sup>

Finally, the HPC found evidence that commercial payers have limited abilities to constrain prices through tiered or limited networks. Only 18 percent of members of the four largest commercial payers in Massachusetts are currently in limited or tiered plans, which the HPC determined was evidence that "the majority of commercially insured patients in the state still prefer broad networks."<sup>28</sup> Further, the HPC found that such networks may not be successful in the SSH region as in other regions of the state. The largest provider of limited network plans is not available in the SSH region. More importantly, the size and market power of the combined Partners/SSH entity may allow it to resist efforts by commercial payers to introduce tiered or limited network plans in its area by refusing to participate in such plans.<sup>29</sup>

As a result of its analysis, the HPC concluded that:

[T]he combined market share of 50% in SSH's PSA, the merger of direct competitors, and the dramatic increase in HHIs raise significant concerns that this transaction will substantially reduce competition in SSH's PSA and confer market leverage to the parties. As a result, we anticipate that the parties will be able to leverage higher

prices during future contract negotiations with payers.<sup>30</sup>

## Partners', Brigham and Women's, and SSH's Response to the HPC Preliminary Report

On January 17, 2014, Partners, Brigham and Women's Hospital, and SSH submitted a joint response to the Preliminary Report (the "Response"). The Response strongly criticized the Preliminary Report, in particular its findings that health care costs will increase, its discounting of cost savings and efficiencies as a result of the acquisition, and its "faulty" antitrust analysis.

The Response argued that the Preliminary Report omitted "any consideration of savings" associated with the acquisition, in particular with the parties planned efforts at "Population Health Management" ("PHM").<sup>31</sup> The Response claimed that the expected PHM efforts following the acquisition have the potential to achieve millions of dollars in savings per year that were not considered in the Preliminary Report.<sup>32</sup> The Response also faulted the assumptions made by the HPC when it estimated that total costs would rise by \$23-\$26 million per year. These assumptions included that the acquisition would result in increased provider rates from the Harbor and SSPHO physician groups adopting the higher rates charged by the Partners-affiliated physicians and from higher facility fees that would be charged by Partners following the acquisition. The Response characterized these as "faulty" assumptions based on pure

<sup>26</sup> *Id.* at 42.

<sup>27</sup> *Id.*

<sup>28</sup> *Id.*

<sup>29</sup> *Id.* at 42-43.

<sup>30</sup> *Id.* at 43.

<sup>31</sup> *Response, supra* note 5, at 4.

<sup>32</sup> *Id.* at 4-5.



speculation or a misunderstanding of Partners' payer contract terms.<sup>33</sup>

The Response criticized the Preliminary Report's analysis of the competitive effects of the acquisition most strongly. It pointed to the HPC's acknowledgment that its analysis does not fully apply the well-settled principles of antitrust law to support its conclusions, but instead provided only a preliminary assessment of the competitive effects of the merger, and concluded that the section predicting anticompetitive effects as a result of the acquisition should be stricken from the report.<sup>34</sup>

The Response also noted that other agencies have much greater experience with antitrust analysis of transactions of this nature, which the HPC acknowledged along with the fact that it could perform only an abbreviated analysis in the limited time in which it was able to produce the report.<sup>35</sup> The Response also argued that the first, and most important, step in an analysis of this type is to create a "robust, reliable market definition produced through application of accepted principles....Metrics such as market shares and market concentration can only be calculated in the context of an appropriately defined product and geographic market."<sup>36</sup> According to the Response, "all relevant antitrust precedents and guidelines reject the methodologies utilized in the HPC Report."<sup>37</sup> Thus, the analysis is "unreliable," and is "as likely to harm competition by stopping a transaction that would benefit consumers as it is likely to stop an anticompetitive merger."<sup>38</sup>

The Response further argued that challenges to health care mergers without proper market definitions have failed because measures of market power, concentration, and anticompetitive harm "cannot be reliable if they are not based on sound market definitions."<sup>39</sup>

The Response criticized the market definition used by the HPC for a number of failings. First, it failed to analyze potential competitors to SSH and depended on SSH's PSA as a proxy for the geographic market. This failed to include potential suppliers where consumers *could* go to receive services. The Response argued that the HPC's shortcut has been expressly rejected by courts analyzing health care mergers.<sup>40</sup>

Second, the Response argued that the HPC excludes from its market definition hospitals outside of the SSH PSA, despite evidence that hospitals located outside of SSH's PSA regularly draw patients from inside the region, including hospitals owned by Partners itself. The Response claimed that "it is hornbook antitrust law that if there is evidence that consumers regularly seek treatment at hospitals outside of the alleged geographic market, then that market has been drawn too narrowly and cannot form the basis of an analysis of market power, market concentration, or possible anticompetitive effects."<sup>41</sup>

Finally, the Response argued that the HPC erred by dismissing actual and potential competition from a number of hospitals located near SSH. The HPC had concluded that Partners and SSH

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<sup>33</sup> *Id.* at 7.

<sup>34</sup> *Id.* at 5-6.

<sup>35</sup> *Id.* at 5.

<sup>36</sup> *Id.* at B-1.

<sup>37</sup> *Id.* at B-1.

<sup>38</sup> *Id.* at B-1.

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<sup>39</sup> *Id.* at B-2 (citing *Cal. v. Sutter Health Sys.*, 130 F.Supp.2d 1109 (N.D.Cal. 2001) and *U.S. v. Long Island Jewish Med. Ctr.*, 983 F. Supp. 121 (E.D.N.Y. 1997)).

<sup>40</sup> *Id.* at B-3 (citing *FTC v. Tenet Health Care Corp.*, 186 F.3d 1045, 1052 (8th Cir. 1999) and *Home Health Specialists v. Liberty Health Sys.*, 1994 U.S. Dist. LEXIS 11947, \*4-16 (E.D. Pa. 1994)).

<sup>41</sup> *Id.* at B-4.



failed to “describe[] the extent to which these hospitals are able to attract commercially insured patients from SSH’s PSA.”<sup>42</sup> However, the Response argued that these hospitals should have been included in the analysis, and the HPC erred by presuming that it could exclude certain competitors from its analysis, which would force Partners to prove that the hospitals were competitors in the market.<sup>43</sup>

### HPC’s Final Report

The HPC issued its final report on February 19, 2014. The Final Report largely adopted the analysis of the Preliminary Report, and concluded that the transactions warranted further review. The HPC referred its report to the Massachusetts Attorney General’s Office.<sup>44</sup>

The Final Report included analysis of the arguments made by Partners, Brigham and Women’s Hospital, and SSH, as well as statements made by experts retained by the HPC to support its analysis and its findings.

The HPC concluded that its analysis showed ample support for a conclusion that SSH and Partners are the top two choices for health care providers for residents of the SSH region based on patient preference and the quality of care data reviewed by the HPC. The HPC concluded that based on its analysis, “it is likely that a full antitrust review, including a willingness to pay (WTP) analysis, would similarly find that SSH and Partners currently restrain each other’s ability to raise prices to insurers.”<sup>45</sup>

The HPC also argued that the fact that patients from within the SSH region currently travel to Partners’ hospitals for care supports its finding

that Partners and SSH are currently primary competitors and constraints on each other’s abilities to raise prices.

The HPC also rebutted the Response’s arguments that its analysis was not supported by precedent. The Final Report states that its approach is consistent with antitrust guidelines, such as the FTC and DOJ’s endorsement of PSA market shares as an “initial screen” to a full antitrust analysis in a “streamlined analysis” to determine whether an accountable care organization is likely to raise competitive concerns. The HPC further noted that its analysis was in line with its mandated function under state law to examine factors related to a provider organization’s market position within its primary service area.<sup>46</sup>

Tasneem Chipty, an economist with the consulting firm The Analysis Group, submitted a statement on behalf of the HPC. He stated his understanding that the antitrust analysis was not intended to be a full antitrust review, but was intended to “provide framing of the relevant issues to guide a recommendation for (or against) further antitrust review.”<sup>47</sup> Chipty concluded in an “initial screen” that, because Partners and SSH are the first choices for a large percentage of patients in the SSH PSA, the transaction warrants further antitrust scrutiny.<sup>48</sup> Chipty further concluded that the Response’s critiques of the Preliminary Report failed because: (1) the HPC and its report are intended to be a preliminary screen to determine whether a transaction warrants further scrutiny; (2) the HPC’s analyses are consistent with the DOJ and FTC Guidelines for Antitrust Enforcement of Accountable Care Organizations (“ACO Guidelines”), and are used as a screen to

<sup>42</sup> *Preliminary Report*, *supra* note 2, at 44.

<sup>43</sup> *Response*, *supra* note 5, at B-4.

<sup>44</sup> *Final Report*, *supra* note 6, at 59.

<sup>45</sup> *Id.* at Exh. B-1, at 7.

<sup>46</sup> *Id.* at Exh. B-1, at 9.

