

Saint Louis University Journal of Health Law & Policy

Volume 11
Issue 1 *Coping with Health Care Market
Concentration*

Article 9

2017

Taking Quality of Health Care Seriously in Provider Merger Analysis

Kent Bernard
Fordham University School of Law, kent.bernard@gmail.com

Follow this and additional works at: <https://scholarship.law.slu.edu/jhlp>



Part of the [Health Law and Policy Commons](#)

Recommended Citation

Kent Bernard, *Taking Quality of Health Care Seriously in Provider Merger Analysis*, 11 St. Louis U. J. Health L. & Pol'y (2017).

Available at: <https://scholarship.law.slu.edu/jhlp/vol11/iss1/9>

This Related Article is brought to you for free and open access by Scholarship Commons. It has been accepted for inclusion in Saint Louis University Journal of Health Law & Policy by an authorized editor of Scholarship Commons. For more information, please contact [Susie Lee](#).

TAKING QUALITY OF HEALTH CARE SERIOUSLY IN PROVIDER MERGER ANALYSIS

KENT BERNARD*

ABSTRACT

Traditionally, antitrust analysis had no method to quantify the benefits of better health care outcomes from a potential merger to balance them against the potential for increased costs. However, a branch of health care economics allows for that calculation. This approach has not been used in antitrust analysis to date, but United States law is flexible enough to allow such an approach, and the 2010 Horizontal Merger Guidelines contemplate it in Section 5. It enables us to use established procedures to put quality of care into health care merger analysis.

* Adjunct Professor, Fordham University School of Law; J.D. 1975, University of Pennsylvania; B.A. 1972 Colgate University. I would like to thank Jim Furniss, of GfK, for his infinite patience in guiding me through health care economics and QALYs. He is absolved of any responsibility for any errors that I have made. I also want to thank Alyssa Black-Dorward and the staff of the Fordham Law Library for their research assistance.

I. INTRODUCTION: A CLASH OF PARADIGMS

Antitrust starts with costs, prices, and economics. Health care starts with relieving pain and curing disease. Are we really surprised that the two do not mesh seamlessly?

A critical factor that tends to get lost in the discussion of costs, usage, and prices is whether one starting point or the other leads to better outcomes for patients, which should be a goal of any health care system.¹ It is difficult to deny that there are some very important distinctions between the market for health care and the market for widgets. But what makes this area so tricky is that both sides have legitimate arguments. From the antitrust side, it may indeed be likely that consolidation above a certain level will lead to (or at least allow) higher prices.² But from the health care side, there is evidence that some consolidation may be necessary in order to achieve better clinical outcomes.³ The atomistic market, beloved by antitrust enforcers and scholars, may be great for a person's wallet but detrimental to a person's health.

Current antitrust enforcement theory teaches that more providers lead to lower prices and that high post-merger Herfindahl-Hirschman Index (HHI) numbers are a sufficient basis to assume that prices will increase if the merger is allowed.⁴ On the other side, there is an argument that more providers actually can lead to higher costs and duplication of services,⁵ and there is certainly a

1. See Michael S. Jacobs, *Presumptions, Damn Presumptions and Economic Theory: The Role of Empirical Evidence in Hospital Merger Analysis*, 31 IND. L. REV. 125, 127 (1998). The Federal Trade Commission (FTC) and Department of Justice's (DOJ's) position on certificate of need (CON) laws highlights the tension between assuming that traditional antitrust concepts outweigh all other factors and the desire or need to take other factors into account. FED. TRADE COMM'N & DEP'T OF JUSTICE, JOINT STATEMENT OF THE FEDERAL TRADE COMMISSION AND THE ANTITRUST DIVISION OF THE U.S. DEPARTMENT OF JUSTICE TO THE VIRGINIA CERTIFICATE OF PUBLIC NEED WORK GROUP (Oct. 26, 2015), https://www.ftc.gov/system/files/documents/advocacy_documents/joint-statement-federal-trade-commission-antitrust-division-u.s.department-justice-virginia-certificate-public-need-work-group/151026ftc-dojstmtva_copn-1.pdf. Competition in health care markets can benefit consumers, *id.* at 5, CON laws can impede free competition, *id.* at 2, and while the laws were enacted years ago to control costs and mitigate the consequences of the cost-based reimbursement structure, that reimbursement system has "changed significantly," and CON laws no longer work, *id.* at 8. It would be helpful if that same recognition of the changes in health care reimbursement and policy were brought over into Agency actions involving other areas of health care.

2. See Martin Gaynor, *New Health Care Symposium: Consolidation and Competition in US Health Care*, HEALTH AFF. BLOG (Mar. 1, 2016), <http://healthaffairs.org/blog/2016/03/01/new-health-care-symposium-consolidation-and-competition-in-us-health-care/> (last visited Oct. 1, 2017).

3. See FED. TRADE COMM'N & DEP'T OF JUSTICE, *supra* note 1, at 9.

4. *Id.* at 2; *Herfindahl-Hirschman Index*, U.S. DEP'T OF JUSTICE (Jul. 29, 2015), <https://www.justice.gov/atr/herfindahl-hirschman-index> (last visited Sept. 25, 2017).

