
# Integrating healthcare quality concerns into a competition law analysis: *Mission impossible?*

Theodosia Stavroulaki

Thesis submitted for assessment with a view to obtaining
the degree of Doctor of Laws of the European University Institute

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European University Institute
**Department of Law**

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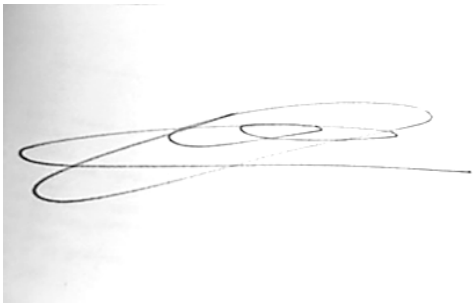

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*...Rise Up With Me Against*

*The Organization of Misery...*

Sir Michael Marmot

*The Health Gap: The Challenge of an Unequal World*,

Pablo Neruda

# Abstract

Healthcare markets have started being created in Europe. Indeed, some European countries, such as the UK and the Netherlands, have started adopting the *choice and competition model* for healthcare delivery. Taking as a starting point that as health systems in Europe move towards market driven healthcare delivery, the application of competition law in these systems will increase, the goal of this doctoral thesis is (a) to identify some of the competition problems that may be raised in light of the reality that especially in hospital and medical markets the pursuit of competition and the pursuit of essential dimensions of healthcare quality may inevitably clash (b) to demonstrate that competition authorities would be unable to address some of these competition problems if they did not pose and address a fundamental question first: how should we define and assess quality in healthcare? How should we take healthcare quality into account in the context of a competition analysis? In delving into these questions, this doctoral thesis explores how the notion of healthcare quality is defined from antitrust, health policy and medicine perspectives and identifies three different models under which competition authorities may actually assess how a specific anticompetitive agreement or hospital merger may impact on healthcare quality. These are: (a) the *US market approach* under which competition authorities may define quality in healthcare strictly as choice, variety, competition and innovation (b) the *European approach* under which competition authorities may extend the notion of consumer welfare in healthcare so that it encompasses not only the notions of efficiency, choice and innovation, but also the wider objectives and values European health systems in fact pursue (c) the *UK model* under which competition authorities may cooperate with health authorities when they assess the impact of a specific transaction on healthcare quality. The thesis identifies the main merits and shortcomings of these models and emphasizes that what is crucial for the adoption of a holistic approach to healthcare quality is not only the model under which healthcare quality is actually integrated into a competition analysis but also competition authorities' commitment to protect all dimensions of this notion.

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# Introduction

## 1. Setting the stage: Background and the Research Question

Healthcare markets have started being created in Europe. Indeed, some European countries, such as the UK and the Netherlands, have started adopting the *choice and competition model* for healthcare delivery. This model is mainly based on the quasi-market system[1] where patients can choose and the money follows the patients.[2] This model introduces external incentives, and patients (or insurance companies) can choose providers on the basis of quality information.[3] The choice and competition model is one of the four fundamental models for delivering public services. The others are models that (a) rely on *trust*, when professionals and others who work in public services are simply trusted to deliver good service, with no interference from the government or anyone else (b) use *command and control* or else *hierarchy*, where the state or the agency of the state engages in services delivery though managerial hierarchy in which senior managers give orders or instruction concerning delivery to subordinates (c) rely *upon voice*, where users try to get a good service, by communicating their views directly to providers in various ways.[4]

*What are the main facets of the choice and competition model?* Generally, competition in the public service is the presence of a number of providers, each of which for one reason or another are motivated to attract users of the particular service.[5] This is to be contrasted with a unitary or monopoly service, where there is only one provider that has to be used by everyone who wishes to receive the service.[6] Especially with regards to health services, competition can actually take two

[1] Quasi markets are markets where the provision of a service is undertaken by competitive providers as in pure markets, but where the purchasers of the service are financed from resources provided by the state instead of from their own private resources, G. Le Grand, 'Quasi-Market versus State Provision of Public Services: Some Ethical Considerations', (2011) 3 (2) *Public Reason*, 80-89.
[2] S. Nuti, F. Vola, A. Bonini, and M. Vainieri, 'Making governance work in the health care sector: evidence from a 'natural experiment' in Italy' (2016) 11, *Health Economics, Policy and Law*, 18.
[3] *Ibid.*
[4] G. Le Grand, *The Other Invisible hand, Delivering Public Services through Choice and Competition* (Princeton University Press, 2007), 14.
[5] *Ibid*, 41.
[6] *Ibid.*

main forms: *Competition in the market* which is the most commonly recognized form of competition, with several providers making alternatives available to those who decide what to consume[7] and *competition for the market* where several providers compete for the right to provide a service or good.[8] Importantly, while the notions of choice and competition are highly related, they are not identical. This is because patient choice may also exist without competition between health care providers. Providers for example can be heterogeneous at the eyes of patients by some exogenous characteristic, such as geographic location and choice of patients be exerted over that.[9] This, however, is usually not the case. Choice in most of cases is combined with competition.[10]

*Why do health systems in Europe move towards market driven healthcare delivery?* EU health systems aim to meet a range of goals, among which the following have a high degree of importance: (a) equitable access to improved quality of care (b) cost-effectiveness in service organization and delivery and (c) transparency and accountability.[11] These systems, however, also share common concerns, notably increasing costs that are due mainly to three factors: rising life spans, increasing expectations and technological developments.[12] Undoubtedly, while these factors improve the quality of life of EU citizens and contribute to health improvements, they also constrain national health budgets. In this light, some countries in Europe have started to experiment to some degree with market delivery of healthcare services as a device to control the cost of healthcare services.[13]

Competition is also seen as a solution to problems that government-run and regulated health systems did not solve.[14] In the Netherlands, for example, health reforms were designed to

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[7] European Commission, Expert Panel on Effective Ways on Investing in Health (EXPH), 'Competition among health care providers, Investigating policy options in the European Union', The EXPH adopted this opinion at the 10th plenary meeting of 7 May 2015 after public consultation, 31.
[8] *Ibid*, 26.
[9] *Ibid*, 24.
[10] *Ibid.*
[11] European Commission*, supra n.* 7, at 14-15.
[12] W. Sauter 'The Impact of EU Competition Law on National Healthcare Systems' (2013) 38(4) *European Law Review* 457, 458.
[13] *Ibid.*
[14] European Commission, *supra* n. 7, at 15.

counter widespread public dissatisfaction with lengthening waiting lists.[15] The same can also be said for the UK.[16]

Seeing competition as a solution to improve healthcare performance reflects also J. Le Grand's views that the choice and competition model for healthcare delivery can improve the quality, efficiency and responsiveness of a health system.[17] If the money follows the choice, Le Grand argues, providers will be strongly incentivized to improve the quality and responsiveness of their services as well as the efficiency with which they are delivered.[18] Le Grand points out equity will be also promoted, because under this model the less well - off will also be entitled to choose and exit, if necessary. Nonetheless, for the choice and competition model to optimally work, Le Grand warns, specific conditions must be met. According to him these are: (a) there have to be alternative providers from which to choose, (b) there have to be easy ways for new providers to enter the market and correspondingly for failing providers to leave or exit from it (c) there have to be ways of preventing existing providers engaging in anticompetitive behaviour.[19] In other words, the competition *must be real.*

*The role of competition in healthcare is a much - debated issue.* Critiques of the choice and competition model in healthcare point to the lack of genuine competition in the real world, the difficulty of providing information of a good enough quality to patients to enable them to make sensible choices,[20] and that patients do not necessarily have the ability and the knowledge to make choices that will improve their welfare. They further warn that the risk of cream skimming is a serious one and that introducing the choice and competition model as a means to improve efficiency may raise serious equity concerns. In brief, the argument is that the introduction of the choice and competition model for delivering public services may harm a health system's healthcare quality,

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[15] W. Sauter 'The role of competition rules in the context of healthcare reform in the Netherlands' *TILEC Discussion Paper* No. 2010-004, 4.
[16] C. Propper, S. Burgess and D. Gossage, 'Competition and Quality: Evidence from the NHS Internal Market 1991-9', (2008) 118(525) *The Economic Journal*, 138, 139.
[17] G. Le Grand, *supra* n. 4, at 98.
[18] *Ibid.*
[19] *Ibid*, 106.
[20] J. Le Grand, 'Choice and Competition in publicly funded healthcare', (2009) 4(4) *Health Economics, Policy and the Law*, 480.

defined from health policy perspective as a multidimensional concept encompassing the notions of safety, access, equity, continuity, effectiveness.

In contributing to this debate, this doctoral thesis demonstrates that Le Grand's conditions reflect the idiosyncratic features and the special character of healthcare markets only partially and that the risk that the introduction of the choice and competition model in healthcare services may harm key facets of healthcare quality *is a real one*. Nonetheless, it should be clarified that the primary goal of this thesis is not to take a stance on whether competition in healthcare provision is good or bad. This study's focus is much narrower. Taking as a starting point that as health systems in Europe move towards market driven healthcare delivery, the application of competition law in these systems will increase, the goal of this thesis is (a) to identify some of the competition problems that may be raised in light of the reality that especially in hospital and medical markets the pursuit of competition and the pursuit of essential dimensions of healthcare quality may inevitably *clash* (b) to demonstrate that in addressing some of these problems, Competition Authorities may inevitably have to balance the goals of choice and competition against key aspects of healthcare quality, such as safety, equity and access. *Why*?

As discussed, Le Grand speaks about easy exit when he identifies the conditions under which the choice and competition model should apply in healthcare. Nonetheless, proposing easy exit as a means to improve efficiency and quality may inevitably harm access and equity. Indeed, considering the high barriers to entry that characterize healthcare markets, this danger is real. *Should competition authorities allow a hospital merger although it leads to market power on the basis it will ensure the financial stability of the merging parties and will guarantee access to health services in rural and disadvantages areas*? Second, Le Grand suggests that for the choice and competition model to bring its benefits there have to be alternative providers from which to choose.[21] In other words, to Le Grand, the more the players, the higher the quality. Nonetheless, health policy researchers often tell a different story. Especially when hospital mergers are at issue, they insist that in specific cases hospital consolidation, not competition, brings quality improvements. For example, a merger increases patient volumes for hospital providers. In light of medical research showing a relationship between procedure volumes

[21] *Ibid*, 485.

and patient volumes, the higher volumes a merger brings can enhance the overall quality of the services provided.[22] *Should competition authorities clear a hospital merger although it increases market power in the relevant market because it increases safety?*

GPs in the Netherlands and the UK also do not only offer their medical services but they act as gate-keepers too. Therefore, they refer patients to hospitals for treatment. Because of their medical expertise, medical professionals often perceive themselves as the guardians of healthcare quality. To them, professional discretion and freedom are the necessary conditions for the protection of healthcare quality and not choice and competition. Assessing healthcare quality through this lens, they often feel that they are entitled to intervene in the healthcare markets they operate in order to correct the market failures pervading them and guarantee quality. They may, for instance, agree to boycott hospitals that do not meet their standards of healthcare quality. *Should competition authorities be allowed to balance restrictions of choice and competition against the goal of safety?*

Competition Authorities would be unable to adequately examine these questions if they had not previously explored how they should define and assess quality. In this light, this doctoral thesis poses a fundamental question that seeks to investigate: *how can the application of competition law in healthcare take into account healthcare quality?*

## 2. The Hypothesis and Methodology

This study demonstrates that the question of how to define and assess healthcare quality in the context of a competition analysis is a challenging one. Generally, quality plays a central role in competition analysis. Indicatively, the Commission's Guidelines regarding Horizontal Cooperation Agreements emphasize that for an agreement to have restrictive effects on competition within the meaning of Article 101(1) TFEU it must have, or be likely to have, an appreciable *adverse impact on at least one of the parameters of competition on the market, such as price, output, product quality, product variety or innovation*.[23] Although quality is not specifically defined in the Commission's Guidelines and Notices,

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[22] K. Madison, 'Hospital Mergers in an Era of Quality Improvement', (2007) 7 *Hous. J. Health L. & Policy* 265, 276.
[23] Communication from the Commission, Guidelines on the applicability of Article 101 of the Treaty on the Functioning of the European Union to Horizontal Co-operation Agreements (Text with EEA relevance) 2011/C 11/01, para 3.

it is a concept that is highly related with the notions of *innovation, choice and product entry*.[24] Seeing quality as a notion that mainly relates to choice and innovation is in line with the central mantra of competition policy that competition market forces, besides lowering prices, can increase efficiency, product quality and ultimately consumer's welfare.[25] The thesis' hypothesis is that if competition authorities defined and perceived quality in the healthcare sector as choice, competition and innovation they may fail to take into account the notion of *healthcare quality as a whole*. More specifically, if competition authorities adopted this approach, which the thesis calls '*the market approach',* they may fail to integrate into their analysis the insight of medicine and health policy research on how healthcare quality is defined and achieved. Additionally, a competition analysis that assesses healthcare quality strictly as choice, competition and innovation may not fully reflect the economic characteristics of healthcare markets and may disregard the insights of behavioral economics research pointing out that in healthcare markets consumers do not necessarily have the ability and knowledge to construct choices that improve their welfare. More importantly, if competition authorities adopted this *market approach*, they may apply competition law in healthcare in a way that disregards the main objectives of their health systems. In testing this hypothesis, the thesis uses as a case study the *US antitrust approach in healthcare*. I chose this case study not only because in the US health care provision is mainly based on the market rationale. I also chose it because (a) the health care market in the United States is subject to competition legislation that is applicable across all sectors of the economy and health care is covered by the Federal Trade Commission (FTC), the general competition authority, and the Department of Justice (b) the US antitrust law remains faithful to the belief that more competition will generally ensure quality and social objectives such as equity should not become part of the antitrust agenda.

In seeking alternative solutions, the thesis identifies two additional approaches under which healthcare quality concerns may be integrated into a competition analysis. Competition Authorities in Europe, for example, may choose to *widen the notion of consumer welfare* in healthcare by integrating into their definition the views of medical professionals and health policy researchers on how healthcare quality is assessed and achieved. In other words, in line with the health policy perspective,

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[24] DAF/COMP(2013)17 'Roundtable on the role and the measurement of quality in competition analysis', Note by the European Union, para 17.
[25] A. Ezrachi, M. E. Stucke, 'The Curious Case of Competition and Quality' (2015) 3 *Journal of Antitrust Enforcement*, 227.

they might define quality in healthcare as a multidimensional concept consisting of the goals of efficiency, equity, acceptability, access, safety, effectiveness. This, the thesis calls, the *European approach*. I chose this term because European health systems animated by the belief that entities such as health derive equity significance from their ability to enable people to flourish, they are dedicated to protecting equity and access to health services. Therefore, European Competition authorities may be tempted to choose this approach. In attempting to strike the appropriate balance between the goals of competition and the protection of healthcare quality, Competition Authorities may also choose to cooperate with health authorities when they assess the impact of a transaction, e.g. merger or an agreement on healthcare quality. Since following the introduction of the Health and Social Care Act of 2012 (HSCA 2012), a similar model has been adopted in the UK when NHS hospital mergers are at stake, the thesis calls this option *the UK approach*.[26]

The thesis does not aim to propose that a particular approach is better than others. In contrast, it aims to expose the advantages and limits of each approach. To reach this goal the thesis examines some article 101 TFEU (or in the US context section 1 of the Sherman Act) and merger cases that involve horizontal restraints in medical and hospital markets mainly in the US and in the UK. I chose to focus mainly on horizontal restraint cases in these markets considering the rich body of case law in these markets especially in the US.

In delving into the thesis' research question, testing the hypothesis and identifying the approaches under which competition authorities in Europe may integrate healthcare quality concerns into their analysis, I did not employ only a doctrinal analysis. I also conducted empirical research in the US. In 2015, after receiving an award from the Antitrust Section of the American Bar Association I had the opportunity to spend three months in the US and conduct interviews with officials from the FTC and numerous scholars and experts in the area of healthcare antitrust. This three - month interaction with the US antitrust community allowed me to better understand how healthcare markets work and what their limits are. It also allowed me to identify the challenges antitrust enforcers face in applying competition law in healthcare with an eye to protect healthcare

[26] A similar model has been adopted in the Netherlands. For the purposes of the thesis the Dutch model will not be thoroughly analyzed as a separate case study mainly due to language restrictions.

quality. Undoubtedly, the practical insight I gained though this experience enriched and expanded the findings of this study significantly.

## 3. Contribution to the field

This doctoral thesis builds its arguments inspired by three fields: health policy and economics, moral philosophy and competition law:

As noted, this doctoral thesis' research question is how healthcare quality can be taken into account in the context of a competition law analysis. Undoubtedly, exploring this question requires an adequate understanding of the healthcare quality notion. For this reason, the thesis departs from the seminal work of Avedis Donabedian, physician and founder of the study of quality in health care and medical outcomes research who sees healthcare quality as a multidimensional concept whose main facets are, among others, effectiveness, efficiency, acceptability, equity. In exploring how the choice and competition model in healthcare works and explaining the increasing adoption of this model at EU level, this study particularly focuses on J. Le Grand's research who has extensively written on the main merits of the choice and competition model in healthcare and its ability to bring quality improvements in healthcare services. This thesis' main goal is not to explore the general merits or demerits of this model but to examine and discuss how the application of this model in healthcare may conflict with essential dimensions of healthcare quality. To this end, the thesis engages with the health economics literature demonstrating that given the market imperfections pervading healthcare markets, the belief that markets in healthcare always and necessarily improve healthcare quality should not be unquestioned. Inspired also by the voices of Debra Satz, Michael Sandel and Elizabeth Anderson, this doctoral thesis indicates that healthcare markets may also harm the moral values that apply in medicine and may undermine the notion of trust in the doctor – patient relationship, an essential determinant in health outcomes. The thesis also tests Le Grand's narrative that the introduction of the choice and competition model in healthcare will necessarily lead to quality improvements by bringing to the fore the insight of behavioral economics research highlighting that especially in healthcare consumers face serious difficulties in choosing healthcare providers or medical treatment and as a result more choice does not necessarily imply better outcomes.

Again, I clarify that the main goal of this doctoral thesis is not to take a stance on whether competition in healthcare is either good or bad. In contrast, this study aims (a) to identify the competition problems that may arise in hospital and medical markets in light of the reality that the pursuit of choice and competition in healthcare may be incompatible with the pursuit of essential dimensions of healthcare quality and (b) to analyze how competition authorities can assess and take into account healthcare quality concerns when they address these problems.

These issues, albeit important, both form competition law and health policy perspectives are highly underexplored in Europe. This is because so far the literature on the application of competition law in healthcare has mainly focused on the question of whether and under what rules EU competition law applies in national health systems. Lear, Mossialos and Karl, for example, by examining how the application of competition law has developed so far across Europe point to the fact that the gradual introduction of market forces to particular health services in Europe exposes healthcare providers to the application of competition law.[27] Odudu's research in healthcare has a narrower focus as it mainly concerns the application of competition law in the UK healthcare sector. Odudu has examined the question of whether NHS hospitals are undertakings.[28] Concluding that rarely will medical service providers fall outside the scope of the concept of an undertaking, Odudu argues that attention should now turn to the development and articulation of the procedural rules and remedies suitable for the sector and the reasons why certain services may not be provided in a socially desirable manner without exemption from the competition rules.[29] Van de Gronden and Sauter have also examined whether and under what conditions healthcare providers are considered undertakings.[30] The authors have raised the concern that in the healthcare sector where the pursuit of social objectives is at stake, the antitrust enforcers that apply competition law in this sector may inevitably have to balance these objectives against the goal of competition. Nonetheless, neither do they specify these objectives nor do they examine how these objectives should be taken into account

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[27] J. Lear, E. Mossialos and B. Karl, EU Competition law and Health Policy' in E. Mossialos, G. Permanand, R. Baeten and T. Hervey (eds) in *Health systems governance in Europe: the role of European Union law and policy* (Cambridge, Cambridge University Press, 2010)

[28] O. Odudu, 'Are state owned healthcare providers undertakings subject to competition law?' (2011) 32 *European Competition law Review*, 231.

[29] *Ibid.*

[30] L. Hancher and W. Sauter, *EU Competition and Internal Market Law in the Healthcare Sector* (Oxford, Oxford University Press, 2012) 225-239.

by competition law. Sauter has extensively researched on the application of competition law in the Dutch healthcare sector.[31] His research mainly focuses on how the model of choice and competition has been introduced in the Netherlands and what the main facets of the Dutch sector specific regulation are. Sauter and Canoy have also examined the Dutch experience of hospital mergers.[32] In their work they specify cases in the Netherlands where the Dutch competition authority faced the question of whether it should clear a merger on the basis that the examined merger would guarantee quality. Their analysis, however, does not examine how healthcare quality should be defined and how it should be taken into account by competition authorities when clashes between the goals of competition and the objective of healthcare quality come to the fore. [33] Undoubtedly, the literature in the US in the relevant field is richer.[34] This literature mainly examines how healthcare quality concerns have been raised in the context of some US antitrust cases and how and to what extent the FTC and the US Courts have taken these concerns into account. Nonetheless, this literature has not shined a light on the issue of whether defining quality strictly as choice, competition and innovation may not be in line with the economic characteristics of healthcare markets and the policy goals health systems pursue.

Given the limited attention that has been devoted by literature to the notion of healthcare quality and the question of how it can be taken into account in the context of a competition assessment, the thesis aims to fill an important gap in the existing literature. Nonetheless, it should be noted that the novelty of this thesis does not only rest on the questions it raises but also on the way it examines them. Indeed, this thesis premised on the idea that antitrust enforcers may not protect healthcare quality *as a whole* if they do not transform the way they assess and evaluate quality

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31 W. Sauter, 'Experiences from the Netherlands; The application of competition rules in healthcare' in M. Krajewski, J. Willem Gronden, E. M. Szyszczak, U. Bøegh Henriksen (eds.) *Healthcare and EU Law,* 337.

32 M. Canoy, W. Sauter, 'Hospital Mergers and the Public Interest: Recent Developments in the Netherlands' TILEC DP 2009-035, 1-10.

33 *Ibid*, 7-8.

34 For example see, P. J. Hammer and W. M. Sage, Antitrust, Health Care Quality, and the Courts, (2002) 102 *Columbia Law Review,* 545, T. Greaney, 'Quality of care an market failure: Defenses in antitrust healthcare litigation' (2000) 21 *Connecticut Law Review*, 605, T. Kauper, 'The Role of Quality of Health Care Considerations in Antitrust Analysis' (1988) 51 Contemp Probs 273, P.J. Hammer, 'Antitrust beyond Competition: *Market Failures*, Total Welfare, and the Challenge of Intramarket Second-Best Tradeoffs' (2000) 98 *Mich . L . Rev.* 849, D. Hyman, 'Five Reasons Why Health Care Quality Research Hasn't Affected Competition Law and Policy' (2004) 4 *International Journal of Health Care Finance and Economics,* 159.

in the healthcare sector integrates in its analysis the perspectives and voices of antitrust enforcers, medical professionals and health policy makers on how healthcare quality should be protected and assessed. In sum, adopting a *holistic approach* to the notion of healthcare quality, this study connects the dots between three different disciplines: medicine, health policy and antitrust.

## 4. The structure of the thesis

This doctoral thesis is organized as follows:

Chapter I provides a thorough analysis of the most influential definitions of healthcare quality. It examines how healthcare quality is measured and assessed. This chapter underlines that the choice of the main dimensions of healthcare quality is critical as this choice would inevitably influence the main policies regulators and health policy makers would implement and adopt. Additionally, it raises the claim that health care quality can be pursued only to the extent all key players in a health system commit to the wider quality objectives the system pursues *as a whole*. This is because although all participants in a healthcare system pursue quality at different levels and through different perspectives, their responsibilities in ensuring quality are in fact correlated.

Chapter II critically examines the main narrative of some health economists and health policy makers that the choice and competition model for providing healthcare will necessarily improve healthcare quality. This chapter demonstrates that under this model, specific aspects of healthcare quality, such as equity and continuity may in fact be harmed. Importantly, this chapter also identifies some competition problems that might be raised in light of the reality that in medical and hospital markets the goal of competition and the goal of healthcare quality may inevitably clash. In accommodating these conflicts this chapter identifies three main policy options under which competition authorities can take into account healthcare quality: (a) *the market approach* under which healthcare quality is defined as choice, innovation and competition (b) the *European approach* under which healthcare quality is considered a multidimensional concept consisting of multiple health policy objectives (c) the *UK approach* under which Competition Authorities cooperate with health authorities when they assess the impact of a merger on healthcare quality.

Chapters III and IV test this thesis' main hypothesis. Chapter III by examining some US antitrust cases that involve breaches of antitrust law by medical associations identifies how the FTC

and the US Courts conceive healthcare quality and how they respond to medical professionals' claims that their anticompetitive behaviour is necessary for the protection of healthcare quality. This chapter shows that in assessing these claims the antitrust enforcers remain faithful to the dogma that healthcare quality is ensured only to the extent choice and competition are ensured. This chapter points to the merits and weaknesses of this approach and proposes that only if the US antitrust enforcers applied a less formalistic approach they could take into account the notion of healthcare quality *as a whole*.

Chapter IV, by analyzing the applicable framework for hospital mergers in the United States and by examining the main US hospital merger cases where quality claims were addressed and examined asks: How do the US antitrust enforcers and the courts perceive quality of care? What are the quality dimensions they actually value? It highlights that the FTC and the US courts, by focusing on the price concerns of hospital mergers and by retelling the story that vigorous competition will necessarily ensure healthcare quality ignore the perspective of healthcare quality research indicating that in healthcare under special conditions, consolidation, coordination and integration may lead to quality improvements and not vigorous antitrust. Most importantly, they might ban mergers that may in fact contribute to the US health policy objectives of more integrated and coordinated care.

Chapter V raises the crucial question of whether Competition Authorities in Europe should extend the notion of consumer welfare when they apply competition law in healthcare in order to protect the notion of healthcare quality *as a whole* and ensure that their competition analysis is in line with the policy objectives their health systems continuously aim to meet. It also examines how and under what techniques competition authorities may extend the notion of consumer welfare in healthcare so that they can balance potential conflicts between the goal of competition and the non-economic facets of healthcare quality. It concludes that both under the more economic approach of European Commission as well as the more pluralistic approach of European Courts, *this mission is possible*.

Chapter VI analyzes a different approach under which Competition Authorities in Europe may attempt to balance conflicts between the goal of competition and essential facets of healthcare quality. Under this approach, which the thesis calls the *UK approach*, competition authorities are responsible for the protection of competition in healthcare, while health authorities are responsible

for advising competition authorities on issues relating to the protection of healthcare quality and the policy objectives their systems pursue. This policy option has in fact been adopted in the UK when mergers between NHS hospitals are involved. As the HSCA 2012 provides, mergers involving one or more NHS hospitals are subject to the Enterprise Act 2002 (HSCA 79) and are reviewed by the CMA with Monitor, the health services regulator in the UK, taking an advisory role in relation to the benefits of the merger for patients.[35] This chapter asks: *Can the cooperation of these authorities ensure that healthcare quality in the merger assessment of NHS hospitals is actually taken into account as a whole? And, if yes, how?* This chapter argues that the CMA takes into account in its assessment the objective of continuous access to NHS services without either widening the notion of consumer welfare or explicitly stating that a competition law framework aiming to ensure quality should not disregard the wider objectives of the sector at which it applies. This chapter shows that the CMA considers this non - competition concern in its merger assessment mainly by integrating in its analysis the views of various authorities that their primary objective is not to ensure competition but to ensure the continuity of the NHS services.

The final part of this doctoral thesis concludes.

[35] M. Sanderson, P. Allen, D. Osipovic, 'The regulation of competition in the National Health Service (NHS): what difference has the Health and Social Care Act 2012 made?' (2017) 12 *Health Economics, Policy and Law*, 1, 7.

# I. The notion of healthcare quality from health policy perspective: *How is it defined and assessed*?

Healthcare quality, a long standing concern of physicians and their patients, has become a central concern of policy makers.[36] Hence, the quality of healthcare is on the agenda in most health care systems.[37] Much of this interest in quality of care has developed in response to recent dramatic transformations of health care systems, accompanied by new organizational structures and reimbursement strategies that affect quality.[38] It is also the result of public, political and professional dissatisfaction with health services at global level.[39]

Despite the growing importance of healthcare quality issues, only of late has systematic evidence about quality of care began to be collected in most health care systems.[40] The primary concerns concerning quality of care relate particularly to access and continuity of care, clinical effectiveness, patient safety, value for money, consumer responsiveness and public accountability.[41]

At EU level improving quality of care has become top priority. EU Member States have started implementing strategies to improve the quality of health services in view of (a) unsafe health systems (b) unacceptable levels of variations in performance, practice and outcome (c) ineffective or inefficient healthcare technologies (d) unaffordable waste from poor quality (e) user dissatisfaction (6) unequal access to health services (f) waiting lists (g) unaffordable costs to society (h) waste from poor quality.[42]

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[36] K. Madison, 'Legal and Policy Issues in measuring and Improving Quality', in I.G. Cohen, A. Hoffman, W. M. Sage, (eds.)*The Oxford Handbook of US Health Law,* 680.
[37] J. Mainz, 'Defining and classifying clinical indicators for quality improvement' (2003) 15(6) *International Journal for Quality in Health Care*, 523.
[38] *Ibid.*
[39] C. Shaw, I. Kalo, (2002) 'A background for national quality policies in health systems', Policy Document No EUR/02/5037153 Copenhagen, WHO Regional Office for Europe, Part 1, 1-2.
[40] J. Mainz, *supra* n. 37, at 523.
[41] C. Shaw, I. Kalo, *supra* n. 39, at 523.
[42] *Ibid.*

In the US healthcare agenda, the issue of measuring and assessing healthcare quality has also become priority. In fact, the Patient Protection and Affordable Care Act (ACA) illustrates the growing importance of quality measurement in the evolving American healthcare system.[43] The ACA's third section is titled 'Improving the Quality and Efficiency of Health Care' and at its heart is a requirement to develop a national quality improvement strategy.[44] Within this strategy healthcare quality improvements are pursued through quality reporting, care coordination, chronic disease management and patient-centered education.[45]They are further pursued through the appropriate use of best clinical practices, evidence based medicine, and health information.[46]

Improving performance requires that decision makers in healthcare care are able to measure the extent to which the systems contribute to the desired outcomes, identify the factors that influence attainment and develop policies that can actually lead to better results.[47] Adopting policies that improve outcomes, however, requires that policy makers and regulators know how to assess end measure healthcare quality. Indeed, any initiative for healthcare quality improvements would fail if health policy makers and regulators were unable to define, assess and measure healthcare quality. For this reason, this section dedicates to exploring how the notion of healthcare quality has developed so far. In fact, it examines how healthcare quality is defined, measured and assessed. By analyzing the main facets of the notion, this section argues that the meaning attached to healthcare quality should reflect the main health policy objectives a State has chosen to pursue in all different levels of its healthcare system.

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[43] Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119 (2010), as amended by Health Care and Education Reconciliation Act of 2010, Pub. L. No. 11-152, 124 Stat. 1029 (2010), para 3011.
[44] Agency for Healthcare Research and Quality, About the National Quality Strategy.
[45] Patient Protection and Affordable Care Act, Pub. L 111–148—Mar. 23, 2010 124 Stat. 135, EC. 2717, 'Ensuring the Quality of Care'.
[46] *Ibid.*
[47] D. Evans, D. B. Evans, T. Tan-Torres Edejer, J. Lauer, J. Frenk, J. Christopher, L. Murray 'Measuring quality: from the system to the provider (2001) 13(6) *International Journal for Quality Health Care*, 439.

## 1. How is healthcare quality defined?

The literature on quality of care in health systems is very extensive and at the same time difficult to systematize.[48] Depending on the disciplinary paradigm, quality can be understood in diverse ways, using different terms, labels and models.[49] Arguably, the definitions put forward by the seminal work of Avedis Donabedian and by the Institute of Medicine (IOM) have been the most influential.[50] Interestingly, these definitions reveal the different perspectives between medical professionals and health services researchers on what healthcare quality actually is and how it should be assessed and evaluated.

Avedis Donabedian, whose seminal research on healthcare quality has been prominent for health services research, in 1980 defined quality of care as the kind of care which is expected to maximize an inclusive measure of patient welfare, after one has taken account of the balance of expected gains and losses that attend the process of care in all its parts.[51] Donabedian insisted that before defining the term it is necessary to decide whether monetary cost should enter the definition. He thus distinguished a *maximalist* specification from an *optimalist* specification of quality.[52] The maximalist specification ignores monetary costs and defines the highest quality as the level that can be expected to achieve the greatest improvement in health. In contrast, in the optimalist specification of quality, very expensive interventions that do not achieve a great improvement in health should be avoided.[53] Initially, Donabedian defined quality from a maximalist perspective. Later, though, he opted for the concept of *value*, with quality defined as the maximum that is possible given the *inputs that are available.*[54]

Ten years later, the Institute of Medicine (IOM) in the USA, after thorough review and extensive consultation, defined quality of care as 'the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current

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[48] H. Quigley, M. McKee, E. Nolte, I. Glinos, 'Assuring the quality of healthcare in the European Union, A case for Action', European Observatories on Health Systems and Policies, Chapter 1, 1.
[49] *Ibid.*
[50] *Ibid.*
[51] *Ibid*, 2.
[52] *Ibid*, 3.
[53] *Ibid.*
[54] *Ibid.*

professional knowledge'.[55] IOM's definition has been highly influential. In fact, it has been adopted by prominent institutions in the US, such as the United States Department of Health and Human Services and the National Committee for Quality Assurance.[56] This definition: (a) includes a measure of scale (b) encompasses a wide range of elements of care with references to health services (c) identifies both individuals and populations as targets for quality assurance efforts (d) is goal oriented making a distinction within healthcare goals depending on whether they emanate from government, patients, administrators, healthcare practitioners or other participants in the healthcare system (e) recognizes the importance of outcomes (f) highlights the importance of individual patients' and society's preferences and values (g) implies that the patients have been taken into account in the healthcare decision and policy making (h) underlines that the state of technical, medical and scientific knowledge places constraints on professional performance.[57]

Obviously, Donabedian's and IOM's definitions on healthcare quality are not identical. Compared to the definition adopted by Donabedian, IOM's definition narrows the goal from improving total patient welfare to improving health outcomes.[58] IOM's term also shifts the focus from patients to individuals and populations, hence allowing quality of care also to incorporate health promotion and disease prevention and not just cure and rehabilitation.[59] It also adds 'desired outcomes' to the definition so as to emphasize the need to consider the perspective of the recipients of services.[60]

IOM's definition differs from Donabedian's one in one more essential aspect: the treatment of resource constraints.[61] As noted, Donabedian's initial definition was absolutist, reflecting what was maximally feasible for the patient given the current knowledge.[62] Nonetheless, broadening his approach at a later stage, Donabedian integrated the concept of value in his

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55 *Ibid.*
56 *Ibid.*
57 *Ibid,* 3-4.
58 D. Evans, et al. *supra* n. 47, at 442.
59 *Ibid.*
60 *Ibid.*
61 *Ibid*, 443.
62 *Ibid.*

definition so that quality was the maximum possible for the inputs available.[63] The IOM returned to the original Donabedian definition and explicitly rejected the inclusion of resource constraints in the definition of quality on the grounds that it should not fluctuate just because resources are constrained or unavailable.[64]

The definition and assessment of quality was initially within the purview of health professionals and health service researchers.[65] Nonetheless, research on what the main components of healthcare quality should be is now undertaken by a wider range of institutions, such as the World Health Organization (WHO) and the Council of Europe. The latter, for example, has defined quality of care as 'the degree to which treatment dispensed increases the patient's chances of achieving the desired results and diminishes the chances of undesirable results, having regard to the current state of knowledge'.[66] In the same line, WHO has defined quality as 'the level of attainment of health systems intrinsic goals for health improvement and responsiveness to legitimate expectations of the population'.[67]

## 2. Deconstructing the notion: *What are the main dimensions of healthcare quality?*

Health policy researchers, medical associations and international organizations have extensively attempted to translate the most influential definitions into measurable indicators. This task is essential. Translating broader quality definitions into specific indicators equips health policy makers with the necessary tools to assess the quality of their healthcare system in all different levels this system operates.

Donabedian, for example, conceives quality as a multidimensional concept whose main attributes are effectiveness, efficacy, efficiency, acceptability, optimality, equity, legitimacy.[68] To

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[63] *Ibid*, 3.
[64] *Ibid.*
[65] H. Quigley, et al, *supra* n. 48, at 2.
[66] *Ibid.*
[67] *Ibid.*
[68] A. Donabedian, *An introduction to Quality Assurance in Health Care, (*Oxford University Press 2003) 4.

Donabedian, these attributes, when measured, reflect healthcare quality's magnitude.[69] The Council of Europe has also distinguished the term's key dimensions, namely, effectiveness, efficiency, access, safety, appropriateness, acceptability, satisfaction, efficacy.[70] The OECD in its Health Care Quality Indicator ('HCQI') Project[71] has also identified the notion's core facets. These are: effectiveness, safety, responsiveness, accessibility, equity and efficiency.[72] The WHO has also indicated that a health care system pursuing quality improvements should always aim to be effective, efficient, accessible, acceptable, equitable and safe.[73] The UK Department of Health in its 1997 report entitled *'A first class service: Quality in the new NHS'*[74] has also acknowledged the concept's multidimensional nature. In identifying its main characteristics, it concluded it consists of the following elements: effectiveness, efficiency, access, equity, timeliness, health improvement.[75] The IOM also sees quality as a multidimensional concept embodying the notions of effectiveness, efficiency, safety, equity and timelessness.[76]

This literature reveals that the most frequently used dimensions of healthcare quality are effectiveness, efficiency, access, safety, equity, appropriateness, timeliness, acceptability, patient responsiveness, satisfaction, health improvement and continuity.[77] More importantly, this literature helps us to observe two important things: first that the IOM does not consider *access* essential part of the healthcare quality definition; second that the Council of Europe has excluded the notion of *equity* from the definition of healthcare quality. Understanding the reason why the choice of the healthcare quality definition is essential from health policy perceptive requires thorough analysis of its key facets. For this reason, the remaining section devotes to this task.

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[69] *Ibid.*
[70] H. Quigley et al, *supra* n. 48, at 5.
[71] The OECD Health Care Quality Indicators project, initiated in 2002, aims to measure and compare the quality of health service provision in the different countries. An Expert Group has developed a set of quality indicators at the health systems level, which allows to assess the impact of particular factors on the quality of health services, see http://www.oecd.org/els/health-systems/health-care-quality-indicators.htm.
[72] E. Kelley, J. Hurst, OECD Policy Report DELSA/HEA/WD/HWP (2006) (3) 'Health Care Quality Indicators Project Conceptual Framework Paper', 12-13.
[73] WHO, (2006) Quality of care, A Process for Making Strategic Choices in Health Systems, Geneva, World Health Organization, 9-10.
[74] UK Department of Health, *A first class service: Quality in the new NHS'* available at: http://webarchive.nationalarchives.gov.uk/+/http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4006902.
[75] Quigley, et al, *supra* n. 48, at 5.
[76] *Ibid.*
[77] *Ibid*, 4.

E*ffectiveness* is defined as the degree to which improvements in health now attainable are, in fact, attained.[78] This implies a comparison between actual performance and the performance that the science and technology of health care, ideally or under specified conditions, could be expected to achieve.[79] In evaluating the notion of e*ffectiveness* the following questions require assessment: Is the treatment given the best available in a technical sense, according to those best equipped to judge?[80] What is the overall result of the treatment? What is their evidence?[81]

The dimension *of safety* relates to risk reduction. It refers to the degree to which healthcare processes avoid, prevent and ameliorate adverse outcomes or injuries that stem from the processes of healthcare itself.[82] Safety is a dimension that closely relates to *effectiveness*, although distinct from it in its emphasis on the prevention of unintentional adverse events on patients.[83]

*Efficiency* is the system's optimal use of available resources to yield maximum benefits or results.[84] This dimension is essential not only because it is included in all definitions proposed by the main key players in health care but also because it is linked with one of the main challenges decision makers in health care face: the challenge of reconciling growing demand for health care services with available funds.[85] Undoubtedly, achieving (greater) efficiency from scarce resources is considered a major criterion for priority setting.[86]

The efficiency concept is a broad one. In fact, it consists of three narrower dimensions: *technical*, *productive* and *allocative* efficiency. Technical efficiency refers to the physical relation between resources (capital and labour) and health outcomes.[87] A technically efficient position is achieved

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[78] A. Donabedian, *supra* n. 68, at 5.
[79] *Ibid*, 5-6.
[80] R. Maxwell, 'Dimensions of quality revisited: from thought to action', (1992) (1) *Quality in Health Care*, 171.
[81] *Ibid.*
[82] E. Kelley, J. Hurst, *supra* n. 72, at 13.
[83] *Ibid.*
[84] *Ibid.*
[85] S. Palmer, D. Torgerson, 'Definitions of Efficiency', (1999) 318 (7191) *British Medical Journal*, 1136.
[86] *Ibid.*
[87] *Ibid.*

when the maximum possible improvement in outcome is obtained from a set of resource inputs.[88] Technical efficiency does not directly compare alternative interventions, where one intervention produces the same (or better) health outcome with less (or more) of one resource and more of another.[89] This comparison is linked with *productive efficiency* which means the maximization of health outcome for a given cost, or the minimization of cost for a given outcome.[90] To inform resource allocation decisions in this broader context a global measure of efficiency is required.[91] This measure is the *allocative efficiency* dimension which takes into account the *productive efficiency* with which healthcare resources are used to produce health outcomes but also the efficiency with which these outcomes are distributed among the community. Thus, *allocative efficiency* is achieved when resources are allocated so as to maximize the welfare of the community.[92]

Donabedian has also identified the narrower dimensions of the efficiency objective. In general, Donabedian sees efficiency as the ability to lower the costs *without* diminishing attainable improvements in health.[93] Thus to Donabedian, the mere reduction in cost does not denote efficiency unless health benefits are either unaffected or improved.[94] His analysis foresees three ways of improving efficiency in health care. One way is for healthcare practitioners to prescribe and implement care that does not include harmful, useless or less effective remedies or methods.[95] Donabedian calls this *clinical efficiency* because it depends on clinical knowledge, judgment and skill.[96] A second way is by producing more efficiently the goods and services that are used in the provision of care. For example, when hospitals run at higher occupational rate costs are lowered. Donabedian names this *productive efficiency*.[97] The third way Donabedian predicts is the distribution of care among different classes of patients (characterized by age, sex, economic status, place of residence, economic

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[88] *Ibid.*
[89] *Ibid.*
[90] *Ibid.* S. Palmer and D. Torgerson provide the following example: Consider, for example, a policy of changing from maternal age screening to biochemical screening for Down's syndrome. Biochemical screening g uses fewer amniocenteses but it requires the use of another resource biochemical testing. Since different combinations of inputs are being used, the choice between interventions is based on the relative costs of these different inputs.
[91] *Ibid.*
[92] *Ibid.*
[93] A. Donabedian, *supra* n. 68, at 6.
[94] *Ibid.*, 9-10.
[95] *Ibid.*, 10.
[96] *Ibid.*
[97] *Ibid.*

status) in a way proportionate to expected improvements in health.[98] In other words, resources are allocated to population subgroups who are perhaps sicker or are more likely to benefit from care, and do so for longer periods of time and at a proportionally lower cost.[99] By doing so a system aims for what is called *distributional efficiency,* an aspect of quality that Donabedian conceives at societal level.[100]

Policy makers in decision analysis aiming to improve efficiency in resource allocation apply various economic evaluations.[101] The three most essential are (a) *cost-benefit analysis*, which involves placing monetary values on all the possible costs and benefits of an intervention and the total costs are then compared with the total benefits after discounting (b) *cost-effectiveness analysis*, which involves assessing the costs and cost-savings in terms of a predefined unit of health outcome and (c) *cost-utility analysis* which is a form of cost-effectiveness analysis in which the outcome is expressed in terms of utility or quality.[102] The unit value may be quality-adjusted life year (QALY)[103] or disability-adjusted life year (DALY).[104]

The dimension of *accessibility or access* reflects the ease with which health services are reached.[105] Access can be physical, financial or psychological and requires that health services are a priori available.[106] When the *access* of a healthcare system is evaluated and assessed the following

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[98] *Ibid.*
[99] *Ibid.*
[100] *Ibid.*
[101] T.Y.Lai, G. M. Leung 'Equity and efficiency in healthcare: are they mutually exclusive'? (2010) 16(1) *HKJOphthalmol*, 2.
[102] *Ibid.*
[103] The term 'quality-adjusted life year' (QALY) was first used in 1976 by Zeckhauser and Shepard to indicate a health outcome measurement unit that combines duration and quality of life (Zeckhauser and Shepard 1976). The main use of QALYs is within the framework of cost-effectiveness analysis, to assess the improvement in quality-adjusted life expectancy obtained through a specific health intervention relative to a situation in which either no intervention or a standard alternative intervention is provided. The QALY framework provided a basis for the development of a number of health outcome measures, including the disability-adjusted life year (DALY) in the early 1990s. The DALY is primarily a measure of disease burden (disability weights measure loss of functioning). As a measure of outcome in economic evaluation, the DALY differs from the QALY in a number of aspects. Most importantly, the DALY incorporates an age-weighting function assigning different weights to life years lived at different ages, and the origins of disability and quality of life weights differ significantly, see F. Sassi, 'Calculating QALYs; Comparing QALY and DALY calculation', (2006) 21(5) *Health Policy and Planning*, 402-408.
[104] T.Y.Lai, G. M. Leung *supra* n. 101, at 2.
[105] E. Kelley, J. Hurst, *supra* n. 72, at 13.
[106] *Ibid.*

questions become relevant: Can people get treatment when they need it?[107] Are there any identifiable barriers to service, such as distance, inability to pay, waiting lists and waiting times – or other similar straightforward breakdowns in supply?[108]

*Acceptability* is the conformity to the realistic wishes, desires and expectations of patients.[109] Donabedian argues that acceptability consists of the following narrower elements: (a) accessibility, which is the ease with which persons can obtain care[110] (b) the patient-practitioner relationship, the main attributes of which are personal concern, empathy, respectfulness, avoidance of condescension, willingness to take time, effort to explain, honesty, truthfulness and good manners[111] (c) the amenities of care or in other words the desirable aspects of the circumstances under which care is given.[112] These can be privacy, comfort, restfulness, cleanliness, the availability of adequate parking, good food[113] (d) patient preferences regarding the effects, risks and cost of care[114] (e) what patients perceive as *fair* and *equitable*.[115]

*Equity* is a dimension closely related to *access*, although it is also used as a metric to assess health-system financing and outcomes, health status.[116] Equity defines the extent to which a system deals fairly with all concerned.[117] Equity, in this context, deals with the distribution of healthcare and its benefits among people.[118]

The concept of *equity* determines how healthcare resources will be distributed. Equity in healthcare aims to address health inequalities. Economic research in health inequalities warns that we should be more averse to or less tolerant of inequalities in health than inequalities in other

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[107] R. Maxwell *supr*a n. 80, at 171.
[108] *Ibid.*
[109] A. Donabedian, *supra* n. 68, at 18.
[110] *Ibid.*
[111] *Ibid*, 19.
[112] *Ibid*, 20.
[113] *Ibid.*
[114] *Ibid*, 21.
[115] *Ibid*, 22.
[116] E. Kelley, J. Hurst, *supra* n. 72, at 13.
[117] *Ibid.*
[118] *Ibid.*

dimensions such as income.[119] For example, income incentives are needed to elicit effort, skill and enterprise.[120] These incentives or differences in reward have the effect of increasing the size of total income from which in principle the society as a whole can gain, mainly through taxation.[121] While this incentive argument applies in income, it surely does not apply in health since inequalities in health do not directly provide people with similar incentives to improve their health from which society as a whole benefits.

Health is also a special good [122] as it directly affects a person's well – being. Health enables a person to function as an agent - that is to pursue the various goals and projects in life that he or she actually values.[123] Therefore, entities such as health derive equity significance from their ability to enable people to 'flourish'.[124] In that sense, inequality in health equals to inequality in opportunity. For this reason, Amartya Sen claims that any conception of social justice that accepts the need for a fair distribution as well as efficient formation of human capabilities cannot ignore the role of health in human life.[125] If it is, however, agreed and felt that all residents of a political jurisdiction ought to have equal opportunities for their lives to flourish, then it follows that health care is one of the goods and services whose right distribution should be ensured.[126]

Striving for health equity becomes also important considering what the main determinants of population health are. These are genetics, the physical and social environment such as working conditions, pollution, cultural norms and position in the social hierarchy and health-related lifestyle referring to people's behavior regarding diet, exercise, and substance use.[127]

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[119] See for example, S. Anand, 'The Concern of Equity in Health' in (eds.) S. Anand, F. Peter, A. Sen *Public Health Ethics and Equity* (Oxford, Oxford University Press, 2004), 16.
[120] *Ibid.*
[121] *Ibid*, 17.
[122] That health is a special good has been recognized through the ages. We find this view in ancient Greek poetry, and in the Hippocratic texts. Democritus in his book *On Diet*, written in the fifth century before BC states: without health nothing is of any use, not money nor anything else.
[123] *Ibid*, 18.
[124]A. J Culyer, 'Equity - some theory and its policy implications' 2001 (27) *Journal of Medical Ethics,* 275, 276.
[125] A. Sen 'Why Health Equity?' in (eds.) S. Anand, F. Peter, A. Sen *Public Health Ethics and Equity*, 23.
[126] A. J Culyer, *supra* n. 124, 276.
[127] J. Olsen, 'Concepts of Equity and Fairness in Health and Health Care' in S. Glied and P. C. Smith (eds), *The Oxford Handbook of Health Economics*, 816 (Oxford, Oxford University Press, 2011).

Genetic endowments are health preconditions reflecting a 'biological lottery' over which people have no control. The environment in which people happen to live represents also their opportunities that—at least for children—reflect 'a social lottery' over which also they have no control. Lifestyle is the determinant over which people have most discretion, but precisely how much of that reflects sovereign consumer preferences and how much reflects social conditioning is also a very contentious issue.[128] Indeed, a less nutritious diet may be chosen because of restrictions on income.[129] Less physical activity may be also chosen as a result of lack of leisure facilities or income. Promotion of health-damaging products is often targeted at certain groups in society, such as young working-class men.[130] This puts them under greater pressure than others to consume these products.[131] Thus, equity in health has an instrumental value since it aims to compensate specific groups of a society for the disadvantages and the suffering they incur for reasons beyond their control.

*Appropriateness* is the degree to which provided healthcare is relevant to the clinical needs given the current best evidence.[132]

*Continuity* addresses the extent to which healthcare for specified users over time is coordinated across providers and institutions.[133]

*Timeliness* refers to the degree to which patients are able to obtain care promptly.[134] It includes both *timely access to care and coordination of care.*[135] There are clinical elements of timeliness: the length of time from admission of heart attack to the administration of thrombolytic therapy for

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[128] *Ibid.*
[129] M. Whitehead, WHO (2000) Policy Report EUR/ICP/RPD 4147734r 'The concepts and principles of equity and health', 6
[130] *Ibid.*
[131] *Ibid.*
[132] E. Kelley, J. Hurst, *supra* n. 72, at 14.
[133] *Ibid.*
[134] *Ibid.*
[135] *Ibid.*

example.[136] There are also patient centeredness aspects of this notion, such as patients' perceptions of their ability to get an appointment for needed urgent care.[137]

### 3. Choosing the main dimensions of healthcare quality: *Why is it essential*?

The choice of dimensions to measure quality of care is critical as it will influence the main health care policies adopted.[138] In fact, it will influence how the healthcare system will be designed, how resources will be allocated and how interventions will be prioritized. This implies that health policy makers should be accurate in how they define quality and how they translate each specific dimension of the term into specific objectives and goals. My analysis will build on this argument by further exploring two essential aspects of healthcare quality: efficiency and equity. I choose to elaborate more on these two specific dimensions of healthcare quality, as health policy makers and regulators[139] aiming to integrate both objectives into the healthcare quality definition might have to complete the difficult task of accommodating potential conflicts between these two objectives.

To begin with, as discussed, equity implies *equality*. It assesses the extent to which healthcare systems deal fairly with all concerned. Surely, this broad definition helps us to acquire a preliminary understanding of what equity means. It does not, however, allow us to shape a concrete idea as to the specific policy goals a healthcare system pursuing equity should struggle to achieve. More importantly, it does not answer the crucial question: *equality of what*? For this reason, a number of narrower definitions of equity have been proposed and discussed at length in the health economics literature.[140] The most frequently discussed are: (a) equality of expenditure per capita (b) equality of input (resources) per capita (c) equality of input for equal need (d) equality of (opportunity of) access for equal need (e) equal utilization for equal need (d) equality of health[141] (e) equity as choice.[142]

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136 *Ibid.*
137 *Ibid.*
138 H. Quigley, et al *supra* n. 48, at 6.
139 And Competition authorities as I will demonstrate in the following chapter.
140 A. Wagstaff, 'QALYS and the Equity-Efficiency Trade- Off', (1991) (10) *Health Economics*, 21, 29.
141 G.H. Mooney, 'Equity in Health Care: Confronting the Confusion', (1983) 1(4*) Effective Health Care*, 179, 180-181,
142 A. Wagstaff, *supra* n. 140, at 30.

Defining equity as *equality of expenditure per capita* suggests that if the budget available for health care is allocated to different regions, say, pro rata with the size of the regional population, then this would result in an equitable allocation.[143] Defining equity as *equality of input or resources per capita* demands a different arrangement in resource allocation. It actually demands that if the prices of different resources, such as land, varied across different regions then those regions with higher than average prices should not be penalized as would be the case under the first definition.[144] Therefore under this definition relatively high - priced regions would receive more (and vice versa for low priced areas).[145]

Defining equity as *equal treatment for equal need* necessitates that persons in equal need of health care receive the same treatment, irrespective of personal characteristics that are irrelevant to need, such as ability to pay, gender, place of residence.[146] Under this term, the greater the morbidity in a population the greater the health care resources it merits. Thus, if it was possible to say that for one population its 'need' was 10% greater than that of another of the same size then under this definition, ceteris paribus, that population would receive 10% more resources than the other.[147]

Under the definition *equal access to available care for equal need* equity implies equal entitlement to the available services for everyone and a fair distribution throughout the country based on health care needs.[148] Providing the same level of service can be more expensive in rural areas than in urban areas. Hospitals serving remote areas are likely to have to bear higher costs (e.g. maternity cases from remote areas are admitted well before the due date). Patients in rural areas normally also have higher costs to bear either in travel or inconvenience or in foregoing health benefits by not being treated at all or accepting potentially lower quality care locally.[149] In effect, defining equity in this way would require health policy makers to take due account of these barriers and apply policies that would actually reduce them. It would certainly require that resources and facilities are not unevenly

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[143] G.H. Mooney, *supra* n. 141, at 180.
[144] *Ibid.*
[145] *Ibid.*
[146] A. Wagstaff, *supra* n. 140, at 30.
[147] G.H. Mooney, *supra* n. 141, at 180.
[148] M. Whitehead, *supra* n. 129, at 9.
[149] G.H. Mooney, *supra* n. 141, at 180.

distributed around the country, clustered in urban and more prosperous areas and scarce in deprived and rural neighborhoods.[150]

Defining equity as *equal utilization rates for equal need* would require additional policy interventions. This is because individuals do differ with respect to tastes and preferences for health and healthcare. People experience different thresholds of pain; some are more informed about health and health care matters; some are more ready to sit in GPs' surgeries than others or to travel long distances to receive care.[151] This means that equality of access and equality of utilization do not necessarily converge. Access is a function of *supply*.[152] Utilization is a function of *both supply and demand*.[153] If the supply side or in other words *access* has been organized in such a way that there is equality of access for equal need but not equality of utilization for equal need, this means that the only remaining variable creating the inequity is demand. To address this inequity there might be a desire to discriminate positively in favor of those who are less willing to utilize health care.[154]

Adopting a definition of equity that amounts to *equality of health* would again require different type of interventions. In fact, it would require health policy makers to see and address equity as a *multidimensional* notion. It would require health policy makers to focus not only on how fairly healthcare is redistributed but also on how fairly the social determinants of health are distributed among different groups of a society. What short of policies should health policy makers pursue if they defined equity as *equality of health*? Certainly, the menu of options would include equalizing access to medical care. However, it would also include a broader set of policies aimed at equalizing the main determinants of population health, such as health-related lifestyle, physical and social environment, working conditions. Investment in basic education and employment, income security and other forms of antipoverty policy would also occupy the health policy agenda.[155]

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[150] M. Whitehead, *supra* n. 129, at 9.
[151] G.H. Mooney, *supra* n. 141, at 181.
[152] *Ibid.*
[153] *Ibid.*
[154] *Ibid.*
[155] N. Daniels, B. Kennedy, I. Kawachi, 'Why Justice is Good for our Health' (Oxford: Oxford University Press, 2007) in R. Bayer, L.O. Gostin, B. Jennings (eds.) *Public Health Ethics, Theory and Practice*, 221.

Viewing equity *as choice* may imply a different setting in how a healthcare system is designed or financed. Linking equity with choice reflects Le Grand's conception of equity. Le Grand argues that inequality is not necessarily inequitable.[156] He alleges that inequalities are inequitable only to the extent they reflect inequalities in the constraints people face.[157] He therefore asserts that inequalities are not inequitable if they simply reflect differences in tastes.[158] To unfold his thinking Le Grand provides an example of two people who face the same constraints but have different preferences.[159] Their levels of health are different because the one is a smoker and the other is not.[160] Le Grand comments that this is not inequitable.[161] Both were fully aware of the dangers involved; both were unconstrained in their choice by other factors; both have made informed decisions based on their own preferences. The results of these decisions are different but that is reflected in disparities in their health states; that is the outcome of their own decision; exercised over the same range of choices and hence is not inequitable.[162] Le Grand does not suggest that equity considerations of this kind should play a role in the actual allocation of treatment.[163] However, he denotes that smokers, for example, should be charged an annual premium to cover the expected costs of treatment but should continue to receive the same treatment. Accepting Le Grand's definition of equity would have some broader policy implications: it would imply that it might well be equitable for a person's non - health characteristics to influence his rights vis-à-vis the healthcare sector.[164] Any discrimination, though, should be confined to the finance of healthcare.

The above analysis reveals that different perceptions of equity may require different health policy interventions. Equality of access, for instance, does not guarantee equality of treatment amongst those in equal need.[165] More importantly, it does not guarantee equal utilization. Equality of access is about equal opportunity: the question of whether or not this opportunity is exercised is not

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156 A. Wagstaff, *supra* n. 140, at 33.
157 *Ibid.*
158 *Ibid.*
159 *Ibid*, 34.
160 *Ibid.*
161 *Ibid.*
162 *Ibid.*
163 *Ibid.*
164 *Ibid.*
165 *Ibid.*, 32.

relevant to equity defined in terms of access.[166] It is, however, relevant if equity is defined in terms of utilization.[167] In the latter case health policy makers are required to think and implement policies that influence not only supply but also demand in healthcare.[168] For example, if in antenatal care policy makers wished to achieve equal visiting at outpatient clinics for those at equal risk irrespective of social class, then if lower social classes were currently relatively low utilizers, policy makers may want to implement health education campaigns that would make low utilizers more aware of the risks of pregnancy or the effectiveness of antenatal care.[169]

Similar issues and concerns arise if we also think of the various definitions aiming to describe the *efficiency* concept. One way to define efficiency is to say that efficiency is the sum of narrower efficiency concepts such as *technical*, *productive* and *allocative* efficiency. Another way is by adopting Donabedian's paradigm and see efficiency as a broader concept consisting of *clinical*, *productive* and *distributional* efficiency. Do these definitions fully converge? Considering that *distributive* and *allocative* efficiency do not necessarily converge, the answer is *not necessarily*. As discussed, while distributive efficiency refers to the distribution of care between different classes of patients, *allocative* efficiency refers to the maximization of the welfare of the total community.

Choosing how to define quality is also critical from an additional point of view: because defining quality as a multidimensional concept inevitably requires healthcare policy makers to trade - off between dimensions of quality that under certain conditions can be mutually exclusive. This can be the case when resource allocation is at issue and, as noted, health policy makers have to strike the appropriate balance between potentially conflicting dimensions of healthcare quality, such as equity and efficiency. To elaborate:

Allocation decisions concerning the prioritization of healthcare resources across competing interventions involve evaluating the impact on both costs and health outcomes.[170] Healthcare studies

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166 G.H. Mooney, *supra* n. 141, at 183.
167 *Ibid.*
168 *Ibid.*
169 *Ibid.*
170 S. Whitehead, S. Ali, 'Health Outcomes in Economic Evaluation: the QALY and utilities' (2010) 96 *British Medical Bulletin*, 5.

use many different measures of health outcomes to demonstrate the effect of a treatment.[171] One study may report survival rates, whereas another may focus on pressure ulcer incidence and pain-free days.[172] When faced with such different types of outcome measures arising from different interventions, it is difficult to determine where healthcare resources should be most *efficiently* directed.[173] If survival alone is used to differentiate between different healthcare interventions, any impact on the quality of life associated with an intervention is ignored.[174] To enable comparisons across different areas of healthcare, a common measure seems necessary, one that encapsulates the impact of a treatment on a patient's length of life and also the impact on their health-related quality of life.[175] This, as noted, is quality-adjusted life year or else QALY.

The conventional approach to economic analysis evaluates healthcare interventions with the aim to maximize the efficiency of the healthcare system in producing the greatest number of QALYs, given available resources.[176] The implicit assumption underlying this means of measuring health outcomes is that all QALY's are of equal social value, irrespective of who accrues them.[177] A QALY gained and lost is blind to health conditions and personal characteristics, including sex, age, severity of disease, level of deprivation, social role of individuals, area of residence and other individual characteristics.[178] Under this method of measuring health outcomes what actually counts is the sum total of the population health and not the distribution of healthcare.[179]

The health maximization decision rule has been severely criticized on grounds of fairness in healthcare decision-making.[180] This is because the application of the principle of health maximization systematically favors those with longer life-expectancy or generally those that can benefit more from treatment, such as young people and women.[181] To the extent though economic evaluation in

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171 *Ibid.*
172 *Ibid.*
173 *Ibid.*
174 *Ibid.*
175 *Ibid*, 6.
176 *Ibid*, 14.
177 *Ibid.*
178 *Ibid*, 14.
179 *Ibid.*, 15.
180 F Sassi, L Archard, J. Le Grand, 'Equity and the economic evaluation of healthcare' (2001) 5(3) *Health Technology Assessment,* 14.
181 *Ibid*, 14.

healthcare favors those with greater capacity to benefit, it inevitably discriminates against individuals or groups who suffer from more severe illnesses, such as the disabled, who, all things be equal, are less able to benefit from treatment. It may also disadvantage the poorest groups of our societies. Consider the case of Antony, who is relatively rich, well - educated and well - nourished and Brenda who is poor and relatively ignorant of efficient production methods.[182] Both suffer from the same ailment and both undergo the same treatment. Yet because of Antony's personal and environmental characteristics, Antony would be better able to respond to treatment and thus would gain a greater number of QALY's. Therefore, rationing in favour of those most able to benefit inevitably imposes the possibility of a 'double jeopardy' on certain less fortunate individuals.[183]

Therefore, to the extent equity and efficiency conflict, in healthcare systems pursuing both objectives, healthcare policy makers would have to seriously think and consider how to address equity- efficiency tradeoffs.[184] The following example highlights how such tradeoffs may practically emerge in the resource allocation process. It may be possible to save more lives in total with a given smoking cessation budget by focusing on 'easy-to-reach' affluent smokers rather than 'hard-to-reach' deprived smokers.[185] Nonetheless, a decision maker aiming to achieve greater distributional health equity might have to trade off equity versus efficiency which may result in sacrifice of health gains.[186]

Research in health economics indicates that balancing these two objectives in the resource allocation process is possible. For example, equity weighting can guarantee a more equitable distribution of healthcare resources.[187] These weightings can allow health gains to be adjusted according to the socioeconomic characteristics of the recipients such as health status, age, sex, and socioeconomic status. Resource allocation decisions can then be made with the complementary aim of maximizing the equity-weighted sum of health gains.[188]

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[182] J. Pereira, 'What Does Equity in Health Mean?', Centre for Health Economics, (1989) 61 Discussion Paper, York: Centre for Health Economics, 36.
[183] *Ibid.*
[184] R. Cookson, M. Drummond and H. Weatherly 'Explicit incorporation of equity considerations into economic evaluation of public health interventions' (2009) 4(2) *Health Economics, Policy and Law*, 231, 234.
[185] S. Whitehead, S. Ali, *supra* n. 170, 15-16.
[186] *Ibid*, 15.
[187] T.Y.Lai, G. M. Leung, *supra* n. 101, at 4.
[188] *Ibid.*

The above discussion should not lead to the conclusion that e*fficiency* and *equity* necessarily and always clash. Indeed, targeting healthcare to socially disadvantaged groups may sometimes increase efficiency in the sense that morbidity correlates with social deprivation and therefore more QALYs may be gained by prioritizing the delivery of healthcare towards the less well off.[189]

This analysis shows that the question of how to define quality is a normative one. Arguably, this question cannot be adequately addressed if a previous one has not been explored and discussed by our societies and health policy makers first: what is the meaning we, as a society, want to attach to healthcare? Do we think that health has an intrinsic value? Do we see access to healthcare as a way of reducing inequalities? And, *if yes*, what are the policies, we as a society, commit to support to achieve this goal?

## 4. Levels of analysis in the concept of quality

The above analysis discussed the quality dimensions a health care system that continuously aims to improve should focus on. Quality improvements, however, cannot be achieved if not all functions of a health system commit to the quality goals the health system *as a whole* pursues. As Donabedian insists, the commitment to quality should pervade the institution at all tis levels and in all its aspects.[190] This, Donabedian maintains, would amount to a fundamental change in the ethos of the institution as it would lead to a tradition or culture where the pursuit of quality occupies its rightfully commanding position.[191] Surely, the core responsibilities of health policy makers and healthcare providers for quality improvement are different. Indeed, health policy makers' main responsibility is to develop strategies for improving quality outcomes which apply across the system *as a whole*.[192] On the other hand, healthcare providers' main responsibility is to ensure that the services they provide are of the highest possible standard and meet the needs of individual service users, their families, and communities.[193] Nonetheless, the fact that their responsibilities in improving quality are different does not imply that they should not both be committed to the broad

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189 S. Whitehead at al, *supra* n. 170, at 16.
190 A. Donabedian, *supra* n. 68, at xxx.
191 *Ibid*, xxxi.
192 WHO, (2006), *supra* n. 73, at 10.
193 *Ibid.*

quality objectives the system pursues *as a whole*.[194] While it is important to recognize the differences in their roles and responsibilities, it is equally important to recognize the connections between them. Decision-makers, for example, cannot hope to develop and implement new strategies for quality without properly engaging health-service providers, communities, and service users.[195] Conversely, healthcare providers cannot only rely on their own capacities and qualifications to perform well as their performance also depends on the health system's characteristics and material resources, such as facilities and equipment.