<sup>47</sup> *Id.* at Exh. C, at 1.

<sup>48</sup> *Id.* at Exh. C, at 2.



determine potentially anti-competitive effects; and (3) market definition is *not* the “bedrock first principle” of antitrust analysis as the parties claim.<sup>49</sup>

## Analysis

Because this is the first major transaction of this kind reviewed by the HPC, it is not clear how its Final Report will be received by the Massachusetts Attorney General’s Office or any federal antitrust agency review of the transaction. Indeed, the HPC itself noted that there appears to be no precedent for a “policy-oriented, prospective review of health care transactions” distinct from an antitrust or consumer-protection oriented review.<sup>50</sup>

Although the HPC is directed by law to review the effects of this type of transaction on the marketplace, it is not clear whether its analysis will affect that of federal or state agencies which may conduct a similar antitrust review. The HPC itself noted that other agencies have more experience with antitrust analysis. Further, it noted that its analysis is most useful as an initial screen to determine whether a transaction may have anticompetitive effects. Other agencies analyses of transactions, especially of large transactions that trigger antitrust filing requirements, may duplicate the HPC’s analysis and may result in a more robust and reliable determination of the competitive impact of the transaction.

Finally, the Response’s most strident criticism of the Preliminary Report was related to its antitrust analysis, specifically, the analysis derived from its definition of the relevant geographic market involved in the transaction. The Final Report responded in part by noting that its methodology mirrors that used by the

DOJ and FTC in their ACO Guidelines. However, the ACO Guidelines are a relatively new set of guidelines promulgated to inform accountable care organizations formed in response to incentives in the Patient Protection and Affordable Care Act’s Medicare Shared Savings Program. It is not clear from the guidelines that the same relevant market analysis is appropriate, even at a preliminary stage, for the analysis of a horizontal merger between hospitals or between managed care networks.

## Conclusion

Now that the HPC has issued its Final Report, the Massachusetts Attorney General must decide whether to further investigate the proposed transaction and/or bring any enforcement action to seek relief on behalf of payers or patients in Massachusetts. The ultimate decision on this matter by the Attorney General’s office, and whether it cites to or relies on any of the HPC’s conclusions, could potentially have significant implications for the role of the HPC in future transactions in the state of Massachusetts, as well as other states that have implemented or are contemplating similar local advisory bodies in the health care arena.

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<sup>49</sup> *Id.* at Exh. C, at 2-3.

<sup>50</sup> *Preliminary Report*, *supra* note 2, at Introduction.



## Notifications and Names: FTC Workshop Explores Effect of State Legislation and Naming Conventions on Follow-On Biologic Competition

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### Introduction

Biologic medicines represent some of the most significant—both clinically and financially—pharmaceutical products in the United States today. Biologics have had remarkable success in the treatment of patients with many common diseases and disorders such as cancer, diabetes, multiple sclerosis, arthritis, and anemia. However, biologics remain one of the most expensive categories of medicines on the market. According to the Federal Trade Commission (“FTC”), the cost of one year of treatment of a biologic medicine can range from \$50,000 to \$250,000.<sup>2</sup>

Biologics’ active drug substances are cultivated from living organisms by means of recombinant DNA or controlled gene expression methods. Biologics include a wide range of products such as vaccines, blood and blood components,

allergens, somatic cells, gene therapy, tissues, and recombinant therapeutic proteins.<sup>3</sup>

Biologics are “typically larger and more structurally complex molecules” than the traditional small molecule drugs.<sup>4</sup> Therefore, production of biologics requires more difficult and expensive manufacturing processes and techniques to ensure consistency.<sup>5</sup>

A biologic can either be introduced by an innovator company or by a follow-on competitor. The follow-on biologic is a subsequent version of the reference biologic. Follow-on biologics further divide into biosimilars and interchangeable biologics. Biosimilars are follow-on biologics that may not be completely identical, but which are so “highly similar” to the previously approved reference biologic that “notwithstanding minor differences in clinically inactive components,”<sup>6</sup> the same clinical outcome can be expected. Interchangeable biologics are follow-on

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<sup>2</sup> Federal Trade Commission, Notice of Workshop and Request for Comments, Public Workshop: Follow-On Biologics: Impact of Recent Legislative and Regulatory Naming Proposals on Competition, 78 Fed. Reg. 68,840 (November 15, 2013), available at [http://www.ftc.gov/sites/default/files/documents/federal\\_register\\_notices/2013/11/131115biologicsfrn.pdf](http://www.ftc.gov/sites/default/files/documents/federal_register_notices/2013/11/131115biologicsfrn.pdf).

<sup>3</sup> U.S. Food and Drug Administration, Vaccines, Blood and Biologics, <http://www.fda.gov/BiologicsBloodVaccines/ResourcesforYou/Consumers/default.htm> (last visited Feb. 27, 2014).

<sup>4</sup> Health Policy Brief, Biosimilars, Health Affairs, 1 (Oct. 10, 2013), [http://healthaffairs.org/healthpolicybriefs/brief\\_pdfs/healthpolicybrief\\_100.pdf](http://healthaffairs.org/healthpolicybriefs/brief_pdfs/healthpolicybrief_100.pdf).

<sup>5</sup> *Id.*

<sup>6</sup> 42 U.S.C. § 262(i)(2) (2011).



biologics that produce the same clinical result as the FDA-licensed biological reference product in any given patient. Additionally, to be approved as interchangeable, a biologic needs to show that if administered more than once, the safety and reduced efficacy risks of switching from the reference biologic to an interchangeable biologic, or alternating between the reference biologic and an interchangeable biologic, cannot be greater than the risks posed by use of the reference product without alternating or switching.<sup>7</sup>

In addition to the structural differences outlined above, biologics, unlike traditional small molecule drugs, are not regulated under the Food Drug and Cosmetic Act,<sup>8</sup> and Hatch-Waxman Act of 1984,<sup>9</sup> and are therefore not subject to the Hatch-Waxman's accelerated FDA approval processes. Biologics are also not covered by state laws that allow pharmacists to automatically substitute therapeutically-equivalent small molecule generics for reference brand name drugs.

To address this void, Congress passed the Biologics Price Competition and Innovation Act<sup>10</sup> ("BPCIA"), which introduced an abbreviated approval pathway for follow-on biologics. The provisions of the BPCIA were patterned, in some respects, after the Hatch-Waxman Act and allow an applicant—who is seeking FDA approval of a follow-on biologic product—to rely on certain existing scientific knowledge about the safety and effectiveness of the approved reference biologic in their application for approval.<sup>11</sup>

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<sup>7</sup> § 262(k)(4).

<sup>8</sup> 21 U.S.C. ch. 9 § 301 et seq.

<sup>9</sup> Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended 21 U.S.C. §355 (1994)).

<sup>10</sup> 42 U.S.C. § 262 (2011).

<sup>11</sup> *Id.*

In several other respects, however, the BPCIA is different from the Hatch-Waxman Act. First, assessments of biosimilarity differ under the BPCIA to account for the difference in analytical processes available for biologic medicines. Second, the BPCIA includes a 12-year exclusivity period for the innovator product, instead of a 5-year period provided by Hatch-Waxman.<sup>12</sup> Notwithstanding these differences, the purpose of the BPCIA was largely the same: promoting competition in the market and thereby reducing the cost of these expensive medicines for consumers.

In practice, the BPCIA has had limited effect on competition from follow-on biologics. In fact, since the introduction of the BPCIA, no follow-on biologic has received FDA approval via the abbreviated pathway, although several applications are currently pending review by the FDA,<sup>13</sup> and several issues have arisen. Firstly, despite the fact that no follow-on biologics have been approved, several states have proposed or enacted legislation that imposes certain restrictions on the substitution of follow-on biologics for the reference product. Secondly, debate has grown over the naming conventions that should be adopted for follow-on biologics. To explore and address these issues, the FTC held a day-long workshop on February 4, 2014 to discuss the impact on competition of these recent legislative and regulatory naming proposals.<sup>14</sup>

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<sup>12</sup> § 262(k)(7).

<sup>13</sup> Steven Kozlowski, Director, Office of Biotechnology Products, U.S. Food & Drug Admin., Remarks at 11th EGA International Symposium on Biosimilar Medicines: U.S. FDA Perspectives on Biosimilar Development and Approval (April 26, 2013); *see also* Food and Drug Administration, Information for Consumers (Biosimilars), *available at* <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/TherapeuticBiologicApplications/Biosimilars/ucm241718.htm> (last updated November 3, 2011).

<sup>14</sup> Federal Trade Commission, *supra* note 2.