5. See Martin Gaynor & Robert Town, *The Impact of Hospital Consolidation—Update*, THE SYNTHESIS PROJECT 1 (June 2012), https://www.rwjf.org/content/dam/farm/reports/issue_briefs/

strong argument that fewer providers (each doing a higher volume of procedures) can lead to higher quality outcomes.⁶ While the appellate courts have endorsed the Federal Trade Commission's (FTC's) position opposing the consolidation of providers,⁷ states recently have exercised the *nuclear option* of ousting the federal antitrust authorities from the field by passing legislation, which effectively creates a state action immunity for a state determination that a health care provider merger should be allowed.⁸ In a recent West Virginia case, Cabell Huntington Hospital proposed to acquire the only other hospital in Huntington, St. Mary's Medical Center.⁹ The FTC filed an administrative complaint to stop the acquisition, and the West Virginia legislature responded by passing legislation that effectively cloaked the transaction in state action

2012/rwjf73261; Hanh Q. Trinh et al., *Hospital Service Duplication: Evidence on the Medical Arms Race*, HEALTH CARE MGMT. REV. 192, 197 (2008). I refer to this as the *Field of Dreams* phenomenon. In the words of the voiceover in Ray Kinsella's head, "If you build it, he will come." FIELD OF DREAMS (Universal Pictures 1989). The idea is that if there are more facilities, there will be pressure to use them more. See Richard Cauchi & Ashley Noble, *CON-Certificate of Need State Laws*, NAT'L CONF. OF STATE LEGIS. (Aug. 25, 2016), <http://www.ncsl.org/research/health/con-certificate-of-need-state-laws.aspx> (last visited Sept. 30, 2017). This belief led to the enactment of CON laws, allowing the government to determine if there is a need for a new facility before allowing it to be built. *Id.* The idea is to coordinate the provision of services to obtain the best outcomes at the best cost. See Mary S. Vaughan-Sarrazin et al., *Mortality in Medicare Beneficiaries Following Coronary Artery Bypass Graft Surgery in States with and without Certificate of Need Regulation*, 15 JAMA 1859, 1859 (2002) ("Certificate of need laws also were intended to ensure quality of care and clinical proficiency by limiting the number of health care facilities performing complex medical procedures."). The understanding was that more providers could result in higher, rather than lower costs. See Cauchi & Noble, *supra*. The states see the restrictions as putting a cap on the upward costs caused by excess capacity in this marketplace. See *id.* The FTC and DOJ believe that such laws restrict competition and thereby lead to higher prices. FED. TRADE COMM'N & DEP'T OF JUSTICE, *supra* note 1, at 9. Ultimately, the debate is not over specific state laws, but rather over the structure and operation of health care markets. See *id.*

6. See *infra* notes 13–16 and accompanying text.

7. See, e.g., Fed. Trade Comm'n v. Penn State Hershey Med. Ctr., 838 F.3d 327 (3d Cir. 2016); Fed. Trade Comm'n v. Advocate Health Care Network, 841 F.3d 460 (7th Cir. 2016).

8. See, e.g., FED. TRADE COMM'N, STATEMENT OF THE FEDERAL TRADE COMMISSION: IN THE MATTER OF CABELL HUNTINGTON HOSPITAL, INC., DOCKET NO. 9366 1 (July 6, 2016), https://www.ftc.gov/system/files/documents/public_statements/969783/160706cabellcommstmt.pdf ("This case presents another example of healthcare providers attempting to use state legislation to shield potentially anticompetitive combinations from antitrust enforcement."). State action immunity classically requires that there be a "clear articulation" of the state's desire to suspend the normal rules and that there be "active supervision" of the conduct to be immunized. California Retail Liquor Dealers Ass'n v. Midcal Aluminum, 445 U.S. 97, 105 (1980); AM. BAR ASS'N SECTION OF ANTITRUST LAW, ANTITRUST LAW DEVELOPMENTS 1271–72 (Jonathan I. Gleklen et al. eds., 7th ed. 2012); Herbert Hovenkamp, *Rediscovering Capture: Antitrust Federalism and the North Carolina Dental Case*, CPI ANTITRUST CHRON., Apr. 2015 (2), at 7–8.

9. *Case Summary*, FED. TRADE COMM'N, <https://www.ftc.gov/enforcement/cases-proceedings/141-0218/cabell-huntington-hospitalst-marys-medical-center-matter> (last visited Sept. 27, 2017).

immunity.¹⁰ The FTC then dismissed the Complaint but noted that it disagreed with West Virginia's analysis.¹¹

The debate over which system costs more may never end. But the debate also ignores the question of whether one approach provides better care than the other in a given situation. The FTC has articulated the cost issue.¹² This article will articulate the health care argument and then show how it can be integrated into the more traditional antitrust analysis.

On the health care side, the principle is simple: "Surgery is about practice and volume."¹³ For quality purposes, for any given procedure, each hospital should perform a sufficient number of those procedures to achieve the best clinical result. For example, The American College of Surgeons Guidelines for standards on cardiac surgery states that an annual volume of 100 to 125 open heart surgeries per hospital per year is necessary to assure acceptable clinical quality for that type of procedure, and it is likely that 200 of such procedures per year are necessary for the program to function effectively.¹⁴

A certain level of volume is a necessary condition for the best patient outcomes.¹⁵ This rule holds generally across countries and procedures.¹⁶ For example, "[w]hen Denmark reduced by two-thirds the number of hospitals . . . perform[ing] colorectal cancer surgery, post-operative mortality rates after two years improved by 62%."¹⁷ Further, "[f]ewer people have died of strokes in London since [the National Health Service] merged 32 specialist sites into eight."¹⁸

The focus here is on prioritizing quality of health care. The FTC argues that "[t]he elimination of substantial competition between merging hospitals tends to

10. FED. TRADE COMM'N., *supra* note 8, at 1.

11. In the Matter of Cabell Huntington Hosp. Inc., Pallottine Health Servs., Inc., and St. Mary's Medical Ctr., Inc., Docket No. 9366 (Fed. Trade Comm'n. July 6, 2016).

12. See generally U.S. DEP'T OF JUSTICE & FED. TRADE COMM'N, HORIZONTAL MERGER GUIDELINES (Aug. 19, 2010), <https://www.ftc.gov/sites/default/files/attachments/merger-review/100819hmg.pdf>.

13. *The National Health Service: Accident and Emergency*, ECONOMIST, Sept. 10, 2016, at 50.

14. *Guidelines for Standards in Cardiac Surgery*, AM. COLL. OF SURGEONS (Feb. 1, 1997), <https://www.facs.org/about-acsguidelines/cardiac-surgery> (last visited Sept. 27, 2017); see also *Children's Heart Surgery: The Need for Change*, NAT'L HEALTH SERV. (Apr. 2010), http://www.chfed.org.uk/wp-content/uploads/2012/06/The_Need_for_Change.pdf.