In line with this analysis, Donabedian, proposes that the notion of healthcare quality should be assessed in four different levels. In fact, his analysis takes account of the actors involved in the *process* of care (providers, patients, communities) as well as the setting in which health care actually takes place.[196] This classification not only distinguishes between different levels of quality but also identifies specific elements that define quality at each level.[197] At the core, Donabedian places the care provided by practitioners and other providers (individual level). These are further defined by two elements of performance: technical performance and the management of interpersonal relationships.[198] The former depends on the knowledge and judgment used in arriving at the appropriate strategies of care and on the skills needed to implement those strategies.[199] The second element relates to the way in which technical care is implemented and on which its success depends.[200] The second level (unit level) involves the amenities of care, focusing on the desirable attributes of the settings in which care is provided.[201] The third level (local level) refers to the actual implementation of care, responsibility for which is shared between the provider and the patient.[202] The final level (central level) refers to the care received by the community *as a whole* and considers *issues of social distribution* of levels of quality.[203] Thus, according to Donabedian, the definition of

194 *Ibid.*
195 *Ibid.*
196 H. Quigley, et al *supra* n. 48, at 7.
197 *Ibid.*
198 *Ibid.*
199 *Ibid.*
200 *Ibid.*
201 *Ibid.*
202 *Ibid.*
203 *Ibid.*

quality becomes either narrower or more expansive, depending on how the concept of health and related responsibilities are being defined.[204]

Donabedian's analysis as to the different levels of quality assessment is not the only one. Saturno and other scholars have identified three levels of quality that relate to the delivery of care.[205] The first one refers to a general concept of quality that is applicable to any service or product or institution in the health system.[206] The second one is applicable to a specific group of services. The third one refers to a specific product or service that is provided in health institutions.[207] The Council of Europe has also proposed a similar analysis. In fact, its approach takes into account of the different administrative and organizational tiers of the health system emphasizing the need to improve quality of care at each level of service delivery.[208] These are central (country, district); local (hospital, local or regional organization for home care, collaboration practices); unit (practice team, hospital unit) and individual level (individual health care provider).[209]

## 5. How is healthcare quality assessed and measured?

### 5.1 The structure, process and outcome measures

Providers seeking to deliver high-quality care must understand the relationship between their actions and their patients' health. When providers do not know what high-quality care is, they cannot deliver it.[210] Therefore, healthcare measurement can facilitate providers' internal efforts for quality improvement. Regulators and patients must also be able to measure and assess the quality of care that a particular provider has provided in the past, is proposing to provide in the present, or is likely to provide in the future.[211] Hence, it is also an essential tool for regulators, patients, private or public payers to assess providers' quality performance. Therefore, narrower approaches and

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[204] *Ibid.*
[205] *Ibid.*
[206] *Ibid.*
[207] *Ibid.*
[208] *Ibid.*
[209] *Ibid.*
[210] K. Madison, *supra* n. 22, at 680.
[211] *Ibid.*

measures for measuring health care quality deem necessary. These, Donabedian called, *structure, process and outcome.*[212]

By *structure* Donabedian means the relatively stable characteristics of the providers of care, of the tools and resources they have at their disposal and the physical and organizational settings in which they work.[213] The assessment of structure is a judgement on whether care is being provided under conditions that are either conducive or inimical to the provision of good care.[214] Structure refers to health system characteristics that affect the system's ability to meet the health care needs of individual patients or a community.[215] The concept includes the human, physical and financial resources that are needed to provide medical care.[216] It also embraces the number, distribution and qualifications of professional personnel and the number, size, equipment, and geographical disposition of hospitals and other facilities.[217] The following indicators are relevant to the assessment of structure: proportion of specialists to other doctors, access to specific technologies or specific units.[218]

*Process* denotes what is actually done in giving and receiving care.[219] It includes the practitioner's activities in making a diagnosis, treatment, rehabilitation, prevention and patient education.[220] Process is assessed by indicators showing what the provider did for the patient and how well it was done.[221] The proportion of patients assessed by a doctor within 24 hours of referral or the proportion of patients treated according to clinical guidelines are considered process indicators.[222]

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[212] R. H. Brook., 'Measuring Quality of Care' (1996) 335, *The New England Journal of Medicine*, 966.
[213] A. Donabedian, *Volume 1: The Definition of Quality and Approaches to Its Assessment (*Ann Arbor, MI: Health Administration Press, 1980*)* 81.
[214] J. Mainz, *supra* n. 37, at 525.
[215] *Ibid.*
[216] *Ibid.*
[217] A. Donabedian, *supra* n. 213, at 81.
[218] *Ibid*, 526.
[219] *Ibid.*
[220] *Ibid.*
[221] J. Mainz, *supra* n. 37, at 525.
[222] *Ibid.*, 526.

*Outcome* refers to the patients' subsequent health status.[223] Outcome reflects changes in a patient's current and future health that can be attributed to antecedent healthcare.[224] Therefore, indicators assessing outcomes aim to capture the effect of care processes on the health and wellbeing of patients and populations.[225] Outcome indicators can be mortality, morbidity, functional status, work status, quality of life and patient satisfaction.[226]

### 5.2 Structure, process and outcome: *When to use what*?

Of the structural indicators, measures that predict variations in processes or outcomes of care have the greatest utility and such measures often focus on hospital or provider characteristics.[227] For example, regarding pediatric quality of care, one consistent finding has been that hospitals caring for higher volumes of patients with similar conditions have better adjusted mortality rates.[228] This also applies for surgical procedures.[229] Therefore, structural and outcome measures are highly associated.

Outcome and process measures are also interrelated. In fact, specific characteristics of process signify quality because they contribute to desirable outcomes.[230] Conversely, some characteristics of process signify poor quality because they are known to result in undesirable outcomes. Once it has been established that certain procedures used in specified situations or for certain patients are clearly associated with good results, the presence or absence of these procedures for such patients or situations is accepted as evidence of good or bad quality.[231]

The advantages and disadvantages of process versus outcome measures have been substantially examined.[232] To start with, process data are 'contemporaneous';[233] they are taking place

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[223] Brook, *supra n.* 212*,* 967.
[224] A. Donabedian, *supra* n. 213, at 83.
[225] J. Mainz, *supra* n. 37, at 526.
[226] *Ibid.*
[227] *Ibid.*
[228] *Ibid.*
[229] *Ibid.*
[230] *Ibid*, 527.
[231] *Ibid.*
[232] *Ibid.*
[233] *Ibid.*

in the now; therefore, they offer current, even immediate, indications of quality.[234] Process data are also easy to be obtained by the medical record, by questioning patients or by direct observation if care is supervised.[235] Comparisons of process data are also easier to interpret and much more sensitive to differences in quality of care than comparisons of outcome data.[236] For example, a process indicator can measure whether or not a stroke patient receives the right medication, whereas 30-day mortality rates from stroke patients are more difficult to interpret.[237]

Outcome measures can also be appealing for different reasons. First and foremost an outcome measure is a measure of something that is important in its own right.[238]Indeed, it is always interesting to know that death rate from myocardial infraction varies from hospital to hospital, even if the reasons for the differences have nothing to do with the quality of care.[239] Additionally, outcome measures grasp all aspects of the processes of care and not simply those that are measurable or measured.[240]

Considering the pros and cons of each measure a crucial question begs for answer: when should each measure be used? As noted, the relationship between process and outcome is probabilistic. That means that in a given case, or in a small number of cases, we cannot be certain that a given set of processes eventuated in one specific outcome.[241] Indeed, a patient admitted to a hospital with a heart attack may receive atrocious care, yet despite this, is likely to survive.[242] Therefore, process measures can be the direct measures of healthcare quality provided that a link has already been established between a given process and an outcome.[243] Process measures are useful, though, when we need results of comparisons in a short time frame and when the processes affect

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[234] *Ibid.*
[235] *Ibid.*
[236] J. Mant, 'Process versus outcome indicators in the assessment of quality of care', (2001) 13(6) *International Journal of Quality in healthcare*, at 479.
[237] J. Mainz, *supra* n. 37, at 527.
[238] *Ibid.*
[239] *Ibid.*
[240] *Ibid.*
[241] A. Donabedian, *supra* n. 213.
[242] J. Mant, *supra* n. 230, at 475.
[243] *Ibid.*

important long term outcomes.[244] They are also the best way to compare provider groups or individual providers who contribute only part of the care received by a patient. In this specific circumstance if we looked at outcomes only, we would not be able to tell which providers to credit for a good outcome or if all should share the credit.[245]

The outcome of care is determined by several factors related to the patient, the illness and healthcare.[246] Differences in outcome may be due to case mix and other confounding factors.[247] Therefore, standardized data collection and risk adjustment are important for interpreting outcome data.[248] Outcome indicators are a more effective tool for measuring quality, when health care services have major effects on outcome.[249] In contrast, when factors such as lifestyle and socio economics circumstances, rather than healthcare, are the major determinants of outcome, it would be a misnomer to refer to an outcome measure as a performance indicator since it would be acting as a broader barometer of the health of the population.[250] Outcome measures are extremely useful for tracking care given by high volume providers over long periods of time, and for detecting problems in implementation of processes of care.[251] As the perspective narrows to hospitals and departments or providers, outcome measures become less useful, although still important.[252] The broader the perspective required, the greater the relevance of outcome indicators.[253]

Outcome studies are considered particularly problematic when we are using comparisons for coercive or competitive purposes.[254] Providers in these situations have a big stake in the action that follows from the results. Therefore, they may start gaming to evade them. They may, for example, avoid enrolling sicker patients to achieve better outcomes. They may also attempt to achieve better outcomes by withholding risky procedures from higher risk patients. Gaming to

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244 R. H. Palmer 'Using health outcomes data to compare plans, networks and providers' (1998) 10(6) *International Journal for Quality in Healthcare*, 477, 482.
245 *Ibid.*
246 J. Mainz, *supra* n. 37, at 527.
247 *Ibid.*
248 *Ibid.*
249 J. Mant, *supra* n. 230, at 475.
250 *Ibid.*
251 J. Mainz, *supra* n. 37, at 527.
252 J. Mant, *supra* n. 230, at 476.
253 *Ibid.*
254 R. H. Palmer, *supra* n. 244, at 482.

ensure better-looking health outcomes data would undoubtedly produce negative effects on patients by restricting access.[255]

In sum, a reasonable strategy is to select measures that meet the needs of each particular condition or treatment; sometimes this will be structure, sometimes it will be outcome measures; [256]More often, it will be a combination of two.[257]

## 6. Conclusion

This chapter attempted to achieve a difficult goal: to provide an accurate and at the same time accessible analysis on the most influential definitions of healthcare quality. More than that, it aimed to explain why the choice of the appropriate definition of healthcare quality is essential from health policy perspective. It underlined that the choice of the main dimensions of healthcare quality is critical as this choice would inevitably influence the main policies regulators and health policy makers would implement and adopt.

In delving into these issues this chapter highlighted that the notion of healthcare quality is a *multidimensional* one consisting of these main dimensions: effectiveness, safety, efficiency, acceptability, equity, appropriateness, continuity, timeliness. It also explained that exactly because healthcare quality is a multidimensional concept, especially when resource allocation is at issue, health policy makers and regulators may have to strike the appropriate balance between potentially conflicting dimensions of healthcare quality, such as equity and efficiency. More specifically, it claimed that a decision maker aiming to achieve health equity might have to trade off equity versus efficiency which may result in sacrifice of health gains. Additionally, it emphasized that health care quality can be pursued only to the extent all key players in a health system commit to the wider quality objectives the system pursues *as a whole*. This is because although all participants in a healthcare system pursue quality at different levels and through different perspectives, their responsibilities in ensuring quality are in fact correlated.

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[255] *Ibid.*
[256] J. Mainz, *supra* n. 37, at 527.
[257] *Ibid.*

This chapter also analyzed how healthcare quality is measured. It explained that quality is analyzed under the structure, outcome and process measures. It also stressed that quality measuring is an essential tool for regulators, patients, private or public payers to assess providers' quality performance. At the same time, it is also a tool that facilitates providers' efforts to evaluate and improve their performance.

## II. Towards the *marketization* of EU healthcare systems: What is the healthcare quality debate about?

Healthcare markets have started being created in Europe. Indeed, some European countries, such as the UK and the Netherlands, have started adopting the *choice and competition model* for healthcare delivery. These countries see *competition* as an instrument that will stimulate organizations to be more efficient and responsive to consumer preferences.[258] Competition between providers can take various forms, according to whom or what they compete for and what are the variable(s) used in that process of competition.[259] Health care providers may compete for patients based on price, or based on quality, or both. The main forms competition can take are: (a) *Competition in the market* which is the most commonly recognized form of competition, with several providers making alternatives available to those who decide what to consume.[260] In the case of healthcare markets, the decision-maker regarding use of a particular alternative or provider can be the patient or a health professional, usually a medical doctor, on behalf of the patient[261]; (b) *Competition for the market* where several providers compete for the right to provide a service or good.[262]

*Competition* among health-care providers is distinct from *patient choice*.[263] The value of choice has gained important status in several European countries as a principle underpinning their health system, and as an instrument for making the allocation of health system resources responsive to patient preferences and enhancing patient empowerment.[264] Patient choice may be combined with different degrees of competition among health-care providers; between public providers only, between public and private providers, and with different restrictions for entry to the market.[265] While patient choice can also exist without competition between health-care providers, this is, usually, the

[258] European Commission, *supra* n 7, at 11.
[259] *Ibid*, 21.
[260] *Ibid*, 33.
[261] *Ibid.*
[262] *Ibid*, 26.
[263] *Ibid*, 4.
[264] *Ibid*, 6.
[265] *Ibid*, 4.

exception.[266] Patient choice occurs usually in settings in which competition between health-care providers is present.[267]

The extent to which European countries have implemented the choice and competition model varies across Europe. The Netherlands, for example, has opted for a system of regulated competition and private insurance, with wide-ranging reforms implemented since the mid-2000s to reinforce the role of market mechanisms.[268] In fact, in 2006, competition among health insurers was reinforced with the introduction of the Health Insurance Act, which made private health insurance mandatory for everyone.[269] Insurance companies have to accept citizens as their customers and health insurance is compulsory to all citizens to avoid 'free-riders' of the system.[270] As not all citizens have equal health risks, a risk-adjustment model compensates insurers for inequalities in health risks in their populations.[271] Furthermore, there is a nationally defined basic package that specifies the care that all insurers must provide and that leaves other forms of care to be insured via optional additional insurance schemes.[272] The basic idea behind the reform was to give risk-bearing health insurers appropriate incentives to act as prudent buyers of health services on behalf of their customers.[273] To that end, the Health Insurance Act allows health insurers to selectively contract with health care providers.[274] As healthcare insurance companies are not automatically expected to only want what is best for their clients, patients are positioned as a countervailing power by being given the option to choose their insurer.[275]

The English NHS saw in the early 1990s the introduction of the notion of 'internal market', with competition between providers of healthcare but not between 'health insurance'.[276] The late 1990s had an end to this 'internal market' experience, with a move to a system with an emphasis on

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266 *Ibid*, 24.
267 *Ibid.*
268 *Ibid*, 54.
269 *Ibid.*
270 Teun Zuiderent-Jerak Kor Grit and Tom van der Grinten, 'Markets and Public Values in Healthcare', *Erasmus University Rotterdam, iBMG Working Paper* W2010.01, 13.
271 *Ibid.*
272 *Ibid.*
273 European Commission, *supra* n. 7, at 54.
274 *Ibid.*
275 Teun Zuiderent-Jerak Kor Grit and Tom van der Grinten, *supra* n. 270, at 3.
276 European Commission*, supra n.* 7*,* at 47.

quality but not on price, with 'prices' (tariffs) set by the Department of Health.[277] The gradual steps that have been taken to facilitate competition in the NHS are: (a) splitting the responsibility for providing healthcare from the responsibility for purchasing it; (b) allowing some NHS care to be provided by the independent sector; (c) establishing the Any Qualified Provider (AQP) principle, under which qualified providers have contracts with NHS commissioners giving them the right to provide certain NHS services; (d) introducing Payment by Results (PbR), the payment of fixed national tariff prices for treatments provided.[278] The delivery of healthcare through market provision has been further reinforced by the HSCA 2012 that attempted to further promote choice and competition in the NHS Services.[279]

*How may the creation of healthcare markets affect the multiple facets of healthcare quality?* Examining this question seems essential since the idea of competition in healthcare has provoked strong reactions from commentators, with some considering it *anathema* and others seeing it as a *magic bullet*.[280] To adequately address this question this chapter first examines the question of why some countries in Europe move towards market driven healthcare delivery. By drawing inspiration from the recently created healthcare markets in Europe, this chapter then analyses how the marketization

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[277] *Ibid.*

[278] For a comprehensive review of the market reforms of the healthcare system in the UK, J. Cylus, E Richardson, L. Findley, M. Longley, C. O'Neill, D. Steel, (2015) 17(5) *United Kingdom: Health system review. Health Systems in Transition*, 16.

[279] The market reforms in the UK are examined in detail in chapter VI of the thesis.

[280] European Commission, *supra* n. 7, at 8. 111. The expected impact of competition on the efficiency of allocation of resources, namely upon prices and quality, is context specific. That is, economic theory does not provide an unambiguous prediction regarding the impact of increased competition on quality when both quality and price are available strategic variables for the health care provider. Theoretical work suggests that competition can generally be beneficial to quality levels when prices are regulated. Under regulated prices, and with a positive margin to health care providers from treating patients, the more sensitive demand is to quality, the higher the expected positive impact of competition on quality levels. An important qualification needs to be mentioned: if regulated prices are too low, and determine a negative margin, competition will harm quality. With unregulated prices, the predictions from theory are context sensitive and no general result is obtained. That is, increases (or introduction) of competition may result in higher or lower quality levels, and generally results in lower prices. Market outcome is determined by the nature of competition and by how sensitive patients are to prices and to quality. When providers of health care have freedom in setting their prices (that is, prices are not regulated or negotiated with health care insurers or public health systems), more competition leads to the use of prices as a way to be favored by patients. But if patients choose a provider based more on quality than on price, more competition drives up the need for more quality which increases costs and require higher prices. Thus, the interaction of price and quality in health care markets with competition is not an easy one to determine final effects. Most importantly, the occurrence of these effects is based on the presumption that quality is recognizable to patients (or whoever decides on their behalf), and that information on quality is available and trustworthy. See European Commission, *supra* n. 7, 44.

in healthcare might particularly harm the non-economic facets of healthcare quality, such as *equity*, *continuity* and *acceptability,* or else the notion of *trust* in the patient–doctor relationship.

An additional relevant consideration is that as long as health systems in Europe move towards market driven healthcare delivery, the application of competition law in these systems will inevitably increase. Therefore, this chapter also identifies the main competition problems and the hard questions that European competition authorities concerned with healthcare quality should expect to address and examine.

## 1. Towards the Marketization of EU Healthcare Systems: What is the rationale behind this trend?

The EU Member States have a range of different healthcare systems which can be divided into two basic types: Bismarck systems that are insurance-based and Beveridge systems (centralized or decentralized) that are tax-funded.[281] EU health systems aim to meet a range of goals, among which the following have a high degree of importance: (a) equitable access to improved quality of care; (b) cost-effectiveness in service organization and delivery and (c) transparency and accountability.[282] These systems, however, also share common concerns, in particular soaring costs that are due mainly to three factors: rising life spans (and therefore ageing populations), increasing expectations, and technological developments.[283] Whereas these three factors also have beneficial aspects – in terms of longer healthier lives – they create strains on national budgets.[284] Thus, some European Countries have started to introduce competition in the delivery of health services as a device to reduce the cost of these services.

Competition is also looked at as a solution to problems that government-run and regulated health systems did not solve.[285] Seeing competition as a solution to improve healthcare performance

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[281] W. Sauter, *supra* n.12, at 459.
[282] European Commission*, supra n.* 7, at 14-15.
[283] W. Sauter, *supra* n. 12, 458.
[284] *Ibid.*
[285] European Commission, *supra* n. 7, 15. In the Netherlands for example, health reforms were designed to counter widespread public dissatisfaction with lengthening waiting lists, see W. Sauter, *supra.* 12, at 4.

reflects also Le Grand's observations that many countries where healthcare is funded from the public purse face serious problems with their systems of care delivery.[286] Public funding is often accompanied by public delivery;[287] that is, by hospital and other medical facilities owned and operated by the State. While on occasion, such institutions can work successfully, in many other cases, they do not.[288] According to Le Grand these institutions are directly funded from government, with budgets that are determined historically and that may bear little relationship to their performance or activities.[289] Therefore, they often provide low-quality services, they are inefficient in their use of resources, and unresponsive to the needs and wants of their patients.[290] These institutions, Le Grand further claims, are usually close to monopolies with patients having relatively little alternative sources of treatment, especially if they are poor and cannot afford whatever private facilities may be available.[291]

In light of these concerns, critics of the public delivery form of health service claim that if patients had more choice regarding where they could go for treatment, and if the money followed the choice, so that medical facilities would only successfully obtain resources if they successfully attracted patients, then the resultant competition would provide a powerful incentive for these facilities to improve almost all aspects of the service they provide: their quality, their responsiveness and their efficiency.[292] Such quasi-markets, they claim, would also be more equitable, with choices that are currently reserved only for those who can afford private care being extended to the less well off, and with the resultant rise in standards benefiting everyone.[293]

Le Grand, however, underlines that the choice and competition model for healthcare delivery can actually enhance the quality, efficiency, equity and the responsiveness of a health system to the extent specific conditions are met. These conditions are: (a) there have to be alternative providers from which to choose; (b) there have to be easy ways for new providers to enter the

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[286] J. Le Grand, *supra* n. 20, at 479.
[287] *Ibid.*
[288] *Ibid.*
[289] *Ibid.*
[290] *Ibid.*
[291] *Ibid.*
[292] *Ibid,* 480.
[293] *Ibid.*

market, and, correspondingly, for failing providers to leave or exit from it;[294] (c) there have to be ways of preventing existing providers engaging in anti-competitive behavior (d) patients should be given the relevant information and be helped in making choices (e) there should be help with transport costs, preferably targeted at the less well - off (f) the opportunities and incentives for 'cream-skimming' should be eliminated, either through not allowing providers to determine their own admissions or through properly risk adjusting their payment.[295]

## 2. Is the market for health care *special*?

The conditions Le Grand finds essential so that competition in healthcare delivers actual benefits to patients cannot easily be met in reality. And even if they were, they might not address all the risks to healthcare quality market driven healthcare delivery actually creates. This section elaborates on this argument by posing two important questions: *what are the market imperfections pervading healthcare markets? Can indeed choice drive quality competition?* This section also identifies the reasons why the injection of market values in hospital and medical services may jeopardize certain facets of healthcare quality.

### 2.1 Healthcare markets or else a world of market imperfections

Generally, the belief that market competition provides a preferred set of policies in healthcare is not an unquestioned one. Some health economists do insist that the analogy from the commercial sector does not readily apply in healthcare, where the introduction of economic incentives, such as competition, tends to have perverse effects.[296] They warn that genuine competition does not exist in the real world[297] and that patients face considerable difficulties in choosing treatment and healthcare providers. They further insist that the danger of 'cream-skimming' (the selection, by providers, of easier or cheaper patients to treat)[298] is a real and serious

[294] *Ibid*, 485.
[295] *Ibid,* 488.
[296] M. Fotaki, 'What market based patient choice can't do for the NHS: The theory and evidence of how choice works in healthcare, Centre for Health and the Public interest', March 2014, 7.
[297] J. Le Grand, *supra* n. 20, at 480.
[298] *Ibid.*

one. All this, they argue, would vitiate the alleged advantages of choice and competition, and instead create a system encouraging exploitation and inequity.[299]

In attempting to explain why healthcare markets work differently than others, health economist J. Olsen, has noted: '…[W]e can think of real world markets located on a spectrum ranging from (almost) perfect to (almost) imperfect. The market for healthcare stands out as being almost completely imperfect'.[300] This is because the set of assumptions, which should be met so that market forces result in socially desirable outcomes, are not met in healthcare.[301]

But what is a market, a perfect market and an imperfect one? To begin with, *markets* are institutions in which exchanges take place between parties who voluntarily undertake them.[302] A market is 'a meeting or gathering place of people for the purchase and sale of provisions or livestock' and as 'the action or business or buying and selling'.[303] A *perfect market,* or a perfectly competitive market, is one in which there is such a large number of sellers that none of them is able to influence the price.[304]

The perfectly competitive market is a very attractive mechanism for distributing goods and services[305]: Sellers produce the goods and services that buyers desire in the least costly manner, prices approximate marginal costs, and resources are allocated to their most valued ends.[306] Once everyone stops trading because they see no more advantage, the market is in equilibrium.[307] This outcome is desirable for a number of reasons. First and foremost, people are making their own choices. Second, the only goods and services produced are those that people demand and they are produced without wasting economic resources. By not engaging in any more trades, people reveal

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[299] *Ibid.*
[300] J. Olsen*, Principles in Health Economics and Policy* (Oxford, Oxford University Press, 2009) 49.
[301] T. Rice, 'Can Markets Give Us the Health Care System We Want?' (1997) 22(2) *Journal of Health Politics, Policy, and Law* 383, 384.
[302] D. Satz, *Why Some Things Should Not Be for Sale: The Moral Limits of Markets* (Oxford, Oxford University Press, 2010) 15.
[303] New Shorter Oxford English Dictionary, 1699.
[304] J. Olsen, *supra n.* 300*,* at 48.
[305] *Ibid.*
[306] W. M. Sage, David A. Hyman, and Warren Greenberg, 'Why Competition law matters to healthcare quality', (2013) 22(2) *Health Affairs*, 31, 32.
[307] T. Rice, *supra* n. 301, at 386.

themselves to be as satisfied with their economic lot as far as possible, given the resources with which they began.[308]

Nevertheless, the pure competition model leads to the above desirable outcomes only to the extent a number of conditions are satisfied for an entire industry: These conditions are: (a) a large number of firms no one of which can influence price; (b) the absence of barriers to entry to new firms that might seek to enter the industry; (c) homogenous products; (d) perfect information about prices, quality and output on the part of both consumers and firms; (e) impersonal transactions; (f) many buyers and sellers; (g) private goods; (h) selfish motivation.[309]

Most real - world markets do not satisfy all the above conditions entirely. Nevertheless, healthcare markets do not satisfy any of them because of the numerous imperfections pervading them. These market imperfections or, in other words, market failures, absent any intervention correcting them, can substantially undermine quality-based competition.[310] To elaborate: In healthcare a variety of circumstances undermine the neoclassical assumption that buyers and sellers possess perfect information to assess the quality and costs of the services provided.[311] Having perfect information mainly means that buyers can predict how much they want to buy and when, i.e. there is no uncertainty involved, and buyers know the quality of the good, either through own experience from previous consumption or availability of product information.[312]

In contrast with this assumption, in healthcare markets, information is asymmetrically distributed among providers, patients and payers.[313] Due to the technical nature of medical information and the complexity of diagnoses and treatments alternatives, patients and third party payers may find it difficult to evaluate the cost and quality of health services.[314] Indeed, the effects of most treatments are random to some degree, and patients are not well-equipped to evaluate the

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[308] *Ibid.*
[309] J. Olsen, *supra* n. 300, at 48.
[310] T. L. Greaney, 'Quality of Care and Market Failure. Defenses in Antitrust Health Care Litigation', 1989 (21) *CONN. L. REv.* 605, 633.
[311] *Ibid*, 634.
[312] J. Olsen, *supra* n. 300, at 49.
[313] Furrow, T. Greaney, S. Johnson, T. Jost, R. Schwartz, *Health Law* (West Academic Publishing, HornBook Series: 2014), 701-702.
[314] *Ibid.*

relevant information on treatment effects.[315] Moreover, individuals rarely confront the same major illness several times, so there is little opportunity to acquire information about the relative performance of different treatment regimes.[316] Trying to combine information from many different patients can be also problematic because of potential differences in their presenting conditions, so consumers may have no objective measures of physician quality.[317]

Asymmetric information arises, for example, when an optometrist fails to perform an accurate screening test for glaucoma.[318] Since absent other indicators, the patient is likely not afflicted with such a low-probability condition, the customer may never know that the test was not correctly performed.[319] Informational asymmetries therefore imply that customers are reliant upon the professional's own honesty and integrity for the quality of care they receive.[320] As a consequence, a patient would want the doctor to be the perfect agent, a doctor who provides the patient with the combination of services which is most preferred by the patient.[321]

Absent regulation, information asymmetries may affect the quality of healthcare services in multiple ways. For example, taking into account that patients may not be able to distinguish quality differences, they might have little reason not to choose a provider offering the service at a lower price - a provider from whom they are, unknowingly, likely to receive lower quality service.[322] Professionals who may wish to offer high-quality services may not survive the erosion of their customer base - customers who are essentially unaware that they are sacrificing quality for price.[323] As a result, in cases where de-biasing consumers is costly and unprofitable, healthcare professionals or providers may be dis-incentivized from investing in quality.

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315 J. M. Poterba, 'Government Intervention in the Markets for Education and Health Care: How and Why?', in *Individual and social responsibility: Child care, education, medical care, and long-term care in America* (University of Chicago Press: 1996), 277, 282.
316 *Ibid.*
317 *Ibid.*
318 J. Kwoka, 'The Federal Trade Commission and the professions*:* A quarter century of accomplishments and some new challenges' (2005) 72(3) *Antitrust Law Journal*, 997, 1000.
319 *Ibid.*
320 *Ibid.*
321 J. Olsen, *supra* n. 300, at 52.
322 J. Kwoka, *supra* n. 318, at 1001.
323 *Ibid.*

The second condition, impersonal transactions, requires that buyers have the same level of trust and confidence in all sellers.[324] Each party to a market transaction must view one's relation to the other as merely a means to the satisfaction of ends defined independently of the relationship and of the other party's end.[325] The medical relationship, however, is intensely personal. Confidence and trust are crucial as is a continuing relationship. When humans are at their most vulnerable and exploitable they need much more secure protection than a market can afford.[326] People, however, are more likely to trust those with whom they repeatedly interact, with whom they share beliefs and values, and with whom they are able to engage in direct communication.[327] Indeed, good care grows out of collaborative and continuing attempts to attune professional knowledge and technologies to diseased bodies and complex lives.[328] Especially when chronic diseases are involved, the continuity of care and the element of trust are much more important values than mobility and choice. Markets, however, can negatively affect all of these factors by increasing the number and heterogeneity of trading partners[329] and by inducing mobility.

The third condition of private goods is also not met in healthcare markets. Private goods are goods where only one person consuming the good is affected by it.[330] On the other hand, public goods are goods and services whose consumption by one individual does not preclude consumption by others (the so called free rider problem).[331] One example is street lights.[332] Individuals can receive the benefits of a public good without having to pay for it.[333] Because of free riders and because provision to many does not cost significantly more than provision to one, producers do not receive adequate compensation for their efforts. As a result, markets tend to undersupply public goods.[334] Somewhere in between pure private goods and pure public goods, lie goods for which more people

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[324] J. Olsen*, supra* n. 300, at 42.
[325] E. Anderson, 'The Ethical Limitations of Markets' 1990 (6) *Economics and Philosophy*, 179, 182.
[326] E Pellegrino, 'The Commodification of Medical and Health Care: The Moral Consequences of a Paradigm Shift from a Professional to a Market Ethic' (1999) 24 *J Med Phil* 243, 249, 254.
[327] *Ibid.*
[328] A. Mol, *The Logic of Care, Health and the Problem of Patient choice* (London: Routledge, 2008).
[329] D. Satz, *supra* n. 302, at 29.
[330] *Ibid.*
[331] T. L. Greaney, *supra* n. 310, at 638.
[332] J. Olsen, *supra* n. 300, 49.
[333] *Ibid.*
[334] T. L. Greaney, *supra* n. 310, at 639.

than the person consuming it are being affected by it.[335] When one person's consumption positively affects another person's utility we have a positive externality e.g. vaccines. When one person's consumption negatively affects another person's utility, we have a negative externality, e.g. smoking.[336]

The fourth condition on which the competition model relies, selfish motivation, is also not met in healthcare markets. This condition assumes that consumers buy goods or services because they yield utility and producers sell goods in order to make a profit. Nevertheless, when healthcare delivery is involved, patients and healthcare providers are also motivated by other, non-economic incentives. Patients do not necessarily disregard any concern with how their condition impacts upon people and doctors do not necessarily practice medicine to maximize their profits. And even if they do, a code of professional ethics often restricts them from doing so.[337]

Competition disciplines companies. To stay ahead of their competitors, companies must produce high enough quality products at low enough prices.[338] Vigorous competition, though, requires numerous buyers and sellers.[339] Nonetheless, in the market for healthcare services, the numbers of independent sellers varies. For example, while in big cities, there is a considerable number of hospitals and general practitioners, the same does not necessarily apply in rural areas. This may lead to monopolistic conditions and may weaken the incentives of healthcare providers to improve the quality of the services they provide. In addition, in some markets, such as hospital markets, less competition and not more may lead to higher quality. Merged hospital entities can improve quality performance by accelerating adoption of information technologies.[340] Electronic medical records, computerized provider order entry, and other electronic systems can improve the safety and quality of medical care through a variety of mechanisms, including faster access to patients' medical histories, clinical decision support systems, and alerts to potentially dangerous drug interactions.[341] Moreover, health policy studies indicate a relationship between procedure volumes

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335 J. Olsen, *supra* n. 300, at 50.
336 *Ibid.*
337 *Ibid.*
338 D. Satz, *supra* n 302, at 29.
339 *Ibid.*, 30.
340 K. Madison, *supra* n. 22, at 276.
341 *Ibid*, 276-277.

and patient outcomes.[342] To the extent that a hospital merger expands patient volumes for hospital providers, and higher volumes contribute to improved quality of care, then a merged hospital entity can indeed result in higher-quality care.[343]

Free entry of healthcare providers is also not a common feature of healthcare markets since there are specific conditions in this sector that prevent entry in the market. First and foremost, a considerable number of professional regulations restrict non- medics from offering their services. Secondly, certain types of professional qualifications are required in most countries for practitioners to receive public funding.[344]

The heterogeneity of healthcare providers and services also adds to the complexity of healthcare markets. The competition model requires that buyers cannot distinguish between products or services of different producers.[345] The quality of the services sold by healthcare providers, though, varies considerably depending upon the professional talents, training, personal attributes and other factors.[346] Variables such as geographic location and variations between outcomes among providers underscore the heterogeneity of healthcare professional markets. More importantly, private hospitals and physicians often attempt to make patients believe that their services are of higher quality than those of public providers by wrapping their services in more attractive amenities.[347]

### 2.2 Risks to equity

Critics of healthcare markets also stress that any healthcare system based on market healthcare delivery carries within it the danger of undermining equity. Markets generally respond to their 'effective demand', to desires backed up by money or by willingness to pay for things.[348] In fact, markets do not distinguish between intense desires and urgent needs.[349] Nevertheless, healthcare

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342 *Ibid*, 275.
343 *Ibid*, 276.
344 J. Olsen, *supra* n. 300, at 51.
345 *Ibid.*, 48.
346 T. L. Greaney, *supra* n. 310, at 636.
347J. Olsen, *supra* n. 300, at 52.
348 E. Anderson, *supra* n. 325, at 183.
349 *Ibid.*

systems wishing to achieve equity aim to respond to population's needs and not to individual desires. This is because they distribute healthcare not on the basis of people's ability to pay but on the basis of people's needs.

More than that, any healthcare system based on market healthcare delivery carries within it the danger of cream-skimming: that, instead of users choosing providers, providers choose users and do so on the grounds of cost.[350] Popular hospitals, for example, perhaps with waiting lists or queues for treatment, may only choose to treat those patients who are easiest or the cheapest to treat.[351] The cream-skimming risk appears also in health insurance services with insurers preferring healthy consumers who however do not feel they require insurance.[352]

### 2.3 The limits of choice: Does more choice mean better outcomes?

Choice for market liberalism is central. Given its focus on property rights, individual freedom, competition and user autonomy, it is firmly rooted in neoclassical economics.[353] It is premised on the belief that the individual is all knowing, calculating, and an inherent utility maximizer, and thus the best judge of his/her own well-being, and that consumer sovereignty and giving people choice will force them to reveal their preferences.[354] The sense of independence that comes with having many available options has been linked with better outcomes.[355]

The beauty of this claim is that it offers a simple solution to many complex problems: Just maximize the number and variety of choices.[356] This claim, however, based on the presumption that human beings do a terrific job of making choices, and if not terrific, certainly better than anyone else would do is quite flawed.[357] Humans predictably err. There is overwhelming evidence that obesity

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[350] J. Le Grand, *supra* n. 20, at 487.
[351] *Ibid.*
[352] W. Sauter, *supra* n. 12, at 12.
[353] M. Fotaki, 'Patient Choice in healthcare and Sweden: From quasi market and back to market? A comparative analysis of failure in unlearning', (2007) 85(4) *Public Administration*, 1059, 1061.
[354] *Ibid.*
[355] E. Peters, W. Klein, A. Kaufman, L. Meilleur, A. Dixon, 'More is not always better: Public policy can lead to unintended consequences', (2013) 7(1) *Social Issues and Policy Review*, 114, 115.
[356] R. Thaler, C. Sunstein, *Nudge: Improving decisions about health, wealth and happiness* (New Haven, Yale University Press, 2008) 9.
[357] *Ibid*, 6.

increases risks of heart disease and diabetes, frequently leading to premature death.[358] Nonetheless, rates of obesity in the United States have almost approached 20% and more than 60% of Americans are considered either obese or overweight. Certainly, this example neither suggests or indicates that humans cannot make good choices. On the opposite, Sunstein observes that people make good choices in contexts in which they have experience, good information and prompt feedback, such as when choosing ice cream flavors.[359] They do less well though in contexts in which they are inexperienced and poorly informed.[360] *Why*?

People generally tend to make biased assessments of risks. They assess the likelihood of risks by asking how readily examples come to mind. These biased assessments of risk perversely influence how people prepare and respond to choices. The pervasive problems are that easily remembered events may inflate people's probability judgements; and if not such events come to mind, their judgements of likelihoods might be distorted downwards.[361] People are also unrealistically optimist when they decide. They overestimate their personal immunity from harm and therefore they fail to take sensible preventive measures.[362] People also suffer from loss aversion which is a kind of cognitive nudge. It presses people not to make changes even when changes are very much in their interests.[363]

Additionally, although generally people appreciate choice, 'the tendency to search long and hard reduces enjoyment from the end result'.[364] This is because not all people have the ability to fully assess any type of information. Some people cannot even comprehend fairly simple information.[365] In one study, where consumers were presented with decision tasks that involved simply locating information in tables and graphs, the results indicated that the youngest participants (aged 18-35) averaged 8% errors and that the oldest participants (85-94) averaged 40% errors.[366]

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358 *Ibid*, 7.
359 *Ibid.*, 9.
360 *Ibid.*
361 *Ibid*, 26.
362 *Ibid*, 33
363 *Ibid,* 34.
364A. Ezrachi, M. E. Stucke, *supra* n. 25, at 247.
365E. Peters, W. Klein, A. Kaufman, L. Meilleur, A. Dixon, *supra* n. 355, at 117.
366 *Ibid.,* 118.

These challenges are magnified especially when people have to translate the choices they face into the experiences they will have.[367] This is because of the ambiguity aversion people exhibit, a notion implying that people prefer choices associated with known outcome probabilities to choices with ambiguous probabilities.[368] Thus, when people have a hard time predicting how their choices will end up affecting their lives, they have less to gain from numerous options and perhaps even by choosing for themselves.[369] In these situations providing more information or options can overwhelm cognitive abilities.[370]

Do analogous challenges affect people's thinking when they choose healthcare providers or treatments? Considering a number of studies finding relatively little evidence of consumerism in healthcare, the answer should be positive. As one physician observer sardonically noted 'consumers devote more effort to select their Halloween pumpkin than they do choosing providers'.[371] In fact, whilst patients appear to want information, they place the responsibility for medical decision-making on the doctor.[372] *How can this lack of consumerism be explained in such an important aspect of people's lives, such as health?*

Surely, one could argue that choosing a doctor, hospital or treatment is a complicated task since the amount of information a patient should actually evaluate in order to make the choice that best serves his/her interests is usually high. For example, choosing the appropriate medical treatment involves assessing the probabilities of benefit or harm from alternative forms of treatment (or from no treatment at all). And, as noted, experimental evidence reveals that individuals face difficulties in making good and rational decisions when they are required to weigh up probabilities. Therefore, to the extent product (or services) attributes increase in complexity, one cannot expect consumers in general (and patients in particular) to invest extensive time and energy into understanding all the available options, in searching for and comparing price and quality, and

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[367] R. Thaler, C. Sunstein, *supra* n. 356, at 76.
[368] E. Peters, W. Klein, A. Kaufman, L. Meilleur, A. Dixon, *supra* n. 355, at 118.
[369] R. Thaler, C. Sunstein, *supra* n. 356, 76.
[370] E. Peters, W. Klein, A. Kaufman, L. Meilleur, A. Dixon, *supra* n. 355, at 117.
[371] T. Rice, *supra* n. 301, at 406.
[372] *Ibid.*

choosing the product or service that closely matches their preferences, all at the expense of other mental pursuits.[373]

Individuals also lack the ability to construct the right choices when they are strongly influenced by fears of regret from a decision.[374] They tend to overweigh the probability or magnitude of a potential adverse result because of the concern that they may regret this decision.[375] Therefore, patients making more autonomous decisions have been shown to perceive greater risk from treatment options compared to those (faced with the same treatment choices) whose physicians chose for them.[376] Patients are more likely to choose conservative measures when empowered to make informed, value - concordant decisions.[377]

Patients' choices regarding health issues do not always lead to the decision that best meets their interest for one additional reason: because they are often socially constructed.[378] This means that when making complex health decisions, patients often rely on their intuition and emotions involving the avoidance of regret as well as trusted networks, rather than objective, impersonal data.

When such biases, norms, and heuristics are present, there are two important implications for legal analysis and regulatory policy: individuals will be prone to make judgment errors, and their behavior as actors in the market may deviate from the precepts of expected utility theory.[379] When patients lack the knowledge, motivation and willingness to invest time and effort in understanding the multiple tradeoffs the available options entail, they may forgo potentially superior options and maintain the status quo to their detriment.[380] Therefore, the introduction of patients' choice into a healthcare system and the consequent need to evaluate a number of different and complex options may itself harm their welfare.[381]

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[373] A. Ezrachi, M. E. Stucke, *supra* n. 25, at 247.
[374] T. L. Greaney, 'Economic Regulation of Physicians: A Behavioral Economics Perspective' (2008) 53 St. *Louis U. L.J.* 1189, 1196.
[375] *Ibid.*
[376] E. Peters, W. Klein, A. Kaufman, L. Meilleur, A. Dixon, *supra* n.355, at 133.
[377] *Ibid.*
[378] M. Fotaki, *supra* n 296, at 13.
[379] T. L. Greaney, *supra* n. 374, at 1196.
[380] A. Ezrachi, M. E. Stucke, *supra* n. 25, at 247.
[381] *Ibid.*

## 2.4 Market principles and medical ethics: *friends or foes*?

Medicine is a calling, not a business. [382] Indeed, the Hippocratic Oath requires doctors to abstain from every voluntary act of mischief or corruption. Maimonides admonished doctors to not allow thirst for profit and vision of renown and admiration to interfere with [their] profession.[383] In pledging fidelity to their professional ethic, doctors historically have been accorded many privileges by broader society, including the ability to determine whom to admit to their ranks, the authority to judge how best to educate future doctors, and the freedom to set and enforce their own professional standards.[384] In effect, the profession promises the public that the care it receives from doctors will be competent, rational and free of compromising self-interest. In exchange, the profession is given not only a substantial degree of autonomy over its own affairs, but a good measure of financial security and social standing as well.[385] This implicit understanding is commonly referred to as a *social contract* between the public and the medical profession. It is in the context of this social contract that the concept of professionalism, defined as the means by which individual doctors fulfil the medical profession's contract with society, takes its meaning.[386] The specific attributes that have long been understood to animate professionalism include altruism, respect, honesty, integrity, dutifulness, honor, excellence.[387]

A serious critique against the creation of markets in fields like healthcare is that the use of market mechanisms reinforces the expression of self-interest and reduces the opportunities for altruism.[388] In fact, there is some empirical basis for the view that the introduction of market incentives does affect the balance of motivation and, moreover, that it does so in some way that

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[382] Quote by Sir William Osler, who was a Canadian physician and one of the four founding professors of Johns Hopkins Hospital.
[383] J. Cohen, 'Professionalism in medical education, an American perspective: from evidence to accountability' (2006) 40 *Medical Education*, 607, 608.
[384] *Ibid.*
[385] *Ibid.*
[386] *Ibid.*
[387] Medical Schools Objectives Project. Learning objectives for medical student education: Guidelines for medical schools. Report 1. Acad Med 1999, 74:13–8.
[388] J. Le Grand, *Motivation, Agency, and Public Policy: Of Knights and Knaves, Pawns and Queens* (Oxford, Oxford University Press, 2003) 40.

turns the *knight*, a person that is altruistic or predominantly public-spirited, into a *knave*, a person that is predominantly motivated by self-interest.[389] *Why*?

Markets leave their mark.[390] Sometimes, market values crowd out non-market values worth caring about.[391] The rise of consumerism, for instance, can change doctor's professional ethics and lead to a decline of professional autonomy, which might cause a decrease in altruistic or service oriented attitudes towards patients.[392] This decrease in professionalism would ultimately harm the notion of trust which carries special weight in the case of medicine, where the stakes are as dear as life itself. [393] Undoubtedly, patients with high trust in their physician are more likely to seek care and do so in a timely manner. They are also more willing to share highly personal and confidential information, adhere more to treatment recommendations and return when needed for follow-up care. All these of course are very important determinants in health outcomes.

An empirical study in the Netherlands aiming to add some empirics to the debate on the relationship between market principles and medical professional ethics[394] confirms that this risk is not a fictional one. Therefore, it should not be ignored by health policy makers and antitrust enforcers.

In sum, some health policy analysts in the Netherlands attempted to answer the research question of how and to what extent market reforms have changed medical professional ethics in the Netherlands.[395] To address this question they conducted an empirical survey. In fact, they performed 27 interviews with surgeons and 28 interviews with GPs in 2008 and 2009.[396] Thus, the survey was conducted 2 years after the introduction of the 2006 Health Insurance Act that made private health insurance mandatory for everyone. To better understand the findings of this empirical study it is

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[389] *Ibid.*, 43.
[390] M. Sandel, *What Money can't buy, the Moral Limits of Markets* (New York, Farrar, Straus and Giroux, 2012) 9.
[391] *Ibid.*
[392] J. Dwarswaard, M. Hilhorst, M. Trappenburg, 'The doctor and the market: About the influence of market reforms on the professional medical ethics of surgeons and general practitioners in the Netherlands' (2011) 19(4) *Health Care Analysis*, 388, 389.
[393] M. Brennan, V. Monson, 'Professionalism: Good for Patients and Health Care Organizations', (2014) 89(5) *Mayo Clin Proc*, 644, 645.
[394] Dwarswaard, M. Hilhorst, M. Trappenburg, *supra* n. 392, at 390.
[395] *Ibid.*
[396] *Ibid*, 391.

important to know that: (a) some of the medical services in the Netherlands have fixed prices while others, such as elective surgery and knee operations, are freely negotiable;[397] (b) private insurers often attempt to attract clients by offering attractive packages such as treatment guarantees.[398] If, for example, a patient is diagnosed with breast cancer, his/her health insurer may guarantee that the patient will get surgery within 2 weeks;[399] (c) The payment system for general practitioners has been changed, in a much more fee-for-service direction. Therefore, GPs who perform minor surgeries or who use new diagnostic tools may charge much more for this service than they could before 2006.[400] It is also important to know that Dutch GPs work in independent practices in the neighborhood of their patients while Dutch surgeons work in hospitals.[401] Patients are referred to surgeons by their GPs who function as gatekeepers to hospital care.[402]

Both GPs and surgeons were asked whether they had noticed any changes in their work after the *marketization* of the Dutch healthcare system.[403] Not surprisingly, only the minority of respondents, one surgeon and seven GPs, reported that they had not noticed any difference in their day-to-day work.[404] All other participants maintained that the market reforms had affected the way they pursued their profession.[405] Eleven surgeons, for example, confessed that they increasingly felt the need to sell themselves and market their performance.[406] Before the marketization took place the doctors' association in The Netherlands (the KNMG) had always stated that physicians should not draw attention to themselves by advertisements.[407] Doctors adhered to this rule. The introduction of market elements in Dutch health care not only made the anti-advertisement principle obsolete but it

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397 *Ibid*, 390.
398 *Ibid.*
399 *Ibid.*
400 *Ibid.*
401 *Ibid*, 191.
402 *Ibid.*
403 Most respondents had an understanding of what marketization meant in the context of Dutch health care in general and their own work in particular, but for those respondents who asked for a clarification the survey conductors provided some examples, such as: more competition between care providers, more marketing and public relations, fear of losing customers, shifting priorities, *Ibid*, 391.
404 *Ibid*, 393.
405 *Ibid.*
406 *Ibid*, 394.
407 *Ibid.*

actually made it illegal for the doctors' association to uphold this traditional rule of medical professional ethics.[408]

Surgeons described the advent of several ways of marketing in healthcare.[409] Some of them did a visiting tour among GPs in the neighborhood, so as to encourage these GPs to send their patients to their hospital.[410] One surgeon reported that his hospital had managed (with quite some effort) to become the first google hit for certain types of operations.[411] Other public relations activities involved publishing advertorials in local newspapers, distributing leaflets, inviting a pop group to sing in the hospital to generate more publicity and buying advertising space on the back of a local bus.[412]

The majority of the surgeons further confessed that the new system made them pay more attention to minor afflictions than they did in the past.[413] Since their hospitals had invested in clinical paths and speedy treatment for patients suffering from varicose veins and inguinal ruptures, the standardization of these simple treatments had become a number one priority.[414] Other surgeons further admitted that they had started spending more medical time and energy on minor routine operations with which hospitals could make more money.[415] Surely, this goes to the detriment of patients in need of major, risky surgical procedures.

Others condemned marketization on the basis it undermines the application of the *primum non nocere medical principle*: 'first of all do not harm'.[416] In fact, some surgeons claimed that some of

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408 *Ibid.*
409 *Ibid.*
410 *Ibid.*
411 *Ibid.*
412 *Ibid.*
413 *Ibid.*, 395.
414 *Ibid.*
415 *Ibid.*, 400.
416 One of the first principles of medical professional ethics, featuring prominently in the Hippocratic Oath is *primum non nocere*: 'First of all, do no harm'. In Dutch GP practice the 'do no harm' principle used to be interpreted as follows: 'Any medical performance by any doctor is a form of medicalization and thereby potentially harmful. If a patient can recover without therapy or medication it is far better to forego treatment. If a patient really needs medication or therapy, he should get it, but preferably as little as possible. Thus, if a patient can be treated at home by his GP this is to be preferred over hospital treatment. Hospital is a sickening environment and hospital treatment takes the patient out of his private surrounding which is unsettling and potentially unhealthy', *Ibid*, 398.

their colleagues performed unnecessary operations. Some GP's also reported that some colleagues started treating conditions that did not even necessitate treatment according to their former ideology.[417] Others also were performing examinations which they would have condemned as unnecessary in the past.[418]

### 3. Reflecting on the complexities of healthcare markets: Do Le Grand's conditions take into account all facets of healthcare quality?

Le Grand's conditions reflect the above market realities only partially. To elaborate: Le Grand suggests that for healthcare markets to optimally work competition must be real and market entry must be easy.[419] Nonetheless, one would wonder how real competition between providers can be and how easy entry can be since healthcare markets are highly regulated in terms of entry. One would also wonder how real competition can be considering that, unlike other markets, in healthcare patients are not indifferent as to who the provider of the service is. They do not easily change healthcare providers because that would harm the continuation of their treatment. The fact that patients do not easily change providers might be an additional reason why entry in healthcare markets is not easy and competition cannot be *real*.

Le Grand does not only speak about easy entry but also about easy exit when he identifies the conditions under which the choice and competition model should apply in healthcare.[420] Indeed, barriers to exit can be harmful to competition. When poor or inefficient suppliers are prevented from exiting a market it can significantly undermine incentives for rivals to compete for market share.[421] However, proposing easy exit as a means to promote efficiency and quality raises equity and access concerns. Ensuring the *continuity* of health services especially in the provision of hospital services, albeit an important source of barriers to exit,[422] is a necessary condition for the protection of equity and access. Therefore, whenever health systems decide to promote competition to guide allocation of resources, there is the need to define a way to penalize non-performing providers

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417 *Ibid.*
418 *Ibid.*
419 J. Le Grand, *supra* n. 20, at 485.
420 *Ibid.*
421 Office of Fair Trading (currently CMA), Policy Report, *Competition in Public Services* (23 May 2013), 9.
422 *Ibid.*

without hurting continuity of service to the population.[423] Should States, for example, leave failing hospitals exit if they operate in rural or disadvantaged areas where access to alternative providers is limited? Alternatively, should Competition Authorities clear a hospital merger that increases market power on the basis it ensures merging entities' financial stability and therefore the continuity of services? These questions cannot easily be addressed. Nonetheless, they are essential both from competition and health policy perspectives.

Le Grand further claims that patients should be given the relevant information and be helped to make choices so that competition in healthcare markets works effectively.[424] Thus, Le Grand proposes that Governments should introduce tools that would help consumers compare healthcare providers. Obviously, Le Grand notes this condition considering that information between patients and healthcare providers is distributed asymmetrically and not all patients have the time, ability and knowledge to evaluate the quality of different healthcare providers and make the right choices. Can the use of choice tools, though, fully correct this market failure and enhance quality competition in healthcare?[425] Considering some choice tools that are used in the UK, such as the *NHS Choices*[426] and *iWantGreatCare*,[427] the answer is not necessarily positive.

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[423] European Commission, *supra* n. 7, at 36.
[424] J. Le Grand, *supra* n. 20, at 488.
[425] Government websites are also an important source of information about healthcare quality in the US. The federal Medicare website now provides aggregate ratings based on patient experiences (Patients who reported that their nurses 'always' communicated well), care processes (Heart attack patients given aspirin at discharge), and outcomes ("Death rate for heart attack patients," "Rate of unplanned readmission after hip/knee surgery," "Central line-associated bloodstream infections"). The ACA has also called for the development of new quality measures, established report programs for additional types of healthcare performance and mandated the creation of a website that will report physician quality. Hospital quality information is also provided by non - governmental institutions such the Joint Commission, which accredits hospitals as well as health - plans. In many states broad coalitions of stakeholders such as hospitals, physicians and health plans have come together to jointly publish quality ratings, K. Madison, *supra* n. 36, 683-685. In the Netherlands, the government also has a web site (www.kiesbeter.nl) to help consumers choose healthcare providers. It used to contain information to assist consumers in selecting health insurance packages, but the government has argued there are sufficient non-governmental web sites available to fulfil this role. The site offers information on the availability of services, waiting lists and aspects of quality of services, including information collected by the Health Care Inspectorate and quality information collected through specific measurements. General information about public health and healthcare can be found at another website – since 2014, VolksgezondheidEnZorg.info. In addition to these governmental initiatives, a variety of independent and commercial web sites offer information on quality, waiting lists, prices, insurance plans and patient satisfaction, see M. Kroneman, W. Boerma. M van den Berg, P Groenewegen, J de Jong, E van Ginneken (2016), *The Netherlands: health system review. Health Systems in Transition*, (2016) 18(2), 46.
[426] http://www.nhs.uk/pages/home.aspx.
[427] https://www.iwantgreatcare.org/.

*NHS Choices* is a government-provided 'choice-tool' providing information on NHS healthcare, social care and healthy life style.[428] It uses a combination of decision tools, government data on service providers and, increasingly, patient feedback to enable patients to compare treatments and services.[429] To reduce puffery, this choice-tool sets strict limits on what can be posted. Further, it does not allow comments about any named or identifiable doctors or nurses.[430] *NHS Choices* provides information for more detailed comparison of the facilities at different hospitals and their performance on, for example, mortality rates, or the percentage of A&E attendances which are admitted, transferred or discharged within 4 hours of arrival.[431]

The second tool, *iWantGreatCare.org*, allows patients to provide feedback on healthcare experiences.[432] Patients rate healthcare professionals on three dimensions; trust, listening skills and whether they would recommend them to others.[433] An overall rating percentage is generated and patients can also provide qualitative feedback.[434] Patients can also rate hospitals again on the basis of specific dimensions. These are respect, involvement, timely information, cleanliness.[435] Patients can search for healthcare providers by geography and specialism to compare ratings and reviews.[436] *iWantGreatCare.org* is funded by providing performance consultancy services to healthcare providers, using the data captured from patients on the site.[437]

Can these choice-tools truly help consumers surpass the challenges they face in choosing providers or treatments in healthcare? Can they fully safeguard that patients have easy access to truthful, important and credible information? To start with, these tools can be used only by people being able to effectively use internet. Some vulnerable groups in our society, thought, do not even have internet access.[438] In addition, tools such as *iWantGreatCare.org* provide information on quality

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[428] Office of Fair Trading (currently CMA), 'Empowering consumers of public services through choice tools', April 2011, OFT1321, 17.
[429] *Ibid.*
[430] *Ibid*, 18.
[431] See for example: https://www.nhs.uk/service-search/scorecard/results/1015.
[432] Office of Fair Trading (currently CMA), *supra* n. 428, at 18.
[433] *Ibid.*
[434] *Ibid.*
[435] See for example: https://www.iwantgreatcare.org/hospitals/northgate-therapy-centre.
[436] Office of Fair Trading (currently CMA), *supra* n. 428, at 18.
[437] *Ibid.*
[438] *Ibid.*

in an over simplistic way. Exactly because patients do not necessarily have the capacity to assess complex information regarding healthcare quality, *iWantGreatCare.org* offers information to patients in a more accessible but less accurate way. Indeed, patients can easily assess hospitals' cleanliness or staff's listening skills. Nonetheless, when choosing healthcare provider, other dimensions of healthcare quality, such as effectiveness and safety, may be much more important and crucial. These dimensions of quality though cannot easily be assessed by patients and therefore they are not included in patients' reviews.

More than that, choice-tools may create incentives for service providers to improve their performance in the areas publicized by them.[439] This can undermine the quality of the service offering. This is because measures that successfully shift providers' attention to an area in need of improvement will have the disadvantage of shifting attention away from other areas.[440] Furthermore, choice-tools that provide information based on patients' views might erode quality competition by providing false information. Patients' experiences are subjective. Therefore, patients may not always provide an accurate assessment of their medical treatment.

*NHS Choices* offers to patients more detailed information on hospitals' performance. In fact, it offers information on health outcomes, such as readmission rates or mortality rates. Quality indicators evaluating hospitals' performance on the basis of health outcomes may be misleading. Differences in health outcome indicators may not necessarily relate to differences in quality between different healthcare providers. The previous chapter indicated that differences in outcomes might relate to differences in the type of patients that are cared for by the different providers.[441] Therefore, factors such as age, gender, co-morbidity, severity of disease and socioeconomic status should be always considered when comparisons are made on the basis of health outcomes.[442] Differences in health outcomes might also relate to differences in the way data are collected.[443] Only if one cannot explain the variation in terms of differences in the type of patient, in how the data were collected, or

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439 *Ibid.*, 24.
440 K. Madison, *supr*a n 22, at 686.
441 J. Mant, *supra* n. 230, at 476.
442 *Ibid.*
443 *Ibid.*

in terms of chance, can quality of care become a possible explanation.[444] This point is extremely crucial since measures that do not accurately reflect quality because of inadequacies in either underlying data or measure design can malign providers, misdirect patients and lead improvement effort astray.[445]

More than that, using outcome comparisons in coercive and competitive situations, where each provider has high stakes in the result, can encourage gaming that produces perverse effects.[446] An example is disclosure of mortality rates rankings leading providers to build an interest in rejecting high complexity, high mortality risk patients in order to improve their ranking position.[447] In other words, using mortality rates to correct the asymmetric distribution of information in healthcare may raise serious equity concerns.

*NHS Choices* provides information not only on the outcome but also on the process of care, such as waiting time. Nonetheless, as the NHS experience in the 1990s reveals publishing information on providers' waiting times may also incentivize providers to game.[448] In the 1990s the Labour Government aiming to induce hospitals' performance applied a targets error system of governance or else a star rating system. Under this regime, health authorities rated hospitals on the basis of specific indicators, such as waiting times. Patients in hospitals Accident and Emergency Department (A&E), for example, should be seen within 4 hours. Life threatening calls made to the ambulance services should be met within 8 minutes.[449] The targets and terror regime produced an impressive improvement in reported performance.[450] Nonetheless whether reported performance accurately reflected reality has been questioned.[451] Ambulance trusts for example achieved the response time target by relocating depots from rural areas to urban areas.[452] For hospital A&E

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444 *Ibid*, 477.
445 K. Madison, *supra* n. 22, at 686.
446 H. Palmer, *supra* n. 244, at 482.
447 European Commission, *supra* n. 7, at 41.
448 Gaming here is defined as reactive subversion such as hitting the target and missing the point or reducing performance where targets do not apply, C Hood and G Bevan, 'What's Measured is What Matters: Targets and Gaming in the English Health Care System' (2005) 84(3) *Public Administration,* 517, 521.
449 *Ibid*, 526-527.
450 L. Stirton, 'Back to the future, lessons on the procompetitive regulation on health services' (2014) 22(2) *Medical Law Review*, 180, 191.
451 *Ibid.*
452 C Hood and G Bevan, *supra* n. 448, at 530.

waiting-time targets, output-distorting gaming response was also documented. First, a study of the distribution of waiting times in A&E found frequency peaked at the four-hour.[453] Surveys by the British Medical Association also reported two types of gaming responses: the drafting in of extra staff and the cancelling of operations scheduled for the period over which performance was measured.[454] Hospitals also required patients to wait in queues of ambulances outside A&E Departments until the hospital in question was confident that that patient could be seen within four hours.[455] Such tactics may have unintendedly caused delays in responding to seriously ill individuals when available ambulances were waiting outside A&E to offload patients.[456] This example demonstrates that, again, gaming may create serious equity concerns.

Exactly because quality indicators may not fully capture all dimensions of healthcare quality, such as effectiveness, patients do rely on doctors' experience and advice when they have to choose either the appropriate medical treatment or healthcare providers. This is the reason why both in the UK and the Netherlands GPs do not only offer their medical services but they also act as gate keepers. From the perspective of healthcare quality this might be desirable. Arguably, if patients cannot adequately assess providers' performance on the basis of the clinical aspects of quality, they might choose provider on the basis of short waiting lists, or secondary aspects of quality such as comfort, meals, decoration. From the perspective of competition, though, this might not be desirable since the more doctors behave as their patients' agents the more their market power increases.

In considering the conditions under which the choice and competition model in healthcare should function, Le Grand also seems to integrate some equity concerns in his proposals. In fact, Le Grand takes the view that the State should reimburse the transport costs of the less well - off patients.[457] Undoubtedly, to a certain extent this intervention would widen the geographical area within which patients can choose providers. Additionally, this measure would facilitate competition between healthcare providers. However, first, this measure cannot apply to patients seeking urgent

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453 *Ibid,* 531.
454 *Ibid.*
455 *Ibid.*
456 *Ibid.*
457 J. Le Grand, *supra* n. 20, at 484.

care. Second, transport cost is not the only barrier less well - off patients face in terms of access to care. Potential restriction to access because of successful gaming is an additional barrier to access. Le Grand's proposals seem to recognize this additional equity concern. Nonetheless, they do not fully address it. More specifically, Le Grand proposes that hospitals and other treatment centers should be required to accept whoever is referred to them.[458] However this proposal does not seem a comprehensive one since it disregards the fact that even if hospitals are required to treat all patients, they can still avoid high risk patients by, for instance, avoid contracting with high quality surgeons specialized in complex high - risk surgeries. Le Grand further proposes that hospitals should receive higher compensation for higher risk patients. However, at the same time admits that this proposal does not fully address potential restrictions to equity as he underlines that risk adjustment is a complex and difficult business.[459]

The analysis above does not aim to criticize Le Grand's conditions. It aims to highlight that the objective of real competition in healthcare might not always be in line with the pursuit of certain aspects of healthcare quality such as safety, access, equity, effectiveness, acceptability and continuity. Indeed, because of the special features of healthcare provision, a free healthcare market without any form of regulation would harm these essential dimensions of healthcare quality. This is the reason why healthcare in Europe is regulated at macro level via State regulation, at a 'meso' level by the management bodies, insurers and/or purchasers of healthcare, and at micro level by providers as such with the latter promoting patients' interests.[460]

## 4. Applying competition law with a view to protect healthcare quality: *What are the challenges*?

The previous section explored what the special characteristics of healthcare markets are. It also highlighted that because of these special characteristics, absent regulation, the introduction of competition in healthcare provision may substantially harm essential dimensions of healthcare

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458 *Ibid.*, 487.
459 *Ibid.*
460 K. Raptopoulou, *EU law and healthcare services, Normative approaches to healthcare systems*, (Kluwer Law International 2015), 152. In the chapters that follow some examples from the applicable regulatory framework in the UK and US that aims to protect healthcare quality in the provision of medical and hospital services will be analyzed.

quality. This section aims to point to an additional issue: that in light of the reality that in medical and hospital markets the introduction of competition may substantially harm specific dimensions of healthcare quality, healthcare providers or medical associations may engage in anticompetitive agreements in order to protect key facets of this notion. This is because, as this section shows, when hospital and medical markets are created, regulation may not always and necessarily protect all facets of healthcare quality. Therefore, key players in healthcare markets might insist that their anticompetitive agreement or transaction is necessary for the pursuit of this goal. Hospitals, for example, may attempt to pursue mergers that may create market power aiming to protect essential dimensions of healthcare quality, such as safety and equity. Medical associations may insist that a specific decision or agreement restricting choice is necessary for the protection of public safety. In light of these concerns, this section discusses the challenges competition authorities should expect to face in addressing these competition law concerns with an eye to protect healthcare quality as *a whole*. To elaborate:

One of the biggest challenges competition authorities in Europe may face in applying competition law in healthcare is how to define, assess and protect quality. Generally speaking, identifying a single exhaustive definition of quality is a challenging endeavor.[461] This is because trying to define quality is a bit like trying to nail jelly to a wall.[462] Quality is a multidimensional concept that encompasses inter alia the durability, reliability, location, design and aesthetic appeal, performance and safety of a product.[463] It is also a relative concept insofar as the level of quality found in any one product is defined by reference to the quality levels of other products.[464] It is also a concept that incorporates a significant element of subjectivity, as certain quality aspects may be valuable only to some consumers or more valuable to some than others.[465] For example, a set of pizza delivery customers might all agree that both the speed of delivery and a diverse menu are important factors but some may consider the delivery speed to be the most important factor, while others care more about whether certain aspects of pizza are available.[466] In sum, quality's multifaceted and indistinct

461 OECD, DAF/COMP (2013)17, *supra* n. 24, at 6.
462 *Ibid*, 12
463 *Ibid*, 6.
464 *Ibid.*
465 *Ibid.*
466 *Ibid*, 11.

nature makes the task of defining it complicated.[467] *How is quality defined and assessed under EU competition law?* To answer this question a short travel to the Commission's guidance seems necessary.