### ***Chairwoman Ramirez's Opening Remarks***

Andrew Gavil, Director of Policy Planning at the FTC, opened the workshop by welcoming attendees.<sup>15</sup> Then, FTC Chairwoman Edith Ramirez offered further welcoming remarks and stressed the significance of biologic medicines for difficult to treat diseases such as cancer, diabetes, and multiple sclerosis. Chairwoman Ramirez also highlighted the high cost of these therapeutics, noting that these costs may prevent some patients from accessing potentially life-saving therapies. Further, she noted that introducing competition into the biologics marketplace represents one of the most promising ways to reduce prices and expand access. While recognizing the need for more robust competition, Chairwoman Ramirez noted the impact of the regulatory landscape on competition for biologics. Specifically, she stressed that the “the ultimate goal . . . is to develop policies that protect patient health and safety, but to do so without unnecessarily chilling competition and deterring investment in follow-on biologics.”

After introducing the general objectives, the Chairwoman summarized the issues to be discussed during the workshop. She pointed out that these issues are not novel. In the 1970s, when generic drugs and the Hatch-Waxman Act were first contemplated, there were similar issues. Because of perceived safety concerns, many states prohibited pharmacists from substituting generic drugs for their branded counterparts. To address these state laws, the FTC studied competitive effects of these “anti-substitution” laws. A staff report issued in 1979<sup>16</sup> concluded that the FDA’s review process

would result in the approval of safe and effective generic drugs and that, if pharmacists were free to dispense generic drugs without unnecessary regulatory hurdles, this would stimulate beneficial price competition for consumers. Subsequently, on the FTC’s recommendation, state legislatures adopted laws allowing for automatic substitution. Chairwoman Ramirez closed with the following guiding principle for the workshop’s discussions: while follow-on biologics are more complex, the basic concept of competition still applies and the ultimate goal remains the same—to develop policies that protect patient health and safety without chilling competition or deterring investment in follow-on biologic medicines.

### ***The Rising Cost of Biologic Medicines***

A fundamental tenet of the discussions at the FTC workshop was the prediction that follow-on biologic competition promises cost savings and increased patient access. There was little debate as to the need for biologic competition, and many speakers highlighted the high cost of, and growing dependence on, biologic medicines.

For example, consumer organization AARP put forward evidence of the rising cost of biologic medicine consumption, a point echoed by payor representatives.<sup>17</sup> According to AARP representative Leigh Purvis, on average biologics are 22 times more expensive than traditional drugs, with the average annual cost of a branded biologic estimated at \$34,500.<sup>18</sup> Even for patients who are insured, lifesaving biologics may be cost prohibitive, because many

<sup>15</sup> Elizabeth A. Jex, an Attorney Advisor in the FTC’s Office of Policy Planning, and Susan DiSanti, an attorney in the Western Regional Office of the FTC, also offered remarks and helped moderate the workshop throughout the day.

<sup>16</sup> FED. TRADE COMM’N, STAFF REPORT TO THE FEDERAL TRADE COMMISSION, DRUG PRODUCT SELECTION (1979).

<sup>17</sup> Steve Miller, M.D., *Customer Perspective on Biosimilars*, FTC FOLLOW-ON BIOLOGICS WORKSHOP, 2 (Feb. 4, 2014).

<sup>18</sup> Leigh Purvis, M.P.A., *Consumer Perspective on Biosimilars*, FTC FOLLOW-ON BIOLOGICS WORKSHOP, 3 (Feb. 4, 2014) (citing E.A. Blackstone and J.P. Fuhr, Jr., “Innovation and Competition: Will Biosimilars Succeed?” *Biotechnology Healthcare*, Spring 2012).



medical plans, including Medicare, include cost-sharing structures.<sup>19</sup> Ms. Purvis described the present costs of biologics as “not sustainable” and urged regulators to implement systems that will make these medicines accessible and affordable, arguing that medical advances are meaningless if no patient can afford to use them.<sup>20</sup>

Some panelists forecasted that more than 50 percent of the U.S. prescription drug budget will be spent on biologics by 2018,<sup>21</sup> and the list of diseases that biologics can be used to treat is expanding.<sup>22</sup> Meanwhile, Harry Travis, Vice President and General Manager of Aetna Specialty and Home Delivery Pharmacy, revealed that even today close to 50 percent of Aetna’s entire drug spend is spent on specialty medicines, mainly biologics. Notably this 50 percent of spend represents only 1 percent of patient prescriptions.<sup>23</sup> Mr. Travis asserted that as spending on biologics continues to increase, it diverts funds away from other drugs and health care costs.

Industry participants and patients alike have high hopes for follow-on biologics to offset these ever expanding costs. Dr. Kesselheim highlighted the successes of generic competition in small molecule drugs in reducing costs and increasing access.<sup>24</sup> Steven Miller, M.D., M.B.A., Senior Vice President & Chief Medical

Officer of Express Scripts referenced a study carried out by Express Scripts which showed the potential savings from the use of follow-on biologics would be at least \$250 billion by 2024.<sup>25</sup> Dr. Miller emphasized the importance of broad stakeholder cooperation in ensuring the success of the follow-on biologic pathway and resulting competition, in order to reduce these costs.<sup>26</sup>

## State Substitution Laws

The first issue on the workshop agenda was the introduction of state legislation that encumbers automatic substitution. The proponents of such laws argue that, since biologics are more complex, automatic substitution afforded to small molecule drugs is inappropriate. The opponents of such laws argue that the current framework already addresses these concerns and anti-substitution state laws are premature.

### *The Basics of State Notification Legislation*

To start, Jessica Mazer, J.D., Assistant Vice President for State Affairs of the Pharmaceutical Care Management Association, identified the main state substitution law proposals.<sup>27</sup> To date, states’ proposed or adopted bills impose the following types of requirements on pharmacists and prescribers when substituting biologics: (1) a requirement that a pharmacist notifies a patient and/or her prescriber upon dispensing an interchangeable biologic within a specified time period; (2) a requirement to record any such substitution; and (3) a requirement that the

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<sup>19</sup> *Id.* at 7-12.

<sup>20</sup> *Id.* at 20.

<sup>21</sup> *Id.* at 3.

<sup>22</sup> *Id.* at 4.

<sup>23</sup> Harry Travis, B.S. Pharm., M.B.A., *Private Payor Perspective on Growth of Specialty Medicines and Naming*, FTC FOLLOW-ON BIOLOGICS WORKSHOP, 2 (Feb. 4, 2014).

<sup>24</sup> Aaron Kesselheim, M.D., J.D., M.P.H., *Lessons for Follow-On Biologics from Small Molecule Drugs*, FTC FOLLOW-ON BIOLOGICS WORKSHOP, 8 (Feb. 4, 2014). Dr. Kesselheim noted that 84 percent of prescriptions in 2012 were filled with generic drugs, saving the health care system up to \$1 trillion dollars in the last 10 years.

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<sup>25</sup> Miller, *supra* note 17, at 6.

<sup>26</sup> *Id.* at 13.

<sup>27</sup> All panelists prepared helpful presentations that can be accessed via the FTC website. See FTC Events Calendar, Follow-On Biologics Workshop: Impact of Recent Legislative and Regulatory Naming Proposals on Competition, <http://www.ftc.gov/news-events/events-calendar/2014/02/follow-biologics-workshop-impact-recent-legislative-regulatory>. Additionally, the FTC posted video recordings of the workshop and will post and official transcript, once available. See *id.*



state's board of pharmacy maintain a list of interchangeable biologics. Notably, these requirements apply to interchangeable follow-on biologics, medicines that must meet a higher standard than biosimilars to secure the FDA approval.

To date, five states have enacted such legislation—Florida, North Dakota, Oregon, Utah, and Virginia.<sup>28</sup> The state with the most extensive additional requirements is North Dakota.<sup>29</sup> North Dakota's legislation, signed into law March 29, 2013, requires that the pharmacist notify the prescribing practitioner orally, in writing, or via electronic transmission within 24 hours of the substitution, and notify the patient who maintains a right to refuse the substitution.<sup>30</sup> The pharmacy and the prescribing practitioner must also retain a written record of the substitution for at least five years.<sup>31</sup> Less extensive, but still substantial, requirements have been adopted in Oregon, Utah, and Virginia. Legislation enacted in Oregon<sup>32</sup> and Utah<sup>33</sup> requires a pharmacist to notify the prescriber of any substitution within three days.<sup>34</sup> Notably, however, both Oregon's and Utah's laws include a sunset provision relating to this clause, meaning the requirement will likely expire before any relevant follow-on biologic becomes available.<sup>35</sup> Virginia too has enacted legislation that requires prescriber notification, with a corresponding sunset provision, though that law affords the pharmacy

five days to notify the prescriber.<sup>36</sup> Additionally, all three of these “middle of the road” laws contain pharmacy record keeping requirements, though only Virginia requires the prescriber to maintain a record for at least two years.<sup>37</sup> Finally, the legislation with the fewest requirements has been enacted in Florida. There is no prescriber notification provision,<sup>38</sup> but the law still requires patient notification and retention of a record by the pharmacist for at least two years.<sup>39</sup>

In California, a bill was passed, but subsequently vetoed by the governor. The California bill required pharmacists to notify both the patient and the physician of any substitution.<sup>40</sup> Governor Brown vetoed this bill, stating that “[t]he FDA, which has jurisdiction for approving all drugs, has not yet determined what standards will be required for biosimilars to meet the higher threshold for ‘interchangeability,’ [and that therefore] to require physician notification at this point strikes [me] as premature.”<sup>41</sup>

As of February 2014, nine states are due to consider follow-on biologics legislation in 2014.<sup>42</sup> Among them is Massachusetts,<sup>43</sup> whose bill contains a slightly novel provision, under which physician notification will not be required until full interoperability of an electronic health

<sup>28</sup> Jessica S. Mazer, J.D., *Introduction to State Biosimilar Substitution Laws*, FTC FOLLOW-ON BIOLOGICS WORKSHOP, 6 (Feb. 4, 2014).