15. See Steve Sternberg & Geoff Dougherty, *Risks are High at Low-Volume Hospitals*, U.S. NEWS (May 18, 2015, 12:01 AM), <http://www.usnews.com/news/articles/2015/05/18/risks-are-high-at-low-volume-hospitals> (last visited Sept. 27, 2017).

16. See *id.*; see also Cheryl Clark, *Welcome Back, Volume—the Original Quality Measure*, HEALTHLEADERS MEDIA (May 21, 2015), <http://www.healthleadersmedia.com/quality/welcome-back-volume-the-original-quality-measure#> (last visited Sept. 27, 2017).

17. *The National Health Service: Accident and Emergency*, *supra* note 13, at 48, 50.

18. *Id.*

weaken a hospital's incentives to deliver higher quality care."¹⁹ The FTC cites what it describes as "substantial empirical literature . . . that the net effect of mergers of competing hospitals on quality [of care] is often negative."²⁰ The FTC's position suggests that to be allowable a merger must increase quality in *all* respects across the board. But this ignores the literature on the need for volume of procedures to develop and maintain quality of outcomes, as noted earlier. Rather, the research cited in support of the FTC's argument actually supports the merger of *selected* activities to improve quality.²¹

The FTC relies heavily on an article by Romano and Balan, reporting on their work for the FTC in a hospital merger case.²² Romano and Balan note that if reimbursement to the hospital is fixed, then the only way to achieve savings from a merger is to cut quality.²³ But the idea that the only way to achieve savings is to increase price or to cut quality is misleading. First, this idea ignores the potential for cost savings through more efficient practices (such as volume purchasing). Second, quality might increase if the merging hospitals believe that higher quality services will attract more patients and fill beds, operating rooms, and the like, which otherwise would be sitting idle. It might even be pro-competitive to increase costs in order to increase quality.²⁴ Third, Romano and Balan recognize that certain surgical procedures exhibit a positive volume-outcome relationship.²⁵ While they recognized the general principle and that the merging parties tried to concentrate certain procedures at certain hospitals to improve quality, they claim to be unable to tell if quality increased because there was no such program before.²⁶ But they also believe that it is not possible to establish a baseline without a critical mass of patients.²⁷

This is a classic *heads I win, tails you lose* argument. A baseline cannot be established unless there is a substantial number of given procedures. But if that substantial number is reached by one of the parties prior to merging, it cannot be proven that the merger will improve quality. Courts should adopt the

19. Fed. Trade Comm'n, Comment Letter on Certificate of Public Advantage Application of Mountain States Health Alliance and Wellmont Health System 31 (Nov. 21, 2016), https://www.ftc.gov/system/files/documents/advocacy_documents/ftc-staff-submission-tennessee-department-health-regarding-certificate-public-advantage-application/161122wellmontcommenttenn.pdf.

20. *Id.*

21. See Gaynor & Town, *supra* note 5, at 5 tbl. 4.

22. Patrick S. Romano & David J. Balan, *A Retrospective Analysis of Clinical Quality Effects of the Acquisition of Highland Park Hospital by Evanston Northwestern Healthcare*, 18 INT'L J. ECON. BUS. 45, 45 (2011).

23. *Id.* at 46.

24. Thanks to Paul Denis and Michael Cowie for suggesting this line of approach (private discussion with the author).

25. Romano & Balan, *supra* note 22, at 48.

26. *Id.* at 52.

27. *Id.* at 50.

approach championed by Alexander the Great when confronted with the Gordian knot. He did not try to untie it; he simply cut it off.²⁸ There are strong data as to the minimum efficient scale for certain medical procedures.²⁹ If neither merging party has the volume alone, but they achieve it if combined, there is a strong case that the merger improves quality. And even if one party has the volume while the other does not, combining them may enable more patients to achieve a higher quality result.

The argument that savings and quality improvements must be merger specific really cannot apply here. The savings here is lives saved through increased quality of medical procedures. The indisputable way to reach that goal is to consolidate procedures into one institution. The alternative to a merger is a set of market allocation agreements between the actual or potential competitors. The problem with that so-called less restrictive alternative is that it happens to be a felony.³⁰

This sets up an interesting problem. Assume that two hospitals want to merge. They argue a need to allocate procedures between them in order to reach the volume required to improve quality of outcomes. The FTC rejoins that while a case can be made that the consolidation will improve quality with regard to procedures A, B, and C, both parties are at an efficient scale right now as to procedures D, E, and F. Therefore, in those areas, reducing competition has no offsetting quality gain for the potential price increases. So, how can these factors be balanced? This turns out to be a subcategory of a more general question: How can one quantify quality benefits and weigh them against costs?

In an earlier article, I proposed a way of integrating traditional antitrust merger analysis with a focus on overall health care expenditures, rather than treating each potential service as a hermetically sealed silo.³¹ In that article, I

28. Zbigniew Herbert, *The Gordian Knot*, KENYON REV., Summer 1984, at 36.

29. See, e.g., Gregory J. Dehmer et al., *SCAI/ACC/AHA Expert Consensus Document: 2014 Update on Percutaneous Coronary Intervention Without On-Site Surgical Backup*, 129 CIRCULATION 2610, 2614 (2014) (recommending the clinical standard that “laboratories performing both primary and elective PCI [percutaneous coronary intervention], with and without on-site cardiac surgery, should perform a minimum of 200 PCIs annually . . . based on an extensive review of studies that identified a signal suggesting worse outcomes in laboratories performing <200 PCIs annually”); see also *supra* text accompanying notes 13–14.

30. See *U.S. Attorney's Manual: Antitrust Resource Manual*, U.S. DEP'T OF JUSTICE, <https://www.justice.gov/usam/antitrust-resource-manual-8-identifying-sherman-act-violations> (last visited Oct. 3, 2017).