To begin with, quality becomes a factor both in antitrust and mergers analysis.[468] The Commission's guidelines regarding Horizontal Cooperation Agreements acknowledge, for example, that for an agreement to have restrictive effects on competition within the meaning of Article 101(1) it must have, or be likely to have, an appreciable adverse impact *on at least one of the parameters of competition* on the market, such as price, output, *product quality*, *product variety or innovation*.[469] Agreements can have such effects by appreciably reducing competition between the parties to the agreement or between any one of them and third parties. R&D agreements for example may restrict the *quality and variety of possible future products or technologies or the speed of innovation*[470] where two or more of the few companies engaged in the development of such a new product agree to co-operate at a stage *where they are each independently rather near to the launch of the product.*[471] Production joint ventures may also restrict quality by incentivizing the parties' agreement to directly align quality.[472] Standardization agreements can also weaken quality competition by setting detailed technical specifications for a product or service and therefore by impeding *technical development and innovation*.[473] Vertical agreements can also reduce the products' quality, limit choice and hamper innovation by softening competition or by facilitating foreclosure and collusion at manufacturer's level.[474] They can additionally reduce the availability and quality of retail services and the level of innovation of distribution at distributors' level.[475]

Quality is also considered under an article 101 (3) TFEU analysis. Given that the aim of EU competition rules is to protect competition on the market as a means of enhancing consumer

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[467] *Ibid*, 6.
[468] *Ibid.*, at 77.
[469] Communication from the Commission, Guidelines on the applicability of Article 101 of the Treaty on the Functioning of the European Union to Horizontal Co-operation Agreements, *supra* n. 23, para 27.
[470] *Ibid,* para 138.
[471] *Ibid.*
[472] *Ibid,* para 157.
[473] *Ibid*, para 166.
[474] Commission Notice, Guidelines on Vertical Restraints, Brussels, SEC (2010) 411, para 101.
[475] *Ibid.*

welfare and of ensuring the efficient allocation of resources[476] agreements that restrict competition may at the same time have pro-competitive effects by way of efficiency gains. The created efficiencies can lower the cost of producing an output (cost efficiencies) but they can also improve the quality of a product or create a new product (qualitative efficiencies).[477] Depending on the individual case qualitative efficiencies can be of equal or greater even importance than cost efficiencies.[478] R&D agreements, in the form of new or improved goods and services produce qualitative efficiencies.[479] Joint production agreements also generate quality improvements by allowing new or improved products or services to be introduced on the market more quickly.[480] Distribution agreements also give rise to qualitative efficiencies. Specialized distributors, for example, can provide services that are better tailored to customer needs or to provide quicker delivery or better - quality assurance throughout the distribution chain.[481]

In the context of a merger analysis quality again plays an essential role. The Commission's substantive test for assessing mergers as embedded in the Merger Regulation is based on significant impediment of effective competition (SIEC).[482] The SIEC test covers not only price and output restrictions but also reduction in innovation or choice and in general any harm to competition resulting from quality reductions.[483] The role of quality is expressly recognized in both the Horizontal and Non - Horizontal merger guidelines.[484] The Horizontal Merger Guidelines[485] underline that effective competition brings benefits to consumers. Therefore, the Commission in the context of its merger analysis prevents mergers that would be likely to deprive customers of the benefits of effective competition, such as low prices, high quality products, a wide selection of goods and services, and innovation.[486] These are the mergers that would significantly increase the merging

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476 Communication from the Commission - Guidelines on the application of Article 81(3) of the Treaty [Official Journal No C 101 of 27.4.2004] (formerly Article 81 (3) TEC), para 33.
477 *Ibid.*
478 *Ibid*, para 69.
479 *Ibid,* 70.
480 *Ibid,* para 71.
481 *Ibid,* para 72.
482 OECD, DAF/COMP (2013)17 *supra* n. 24, at 82.
483 *Ibid,* 83.
484 *Ibid.*
485 Guidelines on the assessment of horizontal mergers under the Council Regulation on the control of concentrations between undertakings, Official Journal C 03, 05/02/2004 P. 0005 – 0018.
486 *Ibid*, para 8.

parties' market power, the ability of one or more firms to profitably increase prices, reduce output, choice or quality of goods and services, diminish innovation, or otherwise influence parameters of competition.[487]

The test also enables to take into account efficiencies, which bring positive effects on quality. For the Commission to evaluate efficiency claims in its merger analysis and be in a position to reach the conclusion that because of the alleged efficiencies there are no grounds for declaring the merger to be incompatible with the common market, the efficiencies have to benefit consumers, be merger-specific and be verifiable.[488] As in the case of article 101 (3) TFEU such efficiencies might be either cost or qualitative efficiencies in the form of new or improved products.[489]

The non-Horizontal Merger Guidelines[490] also provide a similar framework for the assessment of innovation, acknowledging that one of the effects to be analyzed in merger control is the effect on quality. Loss of innovation is thus embedded in the analysis of potential anticompetitive effects.[491] In these guidelines the Commission mentions that it evaluates both the possible anti-competitive effects arising from the merger and the possible pro-competitive effects stemming from substantiated efficiencies benefiting consumers.[492] As the guidelines illustrate, a vertical merger can align the incentives of the parties with regard to investments in new products, new production processes and in the marketing of products.[493] For instance, whereas before the merger, a downstream distributor entity might have been reluctant to invest in advertising and informing customers about the qualities of products of the upstream entity when such investment would also have benefited the sale of other downstream firms, the merged entity may reduce such incentive problems.[494]

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[487] *Ibid.* See also OECD, DAF/COMP (2013)17 *supra* n. 24, at 83.
[488] *Ibid,* paras 80-81.
[489] *Ibid.*
[490] Guidelines on the assessment of non-horizontal mergers under the Council Regulation on the control of concentrations between undertakings, OJ C265, 18.10.2008, 6.
[491] OECD, DAF/COMP (2013)17 *supra* n. 461, 85
[492] Guidelines on the assessment of non-horizontal mergers, *supra* n. 490, at para 21.
[493] *Ibid.*, para 57.
[494] *Ibid.*

This brief overview reveals that quality is not specifically defined in the Commission's guidelines and policy documents. In fact, under EU competition law, quality forms part of a wider category of dynamic effects on competition – effects.[495] In fact, it is considered an important aspect of competition analysis which is highly related with innovation, choice and product entry. Should competition authorities in Europe choose to define quality *as choice, variety and innovation* in healthcare?

Defining and assessing quality *as innovation and choice* in the healthcare sector might be a wise policy option for various reasons. First and foremost, it would guarantee the consistent application of competition law in different sectors. Second, a notion of quality which mainly relates to choice and variety can be easily assessed by competition authorities. Therefore, the enforcement of competition law in the healthcare sector would not entail higher costs for competition authorities. This is because defining quality as choice would be in line with the central mantra of competition policy that competitive market forces, besides lowering prices, can increase efficiency, product quality, the level of services, the number of choices and, ultimately, consumers' welfare.[496] In line with this mantra, the antitrust enforcers when they assess quality they often do not attempt to quantify how a challenged restraint would impact quality; instead, they evaluate quality by relying on two heuristics. One heuristic is that more competition will generally increase quality for a given price or reduce price for a given level of quality.[497] A second heuristic is that when prices and quality vary, consumers will weigh the offerings using an internal price–quality metric.[498] Price adjusts for quality, and consumers rely on the heuristic 'you get what you pay for'.[499]

Nevertheless, if antitrust enforcers defined healthcare quality strictly as choice, innovation and variety they might fail to take into account in their assessment health policy analysts' views on how healthcare quality is achieved. In other words, they might fail to protect the notion of healthcare quality *as a whole*. To elaborate: As I developed in the previous section in healthcare markets more competition or choice does not necessarily lead to quality improvements. Quite the

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[495] OECD, DAF/COMP (2013)17, *supra* n. 24, at 80.
[496] A. Ezrachi and M. E. Stucke, *supra* n. 25, at 227.
[497] *Ibid.,* 228.
[498] *Ibid.*
[499] *Ibid.*

opposite, in some cases less choice might improve health outcomes. For example, in hospital markets research in healthcare quality reveals that larger hospital entities may be more able to develop effective quality improvement mechanisms than smaller ones. Healthcare quality research has demonstrated that peer influence speeds the adoption of beneficial therapies.[500] Clinical evidence has also shown that the mortality of patients has a direct inverse relation to the number of operations carried out by surgeons. Therefore, hospitals may decide to merge in order to increase the volume of their surgeries and therefore the overall quality of their services. Hence, if antitrust authorities were unwilling to divert from their usual heuristic that more choice and competition lead to quality, they may not seriously consider the insights of health policy research on how healthcare quality in hospital services is improved.

More than that, if competition authorities strictly defined quality as *choice* they may also fail to consider in their assessment core objectives of their healthcare system, such as equity. To better develop my argument, again, I provide an example. Socioeconomic status, whether assessed by income, education, or occupation, is linked to a wide range of health problems.[501] Poorer neighborhoods, for example, are disproportionately located near highways, industrial areas, and toxic waste sites, since land there is cheaper and resistance to polluting industries, less visible.[502] Housing quality is also poorer for low-socio economic status families.[503] As a result, compared with high-income families, both children and adults from poor families show a six-fold increase in rates of high blood lead levels while middle-income adults and children show a two-fold increase.[504] Childhood asthma incidence is also rising in urban neighborhoods among poor children, and the severity is greater among these children.[505] Should competition authorities clear a hospital merger, although it leads to market power in the respiratory services market on the basis it will allow the merged entity to employ the most reputable respiratory specialists? Should this merger be allowed on the basis it will ensure merging entities' financial stability and therefore access to respiratory services to the most disadvantaged groups of our society? If choice and competition are the main

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[500] K. Madison, *supra* n. 22, at 276.
[501] N. E. Adler and K. Newman, 'Socioeconomic Disparities in Health: Pathways and Policies', (2002) 21(2) *Health Affairs,* 60.
[502] *Ibid.*
[503] *Ibid.*
[504] *Ibid*, 66.
[505] *Ibid.*

dimensions of healthcare quality, then the answer is clearly negative. This is because in this case competition authorities may not be entitled to integrate equity concerns in their definition of healthcare quality.

Additionally, if the antitrust authorities defined mainly quality *as choice* their assessment might not be fully in line with the economic characteristics of the healthcare markets. Healthcare markets are pervaded by market failures. In these markets, patients face serious difficulties in choosing providers or medical treatments. Indeed, patients do not have the knowledge and capacity to judge and evaluate all aspects of healthcare quality. Of course, they are able to judge the quality of hospitals' amenities. They may also judge healthcare professionals' listening skills or commitment. They may not be able to judge, though, doctors' professional qualifications or hospitals' clinical effectiveness. Search engines that provide information on quality, such as *NHS Choi*ces or *iWantGreatCare.org* may not correct this market failure as they either provide information on specific aspects of quality, such as waiting times and mortality rates, or they provide information on quality that cannot easily be verified since it is often based on patients' personal experiences.

To correct this asymmetry of information and driven by their motivation to protect patients' interests, medical professionals may intervene in the markets they operate by imposing their own views on how healthcare quality is ensured. These interventions, though, may raise serious antitrust concerns. *Why*? Self-regulation is a key component in medicine. Many physicians during their careers are involved in setting, implementing and possibly enforcing professional standards.[506] While creating or enforcing these standards physicians and medical associations may engage in anticompetitive behaviour with a view to protect quality. Some doctors for example highly question the contribution of homeopathy to health outcomes. Indicatively, in the UK some doctors do insist that homeopathic treatments should be banned from the NHS.[507] Indeed, Members of the British Medical Association have claimed that homeopathic remedies should be relegated to shelves labelled placebos and that NHS money should not be spent on treatments that are scientifically implausible.[508] Convinced that homeopathy should not be seen as an alternative form of medical

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[506] W.W White, Professional Self - Regulation in Medicine, (2014) 16(4) *American Medical Association Journal of Ethics*, 275.
[507] https://www.theguardian.com/society/2010/jun/29/ban-homeopathy-from-nhs-doctors.
[508] *Ibid.*

treatment, the British Medical Association may publish guidelines dis-incentivizing doctors from cooperating with homeopathic hospitals or doctors. This decision may be considered anticompetitive on the basis of article 101 TFEU since it restricts competition between medical professionals or between homeopathic and non-homeopathic hospitals. If competition authorities considered that only choice and competition ensure quality in medical markets then this decision is clearly anticompetitive. Nevertheless, if competition authorities considered that the decision of the British Medical Association aims to correct the asymmetry of information in the market for medical services and ensure patients' health safety then they might consider that this agreement also has some procompetitive effects that should not be disregarded prior to careful assessment and examination.

GPs in the Netherlands and the UK also do not only offer their medical services but they act as gate-keepers too. Therefore, they refer patients to hospitals for treatment. GPs may have their own views on which hospital offers good or bad quality services. They might therefore agree to boycott specific hospitals that do not meet their standards of medical treatment. They might for example agree to stop referring patients to these hospitals. If, again, quality would only amount to choice then their agreement is clearly anticompetitive. If however competition authorities took the view that patients may not necessarily make good choices when they choose healthcare providers then they might be more willing to consider that doctors act as patients' agents and therefore their agreement corrects the information asymmetry pervading healthcare markets.

The analysis above clearly demonstrates that defining quality strictly *as choice* may yield conflicts between medical professionals, health policy analysts and antitrust enforcers on how healthcare quality is actually achieved and protected. In Donabedian' s language this conflict would undermine commitment in achieving healthcare quality as not all functions and institutions in the healthcare system would actually agree on what the main facets of healthcare quality are. *What are the alternatives? And what are their pros and cons?*

To avoid conflicts between medical professionals, health policy makers and antitrust enforcers and take into account in their assessment healthcare quality *as a whole* competition authorities may also choose to widen their definition of quality in the healthcare sector by integrating into their definition the views of medical professionals and health policy makers and researchers on

what the main facets of healthcare quality are. In other words, they might define quality in healthcare as a multidimensional concept encompassing a wider set of objectives such as efficiency, equity, acceptability, access, safety, effectiveness. This definition would be in line with the definition that has been adopted by international organizations, Donabedian and the IOM. Would the adoption of this wider definition of healthcare quality *transform* the application of competition law in healthcare? Surely, the answer is positive. This is because if competition authorities adopted a wider definition of healthcare quality they would be able to trade between different components of quality that in certain cases may inevitably clash. They would be able, for example, to balance *safety and effectiveness v. choice and competition*, *acceptability v. choice and competition*, *equity v. choice and competition*. To elaborate on my thinking, again, I give some examples.

The injection of market values in hospital markets can erode public trust in healthcare. The analyzed empirical study in the Netherlands indicated that following the marketization of the Dutch healthcare system doctors and hospitals felt an increasing pressure to increase GPs' referrals by advertising their services.[509] To increase publicity some surgeons even organized visiting tours among GPs in the neighborhood, so as to encourage these GPs to send their patients to their hospital.[510] Obviously, doctors' participation in such marketing efforts may harm public trust in medicine since patients may increasingly start believing that surgeons offer their services guided by their own self - interest and not by their commitment to improve health outcomes. Medical associations animated by their belief that the nurturance of trust in the therapeutic relationship is essential, might engage in self - regulation prohibiting medical professionals from participating in hospitals' marketing efforts. They may issue guidelines aiming to restrict doctors' freedom to advertise themselves by selling their qualifications or special talents. If antitrust authorities defined quality only as choice these practices would be only seen as anticompetitive. Nonetheless if antitrust enforcers saw quality as a wider notion that encompasses also the value of *acceptability*, then they may be more willing to seriously examine medical associations' arguments that their restrictive practices ensure public trust in medicine and therefore improve health outcomes.

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[509] Dwarswaard, M. Hilhorst, M. Trappenburg, *supra* n. 392, at 394.
[510] *Ibid.*

Undoubtedly, the same applies for hospital merger cases. If antitrust enforcers integrated into their healthcare quality definition the perspectives of healthcare quality research they may be less deaf to the claim that a hospital merger should be accepted, although it creates market power, on the basis it improves clinical efficiency, safety and effectiveness. They may also be entitled to ban a hospital merger that may create cost efficiencies on the basis it would lead to closure of facilities in isolated areas with limited access to alternative providers. Furthermore, they would be entitled to clear a merger on the condition that the merging parties accept the commitment to serve the disadvantaged groups of the population at a lower cost. In other words, competition authorities would be entitled to apply competition law in healthcare in a way that would not disregard the main objectives of their health systems.

Integrating, however, a health policy goal, such as equity, into a competition framework is not an easy task for the antitrust enforcers. This is because health policy goals may not always be in line with the goals of competition law and policy. The primary objective of competition law is to enhance efficiency in the sense of maximizing consumer welfare.[511] Microeconomic theory recognizes three fundamental types of economic efficiency: *dynamic*, *productive* and *allocative* efficiency. The notion of allocative efficiency touches on issues of distribution, as it links to a core question from the economist's point of view: *For whom to produce*? In most markets the distribution problem is solved by consumers' willingness to pay. Products and services are distributed to the consumers they are willing and able to purchase. Nonetheless, in healthcare systems pursuing equity, healthcare is distributed quite independently of people's willingness to pay such services. In these systems, healthcare is mainly distributed on the basis of people's needs. However, the pursuit of such an objective implies that *an act of redistribution* takes place between different social groups. This might be in contrast with one of the main goals of EU competition law, the maximization of consumer welfare which is an efficiency objective and not a distribution one.[512] Indeed, the use of a consumer welfare standard may treat the same people unequally in their roles as workers and producers but entails treating all consumers *as equally* deserving with respect to the activity of consumption.[513] This is because competition law is primarily concerned with the overall welfare of society, without

[511] P. Craig, G. De Burca, *EU Law, Text, Cases, Material,* (Oxford, Oxford University Press, 2011).
[512] B. Von Rompuy, *Economic Efficiency, The Sole concern of Modern Antitrust Policy*? (Kluwer Law International, 2012), 48.
[513] *Ibid.*, 48.

distinguishing between different groups of society.[514] Therefore, if antitrust enforcers applied a wider definition of healthcare quality by extending the definition of consumer welfare in healthcare, they would have to balance conflicting components of consumer welfare, such as *equity v. efficiency* that the antitrust scholarship claims they do not have the democratic legitimacy to balance.

More than that, if competition authorities diverted from their main narrative that the consumer welfare objective is only an efficiency one, antitrust infringers may interpret this approach as a sign that the application competition law in the healthcare sector is either more lenient or politically driven. Therefore, the deterrent effect of competition law may be substantially weakened.

Widening the consumer welfare objective as a way to protect health care quality *as a whole* is not the only policy option for competition law policy makers. Member States in Europe may choose to take into account the non–economic facets of healthcare quality in a different way: by requiring competition authorities to cooperate with health authorities in applying competition law in healthcare.

This regime has been adopted in the UK following the adoption of the HSCA 2012.[515] Monitor, the economic regulator for the provision of healthcare services in the UK, is responsible for supervising healthcare providers' financial stability and governance. The CMA is also obliged to cooperate with Monitor with regard to cases involving mergers of NHS hospital mergers. In fact, where the CMA decides to carry an investigation under the Enterprise Act 2002 of a matter involving an NHS hospital, it must immediately notify Monitor of its intention to start an investigation. Monitor is then obliged to provide the CMA with advice on the effect of the transaction on benefits in the form of those stated in the Enterprise Act 2002, relevant customer benefits.[516] *How do competition authorities under this regime balance potential conflicts between the objectives of competition law and health policy? Should for example Competition Authorities, such as the CMA take into account the wider health policy objectives the sector regulators pursue?*

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[514]K J Cseres, 'The Controversies of the Consumer Welfare Standard', (2007) 2(3) *The Competition Law Review*, 121, 124.
[515] Health and Social Care Act (HSCA) available at: http://www.legislation.gov.uk/ukpga/2012/7/contents/enacted.
[516] Section 79 Health and Social Act 2012, Chapter 2, Part 3.

In the chapters that follow, this doctoral thesis critically examines the above analyzed policy options of integrating healthcare quality *into* a competition law framework. These policy options are: (a) the *market approach* in the United States where healthcare is covered by the FTC and the Department of Justice; (b) the *European approach* of widening the *consumer welfare definition* so that the multiple aspects of healthcare quality are taken into account *as a whole* by competition authorities; (c) the *UK model* under which competition authorities cooperate with health authorities when they assess a transaction's impact on healthcare quality.

The thesis examines these different policy options in order to answer the core question of how healthcare quality should be taken into account by Competition Authorities in Europe applying competition law in healthcare. The thesis answers this question by focusing on some article 101 TFEU (or in the US context section 1 of the Sherman Act) and merger cases that mainly concern horizontal restraints in medical and hospital markets in the US and in the UK.

## 5. Conclusion

This chapter has critically examined the main narrative of some health economists and health policy makers that the choice and competition model for providing healthcare can ensure healthcare quality. It has highlighted that under this model, specific aspects of healthcare quality, such as equity, continuity and acceptability may be substantially harmed. It has also identified some competition problems that might be raised in light of the reality that in medical and hospital markets the pursuit of competition and the pursuit of specific facets of healthcare quality may inevitably clash. It has identified three different models under which competition authorities in Europe may accommodate these conflicts: (a) the *market approach* (b) the *European approach* of widening the *consumer welfare definition* in healthcare (c) the *UK approach* under which competition authorities cooperate with health authorities when they assess a transaction's impact on healthcare quality.

The following two chapters will examine the *US market approach*.

## III. Between Antitrust & Professionalism: *Where does healthcare quality stand?* Thoughts on some seminal US antitrust cases

Courts, lawmakers, and commentators once believed that health care markets should not be subject to competition.[517] The Supreme Court applied the antitrust laws to the activities of the American Medical Association (AMA). Nonetheless, it had not expressly decided whether a physician's medical practice constituted 'trade' under the Sherman Act, leaving unsettled the extent to which the antitrust laws could be applied to the activities of the health care professions.[518] In general, what was widely understood and accepted was that a 'learned professions' exception applied to the antitrust laws.[519]

Nonetheless, following the Supreme Court's landmark decision *Goldfarb v. Virginia State Bar*[520]*,* the notion that the 'learned professions' were not engaged in 'trade or commerce' and hence should be exempt from Section 1 of the Sherman Act was rejected.[521] The Goldfarb opinion made clear that learned professions are subject to the rules of antitrust. However, what the opinion did not make clear was whether special treatment of the professions under the antitrust laws was totally precluded. In its famous footnote 17, the Court stated:

'The fact that a restraint operates upon a profession as distinguished from a business is, of course, relevant in determining whether that particular restraint violates the Sherman Act. It would be unrealistic to view the practice of professions as interchangeable with other business activities, and automatically to apply to the professions antitrust concepts that originated in other areas. The *public service aspect, and other features of the professions, may require that a particular practice, which could properly be*

[517] Federal Trade Commission and the Department of Justice, Improving Health Care: A Dose of Competition 11 (July 2004), https://www.ftc.gov/sites/default/files/documents/reports/improving-health-caredose- competition-report-federal-trade-commission-and-department-justice/040723healthcarerpt.pdf., 33.
[518] D. J. Pearlstein ,*Antitrust Law Developments, Volume II,* (ABA, Section of Antitrust Law: 2002), 1325.
[519] Federal Trade Commission and the Department of Justice, *supra* n. 517, at 33.
[520] *Goldfarb v. Virginia State Bar*, 421 U.S. 773, 95 S.Ct. 2004, 44 L.Ed.2d 572 (1975).
[521] B. Furrow, T. Greaney, S. Johnson, T. Jost, R. Schwartz, *supra n.* 313, at 703-704.

*viewed as a violation of the Sherman Act in another context, be treated differently*. We intimate no view on any other situation than the one with which we are confronted today'.[522]

*Goldfarb* marked a crucial watershed in American health policy.[523] Before the Court's ruling, nearly everyone believed that ordinary market competition was profitably inappropriate and certainly unachievable in medical care.[524] The medical profession was accepted as a self- regulating profession appropriately invested with substantial power over large segments of the healthcare industry.[525] After the Court spoke, though, professional competitors were no longer free to regulate either themselves or others in trade restraining ways. Instead, they were actively prohibited from taking collective action to restrict competition. In line with this new approach, one year later, in the *Arizona v. Maricopa County Medical Society*,[526] the Supreme Court held that the antitrust laws fully applied to the health care marketplace.[527]

The application of antitrust law into healthcare has encountered the strong resistance of medical professionals. In fact, what a number of cases in *the post-Goldfarb* era reveal is that medical professionals actively insisted and still insist on professional discretion, freedom from lay interference, self-regulations and practices that run afoul of antitrust principles.[528] Antitrust scholarship provides several reasons why antitrust enforcement in healthcare has not curtailed physicians' attempts to engage in anticompetitive behaviour. These, among others, are under enforcement and uncertainty about legal doctrine governing physician collaboration.[529] Exploring this puzzle again, this chapter asks: *What do medical professionals aim to achieve by resisting the application of antitrust into their profession? What do antitrust enforcers aim to achieve by applying antitrust law into the medical profession?* The answer is simple. Among others, both antitrust enforcers and medical professionals

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[522] Goldfarb v. Virginia State Bar, *supra* n. 520, at 788–89.
[523] C.C. Havighurst, 'Healthcare as a big business: the antitrust response', (2001) 26(5) *Journal of Health, Policy and the Law*, 939.
[524] *Ibid.*
[525] *Ibid.*
[526] Arizona v. Maricopa County Medical Society, 457 U.S. 332 (1982).
[527] Federal Trade Commission and the Department of Justice, *supra* n. 517, at 34.
[528] B. Furrow, T. Greaney et al, *supra* n.313, at 703.
[529] T. Greaney, 'Thirty Years of Solitude: Antitrust law and Physician Cartels', (2007) 7 *Houston Journal of Health Law & Policy*, 189, 195-205.

aim to ensure quality of care. Interestingly, albeit their aim is identical, their approach is different? *Why*?

Primarily, for two reasons, I claim: First because, as the previous chapter demonstrated, medical professionals and antitrust enforcers do not see quality through the same lens. While competition law tends to view quality as the outcome of an economic process, medical professionals view quality as the result of the medical process.[530] Indeed, from an antitrust perspective, quality is the result of a competitive process in which consumers have choices and which provides incentives to producers to improve goods and services in ways that make them more saleable.[531] From medical professionals' perspective, though, quality is effectively binary.[532] You either provide high quality care to a particular patient/population or you don't.[533] Additionally, while medical professionals consider that health outcomes are improved through the attributes of professionalism, such as continuity and altruism, competition authorities mainly believe that vigorous competition and not professionalism improves health outcomes. These conflicting orientations towards quality may inevitably lead in fundamentally different directions on how quality is achieved with both groups asserting their positions in the name of quality.[534]

Accommodating legitimate professional concerns in a competitive market ranks among the most difficult tasks for antitrust.[535] Surely, some quality claims are easy to condemn under antitrust because they amount to little more than naked restraints to competition.[536] Indeed, as Robert Pitofsky has noted, quality-of-care arguments 'have been advanced to support, among other things, broad restraints on almost any form of price competition, policies that inhibited the development of managed care organizations, and concerted refusals to deal with providers or organizations that represented a competitive threat to physicians.'[537] Other claims, though, are obviously more difficult to condemn and judge. In particular, claims that appear as plausible responses to the circumstances

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[530] W. Sage, P. Hammer, 'Antitrust, Healthcare Quality and the Courts', 2002 (102) *Columbia Law Review*, 545, 556.
[531] T, Kauper, 'The role of Quality healthcare consideration in antitrust', (1998) *Law and Contemporary Problems*, 272, 293.
[532] D. Hyman, 'Five Reasons Why Health Care Quality Research Hasn't Affected Competition Law and Policy', (2004) 4(2) *International Journal of Health Care Finance and Economics*, 159, 164.
[533] *Ibid.*
[534] W. Sage, P. Hammer, *supra* n. 530, at 557.
[535] B. Furrow, T. Greaney*, supra n.* 313*,* at 703.
[536] *Ibid.*
[537] Federal Trade Commission and the Department of Justice, *supra.* 517, at 28.

that consumers cannot accurately evaluate the quality of the services they receive and are thus vulnerable to exploitation by unscrupulous providers, often necessitate closer examination by antitrust authorities.[538] To a certain extent these claims serve a clear purpose: they prevent individual professionals from taking advantage of their patients' vulnerability and ignorance. Since opportunistic behavior by physicians harms *patients' trust* in their physicians and generates anxieties harmful to the therapeutic enterprise, there is good reason to consider whether and to what extent a principled basis in antitrust law for deeming such claims compatible with a competitive regime is necessary.[539] *Is this an easy task?* Obviously, the answer is negative. However, this chapter claims, this is not sufficient to justify antitrust enforcers' unexamined and unconditional rejection of medical associations' healthcare quality justifications.

This chapter is structured as follows: First, to set the stage, I identify the heart of the conflict. I explain why medical markets are special and why medical professionals view quality through a different lens. In the second part, I raise the chapter's core research questions. Essentially, I ask: *What are the main concerns and justifications medical associations and physicians raise with an eye to protect quality? How do the antitrust enforcers respond to these claims? Under what techniques do they value them? Do they manage to strike the appropriate balance between the protection of competition and the multiple dimensions of healthcare quality?* To adequately address these questions, I analyze some seminal antitrust cases where healthcare quality claims were actually addressed and examined. The last part concludes.

## 1. Identifying the heart of the debate: *Professionalism v. Antitrust*

Much of healthcare policy is dominated by a debate about different ways of thinking about medical care—about different paradigms.[540] Proponents of the traditional professional paradigm have argued, empirically, that the market cannot work well in medical care and, normatively, should not be permitted to work, at least in some situations.[541] They typically contend that medical care involves technical decisions that are beyond the ability of consumers to make. To them, medical

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[538] C.C. Havighurst, *supra* n. 523, at 946.
[539] *Ibid.*
[540] J. F. Blumstein, 'The Application of the Antitrust Doctrine to the Healthcare Industry: The Interweaving of Empirical and Normative Issues', (1998) 31 *Indiana Law Review*, 91.
[541] *Ibid.*

decision making is basically *scientific*, made by autonomous professional providers and medical associations.[542] Professionals, with much training and a claim to scientific expertise, should be entrusted with medical care decision making because of what is characterized as the asymmetry of information—providers have it, consumers do not.

Physicians and medical associations animated by this belief consider themselves as the guardians of healthcare quality. They actually feel entitled to intervene in the healthcare markets they operate in order to correct the asymmetric distribution of information between patients and doctors and secure quality. These interventions usually take the form of ethical norms controlling the type of advertising that takes place in a world of imperfect information;[543] standards and certification arrangements signaling quality and improving information in the marketplace; price setting for physicians' fees; occupational licensing[544] and other forms of self-regulation. Inevitably, these practices and norms often catch the attention of antitrust which generally assumes that consumers are better served if competitor's independence is preserved.

To fully understand and assess medical associations' claim(s) that self-regulation may in fact correct the asymmetry of information pervading medical markets one should first consider how a free medical market would actually look like. In response to this question, advocates of occupational licensing, insist that a free market may do a poor job of efficiently allocating professional services to consumers because service quality would be too low without licensing.[545] Absent licensing, they argue, the asymmetry of information between professional providers and consumers about the quality of service would inevitably create the 'lemons problem'. If consumers cannot discern quality, they may be willing to pay only for average quality.[546] If consumers, not recognizing superiority when they see it, are unwilling to pay a premium, professionals will be unwilling to incur the necessary

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[542] *Ibid.*

[543] P.J. Hammer, 'Antitrust beyond Competition: Market Failures, Total Welfare, and the Challenge of Intramarket Second-Best Tradeoffs' (2000) 98 *Mich . L . Rev.* 849, 871.

[544] Through occupational licensing boards, states endow medical doctors with the authority to decide who can practice their art and who can enter their profession A. Edlin and Rebecca Haw, 'Cartels By Another Name: Should Licensed Occupations Face Antitrust Scrutiny?' (2014) 162 *U. Pa. L. Rev.*, 1093.

[545] *Ibid*, at 1115.

[546] M. Lao, 'Comment: The Rule of Reason and Horizontal Restraints Involving Professionals' (2000) 68(2) *Antitrust Law Journal*, 499, 513.

costs to provide above-average quality services.[547] Ultimately, the quality of professional services will spiral downward. This would lead to deadweight loss in the form of deterred transactions between high-quality providers and high-quality demanding consumers.[548] Licensure addresses the information asymmetry at the root of the lemons problem by assuring consumers that all providers meet a minimum quality standard.[549]

Medical markets are also pervaded by negative externalities. An individual may be willing to receive poor service for a low price rather than no service at all, but only because he/she does not have to bear the full costs of bad service (e.g., treatment in a public hospital for infection from a careless dermatologist).[550] Licensure or other forms of self-regulation can improve public safety by imposing quality standards on professionals through education or examination and by setting rules of professional practice.

If, however, the story ended here it would be incomplete. This is because licensing is costly. Morris Kleiner, a leading economist studying the effects of licensing on price and quality of service, estimates that licensing costs consumers $116 to $139 billion every year.[551] If licensing or any form of self-regulation lead to price increases, then some consumers must go without professional services—these are the services they could afford in a world without self-regulation. Some would-be practitioners would lose out as well; these are the individuals who do not have licenses but would like to compete with the licensed professionals by offering low-cost services.[552] In sum, self - regulation and professional licensure avoid the deadweight loss associated with the lemons problem and negative externalities but at the same time also result in deadweight loss by harming competition.[553]

The cure, however, should not be worse than the disease: a procompetitive licensing scheme should avoid more deadweight loss than it actually creates. Therefore, if competition

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[547] *Ibid.*
[548] A. Edlin and Rebecca Haw, *supra* n 544, at 1116.
[549] *Ibid.*
[550] *Ibid.*
[551] M. M. Kleiner, Licensing Occupations: Ensuring Quality or Restricting Competition', (Uphon Press: 2006), 65-96.
[552] A. Edlin and Rebecca Haw, *supra* n. 544, at 1115.
[553] *Ibid.*, 1116.

authorities have to decide whether a specific form of self-regulation or professional licensure is pro or anticompetitive, they should be required to weigh harm to competition against quality improvements. *Can the US antitrust enforcers perform this task? And, if yes, how?* By examining medical associations' main quality claims, the following section devotes to answering this question.

## 2. From *Goldfarb* to *Teladoc*: How do the US antitrust enforcers and the Courts take into account healthcare quality?

### 2.1 Protecting healthcare quality by excluding antitrust: *Quality as professionalism*

State Boards[554] active in the field of healthcare often invoke that their anticompetitive actions aiming to protect healthcare quality are immune from antitrust law under 'the state action doctrine'. This doctrine articulates that antitrust laws do not apply to anticompetitive restraints imposed by the States as an act of government.[555] The Supreme Court announced this doctrine in the Parker case, after recognizing that 'nothing in the language of the Sherman Act or in its history suggests that its purpose was to restrain a state or its officers or agents from activities directed by its legislature'.[556] The Parker Court cautioned that a state cannot 'give immunity to those who violate the Sherman Act by authorizing them to violate it or by declaring that their action is lawful'.[557] There are three situations in which a party may invoke the state action doctrine.[558] First, when a state's own actions 'ipso facto are exempt' from the antitrust laws.[559] Second, when private parties act pursuant to a 'clearly articulated and affirmatively expressed as state policy' and their behavior is 'actively

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[554] State (medical) Boards are usually agencies charged with regulating the practice of medicine in a specific State. State medical boards investigate complaints from consumers, discipline physicians who violate the law, conduct physician evaluations and facilitate physician rehabilitation when appropriate. Additionally, state medical boards adopt policies and guidelines designed to improve the overall quality of health care in the state. For more information see: http://www.fsmb.org/policy/consumer-resources/frequent-questions.

[555] United States Court of Appeals, the North Carolina State Board of Dental Examiners, Petitioner V. Federal Trade Commission, No 12-1172, 10.

[556] *Ibid.*

[557] *Ibid.*

[558] *Ibid.*

[559] *Ibid*, 10-11.

supervised by the State itself'.[560] Third, when municipalities or other sub state governmental entities act pursuant to state policy to displace competition with regulation or monopoly public service.[561]

In general, the US Courts have taken the view that 'given the fundamental national values of free enterprise and economic competition that are embodied in the federal antitrust laws, state action immunity is disfavored, much as are repeals by implication'.[562] Thus they recognize 'state action immunity' only when it is clear that the challenged anticompetitive conduct is undertaken pursuant to a regulatory scheme that 'is the State's own'.[563] When examining the state action doctrine in healthcare cases, the FTC and the US Courts do not seem willing to abstain from the Parker doctrine as *the North Carolina State Board of Dental Examiners, the South Carolina State Board of Dentistry and the Teladoc* cases clearly demonstrate.

In the *South Carolina* case[564] the FTC examined whether the South Carolina State Board of Dentistry, the regulatory authority for dentists and dental hygienists in South Carolina, violated federal antitrust law by enacting a regulation that contravened legislation designed to improve access to dental care for South Carolina's most vulnerable citizens, children of low-income families.[565] To make the long story short, in the early 1990s, more than 40 percent of children in South Carolina were Medicaid-eligible and, only 12 percent of those received preventive dental care.[566] In addressing this problem the South Carolina legislature amended the state dental law to permit dental hygienists to provide preventive dental care to children in schools.[567] Since, however, the amended legislation required a dentist to examine each student before performing the services, access to preventive dental care in schools was not improved.[568] Therefore, in 2000, the state legislature again amended its law to make it easier for dental hygienists to provide oral health care in schools.[569] Shortly after these amendments, the Board enacted an emergency temporary regulation that reinstated the

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560 *Ibid.*, 11.
561 *Ibid.*
562 *Ibid.*, 13.
563 *Ibid.*
564 Opinion of the Federal Trade Commission, South Carolina State Board of Dentistry, Docket No. 9311.
565 *Ibid*, 1.
566 *Ibid.*
567 *Ibid.*
568 *Ibid.*
569 *Ibid.*

preexamination requirement.[570] As a result, thousands fewer children in South Carolina received preventive dental care in the latter half of 2001 than in the first half of that year. In 2003, the South Carolina legislature amended the law to state expressly that the dental examination requirements applicable in some settings do not apply to hygienists' work in public health settings.[571] In response to this amendment, the Board restated its position that a dentist must see a patient and provide a treatment plan before a hygienist provides care.[572]

As expected, the FTC initiated antitrust proceedings against the Board.[573] In defending its challenged policy, the Board asserted that it is covered by the state action doctrine as its status as an agency of the State of South Carolina makes its actions those of the State.[574] It further asserted that it acted pursuant to a 'clearly articulated' state policy to displace competition.[575]

The FTC rejected this antitrust defense. In unfolding its legal analysis, the FTC explained that where the actor is neither the state legislature nor the Supreme Court, but is instead a political subdivision of a state or a private party ostensibly acting pursuant to state authorization, the Court has applied a more rigorous analysis to determine whether the entity is excluded from the federal antitrust laws.[576] In such cases, the FTC alleged, the Court has held that the party is not *ipso facto* entitled to state action protection; rather, the party must demonstrate that it acted pursuant to a 'clearly articulated and affirmatively expressed' state policy to displace competition in favor of regulation and that the state actively supervised the actions.[577] Such entities, the FTC explained, lack the political accountability to formulate state competition policy.[578] Declining to treat them, therefore, as equivalent to the state itself, comports fully with the policies of the state action doctrine.[579] The FTC further stressed that Courts have consistently declined to afford *ipso facto* state action status to state licensing or regulatory boards that are composed at least in part of members of

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[570] *Ibid.*, 2.
[571] *Ibid.*
[572] *Ibid.*
[573] *Ibid.*
[574] *Ibid.*
[575] *Ibid.*, 14.
[576] *Ibid.*, 15.
[577] *Ibid.*
[578] *Ibid.*, 18.
[579] *Ibid.*

the regulated industry.[580] To the FTC, the Board's regulation was in direct conflict with the South Carolina statute and inconsistent with the policy ideals behind the state action doctrine: that federalism permits the state as sovereign to displace the national policy of open competition with regulation, only if such anticompetitive intent is clearly shown.[581] In concluding, therefore, it declared that the state action doctrine did not apply.[582]

The *North Carolina* case involved the efforts of the North Carolina State Board of Dental Examiners to prevent non - dentists from providing teeth whitening services in North Carolina.[583] Beginning in the early 1990s, dentists began offering teeth whitening services throughout North Carolina.[584] In about 2003, non-dentists also started offering teeth-whitening services at locations such as mall kiosks, retail stores and spas.[585] Non - dentists' services differ from dentists' teeth whitening in the immediacy of the results, the ease of use, the necessity of repeat applications, the need for technical support, and the price.[586] In-office dentist whitening procedures are fast, effective, and usually do not require repeated applications.[587] In contrast, over-the-counter whitening products typically contain lower concentrations of peroxide and therefore may require multiple applications to achieve results, but they cost far less.[588]

Shortly thereafter, dentists started complaining to the Board about non–dentists' provision of these services.[589] The Board opened an investigation. Relying on North Carolina's Dental Practice Act that provided that it is unlawful for an individual to practice dentistry in North Carolina without a license from the Board, and although the Board did not have any authority to discipline unlicensed

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[580] *Ibid.*, 18.
[581] *Ibid.*, 27.
[582] *Ibid.*, 27-28. In 2006, the Court of Appeals dismissed the Board's interlocutory petition for review for lack of jurisdiction, and the Supreme Court denied certiorari in January 2007. The FTC's 2007 consent required the Board to publicly support the current state public health program that allows hygienists to provide preventive dental care to schoolchildren, especially those from low-income families, see: https://www.ftc.gov/enforcement/cases-proceedings/0210128/south-carolina-state-board-dentistry-matter.
[583] Opinion of the Federal Trade Commission, In the Matter of the North Carolina Board of Dental Examiners, Docket No 9343, 1.
[584] *Ibid.*
[585] *Ibid.*
[586] United States Court of Appeals, the North Carolina State Board of Dental Examiners, s*upra* n. 555, 6.
[587] *Ibid.*
[588] *Ibid.*
[589] *Ibid.*

individuals or to order non - dentists to stop violating the Dental Practice Act,[590] the Board issued at least 47 cease-and-desist letters to 29 non-dentist teeth-whitening providers.[591] The Board also sent letters to mall operators in an effort to stop malls from leasing kiosk space to non-dentist teeth-whitening providers.[592] The Board's expelling strategy was successful.[593] Non-dentists stopped providing teeth whitening services in North Carolina and manufacturers of teeth whitening products used by non-dentists either exited or held off entering North Carolina.[594] Some mall operators also refused to lease space to non-dentist teeth whiteners or canceled existing leases.[595]

Not surprisingly, the FTC initiated antitrust proceedings against the Board. In assessing the Board's strategy, the FTC found that the Board's actions substantially restricted competition by: (a) preventing and deterring non-dentists from providing teeth whitening services in North Carolina (b) depriving consumers of lower prices (c) reducing consumer choice.[596]

In defending its strategy, the Board, among other things, alleged that its challenged conduct should be exempted from the antitrust laws as the state action doctrine applied.[597] To qualify for state action protection, the Board argued, its conduct should only meet the first prong of the Supreme Court's standard, that the challenged restraint must be one clearly articulated and affirmatively expressed as state policy.[598] The Board further claimed that even where the second prong of the state action test applied, that 'the policy must be actively supervised by the State itself,' North Carolina's 'structural legal oversight' of its activities was sufficient enough to satisfy that condition.[599]

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[590] Opinion of the Federal Trade Commission, *supra* n. 583, at 3.
[591] *Ibid*, 4.
[592] United States Court of Appeals, the North Carolina State Board of Dental Examiners, *supra* n. 555, at 7.
[593] *Ibid.,* 8.
[594] *Ibid.*, 7.
[595] Opinion of the Federal Trade Commission, *supra* n.583, at 2.
[596] *Ibid*, 6.
[597] *Ibid*, 7.
[598] United States Court of Appeals, Petition for Review, Case Appeal 12-1172, 8.
[599] *Ibid.*

Claiming that the Board failed to prove 'the active supervision' requirement, the FTC rejected the Board's defense.[600] In analyzing the application of the doctrine, the FTC's reasoning is illuminating. First and foremost, the FTC clarified that the Court has been explicit in applying the antitrust laws to public/private hybrid entities, such as regulatory bodies consisting of market participants.[601] The 'real danger', the FTC claimed, in not insisting on the state's active supervision is that the entity engaged in the challenged restraint may turn out to be 'acting to further [its] own interests, rather than the governmental interests of the State'.[602] Requiring therefore active supervision by the state itself in circumstances where the state agency in question has a financial interest in the restraint that the agency seeks to enforce is entirely consistent with the policies underlying the *Parker* doctrine.[603] Since the North Carolina Board was controlled by North Carolina licensed dentists, thus market participants motivated by their self- interest who were elected directly by their colleagues,[604] the defendant's challenged conduct should be actively supervised by the State for it to claim state action exemption from the antitrust laws, the FTC said.[605]

Before the Appellate Court, the defendant raised, again, the state action defense. The Appellate Court adopted the FTC's analysis fully.[606] The Supreme Court affirmed the lower's court decision. The Supreme Court highlighted that the adequacy of supervision depends on all the circumstances of each case.[607] It outlined, though, the conditions under which the active supervision condition is generally satisfied. First, the Court noted, the supervisor must review the substance of the anticompetitive decision, not merely the procedures followed to produce it.[608] This means, the Court said, that the supervisor must have the power to veto or modify particular decisions to ensure they accord with state policy.[609] Second, the state supervisor may not itself be an active market

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600 *Ibid.*, 10.
601 United States Court of Appeals, the North Carolina State Board of Dental Examiners, *supra* n. 555, at 13-14.
602 *Ibid.*, 8.
603 *Ibid.*, 10.
604 *Ibid,* 13.
605 *Ibid.*, 17.
606 *Ibid.*, 18.
607 Opinion of the Court, North Carolina State Board of Dental Examiners v. Federal Trade Commission, 135 S. Ct. 1101 (2015), 18.
608 *Ibid.*
609 *Ibid.*

participant.[610] Acknowledging that the defendant did not meet these requirements, the Court rejected this antitrust defense.[611]

The state action defense was also raised by the Texas Medical Board, a State agency 'statutory empowered to regulate the practice of medicine in Texas'[612] in the recent *Teladoc* case. The latter concerned a suit brought by *Teladoc*, a telemedicine company, against the Board over a rule[613] that required a 'defined physician-patient relationship' – i.e., a relationship established through either an in-person examination or an examination by electronic means with a health care professional present with the patient – before a physician may prescribe dangerous or addictive drugs to the patient.[614] This anti-telemedicine regulation, the plaintiff argued, violated antitrust law as, ultimately, would reduce choice and access, it would restrict the overall supply of physician services and it would increase prices.[615]

On a motion to dismiss, the Board argued that the telemedicine rules are immune from antitrust scrutiny under the state action doctrine.[616] In attempting to prove that it met the active supervision element, the Board mainly claimed that its decisions are subject to judicial review by the Court of Texas.[617] Noting, though, that the judicial review on which the Board relied merely permitted the Court to determine whether a rule is invalid and therefore did not meet the Supreme Court's mandate in *North Carolina Board*,[618] the Court easily rejected the antitrust immunity defense.[619]

### 2.2 Quality as a public safety claim

The Supreme Court initially dealt with quality claims related to the learned professions in 1978, when the United States brought a civil antitrust suit against the National Society of Professional Engineers, alleging that the association's canon of ethics prohibited its members from

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610 *Ibid.*
611 *Ibid.*
612 Teladoc et al. v. Texas Medical Board et al.; Complaint (Civil Action No. 1:15-cv-00343), 1.
613 The revised section 190.8 of Texas Admin Code.
614 *Ibid.*, 3.
615 *Ibid.*, 8.
616 Teladoc, Inc. et al v. Texas Medical Board, et al, Motion to Dismiss, 1-15-CV-343.
617 *Ibid.*, 13.
618 *Ibid.*, 14.
619 *Ibid.*, 17.

submitting competitive bids for engineering services and therefore violated Section 1 of the Sherman Act.[620] Relying on footnote 17 of the *Goldfarb* decision, the association claimed that its ethical norms served clearly a public safety purpose: they minimized the risk that competition would produce inferior engineering work endangering the public safety.[621] The District Court rejected this justification without examining whether competition had led to inferior engineering work or had adversely affected public safety or welfare.[622] This inquiry is unnecessary, the Court said. Convinced that the ban clearly impedes the ordinary give and take of the market place and operates on its face (as) tampering with the price structure of engineering fee,[623] the District Court did not assess the defendant's public safety claim.

The lower court's view was affirmed both by the Court of Appeals and the Supreme Court.[624] In rejecting the defendant's antitrust defense, though, the Supreme Court grasped the opportunity to clarify to what extent under US antitrust law safety concerns can be assessed under a rule of reason analysis.[625] The Court identified two complementary categories of antitrust analysis. In the first category, there are agreements whose nature and necessary effect are so plainly anticompetitive that no elaborate study of the industry is needed to establish their illegality.[626] They are 'illegal *per se*.' In the second one, there are agreements whose competitive effect can only be evaluated by analyzing the facts peculiar to the business, the history of the restraint, and the reasons why this restraint was imposed.[627] In both cases, the Court held, the purpose of the analysis is to form a judgment about the competitive significance of the restraint and not to decide whether a policy favoring competition is in the public interest.[628]

The Court argued that ethical norms may serve to regulate and promote competition in professional services, and thus fall within the rule of reason. It underlined, though, that in this

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620 National Soc'y of Professional Eng'rs v. United States, 435 U.S. 679, 98 S.Ct. 1355, 55 L.Ed.2d 637 (1978).
621 *Ibid.*
622 *Ibid.*
623 *Ibid.*
624 *Ibid.*
625 *Ibid.*
626 *Ibid.*
627 *Ibid.*
628 *Ibid.*

particular case, the defendant's argument was a far cry from such a position.[629] The Court acknowledged that competition tends to force prices down and that an inexpensive item may be inferior to one that is more costly. There is indeed some risk, the Court said, that competition will cause some suppliers to market a defective product. Therefore, competitive bidding for engineering projects may be inherently imprecise and incapable of taking into account all the variables that are involved in the actual performance of the project. Based on these considerations, a purchaser might conclude that his interest in quality—which may embrace the safety of the end product—outweighs the advantages of achieving cost savings by pitting one competitor against another. Or an individual vendor might independently refrain from price negotiation until he has satisfied himself that he fully understands the scope of his customers' needs. The Court admitted that these decisions might be reasonable. Nonetheless, it stressed, these are not reasons that satisfy the rule of reason.[630]

An alternative approach, the Court declared, would amount to nothing less than a frontal assault on the basic policy of the Sherman Act.[631] The Court underlined that the Sherman Act reflects a legislative judgment that, ultimately, competition will produce not only lower prices but also better goods and services.[632] Therefore, the assumption that competition is the best method of allocating resources in a free market takes into account that all elements of a bargain -- quality, service, safety, and durability -- and not just the immediate cost, are favorably affected by the free opportunity to select among alternative offers.[633] In rejecting the defendant's defense, the Court contended that the statutory policy precludes inquiry into the question whether competition is good or bad. As a result, the judiciary cannot indirectly protect the public against this harm by conferring monopoly privileges on the manufacturers. The rule of reason cannot support a defense based on the assumption that competition itself is unreasonable. Adopting such a view of the rule, the Court explained, would undoubtedly create the 'sea of doubt'.[634]

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[629] *Ibid*, 696.
[630] National Soc'y of Professional Eng'rs v. United States, 435 U.S. 679, 98 S.Ct. 1355, 55 L.Ed.2d 637 (1978).
[631] *Ibid.*
[632] *Ibid*, 693-695.
[633] *Ibid.*
[634] *Ibid.*

Similar concerns and tradeoffs were addressed by the Supreme Court in the seminal *FTC v Indiana Federation of Dentists* case.[635] In this case, the Supreme Court assessed whether the FTC correctly concluded that a conspiracy among dentists to refuse to submit x-rays to dental insurers for use in benefits determinations constituted an antitrust violation.[636] Since the 1970's, dental health insurers, responding to the demands of their policyholders, had attempted to contain the cost of dental treatment by, among other devices, limiting payment of benefits to the cost of the 'least expensive yet adequate treatment' suitable to the needs of individual patients.[637] Implementation of such cost-containment measures, known as 'alternative benefits' plans, required evaluation by the insurer of the diagnosis and recommendation of the treating dentist, either in advance or following the provision of care.[638] To carry out such evaluation, insurers frequently requested dentists to submit, along with insurance claim forms requesting payment of benefits, any dental x-rays that had been used by the dentist in examining the patient.[639] Typically, claim forms and accompanying x-rays were reviewed by lay claims examiners who were entitled either to approve payment of claims or to refer claims to dental consultants for further review.[640] The dental consultants may recommend that the insurer approve a claim, deny it, or pay only for a less expensive course of treatment.[641]

Such review of diagnostic and treatment decisions had been viewed by some dentists as a threat to their professional independence and economic wellbeing.[642] Therefore, in the early 1970's, the Indiana Dental Association, a professional organization comprising some 85% of practicing dentists in the State of Indiana, initiated an aggressive effort to hinder insurers' efforts to implement alternative benefit plans by enlisting member dentists to pledge not to submit x-rays in conjunction with claim forms.[643] The Association's efforts met considerable success: large numbers of dentists signed the pledge, and insurers operating in Indiana found it difficult to obtain compliance with their requests for x-rays, and accordingly had to choose either to employ more expensive means of

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635 FTC v. Indiana Fed'n of Dentists, 476 U.S. 447 (1986) Federal Trade Commission v. Indiana Federation of Dentists No. 84-1809.
636 *Ibid.*
637 *Ibid.*
638 *Ibid.*
639 *Ibid*
640 *Ibid.*
641 *Ibid.*
642 *Ibid.*
643 *Ibid.*

making alternative benefits determinations (for example, visiting the office of the treating dentist or conducting an independent oral examination) or to abandon such efforts altogether.[644]

The FTC initiated antitrust proceedings against the Association. In its complaint, the FTC alleged that the Association's efforts to prevent its members from complying with insurers' requests for x-ray amounted to a conspiracy in restraint of trade and therefore violated Section 1 of the Sherman Act. [645] Absent such a restraint, competition among dentists for patients would have tended to lead dentists to compete with respect to their policies in dealing with patients' insurers[646]. Hence, the FTC claimed that the Association's policy had the actual effect of eliminating such competition among dentists and preventing insurers from obtaining access to x-rays in the desired manner.[647] These findings of anticompetitive effect, the FTC concluded, were sufficient to establish that the restraint was unreasonable, even absent proof that the Association's policy had resulted in higher costs to the insurers and patients than would have occurred had the x-rays been provided.[648]

The defendant raised a public safety defense that, not surprisingly, did not alter FTC's initial assessment. More specifically, the FTC rejected the Association's argument that its policy of withholding x-rays was reasonable because the provision of x-rays might lead the insurers to make inaccurate determinations of the proper level of care, and thus injure the health of the insured patients. The FTC found no evidence that use of x-rays by insurance companies in evaluating claims would result in inadequate dental care.[649]

The Court of Appeals fundamentally diverted from the FTC's findings. Accepting the defendant's characterization of its rule against submission of x rays as merely an ethical and moral policy designed to enhance the welfare of dental patients, the majority concluded that the FTC's findings were erroneous.[650] Applying a rule of reason analysis, the Appellate Court held that by preventing dentists from joining together to promote standards of quality dental care that comport with the American Dental Association's code of professional conduct and the Indiana Dental Code,

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644 *Ibid.*
645 *Ibid.*
646 *Ibid.*
647 *Ibid.*
648 *Ibid.*
649 *Ibid.*
650 Indiana Federation of Dentists, v. FTC, Respondent. No. 83-1700, United States Court of Appeals, Seventh Circuit, 745 F.2d 1124.

the FTC, with absolutely no expertise or training in the highly advanced field of dentistry, unwisely regulated the dental profession and all of its specialties, to the detriment of consumers.[651] Underlying that the group of dental health care insurers should not be permitted to forsake standards of quality and proper dental care in an attempt to lower their dental costs, particularly in this case where there had been no finding that the review of dental x-rays alone had actually reduced dental costs, the Appellate Court vacated the FTC's ruling.[652]

The case reached the Supreme Court. Before the Court, once again, the defendant raised its patient safety defense.[653] In line with the FTC's legal analysis, the Supreme Court found the defendant's argument flawed both legally and factually. Citing the *National Society of Professional Engineers,* the Court held that claiming that an unrestrained market in which consumers are given access to the information they believe to be relevant to their choices will lead them to make unwise and even dangerous choices amounts to 'nothing less than a frontal assault on the basic policy of the Sherman Act'.[654] There is no particular reason to believe that the provision of information can be more harmful to consumers in the market for dental services than in other markets, the Court said.[655] The Supreme Court noted that the insurers deciding what level of care to pay for are not themselves the recipients of those services. The Court, however, did not assess whether this market failure might affect the quality of dental care, as the Court insisted that insurers do not lack incentives to consider patients' welfare because they are themselves in competition for the patronage of the patients.[656]

Similar patient safety concerns were also raised by the Dental Board in the *North Carolina* case where the Board claimed that its strategy against non - dentists aimed to protect public health and patient's welfare.[657] Permitting non-dentists to perform teeth whitening would result *in the production of an inferior service*, the Board held.[658] The FTC rejected the defendant's pro-competitive

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651 *Ibid.*
652 *Ibid*, 81.
653 FTC v. Indiana Federation of Dentists, (1986) No. 84-1809.
654 *Ibid.*
655 *Ibid.*
656 *Ibid.*
657 Opinion of the Commission, In the Matter of North Carolina, *supra* n. 583, 24.
658 *Ibid.* In support of its claim that the challenged restraints are procompetitive, and therefore not an unreasonable restraint of trade, the Board relied upon United States v. Brown University. The Administrative Law Judge (ALJ) took the view that defendant's reliance on Brown is misplaced. Defendant's restraints on non-dentist provided teeth

justification on the basis it was neither cognizable nor plausible.[659] Cognizable is a justification, the FTC explained, that stems from measures that increase output or improve product quality, service or innovation.[660] Plausible is a justification, it further explained, that cannot be rejected without extensive factual inquiry.[661] Having clarified that, the FTC once again declared that the Courts have rejected welfare and public safety concerns as cognizable justifications.[662]

In defending its policy, the Board also alleged that a valid defense to a Sherman Act claim exists where a state agency promotes public health and enforces state's law even if the conditions of the state action doctrine are not met.[663] Adopting, once again, the view that a health or safety defense is extraneous to an analysis of competitive effects, irrespective of the public or private nature of the actors, the FTC rejected the Board's public safety concerns.[664] Before reaching this conclusion though, the FTC did not omit to examine the Board's claim in substance. To substantiate its health safety claim, the Board pointed to four anecdotal reports of harm.[665] The FTC held that four anecdotal reports of harm over a multi - year period based on products considered safe by the FDA and used over the last twenty years cannot constitute adequate evidence of a potential health or safety risk.[666] The FTC noted that although several board members had identified a number of theoretical risks from non-dentist teeth whitening, none was able to cite any clinical or empirical evidence validating any of these concerns.[667] In light of this assessment, the FTC found the Board's claim unsubstantiated.

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whitening services tend to and do remove the service from the market, (e.g., F. 246-56, 324-27), thereby restricting consumer choice. F. 257. By contrast, the restraint in Brown enhanced consumer choice as well as provided social welfare benefits, the ALJ said. See United States of America, Federal Trade Commission, Office of Administrative Law Judges, Docket No 9343, In the Matter of North Carolina Board of Examiners, et al., 5 F.3d 658 (3rd Cir. 1993), 110.

659 *Ibid*, 24-25.

660 *Ibid.*

661 *Ibid.*

662 *Ibid.*

663 *Ibid*, 25-26. Dr. Baumer, Professor of Economics and the Board's expert witness said that a cartel model is an inappropriate method for evaluating governmental licensing boards; that the cartel model ignores evidence that licensing requirements curb fraud and protect public health and safety by preventing consumer harm at the hands of unqualified practitioners; that restricting the unlicensed practice of dentistry is an obvious and desirable consequence of regulation; and that the Board is not a cartel, but rather excludes unqualified practitioners, United States of America, Federal Trade Commission, Office of Administrative Law Judges, Docket No 9343, In the Matter of North Carolina Board of Examiners, 22.

664 *Ibid*, 26.

665 *Ibid.*

666 *Ibid*, 27.