<sup>29</sup> N.D. CENT. CODE § 19-02.1-14.3 (2013).

<sup>30</sup> Mazer, *supra* note 28.

<sup>31</sup> *Id.*

<sup>32</sup> OR. REV. STAT. § 689.522

<sup>33</sup> UTAH CODE ANN. § 58-17b-605.5

<sup>34</sup> Mazer, *supra* note 28, at 7.

<sup>35</sup> *Id.*

<sup>36</sup> VA. CODE ANN. § 54.1-3408.04 (2013); Mazer, *supra* note 28, at 7.

<sup>37</sup> VA. CODE ANN. § 54.1-3408.04 (2013).

<sup>38</sup> FL. STAT. ANN. § 465.0252, § 465.019; Mazer, *supra* note 28, at 8.

<sup>39</sup> Mazer, *supra* note 28, at 8.

<sup>40</sup> S.B. 598; Mazer, *supra* note 28, at 9.

<sup>41</sup> Mazer, *supra* note 28, at 9.

<sup>42</sup> *Id.* at 11. Remarks made during the FTC workshop indicate that in addition to the states identified in Ms. Mazer's presentation, Vermont will also consider follow-on biologics legislation in 2014.

<sup>43</sup> H.B. 3734.



record system.<sup>44</sup> While the proposed bill does require prescriber notification within a reasonable time following a substitution, entry of the substitution into a patient's electronic health record would constitute notification.<sup>45</sup>

### ***Arguments in Support of State Legislation***

During the workshop, various stakeholders participated in the debate as to whether legislation requiring additional steps for biologic substitution is necessary. The proponents argued generally that since biosimilars are very complex and are only similar, rather than identical, automatic substitution afforded to small molecule drugs is inappropriate. They argued that the patient should be notified (and given a choice to refuse such substitution) of the potential risks of taking a medicine that is only similar to what the doctor has prescribed. Notably, while these arguments apply to biosimilars generally, the legislation that has been enacted in the five aforementioned states applies to biologics that have been designated as interchangeable by the FDA, which requires a showing of complete therapeutic equivalence.

Additionally, they argued that the prescriber notification would allow for an accurate and unambiguous medical record, which is necessary to ensure patient safety and proper adverse event reporting. For example, Geoffrey Eich, M.B.A., Executive Director for Regulatory Affairs at Amgen, summarized patient risks that may result from an incomplete medical record.<sup>46</sup> According to Mr. Eich, because biologics persist within the body for a much longer period of time than most chemical drugs, an overlap of exposure to circulating

biologics from different sources is likely.<sup>47</sup>

Latent immune responses, leading to changes in the efficiency or tolerance of a biologic medicine, make attribution to a specific product more challenging, increasing the importance of a complete and accurate medical record, Mr. Eich argued.<sup>48</sup>

Finally, another reason for notification is to ensure effective post-market surveillance, i.e., to promote pharmacovigilance. All biologics are sensitive to unintended occurrences during manufacture and handling—therefore post-market surveillance, facilitated by keeping a record of all substitutions, is an important safeguard to ensure patient safety.<sup>49</sup> In fact, pharmacovigilance was discussed at length during the workshop (mostly in connection with the naming conventions) and is addressed later in the article.

### ***Arguments Against State Legislation***

On the other hand, the opponents of such state laws argue that the current framework already addresses these concerns or, alternatively, that such laws are premature. During the workshop, various stakeholders, including representatives from academia, industry analysts, consumer organizations, dispensers, payors and biosimilar developers argued that the FDA approval process of follow-on biologics is sufficient to ensure that approved follow-on biologics are safe and appropriate for substitution and that the practicalities of medical record keeping render physician notification requirements onerous and unnecessary.

To start the discussion, a consultant at ThinkFDA, LLC, Emily Shacter, Ph.D., presented an overview of the FDA's approach for follow-on biologic approval in order to

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<sup>44</sup> Mazer, *supra* note 28, at 10.

<sup>45</sup> *Id.*

<sup>46</sup> Geoffrey S. Eich M.B.A., *Establishment of a Vibrant U.S. Biosimilars Approval Pathway*, FTC FOLLOW-ON BIOLOGICS WORKSHOP, 4 (Feb. 4, 2014).

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<sup>47</sup> *Id.*

<sup>48</sup> *Id.*

<sup>49</sup> *Id.*



dispute that the complexity of the large molecule makes substitution inherently dangerous. Ms. Shacter explained that the FDA would need to subject follow-on biologics to the most rigorous testing and analysis to ensure approval is granted only where appropriate and focused on the highly advanced nature of analytics used in the industry. Ms. Shacter predicted that only those biosimilars that are “virtually interchangeable” with the innovator biologic would be approved by the FDA.<sup>50</sup> She argued that modern scientific tools can adequately detect variances or potential issues in follow-on biologic structure, and that these tools could be used to sufficiently prove biosimilarity to the FDA.

Second, Jessica Mazer of the Pharmaceutical Care Management Association suggested that given the trust placed in the FDA for approval of small molecule generics, any distrust of the agency in the follow-on biologic realm is misplaced.<sup>51</sup> Once the FDA has approved a follow-on biologic as safe and either interchangeable or highly similar to the reference biologic, such that no clinically meaningful effects would present in the patient, such determination by the FDA should be sufficient. As such, according to Ms. Mazer, state legislation proposing notification or record keeping requirements is not necessary to ensure patient safety.

This view was echoed by both Krystalyn Weaver, Pharm. D., Director of Policy and State Relations at the National Alliance of State Pharmacy Associations and Leigh Purvis, M.P.A. Senior Strategy Policy Advisor with the AARP.<sup>52</sup> Biosimilar developers too relied on this point, including Bruce Leicher, J.D., Senior

Vice President & General Counsel at Momenta Pharmaceuticals, who also referenced the rigorous standards of the FDA.<sup>53</sup>

Finally, Marissa Schlaifer, M.S., R.Ph., Head of Policy at CVS Caremark identified several practical problems with the enacted and proposed notification requirements. Requiring notification and consent for follow-on biologics, according to Ms. Schlaifer, would create unnecessary communication between a pharmacy and a physician’s office. Information exchange between pharmacy and physician is crucial for tasks like readjusting a dose or questioning a treatment because of allergy, and imposing a notification requirement in the case of follow-on biologic substitution has a potential of introducing unnecessary noise into, and therefore disrupt, this critical communication pathway. Ms. Schlaifer also referenced the wealth of information that is recorded and maintained by a pharmacy, information that ensures a patient receives the correct medicine at the appropriate time, and therefore argued that a medical provider’s record may not in fact reflect an entirely comprehensive and accurate patient health record.

### Naming Conventions

After the break, representatives from various camps debated naming conventions for biosimilars. When Congress passed BPCIA, it did not include specific statutory language regarding the naming of approved follow-on products, leaving the decision up to the FDA. Some stakeholders wanted to see biosimilars given nonproprietary names that are completely unique, or at least have a unique suffix or prefix, in order to ensure patient safety and exact adverse event tracking. Others advocated that follow-on biologics should have the same

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<sup>50</sup> Emily Shacter Ph.D., *The Rigorous FDA Review Process for Biosimilars and Interchangeables*, FTC FOLLOW-ON BIOLOGICS WORKSHOP, 9 (Feb. 4, 2014).

<sup>51</sup> Mazer, *supra* note 28, at 12.

<sup>52</sup> Purvis, *supra* note 18, at 15.

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<sup>53</sup> Bruce A. Leicher J.D., *Anti-Competitive Deterrents to Investment and Innovation in Biosimilars and Interchangeable Biologics*, FTC FOLLOW-ON BIOLOGICS WORKSHOP, 13 (Feb. 4, 2014).



nonproprietary names as their reference biologics.