31. Kent Bernard, *An Integrative Approach to Evaluating Healthcare Provider Mergers in the Era of the ACA*, ANTITRUST, Summer 2015, at 64, 67. This approach seemed to be mandated by, or at the very least consistent with, the Patient Protection and Affordable Care Act (ACA). See generally Patient Protection and Affordable Care Act, 42 U.S.C. § 18001 (2010). But even apart from the ACA, the approach of looking to net expenditures and savings in the broader market for healthcare services seems to be the optimum approach to achieve both better outcomes and lower overall costs.

deliberately did not argue improved quality of life per se or improved health care outcomes as cognizable merger benefits, only that improved outcomes could be translated into lower overall health care costs if we simply allowed consideration of benefits in adjacent markets as part of the analysis.³²

In this article, I address the quality of care issue directly. There is a way to utilize existing research in health care economics to create a structure to monetize both the costs and benefits of health care provider mergers, making it possible to take quality seriously and, at the same time, asking whether this particular increase in quality is worth that particular cost. I am not aware of any antitrust precedent for doing this, but I believe that it can and should be done. This article is the first step on that path.

II. BETWEEN A ROCK AND A HARD PLACE

The first premise of U.S. merger analysis is that everything relevant to antitrust is reducible to dollars and cents. Both benefits and harms must be describable in monetary terms. While the FTC claims to always consider arguments regarding improved quality of care,³³ the way it does so is to consider improved quality of care as an efficiency that must somehow weigh against the costs of the merger.

Before dealing with how to consider efficiencies and whether they need to be in the same market as the alleged harm, the basic question must be addressed of whether efficiencies actually are being considered at all. For example, in a recent case, the Third Circuit Court of Appeals stated, “We note at the outset that we have never formally adopted the efficiencies defense. Neither has the Supreme Court. Contrary to endorsing such a defense, the Supreme Court has instead, on three occasions, cast doubt on its availability.”³⁴ The court then admits that other courts of appeals, and the FTC’s own Merger Guidelines, do recognize the defense, but then effectively eviscerates any use of that defense by holding, “[T]he efficiencies defense, because it is aimed at rebutting the Government’s prima facie case that the merger is anticompetitive, must ‘demonstrate that the prima facie case portrays inaccurately the merger’s probable effects on competition.’”³⁵ It is somewhat troubling that courts still doubt the existence of an efficiencies defense. But the approach does raise two issues. First, the defense must demonstrate that the prima facie case is *inaccurate*, according to the court,³⁶ which I would argue is only one way to

32. Bernard, *supra* note 31, at 71–72.

33. Deborah L. Feinstein, Director, Bureau of Competition, Fed. Trade Comm’n, Speech on Antitrust Enforcement in Healthcare: Proscription, Not Prescription 11 (June 19, 2014), http://www.ftc.gov/system/files/documents/public_statements/409481/140619_aco_speech.pdf.

34. Fed. Trade Comm’n v. Penn State Hershey Med. Ctr., 838 F.3d 327, 347 (3d Cir. 2016).

35. *Id.* at 349 (citing Saint Alphonsus Med. Ctr.-Nampa, Inc. v. St. Luke’s Health Sys., Ltd., 778 F.3d 775, 790 (9th Cir. 2015)).

36. *Penn State Hershey Med. Ctr.*, 838 F.3d at 349.

rebut the case. Second, the defense could show that the *prima facie* case is *incomplete*.³⁷

Assume that the economic data show that the merger will lead to a projection of substantially increased economic power in one product (service) market—such as primary care physician services. The defense can concede that while this is where the data lead, the transaction can be defended on the basis that whatever the increase in costs is at the primary care physician level, there will be a greater decrease in costs at the hospitalization level. The relevant factors include the projected anti-competitive impact from a loss of competition in one or more relevant product markets balanced against any countervailing efficiencies or projected decreases in cost across the broader arena for health care services. The comparison is apples to apples or here, dollars to dollars. The concept that the analysis should require the consideration of efficiencies in separate but related markets is consistent with the Patient Protection and Affordable Care Act (ACA),³⁸ yet it stands on its own two feet. Nothing in antitrust law (as opposed to the way it is being viewed currently) prohibits taking such a common-sense view.³⁹

The FTC's approach of treating increased quality of care as an efficiency is questionable, yet it highlights a serious issue. It is simple to assert that a merger will improve quality or make the world a better place for generations yet to come. But how is the agency supposed to evaluate that claim? Balancing requires a common unit of measurement for both factors so that the factors can be netted out. How do you net out better care against increased costs? It is difficult to deny the idea that one should include quality of patient care as a key part of the antitrust merger analysis. When either the cost side or the patient benefit side is missing, the analysis is flawed.

For example, in the recent litigation involving the FTC and St. Luke's Health System, the FTC and the Idaho Attorney General sued to block St. Luke's from acquiring an independent, multi-specialty physician practice group, Saltzer Medical Group.⁴⁰ The suit alleged that "the combination of St. Luke's and Saltzer would give it the market power to demand higher rates for . . . primary care physicians (PCPs) in Nampa, Idaho and surrounding areas, ultimately leading to higher costs for health care consumers."⁴¹

37. *See id.*

38. Bernard, *supra* note 31, at 70.

39. *See id.*

40. Saint Alphonsus Med. Ctr.-Nampa, Inc. v. St. Luke's Health Sys., Ltd., 778 F.3d 775 (9th Cir. 2015).

41. *Cases and Proceedings*, FED. TRADE COMM'N, <https://www.ftc.gov/enforcement/cases-proceedings/121-0069/st-lukes-health-system-ltd-saltzer-medical-group-pa> (last visited Oct. 1, 2017).