667 *Ibid.*

The Appellate Court fully aligned with the FTC's legal reasoning. Interestingly, Circuit Judge Barbara Milano Keenan, who concurred in the majority's opinion, wrote separately to emphasize the narrow scope of the Appellate Court's holding that the Board is a private actor for the purposes of the state action doctrine.[668] Judge Keenan clarified that she did not doubt that the Board was motivated substantially by a desire to eliminate an unsafe medical practice, namely the performance of teeth whitening services by unqualified individuals under unsanitary conditions.[669] Judge Keenan acknowledged that the Board was aware that several consumers had suffered from adverse side effects, including bleeding or 'chemically burned' gums, after receiving teeth-whitening services from persons not licensed to practice dentistry and that many of the mall kiosks where such teeth-whitening services were performed lacked even access to running water.[670] The Board had also received numerous reports that non-licensed persons offered teeth whitening services without using gloves or masks, thereby increasing the risk of adverse side effects.[671] Consequently, in the Judge's view, the record had supported the Board's argument that there is a safety risk inherent in allowing certain individuals who are not licensed dentists to perform teeth whitening services.[672] Emphasizing, though, that only North Carolina is entitled to make the legislative judgment that the benefits of prohibiting non-dentists from performing dental services outweigh the harm to competition, and not a private consortium, Judge Keenan joined the majority opinion.[673]

The Massachusetts Board of Registration in Optometry,[674] the sole licensing authority for optometrists in Massachusetts[675] was also involved in an analogous antitrust dispute. The Board, authorized by Massachusetts' law to take disciplinary action against any licensee engaged in unprofessional conduct, fraud, deceit, or misrepresentation in practice or in advertising, enjoyed considerable power.[676] Following antitrust investigation, the FTC found that the Board restrained competition among optometrists in Massachusetts by conspiring with its members or others to

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668 United States Court of Appeals, the North Carolina State Board of Dental Examiners, *supra* n. 555, at 33.
669 *Ibid.*, 35.
670 *Ibid.*
671 *Ibid.*, 36.
672 *Ibid.*
673 *Ibid.*, 37.
674 Massachusetts Board of Registration in Optometry, Complaint of the Federal Trade Commission, Docket 9195.
675 *Ibid,* para 5.
676 *Ibid,* para 6.

unreasonably restrict truthful advertising by optometrists.[677] Among other things, the Board prohibited optometrists from (a) advertising discounts from their usual prices and fees (b) permitting optical establishments and other commercial practices to truthfully advertise the optometrists' names or professional abilities (c) from making use of truthful advertising that contained testimonials or that is 'sensational' or 'flamboyant'. Importantly, the Board prohibited all the above irrespective of the truth or falsity of the advertisings.[678] The FTC considered that the alleged advertising restrictions had harmed consumers considerably. In fact, because of these restrictions, consumers had been deprived of the benefits of vigorous price and service competition among optometrists' and truthful information about optometrists' services, prices and fees.[679]

In attempting to reverse FTC's findings and justify its policy, the Board argued that the affiliation may cause optometrists to provide *lower quality care* either because a lay person may interfere with the optometrists' independent professional judgment or because the commercial motivation of the optometrist may *lessen* professional standards.[680] In that sense, the advertising ban aimed to prevent consumers from being misled into believing that they are getting a better deal at a large chain store when in fact they may only receive a better price for *inferior* eye care.[681]

In evaluating these claims, the Administrative Law Judge (ALJ) referred to Dr. Kwoka's study[682] that examined the relationship between advertisement restrictions and quality. Relying on the findings of this study, the Judge noted that restrictions on advertising in the market for optometrist goods and services raise total cost to consumers *without affecting quality*.[683] The ALJ further observed that (a) advertising has the effect of lowering the total cost of optometric goods and services (b) *less thorough* eye examinations tend to be given by advertising optometrists than by non-advertising optometrists (c) in markets where advertising is allowed, 55% of the optometrists do

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677 *Ibid,* para 12.
678 *Ibid,* para 12-13.
679 *Ibid,* para 14.
680 J. P Timony, ALJ, Initial Decision, 20th June 1986, 586.
681 *Ibid.*
682 Dr Kwoka is one of four authors of the "staff report on effects of restrictions on advertising and commercial practice in the Professions: The case of optometry, also known as the 'B.E Study' *Ibid*, para 63.
683 *Ibid*, paras 60-66.

not advertise and a higher percentage of all optometrists give higher quality examinations than in markets where advertising is prohibited.[684]

The ALJ also examined the Board's procompetitive claims under the rule of reason.[685] The Judge noted that there was no proof that the prohibited advertising had deceived the public and that deception cannot justify a total ban on truthful advertising. As a result, the Judge rejected the alleged procompetitive claims.[686] On appeal, the FTC fully approved these findings. However, it did so after addressing the issue of the *appropriate standard* for evaluating similar restraints. Relying on work by Tim Muris, the Commission proposed that such restraints should be examined under the so-called '*structured rule of reason.*'[687] According to this method of analysis, the first question to be asked about any restraint is whether the restraint is *inherently suspect*. If not, traditional rule of reason applies, but if so, a second question must be answered: Is there a plausible efficiency justification for the restraint? If not, the restraint can be summarily condemned, but if so, an inquiry must be held into the validity of the justification. If it is valid, a full rule of reason analysis should apply.[688] The test was introduced as an effort to fashion an administratively efficient decision rule for assessing restraints in an era in which the possibility of procompetitive restraints was recognized by the Courts.[689] Applying its proposed test and stating, once again, that defendant's arguments are not cognizable as antitrust defenses because they are premised on the notion that competition itself is inappropriate in optometry, the FTC found all the restraints imposed by the Massachusetts Board anticompetitive.[690]

In attempting to defend its challenged regulation against telemedicine, the Texas Medical Board, in the *Teladoc* case, also raised a patient care defense. The Board asserted that its revised rule 190.8 which prohibited prescription of any dangerous drug or controlled substance without first establishing a defined physician – patient relationship was necessary for the protection of healthcare quality.[691] In substantiating its claim the Board cited affidavit testimonies presented by medical

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[684] *Ibid,* 586.
[685] *Ibid.*
[686] *Ibid*, 588.
[687] J. Kwoka, *supra* n. 318, at 16.
[688] Opinion of the Commission, delivered by Commissioner Calvani, 604.
[689] J. Kwoka, *supra* n. 318, 14.
[690] Opinion of the Commission, *supra* n. 688, at 608.
[691] Teladoc et al. v. Texas Medical Board et al, *supra* n. 612, at 3.

practitioners detailing deficiencies in telephone-only diagnosis. These practitioners claimed that telemedicine can lead to poor quality or insufficient care since correct diagnosis necessitates face to face encounter with patient and physical examination.[692] Relying on a study performed in California, assessing use of Teladoc by a large public employer, the Board raised the concern that Teladoc's model could actually further fragment healthcare and that the limitations of telephone-only consultation may lead to misdiagnosis and higher follow-up visits. The Board also questioned Teladoc's argument that telemedicine improves access to patients who are not connected to other providers. The Board insisted that the population of patients attracted to Teladoc - a more affluent and, likely, a more technologically savvy group - might have fewer access needs than people living in area' s characterized by shortage of primary care or socio-economic disadvantage.[693] The Court was not convinced. Underlying that Teladoc successfully presented significant evidence that put into question the Board's contention that its regulation will improve quality of care and insisting that the Supreme Court has explicitly rejected the notion that improved public safety is a sufficient justification for a society of professionals to adopt an anti-competitive policy, the District Court rejected the Board's quality justifications fully.[694]

The Board appealed the Court's decision to a higher Court. Nonetheless, the Board dropped the appeal due to the influx of amicus curie briefs that were filed with the Court, most of which supported Teladoc's position. This includes a significant brief jointly submitted by the FTC and the Department of Justice (the Agencies).[695] In this brief, the Agencies told the Court to ignore the Board's appeal of Teladoc's case that prevents the Board from implementing a rule that curbs telemedicine practices in the State saying that the Court doesn't have the authority to review the decision and the rule itself should be thrown out.[696] Interestingly, in support of Board's appeal, the AMA and the Texas Medical Association filed a brief jointly.[697] Their analysis is both illuminating and worth discussing. In supporting the Board's patient safety claims, the Associations

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[692] *Ibid.*, 10.
[693] *Ibid.*, 12.
[694] *Ibid*, 13.
[695] E. Teichert, 'Texas drops appeal against Teladoc lawsuit', *Modern Healthcare*, available at: http://www.modernhealthcare.com/article/20161018/NEWS/161019900.
[696] Teladoc et al v. Texas Medical Board et al, US Courts of Appeal for the 5th Circuit, Brief for the US and the FTC as Amici Curiae, 35.
[697] Teladoc plaintiffs – Appellees et al. v. Texas Medical Board et al, Appeal from the US District Court for the Western District of Texas, Case No. 1:15-cv-343, Certificate of Interested Persons.

acknowledged that telemedicine does offer significant potential benefits to patients, such as expanded access to medical care.[698] They clarified, though, that telemedicine is inappropriate for certain medical conditions and therefore carries significant risks.[699] Without the ability to conduct in person physical examinations, treating physicians risk misdiagnosing or mistreating patients especially through over prescription of antibiotics and other medications.[700] In developing their argument they relied on research showing that when physicians cannot directly examine the patient, they may either use a conservative approach or propose the use of antibiotics in cases where the benefit of antibiotics therapy is actually unclear.[701] They emphasized that in recognizing both benefits and risks, medical associations and State medical boards across the US, work to determine what telemedicine practices will best serve patients and the public.[702] Since research indicates that allowing the prescription of dangerous drugs without any physical examination by any health professional leads to poorer care, some regulation of telemedicine is important for the protection of public health.[703] Such regulation, they held, is precisely what the Texas Medical Board undertook with the rules that *Telado*c challenged.[704] As the Board dropped the appeal, unfortunately, their arguments remained unexamined.

### 2.3 Protecting quality by correcting the market imperfection

Another way by which medical associations have attempted to justify antitrust violations is by spelling out that: 'We, as doctors, know better what is best for our patients' welfare. We have better information than them about what quality of care means and how it is achieved. Therefore, it is in our sphere of responsibility to protect people's health and safety'. The FTC and the US Courts have thoroughly examined this quality argument in two seminal cases: the *Wilk* case[705] and the *California Dental Association* (CDA) case.[706]

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698 *Ibid.*, 5.
699 *Ibid.*
700 *Ibid.*, 16.
701 *Ibid*, 22.
702 *Ibid*, 16. The AMA and the Texas Medical Association claimed that several state medical boards have adopted restrictions on the ability to prescribe medications without prior physical examination by the prescribing physician or a patient site presenter, *Ibid*, 23.
703 *Ibid.*, 27.
704 *Ibid.*
705 Wilk v. American Medical Association, 895 F.2d 352 (7th Circuit 1990).
706 FTC Complaint, in the Matter of California Dental Association, Docket 9259, Final Order March 25,1996.

In the *Wilk* case, the core legal issue centered around chiropractors' charges that the AMA engaged in a conspiracy to eliminate the chiropractic profession by refusing to deal with chiropractors.[707] Defendants accomplished this, plaintiffs claimed, by using former Principle 3 of the AMA's Principles of Medical Ethics, which prohibited medical physicians from associating professionally with *unscientific* practitioners.[708] Plaintiffs contended that the AMA used Principle 3 to boycott chiropractors by labelling them *unscientific practitioners* and then advising its members that it was unethical for medical physicians to associate with chiropractors.[709]

The Court rejected the plaintiffs' argument that the defendants' conduct was a per se violation of Section 1, holding that 'a canon of medical ethics purporting, surely not frivolously, to address the importance of scientific method gives rise to questions of sufficient delicacy and novelty at least to escape per se treatment'.[710] Applying the rule of reason the District Court concluded that the AMA, through former Principle 3, had unreasonably restrained trade in violation of § 1 of the Sherman Act.[711] The Court found that the AMA aimed to prevent medical physicians from referring patients to chiropractors and from accepting referrals of patients from chiropractors, so as to prevent chiropractors from obtaining access to hospital diagnostic services and membership on hospital medical staffs.[712] It also aimed to prevent medical physicians from teaching at chiropractic colleges or engaging in any joint research.[713] In sum, its main purpose was to eliminate any cooperation between the two groups in the delivery of health care services.[714]

At trial, the AMA raised the so-called 'patient care defense' formulated by the Court in its earlier opinion in this case.[715] This defense required the AMA to prove that (a) It genuinely *entertained* a concern for what doctors perceived as *scientific method* in the care of each person with whom they had entered into a doctor-patient relationship; (b) this concern was *objectively* reasonable; (c) this concern had been the *dominant* motivating factor in defendant's promulgation of Principle 3 and in

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[707] Wilk v. American Medical Association, *supra* n. 705, at para 15.
[708] *Ibid.*
[709] *Ibid.*
[710] *Ibid.*, para 36.
[711] *Ibid.*, para 17.
[712] *Ibid.*, para 19.
[713] *Ibid.*
[714] *Ibid.*
[715] *Ibid.*, para 21.

the conduct intended to implement it; (d) this concern *for scientific method* in patient care could not have been adequately satisfied in a manner *less restrictive* of competition.[716] Considering that the AMA had failed to meet the defense's second and fourth elements, the District Court rejected this antitrust defense.[717] To elaborate:

Although doubting the AMA's genuineness regarding its concern for scientific method in patient care, the Court concluded that the AMA established that first element.[718] To reach this conclusion the Court considered that while the AMA was attacking chiropractic as unscientific, it simultaneously was attacking other unscientific methods of disease treatment (e.g., the Krebiozen treatment of cancer), and, as the Court noted, the existence of medical standards or guidelines against unscientific practice was relatively common.[719]

The Court, however, found that the AMA had not met its burden of persuasion as to the second element of the defense, whether its concern for scientific method in patient care was objectively reasonable.[720] To carry out this assessment the Court took into account substantial evidence demonstrating that chiropractic can be even more effective than the medical profession in successfully treating certain medical problems, such as back injuries.[721] The Court also noted that the AMA's members did not seem to examine pro-chiropractic arguments with open mind.[722] With these elements in mind the Court held that there was no objectively reasonable concern that would support a boycott of the entire chiropractic profession.[723]

The Court also found that the AMA had carried its burden of proof in establishing the third element of the defense, that its concern about scientific method was the dominant motivating factor in the conduct undertaken.[724] The Court found though that the AMA failed to meet its burden in demonstrating that its concern for scientific method in patient care could not have been

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716 *Ibid*, para 36.
717 *Ibid.*, para 56.
718 *Ibid.*, para 57.
719 *Ibid.*
720 *Ibid.*
721 *Ibid.*
722 *Ibid.*
723 *Ibid.*, 58.
724 *Ibid*, 59.

adequately satisfied in a manner less restrictive of competition.[725] Since the AMA had submitted no evidence of other policies less restrictive of competition, such as public education, the Court easily concluded that the AMA had failed to satisfy the defense's fourth element.[726]

The case reached the Court of Appeal. The Appellate Court identified that the central question in this case was whether the AMA's boycott constituted an unreasonable restraint of trade under § 1 of the Sherman Act.[727] A restraint is unreasonable, the Court said, if it falls within the category of restraints held to be *per se* unreasonable, or if it violates what is known as the rule of reason.[728] Acknowledging that the Supreme Court has been historically slow to condemn rules adopted by professional associations as unreasonable per se, the Appellate Court examined AMA's challenged boycott under the rule of reason.[729]

The AMA argued that it should escape liability under the rule of reason because Principle 3 had overriding procompetitive effects. The AMA essentially alleged that the market for medical services is one where there is '*information asymmetry*'.[730] This market imperfection, the AMA said, increases the risk of fraud and deception on patients by unscrupulous health care providers possibly causing '*market failure*': consumers avoiding necessary treatment (for fear of fraud), and accepting treatment with no expectation of assured quality.[731] In that sense, the AMA's practice ensured that physicians acquired *reputations for quality* (in part, by not associating with unscientific cultists).[732] In other words, it allowed consumers to be assured that physicians would only use scientifically valid treatments. This in effect provided patients with essential information and protected competition.[733]

The Appellate Court was not convinced by this argument. The Appellate Court clarified that getting needed information to the market is a fine goal.[734] Highlighting though that in this

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[725] *Ibid.*
[726] *Ibid.*
[727] *Ibid*, para 34.
[728] *Ibid.*
[729] *Ibid*, para 35.
[730] *Ibid*, para 43.
[731] *Ibid.*
[732] *Ibid* para 43.
[733] *Ibid.*
[734] *Ibid*, at 44.

particular case the AMA was not solely motivated by its altruistic concerns, it rejected this defense.[735] The Appellate Court also agreed with the lower Court's ruling as to the patient care defense. In fact, it fully agreed with the District Court's view that the AMA's boycott was clearly anticompetitive.[736]

The second case, the *CDA* case, involved a voluntary association of local dentists with membership of about three quarters of all California dentists. The antitrust issue in this case concerned CDA's code of ethics, including Section 10 of CDA's professional code which prohibited advertising or solicitation 'false or misleading in any material respect'.[737] CDA's Judicial Council, responsible for enforcing CDA's Code, had released multiple advisory opinions and guidelines elaborating upon the scope of this standard.[738] These opinions, which formed the basis of the FTC's challenge, argued that a statement or claim could be considered false or misleading where: (a) it contained a misrepresentation of fact; (b) it made only a partial disclosure of relevant facts (c) it was likely to create false or unjustified expectations of favorable results and/or costs (d) it related to fees for specific types of services without fully and specifically disclosing all variables and (e) it contained other representations or implications that in reasonable probability would cause an ordinarily prudent person to be deceived.[739]

Regarding price advertising, CDA permitted advertising discounts only with extensive disclosures.[740] CDA's Code of Ethics and accompanying guidelines required that all price advertising be exact and that discount advertising listed the regular fee for each discounted service, the percentage of the discount, the length of time that the discount would be available, verifiable fees, and the specific groups who were eligible for the discount.[741] In enforcing these provisions, CDA had routinely cited members for using phrases such as 'low', 'reasonable,' or 'inexpensive' fees, and

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[735] *Ibid.*
[736] *Ibid.*, at 50.
[737] FTC, Opinion, in the Matter of California Dental Association, Docket 9259, 1-2,
[738] United States Court of Appeals, Ninth Circuit, California Dental Association, v. Federal Trade Commission, Respondent, No. 96-70409.
[739] *Ibid.*
[740] FTC, Opinion, in the Matter of California Dental Association, *supra* n. 373, at 3.
[741] United States Court of Appeals, Ninth Circuit, California Dental Association, *supra* n. at 738.

for failing to include the regular fees for each service covered by across-the-board senior citizen discounts, or coupon discounts for new customers.[742]

Additionally, adopting the approach that non- price claims are *not susceptible* to measurement or verification and therefore likely to be false or misleading in a material respect,[743] CDA prohibited any advertisements that used the words 'quality' irrespective of whether they were false or misleading.[744] In practice, CDA prohibited all quality claims. For example, CDA recommended denial of membership to one dentist because her advertising included the phrase 'quality dentistry,' which CDA thought was not susceptible of verification.[745] Furthermore, albeit without coextensive written regulations, CDA suppressed claims of superiority and the issuance of guarantees.[746] For instance, it found an advertisement containing the phrase 'we can provide the uncompromised standards of excellence you demand' to be an impermissible representation of *superiority*.[747]

In examining the anticompetitive effects of CDA's policies and norms, the FTC rejected the Massachusetts Board analysis, finding instead that the restrictions on discount advertising were illegal per se.[748] CDA's restrictions on advertising 'low' or 'reasonable' fees, and its extensive disclosure requirement for discount advertising, effectively precluded its members from making low fee or across-the-board discount claims regardless of their truthfulness, the FTC declared[749]. Noting that the professional context of this restraint does not lead to a different conclusion[750] as well as that in cases involving agreements not 'premised on public service or ethical norms,' the Supreme Court has repeatedly applied the per se rule,[751] the FTC stressed that a ban on significant forms of price competition is illegal *per se* regardless of the manner in which it is achieved.[752] Applying an abbreviated analysis, the FTC also condemned the non-price advertising restrictions. With regard to

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742 FTC, Opinion, in the Matter of California Dental Association, *supra* n 737, at 11.
743 *Ibid.*, 28.
744 *Ibid,* para 19.
745 *Ibid.*, para 28.
746 *Ibid*, para 29.
747 *Ibid.*, para 29.
748 T. Muris, 'California Dental Association v. Federal Trade Commission: The revenge of footnote 17', *George Maison Law and Economics Research paper*, No 0030, 267.
749 FTC, Opinion, in the Matter of California Dental Association, *supra* n. 737, para 19.
750 *Ibid.*, 25.
751 *Ibid.*, 19.
752 *Ibid.*

these restraints, the FTC said, we cannot say with equal confidence that, as a facial matter, CDA's concerns are unrelated to the public service aspect of its profession, or that 'the practice facially appears to be one that would always or almost always tend to restrict competition and decrease output'.[753] Considering, however, that CDA's broad prohibition on claims relating to the absolute or comparative quality of service found no support in the law governing deception[754] and that CDA offered no convincing argument, let alone evidence, that consumers of dental services had been, or were likely to be, harmed by the broad categories of advertising that it restricts,[755] the FTC concluded that the non-price restrictions were clearly anticompetitive.[756]

Considering that this case concerned a set of ethical guidelines promulgated by a professional organization for the purpose of preventing false and misleading advertising and that the CDA's policies do not, on their face, ban truthful, non- deceptive ads, the Appellate Court rejected the use of per se analysis with regards to price advertising restrictions.[757] The Appellate Court refused to accept CDA's procompetitive justifications that its policy encouraged disclosure and prevented *false and misleading advertising*.[758] Since the record provided no evidence that CDA's policy had in fact led to increased disclosure and transparency of dental pricing, such claim, the Appellate Court alleged, could carry little weight.[759] As to the non-price advertising restrictions, the Appellate Court also disregarded CDA's concern that claims about quality are inherently unverifiable and therefore misleading. While this danger exists, the Court confirmed, it does not justify banning all quality claims without regard to whether they are, in fact, false or misleading.[760] Under these circumstances, the Appellate Court agreed with the FTC's view that the non-price advertising restriction was a naked restraint on output.[761]

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[753] *Ibid.*, 27.
[754] *Ibid*, 38.
[755] *Ibid.*, 40.
[756] *Ibid.*, 42.
[757] United States Court of Appeals, Ninth Circuit, California Dental Association, *supra* n. at 738.
[758] *Ibid.*
[759] *Ibid.*
[760] *Ibid.*
[761] *Ibid.*

Surprisingly, the Supreme Court vacated and remanded the judgment to the Court of Appeal for a fuller inquiry into whether CDA's activities violated antitrust laws.[762] The Court made clear that a quick look analysis should be limited only to cases where an observer with even a rudimentary understanding of economics would conclude that the arrangements in question would have an anticompetitive effect on customers and markets.[763] Considering the special characteristics of the professional services market, the Supreme Court concluded that CDA's practice was not one of these cases. To the Court, CDA's restrictions aimed to eliminate false or deceptive advertising in a market characterized by striking disparities between the information available to the professional and the patient.[764] Examining defendant's restrictions from this perspective, the Court concluded that CDA's restrictions might, instead be procompetitive.[765] Citing Akerlof's famous work 'The market for lemons, Quality Uncertainty and the Market Mechanism', the Court stated that in the market for professional services, in which advertising is relatively rare and the comparability of service packages not easily established, the difficulty for customers or potential competitors to get and verify information about the price and availability of services can magnify the dangers to competition associated with misleading advertising.[766]

The Court acknowledged that the quality of professional services tends to resist either calibration or monitoring by individual patients or clients. According to the Court, this relates to the specialized knowledge required to evaluate these services and the difficulty in determining the degree to which an outcome is attributable to the quality of services or to something else.[767] In examining the market's special characteristics, the Court further recognized that the patient's attachments to particular professionals, the rationality of which is difficult to assess, complicate the picture even more.[768]

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[762] California Dental Association v. Federal Trade Commission, certiorari to the United States Court of Appeals for the Ninth Circuit, No. 97–1625.
[763] *Ibid*, 12.
[764] *Ibid*, 14.
[765] *Ibid.*
[766] *Ibid.*
[767] *Ibid*, 15.
[768] *Ibid.*

In examining the CDA's price advertising restrictions, the Court highlighted that these restrictions 'are very far from a total ban on price or discount advertising'. On the contrary, they might even promote competition by reducing the occurrence of unverifiable and misleading across the board discount advertising.[769] The Court alleged that although across the board discount advertisements are more effective in drawing customers in the short run, the recurrence of such measure of intentional or accidental misstatement, due to the breadth of their claims, might leak out over time to make potential clients skeptical of any such across the board advertising, so undercutting the method's effectiveness.[770] The Court explained that across the board discount advertisements might continue to attract business indefinitely because they mislead customers. From this perspective, their effect can be anticompetitive instead of procompetitive. The Court therefore asserted that CDA's rules reflected the prediction that any costs to competition associated with the elimination of across the board advertising would be out weighted by gains to consumer information that is exact, accurate and more easily verifiable (at least by regulators).[771] As a matter of economics, the Court noted, this view may or may not be correct but neither a Court nor the FTC should initially dismiss it as presumptively wrong.[772]

As to the CDA's non-price advertising restrictions, the Court again abstained from the lower Court's competition analysis.[773] The Court faulted the Appellate Court for giving no weight to the countervailing suggestion that restricting difficult to verify claims about quality or patient comfort would have a precompetitive effect by preventing misleading or false claims that distort the market.[774] As the Court underlined, CDA's restrictions should be assessed differently: as nothing more than a procompetitive ban on puffery.[775] Following the Supreme Court's judgment the FTC announced its decision not to seek further review in the Supreme Court of its case against the CDA and dismissed the complaint.[776]

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769 *Ibid*, 16.
770 *Ibid.*, 17.
771 *Ibid.*, 18.
772 *Ibid.*
773 T. Muris, s*upra* n. 748, at 275.
774 *Ibid*, 20-21.
775 *Ibid.*
776 Federal Trade Commission, Press release, FTC Dismisses Complaint against California Dental Association, available at: https://www.ftc.gov/news-events/press-releases/2001/02/ftc-dismisses-complaint-against-california-dental-association.

## 3. Accommodating tensions between different quality perspectives: What have the US antitrust enforcers solved and what still remains unsolved?

### 3.1 Identifying the core of the FTC's and the US Courts' approach

The descriptive analysis of the relevant case law demonstrates that the US Courts and the FTC do examine healthcare quality arguments in the context of their competition assessment. To the FTC and the Courts, quality of care does matter. However, it matters to the same extent it matters in other industries, such as airline or automotive. Both the US Courts and the FTC are straightforward at this point. With the exception of the *CDA* case, the central message they constantly transmit when they deal with antitrust violations in health services markets is that healthcare is not *special*.

What are the implications of this approach? Two, I argue: First that both the FTC and the US Courts constantly take the view that, as in other markets, quality will be the result of the competitive process. In their view, quality of care is ensured only to the extent choice, vigorous competition and information are ensured. Therefore, when the FTC and the US Courts examine the difficult question of how a challenged restraint may impact quality, they mainly rely on the heuristic that more competition will generally increase quality. Second, when the US antitrust enforcers and the Courts are required to examine whether *less competition* is necessary for the protection of healthcare quality their answer, in the majority of cases, is negative. Consequently, when the FTC and the US Courts are forced to accommodate conflicting views between antitrust and medicine on what actually health care quality is and how it is protected, the bottom line is that *antitrust knows better*. An alternative approach was adopted by the Appellate Court in the *Indiana Federation of Dentists* case, where the Court held that by preventing dentists from joining together to promote standards of quality dental care that comport with the Indiana Dental Code, the FTC with no expertise in the field of dentistry unwisely regulated the dental profession.[777] Not surprisingly, though, the Supreme Court reversed the lower Court's ruling and once again supported the view that vigorous competition ensures quality.

[777] Indiana Federation of Dentists, v. FTC, Respondent. No. 83-1700, *supra* n. 650.

This assessment does not imply that the FTC and the US Courts disregard medical associations' quality claims. On the opposite, they do consider their claims. Nonetheless, they integrate these claims in their antitrust analysis only to the extent they reflect the notion that healthcare markets are pervaded by market imperfections that may erode quality competition. This means that generally they do not seem to foreclose the possibility that improving the workings of an *imperfect market* might make a restraint *less naked*.[778] This conclusion can be easily reached taking into account the Courts' legal analysis in two seminal cases: the *Wilk* and the *CDA* cases.

In the *CDA* case, Judge Souter, in delivering the opinion of the Court, explained how the healthcare market's special features may affect antitrust analysis when price and non-price advertising restrictions are analyzed and assessed. Among other things, Judge Souter identified (a) consumers' difficulties in verifying price information and monitoring the quality of the services they receive, (b) the striking disparities between the information available to the professionals and the patients (c) the patients' attachment to particular professionals, the rationality of which is hard to assess.[779] As the Court noted, all these characteristics, complicate the picture of the medical services' market and require antitrust enforcers to examine under the rule of reason whether certain restraints to competition, such as advertising restrictions, are procompetitive, instead of anticompetitive.[780]

The Court's analysis in the *CDA* case is illuminating for various reasons. First, the Court's analysis leaves no doubt that antitrust enforcers should not shut their ears to medical associations' claims that healthcare markets do differ from other markets. Second, the *CDA* has also been characterized as a setback for what one might consider the quick look antitrust movement.[781] Indeed, the Supreme Court specifically said that the Court of Appeals erred when it held as a matter of law that quick look analysis was appropriate.[782] Nonetheless, the Supreme Court did not clarify: (a) under what conditions the healthcare market's economic and non-economic facets should be examined under the rule of reason analysis; (b) how antitrust enforcers should strike the appropriate

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778 T. Greaney, 'A Perfect Storm on the Sea of Doubt: Physicians, Professionalism and Antitrust' (2002) 14(4) *Loyola Consumer Law Review,* 481, 484.
779 California Dental Association v. Federal Trade Commission, *supra* n 762, at 14-16.
780 *Ibid,* para 15.
781 S. Calkins, 'California Dental Association: Not a quick look but not the Full Monty', (2000) 67 *Antitrust law Journal*, 495, 531.
782 *Ibid*, 532.

balance between restrictions to competition and quality improvements. Not elaborating on these issues, though, the Supreme Court inevitably opened the door to market failure defenses much wider than it had aimed originally.

Arguably, information deficits will be present (albeit in different degrees) in most cases involving health professionals.[783] Unfortunately, though, trial courts will obtain no guidance from *CDA* as to when those problems justify broad rule of reason treatment or when truncated review is 'meet for the case'.[784] Future litigants and Courts, not knowing just how much proof a reviewing court may require to establish that trade was unlawfully restrained, may opt for more extensive discovery, fact finding and analysis than would in fact be necessary, raising the cost and thus the difficulty of bringing successful lawsuits against professional organizations engaged in trade restraining self-regulatory activities.[785]

Surely, this is not the only weak point in Court's analysis regarding the information deficits characterizing healthcare markets. The Court's analysis concerning the extent to which the proposed advertising restrictions may correct these asymmetries has also been criticized. As noted, the Supreme Court held that informational deficits may impair the functioning of the healthcare market and may therefore justify professional interventions, without explaining why and how advertising bans would cure these information deficits. Since advertising at first blush aims to correct market failure by enhancing the stock of information available to buyers, this, undoubtedly, is a critical lapse.[786] The Court also omitted to note that information problems are a double- edged sword when evaluating professional restraints.[787] The same factors that impair consumers' capacity to evaluate care and calculate value also enhance professionals' ability to act opportunistically.[788] Practically, this means that while the Court considered in its analysis one of the market failures pervading healthcare markets, information asymmetry, it omitted to consider another, that doctors are patients' agents and not necessarily the perfect ones. Relying also on the Akerlof's article to underline that dishonest

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783 T. Greaney, *supra* n 778, at 487.
784 *Ibid.*
785 C. Havighust, *supra* n 523, at 950
786 T. Greaney, *supra* n. 778, 488.
787 *Ibid*, 492.
788 *Ibid.*

dealings tend to drive honest dealings out of the market, the Court overreacted as to the extent to which information asymmetries in healthcare sector actually harm quality of care.[789] Indeed, there is reason to doubt the extent of the phenomenon in dental advertising: many dental advertising claims are verifiable and subject to the testing common to experience goods.[790] As economists spell out, the lemons argument ignores the presence of numerous market and governmental institutions that protect consumers.[791] For instance, government regulation of deceptive advertising limits extreme behaviors.[792]

While the Supreme Court in the *CDA* case focused on exploring why healthcare markets might differ from others, in the *Wilk* case, the Seventh Circuit focused more on crafting a process under the rule of reason for assessing quality claims associated with healthcare market's special facets. Was this attempt successful? Considering that there are several reasons to question the wisdom of the Seventh Circuit's 'patient care defense',[793] the answer, I believe, cannot be positive. As analyzed, at issue in this case were the AMA's ethical prohibitions against physician referrals and other forms of cooperation with chiropractors that AMA claimed advanced the profession's purposes of advancing scientific knowledge and improving quality of care.[794] The Seventh Circuit responded to this claim with the patient care defense. This four-part antitrust defense afforded defendant the opportunity to demonstrate a dominant, 'objectively reasonable' concern for issues going to the 'scientific method' underlying the care given to patients; where those criteria were satisfied, the test further required the defendant to demonstrate that less restrictive means of policing quality were not available.[795] This test, which subsequently was never applied by the FTC or the Courts, proved to be demanding. By reformulating the rule of reason, and, by blending subjective and objective standards, this test invited an open-ended inquiry into scientific issues and motives that may inevitably confuse both judges and juries.[796] Indeed, how could the defendants prove that their concerns about chiropractic profession are based on scientific findings considering

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789 *Ibid.*, 493.
790 *Ibid*, 489.
791 T. Muris, *supra* n. 748, at 20.
792 T. Greaney, *supra* n. 778, at 289
793 *Ibid*, 489.
794 *Ibid.*
795 *Ibid.*, 488.
796 *Ibid.*, 489.

that scientists, in general, and doctors, in particular, constantly disagree on whether a specific treatment is scientific? For instance, while some doctors consider homeopathy a pseudoscience—a belief that is incorrectly presented as *scientific*—others believe that this alternative form of treatment has a positive effect on health outcomes. In addition, how can judges and antitrust enforcers assess whether the defendants' primary incentive in excluding competitors is the protection of healthcare quality and not their self-interest? And if reality clearly indicates that defendants' exclusionary strategies are animated both by their commitment to professionalism and their self-interest, how should antitrust enforcers balance their conflicting goals and motives? Which incentive should weight more in their antitrust analysis and assessment?

More than that, one would wonder why the Court introduced a test that required defendants to prove subjective elements, such as their true motivations, although in antitrust market characteristics and effects, and not intentions, dominate the analysis. Indeed, in the *Wilk* case the AMA emphasized that healthcare is burdened with information asymmetries that may harm patients' trust in their doctor and that their strategy aims to correct this market failure. Hence, the Court by formulating its standard in terms of purpose, it is defendants' beliefs that became critical (constrained only by the requirement that those beliefs have a reasonable, objective basis)[797] and not market characteristics and effects.

More importantly, while the Courts seem to embrace the possibility of integrating quality concerns into their analysis in the context of a 'market failure defense', they surely exclude the possibility of considering quality into their assessment in the context of a 'public safety defense'. The Sherman Act reflects a legislative judgment that, ultimately, competition will produce not only lower prices but also better goods and services,[798] the FTC and the US Courts continuously claim. Therefore, adopting an alternative approach one that would accept that less choice and competition may be necessary for the protection of health care quality, would amount to nothing less *than a frontal assault on the basic policy* of the Sherman Act.[799] The US antitrust enforcers and the Courts keep telling the same story even when public safety claims are raised by medical associations and Boards

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[797] T, Kauper, *supra* n. 531, at 323.
[798] [798]National Soc'y of Professional Eng'rs v. United States, 435 U.S. 679, 98 S.Ct. 1355, 55 L.Ed.2d 637 (1978), 762.
[799] *Ibid.*

arguing that their challenged actions are in line with their policy objective of protecting the public from actions that create risks to public safety and health. Unless their policy is covered by the state action doctrine, the Courts constantly say that their patient safety concerns mask economic objections. Judge Keenan noted in the North Carolina case, for example, that the record supported the Board's argument that there was a safety risk inherent in allowing certain individuals, who are not licensed dentists, particularly mall kiosk employees, to perform teeth whitening services.[800] In fact, the Judge acknowledged that she was truly convinced that the Board's strategy was animated by its motivation to protect public health. Nonetheless, the FTC and the Courts instead of analyzing the impact of a specific competition restriction on healthcare quality they only analyze how a challenged restriction affects competition and choice. Since to them the statutory policy precludes inquiry into the question of whether competition is good or bad, any assessment or evaluation as to the risks to healthcare quality some of the available choices actually create, is simply unnecessary.

### 3.2 What are the main pros and cons of the FTC's and the US Courts' approach?

The above analysis revealed that the US antitrust enforcers and the Courts primarily take into account quality by ensuring that competition or choice between medical professionals in the market for healthcare services is not restricted. Their legal analysis is simple: To ensure quality, just maximize the number of available choices and ensure competition. Additionally, it revealed that while the US antitrust enforcers and the Courts seem less unwilling to evaluate quality claims in the context of market failure defenses, they seem clearly less willing to assess quality in the context of patient safety defenses. To them, such justifications are neither cognizable nor plausible. Why do the US antitrust enforcers and the Courts draw such a strict line between these two types of antitrust defenses? Would in fact the outcome of their analysis be different if they widened the range of the justifications they actually consider and accept? In my view, the answer is *not necessarily*.

Clearly, the *Wilk*, *the Massachusetts Board* and the *Teladoc* cases are representative examples of my claim. In the first case the defendants attempted to convince the Court that the market imperfections burdening healthcare markets justify their expelling strategy against chiropractors. In

[800] United States Court of Appeals for the Fourth Circuit, North Carolina, *supra* n. 555, at para 36.

the second case, the optometrists argued that their anticompetitive behavior was actually fueled by their motivation to protect consumers from inferior eye care. In the *Teladoc* case, the Texas Medical Board alleged that their challenged regulation aimed to protect patients from inadequate diagnosis and unnecessary use of antibiotics. Although the rationale behind all these justifications seems to differ, in fact it does not. This is because in all these cases, the alleged quality claims could be structured either as public safety or market failure defenses. In the *Wilk* case, the AMA could have argued, for example, that chiropractors' treatment may lead to inferior patient care. In the *Massachusetts Board* case, the Board could have alternatively argued that consumers in eye care services lack the adequate knowledge to evaluate the quality of the services they receive and thus the challenged regulation ensures that the imperfect market in which its members operate becomes less imperfect. Accordingly, in the *Teladoc* case, the Texas Medical Board could have said that because a physician treating a patient remotely may be called upon to act with limited information, the quality of care may suffer and therefore their regulation ensures that this risk is reduced. More importantly, the US Courts and the FTC would have rejected all these quality claims irrespective of the way they were presented or structured for the simple reason that none of them would have convinced the antitrust enforcers that an alternative, less restrictive strategy was not available.

Why do then the US antitrust enforcers and the Courts constantly reject patient safety claims? I believe, for several different reasons. First, because if they took patient safety justifications into account this might be translated as a *sign of distrust* in the power of markets to always deliver high quality healthcare services. It may also be seen by potential cartelists as a sign that in healthcare markets, antitrust enforcement is more lenient. More importantly, it may be seen by antitrust infringers in other markets as a sign that quality justifies restrictions to competition. Therefore, deterrence may be weakened. Furthermore, if public safety was considered a plausible and cognizable justification, both judges and agencies may be more tempted to shape their decisions in accordance with their political preferences and ideologies. If the Courts and the FTC integrated public safety claims in their analysis one additional risk might emerge: medical associations may be more incentivized to raise safety claims that mask their self-interest. More importantly, accepting patient safety claims as plausible justifications might erode price competition and lead to price increases. In light of these risks, their narrow approach ensures accountability, transparency and vigorous price competition.

What are, however, the *cons* of this approach? First and foremost, insisting that the competitive process will ultimately protect healthcare quality does not necessarily reflect market reality. Research in behavioral economics shows that patients in healthcare markets cannot always construct the choices that are in their best interest since they are either unwilling or not well equipped to evaluate the quality of the services they receive. This means that, absent public intervention healthcare markets cannot guarantee the quality of medical services. In addition, certain aspects of healthcare quality cannot always be protected through vigorous competition. As medical professionals spelt out, quality of medical treatment also depends on non-economic values such as the notions of acceptability and trust, essential features of the patient-doctor relationship. Nonetheless, these features are better served through the doctors' commitment to professionalism and less through vigorous competition.

How would the US antitrust enforcers and the Court reply to this critique? Considering the way they apply the state action doctrine, a plausible answer might be that to the extent regulation exists that exempts a specific activity from the application of antitrust, and this activity is actively supervised by the State, the appropriate *balance* is actually reached between the pursuit of healthcare quality and vigorous antitrust. If such regulation exists and if the conditions of the state action doctrine fully apply, this answer is convincing. If, however, such a regulation does not exist and if State Boards give good reasons why specific practices create serious risks to healthcare quality, this answer is inadequate. Indeed, faithful to the belief that markets always ensure quality and that public health and safety justifications are *extraneous* to antitrust analysis, the US Courts and the FTC would reject such justifications even if reality showed that patients' safety is at risk and therefore medical professionals' intervention seems necessary.

Arguably, this approach suffers from important drawbacks. Essentially, it disregards the fact that unregulated medical markets are pervaded by negative externalities. As a result, an individual might decide to receive a low - quality treatment rather than no service at all because he or she does not fully internalize the cost of bad service. When, however, ill-informed consumers receive low-quality health care, the effects fall beyond those who receive the care. Repercussions of poor care are felt from emergency rooms and inner-city clinics to schools and the workplace – not

to mention on government agencies that may themselves have to pay for the bad outcomes.[801] The FTC and the US Courts by limiting their analysis to the impact of a specific competition restriction to the variety of choices consumers can actually enjoy, they forget to consider the costs to the overall society these choices actually create. Consequently, they end up disregarding that a restriction to competition may avoid more deadweight loss than it actually creates.

Potential risks to healthcare quality may also disincentive consumers from enjoying a specific good or service. This risk is not an imaginary one as the North Carolina case clearly demonstrates. In this case, Judge Keenan illustrated in her separate statement, that the Board was aware that several consumers had received teeth whitening services that did not even respect the minimum standards of hygiene. Inevitably, some consumers were harmed. Because consumers cannot easily assess medical professional's qualifications or medical treatment' adequacy and effectiveness, they might not be able to fully understand and identify the reason why they suffered this harm. In avoiding to suffer again, they might decide to stop receiving teeth whitening services both from dentists and non-dentists. Ultimately, non-licensed or incompetent professionals would harm the reputation of licensed and high qualified professionals. Arguably, this is another form of negative externality the FTC's and the US Courts' analysis underestimates.

Additionally, the Courts' and the FTC's approach with regards to health safety claims may lead to contradictions and considerable confusion taking into account the Supreme Court's antitrust analysis in *the North Carolina case*. As discussed, in this case the Board alleged that permitting non-dentists to perform teeth whitening create risks to healthcare quality. The FTC rejected this justification on the basis that such a justification is not a *cognizable* one, which means one that stems from measures that increase output, *improve product quality* or innovation. Nonetheless, this strict view may lead to contradictory outcomes for the following reason: one important aspect of product's or service's quality is *safety*. In this regard, a competition restrain that may enhance a product's or service's safety would also improve its quality. However, since public safety justifications are not considered *cognizable*, they would be rejected by the FTC and the US Courts, as *extraneous* to an antitrust analysis.

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[801] Teladoc plaintiffs – Appellees et al. v. Texas Medical Board et al, No 16-50017, Case No 1:15-CV-343, 29.

Moreover, an antitrust analysis that practically does not take into consideration medical professionals' views on what health care quality is and how it is achieved disregards that medicine is not only a business but also a calling. Indeed, doctors' motivation to protect quality does not always and necessarily stem from their self-interest, as the FTC and the US Courts constantly argue, but also by their commitment to altruism, excellence, and public service ethos. By considering, however, only economic motives and by overlooking the benefit to the public which occurs from such things as the promotion of scientific medicine and efforts to maintain professional standards, the FTC and the US Courts end up adopting an analysis that is one-dimensional. [802]As Donabedian, however, has argued, the pursuit of healthcare quality cannot be fully achieved if not all functions of a health system commit to the quality goals the health system *as a whole* pursues. Surely, medical professionals and antitrust enforcers are responsible for protecting quality in different ways. While antitrust enforcers are responsible for protecting competition, medical professionals are responsible for ensuring that the services they provide meet the highest possible standard of care. Nonetheless, to them this goal is better achieved more through professionalism and less through vigorous competition. Since, however, doctors' commitment to protect quality is highly linked with their commitment to professionalism, a health care system as well as an antitrust policy that aims to protect quality *as a whole* should not disregard this aspect of the notion. An alternative approach, one that sees doctors mainly as *knaves* and not as *knights*, might seriously undermine their commitment to professionalism and therefore their commitment to protect healthcare quality.

## 4. Conclusion

In this chapter I have identified how the FTC and the US Courts conceive healthcare quality and how they respond to medical Boards' healthcare quality claims. In concluding, I have not claimed that the US antitrust enforcers and the Courts should evaluate healthcare quality defenses and justifications in a more lenient way. Undoubtedly, a more lenient approach may incentivize medical associations to raise quality concerns that mainly disguise self - interests. More importantly,

[802] My argument is inspired by A. Dyer, 'Ethics, advertising and the definition of a profession', (1978) (11) *Journal of Medical Ethics*, 72, 73.

it may reduce price competition and innovation and prohibit citizens from enjoying healthcare services that are essential for their well- being and flourishing. I have argued, though, that the US antitrust enforcers and the Courts should assess and evaluate healthcare quality claims in a less formalistic way when they apply antitrust law in medical markets. In analyzing healthcare quality claims the US antitrust enforcers should evaluate and assess quality claims not only on the basis of the way they are constructed, as market failure defenses or public safety justifications, but also on the basis of the risks to healthcare quality, as a multidimensional concept, each particular case raises. This suggestion implies two things: First, that the antitrust enforcers should consider that healthcare quality is not always the result of more choice and competition but also the result of other dimensions, such as professionalism, acceptability and trust. It further implies that when applying antitrust in medical markets the FTC and the Courts should not take as a starting point that doctors are nothing more than cartelists mainly motivated by their self - interest but also professionals motivated by their public service ethos. Expanding their approach might not necessarily transform their conclusions. It would, however, ensure that antitrust enforcers and medical associations do not constantly try to impose their own views on what the prevailing facets of healthcare quality should be. Indeed, a different approach would ensure that different institutions respect each other's views and perspectives on what healthcare quality is and how it is achieved. In *Donabedian's* language, an alternative approach would ensure that all functions of the health system commit to the quality goals that the system *as a whole* pursues.

## IV. Integrating healthcare quality concerns into the US hospital Merger Cases: *A mission impossible*?

The consolidation of healthcare markets and the impact of this consolidation on prices, costs, and quality, has been a hotly debated topic in the US health care industry.[803] This trend can be traced to the tumultuous period of restructuring the US healthcare industry went through in the 1990s.[804] In view of the continuously raising cost of health care, the need for new and innovative methods of providing more affordable medical treatment emerged. Included in these new methods were the full panoply of managed care organizations,[805] changes in providers' payment and the integration of healthcare delivery.[806] *What actually caused the high cost in healthcare? What initiated this rapid restructuring of the US healthcare industry?*

For most of the 20th century most consumers relied on independent physicians to provide care. Pricing was fee for service (FFS).[807] This form of payment conformed with public sentiment that more care amounts to better care and the treating physician is the best positioned to judge the most appropriate care for any given case.[808] Insurers imposed few constraints on consumer choice of providers and limited oversight of the type and extent of care provided.[809]

Starting in the late 1960s, policymakers began seriously questioning the consequences of these institutional arrangements.[810] Essentially, they started expressing the concern that the

803 D. Lomax and H. Kim, 'The Evolution of Efficiencies and Treatment of Quality of Care Defenses in Light of Changing Health Care Industry Dynamics', (2014) (4) 5 *Competition Policy International*, 2.
804 American Bar Association, Section of Antitrust Law, *Healthcare Mergers and Acquisitions Handbook*, 93 (ABA Book Publishing, 2003), 1.
805 Managed care encompasses a wide array of institutional arrangements for the financing and delivery of healthcare services. Usually when one speaks of a Managed Care Organization, (MCO) one is speaking of the entity that manages risk, contracts with providers, is paid my employers or patient groups, or handles claims processing. Managed care offers a more restricted choice of (and access to) providers and treatments in exchange for lower premiums, deductibles, and copayments that traditional indemnity insurance. Managed care usually uses three strategies to control costs and enhance quality of care: (1) selective contracting (ii) direct financial incentives (iii) utilization review.
806 Federal Trade Commission and the Department of Justice, *supra* n. 517, at 1.
807 FFS means that the payment is based on the number and type of services performed.
808 Federal Trade Commission and the Department of Justice, *supra* n. 517, at 1.
809 *Ibid*, 1.
810 *Ibid.*, 2.

combination of FFS payment, health insurance and consumers' imperfect information about healthcare limit the possibility of effective price competition and create an incentive for physicians to over provide and consumers to consume greater health care resources than would be the case in competitive markets.[811] FFS payment, they claimed, dampened the potential for effective price competition, because FFS guaranteed reimbursement for claimed charges.[812] Thus, providers lacked incentives to lower prices. It also provided little incentive for physicians and other healthcare providers to coordinate and integrate the care they rendered.[813]

In light of these concerns, over the past three decades, state and federal policy has encouraged the emergence of a range of financing and delivery options, and has embraced, to varying degrees, price and non-price competition in healthcare.[814] The rapid growth of managed care in the 1990s' is exactly the result of this new policy orientation towards vigorous price competition in healthcare. This growing demand for decrease in healthcare costs along with the increasing presence of managed care has placed enormous pressure on hospitals to reduce capacity costs, while improving the quality of patient care. To meet these goals, inevitably, hospitals started merging. The result was a period of rapid and substantial consolidation or else a merger wave.

This dynamic trend in the US healthcare industry which had already started in the 1990's has not ceased. In contrast, it has increased following the implementation of the Patient Protection and Affordable Care Act (ACA) which seeks, among other things, to promote higher quality and lower healthcare cost by encouraging coordination of care among health care providers through the creation of Accountable Care Organizations.[815]

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[811] *Ibid*, 8.
[812] *Ibid.*
[813] *Ibid*, 2.
[814] *Ibid.*
[815] D. Lomax, H. Kim, *supra* n. 803, 2, Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119 (2010), as amended by Health Care and Education Reconciliation Act of 2010, Pub. L. No. 11-152. 124 Stat. 1029 (2010), § 3011. Accountable Care Organizations (ACOs) are groups of doctors, hospitals, and other health care providers, who come together voluntarily to give coordinated high - quality care to their Medicare patients. The goal of coordinated care is to ensure that patients, especially the chronically ill, get the right care at the right time, while avoiding unnecessary duplication of services and preventing medical errors, see: https://www.cms.gov/medicare/medicare-fee-for-service-payment/aco/.

*What do hospitals aim to achieve by merging?* Hospital consolidation can improve efficiency, access to care, quality of care, and may lower costs on the basis that the more care a hospital provides, the more efficient and less expensive it becomes.[816] Indeed, hospital mergers can promote efficiency. Hospitals that consolidate can also limit duplication of services or administrative expenses, expand their delivery network and obtain economics of scale.[817] They can also improve quality. The potential mechanisms for quality increases are many.[818]

Acquiring hospitals, for instance, can bring both financial resources and management expertise to the hospitals they require, permitting an expansion of service offerings.[819] Expansions increase quality in the sense that patients gain access to a broader array of services.[820] A merger can also increase the average quality of care received by patients by redirecting patient flows.[821] A merged hospital organization has the opportunity to concentrate service offerings in the higher quality of its facilities, increasing the quality for the patients of the merged organization.[822]

Inevitably, a merger also increases patient volumes for hospital providers. In view of medical research identifying a relationship between procedure volumes and patient volumes,[823] the

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[816]G. Curfman, 'Everywhere, Hospitals are Merging - but Why Should we Care? http://www.health.harvard.edu/blog/everywhere-hospitals-are-merging-but-why-should-you-care-201504017844.

[817] Federal Trade Commission and the Department of Justice, *supra* n 517., 11.

[818] K. Madison, *supra* n. 22, at 275. Health economists have conducted empirical research both in Europe and in the US in order to explore the relationship between hospital consolidation and competition. Theoretical models and empirical papers suggest ambiguity regarding hospital consolidation and healthcare quality (David Dranove & Mark A. Satterthwaite, The Industrial Organization of Health Care Markets, in 1B HANDBOOK OF HEALTH ECONOMICS 1093 Indicatively, Mutter, Romano, and Herbert Wong broadly surveyed hospital mergers in 1999 and 2000 in the US on 25 quality indicators and had ambiguous result as to the relationship between hospital competition and quality (Ryan L. Mutter et al., The Effects of US Hospital Consolidations on Hospital Quality, 18 INT'L J. ECON. BUS. 109, 109 (2011) and R. Blair, D. Sokol, 'Quality-Enhancing Merger Efficiencies', (2015) 100 *Iowa L. Rev.*, 1969, 1991. Other empirical studies include one from Kessler and Jeffrey Geppert, who examine heart attack care and find that increased competition increases welfare. See generally Daniel P. Kessler & Jeffrey J. Geppert, The Effects of Competition on Variation in the Quality and Cost of Medical Care, 14 J. ECON. & MGMT. STRATEGY 575 (2005). In Europe, a widely cited example purporting to show that competition among hospitals increases quality examined the association between the degree of competition in local health care markets in England and the speed of decline in mortality from heart disease (Cooper, Z., S. Gibbons, S. Jones and A. McGuire, 2010, Does hospital competition save lives? Evidence from the English NHS patient reforms, LSE.).

[819] *Ibid.*

[820] *Ibid.*

[821] I*bid.*

[822] *Ibid.*

[823] R. Mesman, G. Westert, B. Berden, M. Faber, 'Why do high volume hospitals achieve better outcomes? A systematic review about intermediate factors in volume outcome relationships' (2015) 119 *Health Policy*, 1055.

higher volumes a merger brings, enhances the overall quality of the services provided. More than that, peer influence speeds the adoption of beneficial therapies.[824] Therefore, a merger facilitating the sharing of experience and expertise among hospital managers and physicians improves the quality of the services provided.[825] Arguably, it is possible to work internally to advance quality or to hire outside consultants to offer their expertise.[826] Nonetheless, the closer relationships a merger develops allow information and management systems to transfer more easily than they otherwise would.[827]

A hospital merger can also make the adoption of information technologies less costly. Electronic medical records, computerized provider order entry and other electronic systems which enhance the safety and quality of medical care, usually produce economies of scale.[828] Therefore, the marginal costs of providing information services decline as more physicians and patients are served by the system, a likely result of the hospital merger.[829] These information systems are also subject to network effects. Especially for electronic medical records, each additional physician that uses a particular system increases its value to other physicians and patients because information is more easily shared among providers.[830]

Although hospital consolidation has the potential to create substantial cost and qualitative efficiencies, it can also harm competition by creating market power. *Can the US antitrust enforcers and the Courts strike the appropriate balance between the quality improvements a hospital merger brings and the risk of market power? Can they assess the quality improvements stemming from the hospital merger and weigh them against potential anticompetitive harm?* And if yes, *how*?

Surely, these questions are not easy. However, a major goal of this chapter is to carefully examine them. First, I explain why and how hospital consolidation can create market power. To achieve this goal, I briefly analyze the framework under which hospitals are paid. Second, I analyze

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824 K. Madison, *supra* n. 22, at 276.
825 *Ibid.*
826 *Ibid.*
827 *Ibid.*
828 *Ibid*, 276.
829 *Ibid.*, 277.
830 *Ibid.*

the applicable framework for hospital mergers in the US. In fact, I see how quality can become a critical consideration under a merger analysis. Third, I delve into the core research questions of this chapter. Focusing on the seminal US hospital merger cases where quality claims were actually examined I address three questions: *How do the US antitrust enforcers and the Courts perceive quality of care? What are the quality dimensions they actually value? What are the challenges the US antitrust enforcers and the Courts face in dealing with defendants' quality claims?* The final part concludes.

### 1. *How are hospitals paid?* A historical perspective

Generally, hospitals are paid by two main payers: the *public*, or in other words the Federal Centers for Medicare and Medicaid Services (CMS) which administers the *Medicare*[831] and *Medicaid*[832] programs, and the *private*. Prior to 1983 insurers mainly paid hospitals on a cost based reimbursement system (or else FFS): they informed their payers about the cost of their services and those amounts were then paid.[833] As noted, the FFS arrangement led to substantial increases in healthcare spending since it rewarded volume and discouraged efficiency. An important initial effort to curb these increases in spending was launched in 1983, when the main public payer, CMS, implemented a more cost - effective payment method, the inpatient prospective payment system (IPPS).[834] This new payment scheme aimed to moderate the rising federal expenditures, create a more competitive market like environment and reduce inefficiencies in hospital operations engendered by reimbursement of incurred cost.[835] Under this form of payment, the amount a hospital receives for treating a patient is based on the diagnosis related group (DRG) *that justified the*

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831 *Medicare* provides coverage for approximately 40 million elderly and disabled Americans. Medicare Part A covers most Americans over 65, and provides hospital insurance coverage. Although Medicare Part B is optional, almost all eligible parties enroll, given substantial federal subsidies to the program. Medicare Part B provides supplementary medical coverage for, among other things, doctors' visits and diagnostic tests. Many Medicare beneficiaries also purchase Medicare Supplemental Insurance (Medigap) policies or have coverage from a former employer.

832 *Medicaid* provides coverage for approximately 50 million Americans. Although the federal government sets eligibility and service parameters for the Medicaid program, the states specify the services they will offer and the eligibility requirements for enrollees. Medicaid programs generally cover young children and pregnant women whose family income is at or below 133 percent of the federal poverty level, as well as many low - income adults. Most states have most of their Medicaid population in some form of managed care. Medicaid pays for a majority of long term care in the United States. Within broad guidelines established by federal law, each State sets its own payment rates for Medicaid services.

833 Federal Trade Commission and the Department of Justice, *supra* n 517, at 8.

834 *Ibid.*, 9.

835 *Ibid.* 5.

*episode of hospitalization*.[836] Each DRG has a payment weight assigned to it, based on the average cost of treating patients in that DRG which reflects both the very ill patients that require more intensive care and the healthy ill who do not cost as much to treat.[837]

Further changes to this system were provided for in the Affordable Care Act of 2010 which provides bundled payments by CMS for services that patients receive across a single episode of care, such as heart bypass surgery or a hip replacement.[838] Such proposals aim to encourage doctors, hospitals and other health care providers to work together to better co-ordinate care for patients both when they are in the hospital and after they are discharged.[839]

*Private payers* provide private health insurance which is obtained primarily through benefits offered by employers and individual purchases.[840] Employers and other groups purchasing private health insurance are collectively named 'third party payers'.[841] The prices of the insurance services private payers offer are negotiated directly between the latter and the hospitals.

As public payers, private payers design and apply cost effective payment schemes. Hospitals are paid on the basis of various payment arrangements and schemes. The most common, though, are per diem rates, per case rates, or discounts-off-charges rates.[842] Under a per diem rate, a hospital receives a fixed price for each day of hospital care *without regard to the actual diagnosis of the patient* or *the resources the hospital uses in the treatment*.[843] Under a per case rate, the hospital receives a fixed price for the hospital stay for a particular type of case, *regardless of the number of days the patient stays* or *the resources the hospital uses in the treatment*.[844] Under a discount-off-charges rate, the hospital

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[836] OECD, Policy Roundtables, Competition in Hospital Services, United States, OECD, DAF/COMP (2012) 9, 241 available at: http://www.oecd.org/daf/competition/50527122.pdf.
[837] *Ibid*, 241.
[838] *Ibid.*
[839] *Ibid.*
[840] *Ibid.*, 243.
[841] *Ibid.*
[842] *Ibid*, 244.
[843] *Ibid.*
[844] *Ibid.*

receives a percentage of the hospital's 'charges' for the hospital stay, where the 'charges' are the prices the hospital charges for each resource used in treating the patient.[845]

Healthcare providers compete with each other to be included in an insurance company's network, which is an important source of patients, who bear lower out of pocket costs for using in network doctors.[846] Robust competition for inclusion enables insurers to negotiate lower reimbursement rates, which lead to lower costs for customers and employers.[847] Once providers are in an insurance company's network, they compete to attract patients by improving the quality of the service offering to patients.[848]

The amount an insurer reimburses network participants for healthcare services is established in a contract negotiation between private payers and the hospitals.[849] The outcome of those negotiations depends primarily on the bargaining dynamics in the relevant market. Generally speaking, where the provider's position is stronger, rates will be higher.[850] Where the insurers' position is stronger, rates will be lower.[851] Physicians need inclusion in insurer networks to recruit patients.[852] Insurers need physicians to participate in a network to make it attractive to policy holders.[853] Therefore, the party with the greater relative strength can negotiate a more favorable

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845 *Ibid.*

846 Alphonsus Medical Center – Nampa, Inc. v. St. Luke's Health System, Ltd., Reply Brief of Appellants St. Luke's Health System, Ltd, et al., No. 14-35173 (9th Cir. Sep. 2, 2014), 5

847 *Ibid.*

848 *Ibid.* See also, In the matter of Advocate Health Care Network, a corporation, et al, Complaint, Docket No. 9369, at 31-39, In the Matter of Penn State Hershey, Medical Center, a corporation et al, Complaint, Docket No. 9368, at 31-38, In the matter of Cabell Huntington Hospital Inc., a corporation, et al, Complaint, Docket No. 9366, at 50-51. On July 6 2016 the FTC dropped the latter complaint in light of a new West Virginia law relating to certain "cooperative agreements" between hospitals in that state, and the West Virginia Health Care Authority's decision to approve a cooperative agreement between the hospitals, with which the West Virginia Attorney General concurred. The FTC's initial complaint, issued in November 2015, alleged that the proposed merger violated U.S. antitrust law. The Commission voted to dismiss the complaint since the passage Cooperative agreement laws seek to replace antitrust enforcement with state regulation and supervision of healthcare provider combinations. "This case presents another example of healthcare providers attempting to use state legislation to shield potentially anticompetitive combinations from antitrust enforcement," the Commission wrote in a statement, https://www.ftc.gov/news-events/press-releases/2016/07/ftc-dismisses-complaint-challenging-merger-cabell-huntington, S. W. Waller, *How Much of Health Care Antitrust is Really Antitrust?,* at 21 http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2819543.

849 Alphonsus Medical Center – Nampa, Inc. v. St. Luke's Health System, Ltd., *supra* n. 846, at 6.

850 *Ibid.*

851 *Ibid.*

852 *Ibid.*

853 *Ibid.*, 4-5.

rate.[854] Relevant questions here are the following: *Does the insurer have buyer power? Does the participating hospital have the status of a 'must have' hospital?*

Bargaining leverage consists largely of the ability to walk away from the negotiating table.[855] This ability is called 'fallback option' or a 'best alternative to a negotiated agreement'.[856] If multiple medical practices are competing for inclusion in the network, an insurer facing a demand for unacceptably high reimbursement rates by one practice will be able to walk away from the negotiation and turn to other practices to form a commercially attractive network.[857]

In markets with no good fall back options, though, the bargaining dynamics might be different.[858] Stripped of acceptable alternatives among medical practices in a given area, an insurer's bargaining strength might be diminished.[859] The same might happen if the hospital is very important to the formation of a marketable network because it has the status of a '*must have hospital*'. A provider having this status might successfully demand higher reimbursement rates. More than that, if it belongs to a multi-hospital system, it might demand that all system hospitals gain access to the payer' s network.[860] Considering consumers' pressure for choice, private payers might find it difficult to resist the hospital's demands and exclude an entire hospital system outright. This will result in insurance companies paying higher fees to providers.[861] Ultimately, not only premiums will be increased but also the percentage of the uninsured population. This is not a trivial concern considering that by 2009, the number of uninsured in the US had risen by 10 million.[862]

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[854] *Ibid*, 6.
[855] *Ibid.*, 6.
[856] *Ibid.*
[857] *Ibid.,* 7.
[858] *Ibid.*
[859] *Ibid.*
860 Federal Trade Commission and the Department of Justice, *supra* n. 517, at 17.
[861] *Ibid.*, at 29.
[862] R. Boscheck, 'Health-Care Cost Containment through Evidence-Based Competition: On the Rebirth of an Old Idea and the Chances for Implementing It Today', (2011) 34 *World Competition*, 661, 666. A new report released in 2016 by the US Department of Health & Human Services finds that the provisions of the Affordable Care Act have resulted in an estimated 20 million people gaining health insurance coverage between the passage of the law in 2010 and early 2016—an historic reduction in the uninsured. Those provisions include Medicaid expansion, Health Insurance Marketplace coverage, and changes in private insurance that allow young adults to stay on their parent's health insurance plans and require plans to cover people with pre-existing health conditions, http://www.hhs.gov/about/news/2016/03/03/20-million-people-have-gained-health-insurance-coverage-because-affordable-care-act-new-estimates.

The above analysis forces us to think the following: Hospitals' bargaining power and consumers' increasing demand for affordable insurance ensuring access and providing choice push the main players in hospital services, hospitals and payers, to shape the negotiation agenda around two main issues: cost containment and consumers' satisfaction through choice. Lower prices in hospitals' fees and insurance's premiums can be achieved through vigorous price competition. Indeed, to gain access to the payers' network, hospitals are strongly incentivized to reduce the prices of the services they offer or to accept cost effective payment arrangements, such as the *per case* or *per diem* payment schemes.

Arguably, fierce price competition along with the application of various cost - effective pricing strategies lead to lower hospital fees and insurance premiums. Do, however, also induce the quality of hospital services? The answer is clearly negative. A hospital receiving a predetermined amount for a specific disease or treatment would definitely have the incentive to reduce the unnecessary costs of treatment. At the same time, though, it might have the incentives to lower the quality of its services. To illustrate, I offer an example: As discussed, under a *per diem* rate, the hospital receives a fixed price for each day of hospital care without regard to the actual diagnosis of the patient or the resources the hospital actually uses for his/her treatment.[863] This practically means that if a hospital treats two patients suffering from a different disease for the same time period, the hospital will receive the same amount for their treatment irrespective of the cost it actually incurred. *Does, however, a patient suffering from hip dislocation run the same health risk with someone suffering from breast cancer? Do they have equal needs? And more importantly, does their treatment require equal resources?* Obviously, the answer is negative.

Undoubtedly, the public payers' payment scheme creates similar concerns. For instance, under the IPPS payment scheme, the amount a hospital accepts for treating a patient is calculated on the basis of the diagnosis related group (DRG) justifying the episode of hospitalization.[864] This means that two hospitals treating two patients diagnosed with the same disease, will receive equal

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[863] OECD, Policy Roundtables, *supra* n. 836, at 244.
[864] *Ibid.* 241.

amount of payment regardless of the *individual needs* and the *special conditions* of each patient. They will also receive the same amount regardless of the quality of care each patient experienced.

### 2. Hospital merger analysis: A short travel to the applicable framework

The Agencies (the Department of Justice and the FTC) analyze hospital mergers using the same analytical framework they use for other mergers.[865] This framework is described in the 2010 Horizontal Merger Guidelines which outline the analytical techniques, practices, and the enforcement policy with respect to mergers and acquisitions involving actual or potential competitors ('horizontal mergers') under the federal antitrust laws.[866] The unifying theme of these Guidelines is that mergers should not create or entrench market power or facilitate its exercise.[867]

A merger enhances market power if it is likely to encourage one or more firms to raise prices, reduce output, diminish innovation, or otherwise harm customers as a result of diminished competitive constraints.[868] The Guidelines clarify that increased market power can be manifested in both price and non-price terms. The latter include reduced product quality, product variety or reduced service. Such non-price effects may coexist with price effects, or can arise in their absence.[869]

Interestingly, the framework under which the Agencies examine whether a merger may lessen price or non-price competition, is identical. The Guidelines illustrate that when the antitrust enforcers investigate whether a merger may lead to a substantial lessening of non-price competition, *they employ an approach analogous to that used to evaluate price competition.*[870] *But how do they shape their assessment as to the extent to which a merger can lessen competition and increase market power?*

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[865] *Ibid.*, 249.
[866] U.S. Department of Justice & Federal Trade Commission, Horizontal Merger Guidelines (2010) [herein after the Guidelines], http://www.justice.gov/atr/public/guidelines/hmg-2010.html.
[867] *Ibid.*, at 2.
[868] I*bid.*
[869] *Ibid.*
[870] *Ibid.*

The Agencies apply a five - step test analytical process for determining whether a transaction should be challenged. These steps are the following: (a) Define the relevant market and determine to what extent concentration in the market would increase as a result of the transaction; (b) Consider the potential impact on concentration and other factors, determining the overall competitive impact of the transaction; (c) Assess whether entry by additional firms into the market would lessen competitive concerns; (d) Consider whether the proposed transaction would result in procompetitive efficiencies; (e) Determine whether, but for the merger, the firm would fail, causing its assets to exit the market.[871]

*How do quality concerns fit into the application of this test? At which steps of merger analysis can quality concerns be in fact integrated into the analysis?* As the applicable 2010 Merger Guidelines suggest, the Agencies can incorporate quality concerns into their analysis when they define the relevant market, evaluate the potential anticompetitive effects of the merger and when they consider its procompetitive efficiencies.

### 2.1 Defining the relevant market

A merger analysis normally starts with the definition of the relevant product and geographic market in which competitive effects are likely to be felt.[872] The Guidelines state that 'the agencies will normally identify one or more relevant markets in which the merger may substantially lessen competition'.[873] As the Guidelines underline, market definition focuses solely on demand substitution factors, i.e., on customers' ability and willingness to substitute *away from one product to another in response to a price increase or a corresponding non-price change such as a reduction in product quality or service*.[874]

Although the Guidelines suggest that in a relevant product market definition test not only a price increase but also a reduction in quality can be a demand substitution factor, they do not explain how quality reduction is measured and assessed and what role it can actually play in the

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[871] *Ibid.*
[872] J. J. Miles, 'Anatomy of a Provider Merger Antitrust Challenge', 15 available at: https://www.healthlawyers.org/Events/Programs/Materials/Documents/PHS15/l_miles.pdf.
[873] Horizontal Merger Guidelines (2010) *supra* n. 866, at 1.
[874] *Ibid.*, at 7.

definition of the relevant product market. The Guidelines do explain the methodological framework for defining the relevant product market on the basis of customers' responses to price increases. This is the Hypothetical Monopoly Test (SSNIP).[875] However, when it comes to the potential customers' responses to quality reductions they are silent.