### ***The Basics of Medicine Naming Conventions***

Generally, a medicine can carry several names—usually, a proprietary brand name, selected by the innovator company, and a nonproprietary active ingredient name.<sup>54</sup> As it relates to the small molecule drugs, a generic is named using the same nonproprietary name as the reference drug. As it relates to a biologic, however, there was a significant debate whether follow-on biologics should bear the same nonproprietary name as the reference biologic. Angela Long, M.S., a Sr. Vice President, Global Alliances and Organizational Affairs and Secretariat, Council of Experts for USP, opened this segment with an overview of the various naming conventions. In the United States,<sup>55</sup> each marketed medicine is assigned a unique nonproprietary name by the United States Adopted Names (USAN) Council. The USAN Council works in conjunction with the World Health Organization International Nonproprietary Name (INN) Expert Committee to standardize drug nomenclature, but USAN is independent of INN. USAN is co-sponsored by the American Medical Association, the United States Pharmacopeial Convention (USP),<sup>56</sup> and the American Pharmacists Association. USP's drug standards are in turn enforced by the FDA. USP's role in naming applies to both drug substances and drug products. When the FDA

approves a small molecule drug for marketing, two things may happen with respect to the nonproprietary name. First, if the applicable USP monograph already exists, monograph's "official title" can be used as a nonproprietary name. Alternatively, if the FDA approves a drug and there is no applicable USP monogram, the FDA provides an "interim established name" that serves as a nonproprietary name until USP creates a monograph.<sup>57</sup> This naming process could hold true with respect to biologics and, according to Ms. Long, USP should be allowed to use its already established naming procedures to assign nonproprietary names to follow-on biologics. This way, if a follow-on biologic were to meet the requirements of an existing USP monograph, it could use the monograph's "official title" as its nonproprietary name. While this may be a logical extension of the current small molecule naming paradigm, opponents argued this approach should not apply to biologics because glycosylation<sup>58</sup> makes proof of sameness very difficult. Glycosylation (i.e., how a protein folds) is a type of modification in a biologic molecule that is hard to see, but which may affect the molecule's activity, immunogenicity, and, in some cases, its pharmacokinetics. Innovator companies have long argued that because process conditions affect glycosylation, it is impossible to create a protein with the same glycosylation patterns in two different processes, and therefore there could never be an identical version of a biologic.

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<sup>54</sup> The FDA has authority to determine nonproprietary names. See 21 U.S.C. § 358, which provides in relevant part: "The Secretary [of HHS] may designate an official name for any drug or device if he determines that such action is necessary or desirable in the interest of usefulness and simplicity." See also 42 U.S.C. § 262(a)(1)(B)(i).

<sup>55</sup> There are no universal global rules governing the classification of new substances.

<sup>56</sup> USP is a scientific nonprofit organization that sets standards for the identity, strength, quality, and purity of medicines. See U.S. Pharmacopeial Convention, About USP, <http://www.usp.org/about-usp>.

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<sup>57</sup> Angela G. Long, M.S., Tina S. Morris, *Introduction to Drug Naming*, FTC FOLLOW-ON BIOLOGICS WORKSHOP, 8 (Feb. 4, 2014).

<sup>58</sup> PTMs are chemical transformations that occur after a protein's translation from RNA and include numerous changes, some well-known and others quite obscure. The best-known PTM is glycosylation, the addition of sugar residues to amino acids bearing amino or hydroxyl groups. See Glycosylation main approval issue with biosimilars posted 01/09/2009, <http://www.gabionline.net/Conferences/Glycosylation-main-approval-issue-with-biosimilars>.



Glycosylation is certainly an intricate concept, but panelists argued that the new generation analytical technology could make proof of sameness possible. For example, Tina Morris, Ph.D., Vice President, Biologics and Biotechnology, USP-NF in the Global Science and Standards Division at USP, stated that “[t]he analysis of complex glycosylation patterns and the level of heterogeneity made visible is directly linked to the resolving power of the applied analytical technology.”<sup>59</sup> Thus, as the analytical technology improves, “generic” biologics may well be a reality.

Further, Ms. Morris argued that while sameness is an important determination for the purpose of finding bioequivalency, molecules do not need to be identical to be assigned the same nonproprietary USP name. In fact, a USP monograph under the same title may describe multiple articles in commerce.<sup>60</sup> Therefore, according to Ms. Morris, if the definition of sameness is the main concern as it relates to the identification test for an existing USP monograph, the proper answer is for the FDA to prescribe additional standards for how to determine said sameness and not to completely overhaul the process and require unique nonproprietary names for biologics.

### ***Arguments in Support of Unique Nonproprietary Names for Biosimilars***

After the overview of general naming conventions, representatives from Amgen, Pfizer and AbbVie took turns arguing that the small molecule naming paradigm is not applicable to biologics and that allowing biosimilars to have the same nonproprietary name will create confusion. Additionally, panelists argued that biosimilars should be uniquely identified to protect patient safety and to promote accurate adverse event reporting.

First, panelists argued that non-unique nonproprietary names would introduce confusion. Gustavo Grampp, Ph.D., Director of R&D Policy at Amgen, noted that since biologics are made from living cells, biosimilars are not in fact structurally identical to the originator biologic or other biosimilars,<sup>61</sup> thus using the same nonproprietary name is scientifically inappropriate.<sup>62</sup>

Emily Alexander, J.D., Director of U.S. Regulatory Affairs in the Biologics Strategic Development group at AbbVie, agreed and cited survey statistics where 76 percent of physicians said that having an identical nonproprietary name implies that two products have identical structures, which in her opinion would not be accurate (and would create confusion) as it relates to biosimilars.<sup>63</sup>

Second, panelists argued that non-unique nonproprietary names would hinder pharmacovigilance. Pharmacovigilance is a process of identifying and assessing adverse events and possible side effects associated with a product. To function properly, this process requires the ability to link specific adverse events or event trends to the responsible product. The shared concern voiced by several panelists was as follows: if doctors and patients report adverse effects using only the non-unique nonproprietary name, it may be impossible to properly attribute product flaws to the correct manufacturer. This concern is especially strong for jurisdictions (e.g., China) that prohibit doctors from prescribing by brand name, but at the same time report adverse effects of its

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<sup>61</sup> Gino Grampp, Ph.D., *A Science-Based Naming Policy for Biologics: FTC Public Meeting on Biosimilar Policy*, FTC FOLLOW-ON BIOLOGICS WORKSHOP, 4-5 (Feb. 4, 2014).

<sup>62</sup> *Id.* at 11.

<sup>63</sup> Emily A. Alexander, J.D., *Reference Biologic Perspectives On Naming*, FTC FOLLOW-ON BIOLOGICS WORKSHOP, 9 (Feb. 4, 2014).

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<sup>59</sup> Long, *supra* note 57, at 20.

<sup>60</sup> *Id.* at 17.



citizens to the FDA (presumptively using nonproprietary names only).

For example, to support her argument that unique nonproprietary names are desirable for effective pharmacovigilance, Helen Hartman, Ph.D., Director, Worldwide Regulatory Strategy at Pfizer, presented results of a study conducted by Pfizer. The study was designed to evaluate the frequency with which a specific manufacturer was reported as part of an adverse event report.<sup>64</sup> Pfizer found that in instances where multiple drugs had the same nonproprietary names (i.e., a small molecule case study), in 14 percent of reports the manufacturer could not be identified; however, where proprietary names were the only identifiers available (i.e., a biologics case study), only in less than 1 percent of reports the manufacturer could not be identified.<sup>65</sup>

Thus, Dr. Hartman concluded that unique names (proprietary and nonproprietary) are preferred for proper attribution. Specifically, Dr. Hartman concluded, based on the study's results, that "[i]n the absence of a requirement that *all* biosimilars and follow-on biologics adopt unique trade names, ... identification of manufacturers in [adverse event] reporting will be hindered if the products share the same [nonproprietary] name" (emphasis in original).<sup>66</sup> Ms. Alexander suggested a milder approach: a biosimilar should have both a distinct brand name and a *related but distinguishable* nonproprietary name. According to Ms. Alexander, under this approach, a "related 'core' non-proprietary name [would] help assess adverse events across a class of products but [a] distinguishing prefix or suffix [would] allow for

differentiation."<sup>67</sup> This approach is similarly taken by Australia and Japan.<sup>68</sup>

### ***Arguments Against Unique Nonproprietary Names for Biosimilars***

In contrast, the opponents of unique names argued that such nomenclature may increase market confusion and does not necessarily promote pharmacovigilance. Multiple groups were represented, including the FTC, biosimilar applicants, patient-advocacy groups, and pharmacy representatives.