The federal district court enjoined the merger and ordered a full divestiture.⁴² The Ninth Circuit Court of Appeals affirmed, noting that while the merger was intended and indeed would have led to improved patient outcomes, the district court had correctly stated that “the ‘huge market share’ of the post-merger entity ‘create[d] a substantial risk of anticompetitive price increases’ and that the post-merger efficiencies provided were not an adequate defense.”⁴³

Quality of care clearly lost out in the court’s balancing, but this article will explore why it did. To claim increased quality of care as an efficiency under current agency practice is to require a balancing of two different types of values: costs and health. Our antitrust vocabulary does not permit this. What is needed is to find, or create, a common measuring system.

The good news is that there is a branch of analysis which enables exactly the kind of analysis needed. To compare the impact of potentially increased costs with potentially increased health, one can either convert costs into health or measure increased health in terms of dollars. This method measures health care outcomes in terms of dollar costs, and it revolves around a basic concept: the Quality Adjusted Life Year (QALY).⁴⁴

III. AN INTRODUCTION TO THE QUALITY ADJUSTED LIFE YEAR (QALY)

In health care economics, the QALY is a pillar of cost-effectiveness analysis.⁴⁵ Put briefly, “[t]he QALY is a measure of survival time adjusted by the quality of that life.”⁴⁶ A good short form description is that “QALYs represent health over time.”⁴⁷ The QALY is measured on a scale of 0.0 to 1.0.⁴⁸ A year of perfect health provides 1.0 QALY.⁴⁹ A year at near death might provide 0.1 QALY.⁵⁰ The QALY concept, when properly applied, can “tell[] us the ‘price’ of buying more healthy years [of life] with a new [or different] treatment.”⁵¹ More important for the purposes here, it can also provide a way to convert better health into a quantified dollar measure, which can be balanced against projected harm from a provider merger.

42. *Saint Alphonsus Med. Ctr.-Nampa, Inc.*, 2014 WL 407446, at *26.

43. *Saint Alphonsus Med. Ctr.-Nampa, Inc.*, 778 F.3d at 782 (citing *Saint Alphonsus Med. Ctr.-Nampa, Inc.*, 2014 WL 407446, at *25).

44. See Oliver J. Wouters et al., *QALYs in Cost-Effectiveness Analysis: An Overview for Cardiologists*, 101 HEART 1868, 1868 (2015).

45. *Id.*

46. *Id.*

47. Peter J. Neumann & Dan Greenberg, *Is the United States Ready for QALYs?*, 28 HEALTH AFF. 1366, 1367 (2009).

48. Wouters et al., *supra* note 44, at 1868.

49. Neumann & Greenberg, *supra* note 47, at 1167.

50. *Id.*

51. Madeline Drexler, *Can Cost-Effective Healthcare = Better Healthcare?*, HARV. PUB. HEALTH (Winter 2010), <https://www.hsph.harvard.edu/news/magazine/winter10assessment/> (last visited Sept. 29, 2017).

So how much is a full QALY (a year of perfect health) worth? While there is a historical consensus around several figures and around how to derive them, there is no universally accepted number.⁵² The currently preferred approach seems to be based on a hypothetical person's willingness to pay for a given beneficial health outcome (in this case, a QALY).⁵³ In addition, baseline markers have become accepted as a matter of historical practice.⁵⁴ The base threshold in the United States is \$50,000 per QALY.⁵⁵ That number traces back to at least 1982 and is believed to have been derived from the cost at that time of dialysis treatment for patients with chronic renal failure—since such treatment is “a federal entitlement to all US citizens under Medicare.”⁵⁶ The argument was simply that “if the US government thinks that dialysis should be offered to all who need[ed] it, then interventions with similar or better cost-effectiveness should likewise be offered to everyone.”⁵⁷ The implicit assumption is that a year on dialysis is 1.0 QALY. Hence the value of that 1.0 QALY is the cost of that treatment: \$50,000.

One valuation approach attempts to measure willingness to pay for an additional year of a full healthy life, and there is much data on this issue alone.⁵⁸ One survey involved some “5500 respondents . . . from panels in six countries.”⁵⁹ The mathematics of the analysis is complicated (at least to lawyers). The U.S. value per QALY was computed to be \$62,000.⁶⁰ The Harvard economist David Cutler found that number too low and advocated for at least \$100,000 per QALY, based on two or three times the per capita annual income in the United States, as a more appropriate measure.⁶¹ And some health care researchers have pointed out that simply adjusting \$50,000 for inflation led to a QALY value of \$74,000 to \$95,000 in 1997 dollars.⁶²

52. Takeru Shiroiwa et al., *International Survey on Willingness to Pay (WTP) for One Additional QALY Gained: What Is the Threshold of Cost Effectiveness?*, 19 HEALTH ECON. 422, 422–23 (2010); Wouters et al., *supra* note 44, at 1872. As will be discussed *infra* in Section III, that imprecision is not fatal to the use of the concept. In most mergers, neither the costs nor the benefits can be accurately expressed with great precision. See DAN H. MCCORMICK, *NONPROFIT MERGERS: THE POWER OF SUCCESSFUL PARTNERSHIPS* 100 (2001).

53. Peter A. Ubel et al., *Commentary, What is the Price of Life and Why Doesn't It Increase at the Rate of Inflation?*, 163 ARCHIVES INTERNAL MED. 1637, 1638 (2003).

54. *See id.* at 1637–38.

55. Wouters et al., *supra* note 44, at 1872.

56. Ubel et al., *supra* note 53, at 1637.

57. *Id.*

58. *See* Shiroiwa et al., *supra* note 52, at 423, 425; *see also* Laura Vallejo-Torres et al., *On the Estimation of the Cost-Effectiveness Threshold: Why, What, How?*, 19 VALUE HEALTH 558, 558 (2016).

59. Shiroiwa et al., *supra* note 52, at 425.

60. *Id.* at 435.

61. Drexler, *supra* note 51.

62. Richard A. Hirth et al., *Willingness to Pay for a Quality-Adjusted Life Year: In Search of a Standard*, 20 MED. DECISION MAKING 251, 333 (2000).