The integration of non-price issues in the definition of the relevant geographic market entails analogous inadequacies. Again, the Guidelines imply that non-price issues impact the definition of the relevant geographic market. They state that, in general, the scope of geographic markets depends on transportation costs.[876] They clarify, though, that other factors such as *reputation, and service availability* can impede long-distance or international transactions.[877] Nevertheless, as in the case of relevant product markets, they omit to address how these non-price factors affect the definition of the relevant geographic market.[878]

### 2.2 Assessing the anti-competitive effects

In theory, when examining the coordinated and unilateral effects of a merger, the Agencies can take quality into account in multiple different contexts. For instance, they gauge whether the merger under examination is likely to diminish innovation competition by encouraging the merged firm to curtail its innovative efforts below the level that would prevail in the absence of the merger.[879] They also evaluate whether the merger *enables innovation that would not otherwise take place*, by bringing together complementary capabilities that could not otherwise be combined.[880]

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[875] In defining the product market, the analyst chooses the narrowest product offered by both merging parties (call it the "candidate market"), assumes a true monopolist (a single present and future seller) of those products, and asks whether, if the monopolist raised its prices, say five to ten percent, the price increase would be profitable. If the price increase would be profitable, the analysis stops and the relevant product market includes only those products. But if the price increase would not be unprofitable— because too many customers would switch to other products to avoid the price increase—the product market must be expanded to include the next-best substitute. The analysis is repeated until the market includes sufficient products so a price increase of all would be profitable, John J. Miles, *supra* n. 872, at 16.
[876] Horizontal Merger Guidelines (2010), *supra* n. 866, at 13.
[877] *Ibid.*
[878] The hypothetical monopolist test requires that a hypothetical profit-maximizing firm that was the only present or future seller of the relevant product(s) to customers in the region would impose at least a SSNIP on some customers in that region.
[879] *Ibid.*, 23.
[880] *Ibid.*

Innovation is not the only quality aspect the Agencies count. Variety and choice also seem to play an important role in the merger's unilateral effects analysis. For instance, the antitrust enforcers evaluate whether the merger is likely to give the merged firm an incentive to reduce variety by ceasing to offer one of the relevant products sold by the merging parties.[881] They also evaluate whether a merger can lead to the efficient consolidation of products and increase variety by encouraging the merged firm to reposition its products to be more differentiated from one another.[882]

A similar logic dominates antitrust enforcers' analysis when they examine the merger's coordinated effects. For example, they investigate whether coordinated interaction can blunt a firm's incentive to offer customers better deals by undercutting the extent to which such a move would win business away from rivals.[883]

### 2.3 Considering the procompetitive efficiencies

A merger's primary benefit to the economy is its potential to generate significant efficiencies and therefore stimulate the merged firm's abilities and incentives to compete, which may result in lower prices, improved quality, enhanced service, or new products.[884]

Efficiencies generated through merger induce competition in multiple ways. For example, if two ineffective competitors merge, they might form a more effective competitor e.g., by combining complementary assets.[885] Efficiencies also induce quality competition by encouraging the creation of new or improved products, even if they do not immediately and directly affect price.[886]

In line with this economic rationale, merging entities often argue that their transaction should not be challenged by the Agencies because of the efficiencies it produces. They claim that the proposed merger does not restrict competition because the cost or qualitative efficiencies it brings

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881 *Ibid.*, 24.
882 *Ibid.*, 22.
883 *Ibid.*, 24.
884 *Ibid.*, 29.
885 *Ibid.*
886 *Ibid.*

outweigh its anticompetitive effects. The Guidelines do explain under what conditions such claims can be successful. For the efficiencies to 'count' in favor of the merger, they require that they be (a) *merger specific* which means accomplished with the proposed merger and unlikely to be accomplished in the absence of either the proposed merger or another means having comparable anticompetitive effects (b) *verifiable*, which means efficiencies that are not vague or speculative or that they cannot be verified by reasonable means and (c) not resulting in reductions in output.[887] The proposed benefits from the efficiencies should be passed-on to customers.[888]

In theory, both quality and cost efficiencies matter in the context of a merger assessment. Indeed, the Guidelines leave no doubt that quality plays a significant role when efficiency claims are assessed. They maintain: 'just as adverse competitive effects can arise along multiple dimensions of conduct, such as pricing and new product development, so too can efficiencies operate along *multiple dimensions'*.[889] In this context, the Guidelines acknowledge that efficiencies relating to research and development can be substantial.[890] They raise the concern, though, that they are generally less susceptible to verification and may be the result of output restriction.[891]

The Guidelines seem *to indirectly discount* claims justifying price increases on the basis of quality improvements since they do not address how the Agencies would accommodate these claims. They note that 'purported efficiency claims based on lower prices can be undermined if they rest on reductions in product quality or variety that customers value.'[892] That means that quality degradation, if it results in lower cost, should not be supported under efficiencies analysis.[893] Nonetheless, when both costs and quality efficiencies increase, the Guidelines, again, are silent.[894] The Guidelines contemplate only situations in which 'efficiencies also may lead to new or improved products, even if they do not immediately and directly affect price'.[895] Mergers, however, could result in products or services that are higher priced but nevertheless benefit society because of their higher

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[887] J. Miles, *supra* n. 872, 31.
[888] *Ibid.*
[889] Horizontal Merger Guidelines (2010) *supra* n. 866, at 31.
[890] *Ibid.*
[891] *Ibid.*
[892] *Ibid.*
[893] R. Blair, D. Sokol, 'Quality-Enhancing Merger Efficiencies', (2015) 100 *Iowa L. Rev.*, 1969, 1972
[894] *Ibid.*
[895] *Ibid.*

quality.[896] Especially in the context of healthcare, while some purchasers might prefer to obtain the previous quality of care at a lower price, it certainly would not be surprising if many purchasers would prefer high quality services, even if obtaining them would require paying more.[897]

Hence, in general, the Guidelines describe what sort of efficiency gains the Agencies value. Nonetheless, they do not describe under what legal and economic test such gains can be balanced against the merger's likely anticompetitive effects. In other words, they fail to explain how the defendants can prove that the efficiencies generated by their proposed transaction may surpass harm to competition. This inadequacy is not trivial. On the contrary, it can prove highly problematic considering the high burden of proof the merging parties bear when claiming that their transaction generates efficiencies exceeding the potential harm to competition. Undoubtedly, the task they are expected to complete is a difficult one. On the one hand, the Guidelines clarify that the Agencies will not challenge a merger if they think that the cognizable efficiencies are sufficient to reverse the merger's potential harm to customers in the relevant market, e.g., by preventing price increases in that market.[898] On the other hand, they reveal that in conducting their analysis, the antitrust enforcers should not simply compare the magnitude of the cognizable efficiencies with the magnitude of the likely restrictions of competition.[899] Therefore, the Guidelines explain what type of efficiency analysis *would not meet* the parties' burden of proof, but they do not explain what type of efficiency analysis *would actually meet* the required burden of proof.

### 3. Quality in the hospital merger analysis of the FTC and the US Courts: Is it actually taken into account?

The previous section examined how quality can become part of a merger analysis taking due account of the guidance the Guidelines offer. Additionally, it briefly discussed the hurdles merging parties may face in introducing quality concerns into a merger assessment. This part seeks to see to what extent the hurdles and inadequacies identified in the previous section have been addressed by the US Courts and the antitrust enforcers in hospital merger cases. In sum, it explores how and to

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[896] K. Madison, *supra* n. 22, at 275.
[897] *Ibid.*
[898] Horizontal Merger Guidelines (2010) *supra* n. 866, at 31.
[899] *Ibid.*, 30.

what extent the Agencies integrate healthcare quality in hospital merger cases into each stage of merger analysis.

### 3.1 Quality concerns when defining the relevant geographic market

Although the Guidelines make clear that quality concerns can be taken into consideration when the relevant product and geographic markets are defined, the case law in hospital merger cases shows that price concerns monopolize this stage of merger analysis.

To define the geographic market the question the Agencies primarily ask is the following: where can *customers* of hospital services practically turn for alternative services should the merger be consummated and *prices become anticompetitive*?[900] Applying the SSNIP test they focus on how customers would respond to a small but significant price increase (5-10 percent) imposed by a 'hypothetical monopolist' through a defined geographic area.[901] If the price increase in the proposed geographic market would cause customers to travel to adjacent areas where sellers offer lower prices 'in sufficient numbers to make the price hike unprofitable' then the proposed geographic market is defined too narrowly.[902] But if the price increases would be profitable because enough consumers would accept it in order to stay within the geographic area, then that area is the relevant geographic market.[903] When the Agencies think of 'customers' they do not consider the final recipients of the healthcare services, namely the patients, but the payers that directly pay for services and bargain with providers.[904] To them, a geographic market is an area of effective competition where buyers can turn for alternative sources of supply.[905] Considering that payers' customers usually demand local care, the antitrust enforcers believe that insurers have little choice but to pay the price increase hospitals demand rather than offer an insurance product excluding access to local care.[906]

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[900] Fed. Trade Comm'n v. Tenet Health Care Corp., 186 F.3d 1045, para 21 (8th Cir. 1999).
[901] US Court of Appeals for the 9th Circuit, Alphonsus Medical Center – Nampa, Inc. v. St. Luke's Health System, District Court for the District Court of Idaho, Case No. 1:12-cv-00560-BLW et al., 11.
[902] *Ibid.*, 11.
[903] *Ibid.*
[904] *Ibid.*, 12.
[905] *Ibid.*, 27.
[906] *Ibid.*, 20. See also In the matter of Advocate Health Care Network, a corporation, et al, Complaint, Docket No. 9369, at 23-26, In the Matter of Penn State Hershey, Medical Center, a corporation et al, Complaint, Docket No. 9368, at 21-25, In the matter of Cabell Huntington Hospital Inc., a corporation, et al, Complaint, Docket No. 9366, at 31-36.

Nonetheless, by concentrating mainly on the above analysis, the FTC and the Courts disregard the quality aspects the definition of a geographic market in the hospital sector may entail. In fact, they disregard that patients' choice of hospitals is determined by a number of non-price variables, the most important of which is quality. Thus, they neglect that from the patients' perspective a different question may seem vital: where could consumers of hospital services practically turn for alternative services should the merger be consummated and *quality reduced?*

Both the FTC and the Courts do recognize that patients focus more on quality and less on price when they choose healthcare providers. However, they choose not to integrate patients' perspectives into their analysis. The St. Luke's case illustrates this point. The Appellate Court in this case underlined that in the primary care service market 'price is not a major strategic factor' in consumers' decisions.[907] Convenience, quality and established relationships with their doctors are the factors consumers primarily care about, the Court confirmed.[908] This is largely because consumers do not pay the medical bills directly: A ten-dollar increase in the price a doctor charges to an insurance company for an office visit may translate to a one-dollar increase in an out of pocket coinsurance payment for a patient. Consumers thus have a hard time seeing what the prices are.[909]

This analysis suffers from an important weakness: Although it recognizes that patients and payers do not necessarily value the same factors when they choose a provider and their decisions are not driven by the same incentives, it deliberately neglects these differences. Insurers do care about the marketability of the insurance products they sell. Thus, their primary interest is to sell to employers health insurance which is relatively cheap and which reflects aspects of quality that can be easily recognized by them and their employees.

Illustrating this point seems essential: employers negotiate with the insurers the terms of the package they will offer to their employees although they will not be the recipients of the healthcare services the insurance covers. Since they act as the agents of their employees, they do not necessarily have strong incentives to choose the insurance product that best meets their employees'

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[907] Alphonsus Medical Center – Nampa, Inc. v. St. Luke's Health System, *supra* n. 846, 28.
[908] *Ibid.*, 28-29.
[909] *Ibid*, 29.

needs. The employers will not be the recipients of the health insurance services. Consequently, they do not have high incentives to invest considerable amount of time and money in order to identify the insurance product that meets the highest standards of quality. They might not even have enough information to choose the product that best suits their employees' needs since it is highly unlikely that they will have a complete picture of their employees' health condition.[910] Surely, they aim to offer attractive insurance coverage so that they will attract good, healthy and productive employees. At the same time, though, they want to ensure that they will not become bankrupt by offering an expensive insurance package covering multiple high risks.

Considering the above, the employers would choose an insurance package primarily on the basis of its price and on the basis of aspects of quality that can be easily identified, meaning without high search costs. Geographic proximity is one of these aspects. Arguably, access is one of the quality dimensions that patients do value especially when inpatient care is involved. However, it is not necessarily the quality dimension they value most. Effectiveness, safety, timelessness, acceptability are also components of quality that define patients' choices. To throw light on this issue, again I provide an example: Hospital A is in Nampa and Hospital B is located 30 km away from Nampa. If residents of Nampa choose a hospital only on the basis of geographic proximity, they will choose the Nampa hospital. However, if hospital B offers more innovative, effective and safe primary care services they might be willing to commute and receive hospital services at hospital B. This aspect, however, would change how a geographic market is defined. Indeed, it might lead to the definition of a wider geographic market.

In two recent cases, the Advocate Healthcare case[911] and the Penn State Hershey Medical center case,[912] two US Courts focused on patients' quality criteria in choosing hospitals when they defined the relevant geographic market. The first case concerned the merger between two leading providers of general acute care ('GAC') inpatient hospital services in the northern suburbs of

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[910] A large majority of consumers in the US purchase health care through multiple agents – their employers, the plans or insurers chosen by their employers. This multiplicity of agents is a major source of problems in the market for health care services. Agents often do not have adequate information about the preferences of those they represent or sufficient incentive to serve those interests, Federal Trade Commission and the Department of Justice, *supra* n. 517, 7.
[911] FTC et al. v. Advocate Healthcare et al. No 1:15-cv-11473, 30 June 2016.
[912] FTC et al. v. Penn State Hershey Medical Center et al., No. 1:15-cv-02362-JEJ 9 May 2016.

Chicago, Illinois. In its administrative complaint, the FTC alleged that the relevant geographic market in which to analyze the effects of the merger was the area in northern Cook County and southern Lake County, defined as the 'North Shore Area.'[913] In reaching this conclusion the FTC took into account that North Shore Area residents strongly prefer to obtain GAC inpatient hospital services close to where they live or work.[914] It would be very difficult for a commercial payer to market successfully to patients in the North Shore Area a health plan provider network that excluded all hospitals located within the North Shore Area, the FTC maintained. Following its complaint, the FTC sought to enjoin the two Chicago-area hospital systems from taking steps to consummate their merger pending the completion of a full administrative trial on the merits.[915] Federal District Court Judge Alonso rejected the FTC's request to temporarily block the deal, however, on the basis that the FTC did not correctly define the relevant geographic market.[916] Judge Alonso insisted that there is 'no formula' for determining the geographic market, but that it should be identified in a pragmatic and factual way and should correspond to the commercial realities of the industry.[917] The Court's analysis focused on the methodology employed by the FTC's expert, Steven Tenn. In constructing the relevant geographic market, Tenn included local hospitals but excluded 'destination hospitals' that 'attract patients from throughout the Chicago metropolitan area, at long distances'. Tenn's assumption that the destination hospitals were not substitutes was based on the notion that patients prefer GAC services near their homes, a point on which evidence was equivocal, Judge Alonso declared.[918] In shaping its view, the Court took into account a number of testimonies. Interestingly, one of them stated that some patients typically sought care in their communities but some also travelled *for a higher level of care.* [919] On appeal, the 7th Circuit reversed the District Court's decision.[920] The Appellate Court stressed that the district court's geographic market finding was clearly erroneous.[921] It noted that the lower Court treated Dr. Tenn's analysis as if its logic were circular, but the hypothetical monopolist test instead uses an iterative process, first proposing a

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[913] In the matter of Advocate Health Care Network, a corporation, et al, Complaint, Docket No. 9369, at 4.
[914] *Ibid*, 27.
[915] FTC et al. v. Advocate Healthcare et al, *supra* n. 911, 51.
[916] *Ibid*, at 9-11.
[917] *Ibid*, at 6.
[918] *Ibid*, at 10.
[919] *Ibid.*
[920] US Court of Appeals, 7th Circuit, Case No. 16-2492, FTC and the State of Illinois v. Advocate Healthcare Network et al.
[921] *Ibid*, 3.

region and then using available data to test the likely results of a price increase in that region.[922] Also, the Court said, the evidence was not equivocal on two points central to the commercial reality of hospital competition in that market: most patients prefer to receive hospital care close to home, and insurers cannot market healthcare plans to employers with employees in Chicago's northern suburbs without including at least some of the merging hospitals in their networks.[923] Additionally, the Appellate Court held, the District Court's analysis erred by overlooking the market power created by the remaining patients' preferences.[924] As the Appellate Court alleged, the District Court focused on the patients who leave a proposed market instead of focusing on hospitals' market power over the patients who remain, which means that the hospitals have market power over the insurers who need them to offer commercially viable products to customers who are reluctant to travel further for general acute hospital care.[925] Soon after the Appellate Court reversed the District Court's decision, the merging parties abandoned their merging plans.[926] 'The Advocate CEO said: 'We have believed since day one that this merger would be a big win for consumers and for health care. As a healthcare ministry, we pursued this merger because it aligned with our mission and our values to advance care and lower costs for the patients and communities we are so privileged to serve.'[927]

The second case, the Penn State Hershey Medical center case, involved the merger of the two largest hospital systems in the area around Harrisburg, Pennsylvania. In this case, the FTC contended that the relevant geographic market was the 'Harrisburg Area'.[928] Again, the FTC based its findings on the assumption that geographic markets for GAC services are inherently local because people prefer to be hospitalized near their families and homes.[929] As in the previous case, the FTC sought a preliminary injunction to stop the deal while it conducted a full administrative trial on the merger's merits. Federal District Court Judge Jones rejected the request for an injunction on

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[922] *Ibid.*
[923] *Ibid.*
[924] *Ibid.*
[925] *Ibid.*, 25-26.
[926] https://www.ftc.gov/enforcement/cases-proceedings/141-0231/advocate-health-care-network-advocate-health-hospitals.
[927] P. Minemye, 'NorthShore, Advocate abandon merger after judge's ruling' 8th Mach 2017, available at: http://www.fiercehealthcare.com/healthcare/northshore-advocate-abandon-merger-after-judge-s-ruling.
[928] In the Matter of Penn State Hershey, Medical Center, a corporation et al, Complaint, Docket No. 9368, 19.
[929] *Ibid*, at 21.

the basis that the government had failed to define a proper geographic market.[930] The geographic market can be determined only after a factual inquiry into the commercial realities faced by consumers, the Court held.[931] The Court pointed to two important issues. First, that in 2014, 43.5% of Hershey's patients traveled to Hershey from outside of the FTC's designated Harrisburg Area, and several thousand of Pinnacle's patients reside outside of the Harrisburg Area. This salient fact, the Court said, strongly indicate that the FTC has created a geographic market that controvert the FTC's assertion that GAC services are 'inherently local,' and strongly indicate that the FTC had created a geographic market that is too narrow because it does not appropriately account for where the Hospitals, particularly Hershey, draw their business. Second, the Court pointed to the fact that the FTC presented a starkly narrow view of the number of hospitals patients could turn to if the combined Hospitals raised prices *or let quality suffer*.[932] Judge Jones underscored that there are 19 hospitals within a 65 - minute drive of Harrisburg, many of which are closer to patients who now come to Hershey. Given the realities of living in Central Pennsylvania, which is largely rural and requires driving distances for specific goods or services, Judge Jones found that, undoubtedly, these 19 other hospitals provided a realistic alternative that patients would utilize.[933] The FTC appealed the decision to the Third Circuit, and oral argument was held on July 26, 2016.[934] The FTC emphasized that Judge Jones' analysis of the relevant geographic market was incorrect as a matter of law.[935] The FTC particularly underlined that at no point in its analysis did the Court discuss how hospital prices are established or describe the bargaining dynamics between hospitals and insurance companies.[936] The Third Circuit reversed the District Court's decision.[937] In line with the FTC's analysis, the Appellate Court, took the view that the District Court in defining the relevant geographic market erred in both its formulation and its application of the proper legal test.[938] The Appellate Court argued that, the District Court defined the geographic market by relying almost exclusively on the number of patients that enter the proposed market and therefore relied on an analysis that more

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930 FTC et al. v. Penn State Hershey Medical Center et al, *supra* n. 912, at 11.
931 *Ibid*, at 7.
932*Ibid*, 10.
933 *Ibid.*
934 B. Levitas, B. Marra, Important Decision for Future Hospital Mergers, (2016) (1) *Competition Policy International*, 2,
935 FTC et al, Appellants, v. Penn State Hershey Medical Center et al Appellees, Reply Brief, No 16-2365.
936 *Ibid*, 32.
937 United Court of Appeals for the 3rd Circuit, No. 16-2365, FTC v. Penn State Hershey Medical Center et al Appellees, Opinion of the Court, Circuit Judge Fisher.
938 *Ibid.*, 16.

closely aligns with a discredited economic theory,[939] not the hypothetical monopolist test.[940] As the Appellate Court underlined, the lower Court relied almost exclusively on the fact that Hershey attracts many patients from outside of the Harrisburg area.[941] The Appellate Court noted that in deciding that patients who travel to Hershey would turn to other hospitals outside of Harrisburg if the merger gave rise to higher prices, the District Court did not consider that Hershey is a leading academic medical center that provides highly complex medical services.[942] Hence, Judge Fisher explained, patients who travel to Hershey for these complex services may not necessarily turn to other hospitals in the area.[943] More importantly, the Appellate Court argued that the District Court by focusing on the likely response of patients to a price increase, completely neglected any mention of the likely response of insurers.[944] Consistent with the mandate to determine the relevant geographic market taking into account the commercial realities of the specific industry involved, when we apply the hypothetical monopolist test, the Court held, we must also do so through the lens of the insurers.[945] This is because while patients, in large part, do not feel the impact of price, insurers do.[946] And they are the ones who negotiate directly with the hospitals to determine both reimbursement rates and the hospitals that will be included in the network.[947] On the basis of this legal reasoning, the Appellate Court reversed the District's Court decision.[948] Soon thereafter the merging parties announced their decision to abandon the envisaged transaction.[949] 'We firmly believe the integration of our two health systems would have served the best interests of patients and the

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939 This discredited economic theory is the Elzinga-Hogarty test that was once the preferred method to analyze the relevant geographic market and was employed by many Courts. Judge Fisher emphasized that subsequent empirical research demonstrated that utilizing patient flow data to determine the relevant geographic market resulted in overbroad markets with respect to hospitals. In stressing the weaknesses of this test, Judge Fisher emphasized that Elzinga himself testified before the FTC that this method 'was not an appropriate method to define geographic markets in the hospital sector', *Ibid*, 18.

940 *Ibid.*

941 *Ibid*, 19.

942 *Ibid.*, 20.

943 *Ibid.*

944 *Ibid.*

945 *Ibid*, 23.

946 *Ibid.* 22.

947 *Ibid.*, 23.

948 *Ibid*, 46.

949 "The parties' decision to abandon this transaction preserves hospital competition in the Harrisburg area," said Debbie Feinstein, Director of the Federal Trade Commission's Bureau of Competition. "Had it been consummated, the merger would have likely led to lower quality and higher cost health care, at the expense of Harrisburg residents and their employers, see: https://www.ftc.gov/news-events/press-releases/2016/10/statement-ftcs-bureau-competition-director-debbie-feinstein.

entire central Pennsylvania community'.[950] But given the time and cost associated with continuing litigation, PinnacleHealth and the Milton S. Hershey Medical Center decided to bring their integration efforts to a close', Pinnacle said in its statement.[951]

The inadequacies of a market definition analysis focusing primarily on price concerns and not on quality were also pointed out in the *Tenet* case,[952] where the Court acknowledged that *the lower court underestimated the impact of non- price competition factors, such as quality, when defining the relevant geographic market*. In this case the lower Court rejected the argument that the Cape Girardeau hospitals and the Poplar hospitals were practicable alternatives on the ground the former were more costly.[953] As the Appellate Court explained, such an analysis is rather narrow since it disregards the patients' willingness to travel for better quality of care. Noting that 'the evidence shows that one reason for the significant amount of migration from the Poplar Bluff hospitals to either Sikeston, Cape Girardeau or St. Louis is the actual or perceived difference in quality of care' as well as that 'healthcare decisions are based on factors other than price', it stressed that the fact that some hospitals are higher priced than others does not necessarily mean that they are not competitors.[954]

### 3.2 Quality as an element in the assessment of the anticompetitive effects

A merger can be anticompetitive if it permits the remaining firms in a market to more closely coordinate prices, quality or output or if it permits the merged entity to unilaterally raise prices, reduce output or quality. Close examination of the US hospital merger cases shows that until recently in most cases the FTC and the US Courts mainly focused on whether the challenged merger is likely to encourage one or more hospitals to leverage their market power and ask price increases from the payers.[955] However, this analysis suffers from one important shortcoming: it discounts the fact that even if a merger allowed the merged entity to successfully negotiate price increases, it might also lead to quality improvements. Thus, assessing the likely anticompetitive effects of the merger

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950 http://healthexec.com/topics/policy/pinnacle-penn-state-hershey-merger-called-after-loss-court.
951 *Ibid.*
952 Fed. Trade Comm'n v. Tenet Health Care Corp, *supra* n. 900.
953 *Ibid.*
954 *Ibid.*
955 See Fed. Trade Comm'n v. Butterworth Health Corp., 946 F. Supp. 1285, 1306 (W.D. Mich. 1996), aff'd, No. 96-2440, 1997 WL 420543, (6th Cir. July 8, 1997), In re Evanston N.W. Healthcare Corp., No. 9315, 2007 WL 2286195, at 1, Opinion of the Commission, at 57-59.

necessitates that the Agencies examine how diminished competition might affect the relevant market not only on prices but also on quality.

The *Promedica* case clearly illustrates my point.[956] This antitrust case involved the proposed merger between two of the four hospital systems in Lucas County, Ohio.[957] The parties to the merger were ProMedica, a dominant hospital provider, and St. Luke's, an independent community hospital. The two merged in August 2010, leaving ProMedica with a market share above 50% in one relevant product market (for so-called primary and secondary services) and above 80% in another (for obstetrical services).[958] The FTC challenged the merger. After extensive hearings, an Administrative Law Judge and later the Commission found that the merger would adversely affect competition in violation of article 7 of the Clayton Act.[959] Essentially, in assessing the merger's anticompetitive effects, the judge argued that to the extent a merger leads to high concentration and price increases, there is no need for the FTC or the Courts to additionally assess the merger's impact on quality. As the judge noted, under Section 7 of the Clayton Act, the FTC must show a reasonable probability that the proposed transaction would substantially lessen competition in the future.[960] Typically, the judge said, the government does so by making a prima facie case showing that the acquisition would produce a firm controlling an undue percentage share of the relevant market, and would result in a significant increase in the concentration of firms in that market. Underlying that the FTC had showed that the envisaged merger would lead to price increases, the judge noted that *it is not necessary to also prove that the merger will likely harm the quality of hospital care.*[961] Accordingly, this decision, the judge said, need not, and does not, conclude whether the evidence demonstrates the likelihood of the anti- competitive effect of decreases in quality as well.

Interestingly, until recently, only in two hospital merger cases, the *United States v. Long Island Jewish Medical Center* case,[962] and the *Tenet case*,[963] quality concerns were analysed at this stage of

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956 ProMedica Health Sys., Inc. v. FTC, 749 F.3d 559 (6th Cir. 2014).
957 *Ibid*, 4.
958 *Ibid.*
959 Promedica Health System, 335. No. 3:11-CV-47, 2011 WL 1219281 (N.D. Ohio Mar. 29, 2011).
960 *Ibid*, 176.
961 *Ibid.*
962 United States v. Long Island Jewish Med. Ctr., 983 F. Supp. 121, 149 (E.D.N.Y. 1997).
963 Fed. Trade Comm'n v. Tenet Health Care Corp, *supra* n. 900.

merger assessment. In the first one, a merger between Long Island Jewish Medical Center and North Shore Health Systems was investigated. Assessing the anticompetitive effects of a merger begs for two questions, the District Court said: First, will, with reasonable probability, the merged entity have enough market power to enable it profitably to increase prices above the competitive levels for a substantial period of time? Second, will the merged entity with its increased market share and leverage reduce the quality of care, treatment and medical services rendered? After examining the second question, the Court concluded that the Government failed to seriously contend that the merger would cause such non - quantitative effects. In fact, it found no evidence that the merged entity would result in reduced service or reduced treatment of its patients.[964] On the contrary, it found that the merging parties' main goal was to improve patients' care in a number of different ways: by improving treatment and doctors' training, advancing medical technology and medical research at both merged hospitals.[965]

In the *FTC v. Tenet Health*, a case involving the merger of two hospitals in Poplar Bluff, Missouri, the U.S. Court of Appeals for the Eighth Circuit, reversing the district court on other grounds and permitting the merger to go forward, took the lower court to task for not sufficiently analyzing the defendants' quality claims.[966] The Appellate Court noted that although the defendants' efficiency claims had been properly rejected by the District court, the latter should have considered evidence of enhanced efficiency in the context of the competitive effects of the merger. It found it significant that a hospital that is larger and more efficient after the merger could provide better medical care than the one provided by the two hospitals separately.[967] The merged entity, the Court pointed out, would be able to attract more highly qualified physicians and specialists and to offer integrated delivery and some tertiary care.[968] In view of 'the significant changes experienced by the hospital industry in the recent past and the profound changes experienced by the hospital industry in the near future' the Court of Appeals spelt out that 'a merger deemed anticompetitive today, could be considered procompetitive in the future'.[969]

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964 *Ibid*, at 21.
965 *Ibid*, at 29-30.
966 *Ibid,* at 30-32.
967 *Ibid.*
968 *Ibid.*
969 *Ibid.*

In the most recent hospital merger cases,[970] the US antitrust enforcers, while mainly focused on the hospital merger's impact on prices, also assessed the merger's impact on quality, but in a rather *narrow* way. The analysis the FTC follows in order to understand and examine to what extent a hospital merger might decrease quality is the following: First, it examines what are the quality improvements the merged entities managed to achieve prior the merger. Second, irrespective of the merged entities' quality claims and the specific facts of each case, the FTC concludes that the examined merger is likely to diminish quality because after the merger the merged hospitals will *necessarily* lack the incentives to invest in quality. The FTC's logic is unfolded in the *Advocate Healthcare Network* case.[971] In this case the FTC acknowledged that the merging parties, Advocate and NorthShore, closely track each other's quality and brand recognition. It further acknowledged that the merging parties have substantially invested in improving and expanding their services and facilities to compete against one another. However, without offering any plausible justification, it easily jumped to the conclusion that 'the transaction will dampen the merged firm's incentive to compete on quality of care and service offerings, to the detriment of all patients who use these hospitals, including commercially insured, Medicare, Medicaid, and self-pay patients'.[972]

Nonetheless, this analysis seems inadequate for the following reasons: First, because it seems to recognize that competition is the only factor that drives quality improvements while doctors' skills, efforts and hospital's management also play a significant role. Second, because it takes for granted that absent competition *any hospital* will lack the incentives to invest in high quality services. Thus, the FTC's analysis is based on a general assumption that might not necessarily apply for all hospitals pursuing alignments.

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[970] See In the matter of Advocate Health Care Network, *supra* n. 913, In the Matter of Penn State Hershey, Medical Center, a corporation et al, *supra* n. 928, Complaint, In the matter of Cabell Huntington Hospital Inc., a corporation, et al, Complaint, Docket No. 9366.

[971] In the matter of Advocate Health Care Network, *supra* n. 913, at 47-50. An analogous analysis the FTC undertakes also in the matter of Penn State Hershey, Medical Center, *supra* n. 928, at 56-62, Complaint, in the matter of Cabell Huntington Hospital Inc., a corporation, et al, Complaint, Docket No. 9366, at 77-85.

[972] In the matter of Advocate Health Care Network, a corporation, *supra* n. 913, at 47-50.

## 3.3 Healthcare quality as an efficiency claim

- *Quality as an equity concern*

The first articulation of this defense is a claim that a not for profit hospital's charitable mission, in combination with governance by a board, comprised of community members ensures that the cost efficiencies achieved through the merger will be passed on to the disadvantaged groups of a society. This argument was credited by the District Court in two cases: the *Butterworth*[973] and the *Long Island Jewish*[974] hospital merger cases. Both of them predate the 2010 Merger Guidelines.[975]

The *Butterworth* case is considered to be one of the most revolutionary hospital merger decisions yet issued.[976] In this case, the District Court for the Western District of Michigan, denied the FTC's motion for a preliminary injunction against a proposed merger of two non-profit hospitals in Michigan, even though it concluded that the Government had established a prima facie case for the anticompetitive effects of the merger. The parties agreed that after the merger the hospitals would control a substantial part of the market for primary care. Nonetheless, the hospitals argued that any anticompetitive effects would be unlikely since (a) the hospitals were non- profit; (b) their boards had committed to passing savings on to the local community; (c) the merger would achieve substantial efficiencies, such as capital avoidance. The Court held that considering the hospital's non-profit status and the board's commitment to the community, the cost savings generated by the efficiencies would invariably be passed on to consumers. Comparing the projected cost savings of approximately $100 million to the likelihood of anticompetitive effects, and considering the non - profit status of the hospitals, the Court alleged that the FTC had 'failed to show that this market power is likely to be exercised to the detriment of the true consumers'.[977]

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[973] See Fed. Trade Comm'n v. Butterworth Health Corp., 946 F. Supp. 1285, 1306 (W.D. Mich. 1996), aff'd, No. 96-2440, 1997 WL 420543, (6th Cir. July 8, 1997).
[974] United States v. Long Island Jewish Medical Center, *supra* n. 962.
[975] Other cases that predate the 2010 Merger guidelines are the following: FTC v. Hosp. Bd. of Dirs. of Lee Cty., 38 F.3d 1184 (11th Cir. 1994); United States v. Mercy Health Servs., 902 F. Supp. 968 (N.D. Iowa 1995), vacated as moot, 107 F.3d 632 (8th Cir. 1997); see also California v. Sutter Health Sys., 84 F. Supp. 2d 1057 (N.D. Cal. 2000), aff'd, 217 F.3d 846 (9th Cir. 2000), amended by, 130 F. Supp. 2d 1109 (N.D. Cal. 2001). Nonetheless, since in these cases there was not substantial discussion on the issue of healthcare quality, these cases are not further analyzed in this chapter.
[976] T. Greaney, 'Night Landings on an Aircraft Carrier: Hospital Mergers and Antitrust Law', (1997) 23 *American Journal of Law and Medicine* 191, 212.
[977] Fed. Trade Comm'n v. Butterworth Health *Corp*, *supra* n. 973. It should be noted that a similar equity concern was raised by the hospital merging entities in the *FTC v. University Health,* Inc. 938 F.2d 1206, 1222 (11th Cir. 1991). More specifically, in this case the merging parties alleged that the envisaged merger would ensure one of the merging parties'

A similar approach was adopted by the District Court in the *Long Island Jewish* case, where a merger between two non- profit hospitals again was examined. Although the Court's decision mainly focused on the government's failure to prove the relevant market, the Court did evaluate the efficiencies resulting from the merger. The Court allowed the merger because it determined that the substantial annual operating savings generated by the merger would be passed on to consumers. Considering the non-profit hospital's mission 'to provide high quality health care to economically disadvantaged and elderly members of the community'[978] the Court expressed the belief that the merger would ultimately benefit consumer.[979] The Court's conclusion was bolstered by an agreement completed between the merged hospitals and the Attorney General of the State of New York foreseeing that the merged hospitals would pass on to the community a substantial part of the cost savings achieved through the merger by providing high quality healthcare to economically disadvantaged and elderly members of the community.[980]

The criticism these decisions have accepted is not trivial. The District Court engaged in rate regulation and did so on an evidentiary record devoid of information or projections about future prices, costs or quality changes in the hospital industry.[981] Nonetheless, rate regulation of hospitals even by fully staffed administrative agencies has not proven effective. More than that, the myriad of difficulties inherent in prospective rate setting is compounded by the rapid changes occurring throughout the industry. Second, the commitments themselves provide no assurance that consumers will not be harmed by diminution of non- price aspects of care such as quality, amenities and waiting times.[982]

The FTC has openly disagreed with these decisions' main rationale. The FTC in general does not accept community commitments as a resolution to likely anticompetitive effects from a

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financial stability and therefore its ability to continue its valuable service to the public as a charitable organization. Nonetheless, the Appellate Court taking the view that the defendants did not in fact allege that this entity was, at the present time, in grave danger of failing, rejected this *equity* claim.

978 United States v. Long Island Jewish Medical Center, *supra* n. 962, at 149.

979 *Ibid.*

980 *Ibid.,* at 149.

981 T. Greaney, *supra* n. 976, at 218.

982 *Ibid.*

hospital or any other merger. As it has declared, such commitments do not solve the underlying competitive problem when a hospital merger has changed market circumstances in ways that increase the likelihood that market power will be exercised.[983] To the FTC, community commitments represent a distinctly regulatory approach to what is, at essence, a problem of competition – and that the problem will remain after the commitment has expired.[984]

Obviously, FTC's considerations are critical. Indeed, when these commitments expire, nothing can impede the merged hospitals from increasing their prices and recouping the profits they forewent during the period they were bound by commitments. Furthermore, the implementation of such commitments might be extremely costly since it necessitates active supervision of the merged entities' finances and promised investments to the communities.

- *The healthcare quality improvement claim*

The core point of this efficiency claim is that a proposed hospital merger will improve quality of care at one or both of the involved hospitals. Hospitals have raised a plethora of quality arguments in order to support the view that on balance their proposed transaction will not harm competition. These include sharing of best practices, establishment of centers of excellence, better ability to recruit physicians, implementation of graduate education programmes and development of new service lines.

In theory, the Agencies do examine these arguments. As members of the FTC have revealed 'when substantiated – meaning that the evidence supports the notion that a hospital merger will improve the quality of care at the affected hospitals such claims may well carry the day, overcoming high market concentration levels, hot documents, health plan concerns about a merger and other factors that weigh in favor of enforcement'.[985]

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[983] Federal Trade Commission and the Department of Justice, *supra* n. 517, 29.
[984] *Ibid.*
[985] J. H. Perry & R. H. Cunningham, Effective Defenses of Hospital Mergers in Concentrated Markets, Antitrust Spring, 43, (2013), http://www.weil.com/~/media/files/pdfs/effective-defenses-of-hospital-mergers_by_jeff_perry.pdf.

But under what conditions do the Agencies and the Courts consider these claims *substantiated*? The bottom line is that both the Agencies and the US Courts are skeptical of efficiencies arguments. While efficiencies claims are easy to make, they are much more difficult to prove, particularly efficiencies that meet the requirements of the Guidelines to count in favour of the transaction.[986] This does not imply that the Agencies and the Courts underestimate the value of quality claims. It might imply, though, that efficiency arguments may have more efficacy before the Agencies at the investigational stage than in litigation.[987]

The notion of healthcare quality was substantially examined in the Evanston case of 2004 which raised the challenging question of how to address quality concerns under a merger analysis. The FTC's case challenging Evanston Northwestern Healthcare's ("Evanston") acquisition of Highland Park Hospital ("Highland Park") was the result of the FTC's retrospective review of hospital mergers announced by FTC Commissioner Tim Muris in 2002. Two years after the retrospective review was initiated, and four years after the transaction was closed, the FTC issued a three - count administrative complaint alleging that the Evanston's acquisition of Highland Park violated the antitrust laws.[988] Given that the merger was consummated well before the Commission commenced this case, the interesting thing about this case is that the FTC exceptionally examined both pre - and post-merger evidence.[989]

The primary reason why this case was litigated by FTC, after the merger, was the substantial price increase in the ENH's rates shortly after the transaction.[990] This price increase was acknowledged both by the FTC and the ENH. Nonetheless, while the FTC thought that this price increase was the result of substantial market power, the ENH insisted it was the result of the substantial quality improvements the merger brought.[991]

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[986] J. Miles, *supra* n. 872, at 30.
[987] *Ibid.*
[988] D. Lomax, H. Kim, *supra n* 803, at 5.
[989] In re Evanston N.W. Healthcare Corp., No. 9315, 2007 WL 2286195, at 1, Opinion of the Commission, at. 4.
[990] *Ibid*, 16.
[991] *Ibid.*

In fact, the ENH contended that the identified price increase related more to increased demand for Highland Park's services due to post-merger quality improvements and less with market power.[992] It alleged that the merger yielded significant procompetitive benefits that outweighed any anticompetitive effects. To successfully support this claim, the ENH presented evidence that it spent over $120 million post-merger to make improvements and expand services at Highland Park in 16 research areas, such as oncology, quality assurance, nursing, cardiac surgery, emergency care, electronic medical records, medical staff integration and academic affiliation.[993]

The FTC rejected these arguments fully. However, it did not miss the opportunity to unfold its legal thinking as to the role of quality in merger analysis. The FTC confirmed that improved quality can be a factor into analysis of efficiencies. It held, though, that in this particular case, the claimed quality improvements *were not the result of cost saving efficiencies* produced by the merger.[994] In contrast, they were presented by the merged parties as benefits *distinct from cost - savings* offsetting any adverse competitive effects.[995] The FTC admitted that the relevant case law did not provide clear answers as to whether, such claimed qualitative benefits ought to fit into a competitive analysis.[996] It also admitted that although some Courts had been more receptive to quality of care arguments, those decisions have added little to the discussion on how qualitative benefits should be weighed against the competitive harm resulted from the merger.[997]

Surprisingly, these uncertainties did not impact on FTC's judgement. As the FTC ruled, the *claims of quality improvements must be subject to the same rigorous analysis* that applies to all claims of procompetitive efficiencies so that they represent more than mere speculation and promises.[998] It concluded that the ENH failed to meet its burden of proof to rebut the merger's alleged anticompetitive effects for the following reasons: First, because the Highland Park had plans in place to improve its quality and expand its services without the merger. Highland, for example, planned to develop a cardiac surgery programme in affiliation with Evanston and to enhance its existing 'center

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992 *Ibid.*
993 *Ibid.,* at 48.
994 *Ibid.*, at 82.
995 *Ibid.*
996 *Ibid.*
997 *Ibid.*
998 *Ibid.*

for excellence' in oncology by launching a joint comprehensive oncology programme with an institution other than Evanston without a merger.[999] Second, because before the merger Highland Park had already begun to make a number of improvements that ENH attributed to the merger. For instance, Highland had already undertaken an internal review of its quality assurance and quality improvement programmes to identify ways to improve these programmes.[1000] Third, because the number of changes that ENH made at Highland Park, after the merger, reflected emerging trends in the industry rather than benefits unique to the merger.[1001] The FTC also questioned the credibility of the proofs submitted by the defendants to substantiate their quality claims noting that ENH's quality claims were based to a large extent on the testimony of the administrators' physicians and less on quality indicators.[1002]

The only quality improvement claim the FTC considered merger-specific was *medical integration and affiliation with a teaching hospital.*[1003] However, the FTC easily rejected even this claim, as it found no verifiable evidence that the alleged efficiency was of sufficient magnitude to offset the merger's competitive harm.[1004] The FTC alleged that while studies have apparently indicated that teaching hospitals have lower risk adjusted mortality rates in certain clinical areas, there is no literature showing that merely being owed by a teaching hospital is associated with improved quality of care.[1005]

In its analysis, the FTC recognized that assessing the impact of quality improvements on a hospital's performance is a complex task.[1006] It also highlighted that outcome measures are not always valid measures of quality.[1007] It concluded, though, that these difficulties should not relieve the merged entity from its '*burden to prove extraordinary efficiencies*'.[1008]

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999 *Ibid*., at 49.
1000 *Ibid*, at 50.
1001 *Ibid.*
1002 *Ibid*., 84.
1003 *bid.,* 51.
1004 *Ibid.*
1005 *Ibid.*
1006 *Ibid*, 85.
1007 *Ibid.*
1008 *Ibid*., at 71. The Commission ruled that the acquisition was anticompetitive, but concluded that in this 'highly unusual case," divestiture, would be too costly and potentially risky and instead imposed a conduct remedy. The Commission's

In *FTC v. Rockford/OSF*,[1009] a three-to-two hospital merger in Rockford, Illinois, the merging parties also claimed qualitative efficiencies in order to rebut the FTC's findings as to the anticompetitive effects of the transaction. The defendants declared that the proposed transaction would result in substantial efficiencies in terms of annual recurring savings and capital avoidance savings.[1010] These cost efficiencies would allow the parties to improve and expand medical services. Ultimately, this would increase consumer welfare.[1011] The quality improvements the Rockford community would benefit from the development of 'Centers of Excellence', the creation of a graduate medical programme and the employment of more specialists.[1012]

The Court held that the claimed quality benefits were dependent on cost savings which were speculative. Consequently, the claimed quality benefits were also speculative. Interestingly, though, the Court clarified that even in case they were not considered speculative, they would still be rejected on the basis of different concerns. First, the Court thought that it was highly uncertain whether increased volume of procedures would enhance quality of care in this particular case. Second, it maintained that it was highly unlikely whether defendants would develop any 'Centers of Excellence'. Third, the Court questioned the parties' claim that the merger would facilitate the recruitment of specialists, as it was not convinced there was empirical evidence confirming that merging entities attract more specialists.[1013] The Court acknowledged the parties' good intentions to improve quality. However, it rejected all their quality claims as it found them non- merger specific.[1014]

In the *Adventist Health System/West* case the Commission affirmed the dismissal by an Administrative Law Judge of an FTC complaint against a 1988 hospital merger in the Ukiah, California area on the basis that the FTC stuff had not adequately defined the relevant geographic

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order required Evanston to set up two separate and independent contract negotiation teams to bargain with managed care organizations to revive competition between Evanston's two hospitals and the Highland Park hospital', *Ibid*, 89.

1009 Fed. Trade Comm'n v. OSF Healthcare Sys., 852 F. Supp. 2d 1069, (N.D. Ill. 2012).

1010 *Ibid.*, at 1088.

1011 *Ibid.*

1012 *Ibid.,* at 1093-1094.

1013 *Ibid.*

1014 *Ibid.,* at 1094.

market.[1015] Interestingly, in this case the judge noted that the proposed merger would not in fact create anticompetitive effects and consequently, there was no substantial need to discuss the merger's claimed efficiencies.[1016] Nonetheless the judge grasped the opportunity to underline that the savings realized by operating a single facility in Ukiah may outweigh the potential costs. More specifically, the judge noted that the creation of a hospital that is larger and more efficient than the merging parties would provide better medical care than each of the merging entities could. Citing a study on the relationship between hospital consolidation and healthcare quality, the judge underlined that quality varies from state to state but teaching, larger and more urban hospitals have better quality in general than non - teaching, small and rural hospitals.[1017]

In the *ProMedica* case there was also a limited discussion on the proposed merger's qualitative improvements.[1018] The parties claimed that the addition of St. Luke's would allow ProMedica to consolidate clinical services to optimize ProMedica's and St. Luke's services and facilities to best meet community needs, as well as produce other efficiencies.[1019] Essentially, the merging parties identified the following efficiencies: clinical integration, expansion and improvement of inpatient obstetrical services, potential to reconfigure services at ProMedica, access for St. Luke's to ProMedica's quality program aimed at increasing patient safety; access for St. Luke's to ProMedica's quality-related technologies.[1020] The judge did examine these claims. Nonetheless, he rejected them as non - merger specific. For example, he found that the evidence did not demonstrate that the elimination of services from one hospital and the transfer of those services to another hospital would result in 'significant economies' that benefit consumers.[1021] Underlying also that quality of medical care is not easily defined or measured as well as that St Luke's was a higher quality hospital than ProMedica, the judge concluded that St. Luke's access to ProMedica's quality program did not constitute verifiable evidence that any improvement from such program may offset the competitive harm that was likely to result from the merger.[1022] The judge also noted that St

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[1015] Adventist Health Sys., 117 F.T.C. 224 (1994).
[1016] *Ibid*, 277-278.
[1017] *Ibid.* The Judge cited this study: 'Hospital Characteristics and Quality of Care' (1992) 268(13) JAMA, 1709.
[1018] ProMedica Health System, 335, *supra* n. 959.
[1019] *Ibid.*, 197.
[1020] *Ibid.*
[1021] *Ibid.*, 198.
[1022] *Ibid.*

Luke's would improve its quality related technologies even absent the merger. Therefore, he also found this claim non - merger specific.[1023] On appeal, the merging parties, did not dispute the judge's findings and conclusions on the lack of procompetitive benefits and efficiencies from the merger. As a result, neither the Commission's nor the Appellate Court's decisions further addressed this issue.[1024]

A seminal case where quality efficiencies were also raised by merging entities is the recent *FTC v. St. Luke's Health System* case, the first fully litigated challenge by the FTC to a hospital acquisition by Saltzer, the largest medical practice in Idaho not owned by a hospital system.[1025] In sum, the merging parties maintained that the merger would improve patient care in three ways.[1026] First, the acquisition of Saltzer would enable it to move away from FFS and towards 'risk-based' care.[1027] Under FFS doctors are paid for each procedure they perform.[1028] Therefore, they are incentivized to increase volume rather than to provide cost effective care.[1029] In contrast, on the basis of risk based care the risk is passed on to the doctors who thus have increased incentives to provide better and more effective care.[1030] Moving away from providing FFS care, the defendants claimed, would not only promote higher quality and cost effective care but would also enable Saltzer to increase access to medical care for the significant population of Medicaid and Medicare patients in Canyon County.[1031] Second, the acquisition would allow them to provide integrated and not fragmented care.[1032] Integrated care improves quality since it involves physicians working together as a team.[1033] This would allow doctors to treat the patient as a whole, rather than each doctor treated an individual symptom without coordination.[1034] Third, owning Saltzer would enable the combined entities to make better use of electronic medical records and data analytical tools, which would also

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1023 *Ibid.*, 201.
1024 ProMedica Health System, Opinion of the Commission Docket 9346, 4 (footnote 5).
1025 D. Lomax, H. Kim, *supra* n. 803, at 3.
1026 Alphonsus Medical Center – Nampa, Inc. v. St. Luke's Health System, *supra* n. 907, 17.
1027 *Ibid.*
1028 *Ibid.*
1029 *Ibid.*
1030 *Ibid.*
1031 Alphonsus Medical Center – Nampa, Inc. v. St. Luke's Health System, Ltd, Findings of Fact and Conclusions of Law, No-0560, DkT, No.14-35173, para 46.
1032 Alphonsus Medical Center – Nampa, Inc. v. St. Luke's Health System, *supra* n. 907, at 18.
1033 *Ibid*, 18.
1034 *Ibid.*

lead to better care.[1035] When a patient sees multiple providers for treatment the electronic health record enables those providers not only to communicate with one another in real time, but also to have a complete picture of the medical progress of that patient as they consider their own treatment approach.[1036] As the defendants argued, an electronic health record 'can make health care delivery more efficient, cost effective, and safe because it makes practice guidelines and evidence databases available to health care providers and improves computerized patient record accessibility'.[1037]

The District Court rejected the above claims in their entirety as it concluded that all the alleged benefits of the acquisition were not merger - specific. The District Court found the promised benefits of integration uncertain, amounting only to an 'experimental stage' in the development of healthcare delivery.[1038] It also found that there is no empirical evidence to support the theory that St. Luke's needs a core group of employed primary care physicians beyond the number it had before the acquisition to successfully make the transition to integrated care.[1039] In the same vein, it considered that the electronic record system already under development by St. Luke's would allow independent physicians not employed by St. Luke's to access St. Luke's patient records.[1040] As to the defendants' claim that the merger would allow them to expand their services to the most disadvantaged groups of the population in Nampa, the poor and the uninsured, the Court stated that there was no shortage of access to medical care for Medicaid patients in Nampa.[1041] The Court diplomatically rejected the integration of such claims into its legal assessment noting that 'even if policy considerations could trump the Clayton Act, they would not do so on this record'.[1042]

On appeal to the Ninth Court, St. Luke's asserted that the District Court erroneously decided that the parties could have raised the quality of healthcare without an affiliation. Appellants dismissed the FTC's examples of where benefits of integrated care were achieved without employment of physicians, arguing that such other arrangements did not answer the question

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[1035] *Ibid.*
[1036] Alphonsus Medical Center – Nampa, Inc. v. St. Luke's Health System, Ltd, Findings of Fact and Conclusions of Law, *supra* n. 1031, para 187.
[1037] *Ibid.*, at 190.
[1038] Alphonsus Medical Center – Nampa, Inc. v. St. Luke's Health System, Ltd., *supra* n. 846, at 18.
[1039] *Ibid.*
[1040] *Ibid.* 19.
[1041] *Ibid.*, 58 -59.
[1042] *Ibid.*, at 59.

relevant to the St. Luke's case: the facts in this case did not support the notion that these parties could achieve these benefits in the same timeframe by some other means. They highlighted that previous attempts at a looser affiliation by Saltzer physicians had failed, and explained that 'only this transaction which allowed St Luke's and Saltzer to share technological infrastructure, sophisticated analytics, all patient information, resources for community research, and both upside and downside accountability for patient outcomes could produce those benefits'.

The FTC agreed with the District Court's legal reasoning fully. More importantly, it exposed its legal thinking as to the relationship between consolidation and the attainment of qualitative efficiencies. The FTC made clear that the Clayton Act contains no healthcare exception. Citing *National Society of Professional Engineers v. United States* case,[1043] it explained that Congress declined to provide 'an exemption' from the antitrust laws 'for specific industries' because it rejected the notion that 'monopolistic arrangements will better promote trade and commerce than competition.'[1044] The FTC pointed out that the antitrust laws do not apply differently depending on the special characteristics of a particular industry.[1045] On the opposite, the FTC declared, they apply to healthcare services 'in the same manner they apply to all other sectors of the economy'.[1046] For this reason, it explained, the antitrust enforcers have not accepted the claim that a presumptively unlawful acquisition can be justified because it allows greater efficiency of operation.[1047] Instead, the only relevant question for the US antitrust enforcers is whether the effect of an acquisition may substantially lessen competition.[1048] Confirming the District Court's analysis, it said that the answer would be clearly yes.[1049]

More than that, the FTC grasped the chance to express its view on the unresolved and complex issue of the legal standard for an efficiency defense. Essentially, the FTC characterized this case as a poor candidate for validating an efficiency defense under the Clayton Act.[1050] The FTC

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[1043] National Society of Professional Engineers v. United States, *supra* n. 620.
[1044] Alphonsus Medical Center – Nampa, Inc. v. St. Luke's Health System, Ltd., *supra* n. 846, at 20.
[1045] *Ibid.*
[1046] *Ibid.*
[1047] *Ibid.*, at 47.
[1048] *Ibid.,* at 21.
[1049] *Ibid.*
[1050] *Ibid.* at 47.

underscored that such a defense could be successful only to the extent St. Luke's overcame the District Court's conclusive finding that the acquisition would harm competition substantially.[1051] In any event, it clarified, even if the Court considered St. Luke's efficiency defense, it should examine it under the two part analysis test the DC Circuit used in the Heinz case.[1052] The FTC acknowledged that especially for cases where there are high concentration levels, the Heinz test is extremely demanding.[1053] As it asserted, a strong presumption of anticompetitive harm demands a precise proof of a very high degree of efficiency.[1054] It also demands that the alleged efficiencies are the *unique* consequence of the merger.[1055]

The Appellate Court affirmed the lower Court's findings and analysis. The Appellate Court underlined that since the Clayton Act focuses on competition and the claimed efficiencies must show that the prediction of anticompetitive effects from the prima facie case is inaccurate, it is not enough to show that the merger would allow St. Luke's to better serve its patients.[1056] Although the District court believed that the merger would eventually improve the delivery of healthcare in the Nampa market, the judge did not find that the merger would increase competition or decrease prices. The Appellate Court agreed with the District Court that the claimed efficiencies were not

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[1051] *Ibid.*

[1052] FTC v. H.J. Heinz Co., 246 F.3d 708, 715 (D.C. Cir. 2001). This case involved the merger between two major entities in the baby food market, Heinz and Beech Nut. The leading company in this market was Gerber. The merging entities supported the view that the envisaged merger would allow them to achieve both cost saving and qualitative efficiencies, namely the creation of a higher quality product as a result of recipe consolidation. The District Court took into account the merging parties' efficiency claims. The Appellate Court however, rejected the defendants' efficiency claims on the basis that they were not merger specific. This case is the first case after the introduction of the 1992 US merger guidelines which provided some analysis with regards to the efficiency defense (see R.D. Blair, C. Piette Durrance, D. D. Sokol, 'Hospital Mergers and Economic Efficiency' (2016) *Washington Law Review*, 57). In this case the Court said that high concentration levels create a prima facie case that a merger is anticompetitive. The Court also said that the majority of Courts have recognized efficiencies as a means to rebut the Government's prima facie case that the merger will lead to restricted output or increased prices. Nevertheless, the Court said, the high market concentration levels present in this case required in rebuttal proof of extraordinary efficiencies which the defendants failed to supply, FTC v. H.J. Heinz Co., 246 F.3d 708, 715 (D.C. Cir. 2001) 18-19. This burden-shifting approach was formulated and discussed in the *United States v. Baker Hughes Inc.* case where the Court clarified that by showing that a transaction will lead to undue concentration in the market for a particular product in a particular geographic area the government establishes a presumption that the transaction will substantially lessen competition. If, the Court continued, the defendant successfully rebuts the presumption, the burden of producing additional evidence of anticompetitive effect shifts to the government, and merges with the ultimate burden of persuasion, which remains with the government at all times (United States v. Baker Hughes Inc. 908 F.2d 981 (D.C. Cir. 1990).

[1053] Alphonsus Medical Center – Nampa, Inc. v. St. Luke's Health System, Ltd., *supra* n. 846., at 48.

[1054] *Ibid.*

[1055] *Ibid.*

[1056] Alphonsus Medical Center – Nampa, Inc. v. St. Luke's Health System, Ltd, United State Court of Appeals, Ninth Circuit, Opinion, No. 14-35173, 28.

merger specific.[1057] It clarified though that even if they were, the defense would nonetheless fail.[1058] To the Court's view, providing better care after the merger is a laudable goal, but the Clayton Act does not excuse mergers that lessen competition or create monopolies simply because the merged entity can improve its operations.[1059] Having said that, the Appellate Court confirmed the District Court's ruling.

In the *Penn State Hershey Medical Center*[1060] case, where the merger of the two largest health systems in the Harrisburg, Pennsylvania area was examined, the defendants also claimed that the transaction would lead to quality improvements. The defendants held that if the merger was consummated the merging entities would transfer patients suffering from less severe illnesses from Hershey to Pinnacle, which had the capacity to treat them.[1061] They also held that this would allow Hershey to avoid constructing a new inpatient bed tower to alleviate its capacity issues.[1062] The FTC took the view that Hershey could alleviate its capacity constraints in a timely manner without the merger. Additionally, it found that the defendants' alleged efficiency plans would result in competitive harm. Defendants' plans would force patients to go to a different hospital than the one they originally chose and as a result they would reduce capacity, the agency alleged.[1063] Illustrating that '*No court ever has found, without being reversed, that efficiencies rescue an otherwise illegal transaction*' the FTC concluded that defendants' efficiency claims were overstated, speculative, unverifiable, not merger-specific, or result from an anticompetitive reduction in output, quality, or services, and were largely non-cognizable.[1064]

Some additional interesting points should be made about this case. As previously noted, the District Court denied the FTC's request for a preliminary injunction mainly because it determined that the Government did not show that the four-county area around Harrisburg was a proper antitrust geographic market. The Court, however, took also the chance to shortly examine the

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[1057] *Ibid.*, 29.
[1058] *Ibid.*
[1059] *Ibid.*
[1060] In the Matter of Penn State Hershey, Medical Center, *supra* n. 928.
[1061] *Ibid.*, at 72.
[1062] *Ibid.*, at 73.
[1063] *Ibid.*, at 74.
[1064] *Ibid.*, at 72.

defendants' alleged quality claims. Diverting from the FTC's efficiency analysis, the Court noted that the efficiencies evidence overwhelmingly indicated that procompetitive advantages would be generated for the hospitals' consumers such that the equities should favour the denial of injunctive relief.[1065] The District Court stated that its decision was informed by 'a growing need' for hospitals 'to adapt to an evolving landscape of health care that includes … the institution of the Affordable Care Act.'[1066] Our determination reflects the healthcare world as it is, and not as the FTC wishes it to be, the Court said. The Court further claimed that it finds it no small irony that the same federal government under which the FTC operates has created a climate that virtually compels institutions to seek alliances such as merging entities. In clarifying its conclusions, the Court held that it is better for the people they treat that such hospitals unite and survive rather than remain divided and wither.[1067] In its appeal the FTC rejected the District's Court legal analysis in its entirety. In line with the Appellate's Court approach in the St. Luke's case, the FTC once again underlined that '*the Clayton Act contains no healthcare exception'* and that the antitrust laws '*apply to hospitals in the same manner that they apply to all other sectors of the economy*.'[1068] On Appeal, the Appellate Court fully aligned with the FTC's views. Quite surprisingly, the Appellate Court said: 'we have never formally adopted the efficiencies defense.[1069] Neither has the Supreme Court'.[1070] Noting however that some Courts of Appeal have taken the view that the efficiencies defense is cognizable the Appellate Court grasped the opportunity to state that only efficiencies that are verifiable, merger specific, can be shown in real terms, offset the anticompetitive concerns in highly concentrated markets [1071] and do not arise from an anticompetitive reduction of output or service.[1072] can be actually considered in the context of a merger analysis.

In the Cabell Huntington Hospital Case,[1073] respondents also claimed that the proposed deal would lead to quality enhancement opportunities. Nonetheless, again, the FTC reached the conclusion that the proposed efficiencies were unsubstantiated and lacked merger-specificity. In this

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[1065] FTC et al. v. Penn State Hershey Medical Center et al, *supra* n. 912, at 15.
[1066] *Ibid.*, at 25.
[1067] *Ibid.*
[1068] FTC et al, Appellants, v. Penn State Hershey Medical Center et al Appellees, Reply Brief, *supra* n. 935, at 57.
[1069] United Court of Appeals for the 3rd Circuit, No. 16-2365, *supra* n. 937, at 33.
[1070] *Ibid.*
[1071] *Ibid*, 35.
[1072] *Ibid.*, 36.
[1073] In the matter of Cabell Huntington Hospital Inc., a corporation, et al, Complaint, Docket No. 9366.

case, the merging parties asserted that the merged entity would realize volume-related improvements in the quality of care through the consolidation of certain clinical service lines.[1074] The FTC found respondents' analysis on this issue unconvincing as it did not account for the fact that the procedures with demonstrated volume-outcome relationships were already largely consolidated at one or the other hospital, and that certain key services might not be consolidated. Respondents also projected quality improvements from 'standardization' across the two facilities and the building of a 'bridge' between the two hospitals' electronic health records systems to render them interoperable. Neither of these initiatives had been substantiated, and neither were merger-specific, the FTC held.[1075]

## 4. Incorporating healthcare quality claims into a merger analysis: A mission *impossible*?

The previous sections investigated to what extent healthcare quality concerns and justifications are examined by the Agencies when they analyze hospital merger cases and under what *techniques*. The current section sees if on the basis of the previous analysis clear answers to the following questions can be provided: what are the dimensions of healthcare quality that the US Courts and the FTC consider in merger analysis? Do the merging parties have the *adequate* techniques to raise *quality claims?* What are the difficulties the use of these techniques entails?

### 4.1 Insufficient guidance in what healthcare quality actually means

The descriptive analysis of the relevant case law in hospital merger cases demonstrates that the Courts and the FTC have not provided sufficient weight to quality arguments. Quality concerns have not clearly become a substantial part of the antitrust enforcers' analysis in the definition of the relevant product and geographic market and in the analysis of the anti-competitive effects of a hospital merger. The Guidelines also do not shed light on how quality is assessed in the context of a merger analysis as they mainly focus on a hospital merger's impact on prices. Consequently, there is no clear articulation as to what sort of quality claims the US Courts and the FTC do value. This does not imply that the Agencies and the Courts neglect these arguments. Officially, members of the FTC

[1074] *Ibid,* at 106.
[1075] *Ibid.*

declare that when substantiated such claims may well carry the day, overcoming high market concentration levels.[1076] Therefore, in theory quality claims in the antitrust enforcers' merger analysis are welcome. In practice, though, they are discounted. *Why*?

First and foremost, the US antitrust enforcers see quality claims with considerable skepticism.[1077] In a recent interview, Debbie Feinstein, former Director of the FTC's Bureau of Competition, said: 'Often, when hospitals and doctors join forces, their goal is not just to control costs or improve care, but to 'get increased leverage' in negotiations with health insurance companies and employers. They say they need better rates so that they will have more money to invest in their facilities. *When you strip that down, it's basically just saying, 'We want a price increase.'* Even if the price increase is motivated by a desire to invest more in the business, that's problematic. That incentive to invest may not be there if you don't have competition as a spur to innovation - if you're not worried about losing business to the hospital down the street'.[1078]

FTC's skepticism is not unjustified. Indeed, to a certain extent, hospitals may want to merge so as to strengthen their negotiation power against insurers. However, they might also want to merge to reduce their costs and improve quality. The FTC and the US Courts by not explaining or suggesting what are the dimensions of healthcare quality they do consider important, make the business of hospitals that do want to merge to improve quality unnecessarily costly and complicated. The FTC acknowledges that asking which measures of quality are most relevant is a very important question. However, instead of providing guidance or introducing a clear framework under which quality of care could be seriously considered, it exclusively relies on the merging parties' analysis to determine which metrics to consider, and what the merger's likely impact on those measures will be.[1079]

Ultimately, the merging parties are left only with one option: to bring quality into merger analysis by relying on the incomplete guidance of the Guidelines. Arguably, this approach suffers

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[1076] J. H. Perry, Richard H. Cunningham, *supra* n. 985, 43.
[1077] D. Lomax, H. Kim *supra* n. 803, 7.
[1078] R. Pear, F.T.C. *Wary of Mergers by Hospitals*, N.Y.Times, Sep 17, 2014 available at: http://www.nytimes.com/2014/09/18/business/ftc-wary-of-mergers-by-hospitals-.html?.
[1079] J. H. Perry, R.H. Cunningham, *supra* n. 985, at 44.

from important shortcomings. First, it does not allow merging parties to bring quality claims that are in line with health policy goals. For example, if the FTC had issued guidelines explaining how healthcare quality is perceived by it and what are the dimensions it values most on the basis of the main objectives of the ACA, such as the pursuit of coordination between healthcare providers, the merging parties would have incentives to complete transactions which contribute to the completion of such objectives. They would know that their merger would be approved only to the extent their quality claims were in line with the objectives of the US healthcare system. This would force them to proceed with mergers that facilitate the completion of these objectives. Second, because the merging parties are not aware of what are the quality dimensions the antitrust enforcers do value, they have the incentives to cherry-pick the quality measures they can more easily prove rather than the ones that are the most important from health policy perspective. Updating the Guidelines to include a more robust discussion of quality efficiencies including the types of quality dimensions the antitrust enforcers consider the most important from a health policy perspective would incentivize the merging parties to focus on quality improvements that actually matter.