First, panelists argued that unique nonproprietary names may actually abet, rather than resolve, patient confusion. Bruce Leicher from Momenta Pharmaceuticals, noted that to be approved by the FDA as a biosimilar a follow-on biologic must show to have no clinically meaningful differences from the reference product.<sup>69</sup> Thus, there is no defensible basis for different nonproprietary names.<sup>70</sup> Mark McCamish, M.D., Ph.D., Global Head of Biopharmaceutical Development for Sandoz International, further disputed the "similar but not identical" claims of the earlier panelists stating that "'non-identity' is a normal principle in biotechnology,"<sup>71</sup> and that no two batches of any biologic are identical. Thus, so long as differences between a biosimilar and its reference biologic do not affect safety or effectiveness, a certain degree of natural variability should be acceptable. Panelists used other countries' examples to show that different nonproprietary names will actually lead to

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<sup>67</sup> Alexander, *supra* note 63, at 10.

<sup>68</sup> *Id.*

<sup>69</sup> Interchangeable biologics must also be demonstrated to be capable of being substitutable at the pharmacy without the need for intervention of a physician.

<sup>70</sup> Leicher, *supra* note 53, at 21.

<sup>71</sup> Mark McCamish, M.D., Ph.D., *Effect of Naming on Competition and Innovation*, FTC FOLLOW-ON BIOLOGICS WORKSHOP, 6 (Feb. 4, 2014).

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<sup>64</sup> Helen B. Hartman, Ph.D., *Looking Into the Future Biosimilar Landscape: A Case Study*, FTC FOLLOW-ON BIOLOGICS WORKSHOP, 7 (Feb. 4, 2014).

<sup>64</sup> *Id.*

<sup>65</sup> *Id.*

<sup>66</sup> *Id.* at 9.



confusion and discrimination of biosimilars, affecting access and affordability.<sup>72</sup>

Second, opponents of the unique nonproprietary names for biosimilars argued that pharmacovigilance does not justify unique naming conventions.<sup>73</sup> Sumant Ramachandra, M.D., Ph.D., M.B.A, Senior Vice President and Chief Scientific Officer at biosimilar developer Hospira, reviewed post-approval market surveillance and concluded that biosimilars do not need a unique nonproprietary name for effective post-market identification because the brand name is already used in nearly all cases and can serve as a differentiator.<sup>74</sup> Responding to suggestions of a unique suffix or prefix to distinguish a biosimilar's name in order to allow for easier adverse event tracking and other post-market safety purposes, Alan Lotvin, M.D., Executive Vice President of Specialty Pharmacy for CVS Caremark, noted that “[s]uch proposals confuse the role of the nonproprietary name, which describes the active ingredient, with the brand name which describes the product.”<sup>75</sup> Finally, according to Mr. Leicher, safety reporting is not dependent on nonproprietary names, and any concerns regarding inadequacy of the reporting relate to all medicines and not biologics in particular.<sup>76</sup> Similarly, Neal Hannan, Attorney Advisor in the FTC's Office of Policy Planning, agreed with Mr. Leicher by suggesting that product names may not be the best way to capture adverse event information at all. In fact, he pointed out inherent flaws in the

way information is currently collected.

Therefore, to the extent adverse event reporting system falls short of collecting the necessary information, the appropriate response is to fix the collection methodology rather than institute unique nonproprietary names for biosimilars.<sup>77</sup>

### **The Effects of Follow-On Biologics on Competition**

Panelists argued state laws inhibiting automatic substitution and preventing follow-on biologics from using the same nonproprietary name as the reference biologic will stifle competition. With respect to state substitution laws, some went as far as describing state substitution laws as “anti-competitive deterrents to investment and innovation.” For example, Mr. Leicher alleged that there has been “a long established campaign against biosimilar innovation and competition” in which state substitution legislation is the next tactic. Some, like Krystalyn Weaver from the National Alliance of State Pharmacy Association and Bruce Lott, Vice President of State Government Relations at Mylan Pharmaceuticals, took a more tempered approach, merely opining on the impact of such laws on biologic competition based on their experience with small molecule generics. Ms. Weaver used the example of Tennessee state legislation meant to regulate certain epilepsy drugs, to demonstrate how inhibiting automatic substitution may impact a generic. In Tennessee, certain epilepsy drugs were carved out and given specific substitution requirements, including physician notification. This resulted in a 29 percent increase in brand usage, increasing costs to the state and to patients. Separately, Dr. Kesselheim noted that 80 percent of prescribing physicians still use the brand name to refer to both an actual brand drug and any available generics. Therefore, panelists argued that the success of follow-on biologic

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<sup>72</sup> *Id.* at 15.

<sup>73</sup> Leicher, *supra* note 53, at 26.

<sup>74</sup> Sumant Ramachandra, M.D., Ph.D., M.B.A., *Lessons for the United States: Biosimilar Market Development Worldwide*, FTC FOLLOW-ON BIOLOGICS WORKSHOP, 7 (Feb. 4, 2014).

<sup>75</sup> Alan M. Lotvin, M.D., *Customer Perspective on Biosimilars and Interchangeable Biologics: Naming and State Legislative Issues*, FTC FOLLOW-ON BIOLOGICS WORKSHOP, 6 (Feb. 4, 2014).

<sup>76</sup> Leicher, *supra* note 53, at 24.

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<sup>77</sup> Neal Hannan, J.D., *Intro to Naming Discussion*, FTC FOLLOW-ON BIOLOGICS WORKSHOP, 5 (Feb. 4, 2014).



competition is dependent on automatic substitution at the dispensary level, as has been the case with small molecule generics. With respect to the unique nonproprietary names, panelists argued that these too could have a negative impact on competition. Specifically, according to some, unique nonproprietary names will have the potential to create unnecessary confusion resulting in lessening of competition among healthcare providers and patients by perpetrating the notion that an interchangeable biosimilar is “different.”<sup>78</sup> Also, some panelists argued that using unique nonproprietary names for biosimilars may create a future barrier for when products are ultimately designated by the FDA as interchangeable. In such cases, panelists argued, the different nonproprietary name would be used to suggest that the active ingredient in the two medicines is different, even though the FDA would have determined otherwise. As Alan Lotvin from CVS Caremark put it, such “naming issue[s] threaten to thwart [the] promise of biosimilars.”<sup>79</sup> Harry Travis from Aetna Specialty and Home Delivery Pharmacy, echoed Dr. Lotvin’s concerns.

In addition to the immediate topics of the workshop, panelists voiced concerns over some additional “roadblocks” that may discourage pharmaceutical developers from pursuing follow-on biologics. For example, Aaron Gal, Ph.D., Senior Analyst at Sanford C. Bernstein Research LLC, listed the following, among others, as potential roadblocks: (1) new intellectual property issues that have not yet been ‘cleaned’ by decades of litigation (unlike small molecule drugs); (2) high rebates from originator manufacturers that make switching to follow-on biologics inefficient for payors; and (3) “first dose” phenomena.<sup>80</sup> Another obstacle

to follow-on biologic entry identified during the workshop was the high cost of biosimilar development itself, detailed by Dr. Ramachandra, from Hospira. According to Dr. Ramachandra, biosimilars are more costly to develop than small molecule generics and require manufacturers to take considerable risk, and legislators must ensure that the marketplace is designed to reward such investment.<sup>81</sup> Dr. Ramachandra advocated for successful biosimilar market formation in the US, which he said, will require a combination of many factors including naming conventions, a stable regulatory environment, payor policies to advance patient access and education.<sup>82</sup>

### ***Effect on Biologic Competition in non-U.S. Jurisdictions***

Mr. Gal used follow-on biologic adoption rates in various European countries to illustrate that the success of the biosimilar pathway is critically dependent on the regulatory environment.<sup>83</sup> He used Germany as an example to demonstrate how a properly modulated regulatory infrastructure could increase follow-on biologics adoption. There, the government has encouraged adoption with quota requirements, independent prescribers have drug budgets so are more disposed to use follow-on biologics as a cost saving measure, and most follow-on biologics originate locally so physicians and patients garner a more favorable view of follow-on biologic quality,<sup>84</sup>

<sup>78</sup> Lotvin, *supra* note 75, at 7.

<sup>79</sup> *Id.* at 6.

<sup>80</sup> Aaron Gal, Ph.D., *Biosimilars: Commercial Perspective*, FTC FOLLOW-ON BIOLOGICS WORKSHOP, 8,

9 (Feb. 4, 2014). “First dose” is a concept that when patients are given their first dose of a drug at a hospital or clinic, where the reference drug is cheaper, they may then find it difficult to switch to a follow-on biologic or generic drug if regulations restrict switching.

<sup>81</sup> Ramachandra, *supra* note 74, at 3.

<sup>82</sup> *Id.* at 17.

<sup>83</sup> Gal, *supra* note 80, at 8-9.