The literature on the topic of computing QALYs is intimidating and deep with different studies done in different countries around the world and numerous subgroups and demographic breakdowns.⁶³ The conclusions reached supported the outcome in previous analyses, which suggested a range of “£20 000–£30 000 per QALY in the UK, or US\$ 50 000–100 000 per QALY in the US.”⁶⁴

In addition to the calculations, researchers have started moving from the realm of numbers to questions such as what quality of life is acceptable. These discussions are data driven and technical.⁶⁵ There is also work differentiating the value of a life-saving QALY from that of a quality-of-life-enhancing QALY.⁶⁶ While this seems complex at first, it shows that there has been an incredible amount of research and thought put into this area. It is difficult to defend ignoring the research simply because it is not what legal scholars are used to seeing.

Presume a QALY in the United States is valued at \$50,000 (or even \$50,000 to \$100,000). For the purposes here, the exact value of a QALY will only be relevant in a very narrow range of cases where the quantified harm exceeds the benefit when a QALY is valued at the lower bound (\$50,000), but the value exceeds the harm when the QALY is valued at the upper bound (\$100,000).

In this way, the QALY analysis is not used to determine whether an expense is justified but rather to determine whether a clinical benefit from provider consolidation outweighs a potential expense from decreasing provider competition.

In a merger analysis, there may be no need to pin down the exact value of a QALY (or the analysis can be run in the alternative at \$50,000 and \$100,000 per QALY to see if the outcome changes). The key is not the number but the concept of the QALY, which enables the transition from unquantified better health care to an analysis that converts health benefit to dollars. And those dollars, the projected benefit in cost-benefit analysis, can then be balanced against the projected harm from the merger—projected from the increase in HHI from the merger, which suggests a power to increase prices. The previously impossible task of balancing cost increases against quality improvement is now possible. Both sides of the equation are expressed in the same terms: dollars.

Before the analysis can be refined, some language in the ACA must be addressed. As a result of political concerns that the law would be seen as supporting a cost-benefit analysis to deny treatment to seniors or the disabled,

63. See Shiroiwa et al., *supra* note 52, at 434.

64. *Id.* at 431; accord Vallejo-Torres et al., *supra* note 58, at 558.

65. See, e.g., Wouters et al., *supra* note 44, at 1871 tbl. 1; Hirth et al., *supra* note 62, at 335–38; Sofie Wouters et al., *Are All Health Gains Equally Important? An Exploration of Acceptable Health as a Reference Point in Health Care Priority Setting*, 13 HEALTH & QUALITY LIFE OUTCOMES 1, 2 (2015).

66. See Cam Donaldson et al., *The Social Value of a QALY: Raising the Bar or Barring the Raise?*, 11 BMC HEALTH SERV. RES. 1, 4 tbl. 1, 6 (2011).

the ACA specifically bars: (1) the Patient Centered Outcomes Research Institute (PCORI) from the use of “dollars-per-quality adjusted life year (or similar measure that discounts the value of a life because of an individual’s disability) as a threshold to establish what type of health care is cost effective or recommended”;⁶⁷ and (2) the Secretary of Health and Human Services from the use of “clinical effectiveness research . . . in a manner that treats extending the life of an elderly, disabled, or terminally ill individual as of lower value than extending the life of an individual who is younger, nondisabled, or not terminally ill.”⁶⁸ This dose of political reality is a reminder that the QALY is merely a tool: a measuring device. It is not a prescription for any particular mode of conduct.

For example, if treatment for one year costs \$1.00, it produces 1.0 QALY in benefits, valued at \$50,000, it makes economic sense to have the treatment. Yet if the treatment costs \$1,000,000 and the benefit is still 1.0 QALY, it would be unwise economically to have the treatment. But neither case compels taking (or not taking) any action. Other factors—moral, political, or otherwise—may come into play and change the ultimate decision. In the case of the limitation on the use of QALYs in the ACA, what appears to have happened is that politics overrode economics in one narrow context.

Nothing in the ACA limits the use of cost-effectiveness data in analyzing a provider merger under the antitrust laws; nor is there any basis to extrapolate such a limitation. The ACA prohibitions on the use of the QALY concept are tightly targeted.⁶⁹ In one sense, even this narrow limitation is willful blindness, ignoring (by law) the lessons of economics. Yet as a reminder that economics is not the only value at stake, it is a perfectly rational moral judgment that economic efficiency must not lead to harming the most vulnerable populations. Regardless of how individuals view that argument, it seems clear that nothing in the law was meant to limit the use of QALY analysis to evaluate the benefits of a merger.

IV. NEW APPROACH

If the QALY provides a way to measure the benefit of actions or treatments, two factors must be addressed. First, there must be a dollar value assigned to a QALY, or else there is no way to compare the benefit of an action to the cost of that action. For example, if a merger of two hospitals will provide an added 100 QALYs as a result of higher cardiac surgical volume and better outcomes, how does that weigh against the potential higher cost per surgery due to the lack of

67. 42 U.S.C. § 1320e-1(e) (2012).

68. *Id.* § 1320e-1(c)(1).

69. They are limited to the Secretary of HHS, *id.* § 1320e-1(c)(1), and Patient Centered Outcomes Research Institute (PCORI), *id.* § 1320e-1(e).

competition from other area hospitals? Second, for evaluation, the number of QALYs added by the transaction must be calculated.⁷⁰

The objective here is to reverse engineer the merger analysis. Assume that two hospitals wish to merge. The antitrust authorities oppose the merger, claiming that it will increase costs through decreased market competition. The hospitals defend based on better quality of care, arguing that combining units will lead to a sufficient volume of procedures to increase quality and survival rates. This hypothetical can be broken down in four ways:

- (1) The authorities show a potential cost increase in a narrow market and reject any showing of benefits in any other markets. This is a traditional approach.⁷¹
- (2) The authorities show a potential cost increase in a narrow market, and the parties argue overall cost savings in the broader health care market (e.g., fewer readmissions, fewer trips to the emergency department, etc.). This is the approach suggested in my prior article.⁷²
- (3) The authorities show potential cost increase in a narrow market, and the parties argue increased health care quality (no quantification is offered). This approach does not succeed under current law.⁷³
- (4) The authorities show a potential cost increase in a narrow market. The parties argue increased health care quality, and they quantify it in terms of QALYs. This is what I am proposing.