### 4.2 Is there a clear analytical framework for incorporating quality claims?

As previously discussed, quality claims can be raised in the context of a merger analysis. The Guidelines are straightforward at this point. However, the question under what analytical framework remains unanswered. Unsurprisingly, the FTC has admitted that it would have serious difficulties in examining qualitative efficiency claims. In a formal speech, Debbie Feinstein made clear that although the FTC will consider merger-specific efficiencies to balance concerns of market power, the agency *is increasingly taking a more stringent approach to how these defenses outweigh competitive harm*. As noted by Feinstein, while the Agencies expect and encourage parties to provide … concrete evidence to support quality claims, there is an outstanding question regarding the extent to which quality improvement claims can be demonstrated with the specificity required to satisfy the FTC's efficiencies standard as they weigh the competitive implications of a transaction.[1080]

[1080] D. L. Feinstein, Director, Bureau of Competition, Fed. Trade Comm'n, Remarks at the Fifth National Accountable Care Organization Summit, *Antitrust Enforcement in Health Care: Proscription, Not Prescription* (June 19, 2014), https://www.ftc.gov/system/files/documents/public_statements/409481/140619_aco_speech.pdf.

Thus, the FTC recognizes the complexities involved in assessing quality claims. More than that, it acknowledges that it does not have the necessary tools to assess qualitative efficiencies and weigh them against harm to competition. As the FTC officials have stated: [I]t is more difficult to determine how best to balance a possible price increase on the one hand and a quality improvement on the other hand. '*To date, however, that is not something we have found necessary to do.* In the handful of transactions we have challenged, we have determined that the quality improvements *were speculative, not substantiated and/or the merger was not necessary to achieve them*'.[1081] This should not come as a surprise. Most competition authorities face analogous challenges. What should come as a surprise, though, is that the FTC does not consider it necessary to find the appropriate mechanism for undertaking such a balancing test, on the basis that most alleged efficiency claims can be easily rejected as non-merger specific or speculative.

Undoubtedly, this policy creates multiple risks. One risk is that it might end up being over-inclusive in case it blocked mergers that would result in efficiencies, but the efficiencies would be too difficult to predict or to prove.[1082] Additionally, the lack of an adequate framework under which quality claims can be actually assessed along with the high costs the articulation of such claims entails may disincentivize the merging parties from bringing quality to the heart of the merger assessment.

The FTC's and the US Courts' approach to efficiencies also demonstrates a problematic asymmetry in merger analysis. Under the FTC's current roadmap for efficiencies, the FTC may prove antitrust harm via predication and presumption while defendants are required to decisively prove countervailing procompetitive efficiencies.[1083] As the above analyzed case law reveals, while the FTC has to predict harm to competition in order to meet its burden of proof, the merging parties have to provide proof of *extraordinary* efficiencies, or *unique* efficiencies. In sum, while the FTC can prove its harm to competition by relying on 'hot business documents'[1084] showing that the

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[1081] *Ibid.,* at 11.
[1082] American Bar Association, *supra* n. 804, 93.
[1083] D. Balto, *Antitrust Enforcement in Reverse: Getting Efficiencies Backwards*, 11 September 2014, http://truthonthemarket.com/2014/09/11/antitrust-enforcement-in-reverse-getting-efficiencies-backwards/.
[1084] According to the FTC a document is 'hot' if it predicts that the merger will produce an adverse price or non-price effect on competition. The most obvious situation involves acquiring party documents that predict a price effect

merged entity's main concern is to increase its bargaining power against insurers, the defendants have to submit proofs of extraordinary efficiencies without (a) being aware of what 'extraordinary efficiency' actually means, or (b) having a framework under which they can balance such efficiencies against harm to competition.

Such asymmetric burdens of proof greatly favour the FTC and eliminate a court's ability to analyze the procompetitive nature of efficiencies against the supposed antitrust claim.[1085] This asymmetry has been identified by the FTC Commissioner Wright:

'Merger analysis is by its nature a predictive enterprise. Thinking rigorously about probabilistic assessment of competitive harms is an appropriate approach from an economic perspective. However, there is some reason for concern that the approach applied to efficiencies is deterministic in practice. In other words, there is a potentially dangerous asymmetry from a consumer welfare perspective of an approach that embraces probabilistic prediction, estimation, presumption, and simulation of anticompetitive effects on the one hand but requires efficiencies to be *proven* on the other'.[1086]

### 4.3 What does the FTC's decision-making policy reveal?

FTC's antitrust enforcement policy in healthcare focuses mainly on cost effectiveness and the maintenance of vigorous price competition between hospitals. This, however, should not be surprising. Indeed, FTC's policy is completely in line with the rationale behind the structure of healthcare financing and delivery in the hospital sector, which as discussed in the first section of this chapter, focuses more on cost effectiveness and less on quality of care. Therefore, when the FTC assesses the anticompetitive effects of a hospital merger it mainly seeks to answer the following questions: How will the transaction impact on the prices hospitals charge? How will the transaction impact on the bargaining power of hospitals? Price concerns also dominate the antitrust enforcers'

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stemming from the merger, Federal Trade Commission, Horizontal Merger Investigation Data Fiscal Years 1996-2011, available at: https://www.ftc.gov/reports/horizontal-merger-investigation-data-fiscal-years-1996-2011.

[1085] D. Balto, *supra n.*1083.

[1086] G. Manne, *Getting efficiencies right at the FTC: Commissioner Wright dissents in Ardagh/Saint-Gobain merger* (15 April 2014), http://truthonthemarket.com/2014/04/15/getting-efficiencies-right-at-the-ftc-commissioner-wright-dissents-in-ardaghsaint-gobain-merger/.

definition of the relevant product and geographic market. To a certain extent, the focus is understandable, since it is the most obvious impact and the one which can be more easily quantified and measured. But it should not be the only focus and, arguably, is not the most important one.[1087] For many providers, contract rates that can be the subject of exercised market power are likely to cover only a minority of services. For example, nationwide, the average hospital derives only about 36% of its revenues for healthcare services from commercial health plans.[1088] Thus while contracted rates to commercial health plans constitute an important component of overall health expenditures, the provision of high quality hospital services should also become a serious component of hospital merger analysis. This policy might not only disincentivize merging parties from integrating quality claims into their efficiency defense. More than that, it might disincentivize health policy researchers from developing research focusing not only on the potential impact of mergers on prices but also on quality. A relevant question that would definitely necessitate further research is the extent to which the types of efficiencies that providers seek to obtain require full integration through an acquisition or merger or whether they can be largely accomplished through a contractual arrangement.[1089] Arguably, this was one of the decisive factors in the St. Luke's case. Undoubtedly, there are some efficiencies that require full integration, some that could be achieved through contract relatively easily, and others that might be achievable through contract, but not as easily and with much more time and expense.[1090] Further research on how to understand to what extent various efficiencies fall along this spectrum would help the antitrust enforcers to better assess whether the efficiencies claims are 'merger specific' or whether they confirm the motto that 'talk is cheap'.

The FTC and the Courts, by narrowing their analysis to the price concerns of a hospital merger, lose the opportunity to gradually develop an analytical framework under which the quality aspects of a hospital merger are examined effectively. The antitrust enforcers do not seem to recognize the inadequacies their analysis entails. This is because they remain faithful to the assumption that more competition between hospitals will necessarily lead to improved quality. Their analysis is driven by the belief that the healthcare sector is not a *special* sector. Their attachment to

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[1087] R. Leibenluft, 'Antitrust Provider collaborations: Where we've been and what should be done now', (2015) (40) *Journal of Health Politics, Policy and the Law*, 847, 859.
[1088] *Ibid.*
[1089] *Ibid.*
[1090] *Ibid.*

this belief can be easily explained: Both the Courts and the antitrust enforcers interpret the antitrust laws when applied to healthcare with the knowledge that they are bound by precedent and that their actions may create precedent in cases involving other industries.[1091] Moreover, the application of antitrust law to any particular set of circumstances is often a difficult task, and is particularly so in healthcare given the overlay of regulation, agency relationships, asymmetrical information, government payment and other factors that result in various market failures.[1092]

On the premise of this belief, antitrust enforcers think that the existing framework is adequate. In fact, they do not seem to consider that their narrow focus on evaluating quality claims does not allow them to integrate into their analysis the insight of health policy research indicating that under certain conditions hospital consolidation and not competition improves health outcomes. They also do not seem to consider that their narrow focus may come in contrast with the pursuit of desirable health policy goals, such as more coordinated or integrated care. 'I don't think there's a contradiction between the goals of health care reform and the goals of antitrust,' Feinstein said in her interview, as she surveyed the wave of mergers, consolidations and affiliations sweeping through the health care industry.[1093]

Again, in theory, under merger regulation hospital mergers improving quality through clinical integration can be approved. One would wonder, though, how the defendants would prove quality claims without having an adequate framework seriously considering them. One would also wonder how health policy objectives could be considered under a hospital merger analysis since the District Court has openly expressed in the St Luke's case that such objectives *should not* be considered under a merger analysis. In the recent *Penn State Hershey Medical Center* case, the FTC also adopted a similar approach as it openly disagreed with the District Court's approach that the perceived needs of the healthcare system should take precedence over antitrust considerations. Whether vigorous antitrust and the pursuit of health policy objectives necessarily and always coincide remains a question unsolved especially taking into account recent state regulations, such as

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[1091] *Ibid.*, at 850.
[1092] *Ibid.*
[1093] R. Pear, *supra* n. 1078.

the bill exempting actions of the West Virginia Health Care Authority and of 'hospitals and health care providers under the authority's jurisdiction' from state and federal antitrust law.[1094]

## 5. Conclusion

The present chapter, by analyzing the applicable framework for hospital mergers in the United States and by examining the seminal US hospital merger cases where quality claims were addressed has asked: How do the US antitrust enforcers and the Courts perceive quality of care? What are the quality dimensions they actually value? It highlights that the Agencies and the Courts, by focusing on the price aspects of hospital mergers and ignoring the core doctrine that in healthcare under special conditions, consolidation, coordination and integration lead to improved quality of care, discourage the development of health policy research focusing on mergers' impact on quality. Due to their narrow approach, the Agencies and the Courts may also disincentivize merging parties from bringing quality of care to the heart of the merger analysis. Most importantly, they might ban mergers that may in fact contribute to the US health policy objectives of more integrated and coordinated care. This chapter suggests that the FTC should issue guidelines explaining the quality dimensions it values most on the basis of the main objectives of the US healthcare system. It should further explain how these dimensions can be balanced against harm to competition.

[1094] L. Schenker, 'West Virginia bill would shield merging hospitals from antitrust laws' http://www.modernhealthcare.com/article/20160218/NEWS/160219892.

## V. Integrating healthcare quality concerns under an EU Competition Law analysis: A *mission possible*?

Chapters III and IV focused on how healthcare quality is perceived and how it is taken into account by the US antitrust enforcers and the Courts in the context of professional restrictions and hospital merger cases. These chapters revealed that the US antitrust enforcers and the Courts do assess quality claims in the context of their competition assessment. However, those actors define, assess and perceive quality as in any other industries. To them, quality in healthcare is not a *special* concept. In fact, in applying a narrow consumer welfare approach[1095] they insist that choice and competition will ensure higher quality. More specifically, Chapter III found that especially when professional restrictions are at issue, the US antitrust enforcers and the Courts mainly take the view that consumer choice is always the best judge of healthcare quality and as a result competition in healthcare markets should be left to flourish without any restrictions or interventions by medical associations. It also highlighted that the policy option of defining quality strictly as choice and competition (a) underestimates the fact that healthcare markets are pervaded by numerous market failures, such as information asymmetries and negative externalities (b) disregards the fact that health outcomes also depend on non-economic values, such as the notions of acceptability and trust, essential features of professionalism (c) also disregards the fact that the notion of healthcare quality can be protected *as a whole* only to the extent it is evaluated at all levels of a healthcare system and only to the extent all functions of a health system commit to the quality goals the health system *as a whole* pursues.

Undoubtedly, the analysis in Chapter IV led to similar conclusions. This Chapter highlighted that FTC's antitrust enforcement in healthcare focuses mainly on cost effectiveness and the maintenance of price competition between hospitals. In applying competition law in hospital

[1095] This notion of consumer welfare approach has not been clearly defined in EU official documents. Generally, under what we will call a *narrow consumer welfare approach*, agreements between undertakings leading to an increase in price, a limitation in output (quantity, quality or range) or a limitation of innovation, are prohibited because they are considered detrimental to consumer welfare. Other interests are assumed to lie outside its scope, see R. Claassen, A. Gerbrandy, 'Rethinking European Competition Law: From a Consumer Welfare to a Capability Approach', (2016) 12(1) *Utrecht Law Review*, 1.

markets, as in medical markets, the US antitrust enforcers remain faithful to the assumption that vigorous competition between hospitals will necessarily lead to improved quality. This policy, however, completely disregards the fact that, as health policy research reveals, under certain conditions *less and not more competition* may improve quality in hospital care. Additionally, this one - dimensional policy of the US antitrust enforcers may de-incentivize health policy researchers from developing research focusing not only on the potential impact of mergers on prices but also on quality. More than that, by re-telling the story that antitrust laws should apply to hospitals in the same manner that they apply to all sectors of the economy, the US antitrust enforcers run the risk of blocking mergers that may actually contribute to the US health policy objectives of more integrated and coordinated care. Hence, under their narrow consumer welfare approach, any health policy goals that may contradict with the dogma that competition and choice ensure quality may not enter into the equation.

In light of the drawbacks the US market approach entails, Competition Authorities may choose to *widen the notion of consumer welfare* when they apply competition law in healthcare so that the multiple dimensions and aspects of healthcare quality, such as safety, acceptability and professionalism are considered in their competition assessment *as a whole*.[1096] They might also widen the notion of consumer welfare in health care to ensure that their competition analysis does not harm or disregard the health policy goals of their systems. Considering that equity is one of the essential objectives of EU healthcare systems, this chapter claims that since the notions of choice and competition may in specific cases contradict with the social objectives of EU healthcare systems, such as equity, Competition Authorities in Europe may choose to extend the notion of consumer welfare in healthcare so that it also includes these non-economic goals. In elaborating on this claim, this chapter first sees what the main objectives of EU healthcare systems are. Focusing on the

[1096] In his inaugural speech as professor of European Law at the University of Leiden, Ottervanger made a similar proposal. Ottervanger calls for a broader interpretation of the concept of consumer welfare in competition law. Ottervanger argues for a *wider definition of consumer welfare* that would embrace the broad concept of consumer protection, including, for example, environmental protection. He points out that the establishment of a single European internal market is simply a means of furthering consumer welfare and general social and economic prosperity, but is not a goal in and of itself. Similarly, competition is a method in order to achieve this internal market, and not a standalone goal. Ottervanger questions whether it would be possible to create room for the concept of the citizen in competition law, and to use a broader definition of consumer welfare to encompass citizen welfare. See P. Kalbfleisch, 'Aiming for Alliance: Competition Law and Consumer Welfare', (2011) 2(2) *Journal of European Competition Law & Practice,* 108, 111-113.

notion of equity and access, it explores how EU Member States conceive these notions by reviewing some international and European human right instruments where these objectives are analyzed. Aiming to further explain how the notions of choice and competition may conflict with some essential objectives of EU healthcare systems, such as equity, acceptability, safety, in its second part, this chapter analyzes the main aspects of the procompetitive regulations that introduced the choice and competition model in the UK since the early 1990s and provides specific examples where conflicts between the objectives of equity and choice, choice and acceptability, or safety and choice actually arise. The main goal of this section is to demonstrate that in light of these potential conflicts healthcare providers or medical professionals acting either as gatekeepers or purchasers of NHS services may engage in anticompetitive behaviour in order to protect essential non-economic facets of healthcare quality that are also the main objectives of their health systems, such as continuity, access, equity, safety.

*Should these values be taken into account by EU competition law? Should Competition Authorities in Europe be allowed to expand the notion of consumer welfare so that they can actually balance conflicting components of healthcare quality, such as equity v. choice and competition? And, if yes, under what legal techniques*? In answering these questions this chapter focuses on article 101 TFEU cases where public policy goals were in fact examined and assessed by the European Commission and the Courts. In exploring whether public policy goals, such as equity, should be considered in a competition assessment, this chapter also replies to the antitrust scholarship's claim that the pursuit of social policy goals and objectives, such as equity, is not and should not become part of the antitrust agenda. This chapter draws conclusions on the basis of the UK healthcare system for mainly two reasons: First, because the UK healthcare system has a long history of providing healthcare through the choice and competition model, and second, because the NHS in the UK attaches importance to equality and distributive ethics and therefore it can be a representative example of healthcare systems in Europe pursuing equity.

## 1. Healthcare Systems in Europe: What are their common values and objectives?

Healthcare systems are a central part of Europe's high levels of social protection and make a major contribution to social cohesion and social justice.[1097] As highlighted by the Council's statement on the common values and principles of the EU healthcare systems (a document which builds on discussions that have taken place in the Council and with the Commission as part of the Open Method of Coordination, and the High Level Process of Reflection on Patient Mobility and healthcare development in the field of health, from hereon 'the Statement'),[1098] there are specific common values and principles that are shared across the European Union about how health systems should respond to the needs of the populations and the patients they serve.[1099]

According to the Statement, the common values and principles between EU healthcare systems are universality, access to good quality care, equity, and solidarity.[1100] *Universality* means that no-one is barred access to health care;[1101] *solidarity* is closely linked to the financial arrangement of the national health systems and the need to ensure accessibility to all;[1102] *equity* relates to equal access according to need, regardless of ethnicity, gender, age, social status or ability to pay.[1103] EU health systems also aim to reduce the gap in health inequalities, which is a concern of EU Members States.[1104] Beneath these overarching values, this statement underlines, there is also a set of operating principles that are shared across the European Union, in the sense that all EU citizens would expect to find them, and structures to support them in a health system anywhere in the EU.[1105] These include: (a) *Good quality care*; this is achieved through the obligation to continuous training of healthcare staff based on clearly defined national standards and ensuring that staff has access to advice about best practice in quality, stimulating innovation and spreading good practice, developing

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[1097] Council Conclusions on Common values and principles in European Union Health Systems, Official Journal of the European Union (2006/C 146/01), 1.
[1098] *Ibid.*
[1099] *Ibid*, 2.
[1100] *Ibid.*
[1101] *Ibid.*
[1102] *Ibid.*
[1103] *Ibid.*
[1104] *Ibid.*
[1105] *Ibid.*, 2.

systems to ensure good clinical governance, and through monitoring quality in the health system.[1106] An important part of this agenda also relates to the principle of safety. (b) *Patient safety*; including the monitoring of risk factors, adequate training for health professionals, and protection against misleading advertising of health products and treatments;[1107] (c) Care that is based on *evidence and ethics*; This means that all systems have to deal with the challenge of prioritizing healthcare in a way that *balances* the needs of individual patients with the financial resources available to treat the whole population.[1108]

The common values between EU healthcare systems are also described in the opinion of a multidisciplinary and independent expert panel that was established by the European Commission in 2012 to provide non-binding advice on matters related to effective, accessible and resilient health systems.[1109] This opinion highlights that the last 60 years, all EU countries have tried to build health systems that share common values such as *solidarity*, *universality*, *equity* and *access* to a comprehensive package of safe and effective health services of high quality.[1110] Most importantly, this opinion highlights that the introduction of (or an increase in) competition in healthcare provision will not always be the best instrument to achieve health system goals nor will it solve all health system problems and may have adverse effects. [1111]As this opinion emphasizes, competition, like other health policy instruments, is unlikely to improve all aspects of health system performance at the same time,[1112] and achieving more of one particular goal may lead to a lower level in another goal. This opinion emphasizes, therefore, that trade-offs in terms of objectives may have to be made.[1113]

More than that, the EU Member States' commitment to ensure equity and access in designing their healthcare systems is reflected in the numerous international and European human right instruments they have signed, such as article 25(1) of the Universal Declaration of Human

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[1106] *Ibid*., 2.
[1107] *Ibid*., 3.
[1108] *Ibid*, 2-3.
[1109] European Commission, *supra* n. at 7. The creation of the Panel goes back to the conclusions on health systems adopted in June 2011 by the Council of Ministers of the EU, which invited the European Commission and the EU countries to initiate a process aiming to identify effective ways of investing in health and to provide them with independent advice on health related questions.
[1110] *Ibid*, 51.
[1111] *Ibid*., 76, para 48.
[1112] *Ibid*, 6.
[1113] *Ibid*, 16.

Rights.[1114] According to this article '*Everyone* has the right to a standard of living adequate for the health of himself and of his family, including food, clothing, housing and medical care and necessary social services.' Additionally, Article 12 (1) of the International Covenant on Economic, Social and Cultural Rights (ICESCR)[1115] declares that States recognize 'the right of everyone to the enjoyment of the highest attainable standard of physical and mental health'.[1116]

A clear understanding of the *normative content of the right to health* is provided in the 14th General Comment (GC 14) of the UN Committee on Economic, Social and Cultural Rights.[1117] This document states (paragraph 12) that the right to health in all its forms and all levels contains a number of interrelated and essential elements, the precise application of which depends on the conditions prevailing in a particular State. These are *availability, accessibility, acceptability, good quality.*[1118]

-The principle of *availability* requires that public health and healthcare facilities, goods and services are available in a sufficient quantity within a State.[1119]

-The principle of *accessibility* requires that (a) health facilities, goods and services are accessible to all, especially the most vulnerable or marginalized sections of the population, in law and in fact, without discrimination on any of the prohibited grounds; (b) healthcare *should be affordable for everyone* and that the payment for health-care services, *whether privately or publicly provided,* should be based on the principle of equity (c) health facilities, goods and services must be within safe *physical reach* for all sections of the population, especially for the vulnerable or marginalized groups; (d) *information*

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[1114] Universal Declaration of Human Rights, Universal Declaration of Human Rights, available at: http://www.ohchr.org/EN/UDHR/Documents/UDHR_Translations/eng.pdf.
[1115] International Covenant on Economic, Social and Cultural Rights Adopted and opened for signature, ratification and accession by General Assembly resolution 2200A (XXI) of 16 December 1966
entry into force 3 January 1976, in accordance with article 27, available at: http://www.ohchr.org/EN/ProfessionalInterest/Pages/CESCR.aspx.
[1116] It should be noted that the USA has signed but it has not ratified the International Covenant on Economic, Social and Cultural Rights, see: https://treaties.un.org/Pages/ViewDetails.aspx?src=IND&mtdsg_no=IV-3&chapter=4&lang=en. The USA has signed the Universal Declaration of Human Rights.
[1117] UNITED NATIONS (UN) COMMITTEE ON ECONOMIC SOCIAL AND CULTURAL RIGHTS-CESCR 2000. Substantive issues arising in the implementation of the International Covenant on Economic Social and Cultural Rights – General Comments No 14 (E/C 12/2000/4).
[1118] *Ibid*, para 12.
[1119] *Ibid*, para 12(a).

*accessibility* is ensured. This includes the right to seek and receive information and ideas concerning health issues.[1120]

-The principle of *acceptability* requires that all health facilities, goods and services must be respectful of medical ethics and culturally appropriate, i.e. respectful of the culture of individuals, minorities, peoples and communities, sensitive to gender and life-cycle requirements, as well as being designed to respect confidentiality and improve the health status of those concerned.[1121]

-The principle of *quality* demands that health facilities, goods and services should be *scientifically and medically appropriate and of good quality*.[1122] This raises the need for skilled medical personnel, scientifically approved and unexpired drugs and hospital equipment, safe and potable water, and adequate sanitation.[1123]

The right to health, like all human rights imposes three types or levels of obligations on States: the obligation to *respect*, to *protect* and to *fulfill*.[1124] The obligation to *respect* requires States to refrain from *denying, obstructing or limiting equal access* for all persons to preventive, curative and palliative health service.[1125] The obligation to *protect* includes, *inter alia*, the duties of States to adopt legislation or to take other measures *ensuring equal access to health care* and health related services provided by third parties;[1126] to ensure that *privatization* of the health sector does not constitute a threat to the availability, accessibility, acceptability and quality of health facilities, goods and services;[1127] to ensure that medical practitioners and other health professionals meet appropriate standards of education, skill and ethical codes of conduct.[1128] The obligation to *fulfill* requires States, *inter alia*, to give sufficient recognition to the right to health in the national, political and legal systems, preferably by way of legislative implementation, and to adopt a national health policy with a

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[1120] *Ibid*, para 12(b).
[1121] *Ibid*, para 12(c).
[1122] In this document, the principle of quality refers to the evaluation of quality *at unit level* according to Donabedian analysis.
[1123] *Ibid*, para 12(d).
[1124] *Ibid*, para 33.
[1125] *Ibid*, para 34.
[1126] *Ibid*, para 35.
[1127] *Ibid.*
[1128] *Ibid*, para 35.

detailed plan for realizing the right to health.[1129] It also includes the provision of a public, private or mixed health insurance system which is affordable for all.[1130]

At the European level, the right to health is also protected. Indeed, the European Convention on Human Rights considers the right to health as part of the right to life or as part of the right to a private life, provided for respectively, in Articles 2 and 8 of the Convention. Two other European legal documents also provide an extended analysis on the core content of the right to health and the right to access to healthcare. These are the European Social Charter (ESC)[1131] and the Convention on Human Rights and Biomedicine (CHRB).[1132] In particular:

-The ESC in its preamble underlines that *'everyone has the right to benefit from any measures enabling him to enjoy the highest possible standard of health attainable'*. The right is further laid down in Article 11 of the ESC which provides that the effective exercise of the right to health requires that States should, either directly or in cooperation with public or private organizations, take appropriate measures designed *inter alia* to remove as far as possible the causes of ill-health.

The main aspects of the right to health are further examined in the interpretation of Article 11 ESC[1133] which explores the core elements embedded in the provision and access to healthcare services. Essentially, this legal document underlines that a healthcare system must be accessible to everyone and that restrictions on the enjoyment of the right by disadvantaged groups' exercise should not be accepted. In particular, it points out that the conditions governing access to care should take into account the Parliamentary Assembly Recommendation 1626 (2003) on 'the reform of healthcare systems in Europe: reconciling equity, quality and efficiency', which, among others, invites Member States to take as their main criterion for judging the success of their healthcare system reforms, the effective access to health care for all, without discrimination, as a basic human

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[1129] *Ibid.*, para 36.
[1130] *Ibid.*
[1131] European Social Charter, Turin, 18.X.1961, available at: http://www.coe.int/en/web/conventions/full-list/-/conventions/rms/090000168006b642.
[1132] Convention for the Protection of Human Rights and Dignity of the Human, Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine, Oviedo, 4.IV.1997.
[1133] This interpretation is conducted by the European Committee of Social rights.

right and, as a consequence, the improvement of the general standard of health and welfare of the entire population.[1134]

In spite of the non-binding effect of the ESC, this legal document is part of a specific mechanism of governance within Europe, which includes a collective complaint procedure and a monitoring procedure based on national reports. Within this context, the European Committee of Social Rights is responsible for evaluating the reports and deciding whether or not the situations in the countries concerned are in conformity with the provisions of the ESC.

- Article 3 of CHRB also refers to the right to healthcare stating that the access to healthcare should be provided in line with the principles of *equity* and *accessibility*. The explanatory report elaborating on the core content of this article underlines that the main purpose of article 3 CHRB is to ensure *equitable access* to healthcare in accordance with the person's medical needs. It further underlines that *access to healthcare must be equitable*, which means access without discrimination.[1135]

The right to health is also protected by the Charter of Fundamental rights of the European Union[1136] which with the entry into force of the Treaty of Lisbon, as article 6 of the Treaty on the European Union states, has the same legal value as the Treaties.

With respect to the right to health, Article 35 of the Charter provides that 'Everyone has the right of *equal access to preventive healthcare* and the right to benefit from medical treatment under the conditions established by national laws and practices. A high level of human health protection shall be ensured in the definition and the implementation of all Union policies and activities.' Arguably, the first part of Article 35 refers to the principles of accessibility, equality and non-discrimination. The second part, clearly underlines that a high level of health protection should be taken into account in the implementation of all union policies and activities.

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[1134] Parliamentary Assembly, Recommendation 1626 (2003) 'The reform of health care systems in Europe: reconciling equity, quality and efficiency', para 10.5. This document does not specifically define the notions of quality, access, equality.

[1135] Explanatory report on the Convention for the Protection of Human Rights and Dignity of the Human, Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine, Oviedo, 4.IV.1997, available at: https://rm.coe.int/16800ccde5.

[1136] Charter of Fundamental Rights of the European Union, (2000/C 364/01).

The above analysis demonstrates that the principles of non- discrimination, accessibility, equity and efficiency can be drawn from all the provisions with regards to healthcare. Indeed, (a) the ESC in its preamble underlines that *'everyone has the right to benefit from any measures enabling him to enjoy the highest possible standard of health attainable'*. Additionally, Article 11 of the ESC articulates that restrictions on the enjoyment of the right by disadvantaged groups *should not be accepted* (b) Article 3 of the CHRB provides that access to healthcare should be provided in line with the principles of *equity and accessibility* (c) GC 14 (paragraph 53) clearly imposes a duty on each State to take whatever steps are necessary to ensure that *everyone* has access to health facilities, goods and services. Especially with regards to the principle of accessibility it emphasizes that healthcare goods and services should be accessible to all, *especially to the most vulnerable groups of the population*. Most importantly, the 14th General Comment (35th paragraph) underlines that States should *ensure* that the *privatization* of the health sector does not constitute a threat to the availability, accessibility, acceptability and quality of health facilities, goods and services.

Arguably, different Member States have different approaches to making a practical reality of these values, principles and their commitment to ensure the right to health. For instance, the UK's commitment to ensure these values is reflected, among others, in the *NHS Constitution* that establishes the principles and values under which NHS in England operates.[1137]

In brief, as the *NHS Constitution* spells out, seven key principles guide the NHS in all it does.[1138] These fundamental principles are: (a) The NHS provides a comprehensive service, *available to all* irrespective of gender, race, disability, age, sexual orientation, religion, belief, gender reassignment, pregnancy and maternity or marital or civil partnership status.[1139] NHS has a duty to each and every individual that it serves and must respect their human rights.[1140] At the same time, it has a wider social duty to promote equality through the services it provides and *to pay particular attention to groups or sections of society where improvements in health and life expectancy are not keeping pace with the*

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[1137]NHS, For England, 27 July 2015, The NHS Constitution, the NHS belongs to us all, available at: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/480482/NHS_Constitution_WEB.pdf.
[1138] *Ibid*, at 2.
[1139] *Ibid.*, 3.
[1140] *Ibid*

*rest of the population;*[1141] (b) Commitment to the highest standards of excellence and *professionalism;*[1142] (c) Access to NHS services *on the basis of clinical need, not on individual's ability to pay*. NHS services are free of charge, except in limited circumstances sanctioned by Parliament; (d) The patient should be at the heart of everything the NHS does.[1143] NHS should support individuals to promote and manage their own health. NHS services must reflect, and should be coordinated around and tailored to, the needs and preferences of patients, their families and their carers;[1144] (e) The NHS should work across organizational boundaries. NHS is an integrated system of organizations and services bound together by the principles and values reflected in the Constitution.[1145] The NHS is committed to working jointly with other local authority services, other public sector organizations and a wide range of private and voluntary sector organizations to provide and deliver improvements in health and wellbeing;[1146] (f) The NHS is committed to providing best value for taxpayers' money; (g) The NHS is accountable to the public, communities, and patients that it serves.[1147]

To what extent do the above international and European human right documents as well as the *NHS Constitution* reflect the notion of healthcare quality as it is defined by the IOM, and international organizations such as the WHO and the OECD? Obviously, in these documents there is not a specific definition of healthcare quality that coincides with the definition that has been adopted by these institutions or by Donabedian. However, it should not be underestimated that especially the analyzed international and European human rights documents acknowledge that healthcare should be provided in accordance with the principles of equity, efficiency, acceptability, access, essential dimensions of the healthcare quality notion. Additionally, it should also not be underestimated that these documents also reflect the notion that *health is special.* This is because in all these documents equity is defined *as equality of access to available care for equal need;* Indeed, all these documents underline that healthcare should be distributed regardless of people's ability to pay for it and that it should be accessible to all, especially to the most vulnerable groups of a society. In other words, these documents reflect the idea that entities such as health derive equity significance from

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1141 *Ibid.*
1142 *Ibid.*
1143 *Ibid.*
1144 *Ibid.*
1145 *Ibid.*, 4.
1146 *Ibid.*
1147 *Ibid.*

their ability to enable people to flourish[1148] and therefor everybody should be able to enjoy it irrespective of his/her health conditions, social status and his/her ability to pay for it.

## 2. Potential conflicts between the notions of competition and choice and the multiple non-economic facets of healthcare quality: Some reflections on the UK example

As noted in Chapter II, in the UK, following the HSCA 2012 the delivery of healthcare through market provision has been further reinforced. At the same time, the service has been made subject overall to a special competition law regime that will be further discussed and analyzed in the following chapter. Nonetheless, it should be noted that important steps have been made by governments of both political complexions to introduce market mechanisms within it as early as in 1990 when the then Conservative government passed the National Health Service and Community Care Act, introducing the 'internal market'.[1149] Intellectual inspiration came mainly from US economist, Alain Enthoven, who advocated the reconfiguration of the NHS according to an 'internal market model', in which competition between providers within the NHS would be a spur to increased efficiency and quality.[1150]

In brief, the Act separated the purchasing ('commissioning') and the provision of healthcare services across the United Kingdom.[1151] Two types of purchasers were created: The District Health Authorities and the General Practice Fundholders (GPFHs).[1152] The latter were larger primary care physicians, who elected to buy a subset of hospital outpatient and elective surgical, diagnostic and pharmaceutical care for the patients on their lists. GPs were expected to act as informed agents on behalf of their patients and secure access to care from providers.[1153] Providers and purchasers were linked by a contract, in the case of private providers in the ordinary private law

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[1148] A.J Culyer, *supra* n.124, 276.
[1149] National Health Service and Community Care Act 1990, available at: National Health Service and Community Care Act 1990, available at: http://www.legislation.gov.uk/ukpga/1990/19/contents.
[1150] L. Stirton, *supra* n. 450, 184.
[1151] J. Cylus, E Richardson, L. Findley, M. Longley, C. O'Neill, D. Steel, *supra* n. 278, 16.
[1152] N. Mays, A. Dixon, L. Jones, (2011) 'Return to the Market: Objectives and Evolution of New Labour's Market Reforms', in N. Mays, A. Dixon and L. Jones (eds) in Understanding New Labour's Reforms of the English NHS, (London: The King's Fund: 2011) 1-15, 3.
[1153] *Ibid.*

form but within the NHS Service they took the form of NHS Contracts.[1154] These contracts were (typically) annually negotiated agreements, taking three distinct forms: *block contracts*, in which providers met all demand for a fixed price;[1155] *cost-and-volume* contracts that specified an upper limit, beyond which further payments were necessary for additional provision;[1156] *cost-per-case contracts* that specified an agreed price to be paid for each patient treated.[1157]

Purchasers were interested in obtaining lower prices so that they could buy more elective priority because, as it was well known, long waiting lists existed for many elective procedures.[1158] Outcome measures, such as mortality rates, were not publicly available to purchasers, the Department of Health or the public until 1999.[1159] While purchasers might have known something about the quality of the supplier, this knowledge would have been very partially comparable across even local hospitals.[1160] Hence, purchasers had a strong incentive to negotiate lower prices and/or higher volumes but a much weaker incentive to negotiate quality improvements.[1161] The internal market for health did not have a dramatic impact on the NHS, probably because the forces of competition were never properly released onto the system.

Although the incoming Labour Government acted quickly to reform the system, the reforms retained important elements of the internal market, notably the purchaser-provider split.[1162] More specifically, although the purchaser–provider split was retained, the GPFHs were abolished on the grounds that they had led to a 'two-tier' service, and Primary Care Trusts (PCTs) involving all GPs were established.[1163] These groups had indicative budgets, and were intended gradually to take over the responsibility for commissioning from the health authorities.[1164]

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1154 T. Prosser, The Limits of Competition law, Markets and Public Services (Oxford, Oxford University Press), 9.
1155 L. Stirton, *supra* n. 450, 186.
1156 *Ibid.*
1157 *Ibid.*
1158 C. Propper, S. Burgess, D. Gossage, *supra* n.16, 142.
1159 *Ibid.*
1160 *Ibid.*
1161 *Ibid.*
1162 T. Prosser, *supra.* 1154, 8.
1163 N. Mays et al, *supra* n. 1152, 5.
1164 *Ibid.*

Under the New Labour leadership, NHS reforms can be divided in two periods: During the first one the focus of health policy was on securing national standards of quality, and against provider competition of any kind.[1165] During this time, the thrust of reforms was marked by a strong focus on top-down policy-making that saw the setting of national standards and targets (e.g. for reducing waiting times) as a means of standardizing care across providers.[1166] To this end, between 1999 and 2002 two new regulatory and oversight organizations were established: the National Institute for Health and Clinical Excellence (National Institute for Health and Care Excellence (NICE) from 2012) and the Commission for Health Improvement (CHI or else CQC from 2009).[1167] Established to pursue better quality, efficiency and consistency within the NHS, NICE had a remit to assess new and existing interventions for their clinical and cost effectiveness and to decide whether an assessed intervention ought to be available in the NHS. CHI complemented NICE's role by monitoring NHS quality, performance and adherence to NICE's guidance. Thus, NICE mainly set the standards and CHI monitored these standards.[1168]

During the second term, the Government strived to foster quality competition by limiting price competition. In order that money could follow the patients and provide an incentive for efficient providers to increase activity through output, the NHS introduced an activity-based payment system for hospitals known as Payment by Results (PbR).[1169] This system of fixed national prices was based on health resource groups – the UK adaptation of the US system of diagnosis-related groups.[1170] The fixed price for each health resource group was calculated on the basis of average costs.[1171] Because price negotiations were not part of the system, competition between providers was theoretically based on *quality*.[1172] Indeed, by limiting price competition, the Government hoped that hospitals would have stronger incentives to win contracts by investing in quality and innovation.

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[1165] *Ibid.*
[1166] *Ibid.*
[1167] J. Cylus, E Richardson, L. Findley et al, *supra* n. 278, at 16.
[1168] *Ibid.*
[1169] N. Mays et al, *supra* n. 1152, at 7.
[1170] *Ibid.*
[1171] The idea was based on the Diagnosis Related Groups (DRGs) originating in the USA, where they were used to calculate payments for physician services under Medicare.
[1172] L. Stirton, *supra* n. 450, at 191.

In enhancing quality competition, the Government also implemented policies that allowed patients to exercise choice at the point of referral. Through these policies, patients could choose between any provider, private or NHS, that had agreed to provide care to NHS standards at the national tariff system.[1173] The Government believed that extending choice at the point of referral would reduce waiting times and would improve responsiveness.[1174] Therefore, from around 2002 onwards in a 'gradual, pragmatic' process stimulated supply side competition through an increase in the diversity of providers of care and the freedom they had to act innovatively.[1175] Essentially, the provision of NHS services was gradually opened up to a variety of accredited providers including both publicly owned and independent providers: most prominent was the establishment of NHS Foundation Trusts[1176] (NHS FTs) and the establishment in 2003 of Independent Sector Treatment Centres (ISTC) that were intended to provide high volume, low-risk surgery to NHS patients.[1177] Patients were also offered choice between providers for their treatment, beginning with pilots of choice for cardiac surgery introduced in 2002 and culminating in the introduction of 'free' choice of any eligible provider at referral in 2008.[1178]

The government also attempted to enhance quality competition by allowing elective patients to choose any provider who met NHS standards and tariffs through the so-called 'choose and book' system.[1179] This was an electronic appointment booking system that was installed in hospitals and GP surgeries to allow GPs and patients to book their appointments online, in the GP surgery, or from home.[1180]

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[1173] A. Dixon, R. Robertson, 'Patient Choice of Hospital', in N. Mays, A. Dixon and L. Jones (eds) *Understanding New Labour's Reforms of the English NHS*, (2011, London: The King's Fund), 53.
[1174] P. Allen and L. Jones, 'Diversity of Health Care Providers' in N. Mays, A. Dixon and L. Jones (eds) Understanding New Labour's Reforms of the English NHS, (2011, London: The King's Fund).
[1175] M. Sanderson, P. Allen, D. Osipovic, *supra* n. 35, 4.
[1176] Under the labor regime, NHS Trusts that achieved a defined level of performance, initially a three-star rating from CHI, could apply to have Foundation Trust status. To gain this status, NHS bodies were assessed on the basis of specific quality factors. These included waiting lists, cleanliness, treatment specific data and financial management. This status allowed the Foundation Trusts to reach a certain level of autonomy. NHS FTs were independent organizations not subject to direction from the Secretary of State for Health. They are public bespoke legal entities that can retain surpluses and borrow funding for capital investment from more sources. They have also greater flexibility with regard to remuneration of stuff, see N. Mays et al, *supra* n. 1135, at 7.
[1177] M. Sanderson, P. Allen, D. Osipovic, *supra* n. 35, 6.
[1178] *Ibid.*
[1179] L. Stirton, *supra* n. 450, 191.
[1180] A. Dixon, R. Robertson, *supra* n. 1173, 55.

New mechanisms to regulate competition were not developed until 2007 when the Principles and Rules for Cooperation and Competition ('Principles and Rules') were launched, administered from January 2009 by the Cooperation and Competition Panel (CCP), a newly established body operating at arm's length from the Department of Health.[1181] These Principles and Rules were based on the premise that both competition and cooperation were desirable, and they took other concerns into account in addition to competition. For example, decisions regarding mergers were not to be considered solely in relation to the protection of competition, but also in the light of patients' and taxpayers' interests in respect of matters such as whether the changes could 'deliver significant improvement in the quality of care.'[1182] The CCP had no enforcement power.[1183] Its advice did not have any statutory basis and was not legally binding. It had a duty to investigate cases that might infringe the Principles and Rules and to make recommendations to the Secretary of State for Health and Monitor (at this stage the independent regulator of Foundation Trusts) in respect of Foundation Trusts, and the local Strategic Health Authority in respect of NHS Trusts, who would then decide what action would be taken.[1184]

As with the Labour Government, the Coalition Government under the HSCA 2012 also attempted to promote quality through (a) promoting choice and competition between healthcare providers (b) restricting price competition and (c) by enforcing quality regulation and ensuring that multiple bodies and regulators are responsible for supervising the quality of NHS services, notably CQC, Monitor and the purchasers of NHS services. More importantly, HSCA 2012, which came into force in April 2013, made a direct correlation between competitive behaviour in the NHS and competition law.[1185] Under the HSCA 2012, Monitor, the new economic regulator for the whole of the NHS took over some of the functions of the former CCP and, along with the CMA has powers to enforce competition law to prevent anti-competitive behaviour.[1186] Whereas the CCP was a non-statutory body, Monitor was given a statutory responsibility to prevent anti-competitive behaviour,

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[1181] M. Sanderson, P. Allen, D. Osipovic, *supra* n 35, 6.
[1182] *Ibid.*
[1183] *Ibid.*
[1184] *Ibid.*
[1185] *Ibid.*
[1186] *Ibid*, 7.

which was against the interests of service users.[1187] Additionally, Monitor under the new regime is also required to promote competition in the procurement and commissioning of NHS services.[1188]

What type of competition problems can this regulatory framework create? Incentivizing healthcare providers to improve the quality of their services through the implementation of specific standards and targets can lead to quick improvements on specific dimensions of quality, such as waiting times. The risk of shame and loss of contracts can undoubtedly force providers to meet the quality standards targets set. Incentivizing, however, healthcare providers to improve specific aspects of quality might incentivize providers to game. Most importantly, this policy may also restrict quality competition between healthcare providers by incentivizing providers to collude on the level of quality specific targets set. Indeed, it is difficult to claim that healthcare providers would have incentives to increase the quality of their services above the levels required by quality regulation considering that the marginal improvement in quality might not even be identified by patients or purchasers of NHS services. How should competition authorities respond to providers' argument that the quality regulation as such restricts quality competition and not the fact that they collude on specific dimensions of healthcare quality?

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[1187] The following chapter will elaborate more on the main reforms the 2012 HSCA introduced and the competition law regime that now applies to providers of NHS services.

[1188] Regulation 2 of the Procurement, Patient Choice and Competition Regulations requires commissioners to act with a view to securing the needs of NHS health care services users and to improving the quality and efficiency of services, including though the services being provided in an integrated way (including with other health care services, health-related services or social care services). Additionally, Regulation 3(4) of the Procurement, Patient Choice and Competition Regulations requires commissioners, when acting with a view to improving quality and efficiency, to consider appropriate means of making such improvements, including through (a) services being provided in a more integrated way (including with other health care services, health-related services or social care services) (b) enabling providers to compete to provide services; and (c) allowing patients a choice of provider. With regards to competition Regulation 10(1) of the Procurement, Patient Choice and Competition Regulations prohibits commissioners from engaging in anti-competitive behaviour when commissioning services unless it is in the interests of NHS health care service users. Regulation 10(2) clarifies that an arrangement for the provision of NHS health care services must not include any term or condition restricting competition that is not necessary for the attainment of intended outcomes which are beneficial for people who use such services or the objective in Regulation 2. This is because where restrictions of competition are not necessary to achieve such benefits, they are unlikely to be in the interests of health care service users. Monitor has published specific guidance explaining how it aims to assess anticompetitive behaviour in the procurement services market. This is the Procurement, patient choice and competition regulations Guidance of 2013. In this document Monitor mentions that when assessing an anticompetitive behaviour it also considers whether the behaviour gives rise to any material benefits to users of NHS health care services, such that the behaviour would be considered to be in the interests of health care service users. These, among others, may be clinical improvements such as increase in the number of patients treated by a provider where higher patient volumes result in better outcomes; and non-clinical benefits such as better patient experience, better access for patients (for example, longer and/or more convenient opening hours, improved surroundings or better amenities).

A regulatory framework that extends choice as a means to achieve quality improvements may pose different but analogous challenges for competition enforcers. This is because patients' choice in healthcare does not necessarily lead to quality improvements. Indeed, evidence from the Labor reforms' period reveals that when patients were asked to name the single most important influence on their choice of hospital, being close to home or work was selected most often, followed by personal experience of the hospital and waiting times.[1189] Additionally, Governments' policies to correct the asymmetry of information between patients and healthcare providers by informing patients on the performance of the market participants do not necessarily transform patients into active choosers.

This is because much of the information available to patients is either irrelevant or is not presented in the most accessible format. Information on the performance of hospitals on *NHS Choices,*[1190] for example, includes four or five hospital sites. The other website that aims to inform patients, *iWantGreatCare.org*,[1191] allows patients to provide feedback on their healthcare experiences. Patients can directly rate and review healthcare professionals and providers (such as GPs, hospital consultants and dentists) as well as social care providers and medicines.[1192] Patients rate healthcare professionals on three dimensions;[1193] trust, listening skills and whether they would recommend them to others. An overall rating percentage is generated and patients can also provide qualitative feedback.[1194] Other patients can then search for healthcare professionals by geography and specialism to compare ratings and reviews.[1195] Relying however on these tools to choose healthcare providers or treatments is risky. Asking patients to evaluate their healthcare providers on the basis of specific dimensions, such as trust and listening skills, might either incentivize providers to focus only on these dimensions at the expense of others, such as professional caliber and effectiveness, or

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[1189] A. Dixon and R. Robertson, *supra* n. 1173, 56.
[1190] (www.nhs.uk)
[1191] iWantGreatCare.org is funded by providing performance consultancy services to healthcare providers, using the data captured from patients on the site.
[1192] Office of Fair Trading, Policy report, Empowering Consumers of Public Services Through Choice Tools, *supra* n. 428, at 18.
[1193] *Ibid.*
[1194] *Ibid.*
[1195] *Ibid*, 16.

might facilitate the flow of false information because each patient's experience is personal and thus subjective.

Since the information on quality these search engines provide is either inadequate or limited, patients do rely on doctors' experience and advice when they have to choose either the appropriate medical treatment or healthcare providers. This is the reason why both in the UK and in the Netherlands GPs do not only offer their medical services but they act as gate keepers too. From the perspective of healthcare quality objective this might be desirable. Arguably, if patients cannot adequately assess providers' performance on the basis of the clinical aspects of quality, they might choose provider on the basis of short waiting lists. From the perspective of competition, though, this might not be desirable since the more doctors behave as their patients' agents the more their market power increases. GPs may have their own views on whether a hospital offers good or bad quality services. In fulfilling their duties as purchasers of healthcare (PCTs, for example during the Labour period)[1196] they may try to impose their own views on the standards of quality healthcare providers should meet. The same can be said when GPs act as gatekeepers. Following a decision made by the British Medical Association or by the purchasers of healthcare, GPs in performing their role as gatekeepers may agree to stop referring patients to specific hospitals that do not meet their quality standards of medical treatment. Undoubtedly, the fact that GPs are among the few actors that see patients go to the hospitals they refer them to and return with their stories of what happened, while also to some extent having insight into the medical outcomes produced, this may well make them crucial actors for qualifying public values, such as healthcare quality in their referrals.[1197] *Is this scenario possible?*

Considering that doctors appreciate the value of professionalism more than the value of choice, the answer should be positive. Doctors distrust the official performance statistics that are available to helps patients to choose preferring to base their advice on their patients' past experience and their relationships with individual consultants.[1198] While GPs could guide patients in choosing

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[1196] As noted at the beginning of this section, the purchasers of the NHS services or else commissioners are basically GPs. While during the labour period they were called PCTs after the introduction of the HSCA 2012, as the following chapter explains, they are called Clinical Commissioning Groups (CCGs).
[1197] Teun Zuiderent-Jerak Kor Grit and Tom van der Grinten, *supra* n. 270, 20.
[1198] A. Dixon, R. Robertson, *supra* n. 1173, 56.

the appropriate treatment or hospital by helping them to understand all the costs and benefits of their options, in fact they don't. A more detailed evaluation of patient choice in four areas of England found that, by January 2009, although patients were entitled to choose any NHS or registered non-NHS provider, most patients who were offered a choice said that they had been given between two and five options, *with the inclusion of a privately run hospital in only 8 per cent of choices.*[1199] Interviews with GPs and patients in the same study revealed that GPs often offered choice in a tokenistic way, rarely initiating a discussion of the merits or of the options available.[1200] Although many GPs could see the benefits of choice in theory, they often resisted the routine offering of choice as they felt that most patients were not interested in making one, preferring the GP to decide on their behalf, and that, in addition, they did not have time to discuss the options with patients. Patients wanted the choice.[1201] Nonetheless they did not want to be active choosers, preferring their GP to choose on their behalf.[1202]

The installation of the electronic appointment booking system called Choose and Book in hospitals and GP surgeries that aimed to facilitate choice by allowing GPs and patients to book their appointments online in the GP surgery or from home did not incentivize doctors to facilitate patients' choice. Interestingly, even before the Choose and Book system began, it generated a negative response from GPs: just over three-quarters (78 per cent) described themselves as feeling 'a little negative' or 'very negative' about the idea of it, and 93 per cent felt that there had been inadequate consultation on the system.[1203] Initial technical difficulties frustrated GPs who, under time pressure in their consultations, found they were often unable to log on to the system or that it crashed during a booking.[1204] They also complained that a lack of training made it difficult to keep up to date with the regular modifications to the system, and that the inability to refer to a named consultant (unlike in a traditional paper-based referral) broke the links they had established with hospital clinicians.[1205] Despite a target of 90 per cent of appointments to be booked through Choose and Book by March 2007 and the inclusion of incentive payments to encourage its use, only half of

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1199 *Ibid*, 54.
1200 *Ibid.*
1201 *Ibid.*
1202 *Ibid.*
1203 *Ibid*, 55.
1204 *Ibid.*
1205 *Ibid.*

first outpatient appointments were being booked through the system by 2010.[1206] GPs were key to the implementation of this policy and their lack of enthusiasm for the program and reluctance to use the Choose and Book system meant implementation stalled.[1207] To protect specific facets of healthcare quality, such as the notions of *safety*, *continuity* and *acceptability* the purchasers of NHS services may issue guidance advising the GPs to abstain from referring patients on the basis of the Choose and Book system and refer patients to specific providers that meet their own standards of healthcare quality. *To the extent GPs may comply with this guidance*, *how should competition authorities evaluate such an agreement? How should they assess the purchasers' of NHS services claim that in certain cases, restricting choice and competition in healthcare markets might be necessary for the protection of healthcare quality?*

Extending patients' choices to foster quality might also harm equity defined as *equality of (opportunity of) access for equal need.* Arguably, extending patients' choice by allowing private providers to offer more profitable routine work inevitably leaves NHS organizations with the essential, complex and emergency care, which they had previously been cross-subsidizing with revenue from routine work.[1208] For example, ISTCs that were introduced during the labour period to offer elective services, have been criticized severely for their potential to compromise equity of access as a result of their being able to select or cherry-pick the more profitable cases because they were set up specifically to treat low-risk, elective patients rather than high-risk, high-cost patients.[1209] In fact, experience during the Labour period demonstrates that where for-profit providers found it difficult to make a profit, or they realized that their business model was ill-fitted to primary care, they withdrew and closed their primary care clinics leaving the purchasers of healthcare to find other practices willing to take the patients.[1210] This, obviously, harmed equity of access to primary care since for-profit providers tended to be established in areas with an insufficient number of GPs.[1211] *How should competition authorities evaluate a decision made by the purchasers of NHS services advising GPs to restrict choice and refer more patients for elective care to NHS hospitals engaging also in risky non - elective procedures so that they can cross subsidize these costly procedures and guarantee the continuity of the services they offer?* As also

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[1206] *Ibid.*
[1207] *Ibid.*
[1208] P. Allen and L. Jones, 'Diversity of Health Care Providers' in N. Mays, A. Dixon and L. Jones (eds) Understanding New Labour's Reforms of the English NHS, (2011, London: The King's Fund) 22.
[1209] *Ibid*, 18.
[1210] *Ibid.*
[1211] *Ibid.*

explained, the Labour Government attempted to induce quality competition and extent choice by introducing PbR, the payment of fixed national prices for the treatments provided by hospitals. The Coalition Government that enacted the HSCA 2012 also enforced a similar regime. It restricted price competition so that providers compete only on quality. Should healthcare providers, such as hospitals, be allowed to agree on the maximum levels of quality of the amenities they offer so as to save more profits and cross subsidize their risky and more costly non - elective surgeries?

These questions become even more important considering a broader array of evidence demonstrating that the conditions you are born, grow, live, work and age have profound influence on health and inequalities in health.[1212] *Poverty damages health.* Subtle differences in neighborhood or in other conditions affecting the people who live there have grave import for health and length of life. To highlight the social gradient in health, Michael Marmot[1213] has pointed out that if you catch the Jubilee tube line, for each stop east from Westminster in central London, life expectancy drops a year. If we live in a neighborhood that is somewhere between the humblest and the most exalted, our life expectancy is somewhere in between the low level in the poor areas and the higher prospects in the richer.[1214] The richer the area, the better is our health. *Why*?

Most obviously, the physical environment is an important determinant of health variations.[1215] As already noted in chapter II, poorer neighborhoods are disproportionately located near highways, industrial areas, and toxic waste sites, since land there is cheaper and resistance to polluting industries, less visible.[1216] Housing quality is also poorer for low-socio economic status families. Compared with high-income families, both children and adults from poor families show a six - fold increase in rates of high blood lead levels while middle-income adults and children show a

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[1212] M. Marmot, *The Health Gap, The Challenge of An Unequal World* (Bloomsbury, 2015) 27.
[1213] Professor Sir Michael Marmot is Director of the International Institute for Society and Health and MRC Research Professor of Epidemiology and Public Health, University College London. Michael Marmot has led a research group on health inequalities for the past 30 years. He is Principal Investigator of the Whitehall Studies of British civil servants, investigating explanations for the striking inverse social gradient in morbidity and mortality. He leads the English Longitudinal Study of Ageing (ELSA) and is engaged in several international research efforts on the social determinants of health. He chairs the Department of Health Scientific Reference Group on tackling health inequalities, see: http://www.who.int/social_determinants/thecommission/marmot/en/.
[1214] *Ibid,* 28.
[1215] N. Rice and P. C Smith, 'Ethics and geographical equity in health care', (2001) 27 *Journal of Medical Ethics*, 256.
[1216] N. E. Adler and K. Newman, *supra* n. 501, 60.

two - fold increase.[1217] Childhood asthma incidence is also rising in urban neighborhoods among poor children, and the severity is greater among these children.[1218] The impact on health of variations in local economic conditions, such as the dominant type of employment, might also create an important area effect.[1219] Inadequacies in social support systems, such as transport, social care and education services, might also have adverse implications for local health outcomes. Poverty is also linked with homelessness, which, as medical literature indicates, is associated with plenty of health problems.[1220] Indeed, nearly 40% of homeless individuals are reported to have some type of chronic disease including increased rates of cardiovascular and infectious diseases along with excessive rates of substance [tobacco, alcohol and cocaine] abuse. Individuals lacking stable housing are more likely to use the emergency department rather than an ambulatory care clinic as their regular source of care.[1221] Most importantly, when homeless individuals finally present for medical attention, they are more likely than the general population to have multiple medical problems, and often their illnesses have progressed to a more severe stage than normally seen.[1222] This helps to explain why homeless patients are admitted to inpatient units 5 times more often and have average lengths of stay that are longer than those who were not considered homeless. In light of this reality, the purchasers of NHS services may issue a decision advising GPs to refer more patients for elective care to NHS hospitals that offer high risk non-elective services in poor disadvantaged areas so that these hospitals can cross-subsidize their more costly non-elective services. *How should competition authorities respond to the purchasers' of NHS services claim that such a decision that restricts choice in the market of elective services is necessary for the financial stability of the NHS hospitals offering high risk costly surgeries in poor disadvantaged areas?*

Competition authorities may face analogous tragic dilemmas in assessing hospital merger cases: *Should, for example, competition authorities be allowed to clear a hospital merger, although it leads to market power in the respiratory or cardiovascular services market on the basis it will allow the merged entity to employ the most reputable respiratory or cardiovascular specialists? Should this merger be allowed on the basis it will ensure merging entities' financial stability and therefore access to these services to the most vulnerable groups of our society?*

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[1217] *Ibid*, 66.
[1218] *Ibid.*
[1219] N. Rice and P. C Smith, *supra* n. 1215, 256.
[1220] C. A. Jones, A. Perera, M. Chow, I. Ho, J. Nguyen and S. Davach 'Cardiovascular Disease Risk Among the Poor and Homeless – What We Know So Far' (2009) 5 *Current Cardiology Reviews*, 69.
[1221] *Ibid.*
[1222] *Ibid.*

One could argue that these questions have more theoretical than practical value in the sense that it is highly unlikely that GPs in performing their role as gatekeepers or purchasers of NHS services would actually engage in anticompetitive behaviour in order to protect essential objectives of their health systems, such as equity, safety or continuity. Nonetheless, a policy report published by CCP in 2011 aiming to provide guidance to purchasers of healthcare (or else commissioners) on when restrictions on patient choice and competition can be justified because of their benefits to patients and taxpayers[1223] proves exactly the opposite. In this report, CCP mentions that the purchasers of healthcare (PCTs during the labour period) constrained patients' ability to choose their routine elective care provider most frequently through influencing GP referral decisions, *and in some cases, directing GPs to refer patients to (or away from) certain providers.*[1224] In this report, CCP indicates that during the Labour period, in some cases PCTs had refused to enter contracts with certain providers for the provision of some, or all, routine elective care services.[1225] PCTs were trying to influence GP referral decisions through four main mechanisms: providing information to GPs about providers; making recommendations to GPs about which providers patients should be referred to; placing prohibitions on the referral of patients to certain providers; and putting in place additional approval processes where GPs wished to refer patients to a particular provider.[1226] Interestingly, in justifying their behaviour, PCTs held that restricting patient choice and competition had the potential, in certain circumstances, to benefit patients and taxpayers through: (a) achieving better value for money by directing patients to the lowest cost provider; (b) *ensuring service continuity* and provider's stability and (c) facilitating the training of clinical staff.[1227] CCP underlines that such alleged benefits should be considered on a case by case basis and should be balanced against the extent of any restrictions involved. Acknowledging that continuity in NHS hospital services is an essential objective of their health system, and therefore should not necessarily be expelled from a competition analysis, in this report CCP states: 'For a restriction on patient choice in routine elective care to deliver benefits in terms of service continuity, the

[1223] Cooperation and Competition Panel, 2011, Review of the operation of 'Any Willing Provider', for the provision of routine elective care, London: Cooperation and Competition Panel Curtis, LE, 2014, para 6.
[1224] *Ibid*, para 7.
[1225] *Ibid*, para 10.
[1226] *Ibid*, para 58.
[1227] *Ibid*, para 13.

potential loss of routine elective care volumes by a provider would need to result in a significant risk that other services – with critical access requirements for patients – could no longer be sustained. While this argument is frequently advanced, we have not yet seen persuasive evidence of this relationship, and we would expect commissioners to rely on robust evidence of this relationship before putting in place such a restriction."[1228]

The above analysis did not aim to support the view that all the above identified competition law problems can be properly addressed and examined only on the basis of a *wider consumer welfare* approach. Surely, competition authorities may address some of the above competition problems by adopting a narrow consumer welfare approach. For example, in addressing healthcare providers' claim that the quality regulation as such restricts quality competition in the healthcare sector and not their agreement to focus on specific dimensions of healthcare quality, competition authorities may evaluate such an agreement without having to widen the notion of consumer welfare. They may take the view that such an agreement restricts quality competition and as a result is clearly anticompetitive. However, in addressing some other of the identified potential competition problems, if competition authorities adopted a narrow consumer welfare approach, then health objectives such as access, equity and acceptability would not enter the equation. *Should therefore competition authorities in Europe extend the notion of consumer welfare when they apply competition law in healthcare so that the non- economic goals their systems pursue are not disregarded in their assessment? And, if yes, how*?

The following section focuses on answering this vital question by examining to what extent the non-economic facets of healthcare quality such as equity, safety and accessibility can be taken into account in the framework of article 101 TFEU. Having explored this initial question, it then explains why in fact competition authorities should not disregard these objectives in the context of their competition assessment.

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[1228] *Ibid*, 16.

## 3. Can EU Competition Law integrate a multidimensional concept such as healthcare quality in its analysis?

### 3.1 Assessment of healthcare quality on the basis of Article 101 (1) TFEU

- **Restrictive Interpretation of the term *Undertaking***

Some non-competition goals have influenced the interpretation of the term *undertaking* which has largely been shaped by the case law of the European Courts.[1229] Given that the concept of an undertaking 'makes it possible to determine the categories of actors to which the competition rules apply'[1230] one technique by which the European Courts have integrated public policy goals into their analysis is by denying the status of an *undertaking* to the entity alleged to be infringing.[1231] *What does this notion actually mean?*

To begin with, the notion is not defined in the EU Treaties.[1232] It is described in Article 1 of Protocol 22 EEA as an entity carrying out activities of a commercial or economic nature. The concept has, however, been developed by the case law of the Court of Justice which has given a functional definition to the term. In particular, in *Hofner and Elser v. Macroton* case the Court defined an undertaking as 'every entity engaged in economic activity regardless of the legal status of the entity and the way in which it is financed'.[1233] In assessing whether an entity is considered an undertaking what is decisive is whether the entity is engaged in an economic activity. The term focuses exclusively on the nature of the activity carried out by the entity concerned. Therefore, it is irrelevant whether the entity is of public or private nature or whether it is engaged in profit or non-profit activity. Consequently, a given entity might be regarded as an undertaking for one part of its activities while the rest may fall outside the competition rules.[1234]

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[1229] C. Semmelmann., Social Policy Goals in the interpretation of Article 81 EC, (Nomos 2008), 108.
[1230] O. Odudu., *supra* n. 28, at 231.
[1231] B. Sufrin, 'The evolution of article 81 (3) of the EC Treaty', (2006) 51(4) *The Antitrust Bulletin*, 915, 956.
[1232] O. Odudu, *The boundaries of EC Competition law, the scope of article 81*, (Oxford Studies in European law, 2006) 24.
[1233] Hofner v Macrotron (C-4111990) [1991] E.C.R. 1-1979; [1993]4 C.M.L.R. 306 at [21].
[1234] A. Jones, B. Sufrin., *EC Competition law*, (Oxford: Oxford University Press: 2014), 124.