<sup>84</sup> *Id.*



with follow-on biologics capturing approximately 75 percent of the market.<sup>85</sup> Dr. Ramachandra too looked at follow-on biologic market development worldwide and reported that trust in follow-on biologics continues to increase in Europe, as do the associated cost savings for patients and payors.<sup>86</sup> Dr. Ramachandra repeated Mr. Gal's point that regional and national policies will drive the rate of adoption of follow-on biologics after approval, as they have done in Europe.<sup>87</sup> Dr. Ramachandra demonstrated a measurable increase in patient access and cost savings in Europe since the introduction of follow-on biologics.<sup>88</sup>

## Conclusion

While many questions remain and no clear winners have emerged, all panelists agreed on one thing—the FTC should be commended for providing a forum for various stakeholders to voice their opinions. As Chairwoman Edith Ramirez made clear in her opening remarks, the FTC continues to be dedicated to finding the right balance between the need for competition in the growing field of biologics and the need for protecting patient safety, promoting effective pharmacovigilance, and addressing other concerns raised by the panelists. In addition to the concerns stated by the panelists during the workshop, the FTC also invited public comments (which were due to the FTC by March 1, 2014 according to the original workshop announcement) to make sure all voices were heard.

After a similar follow-on biologics debate in November 2008, which explored the introduction of an approval process for follow-on biologics, the FTC issued a report that

recommended introduction of a legislative process for an abbreviated FDA approval pathway for follow-on biologics. Subsequently, Congress passed the BPCIA, which created an abbreviated regulatory pathway for FDA approval of follow-on biologics. While the FTC has not committed to a formal report following this workshop, it would be helpful if the FTC issued a comprehensive report with its official stance on the proposed state legislations and naming conventions.

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<sup>85</sup> *Id.* at 8.

<sup>86</sup> Ramachandra, *supra* note 74, at 9.

<sup>87</sup> *Id.* at 11.

<sup>88</sup> *Id.* at 12-13.



## A Profile of Dr. Aviv Nevo (Deputy Assistant Attorney General, U.S. Department of Justice)

*By Spencer Graf<sup>1</sup>  
Charles River Associates*



### Introduction

Dr. Aviv Nevo joined the Department of Justice Antitrust Division as the Deputy Assistant Attorney General (DAAG) almost a year ago in April 2013. This position is often called the “chief economist” at the Division. Dr. Nevo is currently on leave from his position as a professor of economics and marketing at Northwestern University. He has focused his academic research on applied industrial organization and econometrics and has published widely on topics of general interest to antitrust practitioners, including the price competition, estimation of market power, mergers, and consumer welfare. In particular, he is noted for his work in developing methods for the analysis of price competition and mergers in consumer goods and hospitals. In the year that has passed since his appointment, his speeches, interviews<sup>2</sup> and papers add to his already robust body of work and shed light on the trends one may see from antitrust economics at the DOJ. Because Dr. Nevo is an applied econometrician, one may

expect his influence to result in additional emphasis on the use of econometric analysis in merger and other antitrust review. However, one can gain more insight from reviewing Dr. Nevo’s prior work. Much of this has been focused on the nature of econometric evidence that can be used to evaluate potential mergers and policy changes. Of particular significance in the healthcare sector is Dr. Nevo’s recent paper discussing application of structural models as applied to hospital mergers and the bargaining leverage between hospitals and health plans.

### Structural Modeling

Dr. Nevo’s research belongs largely to an area of econometrics known as “structural methods.”<sup>3</sup> These methods try to use economic theory to guide the econometric analysis. The modeling seeks to estimate the specific parameters of an economic model of behavior such as individual consumer choices or firm price setting based on aggregates of consumer choices. The economic model helps define the assumptions regarding how the variables interact with one another, such as how firms react to competitor pricing. In a literal sense, the model provides structure to how the data are analyzed.

<sup>1</sup> Spencer Graf is a Principal at Charles River Associates. He specializes in analysis of antitrust issues arising in litigation, merger review, and other regulatory settings.

<sup>2</sup> The ABA Antitrust Section’s Economics Committee recently published an interview with Dr. Nevo: “Interview with Aviv Nevo, DOJ Deputy Assistant Attorney General for Economic Analysis,” Economics Committee Newsletter, Vol. 13 (1), Winter 2014.

<sup>3</sup> Structural methods are not to be confused with the traditional “structural approach” to antitrust that focuses on market shares and concentration.



Structural methods are commonly used for a pair of reasons. First, it is often the case that relevant factors in competition are unobserved, making it difficult to address merger or other policy concerns. For example, marginal costs are not commonly available. The second use of structural methods is in inferring market effects from simulated changes in the market. Once the economic model has been calibrated and unobserved variables have been estimated, the model can be used to simulate events such as the imposition of a tax, post-merger joint pricing, and coordinated effects.

While not new, structural methods were historically less common in applied industrial organization and empirical analysis of antitrust. Until the past couple decades, structural methods were hindered by the paucity of detailed consumer and other production and sales data. Data have, of course, become increasingly available. Examples include retail scanner data, administrative claims records, and airline ticket coupons. The breadth and depth of the data have expanded the scope of what academics, merging parties and the antitrust agencies can study using structural methods.

From an outside perspective, structural methods can be better understood by contrasting them with some common alternatives. More traditional econometric approaches take a less deterministic approach, where few assumptions are made regarding how variables should interact. In some cases, this is considered a source of strength versus structural methods. These approaches typically look for a “treatment effect,” much as one would imagine a study of the effectiveness of a medication. Researchers seek “natural experiments” on individuals, firms, or aggregates of them where factors affecting market outcomes changed over time and/or differed across geographic regions and thus created “treatment” and non-treatment groups to be studied. These marketplace

changes creating treatments could include completed mergers, firm or product entry or exit, or changes in regulation. Differences in how prices and other factors responded to the natural experiment allow the researchers to identify how the factors interacted.

Under both structural and natural experiment econometric methods, Dr. Nevo has shown concern for what he calls “credible identification” or credible inference.<sup>4</sup> This he divides into internal and external credibility. Internal credibility of an econometric study regards the quality of the econometric work. Does the analysis measure what it claims? An example of an internal credibility issue is whether a relevant economic variable has been omitted from the analysis. Such an omission could exclude an alternative explanation of market outcomes and thus lead to unreliable conclusions.

There is little disagreement regarding the importance of internal credibility and careful econometric design. For this reason, Dr. Nevo has shown greater interest in the discussion of the external credibility of econometric results, in particular in the context of merger review. External credibility refers to how the econometric results could be generalized or extrapolated to new counter-factual situations. It is here that structural and natural experiment methods may diverge according to the specifics of the questions being studied. In the case of mergers, one may seek to predict the effects on price and consumer welfare of removing one independent firm. However, as is often the case, mergers can occur in industries where there have been no prior mergers or where prior mergers involved a different set of regulatory or

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<sup>4</sup> Aviv Nevo & Michael D. Whinston, *Taking the Dogma out of Econometrics: Structural Modeling and Credible Inference*, J. ECON. PERSPECTIVES, 24(2), Spring 2010, at 69-81.



market facts than those currently present. In such a case, it could be difficult to infer the extent of merger effects from analysis of past events. Using Dr. Nevo's terminology, the treatment effect methods may suffer from low external credibility in such a case.

Structural methods show their strength in external credibility according to Dr. Nevo. A structural model begins with a theoretical model of how consumers choose products and/or how firms set prices and compete. A challenge for the researcher is to choose the economic model based on the facts present in the industry. For example, a potential model needs to address if the products are differentiated or if consumers purchase one or multiple units. Dr. Nevo has recently discussed the need for antitrust analysis and especially empirical work to consider additional economic models of how prices are determined.<sup>5</sup> In particular, he has noted that many industries involve a limited number of both buyers and sellers where firms bargain or negotiate over prices. In these cases, the structure of analysis may begin with a bargaining model rather than more common models of competition. Dr. Nevo's research in bargaining models is discussed below.

### Merger Simulation

Dr. Nevo's research using structural methods provides an excellent overview of the use of these methods in merger simulation.<sup>6</sup> For simulation, one needs first to estimate consumer demand for each product. Second, one estimates how firms determine prices given the

estimated demand and the economic model of competition. The second stage is where economic theory is used to inform the choice of structural methods.

To motivate the discussion of these methods, Dr. Nevo has analyzed retail sales of ready-to-eat cereals.<sup>7</sup> These products are differentiated and Bertrand competition is assumed. Retail sales were observed by cereal brand (e.g., Post Raisin Bran) both over time and city. Using these data, he estimated the demand for each product, including the own-price elasticity, the sensitivity of quantity demanded to the product's own price; and the cross-price elasticity, the sensitivity of quantity demanded to price changes in competing products. Once product demand was estimated, Dr. Nevo could estimate the parameters of the pricing model. When fully specified and estimated, the economic model could be used to simulate potential mergers among the companies owning cereal brands. In particular, the simulation was used to calculate the levels of cost efficiencies necessary to offset any predicted price increases. Since it is typically difficult to fully quantify the magnitude of cost efficiencies, the simulation provides a benchmark level that can be used to assess the importance of asserted efficiencies. In related research, Dr. Nevo has used this approach to develop a structural approach test for collusion in the cereal industry.<sup>8</sup>

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<sup>5</sup> Aviv Nevo, *Mergers that Increase Bargaining Leverage*, Remarks as Prepared for the Stanford Institute for Economic Policy Research and Cornerstone Research Conference on Antitrust in Highly Innovative Industries, Jan. 24, 2014.