If a QALY is valued at \$50,000 and if it can be demonstrated to whatever burden level is required (likely preponderance of the evidence in a civil case) that the merger will lead to an increase of 1000 QALYs, then that shows a potential fifty-million-dollar benefit from the merger. The government would have to quantify the proposed harm and show that it exceeds the proposed benefit in order to block the merger.

The United States has seldom, if ever, done this sort of Williamsonian balancing,⁷⁴ because most of the merger challenges are seeking injunctions

70. For purposes here the equation is simply $X = YZ$, where X is the net benefit, Y is the number of QALYs added as a result of the action at issue, and Z is the value of each QALY.

71. See U.S. DEP'T OF JUSTICE & FED. TRADE COMM'N, *supra* note 12, at 8.

72. Bernard, *supra* note 31, at 68.

73. See *supra* text accompanying notes 40–43. The courts recognized that the St. Luke's Hospital Systems merger was intended to and likely would have increased the quality of care. See *id.* But the lack of quantification of the benefit was fatal to the argument. See *id.*

74. See F.M. Scherer, *Merger Efficiencies and Competition Policy* 1–3 (Harvard Kennedy School, Working Paper No. RWP12-048, 2012), https://dash.harvard.edu/bitstream/handle/1/9830356/RWP12-048_Scherer.pdf?sequence=1; see also Carl Shapiro, *A Tribute to Oliver Williamson: Antitrust Economics*, 52 CAL. MGMT. REV. 138, 140–41 (2010) (explaining that the “Williamson tradeoff” in merger analysis is a model which shows that “a relatively modest cost savings would be sufficient to offset rather large price increase, if the ultimate objective of merger analysis is to

against the merger and the harm is not quantified. In Canada, however, the Competition Act provides specifically for a balancing process if the defendants show that the efficiency gains offset the anticipated losses.⁷⁵ U.S. law is flexible enough to allow such an approach as well, and, indeed, the 2010 Horizontal Merger Guidelines contemplate this in Section 5.⁷⁶

Approaches (1), (2), and (3) above deal with costs in the current environment—measured in expenditures for health care services. These approaches suggest spending money in one market saves more money in an adjacent market. But does that entail excluding quality of outcome analysis entirely? Is there a broader issue eclipsed by the narrow focus?

V. QUANTIFYING AND WEIGHING MERGER BENEFITS AND HARM

It is debatable how much better health care outcomes are *worth*, but those better outcomes are the point of the whole system. The approach here is relatively simple to describe, although it may be extremely difficult to prove in any given case. But it enables, for perhaps the first time, arguing for improved quality of care as a quantifiable benefit from a merger and for assigning a dollar value to that benefit.

As noted earlier, the QALY is designed to measure the cost-effectiveness of actions or treatments and to give a numerical dollar value to better health. Combining this potential quantification of benefits with the strong evidence that, in some cases, concentration and consolidation lead to better health outcomes,⁷⁷ there is a real incentive to use those improved outcomes as a counter-balance against the projected added costs resulting from the consolidation.

Use of the QALY concept in antitrust merger analysis is new. In fact, the whole field of health economics seems to be alien to merger law and practice. Given the importance of health care to the economy and the changes urged by the current law and practice, this inadvertent exclusion of an entire field of research and data seems unjustified. But quantification of benefit is only one side of the equation. There must be a way to quantify the anticipated harm.

Most merger cases are litigated through the application for an injunction by the government.⁷⁸ A court is required to “weigh[] the equities and consider[] the

maximize total surplus, . . . [yet today] [m]odern merger analysis generally involves looking at consumer surplus rather than total surplus”).

75. James Musgrove et al., *Tervita Corp v Canada – The Supreme Court of Canada’s First Merger Decision in 17 Years: An Efficient Outcome*, MCMILLAN COMPETITION BULL. 11–12 (Jan. 2015), http://www.mcmillan.ca/Files/179210_Tervita%20Corp%20v%20Canada.pdf.

76. U.S. DEP’T OF JUSTICE & FED. TRADE COMM’N, *supra* note 12, at 15–19.

77. In some cases, consolidation leads to better outcomes by creating units large enough to have a sufficient number of a given procedure to develop the sought for skill and outcome levels. *See supra* text accompanying notes 13–18.

78. *See, e.g.*, Fed. Trade Comm’n v. Penn State Hershey Med. Ctr., 838 F.3d 327, 337 (3d Cir. 2016).

Commission's likelihood of ultimate success" to determine if an injunction would serve the public's interest.⁷⁹

Whether framed in terms of overall health care expenditures and savings or in the language of QALYs, the benefit in the above example is reducible to a dollar figure. A court must then balance the potential benefit against the potential harm from the increased market concentration resulting from the merger.⁸⁰ But the potential harm from increased concentration is quantified in a narrowly-defined market by an HHI, not by a dollar measure.⁸¹ There may be a high HHI in a narrowly defined market but no dollar measure of that potential harm. It is somewhat ironic to be in a situation where the efficiencies are cognizable, but the potential harm really is not. What is needed to complete the analysis is a way to quantify the anticipated harm.

The issue of quantifying harm and benefit has been percolating in Canada, where the Competition Act explicitly provides for an efficiencies defense, which requires the weighing and balancing of costs and benefits.⁸² The Canadian courts also seem to have adopted a total welfare approach, at least to the extent that "the claimed cost savings do not have to be in the same market as the anticompetitive effects in order for the efficiencies to be part of the tradeoff analysis."⁸³

In the recent case of *Tervita Corp.*, the Supreme Court of Canada reversed a finding of a competition law violation resulting from a merger.⁸⁴ While the court found abundant evidence that the transaction likely resulted in prevention of competition, it also held that was not the correct stopping point.⁸⁵ It noted that Section 96 of the Competition Act requires a conscious balancing of harm and benefit.⁸⁶ The case did not deal with health care at all,⁸⁷ so the holding is only

79. 15 U.S.C. § 53(b)(2) (2012).