The functional approach of the European Courts when defining the term *undertaking* has been explained by Advocate General Jacobs in his Opinion regarding the *AOK* Case: 'The Court's general approach to whether a given entity is an undertaking within the meaning of the Community competition rules can be described as functional, in that it focuses on the type of activity performed rather than on the characteristics of the actors which perform it. Provided that an activity is of an economic character, those engaged in it will be subject to Community competition law'.[1235]

Despite the General Court's statement in *SELEX Sistemi Integrati SpA v. Commission*[1236] noting that 'the various activities of an entity must be considered individually', the Court of Justice has developed three certain and necessary conditions for an activity to be considered economic: (a) the offering of goods and services on the market; (b) where that activity could at least in principle be carried on by a private undertaking in order to make profits; (c) where the entity bears the economic or financial risk of the enterprise.[1237] If these requirements are satisfied it is irrelevant that the body is not in fact profit making or that it is not set up for an economic purpose.[1238]

Importantly, in specific cases the Court has not hesitated to take the view that certain healthcare providers are not *undertakings* in order *to ensure* that the social objectives these entities actually pursue are not obstructed by the application of competition law. This approach finds its clearest expression in the *FENIN* case.[1239] In this case, an association of businesses complained that hospitals in the Spanish National Health Service breached competition laws by systematically delaying to pay invoices.[1240] In their view, this unilateral behavior constituted an abuse of a dominant position within the meaning of article 82 EC (now 102 TFEU). The General Court found that the hospitals were not undertakings. In shaping its view, the General Court took into account that they are funded from social security contributions and other State funding, they provide services free of charge on the

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[1236] Case T-155/04 12 December 2006, [2007] 4 CMLR 372, Case C-113/07.
[1237] O. Odudu *supra* n. 1232, at 26.
[1238] A. Jones., B. Sufrin., *supra n.* 1234, 128-129.
[1239] Case C-205/03, Federacion National de Empresas de Instrumentacion Cientifi ca Medica Tecnica y Dental (FENIN) v. Commission of the European Communities [2006] ECR I-6295.
[1240] *Ibid*, para 4, J. Lear, E. Mossialos and B. Karl, *supra* n 27, at 342.

basis of universal coverage and they operate on the basis of the solidarity principle.[1241] The Court of Justice fully aligned with the lower court's legal analysis. Since the goods purchased by the entities would be used to provide public services and would not be resold in the market, the entities' purchasing activity was not economic. As a result, the hospitals should not be considered undertakings.[1242]

The Court has adopted a similar approach in cases involving *conflicts* between the principle of solidarity under which specific social and healthcare funds operate and the protection of competition. This conclusion can be safely held taking into account the Court's legal reasoning in the *Poucet and Pistre*[1243], the *INAIL*[1244] and the *AOK*[1245] cases. In these cases, the Court concluded that the compulsory healthcare insurance schemes at issue were not undertakings since they pursued a social objective and embodied the principle of solidarity. In reaching this conclusion, in the *Poucet and Pistre* case,[1246] the Court elaborated on the principle of solidarity. Solidarity, the Court said, entails the *redistribution of income* between those who are better off and those who, in view of their resources and state of health, would be deprived of the necessary social cover.[1247] The Court held that the schemes at issue were fulfilling an exclusively social function in the discharge of their legally defined duties and therefore could not be considered undertakings. In concluding, the Court took into account that (a) contributions were compulsory[1248] and proportional to the members' income regardless of the member's state of health[1249] (b) benefits were identical for all those who received them and (c) the schemes in surplus contributed to the financing of those with structural financial difficulties.[1250]

In the same vein, in the *INAIL* case,[1251] the Court found that a compulsory scheme providing workers' compensation insurance operated on the principle of solidarity, since the benefits

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[1241] FENIN *supra* n. 1222, para 8.
[1242] *Ibid*., paras 25-28.
[1243] Joined Cases C-159/91 and 160/91, Poucet and Pistre [1993] ECR I-637.
[1244] Case C-218/00, INAIL [2002] ECR I-691.
[1245] AOK Bundesverband v Ichthyol Gesellschaft Cordes (C-264/01, C-306/01, C-354/01 & C-355/0I) [2004] E.C.R. 1-2493.
[1246] Joined Cases C-159/91 and 160/91, Poucet and Pistre *supra* n. 1226, para 3.
[1247] *Ibid*, para 10.
[1248] *Ibid,* para 13.
[1249] *Ibid*, para 10.
[1250] *Ibid*, para 12.
[1251] Case C-218/00, INAIL [2002], *supra* n. 1244.

paid to insured persons were not strictly proportionate to the contributions paid by them and contribution levels were defined by law and were subject to supervision by the State.[1252] The Court stressed that the absence of any direct link between the contributions paid and the benefits granted entails solidarity between better paid workers and those who, given their low earnings, would be deprived of proper social cover if such a link existed.[1253] Because of this element, the Court held that the *INAIL* fulfils an exclusively social function and therefore its activity is not an economic one for the purposes of competition law.[1254]

In the *AOK* case in examining whether the fixing of maximum contributions by the German health insurance funds towards the costs of medicinal products was illegal under the European competition rules, the Court conducted a similar analysis.[1255] The Court found that the insurance funds at issue fulfilled an exclusively social function as they were entirely not profit making and they operated on the basis of the principle of solidarity.[1256] In drawing this conclusion, the Court particularly took into account that it was obligatory for the employees to be insured under the statutory health insurance scheme.[1257] The Court also considered that the social schemes at issue implemented a risk equalization system which made sickness funds insuring the least costly risks contribute to the financing of those insuring more onerous risks.[1258] Interestingly, in this case the Court concluded that the social schemes at issue operated on the basis of the solidarity principle and therefore were not engaged in an economic activity although (a) the insurance premiums did not only depend on the income of the insured party but also on the rate set by the insurance company (b) the sickness funds were in competition with regards to contribution rates in order to attract people for whom insurance under the scheme was obligatory and those for whom it was voluntary.[1259]

In a nutshell, in all the above cases, the Court thought that the social schemes operated under the solidarity principle since: (a) the insurance schemes covered all members of the risk group,

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[1252] *Ibid*, 43-44.
[1253] *Ibid.*, 42-45.
[1254] *Ibid*, 45.
[1255] AOK Bundesverband v Ichthyol Gesellschaft Cordes, *supra* n. 1245,
[1256] *Ibid*, paras 49-55.
[1257] *Ibid.*, para. 6.
[1258] *Ibid*, para 10.
[1259] According to the applicable statute insured persons might freely choose their sickness fund as well as their doctor or the hospital in which they had treatment, *ibid*, paras 8, 56.

irrespective of their risk profile; (b) contributions were proportional to income; (c) the old-age scheme was financed as a pay-as-you-go system; (d) the loss-making schemes were compensated by the profitable ones.[1260] Most importantly, in all these cases, the compulsory affiliation was held to be both an inherent feature and a logical consequence of the solidarity principle.[1261] Obviously, in these cases the Court excluded healthcare funds' activity from the application of competition law in order not to allow competition to obstruct their performance. Access to healthcare services to the most vulnerable groups of a society would be obstructed if redistribution of income between those who are better off and those who are deprived of the necessary social cover did not take place. In balancing two conflicting objectives, solidarity and access to healthcare services against choice and competition between healthcare funds, the Court took the view that the choice of healthcare funds by the healthier and wealthier parts of a society should be restricted so that access to healthcare services is ensured for all parts of the society regardless their ability to pay.

- **The restrictive approach regarding Article 101 TFEU**

Another technique by which European Courts have accommodated conflicting policy objectives is by establishing the principle that competition rules should be interpreted '*in light of the Treaty as a whole*'.[1262] Under this approach any competition law assessment must first examine the overall context in which the agreement was concluded and more particularly its legal and economic context. On the basis of this principle, the European Courts have excluded agreements from the application of Article 101(1) TFEU on the basis they pursue a legitimate objective. In the *Albany*[1263] case for instance, the Court examined whether a decision made by the organizations representing employers and workers in a given sector, in the context of a collective agreement, to set up in that sector a single pension fund responsible for managing a supplementary pension scheme and to request the public authorities to make affiliation to that fund compulsory for all workers in that sector was contrary to Article 101 TFEU.[1264] The Court held that certain restrictions of competition are

[1260] A. Winterstein, 'Nailing the Jellyfish: Social Security and Competition Law', (1999) 23 *European Competition Law Review* 324, 329.
[1261] *Ibid*, 11.
[1262] C. A., Witt, 'Public Policy Goals Under EU Competition Law—Now is the Time to Set the House in Order', (2012) 8(3) *European Competition Journal*, 443, 458.
[1263] Case C-67/96 Albany International [1999] ECR I-5751.
[1264] *Ibid*, at 53.

inherent in collective agreements between organizations representing employers and workers.[1265] The Court also held that the social policy objectives pursued by such agreements would be seriously undermined if management and labour were subject to Article 101 (1) TFEU.[1266] It concluded that the agreements reached in the context of collective negotiations between management and labour *in pursuit of such objectives* should by virtue of their nature and purpose, be regarded as falling outside the scope of Article 101(1) TFEU.[1267]

A few years later, in the *Wouters*[1268] case, the Court undertook a similar analysis when it examined to what extent a Dutch Regulation adopted by the Bar of the Netherlands which prohibited multidisciplinary partnerships between members of the Bar and accountants was compatible with article 101 TFEU.[1269] The Court took the view that the regulation in question constituted an agreement of an association of undertakings which restricted competition. Nonetheless, it alleged that this restrictive effect had to be assessed in the light of the objectives of the regulation in question, namely the protection of the integrity of the legal services.[1270] The Court said: 'For the purposes of application of that provision to a particular case, account must first of all be taken of the *overall context* in which the decision of the association of undertakings was taken or produces its effects. More particularly, account must be taken of its objectives, which are here connected with the need to make rules relating to organization, qualifications, professional ethics, supervision and liability, in order to ensure that the ultimate consumers of legal services and the sound administration of justice are provided with the necessary guarantees in relation to integrity and experience. It has then to be considered whether the consequential effects restrictive of competition are inherent in the pursuit of those objectives'.[1271] The Court concluded that the regulation's restrictions did not go beyond what was necessary for the protection of the proper practice of the legal profession. Consequently, there was no breach of Article 101 (1).[1272]

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[1265] *Ibid*, at 58.
[1266] *Ibid,* at 59.
[1267] *Ibid,* at 60.
[1268] Case C-309/99 Wouters v Algemene Raad van de Nederlandse Orde van Advocaten [2002] ECR I-1577.
[1269] *Ibid,* para 15-17.
[1270] G Monti, 'Article 81 and public policy', (2002) 39(5) *Common market law review*, 1087.
[1271] Case C-309/99 Wouters *supra* n. 1268, para 97.
[1272] *Ibid*, para 109. The *Wouters* approach was also recently followed in Case C-1/12, Ordem dos Técnicos Oficiais de Contas v Autoridade da Concorrência, in relation to the quality of chartered accountant services with the aim of

The same line of legal reasoning can be found in *Meca - Medina*.[1273] In this case rules relating to anti-doping tests by the International Olympic Committee were challenged by two professional swimmers who tested positive during a World Cup competition.[1274] The Commission, after analyzing the anti-doping rules at issue according to the assessment criteria of competition law and concluding that those rules did not fall foul of the prohibition under Articles 101 and 102 TFEU, rejected the applicants' complaint,[1275] a decision confirmed by the General Court.[1276] The Court of Justice found that even if the anti-doping rules at issue were to be regarded as a decision of an association of undertakings limiting the athletes' freedom of action, they do not constitute a restriction of competition incompatible with the common market, within the meaning of Article 101 TFEU, since they were justified by a legitimate objective, the need to safeguard equal chances for athletes, athletes' health, the integrity and objectivity of competitive sport and ethical values in sport.[1277] However, it should be pointed out that the Court of Justice did not follow the General Court's findings that the rules were as such outside the scope of competition law but instead adopted the *Wouters* approach by using a proportionality test to find that article 101(1) TFEU was not infringed. In the *ONP* case the Commission examined a non-economic defence under Article 101(1).[1278] This case concerned the decision by the Ordre National des Pharmaciens (ONP), the professional body of pharmacists in France, to impose minimum prices on the French Market for clinical laboratory tests.[1279] According to the *ONP*, imposing a minimum price was necessary to protect public health and safety. The Commission did not assess the claim under article 101(3) but under Article 101(1) where it considered whether the agreement should fall outside the scope of Article 101(1) according to the exception established by the Court in the *Wouters* line of case law.[1280] The Commission decided that the *Wouters* exception did not apply in this case. Unlike the Dutch bar association in *Wouters*, the *ONP* had no

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attaining sound administration of companies' accounting and taxation issues. Nonetheless, in this case the Court considered that the restriction was not necessary for the pursuit of the claimed objective, see paras 93-100.

[1273] Case C-519/04 P David Meca-Medina and Igor Majcen v Commission of the European Communities.

[1274] *Ibid*, 8.

[1275] *Ibid*, at 20.

[1276] *Ibid*, at 11.

[1277] *Ibid*., at 43.

[1278] *ONP* case 39.510, the case is not available in English.

[1279] A. Wit, *The More Economic Approach to EU Antitrust Law* (Oxford, Hart Publishing, 2016) 172.

[1280] *Ibid.*

regulatory powers for conduct in question.[1281] Also it considered that the existing legislation relating to laboratory tests was sufficient to safeguard public health and safety and that the French State would have intervened if this had not been so. In other words, the Commission did not consider the ONP's actions proportionate. Its assessment under Article 101(3) was limited to stating that ONP had not submitted any evidence that suggested that the conditions for exemption under article 101(3) which required economic advantages benefiting consumers could be fulfilled.[1282]

It is worth noting that the Court in these cases referred in general to the need to achieve legitimate objectives (not public objectives) which meant that competition law was not infringed.[1283] Hence, in areas other than healthcare, the Court seems to have developed an approach that is capable of accommodating issues of general interest in the application of EU competition law.[1284] To the extent certain restrictions of competition are inherent in the pursuit of specific public policy objectives competition law is not infringed. Evidently since in healthcare the pursuit of public policy objectives, such as equity, are often incompatible with the pursuit of competition, a similar approach can actually be adopted by competition authorities also in healthcare.

## 3.2 How can healthcare quality be taken into account on the basis of article 101 (3) TFEU?

### 3.2.1 The Commission's main policy before the modernization of EU competition law

The conditions for taking public policy goals into account have fundamentally changed with the entry into force of Regulation 1/2003.[1285] Under the old regime, the Commission, in its dual function as enforcement agency endowed with a monopoly for granting exceptions under Article 101(3) and a policy making institution, enjoyed broad discretion in applying Article 101(3).[1286] The Commission repeatedly came across cases in which the parties argued that their agreement should be

[1281] *Ibid*, at 173.
[1282] *Ibid.*
[1283] L. Hancher, W. Sauter, *supra n.* 30, at 239.
[1284] *Ibid.*
[1285] H. Schweitzer, 'Competition law and Public Policy: Reconsidering an Uneasy Relationship', *EUI Law Working Papers Law 2007/30*, 5.
[1286] *Ibid.*

exempted from the prohibition of Article 101(1) TFEU as it generated benefits that were actually recognized and protected by other Treaty provisions.[1287] Their claim was essentially based on Article 101(3) TFEU, which stipulates that certain types of beneficial effect generated by an otherwise anticompetitive agreement are capable of exonerating the agreement's restrictive effects, as long as the agreement allows consumers a fair share of the benefits, does not impose restrictions that are not indispensable to the attainment of the benefits and does not enable the undertakings to eliminate competition in respect of a substantial part of the products in question.[1288] The types of benefit referred to in Article 101(3) TFEU are the 'improvement of the production or the distribution of goods' and the 'promotion of technical or economic progress.'[1289]

In evaluating the parties' claim and applying article 101(3) TFEU, while the Commission did not exclude the possibility of taking public policy goals into account, it made use of this possibility rather cautiously.[1290] Such examples are the Commission's *Synthetic Fibres,*[1291] the *Stichting Baksteen,*[1292] the *Ford/VW,*[1293] *the Philips and Osram* [1294] and the *Exxon/Shell* [1295] decisions.

In the *Stichting Baksteen* case[1296] the Commission examined agreements between competitors designed to restructure an industry faced with structural overcapacity (so-called *'crisis'* cartels).[1297] In applying article 101 (3) TFEU the Commission found that this agreement promoted technical and economic progress and should therefore be exempted from the application of article 101(1) TFEU. In reaching this conclusion, the Commission particularly considered that due to the closure of the least efficient production units, production would in future be concentrated in the more modern plants, which would then be able to operate at higher capacity and productivity levels.[1298] The Commission also recognized that since the agreement provided for a coordinated closure of the least

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[1287] C. A. Witt, *supra* n. 1262, 446.
[1288] *Ibid.*
[1289] *Ibid.*
[1290] H. Schweitzer, *supra* n. 1285, 5.
[1291] Commission decision of 4 July 1984, Case IV / 30.810—Synthetic Fibres [1984] OJ L207/17.
[1292] Commission decision of 29 April 1994, Case IV / 34.456—Stichting Baksteen [1994] OJ L131/15.
[1293] Commission decision of 23 December 1992, Case IV/33.814—Ford/Volkswagen [1993] OJ L20/14.
[1294] Commission decision of 21 December 1994, Case IV/34.252—Philips/Osram [1994] OJ L378/37.
[1295] Commission Decision of 18 May 1994, Case IV/33.640—*Exxon/Shell* [1994] OJ L144/20.
[1296] Case IV / 34.456—Stichting Baksteen, *supra* n. 1292.
[1297] G. Monti, *supra*. 1270, at 1071.
[1298] Case IV / 34.456—Stichting Baksteen, *supra* 1292, para. 26.

efficient production units, restructuring would be carried out in acceptable social conditions, including the redeployment of employees.[1299] In a similar manner, in the *Synthetic Fibres* case[1300] the Commission exempted a capacity reduction agreement considering it would lead to product specialization, technical efficiency and innovation.[1301] Again, in applying Article 101(3), the Commission stressed that the coordination of plant closures would make it easier to cushion the social effects of the restructuring by making suitable arrangements for the retaining and redeployment of workers made redundant.[1302]

In the *Ford/VW* case[1303] the Commission examined an agreement between the two motor vehicle manufacturers Ford and Volkswagen on the setting up of a joint venture company for the development and production of a multi-purpose vehicle in Portugal.[1304] Taking the view that the analyzed agreement would actually improve the production of goods through the rationalization of product development and manufacturing, the Commission exempted the joint venture agreement on the basis of Article 101 (3) TFEU. The Commission underlined that both parties of the agreement had extensive know-how in the field of research and car automation and that their cooperation would allow them to complement one another as to their technical expertise.[1305] Interestingly, in shaping its view, the Commission underlined that the joint venture would lead to the creation of about 5000 jobs and would attract investment in the supply industry.[1306] By linking Portugal more closely to the Community through one of its important industries, it would also contribute to the promotion of the harmonious development of the Community and the reduction of regional disparities, one of the essential objectives of the Treaty.[1307] Nevertheless, the Commission did clarify that '*this would not be enough to make an exemption possible'* unless the conditions of Article 85 (3) were fulfilled, but it is an element which the Commission has taken into account'.[1308]

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[1299] *Ibid* para. 27.
[1300] *Ibid* para. 15.
[1301] *Ibid* para. 35.
[1302] *Ibid* para. 37.
[1303] Case IV/33.814—Ford/Volkswagen, *supra* n. 1293.
[1304] *Ibid* para 1.
[1305] *Ibid* para 25.
[1306] *Ibid* para 36.
[1307] *Ibid* para 36.
[1308] *Ibid* para 36.

In the *Philips Osram*[1309] case the Commission exempted a joint venture agreement between *Philips* and *Osram* regarding the manufacture and sale of certain lead glass tubing and components for incandescent and fluorescent lamps.[1310] The Commission found the agreement anticompetitive. Considering, however, that it would contribute to the rationalization of production through the elimination of obsolete facilities and would result in lower total energy usage and a better prospect of realizing energy reduction and waste emission programmes, the Commission, again, exempted the agreement on the basis of article 101(3) TFEU.[1311]

Similarly, in the *Exxon/Shell*[1312] case, the Commission exempted a joint venture for the production of polyethylene concluding that the analyzed agreement would result in a reduction of customers' use of raw materials, their costs and the volume of plastic wastes.[1313] To the Commission, it would additionally reduce the health and environmental risks inherent in the transport of polyethylene.[1314] Interestingly, the Commission noted that the reduction in the use of plastic waste '*would be perceived as beneficial by many consumers at a time when the limitation of natural resources and threats to the environment are of increasing public concern*'.[1315]

### 3.2.2 The main policy after the modernization of EU Competition Law

After a long process that officially started in April 1999[1316] and ended up with the publication in the Official Journal of the *'Modernization Package"* and the procedural reform of EU competition law,[1317] the Commission started diverting from its initial policy substantially. In the brave new world of modern antitrust enforcement, the Commission was willing to accept only one currency: *economic efficiency*.[1318]

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[1309] Case IV/34.252—Philips/Osram [1994], *supra* n. 1294
[1310] *Ibid*, para 1.
[1311] *Ibid* para 25.
[1312] Case IV/33.640—Exxon/Shell [1994], *supra* n. at. 1295.
[1313] *Ibid.,* para 67-68, C. A Witt, *supra* n. 1262, 451.
[1314] *Ibid.*, para 68.
[1315] *Ibid*, para 71.
[1316] Commission White Paper of 28 April 1999 on Modernization of the Rules Implementing Articles 85 and 86 of the EC Treaty, COM(1999) 101 final, OJ [1999] C132/1; A. Komninos, 'Non-competition Concerns: Resolution of Conflicts in the Integrated Article 81 EC', University of Oxford Centre for Competition Law and Policy, *Working Paper (L) 08/05*, 2.
[1317] *Ibid.*
[1318] B. Van Rompuy, *supra* n 512.

Setting the stage for the application of its new *more economic approach,* in 1999, the Commission published a White Paper on the modernization of the rules implementing Articles 101 and 102 TFEU.[1319] The prior authorization system established by Regulation 17, which had conferred upon the Commission the exclusive power to authorize notified agreements and apply Article 101(3) TFEU, had become unmanageable in a Community of 15.[1320] Following the recommendations of the White Paper, Regulation 1/2003 eventually abolished the authorization system entirely and made the national competition authorities the primary enforcers of Articles 101 and 102 TFEU.

Arguably, although it was not the direct aim of the White Paper to change substantive competition law as such,[1321] in fact it did. This is because the White Paper contained two interesting comments on the substantive interpretation of the competition rules.[1322] First, it stated that the Commission, in its handling of individual cases, would adopt a more economic approach to the application of Article 101(1) TFEU, which would limit the scope of its application to undertakings with a certain degree of market power.[1323] Second, it underlined that the purpose of Article 101(3) was to provide a legal framework for the *economic* assessment of restrictive practices rather than to let the competition rules be set aside because of political considerations.[1324] Under the old regime, an essential facet of the Commission's decision making practice was its broad margin of discretion. Under the new regime, this facet could not survive.[1325]

The movement towards a more economic approach was soon reflected in the Commission's soft law instruments: its guidelines and notices. More specifically, in its 2004 Guidelines on the application of Article 81(3) (now 101(3)), the Commission spelt out that the goal of the cartel prohibition is the protection of consumer welfare.[1326] The objective of Article 101 TFEU, the Commission said, is to protect competition on the market as a means of enhancing consumer

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[1319] C. A. Witt, *supra* n 1262, 453.
[1320] *Ibid.*
[1321] A. Komninos, *supra* n. 1316, 2.
[1322] C. A. Witt, *supra* n 1262, 453.
[1323] White Paper on Modernization of the Rules Implementing article 85 and 86 of the EC Treaty, para 78.
[1324] *Ibid.*, para 57.
[1325] H. Schweitzer., *supra* n. 1285, 8.
[1326] B. Baarsma, 'Rewriting European Competition Law from an Economic Perspective', (2011) 7(3) *European Competition Journal*, 559-585.

welfare and of ensuring an efficient allocation of resources.[1327] Interestingly, the draft version of the 2004 Guidelines on article 81(3) stated that 'it is not, on the other hand, the role of Article 101 TFEU and the Authorities enforcing this Treaty provision to allow undertakings to restrict competition in the pursuit of general interest aims'.[1328] Nonetheless, this passage was softened in the final version of the Guidelines: 'Goals pursued by other Treaty provisions can be taken into account to the extent that they can be subsumed under the four conditions of Article 101(3).'[1329]

The Commission's new *more economic approach* substantially transformed also its view on what type of advantages may outweigh an agreement's anticompetitive effects in the context of article 101 (3) TFEU. More specifically, again, in its 2004 Guidelines on Article 101 (3) TFEU, the Commission advocates a narrow interpretation of Article 101 (3) TFEU that mainly accepts quantifiable, efficiency benefits under the first condition of that provision.[1330] The Guidelines make clear that the purpose of the first condition of Article 101(3) is to define *the types of efficiency gains* that can be taken into account and be subject to the further tests of the second and third conditions of Article 101(3). The aim of the analysis is to ascertain what are the objective benefits created by the agreement and what is the economic importance of such efficiencies.[1331] Given that for Article 101(3) TFEU to apply the pro-competitive effects flowing from the agreement must outweigh its anti-competitive effects, it is necessary to verify what is the link between the agreement and the claimed efficiencies and what is the value of these efficiencies'.[1332] These efficiencies can be either cost efficiencies or efficiencies of qualitative nature that create value in the form of new or improved products or greater product variety.

Surely, the emphasis on economic efficiency gains within the scope of Article 101(3) is neither surprising nor ground breaking.[1333] Many exemption decisions from the early years were based on exactly such efficiency effects. Nonetheless, the novelty lies in the fact that the guidelines consider

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[1327] Commission's Guidelines on the application of article 81 (3) of the EC Treaty, *supra* n., para 13.
[1328] J. Nowag, *Environmental Integration in Competition and Free Movement Laws* (Oxford, Oxford University Press, 2016) 230-231, Draft Commission Notice - Guidelines on the Application of Article 81(3), para 38.
[1329] *Ibid*, 42.
[1330] *Ibid*, paras 49-50.
[1331] *Ibid* para 50.
[1332] *Ibid.*
[1333] A. Wit, *supra* n. 1279, 166.

no other effect capable of offsetting competitive harm.[1334] Therefore, one can conclude from these Guidelines that social benefits, industrial policy considerations, environmental benefits, the reduction of regional disparities or furthering the harmonious development of the Union, cannot as such outweigh an agreement's anticompetitive effects[1335]

This is also reflected in the Commission's decision - making practice after the introduction of the White Paper and the subsequent *Modernization* of EU Competition law. In the new *more economic approach* era, where decisions assess an agreement's alleged beneficial effects, they take into account economic efficiencies only. The *French beef market* case[1336] perfectly reflects this change. In this case, the Commission examined an agreement concluded by six French federations the main purpose of which was to set a minimum purchase price for certain categories of cattle and suspend imports of beef into France.[1337] The agreement was concluded as a response to the sharp drop in beef consumption in Europe after the mad cow disease crisis. The Commission found that the agreement had the object of restricting competition.[1338] The Commission did not examine whether the analyzed agreement may be exempted under Article 101(3) TFEU since the parties had not formally sought an exemption.[1339] It did, however, grasp the opportunity to highlight that even if the examined agreement had been notified, it would not have qualified for exemption as 'it is well established that exemption can be granted only when the four tests of Article 81(3) of the Treaty are all satisfied'.[1340]

Since the *French Beef case*, the Commission has not discussed industrial or social policy benefits in an actual decision.[1341] In fact, while no actual case presented itself, at Union level, the Commission grasped the opportunity to expose its views on Commission's stance with regards to crisis cartels in a case pending before the Irish High Court in 2010.[1342] The case involved another restructuring agreement, this time in the Irish beef Industry, which was also suffering from

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1334 *Ibid.*
1335 *Ibid.*
1336 Commission Decision of 2 April 2003, Case COMP/C. 38.279/F3—French Beef OJ [2003] L209/12.
1337 *Ibid*, para 1.
1338 *Ibid*, para 127.
1339 *Ibid* para 130.
1340 *Ibid.*
1341 A. Wit, *supra* n. 1279, 169.
1342 *Ibid.*

significant overcapacity following another outbreak of BSE.[1343] In this case, the Commission identified the efficiencies an agreement aiming to reduce overcapacity can achieve.[1344] It noted that a restructuring agreement that cuts capacity by facilitating the complete exit of certain players from the market can lead to cost savings, if the remaining parties increase output and capacity utilization.[1345] However, it clarified that so called 'crisis cartels' aiming to reduce overcapacity cannot be justified by economic downturns and recession induced falls in demand.[1346] The Commission stressed that competition in periods of crisis may force the least efficient undertakings to exit a market and this is part of the competitive process. However, the Commission did not exclude the possibility of granting an exemption in situations where market forces alone cannot solve the overcapacity problem.[1347] Once again, the conclusion one can draw from this submission is that the only types of benefit the Commission now considers relevant in the assessment of restructuring agreements under Article 101(3) TFEU are indeed economic efficiencies.[1348] In applying Article 101(3), employment or other social concerns no longer seem to enter into the equation.

The *CECED* case[1349] also reflects the Commission's commitment to applying a more economic approach with regards to article 101(3) TFEU. Nonetheless, it reflects at the same time the Commission's commitment to fostering environmental objectives through competition law.[1350] This case concerned an agreement that was entered into by most manufacturers of washing machines in Europe and was designed to phase out washing machines which consumed high quantities of electricity.[1351] This agreement was considered anticompetitive for mainly two reasons: First, because it reduced consumer choice. Second, because those manufacturers without any expertise in building the more energy-efficient washing machines would be at a competitive disadvantage as they adapted to the new market conditions.[1352] The Commission, however, granted

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[1343] *Ibid.* Bovine Spongiform Encephalopathy.
[1344] Observations of the Commission under article 15, para 3 of Regulation 1/2003 in 2003 No 7764P, the Competition Authority v. Beef Industry Development Society LTC (BIDS), available at: http://ec.europa.eu/competition/court/amicus_curiae_2010_bids_en.pdf.
[1345] *Ibid,* 24-28.
[1346] *Ibid*, 33.
[1347] *Ibid,* 35-39.
[1348] A. Wit, *supra* n. 1279, 169.
[1349] Commission Decision of 24 January 1999, Case IV.F.1/36.718—CECED [2000] OJ L187/47.
[1350] G. Monti, *EC Competition law* (Cambridge: Cambridge University Press, 2007) 92.
[1351] *Ibid*, para 23
[1352] *Ibid* para 30-37.

an exemption considering that the agreement would lead to reduced energy generation and pollution. As the Commission argued, the future operation of the total of the installed machines providing the same service with less indirect pollution would be more economically efficient than without the agreement.[1353] In its analysis it highlighted both the individual and the collective benefits of the agreement: As to the individual economic benefits the Commission stressed that savings on electricity bills would allow the consumers to recoup the increased costs of upgraded, more expensive washing machines within nine to forty months.[1354] As to the agreement's collective benefits, the Commission noted: 'According to Article 174 of the EC Treaty, environmental damage should be rectified at source. The Community pursues the objective of a rational utilization of natural resources, taking into account the potential benefits and costs of action. Agreements like *CECED*'s must yield economic benefits outweighing their costs *and be compatible with competition rules. Although electricity is not a scarce resource and consumption reductions do not tackle emissions at source, account can also be taken of the costs of pollution.'*[1355] The Commission then estimated the savings in marginal environmental damage from avoided emissions, and found on the basis of 'reasonable assumption' and *CECED's* estimates that the benefits to society yielded by the agreement would be at least seven times greater than the increased purchase cost of more energy-efficient washing machines.[1356] These environmental advantages for society, the Commission said, would adequately allow consumers a fair share of the benefits, even if no benefits accrued to individual purchasers of washing machines.[1357]

Monti suggests that there are two methods to interpret the combination of economic and ecological considerations.[1358] The first, drawing on ecological modernization theories, suggests that the environment has an economic value. The environmental costs and benefits of a practice are as economically relevant as its impact on other aspects of economic efficiency. In this light, *CECED* actually *widens the notion of economic efficiency* to take into account an agreement's positive impact on sustainable development.[1359] This interpretation is consistent with the Commission's stance on the

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[1353] *Ibid* para 48.
[1354] *Ibid* para 52-53.
[1355] *Ibid*., 55.
[1356] *Ibid* para 56.
[1357] *Ibid.*
[1358] G. Monti, *supra* n. 1350, 93.
[1359] *Ibid.*

White Paper of 1999 that Article 101(3) is to provide a legal framework for the *economic* assessment of restrictive practices. A second method to interpret the role of environmental protection in competition cases is to suggest that the duty imposed by Article 11 TFEU to integrate environmental protection in the EU policies and activities means that environmental protection is normatively superior to EU competition law and thereby act as a trump to justify even anticompetitive agreements if they are necessary to safeguard the environment.[1360] Whatever the interpretation, as *CECED* is the first case where the Commission was engaged in the economic quantification of environmental benefits[1361] in order to exempt an agreement on the basis of Article 101(3) TFEU, the point the Commission wishes to make through *CECED* is clear: environmental concerns matter as long as they are 'calculated' and translated into efficiency gains.[1362]

One year after *CECED*, in *DSD*, the Commission granted an individual exemption on the basis that the agreement, in addition to generating economies of scale, gave 'direct practical effect to environmental objectives' laid out in Community Law by a Directive on 'Packaging Waste'.[1363] The Commission noted: 'There are positive network effects in the collection of household packaging waste, and substantial scale and scope advantages can be achieved, so that to entrust collection to a single collector for the duration of the agreement produces gains in efficiency. At the same time *DSD*, the purchaser of the service, is given the assurance that its requirements can be met on a regular and reliable basis, in a sensitive area which was previously organized under public law'.[1364] This decision indicates the increased significance that achieving environmental goals through private agreements plays in the eyes of the EU.[1365] The Commission took the same approach in *EASE* where 16 major manufacturers of video recorders and televisions had made a voluntary commitment to reduce the electricity consumption of televisions and video recorders when they are in standby mode. Noting that the energy saving and environmental benefits of the scheme clearly represented

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[1360] *Ibid.*, 94.
[1361] J. Nowag, *supra* n. 1328, 230.
[1362] A. Maziarz, 'Do Non - Economic Goals count in interpreting Article 101(3)?' (2014) 10(2) *European Competition Journal*, 341, 351.
[1363] G. Monti, *supra* n. 1270, at 1074, DSD O.J. 2001 L 319/1.
[1364] O.J. 2001 L 319/1 para 145.
[1365] G. Monti, *supra* n. 1270, 1074.

technical and economic progress and, by their nature, would be passed on to consumers, the Commission closed the case via a comfort letter.[1366]

### 3.2.2 The Court's Broad Approach to Article 101(3) TFEU

In contrast with the Commission's more economic approach which following the modernization of EU Competition law exempts agreements from the application of Article 101 (3) TFEU only to the degree they create efficiencies, the Court keeps adhering to a formula coined in the 1960s, according to which an agreement can be exempted to the extent it yields 'appreciable objective advantages of such a kind as to compensate for the resulting disadvantages for competition'.[1367] This formula is found in the *Grundig-Verkaufs-GmbH v Commission* case where the Court held that '… *the content of the concept of improvement is not required to depend upon the special features of the contractual relationships in question. This improvement must in particular show appreciable objective advantages of such a character as to compensate for the disadvantages which they cause in the field of competition'*.[1368] A similar, broad interpretation of the concept of improvement was also adopted by the Court in a more recent case of 2009, the *GlaxoSmithKline v Commission* case, where the Court once again held that 'in order to be capable of being exempted under Article 101(3) TFEU, an agreement must contribute to improving the production or distribution of goods or to promoting technical or economic progress. That contribution is not identified with all the advantages which the undertakings participating in the agreement derive from it as regards their activities, *but with appreciable objective advantages of such* a *kind as to compensate for the resulting disadvantages for competition'*.[1369]

Nothing in the Court's approach suggests that the appreciable objective advantages article 101(3) TFEU requires are limited to increases in material consumer welfare.[1370] In contrast,

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[1366] European Commission, XXVIIIth Report on Competition Policy 1998, Published in conjunction with the `General Report on the Activities of the European Union 1998'), 152.
[1367] A. Witt, *supra* n. 1262, 468.
[1368] Judgment of the Court of 13 July 1966. - Établissements Consten S.à.R.L. and Grundig-Verkaufs-GmbH v Commission of the European Economic Community. - Joined cases 56 and 58-64.
[1369] Judgment of the Court (Third Chamber) of 6 October 2009. GlaxoSmithKline Services Unlimited v Commission of the European Communities (C-501/06 P) and Commission of the European Communities v GlaxoSmithKline Services Unlimited (C-513/06 P) and European Association of Euro Pharmaceutical Companies (EAEPC) v Commission of the European Communities (C-515/06 P) and Asociación de exportadores españoles de productos farmacéuticos (Aseprofar) v Commission of the European Communities (C-519/06 P) para. 92.
[1370] A. Witt., *supra* n. 1262, 468.

the Court's definition does not even stipulate that the advantages in question must be of an economic nature.[1371] Therefore in interpreting the types of benefits an exemption under article 101 (3) TFEU requires, the Court, diverting from the Commission's more economic approach, takes the view that a broader notion of consumer welfare is possible.

## 4. How can healthcare quality be evaluated on the basis of these techniques as a whole?

In light of the above analysis it may be concluded that there are two basic approaches under which the non-economic facets of healthcare quality can be taken into account under an Article 101 TFEU analysis: the Commission's more economic approach on the basis of article 101(3) TFEU and the Court's *wider*, more *pluralistic* approach under Articles 101(1) and (3).[1372] Under the Commission's approach, a competition assessment may primarily focus on arguments related to market structure, efficiencies and consumer welfare.[1373] In contrast, under the Court's approach economic analysis plays a crucial role, but non-competition concerns and social objectives are not excluded from its competition assessment.[1374] In light of the analysis in the previous section, this section delves into the question of whether and how the protection of the non-economic dimensions of healthcare quality, such as equity, could be considered under both approaches.

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[1371] *Ibid.*

[1372] In EU Member States, such as the UK and the Netherlands, where competition has been introduced in their health systems through procompetitive regulation, it is highly unlikely that healthcare providers or purchasers of NHS services will not be considered undertakings. This is the reason why this legal technique is not discussed separately in this section. This legal technique of protecting healthcare quality through the exclusion of the application of competition law may be adopted by competition authorities only in jurisdictions where there is no specific procompetitive regulation that introduces competition in the health system, such as Italy and Greece.

[1373] S. Lavrijssen, 'What role for national competition authorities in protecting non-competition interests after Lisbon?' (2010) 35(5) *European Law review*, 636, 640.

[1374] *Ibid.*

## 4.1 Integrating healthcare quality in the context of the Commission's *more economic approach*

In general, public policy objectives may be taken into account by Competition Authorities in Europe on the basis of article 101(3) in accordance with the Commission's economic assessment in the *CECED* case. The agreement at issue in this case was entered into by most manufacturers of washing machines in Europe and was designed to phase out washing machines which consumed high quantities of electricity.[1375] The Commission found the agreement anticompetitive. Nonetheless, the Commission exempted the agreement from the application of article 101 TFEU as it would reduce energy generation and pollution. Interestingly, in its assessment the Commission alleged that agreements like *CECED* may yield economic benefits outweighing their costs and therefore could be compatible with competition rules. In this case the Commission did not apply an intensive proportionality test when assessing whether the agreement qualified for exemption: it examined other, less restrictive means to realize the environmental benefits concerned, though not in an in-depth way.[1376] Commentators have argued with regard to the protection of the environment that the Commission *is willing to adopt a broad welfare approach.*[1377] Accordingly, environmental benefits can be translated into economic values that are of importance for consumers and that can, like productive efficiencies, be directly balanced as independent factors against the restriction of competition.[1378] This approach is justified by the high priority that both TEU and TFEU place on sustainable development.[1379] As the Commission in this case translated reduced pollution levels into *efficiencies*, in an analogous manner, competition authorities in Europe could translate for example reduced harm to safety or increased access to healthcare services into efficiencies. *Is this mission possible?*

Prior to answering this question, we should first discriminate between cases where the concept of efficiency may conflict with some non-economic facets of healthcare quality, such as

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[1375] *CECED*, *supra* n. 1349, para 23
[1376] S., Lavrijssen, *supra* n. 1373, 643.
[1377] *Ibid.*, G. Monti, *supra* n. 1270, at 1075.
[1378] S., Lavrijssen*, supra n.* 1373*,* 643.
[1379] *Ibid.*

equity, and cases where they may in fact align. To elaborate on my argument, I provide an example. In the UK, the purchasers of NHS services may agree to buy more elective care from NHS hospitals that offer risky non-elective services in poor urban areas so that these hospitals can cross-subsidize their more costly non-elective services. These bodies may argue that their anticompetitive agreement ensures hospitals' financial stability and therefore increases access for all parts of our society and it should therefore be exempted on the basis of article 101(3) TFEU. Should competition authorities in this case translate the protection of equity or increased access into efficiencies? I believe that in this case competition authorities may not have to perform this task in order to integrate equity concerns into their analysis as this agreement may not only increase access for the disadvantaged groups of a society but it may also yield productive and allocative efficiencies. As explained in the first chapter, allocative efficiency is achieved when resources are allocated so that the welfare of the *community* is maximized. If the agreement at issue aims to guarantee the financial stability of hospitals that are located in urban areas then access to risky and complex non-elective surgeries is ensured not only for the disadvantaged groups of a specific geographic area but *for the community as a whole*. In this case the objectives of efficiency and equity may align and therefore equity concerns may not have to be translated into a broader concept of efficiencies. In other cases, however, especially when the notion of safety, continuity or acceptability is at stake, competition authorities may indeed have to translate these notions into a wider notion of qualitative efficiencies in order to grant an exemption on the basis of article 101(3) TFEU. They might for example have to take the view that the protection of continuity and trust in the patient-doctor relationship improves health outcomes and safety or that a restriction of choice may be necessary so that health improvements are achieved. To highlight my point, again, I provide an example. As noted, GPs in the UK act as gatekeepers too. In performing this role and in agreement with the purchasers of NHS services, they may boycott specific hospitals that do not meet their standards of healthcare quality by not referring patients to these hospitals. In this case, Competition Authorities could take the parties' agreement quality argument into account on the basis of article 101(3) TFEU by translating their safety argument into qualitative efficiencies.

Translating however the non - economic facets of healthcare quality into efficiencies may be a much more complex task in cases where these facets contradict with the main goal of competition law, efficiency, in the sense of maximizing consumer welfare. As the first chapter of this thesis indicated there are different concepts of equity. Equity can be viewed as equality of

expenditure per capita, equality of input (resources) per capita, equality of (opportunity of) access for equal need, equal utilization for equal need, equality of health,[1380] equity as choice.[1381] In healthcare systems pursuing equity as *equality of opportunity of access for equal need*, healthcare is distributed quite independently of people's willingness to pay such services. In these systems, healthcare is mainly distributed on the basis of people's need. However, the pursuit of such an objective implies that *an act of redistribution* takes place between different social groups. This in some cases might be in contrast with one of the main goals of EU competition law, the *maximization of consumer welfare*, which is an efficiency objective and not a distribution one. Indeed, the use of a consumer welfare standard may treat the same people unequally in their roles as workers and producers but entails treating *all consumers as equally* deserving with respect to the activity of consumption.[1382] To shed some light on my point, again I provide an example. GPs in the UK in their role as gatekeepers may conform to a decision made by purchasers of NHS services to refer more patients for elective care in NHS bodies located in disadvantaged rural areas so that these bodies can cross subsidize their high demand for respiratory, cardiovascular or emergency care services. In this case, the parties of the agreement restrict the choice of consumers seeking elective services in order to ensure choice and access to the disadvantaged groups of our society seeking non-elective costly services. In this case, the parties' anticompetitive agreement may analogize to an exercise of distributive justice since it restricts choice for consumers seeking elective services to ensure choice and access to consumers seeking urgent non - elective services in disadvantaged rural areas. At the same time, it involves an economic taking from entities specializing in elective care to entities specializing in non-elective care. In cases where the objectives of equity and efficiency conflict competition authorities may choose again to widen the notion of consumer welfare in healthcare by integrating equity concerns into their analysis. By widening this notion, they could actually balance conflicting facets of healthcare quality such as equity v. efficiency. *Under what techniques could they perform this task?*

In a way analogous to *CECED*, competition authorities *may translate increased equity gains into efficiency gains*. This could be achieved, for example, if the antitrust enforcers incorporated into the Article 101(3) framework *a wider notion of efficiencies*, such as the one introduced by Donabedian.

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[1380] G.H. Mooney, *supra* n.141, 180-181,
[1381] A. Wagstaff, *supra* n.140, 30.
[1382] B. Von Rompuy, *supra n.* 512, 48

Donabedian has identified three different types of efficiencies in healthcare: (a) *clinical efficiency*, which requires that health care practitioners prescribe and implement care that does not include harmful, useless, or less effective remedies or methods;[1383] (b) *production efficiency* which requires the efficient production of the goods and services that are used in providing care;[1384] (c) *distributional efficiency* which requires the distribution of care among different classes of patients (characterized by age, sex, ethnicity, economic status, place of residence, kind of illness) in a way *proportionate* to expected improvements in health.[1385] In that sense, competition authorities in Europe may take equity concerns into account by weighing distributional efficiency against harm to competition. In a way also analogous to *CECED* and *DSD* competition authorities in Europe may take the view that the protection of the non-economic facets of healthcare quality, such as equity, has an economic value. Indeed, reducing health inequalities has an economic value since improvements in health for all parts of the population leads to economic growth. This is because health may be not only a consequence but also a cause of high income.[1386] This can work through a number of mechanisms. The first is the role of health in labor productivity. Healthy workers lose less time from work due to ill health and are more productive when working. The second is the effect of health on education.[1387] Childhood health can have a direct effect on cognitive development and the ability to learn as well as school attendance.[1388] In addition, because adult mortality and morbidity (sickness) can lower the prospective returns to investments in schooling, improving adult health can raise the incentives to invest in education.[1389] The third is the effect of health on savings. A longer prospective lifespan can increase the incentive to save for retirement, generating higher levels of saving and wealth, and a healthy workforce can increase the incentives for business investment.[1390] In addition, healthcare costs can force families to sell productive assets, forcing them into long-term poverty.[1391] By attaching an economic value to the objective of equity competition authorities may say that an anticompetitive agreement aiming to protect equity impacts positively on *economic progress*. This

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[1383] A. Donabedian, *supra* n. 68, 10.
[1384] *Ibid.*
[1385] *Ibid.*
[1386] D. E. Bloom, D. Canning 'Population Health and Economic Growth', Commission on Growth and Development, The World Bank, Working Paper No.24, 1.
[1387] *Ibid.*
[1388] *Ibid.*
[1389] *Ibid.*
[1390] *Ibid.*
[1391] *Ibid*, 2.

technique would in fact be in line with the Commission's position in the 1999 White Paper underlying that the purpose of Article 101(3) is to provide a framework for the *economic assessment* of restrictive practices. Another method, under which Competition Authorities may integrate equity considerations into their analysis, is by taking into account that societies pursuing the objective of equity as equality of opportunity of access *are not indifferent as to who consumes healthcare*. These societies consider that equity in health has an instrumental value since it aims to compensate specific groups of a society for the disadvantages and suffering they incur for reasons beyond their control. They also consider that entities such as health derive equity significance from their ability to enable people to flourish. For this reason, in these societies healthcare resources are not unevenly distributed, clustered in urban areas and scarce in rural areas. In light of these concerns, competition authorities may recognize that consumer welfare is an aggregation of individual interests that are diverse and that can be combined only by some process of weighing the circumstances of different groups.[1392] Therefore, competition authorities may support the view that ensuring access and therefore choice for the most vulnerable groups of a society weighs more than ensuring choice for groups of a society in less need. Going back to the example at issue, competition authorities might, for example, say that ensuring choice for the vulnerable groups of our society seeking urgent non – elective care in isolated areas weighs more than protecting choice for other, less vulnerable groups of our society seeking elective care.[1393] Therefore although the agreement at issue restricts choice in the relevant market for elective services and is therefore anticompetitive on the basis of Article 101 TFEU, at the same time it extends choice in the market of non ‑ elective urgent services targeted to the most vulnerable groups of a society and is therefore procompetitive on the basis of Article 101(3) TFEU.

### 4.2 The protection of healthcare quality as a legitimate objective-public goal

The protection of the non-economic aspects of healthcare quality, such as equity, may also be considered if they are seen as public policy objectives the pursuit of which requires an exception from the application of competition law. Arguably, the equity objective could be

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[1392] A. Atkinson, *Inequality, What can be done?* (Cambridge, Harvard University Press, 2015) 126.

[1393] Professor Lianos has also advanced an argument in favour of distributive justice objective of EU competition law based on the political and moral philosophy of J. Rawls when article 101(3) is at issue, see I. Lianos, 'Some Reflections on the Question of the Goals of EU Competition Law' (2013) *CLES Working Paper Series*, 3/2013, 21-23.

considered a *legitimate objective* whose protection requires an exception on the basis of Article 101(1) TFEU. This approach would be in line with the principles established by the Court in the *Wouters*, the *Albany* and the *Meca Medina* cases. In these cases, the Court established the principle that any agreement should be interpreted in light of its objectives, its legal and economic context. More specifically, in the *Wouters* case the Court granted an exception on the basis of Article 101(1) TFEU in order to ensure the legitimate objectives the anticompetitive Dutch regulation aimed to pursue, the integrity and quality of professional services. The Court followed the same approach also in the *Albany* and the *Meca Medina* cases. In these cases, the Court again exempted the anticompetitive agreements at issue in order to ensure the protection of labour and the integrity of sports. In addition, the Courts and the antitrust enforcers may take the non-economic aspects of healthcare quality into account on the basis of Article 101(3) TFEU by adopting a wider interpretation of the notion of' '*technical and economic progress',* as the Court did in the *GlaxoSmithKline v Commission* case as well as the *Grundig-Verkaufs-GmbH v. Commission* case. As noted, nothing in these cases suggests that the appreciable objective advantages Article 101(3) requires are limited to increases in consumer welfare. Therefore, under this approach the non - economic facets of healthcare quality, such as equity, could be integrated into a competition assessment even if they were not translated into efficiencies.

In that regard, one may argue that the application of the Court's *more pluralistic approach* may be more appropriate in cases where the economic facet of the non-competition concerns is not evident enough or where there are no discernible positive effects of an economic nature that can lead to an anti-competitive agreement being assessed under a more economic approach.[1394] In these cases, if a strict economic assessment approach was applied, a number of non-competition concerns which might be fundamental from a public policy perspective, such as the protection of equity, would be ignored either because their contribution to efficiency is indirect or because they cannot be easily translated and assessed into economic terms

[1394] A. Komninos, *supra* n. 1316, 10.

## 4.3 Obstacles to a holistic protection of healthcare quality

Antitrust scholarship might criticize my proposal that competition authorities in Europe could protect the multiple facets of healthcare quality by extending the notion of consumer welfare both on normative and legal grounds. In the section that follows, I will identify the potential criticism and I will also explain why this approach could be applied by competition authorities without harming the goals of EU competition law and policy.

On normative grounds, critics of my proposal would argue that if competition authorities adopted *a wider definition of consumer welfare in their competition assessment*, they would balance conflicting goals, *such as equity v. efficiency* that the competition authorities do not have the democratic legitimacy to balance. According to this argument, when competition law adjudicators excuse a restriction of competition by undertakings on account of non-efficiency gains they are sanctioning an economic taking from consumers and such a practice can be considered as an act of distributive justice.[1395] Competition law confers on consumers '… a property right or entitlement to purchase competitively priced goods' and 'higher than competitive prices constitute unfair takings of consumers' property'.[1396] In that sense, the Commission has defined protecting effective competition as implying 'protection of the consumer's interest by ensuring low prices'.[1397] Consequently, delimiting the legal right in respect of free competition by reference to the integration clauses in the TFEU may analogize to an exercise of distributive justice to the extent it involves an economic taking from one social group to the other. In such instances, government actors actually exercise distributive justice, and the Courts merely superintend their decisions for constitutionality.[1398]

The argument that competition authorities may lack the democratic legitimacy to balance competition with non - competition goals is important. This argument however disregards the fact that the Commission already exercises to a certain extent distributive justice when it applies article 101 (3) TFEU. Article 101 (3) TFEU maintains that an anti-competitive agreement is exempted if it

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[1395] F. Kieran 'A separation approach to non – efficiency goals in the EU Competition law', (2013) 19 *European Public law*, 199.
[1396] *Ibid.*
[1397] *Ibid.*
[1398] *Ibid*, 200.

increases efficiency, with two conditions: First, that the efficiencies resulting from the restricting agreement be passed on to consumers (as a way of preventing too much wealth being accumulated by the parties to the agreement) and second, that competition is not eliminated in a substantial part of the product in question signifying that the agreement cannot suffocate the economic freedom of other market participants.[1399] These conditions reflect the ordoliberal concern over the accumulation of economic power, which requires the Commission to grant exceptions based not only on utilitarian values of total efficiency but also on distributive justice.[1400] Therefore, the Commission practices redistributive justice when it applies Article 101(3). This objection is also rebutted by existing legal and political research showing that, in practice, it is difficult to make a distinction between policy-making and policy implementation.[1401] Even where decisions appear to be purely concerned with implementation, the complexity of the economic and legal analysis that must be carried out prior to adopting a decision on, for example, a research and development agreement, and the potentially conflicting interests of the different market parties, mean that an NCA often has to make difficult socio-economic choices.[1402] In the *CECED* case, for instance, the Commission engaged in an economic assessment in order to incorporate environmental concerns in its analysis. However, in applying Article 101(3) it also made a difficult socio-economic choice: It deprived consumers of the choice to prefer a cheaper washing machine now rather than an expensive one with electricity savings in the future in order to promote its sustainable development policy.[1403] Therefore, rather than deny that NCAs enjoy a degree of discretion - they do make complex economic and legal assessments and may make policy choices (e.g. when setting priorities) - it is more useful to accept this as a fact of life and search for the limits to this discretion and for mechanisms to ensure that NCAs exercise their powers in a way that is transparent and consistent.[1404]

Most importantly, this argument completely disregards the fact that if competition authorities do not take into account in their assessment the non - economic goals their societies democratically have decided to pursue, such as equity, these competition assessments then are

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[1399] G. Monti, *supra* n 1270, 1061.
[1400] *Ibid.*
[1401] S., Lavrijssen, *supra* n. 1373, 654.
[1402] *Ibid.*
[1403] B. Sufrin., *supra* n. 1231, 956.
[1404] S, Lavrijssen, *supra* n. 1373, 638.

not legitimate, in the sense that they do not match 'the substantive goals of the society in question'.[1405] Surely, one could claim that competition authorities should not be expected to engage in healthcare resource allocation or to assess to what extent a specific agreement benefits the poorer or the wealthier parts of our society. Nonetheless, when it comes to inequalities and social justice in a developed economy, antitrust law cannot be calibrated to help, but it can be calibrated *not to harm*.[1406] This point is crucial. Indeed, in cases where health policy objectives conflict with the goals of choice and competition, if competition authorities did not take these health objectives into account, these objectives may be substantially harmed. I will elaborate on this argument by providing two examples. As previously discussed, in a considerable number of competition cases, such as the *INAIL,* the *Poucet and Pistet* and the *AOK* cases the Court held that the compulsory healthcare insurance schemes at issue were not undertakings since they operated on the basis of the principle of solidarity and as result their activity was not subject to the rules of EU competition law. In all these cases, the compulsory affiliation was held to be both an inherent feature and a logical consequence of the solidarity principle. Essentially, in these cases the Court balanced two conflicting objectives: the goal of solidarity with the goals of competition and choice. Acknowledging the risk of cream-skimming, the Court in these cases decided to deprive the wealthier and healthier parts of a society from the freedom to choose healthcare funds so as to ensure that the access to healthcare services for the sicker and poorer parts of a society is not restricted. If the Court in these cases had taken the opposite view and had concluded that health policy objectives should not become part of a competition assessment, the goals of equity and accessibility may be undermined. Indeed, if compulsory affiliation was not an inherent feature of the healthcare funds' operation, the employees' contributions would be proportionate to their risk profile and not to their income. Additionally, the insurers would have the incentive to insure only the healthy parts of the population that would not need care and healthy patients would have no incentives to take out insurance.[1407] This may lead to a race to the bottom with insurers both weeding out costly consumers and barring them at the gate.[1408] Therefore the values of equity and accessibility would be seriously harmed. The same analysis could in fact be applied in

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[1405] A. Gerbrandy, 'Addressing the legitimacy problem for competition authorities taking into account non-economic values: the position of the Dutch Competition Authority' (2015) 40(5) *European Law Review* 769, 773.
[1406] D. A. Crane, 'Antitrust and Wealth Inequality', (2016) 101 *Cornell L. Rev.* 1171, 1176.
[1407] L. Hancher, W. Sauter W, *supra* n. 30, 341.
[1408] *Ibid.*

one of the potential competition problems I presented in the previous section. In the UK hospitals do not compete on price but on quality since they are paid on the basis of fixed tariffs for the treatments they provide. To ensure their financial stability, healthcare providers may agree on the maximum levels of quality of the amenities they offer so as to save more profits and cross subsidize their risky non-elective surgeries. In other words, they may restrict quality competition with regards to a specific dimension of quality, acceptability, in order to ensure the safety and continuity of non-elective risky services. This agreement is clearly anticompetitive since it restricts quality competition on a specific dimension of quality. Nonetheless, it cannot be disregarded that this agreement also has same procompetitive effects. As already highlighted in the second chapter medical markets are pervaded by information asymmetries. Consequently, patients cannot easily evaluate all dimensions of healthcare quality, such as effectiveness and safety. Surely, they can evaluate the quality of the amenities providers offer or doctors' listening skills. To attract patients, providers may therefore attempt to compete only on the aspects of quality patients can in fact evaluate such as the quality of the facilities they offer. This however might disincentivize them from investing in aspects of quality that actually matters for health outcomes, such as the safety of non-elective risky procedures. By restricting therefore quality competition with regards to one dimension of quality, acceptability, they may actually ensure the safety and the continuity of the risky non-elective services. A court or a competition authority that may not consider the procompetitive effects of this agreement would disregard that safety is one of the most important objectives of EU health systems. More than that, if competition authorities applied competition law in a way that disregards these objectives, their application of competition law would also disregard the fact that the EU does not have exclusive competence in the field of healthcare and that, in contrast, it is up to national governments to organize healthcare and ensure that it is provided.[1409]

Additionally, the integration of non-competition goals, such as equity, into a competition assessment is in line with the horizontal Treaty provisions requiring that specific objectives should be taken into account in the definition and implementation of all EU policies and activities, thus including antitrust enforcement.[1410] Article 7 TFEU maintains that the Union

[1409] https://europa.eu/european-union/topics/health_en.
[1410] B. Van Rompuy, *supra* n. 512, 223-224.

*shall ensure consistency* between its policies and activities, taking all of its objectives into account and according to the principle of conferral of powers. Article 9 TFEU states that the Union shall more specifically *take into account* requirements linked to the promotion of a high level of employment, the guarantee of *adequate social protection*, the fight against social exclusion, a high level of education and training and *the protection of human health* in defining and implementing its policies and activities. Article 11 maintains that environmental protection requirements must be integrated into the definition and implementation of the Union's policies and activities, in particular with a view to promoting *sustainable development*. Article 12 states that consumer protection requirements shall be taken into account in defining and implementing other Union policies and activities. Article 167(4) states that the Union shall take *cultural aspects* into account in its action under other Treaty provisions. Article 168 TFEU states that *a high level of human health shall be ensured* in the definition and implementation of all Union policies and activities. Article 175 TFEU states that the formulation and implementation of the Union's policies and actions and the implementation of the internal market shall take into account the objectives set out in Article 174 TFEU and shall contribute to their objectives. Article 208(1) TFEU states that the Union shall take into account the objectives of *development cooperation* in the policies that it implements which are likely to affect developing countries.

As a matter of law, it is unclear what impact the cross-sectional clauses should have on the application of the EU competition rules. Nonetheless, the wording of the clauses relating to *environmental protection* and *human health* is notably stronger than the ones relating to other policies. With regards to human health the Treaty states that a high level of human health *should be ensured* in the *definition* and *implementation* of all Union policies and activities. The choice of the specific wording '*shall be ensured*' should not be ignored especially because for the other cross - sectional articles of the Treaty a different wording has been chosen: *the Union shall take into account*. [1411]

Critics of my proposal may also point to two important issues. The first one is that indirect economic benefits or health policy objectives should not be taken into account as this approach would be in contrast with the Commission's Guidelines with regards to the application of Article 101(3) mentioning that competitive harm in one market cannot generally be

[1411] *Ibid.*

compensated by positive effects elsewhere.[1412] Indeed the Guidelines maintain: 'The assessment under Article 81(3) of benefits flowing from restrictive agreements is in principle made within the confines of each relevant market to which the agreement relates. *The Community competition rules have as their objective the protection of competition on the market and cannot be detached from this objective. Moreover, the condition that consumers must receive a fair share of the benefits implies in general that efficiencies generated by the restrictive agreement within a relevant market must be sufficient to outweigh the anti-competitive effects produced by the agreement within that same relevant market. Negative effects on consumers in one geographic market or product market cannot normally be balanced against and compensated by positive effects for consumers in another unrelated geographic market or product market. Only where two markets are related (and) the group of consumers affected by the restriction and benefiting from the efficiency gains are sustainably the same can such benefits be taken into account.*'[1413] Yet, in a number of cases, the Commission takes positive effects on different markets into account where the consumers are not substantially the same. For example, R&D agreements will typically not benefit the current consumers of the product but yield dynamic efficiencies that in fact benefit future consumers.[1414] Another example is the effects on downstream markets which are typically relevant in the Article 101(3) analysis of consumer benefit.[1415] In these cases the restriction is upstream and the benefit occurs several steps down the value chain. More importantly, the Courts have reaffirmed that advantages in other markets can be considered without endorsing the condition that the affected consumers need to be substantially the same. The GC in GSK explained that 'advantages may arise not only in relevant markets but also on other markets'.[1416] Moreover, in *MasterCard*[1417] the General Court clarified that 'it is settled case-law that the appreciable objective advantages to which the first condition of Article 81(3) EC relates may arise not only for the relevant market *but also for every other market on which the agreement in question might have beneficial effects, and even, in a more general sense, for any service the quality or efficiency* of which might be improved by the existence of that agreement.'[1418]

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[1412] Commission's Guidelines on the application of article 81 (3) of the EC Treaty, *supra* n 476, para 43.
[1413] *Ibid.*
[1414] J. Nowag, *supra* n 1328, 235.
[1415] *Ibid.*
[1416] Case T-168/01, GlaxoSmithKline Services Unlimited v Commission [2006] ECR II-2969, para. 248, See also comment by A. Ezrachi, *EU Competition Law: An Analytical Guide to the Leading Cases* (Bloomsbury, 2015).
[1417] Case T – 111/08 Mastercard v. European Commission.
[1418] *Ibid.*, 228.

The second point is that the consideration of non - economic concerns under a competition law analysis may undermine the consistent and uniform application of competition law throughout the EU Member States.[1419] However, the fact that NCAs balance non-competition with competition interests does not mean that they cannot work objectively and impartially. Moreover, the case law of the Court of Justice requires the Commission and the NCAs to take into account the economic and legal context in which anti-competitive practices are manifested each time they make an assessment, and does not require NCAs to adopt uniform decisions irrespective of the relevant context.[1420] Indeed, what matters is that the Commission and the NCAs apply consistent legal and economic methodologies and fair procedures for weighing conflicting interests, ultimately resulting in decisions that prohibit practices that are not in the interests of consumers.[1421]

## 5. Conclusion

This chapter examined the crucial question of whether the Competition Authorities in Europe should extend the notion of consumer welfare when they apply competition law in healthcare in order to protect the notion of healthcare quality *as a whole or* else in Donabedian's language at *all levels of a healthcare system*.

To clarify, this chapter did not claim that all the above analyzed potential competition problems require an assessment under a wider consumer welfare approach. Indeed, competition authorities may assess under a narrower consumer welfare standard whether providers restrict quality competition by colluding on specific levels of quality. It argued thought that especially in cases where the notions of choice and competition conflict with the health policy objectives of EU healthcare systems, such as equity, continuity, safety, competition authorities may seriously consider whether they should integrate in the concept of consumer welfare these objectives so that their assessment does not harm them. Elaborating on this argument, this chapter presented specific examples from the UK procompetitive regulation in healthcare where these conflicts may in fact arise. It also examined how and under what techniques competition authorities may extend the notion of consumer welfare in healthcare so that they can balance conflicts between the goals of

[1419] C. Townley, *Article 81 EC and Public Policy* (Oxford: Hart Publishing 2009) 38-39.
[1420] S., Lavrijssen, *supra* n. 1373.
[1421] *Ibid.*

competition and the non-economic facets of healthcare quality. It concluded that both under the more economic approach of European Commission as well as the more pluralistic approach of the European Courts, this *mission is possible*. This chapter emphasized that if competition authorities did not consider these non-economic objectives of EU healthcare systems in their competition assessment, inevitably their assessments would lose their legitimacy in the sense that they would not match the substantive goals of societies that have democratically decided to pursue health policy objectives, such as equity. In concluding, I also note that the analysis in this chapter could also apply in hospital merger cases where conflicts between the notions of efficiency and equity might appear. However, since Member States assess their merger cases on the basis of their national legislation, I did not make a separate analysis with regards to merger cases.

# VI. Ensuring healthcare quality through the cooperation of multiple actors in merger enforcement: *A mission more possible*?

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The previous chapter raised the question of whether competition authorities in Europe might choose to protect healthcare quality *as a whole* by widening the notion of consumer welfare in healthcare. In elaborating on this policy option, that chapter first explained the main aspects of the procompetitive regulations that introduced the choice and competition model in the UK since the early 1990s. That chapter claimed that this procompetitive regulation might harm specific dimensions of healthcare quality, such as equity, acceptability and safety. In light of this concern, it claimed that GPs performing their role either as gatekeepers or commissioners might engage in anticompetitive behaviour in order to ensure these essential facets of healthcare quality. Drawing inspiration from the UK procompetitive regulation, the previous chapter took the view that Competition Authorities in Europe that have started introducing the choice and competition model in providing healthcare services might inevitably have to address similar competition problems. In addressing these problems competition authorities might have to strike the appropriate balance between the notions of choice and competition and essential objectives of their health systems, such as equity. Taking the view that under a narrow consumer welfare approach Competition Authorities in Europe might not be able to take into account in their assessment the main objectives and values of their health systems as well as some non – economic facets of healthcare quality, such as the notions of acceptability and professionalism, the previous chapter raised the question of whether Competition Authorities in Europe might choose to take these elements into account by *widening the notion of consumer welfare in healthcare.*

This chapter aims to analyze a different policy option under which Competition Authorities in Europe may attempt to balance conflicts between competition and essential facets of healthcare quality. This is the policy option that was in fact introduced by the HSCA 2012 that made a direct

correlation between competitive behaviour in the NHS and competition law.[1422] Under this policy option, competition authorities are responsible for the protection of vigorous competition in healthcare, while health authorities are responsible for advising competition authorities on issues relating to the protection of healthcare quality. This policy option has in fact been adopted in the UK when mergers between NHS FTs are involved. As the HSCA 2012 provides, mergers involving one or more NHS FTs are subject to the Enterprise Act 2002 (HSCA 79) and are reviewed by the CMA with Monitor, the health services regulator in the UK, taking an advisory role in relation to the benefits of the merger for patients.[1423] *Can the cooperation of these authorities ensure that healthcare quality in the merger assessment of NHS FTs is actually taken into account as a whole? And if yes, how?*

To adequately examine this question this chapter first outlines the main healthcare reforms the Coalition Government introduced following the HSCA 2012. It particularly examines the main responsibilities of the key bodies that are active in healthcare, notably, Monitor, the commissioners, the CQC and NHS England. In analyzing these reforms, this chapter illustrates that some specific facets of the regulatory framework under which NHS FTs operate, may incentivize NHS FTs to merge. It additionally highlights that while CMA is responsible to ensure competition in the provision of NHS services, Monitor is responsible under the HSCA, not only to promote competition but also to ensure the continuity of these services. In light of this concern, this chapter points out that Monitor's involvement in the assessment of mergers between NHS FTs may in fact transform CMA's merger analysis with regards to NHS FTs. *Is this scenario a possible one*? In considering this question, this chapter reviews the competition law framework under which mergers between NHS FTs are assessed by Monitor and the CMA. It particularly explores how under this framework, Monitor and the CMA assess quality when they examine mergers between NHS FTs. It also reviews some recent merger cases between NHS FT and sees whether and to what extent the conflicting objectives between these actors may indeed *transform* CMA's merger analysis with regards to NHS FTs.