<sup>6</sup> For an overview of merger simulation, see e.g., Aviv Nevo, "Merger Simulation," *The New Palgrave Dictionary of Economics*, 2008.

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<sup>7</sup> Aviv Nevo, *Mergers with Differentiated Products: The Case of the Ready-to-Eat Cereal Industry*, *RAND J. ECON.*, 31(3), 2000, 395-421.

<sup>8</sup> Aviv Nevo, *Measuring Market Power in the Ready-to-Eat Cereal Industry*, *ECONOMETRICA* 69(2), 2001, 307-342.



## Mergers that Increase Bargaining Leverage

As noted before, Dr. Nevo has shown interest in expanding the toolkit used for structural methods in antitrust analysis to include bargaining leverage. There are many industries where suppliers and distributors negotiate or bargain over prices. For example, cable and satellite companies may bargain with programming suppliers to form a programming bundle to offer to consumers. In health care, managed care organizations (MCOs) bargain with hospitals and physicians to form a provider network. In another setting, smartphone producers may bargain with technology patent holders to form a feature bundle on a smartphone. Other examples can include global distribution systems (GDSs) assembling airline fare content to offer to travel agents, and retailers choosing products to put on shelves.<sup>9</sup> Dr. Nevo and co-authors have developed a framework for addressing these bargaining situations in antitrust review.<sup>10</sup> In speeches over the past year, Dr. Nevo has used the material in this working paper to illustrate how bargaining can be used in a structural methods analysis of mergers, particularly hospital mergers.

Markets involving negotiated prices contrast with “standard” markets such as consumer goods where the price is posted and consumers

choose whether and how much to buy at the given price. In these “standard” markets, there are common economic modeling tools to analyze mergers. Dr. Nevo and his co-authors contend that these common tools fall apart in markets such as those for hospital services. The standard models rely on the general tendency of consumers to seek low prices and eschew high ones. However, this tendency is not necessarily applicable for insured consumers, because they do not pay the full price for hospital services directly from their own pockets. In economic terms, consumer demand for services from a particular hospital is more inelastic. An MCO, on the other hand, is likely to be more sensitive to the price paid to the provider. The authors propose to solve this issue in the model by first modeling consumer preferences across hospitals and then modeling how MCOs negotiate with hospitals depending on the preferences of their enrollees.

### *Negotiating Model used by Authors*

In the MCO-hospital negotiation, the “product” that an MCO purchases is not a single episode of care, but rather the MCO negotiates with the hospital over whether the entire hospital is in or out of the MCO’s network. It is all or nothing.<sup>11</sup> If the hospital is in-network, some of the MCO’s enrollees would choose that hospital because it gives them the highest satisfaction. That satisfaction is based on various characteristics such as closeness to home, services provided (e.g., having a maternity ward), quality, and out of pocket cost to the enrollee. If instead that hospital is out of the

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<sup>9</sup> Bargaining is not limited to technology and health care and is not new to antitrust analysis. For example, bargaining was addressed in the FTC’s challenge to Heinz’s acquisition of Beech-Nut. In that case, which involved baby food suppliers, it was explained that retailers bargained with baby food suppliers as the retailers assembled a selection of baby food products to market on store shelves. *FTC v. H.J. Heinz Co.*, 246 F.2d 708 (D.C. Cir 2001).

<sup>10</sup> Gautam Gowrisankaran, Aviv Nevo, and Robert Town, *Mergers When Prices Are Negotiated: Evidence from the Hospital Industry*, NBER WORKING PAPER NO. 18875, March 2013.

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<sup>11</sup> For hospital negotiations, it may make sense to model an all or nothing negotiation. However, not all bargaining situations require such an approach. In the distribution of airline fare information and bookings, the airlines supply air fare content to distributors. The bargaining between airlines and distributors may involve whether certain subsets of fares, such as webfares, are available to the distributor.



network, the enrollees have to consider the other available hospitals. For the enrollees that have to choose an alternative hospital, there is clearly lower satisfaction from choosing the “second-best” hospital. The difference between best and second-best satisfaction is the value of adding the preferred hospital to the MCO’s network for that enrollee. For the sake of simplicity, imagine as do Dr. Nevo and his co-authors that the insurers care directly about enrollee satisfaction. As a consequence, the MCO has preferences over hospitals based on their characteristics and prices paid for services.

In order to motivate the merger analysis, one can consider a stylized version of the economic model where the MCO is creating a local network and bargaining with an additional hospital. Each side brings its bargaining leverage to the negotiation over price. For the MCO, that leverage comes from the threat to exclude the hospital. For the hospital, the leverage is based on enrollee preferences over hospitals. Consumers consider the hospitals substitutes but prefer a network with more hospitals. However, as more hospitals are added to the network, there is a diminishing value to consumers from adding an additional hospital.

As a concrete example, imagine that the penultimate hospital added to the network brings satisfaction value of 5 and the last hospital brings just 3. For simplicity, assume that the MCO has all of the bargaining power and negotiates with each hospital separately. The MCO can approach each hospital as if it were the very last one added to the network. It can then make a take it or leave it offer equal the value of the last hospital added to the network. That is, each hospital in the network is offered a price of 3.

Now, imagine that two hospitals merge. Before the merger, the MCO negotiates a price of 3

from each of them. After the merger, a single company now negotiates two hospitals as an all or nothing deal. The value of the last two hospitals together is 8. That is, 3 for the last and 5 for the next to last. The MCO must now negotiate a total price of 8 with the merged company, which comes out to an average of 4 for each of the merged hospitals. Thus, the merger increased bargaining leverage for the hospitals and increased price.

This example is simplified. The distribution of bargaining power between supplier and distributor could lie anywhere between entirely with the supplier or entirely with the distributor.<sup>12</sup> Actual hospitals may differ from one another on many characteristics and contribute differently to the total network value. However, the upshot of the model is that the merger creates the potential for increased hospital bargaining leverage and higher prices would ensue if the incremental gain to the network’s value is diminishing by adding more hospitals.<sup>13</sup>

#### ***Application to Inova proposed acquisition of Prince William Health System***

The authors propose an econometric methodology to illustrate the application of their negotiation model. In 2008, the FTC challenged the proposed merger of Inova Health System Foundation (Inova) and Prince William Health System. Inova already owned five hospitals in Northern Virginia. The FTC argued that the addition of Prince William would enhance Inova’s bargaining leverage with health insurers

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<sup>12</sup> Although the bargaining model is proposed as an alternative to so-called standard models, the authors note that the Bertrand outcome results when the supplier has all of the bargaining power.

<sup>13</sup> In some imaginable applications of bargaining models, some of the suppliers may be complementary to those already in the network. This could mitigate or eliminate the enhancement of bargaining leverage in the example.



leading to higher prices for acute inpatient services in Northern Virginia.

The authors used patient discharge data and insurer administrative claims data to estimate the demand for care at each hospital and the bargaining model that determines prices paid by the insurers. The authors found that the Inova–Prince William merger would have resulted in prices paid by insurers at these hospitals rising about 3 percent. Based on the economic model, the price increase is due to increased bargaining leverage.

The authors consider the proposed remedy in Promedica, where the merged hospitals would establish separate, firewalled team for negotiating with MCOs. They contend, as did the FTC, that this remedy would not prevent the increase in bargaining leverage and consequent upward pressure on price. Each hospital team would have increased bargaining leverage, since it would know without coordination that the MCOs are negotiating over both hospitals. Finally, the authors consider a number of other implications from their results. Notably, they find that patient cost-sharing could significantly affect the negotiated hospital prices. This cost-sharing from co-insurance increases consumer sensitivity to price, which ultimately enhances the MCOs bargaining power. In turn, this tends to lower the negotiated prices. Currently, consumers pay only 2-3 percent of the total hospital cost via coinsurance and copays. The authors estimate that prices would rise almost 4 percent if consumers paid no coinsurance, and thus had no out-of-pocket exposure to hospital prices. If co-insurance rose to 30 percent of total hospital cost, prices would fall roughly 16 percent.

## Conclusion

Even prior to Dr. Nevo's arrival at DOJ, antitrust review has been adapting to the increasingly large amounts of data produced in

mergers and other settings. With the influx of more voluminous and detailed data has also come a greater interest in the types of structural methods used by Dr. Nevo. Structural methods and merger simulation can be time consuming, even when data are available. However, it can be expected that econometric evidence leveraging both structural methods and simulation will take a prominent role in antitrust analysis.

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