80. *The Merger Guidelines and the Integration of Efficiencies into Antitrust Review of Horizontal Mergers*, U.S. DEP'T OF JUSTICE, <https://www.justice.gov/archives/atr/merger-guidelines-and-integration-efficiencies-antitrust-review-horizontal-mergers> (last visited Sept. 30, 2017).

81. See, e.g., *Penn State Hershey Med. Ctr.*, 838 F.3d at 346–47.

82. Competition Act, R.S.C. 1985, c. C-34, s. 96 (Can.); see also Margaret Sanderson, *Efficiency Analysis in Canadian Merger Cases*, 65 ANTITRUST L.J. 623, 625 (1997).

83. Sanderson, *supra* note 82, at 632.

84. *Tervita Corp. v. Comm'n of Competition*, [2015] 1 S.C.R. 161, 230, para. 1 (Can.). The history is somewhat convoluted. The Canadian Commissioner of Competition challenged the completed acquisition by Tervita of a hazardous landfill site, alleging that but for the acquisition someone else would have bought the site and run it in competition with Tervita. *Id.* at 174–75, para. 1. The Competition Tribunal upheld the Commissioner challenge and rejected the efficiencies defense put forward by Tervita on the basis that gains were not likely to offset the anti-competitive effects from the transaction. *Id.* at 177, para. 10. The Federal Court of Appeal upheld the Tribunal decision, rejecting the efficiency defense on the ground that any efficiency gains were marginal and insignificant. *Id.* at 182, para. 31. The Supreme Court of Canada reversed. *Id.* at 230, para. 1.

85. *Id.* at 199, para. 83.

86. *Id.* at 202, para. 90.

87. *Id.* at 174–75, paras. 1, 2.

suggestive for our purposes. But it is instructive nonetheless. The Canadian court held that the Commissioner of Competition had to quantify all anti-competitive effects that were quantifiable.⁸⁸ Any effects that were reasonably measurable could not be considered on a qualitative basis if no quantitative evidence was provided.⁸⁹ Since the Commissioner failed to provide measurements of the quantifiable anti-competitive effects, even small, quantified efficiency gains from the merger were sufficient to offset the unquantified anti-competitive effects alleged.⁹⁰

In one sense, this was an easy example. The government was required to quantify the harm wherever possible but failed to do so. To balance harm and benefit in U.S. health care provider cases, one must look at how the harm could be quantified. One possible approach can be derived from the FTC's victory in the first *Staples* case.⁹¹ In that case, there was evidence that for a sample accounting for ninety percent of Staples' sales, its prices were thirteen percent higher in markets where Staples had neither an Office Depot or an OfficeMax store (as opposed to markets where it had both as competitors).⁹² Multiplying the price differential by the sales volume yielded a first estimate of quantified damages. Under this proposal, the defendants would then be allowed to set out quantified efficiencies, and the court would strike a balance.⁹³ The process of quantifying harm can be difficult. In the United States, antitrust enforcement agencies generally have not been required to take such a step. But if the merging parties can quantify the benefits from the proposed transaction, then the enforcement agencies should not be allowed to rely on unquantified or unmeasured presumptions of harm.

VI. CONCLUSION

In my previous article, I suggested a straightforward approach to determining if the net effects of a health care supplier merger were anti-competitive.⁹⁴ It simply suggested removing market definition blinders to consider the argument that while a merger might allow for increased costs in one area of the health care universe (e.g., primary care physician services), it might reduce costs by an even greater amount in an adjacent market (e.g., hospital services).⁹⁵ While issues such as quantum of proof remain, the suggested

88. *Id.* at 212, para. 124.

89. *Tervita Corp.*, 1 S.C.R. at 212, para. 124.

90. *Id.* at 166.

91. *Fed. Trade Comm'n v. Staples, Inc.*, 970 F. Supp. 1066, 1093 (D.D.C. 1997).

92. *Id.* at 1075–76.

93. Issues of timing and duration of pricing are set aside for the moment. They raise factual complications but do not change the underlying analytical basis.

94. *See Bernard, supra* note 31, at 68.

95. *Id.* at 70.

approach could be implemented by regulatory agencies and courts tomorrow with minimal disruption of current practices.

The concepts in this article represent more of a radical shift for competition lawyers. Specifically, it advocates a wholesale integration of certain health care economics concepts into antitrust analysis. Neither the concepts, nor their applications, are simple. There are debates among health care economists about the proper calculation and use of QALYs. Here, it is enough to recognize that the proposed analysis provides tools that quantify the idea of better health care. This facilitates balancing a better health care outcome against the costs to attain it. This is part of what the National Health Service tries to do in the U.K.,⁹⁶ and the QALY concept is being used around the world to determine the cost-effectiveness of medical treatments of all kinds.

There is no a priori reason for competition law to ignore this vast body of research in trying to determine the positive or negative economic impact of a merger transaction. That said, making the case that a transaction is net beneficial based on the number and value of QALYs added (and that this is a greater dollar amount than the potential cost increase from the transaction) is a very difficult problem. But it is a problem worth solving. It provides a way to make a case-by-case determination of the proper balance between the lower costs generated with a large number of competing suppliers against the better clinical outcomes generated with a smaller number of suppliers performing a higher volume of the procedure in question. It lets the U.S. courts and agencies move towards an intelligent weighing of care and cost, which should be the ultimate goal of antitrust in health care provider merger analysis.

96. See, e.g., Cooper Hartwell et al., *The Clinical Effectiveness and Cost-Effectiveness of Peginterferon Alfa and Ribavirin for the Treatment of Chronic Hepatitis C in Children and Young People: A Systematic Review and Economic Evaluation*, 18 HEALTH TECH. ASSESSMENT (2014).