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[1422] M. Sanderson, P. Allen, D. Osipovic, *supra* n. 35, 7.
[1423] *Ibid.*

## 1. A short introduction to the main facets of the HSCA of 2012: How does this framework force hospitals to merge?

### 1.1 The main facets of the procompetitive regulation in healthcare following the Social Act of 2012

The quasi-market and accompanying regulatory mechanisms, the previous chapter noted, were first introduced to the English NHS in 1990 when the then Conservative Government passed the National Health Service and Community Care Act that introduced the internal market. Essentially, this Act separated the purchasing and the provision of healthcare services across the UK. Despite a softening of the rhetoric about competition and markets, the New Labour government elected in 1997 continued with the purchaser/provider and from around 2002 onwards in a 'gradual, pragmatic' process stimulated supply side competition through an increase in the diversity of providers of care.[1424] During the Labour period, as the previous chapter also noted, the provision of NHS services was gradually opened up to a variety of accredited providers including both publicly owned and independent providers such as the ISTCs.[1425] Patients were also offered choice between providers for their treatment at the point of referral.[1426] New mechanisms to regulate competition were developed in 2007 when the Principles and Rules for Cooperation and Competition were launched, administered from January 2009 by the CCP.[1427]

The formation of a Coalition Government in May 2010 heralded a new phase in competition in health services.[1428] In fact, the White Paper, *Equity and Excellence*, *Liberating the NHS* that was published in July 2010 set out the government's vision for a reformed health service.[1429] Legislation implementing the reforms was, after a difficult passage, enacted in the HSCA 2012.[1430] The White Paper's main theme was *patient choice*. Indeed, the White Paper made it clear that

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[1424] *Ibid*, at 4.
[1425] *Ibid.*
[1426] A. Dixon, R. Robertson, *supra* n. 1173, at 53.
[1427] M. Sanderson, P. Allen, D. Osipovic, *supra* n. 35, at 6.
[1428] L. Stirton, *supra* n. 450, at 191.
[1429] E. Spencelayh, J. Dixon, 'Mergers in the NHS Lessons from the decision to block the proposed merger of hospitals in Bournemouth and Poole', The Health Foundation, Policy Analysis 2014, 9.
[1430] L. Stirton, *supra* n. 450, at 192.

increasing the diversity of supply of providers of clinical care was a key objective.[1431] It also outlined the government's intention to amend the role of Monitor. Monitor was to become an economic regulator with responsibility for promoting competition, regulating prices and safeguarding the continuity of services.[1432]

Essentially, the HSCA that was introduced on 19 January 2011 gave effect to the policies set out in *Equity and Excellence.*[1433] In sum, the Act continued the long stand policy that the NHS should operate as a market, in which health care is provided to patients because it is bought from hospitals and other service providers by 'purchasers' on their behalf.[1434] The government confirmed that its main intention was to allow *any willing provider* to provide services thereby giving patients greater choice and stimulating innovation and improvement through greater competition.[1435]

The government initiated the reforms hoping to make the market *more real.* The government believed two things: The first was that some NHS bodies were unwilling to participate fully in the market, because they did not have enough incentives to do so.[1436] In fact, some NHS purchasers had very close relationships with NHS providers and were therefore reluctant to consider alternatives. In light of this barrier to entry, the private sector had low incentives to be involved in the provision of the NHS services. The second was that where NHS bodies wanted to engage in market behaviour, they were unable to do so because they were too constrained by top down regulation from central government.[1437] *Under what reforms did the Coalition government attempt to make the market more real?*

To begin with, on the purchaser side, the HSCA 2012 introduced radical institutional reforms. The Act abolished the PCTs that the Labour government had established. In their place, consortia of GP practices, known as Clinical Commissioning Groups (CCGs) purchase care for their

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1431 M. Sanderson, P. Allen, D. Osipovic, *supra* n. 35, at 4, NHS, Department of Health, 'Equity and excellence: Liberating the NHS' July 2010, 5.
1432 NHS, 'Department of Health, Equity and excellence: Liberating the NHS', July 2010, 4.
1433 E. Spencelayh, J. Dixon, *supra* n. 1429, 10.
1434 A.C.L Davies, 'This time, it's for real: the Health and Social Care Act 2012', (2013) 76 (3) *Modern Law Review*, 564.
1435 E. Spencelayh and J. Dixon, *supra* n. 1429, at 10.
1436 A.C.L Davies., *supra* n. 1434, at 566.
1437 *Ibid.*

patients.[1438] CCGs are responsible for commissioning urgent and emergency care, some out-of-hours primary medical services, elective hospital care, community health services, maternity and newborn services.[1439] Since there is limited scope to negotiate on price, because of the tariff pricing system, the focus of the commissioning process is on the speed, quality and quantity of the services to be provided.[1440] CCGs are supported in their work by an array of non-statutory bodies, including clinical senates and clinical networks.[1441] As already noted, Monitor ensures the compliance of CCGs with procurement regulation, including the Procurement Choice and Competition Regulations, and national and EU procurement law.[1442]

The HSCA 2012 also established the NHS Commissioning Board (now NHS England) that is responsible for overseeing CCGs and for commissioning primary care services (to avoid a potential conflict of interest with GP-led CCGs) and some specialized services.[1443] In undertaking its duties, NHS England is guided by Clinical Reference Groups (CRGs). These are service-specific teams of professionals and patients who produce national specifications and policies in respect of different clinical areas, including, for example, guidance on the minimum number of procedures that have to be provided by a hospital to safeguard quality.[1444] CCGs have statutory obligations towards NHS England, including improving the quality of services and complying with certain financial and auditing obligations.

NHS England has a concurrent duty with the Secretary of State to promote a comprehensive health service.[1445] It has also a statutory duty to exercise its functions with a view to securing continuous improvement in the quality of services.[1446] This statutory duty is to be exercised

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[1438] L. Stirton, *supra* n. 450, at 192.
[1439] NHS England, Understanding the New NHS, A Guide for everyone working and training within the NHS, available at: https://www.england.nhs.uk/wp-content/uploads/2014/06/simple-nhs-guide.pdf, 13.
[1440] A.C.L Davies., *supra* n. 1434, at 571.
[1441] L. Stirton, *supra* n. 450, at 193, NHS England, 'Developing Clinical Senates: The Way Forward', available at: https://www.england.nhs.uk/2013/01/clinical-senates/.
[1442] L. Stirton, *supra* n. 450, at 194, Article 76 HSCA.
[1443] C. Ham, B. Baird, S. Gregory, J. Jabbal and H. Alderwick 'The NHS under the Coalition Government, Part one', February 2015, The Kings Fund, 29.
[1444]Ashford and St Peter's and Royal Surrey County, CMA report on the anticipated merger of Ashford and St Peter's Hospitals NHS Foundation Trust and Royal Surrey County Hospital NHS Foundation Trust, 16 September 2015, para 2.34.
[1445] National Health Services Act 2006 1, 1.1, 9.
[1446] *Ibid*, 13E.

in conjunction with statutory duties to promote autonomy, choice, reduction of inequality, effectiveness and efficiency, and various other duties.[1447] In seeking to secure the provision of high quality services, NHS England is statutorily obliged to have reference to guidelines laid down by the NICE.[1448] NHS England works closely with NICE in order to establish a Commissioning Outcomes Framework that provides transparency and accountability in relation to the quality of services commissioned by CCGs and their contribution to improving performance in relation to the NHS Outcomes Framework.[1449]

Most importantly, the HSCA 2012 transformed Monitor into the main sector regulator for NHS services. In general, Monitor is obliged to protect and promote the interests of people who use health care services by promoting provision of health care services which— (a) is economic, efficient and effective, and (b) maintains or improves the quality of the service.[1450] As the HSCA underlines, when carrying out its duties, Monitor, must take due account, amongst other things, of (a) the desirability of *securing continuous improvement* in the efficiency with which NHS health care services are provided (b) the need for commissioners of health care services to ensure fair access to the NHS services (c) the need for commissioners of health care services for the purposes of the NHS to ensure that people who require health care services for those purposes are *provided with access* to them (d) the desirability of persons who provide health care services for the purposes of the NHS co-operating with each other in order to improve the quality of health care services (e*) the need to promote research* into matters relevant to the NHS by persons who provide health care services.[1451]

In brief, Monitor is mainly responsible for (a) *ensuring continuity of essential services in the event of financial failure*, (b) *price-setting* (c) *tackling anti-competitive behaviour*. To elaborate:

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[1447] *Ibid*, 13F-13Z.
[1448] The duty to have reference to NICE guidelines is a reference to NICE's power to issue guidelines under section 234 of the HSCA 2012, which came into force on 1 April 2013.
[1449] The NHS Outcomes Framework provides a national overview of how well the NHS is performing, is the primary accountability mechanism between the Secretary of State for Health and NHS England and drives up quality throughout the NHS by encouraging a change in culture and behaviour focused on health outcomes not process, Source: Department of Health (November 2013), The NHS Outcomes Framework 2014/15.
[1450] Article 62 HSCA 2012.
[1451] Article 66 HSCA.

Monitor *ensures continuity of essential services* by assessing risks to the continued provision of NHS services and by exercising proactive financial oversight.[1452] Monitor performs these duties through the licensing requirements and conditions that NHS FTs are required to meet.[1453] In fact, since April 2013, all NHS FTs are obliged to hold a license from Monitor stipulating the specific conditions they must meet, including financial sustainability and governance requirements.[1454] In elaborating on how Monitor assesses whether there is a significant risk to the financial sustainability of a provider of key NHS services which endangers the continuity of those services and/or poor governance at an NHS FT, Monitor has published the Risk Assessment Framework.[1455] Under this framework, Monitor determines FTs' governance rating using information from a range of sources including outcomes of CQC inspections and aspects related to financial governance and delivering value for money. Trusts that achieve high standards in relation to these matters are given a green rating. In contrast, when Monitor recommends a regulatory action, a red rating is given. NHS FTs can also be under review.[1456] Given the reputational impact of this *traffic light system*, an NHS FT under review is incentivized to alleviate governance concerns, even if no formal enforcement action is taken.[1457]

Monitor is also responsible for enforcing license conditions.[1458] In fact, Monitor is entitled to enforce monetary penalties, accept enforcement undertakings, or revoke a provider's license if the provider has failed to comply with a license condition.[1459] Licensing serves one essential role: it offers a way of dealing with one of the perennial problems of the NHS markets, namely, 'provider failure'.[1460] In general, if the market is to operate normally, it must be possible for unsuccessful providers to go out of business. But in a public service, essential services cannot usually be allowed to fail because of the adverse impact of those who use them.[1461] For NHS FTs, this problem is addressed through the Trust Special Administration (TSA) regime. Under this regime, Monitor is

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[1452] Monitor Risk Assessment Framework, 2015, 8.
[1453] Articles 85 and 88 HSCA 2012.
[1454] Monitor Risk Assessment Framework, *supra* n. 1452, 4.
[1455] *Ibid.*
[1456] *Ibid*, 6.
[1457] Ashford and St Peter's and Royal Surrey County, CMA report, *supra* n. 1444, at 16.
[1458] Section 88 of HSCA, 2012.
[1459] Monitor, Enforcement Guidance 2013, Chapter 3.
[1460] A.C.L Davies., *supra* n. 1434, at 570.
[1461] *Ibid.*

authorized to appoint a TSA to a NHS FT if it considers that the trust is, or is likely to become, unable to pay its debt or where there is a serious failure by the FT to provide services of sufficient quality.[1462] Prior to triggering this regime, Monitor must consult the Secretary of State, the commissioners and the CQC. TSAs are required to make recommendations to Monitor about actions to secure into the future the delivery of quality, safe and financially sustainable essential services of the FT in administration.[1463]

Monitor as an economic regulator for the health sector *as a whole*, is also responsible for the administration of the national tariff prices chargeable for services on the NHS or else *price setting*.[1464] The pricing provisions of the HSCA 2012 comprise a comprehensive payments system, including a set of specific currencies units of healthcare for which payments are made, and associated prices, as well as a set of principles, rules and methods to determine prices and govern modifications and variations to national tariffs.[1465] The national tariffs are set each year and apply to the majority of acute healthcare services provided in hospitals, including admitted patient care, outpatient attendances and A&E services.[1466] The tariff for each service (or unit of activity) is intended to cover the cost of providing that service. It is calculated on the basis of the *national average costs* reported by NHS providers and a market forces factor (MFF) which takes account of local differences in costs, for example costs of land and labour.[1467]

Monitor is also responsible for *tackling anticompetitive behaviour* as the Act gave Monitor competition powers in the Competition Act 1998 concurrently with the CMA.[1468] On the basis of clause 62(3) of the HSCA 2012, Monitor is obliged to exercise its functions with a view to preventing anticompetitive behaviour which *is against the interests of people who use these services*. Thus Monitor can investigate anti-competitive agreements, such as cartels, or allegations of abuse of

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[1462] The trust special administration provisions are set out in sections 65A–65O of the NHS Act 2006, as inserted by section 174 HSCA 2012 and amended by the Care Act 2014.
[1463] NHS trust and foundation trust special administration - A guide for unsecured creditors, Department of Health, November 2015.
[1464] Chapter 4 of the HSCA 2012, article 115, L. Stirton, *supra* n. 450, at 193. The national tariff replaced the PbR system, under which (broadly speaking) commissioners paid healthcare providers for each patient seen or treated, taking into account the complexity of the patient's healthcare needs.
[1465] Ashford and St Peter's and Royal Surrey County, CMA report, *supra* n. 1444, at para 250.
[1466] *Ibid*, para 2.52.
[1467] *Ibid.*, 2.54.
[1468] Article 72 HSCA 2012.

market power.[1469] Monitor also has the authority, again concurrently with the CMA, to undertake market investigations, where there are concerns about the operation of competition.[1470] CMA is also obliged *to cooperate* with Monitor with regard to cases involving mergers of NHS FTs. In fact, where the CMA decides to carry an investigation under the Enterprise Act 2002 of a matter involving an NHS FT, it must immediately notify Monitor of its intention to start an investigation.[1471] Monitor is then obliged to provide the CMA with advice on the effect of the transaction on benefits in the form of those stated in the Enterprise Act 2002, *relevant customer benefits*.[1472]

Under the HSCA 2012, CQC remained the independent regulator of health and social care in England. CQC's role is to monitor, inspect and regulate services to make sure they meet fundamental standards of quality and safety as well as to publish inspection ratings to help patients choose care.[1473] Although quality regulation did not feature initially as a policy priority, the Coalition Government significantly altered the policy and legislative framework for quality regulation.[1474] This was partly in response to the findings of the Francis Inquiry into failures of care at Mid Staffordshire NHS Foundation Trust.[1475] The new regulatory model requires CQC to investigate whether the care

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[1469] L. Stirton, *supra* n.450, at 193.
[1470] *Ibid*.
[1471] Article 79(4) HSCA 2012.
[1472] Article 79(5) HSCA 2012.
[1473] Memorandum of Understanding between Monitor and the Care Quality Commission, 2.
[1474] C. Ham, B. Baird, S. Gregory, J. Jabbal and H. Alderwick, *supra* n. 1443, 41.
[1475] *Ibid*, 40. Between 2005 and 2008 conditions of appalling care were able to flourish in the main hospital serving the people of Stafford and its surrounding area. During this period this hospital was managed by a Board which succeeded in leading its Trust (the Mid Staffordshire General Hospital NHS Trust) to foundation trust (FT) status. In preparation for its application for FT status, the Trust had been scrutinized by the local Strategic Health Authority (SHA) and the Department of Health (DH). Monitor had subjected it to assessment. It appeared largely compliant with the then applicable standards regulated by the Healthcare Commission (HCC). Local scrutiny committees and public involvement groups *detected no systemic failings*. In the end, the truth was uncovered in part by attention being paid to the true implications of its mortality rates, but mainly because of the persistent complaints made by a very determined group of patients and those close to them. This group wanted to know why they and their loved ones had been failed so badly. The setting up of the Mid Staffordshire NHS Foundation Trust Public Inquiry was announced to Parliament by the then Secretary of State for Health on 9 June 2010. The first inquiry heard harrowing personal stories from patients and patients' families about the appalling care received at the Trust. On many occasions, the accounts received related to basic elements of care and the quality of the patient experience. These included cases where: Patients were left in excrement in soiled bed clothes for lengthy periods; Assistance was not provided with feeding for patients who could not eat without help; Water was left out of reach; In spite of persistent requests for help, patients were not assisted in their toileting; Wards and toilet facilities were left in a filthy condition; Privacy and dignity, even in death, were denied; Triage in A&E was undertaken by untrained staff; Staff treated patients and those close to them with what appeared to be callous indifference. There was a lack of basic care across a number of wards and departments at the Trust; The culture at the Trust was not conducive to providing good care for patients or providing a supportive working environment for staff; there was an atmosphere of fear of adverse repercussions; a high priority was placed on the

that is being provided is safe, effective, caring, responsive to people's needs, and well led.[1476] The changes the new regulatory framework introduced mainly include: (a) a new form of 'intelligent monitoring' of providers to assess ongoing risks to the quality of care, thereby anticipating services at risk of failing before they do so.[1477] Under this regime, providers should be assessed on the basis of 150 quality indicators.[1478] This regime also foresees (b) greater use of qualitative data drawing on the experience and expertise of clinicians, patients (c) specialist inspections under the auspices of 'chief inspectors' (for hospitals, general practice and adult social care) with visits by large teams of experts (c) a new form of performance ratings for individual services and the trust as a whole, from 'outstanding' to 'inadequate'.[1479]

### 1.2 The effect of the procompetitive regulation on the hospitals' incentives to merge

The previous section indicated that the Coalition Government in introducing the HSCA 2012 attempted to protect healthcare quality by (a) promoting choice and quality competition

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achievement of targets; the consultant body largely dissociated itself from management; there was low morale amongst staff; there was a lack of openness and an acceptance of poor standards; *Management thinking during the period under review was dominated by financial pressures and achieving FT status, to the detriment of quality of care*; There was a management failure to remedy the deficiencies in staff and governance that had existed for a long time, including an absence of effective clinical governance; There was a lack of urgency in the Board's approach to some problems, such as those in governance; Statistics and reports were preferred to patient experience data, with a focus on systems, not outcomes; *There was a lack of internal and external transparency regarding the problems that existed at the Trust*. One of the key issues raised in the report was the role played by external organizations which had oversight of the Trust. The report noted that: 'The Inquiry has received a considerable number of representations that there should be an investigation into the role of external organizations in the oversight of the Trust. Concern is expressed that none of them, from the PCT to the Healthcare Commission, or the local oversight and scrutiny committees, detected anything wrong with the Trust's performance until the HCC investigation. While such an investigation is beyond the scope of this Inquiry, local confidence in the Trust and the NHS is unlikely to be restored without some form of independent scrutiny of the actions and inactions of the various organizations to search for an explanation of why the appalling standards of care were not picked up. It is accepted that a public inquiry would be a way of conducting that investigation, but also accepted that there may be other credible ways of doing so'. See: The Mid Staffordshire NHS Foundation Trust Public Inquiry chaired by Robert Francis QC, Report of the Mid Staffordshire NHS Foundation Trust Public Inquiry, Executive Summary, 1-13.

[1476] C. Ham, B. Baird, S. Gregory, J. Jabbal and H. Alderwick, *supra* n. 1443, 45.

[1477] *Ibid*, 16.

[1478] *Ibid.*, 42. Intelligent Monitoring is built on a set of indicators that look at a range of information including patient experience, staff experience and performance. The indicators relate to the five key questions CQC asks of all services: Are they safe, effective, caring, responsive, and well-led? Each trust's Intelligent Monitoring report is publicly available in line with CQC's commitment to transparency. See, Care Quality Commission, 'Intelligent Monitoring: NHS acute hospitals, Guidance, 4, available at: http://www.cqc.org.uk/sites/default/files/20150526_acute_im_v5_indicators_methodology_guidance.pdf.

[1479] C. Ham, B. Baird, S. Gregory, J. Jabbal and H. Alderwick, *supra* n. 1443, 42. See: http://www.cqc.org.uk/news/releases/cqc-refreshes-its-priority-bands-inspection.

between healthcare providers (b) enforcing quality regulation and ensuring that multiple actors and regulators are responsible for supervising the quality of NHS services. This section aims to demonstrate that specific dimensions of this framework incentivize hospitals to merge. These dimensions are: the tariffs setting, the vigorous enforcement of quality regulation, the TSA regime. To better explain my argument, I provide some examples.

Monitor sets the national tariffs each year. These tariffs apply to the majority of acute healthcare services provided in hospitals, including admitted patient care, outpatient attendances and A&E services. The tariff aims to cover providers' costs in providing healthcare services. Obviously, in calculating the tariff Monitor must take into account providers' incentives to provide not only efficient but also quality services. Under the applicable regime, one of the autonomies NHS FTs enjoy is that they can keep their potential surpluses. Exactly because they enjoy this freedom, they have the incentives to cut their costs and provide efficient services. As long as the tariff covers their costs, they also have incentives to increase the volume of the patients they treat. Nonetheless, if the tariff is not high enough to cover the costs they in fact undertake, hospitals may face serious financial distress. This risk is a serious one as the *marginal rate rule* example clearly demonstrates. The marginal rate rule was introduced in 2010/11 in response to concerns about growth in the volume of patients being admitted to hospital as emergencies.[1480] This rule sets a baseline value for income from emergency admissions for each provider. For emergency admissions above this baseline, the provider receives only 30% of the normal price.[1481] The mindset at the time expected that increased demand was being driven by providers and that a disincentive for admitting emergency patients would bring admissions down.[1482] After the rule was implemented though, this belief proved to be false. Since demand for urgent and emergency care was real it continued to rise. Therefore, the only effect marginal tariff had in practice was the transferring of risk to providers. Obviously to avoid financial failure *providers not being able to diversify this risk might seriously consider to merge.*

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[1480] Monitor and NHS England's review of the marginal rate rule, 2 available at: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/300862/Monitor_and_NHS_England_U2019s_review_of_the_marginal_rate_rule.pdf.

[1481] *Ibid.*

[1482] NHS Confederation, 'The marginal rate for emergency admissions What you said, what we did, what has and still needs to be done', 2, available at: http://www.nhsconfed.org/~/media/Confederation/Files/public%20access/Marginal_rate_for_emergency_admissions.pdf.

Providers might also choose to merge in order to meet the high standards of healthcare quality the applicable framework actually sets. As noted, healthcare providers, such as NHS acute hospitals, are rated by CQC on the basis of approximately 150 quality indicators. These indicators aim to measure the safety, effectiveness, caring, responsiveness, and leadership of the providers. They are also tools to support inspection by monitoring risk and highlighting areas of focus for an inspection. After each inspection, CQC produces a report that reflects the overall judgement of providers' quality of care. These reports are published and therefore are available to the people that choose treatment and providers, namely patients, GPs, commissioners. Unless hospitals perform well in these reports, they run the risk of losing contracts and patients. Consequently, healthcare providers feel extreme pressure to meet the quality standards CQC periodically sets. Because of this pressure, hospitals have high incentives to employ high quality stuff, invest in research, patients' convenience and amenities. Nonetheless, if the tariff they receive for the services they offer is not high enough to allow them to meet these quality standards they might choose either to cease investments in quality at the expense of their rating, or invest in quality at the expense of their financial performance. *This risk, again, is real.* After the Francis report was published and quality regulation received greater attention by the Coalition Government, NHS providers attempted to improve their performance and avoid bad ratings by recruiting additional nurses and other staff.[1483] While this was understandable, it inevitably accentuated growing financial pressures in a system where providers were already struggling to balance their budgets. The government responded by redirecting funding into frontline care, but despite this, many providers struggle to avoid going into deficit.[1484] *Instead of losing their license or exiting the market, NHS FTs, again might choose to merge.*

Under the TSA regime, as noted, Monitor is authorized to appoint a TSA to a NHS FT if it considers that the trust is, or is likely to become, unable to pay its debt or where there is a serious failure by the FT to provide services of sufficient quality. The duty of a TSA is twofold: (a) to acquire full control of the FT, replacing the functions of the FT board (all members of the board are legally suspended from their board governance responsibilities and governors are suspended too) and, (b) to produce recommendations in a report to the Secretary of State about actions to secure

[1483] C. Ham, B. Baird et al *supra* n. 1443, 16.
[1484] *Ibid.*

into the future the delivery of quality, safe and financially sustainable essential services of the NHS Trust in administration. *The proposed solution is likely in most cases to involve merging all or part of the business of the failing trust with another foundation trust or NHS trust.*

In all of the above cases, if the merger between NHS FTs is not approved, the merging entities might have to exit the market. Inevitably, this would harm essential objectives from health policy perspective, such as the continuity of healthcare services and access to them regardless of peoples' ability to pay for them. *Can the CMA in its merger assessment take these non - competition goals into account?* In general, one could argue that the CMA should not consider these goals as these goals cannot be seen as *customer benefits* in the sense of the benefits described in the Enterprise Act of 2002. Indeed, article 30 of the Act indicates that 'a benefit is a relevant customer benefit if it is a benefit to relevant customers in the form of (a) lower prices, higher quality or greater choice of goods or services in any market in the United Kingdom (whether or not the market or markets in which the substantial lessening of competition concerned has, or may have, occurred or (as the case may be) may occur); or (b) greater innovation in relation to such goods or services.

Nonetheless, if the analysis stopped here, the answer to the above question would be incomplete. This is because as noted, under article 79 of the HSCA 2012 the CMA is obliged to receive Monitor's advice in relation to the benefits of the merger for patients. *Could Monitor's involvement in the merger assessment transform how the notion of customer benefits is in fact assessed?* Answering this question requires us to recall Monitor's main duties in accordance with the HSCA.

Monitor is mainly responsible for promoting competition, regulating prices, securing continuity of supply where there is no alternative provider(s). Monitor is also obliged to protect and promote the interests of people who use health care services by promoting provision of health care services which— (a) is economic, efficient and effective, and (b) maintains or improves the quality of the service.[1485] Especially with regards to competition, Monitor must exercise its functions with a view to preventing anti-competitive behaviour in the provision of health care services for the purposes of the NHS *which is against the interests of people who use such services.*[1486] With the exemption of

[1485] Section 62, HSCA 2012.
[1486] Section 62, HSCA 2012.

promoting competition,[1487] when carrying out its duties, Monitor, must take due account, among others, the need for commissioners of health care services to ensure fair access to the NHS services.[1488]

Promoting competition and securing continuity of supply and access are goals and that can be potentially conflicting. To the extent healthcare providers do not feel that they will exit the market if they fail to provide high quality services, their incentives to compete on quality become, inevitably, weak. *In performing its multiple duties can Monitor strike the appropriate balance between these potentially conflicting objectives?* In theory, *yes*. This is because the HSCA clearly states that when Monitor exercises its competition function, it can take into account its general non - competition duties *only if these relate to matters to which the CMA is entitled to have regard.*[1489] Especially in the case of mergers, the HSCA additionally states that Monitor must provide the CMA with advice on the transaction's potential customer benefits in the form of those within section 30(1)(a) of the Enterprise Act 2002.[1490] This in general means that at least in principle Monitor should not exercise its competition function with an eye to protect access to NHS services or the financial stability of the merged entities. However, since clause 39(4) of the HSCA additionally states that Monitor can also provide the CMA with advice *on any other matters* relating to the merger, *as Monitor considers appropriate*, the integration of social concerns into the merger analysis cannot be totally precluded. The injection of non-competition goals into the merger assessment through the Monitor's involvement cannot also be precluded considering two things: first that Monitor is likely to be exercising its regulatory powers in a continuous manner which makes it difficult to accept that it will be able to adopt decisions in the vacuum.[1491] It is difficult for example to accept that Monitor will not be tempted to widen the notion of customer benefits when assessing hospital mergers in cooperation with the CMA although one of its main regulatory tasks is to ensure the continuity of healthcare services especially in case a provider faces the risk of exiting the market because of financial failure. It is also difficult to see why Monitor would not accept the argument that a merger is necessary for the continuous provision of healthcare services in poor remote areas despite its adverse effects on competition as in performing

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[1487] Section 74, HSCA 2012
[1488] Section 66, HCSA 2012.
[1489] Section 74, HSCA 2012.
[1490] Section 79 HSCA 2012
[1491] A. Sanchez Graells, 'Monitor and the Competition and Markets Authority', *University of Leicester School of Law Research Paper No. 14-32*, 9.

its regulatory tasks Monitor is obliged to take into account the need for commissioners of health care services to ensure *fair access* to the NHS services.

*Should the risk of exiting be taken into account when mergers are reviewed?* Should the continuity of services be taken into account by CMA and Monitor when in the context of their merger assessment examine whether a merger may yield *customer benefits*? This question is *crucial but not easy*. This is because if CMA and Monitor excluded any equity or accessibility concerns from their merger analysis, then their analysis may harm health policy objectives, such as continuity and equity which are in fact pursued by other NHS bodies, such as the CCGs or the NHS England. Surely, even if CMA and Monitor did not consider these objectives in their analysis, access to NHS services would not be completely restricted. This is because in case of financial failure, as noted, Monitor would apply the TSA regime. Nonetheless, especially in rural cases where alternative providers may be limited, the risk of restricted access in the short term cannot be excluded. However, integrating equity concerns into a hospital merger assessment so that continuity is ensured may harm the efficiency of the merged entities in the long term. This is because evidence shows that trust mergers present significant challenges to the organizations that acquire services.[1492] The experience of the Heart of England NHS Foundation Trust in taking over Good Hope Hospital in 2009 is a good illustration, whereby a well-performing organization found its performance adversely affected over several years following the acquisition. King's College Hospital NHS Foundation Trust has also run into similar difficulties following the acquisition of Princess Royal University Hospital in south London.[1493] Therefore, even if CMA and Monitor accepted proposed mergers in order to make a merger assessment that is in line with essential objectives of the UK healthcare system, they might end up protecting these objectives in the short term but definitely not in the long term.

The section that follows is dedicated to delving into these tradeoffs. Essentially, it explores whether and to what extent these conflicting objectives between CMA, Commissioners, and Monitor may transform the assessment of mergers between NHS FTs. To conclude this assessment, the section that follows first reviews the competition law framework under which mergers between

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[1492] C. Ham, B. Baird et al *supra* n. 1443, at 14.
[1493] *Ibid.*

NHS FTs are examined by Monitor and the CMA. It also explores how under this framework, Monitor and the CMA assess quality when they examine mergers between NHS FTs. It also sees what the dimensions of quality that actually matter to them are, when they evaluate the merger's impact on quality competition. To adequately analyze these issues it also reviews some recent merger cases between NHS FT and sees whether and to what extent the above identified conflicting objectives between these different actors in healthcare transform CMA's merger analysis with regards to NHS FTs.

## 2. How does the CMA integrate quality concerns in the context of NHS mergers?

The HSCA 2012 expressly gave the CMA exclusive jurisdiction over mergers between NHS FTs. In addition, the CMA has jurisdiction to review mergers between an NHS FT and an NHS trust and mergers between NHS trusts and other enterprises in England (NHS mergers).[1494] Not surprisingly, since under the HSCA healthcare providers compete on quality and not on price, the CMA when assessing a mergers' impact on competition, its analysis focuses on quality. Mergers solely between NHS trusts are not reviewable by the CMA, but by Monitor.[1495]

The general framework under which CMA reviews mergers is described in the 2010 Merger Assessment Guidelines. In 2014 the CMA issued specific guidance (the Guidance) with regards to mergers involving a National Health Service (NHS) foundation trust and mergers between NHS trusts and other enterprises in England.[1496] In this Guidance, although the CMA recognizes that mergers between NHS trusts (NHS mergers) may yield substantial qualitative and cost efficiencies, such as financial savings, sharing of best practices, better delivery of integrated care and service reconfiguration to generate better outcomes for patients or value for money for the taxpayer, it also

[1494] CMA Guidance on the Review of NHS Mergers, 31 July 2014, CMA29, 4.
[1495] NHS trusts are under the common control of the Secretary of State for Health. Monitor advises the NHS Trust Development Authority (TDA) on the impact mergers between NHS trusts will have on choice and competition. As far as possible, Monitor adopts an approach that is consistent with the approach taken by the CMA for NHS foundation trusts and other enterprises. TDA takes into account Monitor's advice and any recommended actions when making its final decision on whether to proceed with a proposed merger.
[1496] CMA Guidance, *supra* n. 1494.

acknowledges that they may also reduce quality competition by eroding NHS providers' incentives to improve services for patients.[1497]

Therefore, when the CMA assesses an NHS merger, it examines both the potential (a) adverse effects for patients and/or commissioners arising from a loss of competition and (b) benefits of a merger for patients and commissioners.[1498] In making this assessment, the CMA aims to ensure that the merger is *in the overall interest of patients*.[1499] Interestingly, in carrying out this review, it seems that CMA does not undertake a strict competition assessment. Indeed, to a certain extent the CMA may take into account the health policy goals pursued by CQC, Monitor or the commissioners. This is because in analyzing a merger case, the CMA gathers and evaluates evidence from various resources including the merging providers, the Department of Health, Monitor, NHS England, the CQC, commissioners, local patient representatives, and third party providers.[1500] Additionally, in assessing the effect of an NHS merger on competition, the CMA also particularly considers the structure and the regulatory regime the merging entities are subject to.[1501]

In brief, to identify the potential costs and benefits of an NHS merger the CMA applies a two-phase merger control regime. At Phase 1, the CMA determines whether it believes that the merger results in a realistic prospect of a substantial lessening of competition (SLC).[1502] If so, the CMA has a duty to launch an in depth assessment (Phase 2), although merging parties may offer to modify aspects of the transaction to remedy any competition concerns identified (known as Undertakings in Lieu), thereby obtaining a resolution at Phase 1, conditional on acceptance of the remedies. The CMA also has the discretion not to launch a phase 2 investigation if it believes that (a) the market is not of sufficient importance to justify a phase 2 investigation (b) there are benefits to customers arising from the merger that outweigh the effect of the SLC (c) the anticipated merger is not sufficiently advanced or likely to proceed to justify a phase 2 investigation.[1503] As noted, Monitor has a statutory duty to advise the CMA *on the benefits of NHS mergers that are reviewed by the CMA or on*

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[1497] *Ibid*, 1.
[1498] *Ibid*, 2.
[1499] *Ibid.*
[1500] *Ibid.*
[1501] *Ibid.*
[1502] *Ibid*, 23.
[1503] *Ibid.*, 42.

*any other matters it considers appropriate*.[1504] Monitor's advice, though, is not binding on the CMA. Nonetheless, the CMA clarifies that it places significant weight on Monitor's expert advice on the *benefits of a merger*.[1505]

At phase 2, a CMA panel of independent members conducts an in depth investigation to assess: (a) whether a relevant merger situation has been or will be created[1506] (b) if so, whether the creation of that situation has resulted, or may be expected to result, in an SLC with worse outcomes for patients and/or commissioners within any market or markets in the UK for goods or services (where both limbs are satisfied, this is referred to as an 'anti-competitive outcome').[1507] If the CMA panel finds that there is an anticompetitive outcome it must decide: (a) whether action should be taken by it, or by others, to remedy, mitigate or prevent the SLC concerned or any adverse effect that has resulted from, or may be expected to result from that SLC (b) if action is to be taken, what action should be taken and what is to be remedied, mitigated or prevented.[1508]

*How and under what techniques does CMA assess whether a SLC had occurred? How does the CMA assess quality at this stage of merger assessment? And most importantly, does the CMA consider the wider health policy objectives of the UK health system when making this assessment?* The section that follows is dedicated to examining these core questions.

### 2.1 Quality concerns in assessing SLC

To begin with, SLC occurs when rivalry is substantially less intense after the merger than would otherwise have been the case, resulting in a worse outcome for patients or commissioners.[1509]

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[1504] Section 79, HSCA 2012.
[1505] CMA Guidance, *supra* n. 1494, at 23.
[1506] The CMA has jurisdiction to examine a merger where two or more enterprises cease to be distinct and — either the UK turnover of the acquired enterprise exceeds £70 million — or the enterprises which cease to be distinct supply or acquire goods or services of any description and, after the merger, together supply or acquire at least 25% of all those particular goods or services of that kind supplied in the UK or in a substantial part of it. Transactions which do not give rise to a relevant merger situation are still subject to general competition provisions contained in the Act and the Competition Act 1998. In healthcare, entire organizations such as NHS foundation trusts and NHS trusts controlling hospitals, ambulance services, mental health services, community services and individual services or specialties may be enterprises for the purpose of UK merger control.
[1507] CMA Guidance, *supra* n. 1494, at 6.
[1508] *Ibid.*
[1509] *Ibid.*, 7.

In assessing an NHS merger the CMA identifies whether the merger may result in SLC in two distinct markets. These are (a) *competition in the market* or else competition to attract patients and (b) *competition for the market* or else competition to attract contracts to provide services.[1510] Competition in the market occurs where patients *have a choice* between providers of the same service.[1511] Since payments for NHS services are made to NHS FTs on the basis of nationally mandated prices across England, competition in the market is exclusively based on quality.[1512] On the other hand, *competition for the market* occurs because commissioners have to select which provider or providers are best placed to provide services to patients.[1513] This form of competition is based mostly on quality and for a limited amount of cases, also on price.

The application of the SLC test involves a comparison of the merger scenario against the competitive situation without the merger.[1514] The competitive situation that would likely exist if the merger did not take place is referred to as 'the counterfactual'.[1515] Therefore, the selection of the appropriate counterfactual is an essential step in determining whether or not there is an SLC.[1516] The counterfactual may be either *more* or *less* competitive than the prevailing conditions of competition.[1517] Examples of possible counterfactuals are: the prevailing conditions of competition, a provider ceasing to provide specific or all services (exiting provider), another merger than the one under review (involving one of the merging providers), loss of potential entrant.

More specifically, in forming a view on an exiting provider scenario, the CMA considers three limbs: (a) whether the provider *would exit*, (b) whether there would be *an alternative acquirer* for the provider's assets and (c) where the patient and the commissioner contracts of the provider would go in the *event of the provider's exit*.[1518] In assessing the first limb, the CMA particularly takes into account the regime that is in place to ensure that NHS hospitals and other providers meet certain regulatory obligations including those in provider licenses relating to financial and clinical

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[1510] *Ibid.*, 23-24.
[1511] *Ibid*, 23.
[1512] *Ibid.*
[1513] *Ibid.*
[1514] *Ibid*, 24.
[1515] *Ibid.*
[1516] *Ibid.*
[1517] *Ibid.*
[1518] *Ibid.*, 26.

measures.[1519] If, for instance, one of merging parties is placed into the TSA process, this may lead to the dissolution of the provider.[1520] If this scenario seems inevitable, the CMA may consider that the provider would exit absent the merger. Therefore, the merger would not lead to a SLC. In assessing the second limb, whether there would be *an alternative acquirer* for the provider's assets, the CMA particularly takes into account quality as it seriously examines any submissions as to why another provider would not have delivered safe clinical services or not done so on a financially viable basis.[1521] On the other hand, when the CMA examines the third limb, where the patient and commissioner contracts would go, absent an alternative provider, the Guidance does not clarify to what extent quality concerns enter into the CMA's analysis. The Guidance states that if, absent the merger, patients' and commissioners' contracts are likely to have been dispersed across several providers, the merger, by transferring most or all of the commissioner and patients contracts to the acquiring provider may significantly restrict competition.[1522] If on the other hand, the majority of the commissioner contracts and patients are expected to switch to the acquiring provider, the merger will be considered to have little impact on competition.[1523] In other words, when assessing this counterfactual scenario, the CMA assesses *how the contracts would have been dispersed but not how they would have been performed.*

Quality considerations become also part of the CMA's assessment when the most possible counterfactual scenario appears to be that one of the merging parties would cease to provide *specific* services. According to the Guidance, when this countervailing scenario is assessed, merging parties can make submissions as to whether one of the alternative providers is less likely to be a strong alternative choice for patients or commissioners due to clinical of financial difficulties and therefore less likely to exercise a strong competitive constraint on the other merging provider.[1524]

Exactly because if CMA concludes that the most appropriate counterfactual scenario is the exiting provider scenario, the CMA will propose that the merger will have little impact on

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[1519] *Ibid*, 27.
[1520] *Ibid.*
[1521] *Ibid*, at 31.
[1522] *Ibid.*
[1523] *Ibid*, 29.
[1524] *Ibid.*, 30.

competition, in many NHS merger cases the merging entities attempt to prove that absent the merger they may exit the market. Indeed, in the *UCLH* case[1525] which concerned the transfer of all neurosurgery inpatient and day care services from Royal Free London NHS Foundation Trust (RFH) to University College London Hospitals NHS Foundation Trust (UCLH), the parties submitted that absent the merger the appropriate counterfactual was the unplanned cessation of neurosurgery at RFH for reasons of clinical safety.[1526] The reason for this was that the London Deanery had already informed RFH that, due to its size, its neurosurgery medical rota was not sustainable and the funding for training posts would in fact be removed. Considering that even without the funding, it would have been possible for RFH to continue its services, the CMA did not find that the exiting provider scenario was the appropriate one.[1527] Interestingly, although the CMA refused to accept that due to the parties' financial difficulties exit was inevitable, it took into account in its assessment the parties' financial and quality concerns *indirectly* when it examined the competitive constraint that RFH would have on UCLH absent the transaction.[1528] Considering the commissioners' views that given RFH's small size there were risks associated with the unit as well as that the proposed merger would actually improve quality, the CMA concluded that there would be sufficient choice of remaining neurosurgery providers post-transaction to mitigate any competition concerns arising from the merger. Having reached this conclusion, the CMA accepted the merger.[1529]

In a similar manner, in the *Ashford* case, which involved the merger between Ashford and St Peter's Hospitals NHS Foundation Trust (ASP) and Royal Surrey County Hospital NHS Foundation Trust (RSC) the merging parties submitted that, if the merger did not proceed, the financial and clinical sustainability of their organizations would be at serious risk given the financial challenges they faced. According to the parties, these financial challenges were highly related to the external environment in which they operated.[1530] The parties claimed that the environment they operated was characterized by: (a) tight funding allocations for commissioners combined with increasing demand for health services, circumstances that are common across the NHS; (b) relatively

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[1525] Acquisition by University College London Hospitals NHS Foundation Trust (UCLH) - Royal Free London NHS Foundation Trust's neurosurgery services ME/5574-12, decision.
[1526] *Ibid*, at 22-23.
[1527] *Ibid.*, para 30.
[1528] *Ibid.* para 81.
[1529] *Ibid.*, 86.
[1530] Ashford and St Peter's and Royal Surrey County, *supra* n. 1444, 3.10.

close proximity to central London teaching hospitals, from which many specialized services for patients in Surrey had historically been delivered, combined with a push by commissioners towards greater centralization of these services.[1531] In light of these factors, absent the merger the parties expected to remain in or enter into deficit.[1532] The parties insisted that absent the merger (a) they would not be able to sustain safe levels of nursing over time, consistent with the latest national guidance (b) they would not be able to deliver seven-day services.[1533] An inability to meet these standards of quality would have a significant adverse effect on the competition they offered to each other and to other providers.[1534] In evaluating the parties' claims and choosing the appropriate counterfactual, the CMA took into account Monitor's financial failure regime as well as the merging entities' ratings. While the CMA did not consider that the parties would exit the market, the CMA acknowledged that the parties would come under financial pressure, mainly due to continued tariff deflation and increasing requirements to deliver quality and efficiency improvements compounded by the increasing difficulty and cost of sourcing skilled staff. According to the CMA, these difficulties would have an adverse impact on the providers' ability to offer the same or a better range and quality of services.[1535]

In the *Heatherwood* merger case,[1536] the merging parties again raised the claim that the proposed merger was necessary for their financial stability. In fact the parties claimed that Heatherwood and Wexham Park Hospitals, two of the merging parties, were struggling trusts and that the quality of their services had deteriorated over time.[1537] In proving their claim, the merging entities submitted to the CMA the CQC's recent inspections. They also informed CMA that HWPH were subject to regulatory intervention by Monitor due to not complying with some of their license conditions.[1538] Monitor confirmed the parties' allegations. In fact, Monitor informed the CMA that HWPH had been in significant breach of their licensing conditions since July 2009 and that they had

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[1531] *Ibid*, 3.11.
[1532] *Ibid.,* para 4.6-4.7.
[1533] *Ibid*, para 4.8.
[1534] *Ibid.* 4.10.
[1535] *Ibid.* para 4.45.
[1536] Anticipated acquisition of Heatherwood and Wexham Park Hospitals NHS Foundation Trust by Frimley Park Hospital NHS Foundation Trust ME/6432-14, decision.
[1537] *Ibid.*, para 20.
[1538] *Ibid.*, para 21.

been subject to numerous regulatory interventions.[1539] The CMA, once again, was not convinced by the merging parties' allegations that due to their clinical or financial difficulties, they would exit.[1540] This is because, according to the CMA, the parties had not submitted compelling evidence demonstrating that absent the merger, HWPH would have inevitably exited.[1541]

Interestingly, in this case, Monitor provided the CMA with its advice pursuant to section 79(5) of the HSCA 2012. Monitor submitted that based on the information available to it, it was not able to determine that any relevant customer benefits for the purposes of the Act would arise.[1542] Nonetheless, with respect to its advice *on matters relating to the proposed acquisition*, Monitor stated that in light of HWPH's sustainability, quality and management issues, the merger appeared as the best available solution to the problems at HWPH and the most likely way of achieving the necessary improvements to services for patients.[1543] Monitor clarified that Heatherwood and Wexham FT had faced significant sustainability, quality and management issues for a long time and had been subject to numerous regulatory interventions.[1544] Monitor expressed its belief that the proposed acquisition was likely to deliver a quicker and more sustainable solution to these issues than further regulatory intervention by Monitor could achieve. For these reasons, Monitor took the view that the proposed acquisition was the best available solution to the merging parties' problems and the most likely way of achieving the necessary improvements to services for patients.[1545] CCGs, some competing NHS providers, patients, and local representatives also supported the merger. These parties specifically referred to FPH's ability to deal with management issues at HWPH and wider clinical and financial issues faced by the trust, the opportunity for FPH to increase scale and thus be better able to deal with the increasing pressure faced by NHS FTs, and the provision of better services and better quality outcomes for patients locally.[1546]

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[1539] *Ibid.*, para 22.
[1540] *Ibid.*, para 24.
[1541] *Ibid*, para 31.
[1542] *Ibid*, para 18.
[1543] *Ibid.*
[1544] Heatherwood and Wexham Park Hospitals NHS Foundation Trust: Monitor's advice on proposed merger, 1-2.
[1545] *Ibid.*
[1546] Heatherwood and Wexham Park Hospitals NHS Foundation Trust merger decision, *supra* n. 1536, paras 108-109.

In the *Bournemouth* case, where the Competition Commission (CC) examined the merger between the Royal Bournemouth and Christchurch Hospitals NHS Foundation Trust (RBCH) and Poole Hospital NHS Foundation Trust (PH) the parties also attempted to convince CC that due to the financial and clinical challenges they faced, many of which were common to acute NHS hospitals the most appropriate counterfactual was the provider exiting scenario.[1547] Again, in assessing this claim, the CC particularly considered the merging parties' financial situations as well as Monitor's failure regime. The CC concluded that in the counterfactual both parties would remain as stand-alone entities, providing broadly similar service offerings to their current offerings.[1548] Therefore, the merging parties' proposed counterfactual scenario was not accepted.

In examining whether an SLC is likely to occur, the CMA follows the following steps: (a) it identifies the relevant markets (b) it examines the unilateral and coordinated effects on competition (c) closeness of competition (d) it assesses countervailing factors such as merger benefits, entry and expansion, countervailing buyer power. The CMA, as the following analysis demonstrates, takes into account quality concerns in all these levels of merger analysis. In particular:

### 2.1.1 Defining the relevant market

In defining the relevant product market, the CMA takes the view that each specialty constitutes a separate market. Within each specialty CMA treats outpatient and inpatient as separate markets noting that there is an asymmetric constraint between inpatient and outpatient, with inpatient providers capable of readily supply-side substituting into outpatient services but not vice versa.[1549] CMA also considers that outpatient services that are provided only in the community should be viewed as separate markets.[1550] The CMA also considers that non-elective and elective activities are separate markets, although the provision of elective activities may be constrained to

[1547] Competition Commission, Royal Bournemouth and Christchurch Hospitals NHS Foundation Trust/Poole Hospital NHS Foundation Trust, para 16. This is the first merger involving NHS foundation trusts that was considered by the CC.
[1548] *Ibid*, para 21.
[1549] CMA Guidance, *supra* n. 1494, at 12.
[1550] CC's Bournemouth and Poole merger decision, *supra* n. 1547, para 5.53.

some extent by non-elective providers.[1551] Private services are also considered separate markets from NHS services.[1552]

When defining the geographic market, the CMA considers that location is important to patients/GPs when they choose a hospital, and hospitals providing the same services in different locations are not perfect substitutes for one another.[1553] Essentially, this view reflects CMA's Guidance stating that, in publicly funded healthcare services, the relevant geographic market may be based on the locations of providers and will be informed by an assessment of the willingness of patients to travel for consultation or treatment, *the catchment area.*[1554] By identifying the catchment area the CMA actually identifies the extent of the areas (in terms of travel distance from the hospital) from which a large proportion of patients originate.[1555] This provides an indication of the area in relation to which the merging hospitals are likely to be important alternatives to each other for patients/GPs.

The CMA considers that the catchment area depends on many factors, including drive-times, public transport, and availability. Considering that the large majority of patients travel to hospital by car, the CMA approximates catchment areas by using drive-times or 'isochrones'.[1556] As part of its assessment, the CMA also considers the constraints posed on the parties by rivals located further away than implied by the isochrones.[1557]

To identify the catchment area and calculate driving times, the CMA takes into account the area from which 80% of patients travel (calculated mainly from their GP practice) split by specialty and type of service (elective, non-elective and outpatient). Having assessed the areas from which 80% of patients travel, the CMA then calculates the drive-times that capture 80% of the patients treated by each merging hospital. By using the drive-time data and by drawing isochrones around the

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[1551] CMA Guidance, *supra* n. 1494, 32.
[1552] *Ibid*, para 6.38.
[1553] CC's Bournemouth and Poole merger decision, *supra* n. 1547, para 5.56, Heatherwood and Wexham Park Hospitals NHS Foundation Trust by Frimley Park Hospital NHS Foundation Trust, merger decision, *supra* n. 1536, at 14.
[1554] CMA Guidance, *supra* n. 1494, 32.
[1555]Ashford and St Peter's and Royal Surrey County, *supra* n. 1444, para 5.33, Bournemouth and Poole, *supra* n. 1547, at 5.57, Acquisition by University College London Hospitals NHS Foundation Trust (UCLH), *supra* n. 1525, Anticipated Acquisition of Chelsea and Westminster NHS Foundation Trust of West Middlesex University NHS Trust, decision, *supra* n 1586, at 52-56.
[1556] CC's Bournemouth and Poole merger decision, *supra* n 1547, 5.58.
[1557] *Ibid.*

sites of the merging parties the CMA maps the catchment area of each merging hospital.[1558] This task then allows the CMA to identify to what extent the merging parties' catchment areas overlap by specialty.[1559] The CMA notes that the catchment area is typically narrower than the geographic market identified using the hypothetical monopolist test.[1560] It underlines though that it takes this into account in its competitive assessment when it looks at other providers and the competitive pressures they place on the merging parties.[1561]

*Does this definition of the geographic market take into account quality*? Indirectly, yes. To the extent patients choose healthcare provider not only on the basis of the location but also on the basis of the quality of the services they receive by each provider, then it could be held that the driving time data and the drawing isochrones reflect the patients' concerns on hospitals' quality. Indeed, especially for elective care, the higher the quality of a specific provider, the more the patients may be willing to travel to enjoy its services. Nonetheless, since reality actually shows that patients can assess specific dimensions of quality, such as waiting times, as well as that GPs often refer patients to specific hospitals because of their patients' relationship with a specific consultants, it could be argued that patients' and GPs' choice of hospital does not necessarily reflect the overall performance of the hospital.

### 2.1.2 Examining the effects on competition

As noted, the CMA measures a merger's impact on quality in two distinct markets: the competition *in the market* and competition *for the market*. For this reason, I will also analyze CMA's assessment in these two markets in separate sections.

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[1558] Ashford and St Peter's and Royal Surrey County, CMA report, *supra* n. 1444, para 5.41.
[1559] *Ibid*, *para* 5.42.
[1560] *Ibid.*, 5.51.
[1561] *Ibid.* CC's Bournemouth and Poole merger decision, *supra* n. 1547, para 5.71.

- ***Competition in the market***

When examining how and to what extent an NHS merger may restrict quality in competition in the market, the CMA applies a *narrow* approach as to the dimensions of quality it incorporates in its analysis. This is because when the CMA measures the impact of an NHS merger on quality, the CMA focuses its analysis mainly on clinical factors, such as infection rates, mortality rates, ratio of nurses or doctors to patients, equipment, best practice, and non-clinical factors such as waiting times, access cleanliness and parking facilities.[1562] At first sight any assessment with regards to the merger's impact on health policy objectives, such as equity and accessibility seems to be excluded. Nonetheless, as the *UCLH* merger case indicates, the CMA might indirectly take these concerns into account as part of its assessment. Indeed, in this case the CMA instead of explicitly stating that it examined the merger's impact on patients' access to hospital services, the CMA stated that it examined the transaction's impact on travelling time for patients.[1563] In other words, instead of raising the question of whether the transaction would impact on patients' access to NHS health services, it in fact asked whether the transaction *would increase patients' travelling time*.

In assessing the merger's anticompetitive effects on competition *in the market* the CMA assesses the extent and nature of current competition. In brief, the CMA identifies which services are provided by both merging providers (the overlap services) and then it asks whether, in respect of each of the overlap services: (a) patients and/or GPs have and exercise choice of provider (b) quality and/or price influences that choice (c) the merging providers have an incentive to compete to attract patients absent the merger (d) the merging providers are close competitors.[1564] Again, this stage of merger analysis is essential. This is because if the CMA reaches the conclusion that the merging parties are not close competitors, or they do not have incentives to compete or quality does not drive GP's or patients' choice, then the CMA will take the view that the merger will not have an impact on quality competition. Therefore, the merger will be accepted.

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[1562] CMA's Guidance *supra* n. 1494, para 1.5.
[1563] Acquisition by University College London Hospitals NHS Foundation Trust (UCLH), *supra* n. 1525, para 60.
[1564] *Ibid.*

Very importantly, when analyzing these issues the CMA takes into account not only the merging parties' views but also third parties views' such as commissioners.[1565] Especially when evaluating merging parties' incentives to compete in the overlap services, the CMA particularly examines whether and how the regulatory framework may affect the merging parties' incentives to compete. In fact it considers: (a) the profitability of increasing activity given the tariff and cost structures (b) capacity constraints (c) the relationships the merging providers have with CCGs.[1566] Interestingly, while the CMA thinks that the merging parties in general have high incentives to compete with regards to elective services, it constantly takes the view that the merging parties do not have high incentives to compete with regards to non-elective services. To elaborate:

In the *Bournemouth* merger case for example the CC examined the merger's impact on competition both on elective and non - elective services.[1567] In assessing the merger's impact on non - elective services the CC thoroughly examined the regulatory framework in which NHS FTs operate. The CC observed that in non - elective services patients do not have a choice of hospitals because they are transported by emergency services according to ambulance protocols.[1568] In these services, the CC emphasized, there is less opportunity for patients to make a choice based on quality since they do not have the benefit of GP guidance.[1569] This is the reason why, the CC underlined, limited information is publicly available to patients on which to compare the quality of non-elective services (with the exception of A&E departments where reviews are available on the *NHS Choices* website).[1570] In shaping its view, the CC further examined whether the profitability of non -elective services in fact restricted the parties' incentives to compete. The CC concluded that the merging parties did not have high incentives to attract additional patients, due to the 30 per cent marginal rate tariff for emergency services.[1571] Analyzing this regime, the CC found that only 30 per cent of the normal tariff is paid on all services resulting from emergency admissions once the *total value* of *all* these services in a given year exceeds the value or 'baseline'.[1572] The CC noted that as the intention

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1565 CMA's Guidance *supra* n. 1494, para 7.22.
1566 *Ibid,* para 61.
1567 CC's Bournemouth and Poole merger decision, *supra* n. 1547.
1568 *Ibid.* para 55.
1569 *Ibid.*
1570 *Ibid.* 6.255.
1571 *Ibid.,* para 55.
1572 *Ibid.*, 6.261.

of this tariff was to keep the number of emergency admissions to a minimum, the parties did not have strong incentives to compete.[1573] In light of this reality, the CC found that the proposed merger would not result in an SLC in relation to non- elective services.[1574]

In contrast, in the same case, in assessing whether the examined merger would result in SLC in elective services, the CC took exactly the opposite view. In this type of services, the CC said, patients and GPs do exercise the right to choose provider for their first consultant – led outpatient appointment, a right which is enshrined in the NHS Constitution.[1575] In this type of services, the CC also said, quality influences choice as evidence from economic literature on choice and competition in the NHS demonstrate that in addition to location, waiting times, infection rates and mortality rates are quality factors that do affect choice of hospital.[1576] The CC further explored the issue of quality competition between hospitals via the patient and GP surveys the CC commissioned.[1577]

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[1573] *Ibid,* 6.272.
[1574] Ibid.
[1575] *Ibid*, para 42.
[1576] *Ibid*, para 6.88
[1577] In this survey the CC asked patients and GPs: *(a)* whether patients were aware that they could choose which hospital they went to; *(b)* what factors patients/GPs considered important in relation to choosing a hospital; *(c)* the factors that were discussed between the GP and the patient (where a discussion occurred); *(d)* which hospitals were discussed/considered; and *(e)* how patients would change their behaviour/GPs would change their recommendations in response to a change in quality or if the treatment they were being referred for was unavailable. In the latter case, where respondents indicated that they would choose a different hospital, the CC asked how strongly they preferred their first option to the second option (on the basis that if they strongly preferred their first option they might be less likely to react to the changes in quality of the magnitude the CC might be concerned about). Specifically, it examined the factors that influence choice and the extent to which patients and GPs would react to changes in relative quality of the merger trusts. It found that the five aspects named most frequently as 'essential/very important' all related to aspects of clinical quality, namely: clinical expertise of healthcare professionals; availability of specialist medical equipment at the hospital; quality of nursing care; clinical outcomes; and quality of aftercare in follow-up visits. It also showed that the next most frequently-named aspects related to waiting times, ease of access/parking, appointment times offered and previous experience. In order to better understand the strength of quality competition between the parties, the CC also looked at the extent to which patients/GPs respond to changes in quality generally or, to put it another way, by how much quality would need to decrease/increase in order to induce a change in hospital choice. Acknowledging that there are many dimensions of quality, some of which are difficult to quantify, the CC used waiting time as measure to complete its assessment. Focusing on one measure of quality, waiting time, is practical and provides useful indicative results for these purposes, the CC acknowledged. The survey indicated that if waiting times were to increase by 10 per cent at RCBH, 26 per cent of RBCH patients would switch hospital, which implied an (own) waiting time elasticity of 2.6. This result, lead the CC to conclude that a significant proportion of patients exercised choice in relation to hospitals. The CC also examined the evolution of hospital shares over time at the GP practice level, which showed some variation over time, indicating that factors other than location were likely to be influencing patients' choices.

In addition, in contrast with non-elective services, in elective services, the CC said, there are incentives for the parties to compete to attract patients in order to earn income.[1578] The CC concluded that although the parties' incentives were weakened to some extent by uncertainty over payment for extra activity and, at the aggregate level, by constraints on expanding overall capacity, incentives to compete for elective services remained.[1579] In reaching this conclusion the CC particularly considered that the merging parties' elective surgeries appeared to be generally profitable at the margin. It also considered that the merging parties tended to be remunerated fully by the CCGs when they exceeded planned activity. Therefore, the merged entities had incentives to increase their volume.[1580] The CC also took into account that the applicable quality regulatory framework did not undermine parties' incentives to compete. In reaching this finding, the CC particularly examined whether regulatory factors might crowd out the scope for current or future competition to influence quality, because they either imposed quality standards or provided financial rewards to an extent that removed the parties' incentives or ability to compete on quality.[1581] The CC noted that NHS providers, including foundation trusts, are subject to a range of legal obligations, policy guidance and best practice relating to the quality of health services they provide. It also noted that failure to meet some quality criteria may have negative ramifications as specific regulatory requirements exist to prevent some aspects of quality from falling below specified minimum thresholds. In CC's view, though, such requirements did not act so as to change the parties' incentives for quality at the margin, since both parties were well rated in terms of the quality of the services they provided and may be above the minimum standards or national average in many areas. The CC particularly emphasized that national targets (such as waiting time targets) do not entirely remove a role for quality competition as hospitals are incentivized by published information about their performance in relation to the target not only to meet targets but perform well in relation to their closest competitors.[1582] Noting that all UK hospitals are subject to the same set of regulations

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[1578] *Ibid*, 6.124.
[1579] *Ibid*, 48.
[1580] It should be noted that the parties disagreed with CMA's analysis on the basis that if they engaged in expanding activity without commissioner approval they would not expect to be remunerated in the same way as they had been in the last three years. They claimed that in 2009/10 they expanded their activity significantly above the agreed level and were not fully paid for the activity they carried out (see paragraph 6.158); and that since then, *they had been careful not to take on additional activity without the support of commissioners*, and that when activity exceeds the pre-agreed level it was for reasons acceptable to the commissioner and they could expect to be paid.
[1581] CC's Bournemouth and Poole merger decision, *supra* n. 1547, para 6.179.
[1582] *Ibid.*, 6.182.

as the parties and vary significantly in terms of quality the CC concluded that quality regulation does not impede competition on quality.[1583] In light of this analysis, the CC concluded that the merger would be likely to lead to unilateral effects in the elective inpatient specialties.[1584] According to the CMA, the loss of actual competition between the parties would result in less pressure to maintain and improve the quality of the services that they offered to patients.[1585]

In the *Ashford* merger case, the CMA also assessed the merger's impact on parties' incentives to compete on quality on both elective and non - elective services. In assessing the merger's anticompetitive effects in elective services, the CMA particularly examined how commissioning arrangements, capacity and payment structures may impact on the merging parties' incentives to compete with one another.[1586] After assessing the structure of the parties' commissioning arrangements, profitability and capacity levels, the CMA considered that premerger the parties *had an incentive* to maintain current levels of patient referrals and attract additional patient referrals for elective services.[1587] In shaping its view, the CMA examined the commissioners' and regulators' role in responding to falling service quality, by redesigning services or patient pathways. It also considered commissioners' submissions indicating that following intervention, the threat of financial penalties or service removal acts as a significant motivator for trusts to improve their offering to patients.[1588] Considering though that in the elective services the merging parties faced competitive constraints and therefore patients and GPs would be able to choose another hospital, if the quality of their services declined and that in some services the parties already worked very closely together and operated with a high degree of clinical integration, the CMA concluded that the merger would not result in SLC with regards to elective services.[1589]

In the same case, in assessing the merger's effect in non-elective services, the CMA repeating its analysis in the *Bournemouth* case,[1590] emphasized that the providers do not have high

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[1583] *Ibid.*, 6.180-6.181.
[1584] *Ibid.*
[1585] *Ibid.*
[1586] Ashford and St Peter's and Royal Surrey County CMA's report, *supra* n. 1444, at para 6.43.
[1587] *Ibid*, para 6.63.
[1588] *Ibid*, para 6.73.
[1589] *Ibid.*, para 22.
[1590]CC's Bournemouth and Poole merger decision, *supra* n. 1547.

incentives to compete with respect to these services. The CMA again maintained that the patients who need emergency services often cannot choose which hospital they attend. It also found that emergency services are generally not profitable which further reduces any incentive to compete for emergency patients.[1591] The CMA observed that in the last two years, the merging parties had exceeded the baseline for emergency admissions with their main commissioners. Therefore, the revenue earned on marginal non-elective admissions was 30% of the full tariff.[1592] Taking due account of all these factors, the CMA concluded that the parties had little or no financial incentive to attract additional non-elective referrals. On the basis of this finding, the CMA held that the merger would not result in a substantial lessening of competition with regards to emergency services.[1593]

Additionally, when examining closeness of competition between competitors, the CMA again takes into account quality. Nonetheless, the analysis under which the CMA integrates quality when it assesses closeness of competition does not fully reflect the economic reality of healthcare markets. To further illustrate my point, I first explain how CMA assesses closeness of competition.

When assessing closeness of competition, the CMA's starting point is to consider referral patterns and the overlaps between the catchment areas of the merging providers together with those of any other local providers, given that location is usually important in patients' choice of hospitals.[1594] The CMA may also survey patients or use existing evidence on diversion ratios (for example, evidence of where patients went in the event of a temporary reduction of quality). The *Ashford* merger perfectly illustrates under what methodology the CMA measures closeness of competition.[1595] In this case in assessing closeness of competition the CMA (a) asked patients what they would have done if the hospital they were attending did not offer the treatment they required or provided lowered quality services (b) used and analyzed referral data. In analyzing these referral data, the CMA looked at the share of patients referred to each provider from GP practices that referred at least one patient to either one of the parties over four years. As a proxy for assessing to which hospital patients/GPs of the parties might switch their choice in response to a reduction in quality at

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[1591] *Ibid.*, 7-20-7.22.
[1592] *Ibid.*
[1593] *Ibid.*, 55.
[1594] CMA's Guidance, *supra* n. 1494, at 6.53.
[1595] Ashford and St Peter's and Royal Surrey County merger case, *supra* n. 1444.

the relevant party, the CMA assumed that patients/GPs would switch providers in accordance with the share of patient/GP referrals received by the other providers at the GP practice concerned (proportional analysis).[1596] The CMA underlined that GP referral analysis is based on the actual choices of provider (at outpatient level, and inferred choices for day-cases and inpatients), which allows CMA to determine historical patient/GP preferences.[1597] The CMA used this information to infer the providers to which patients/GPs might switch in the event of a decline in quality at one of the merging parties, making the assumption that historical patient/GP preferences of provider provide good predictions of future patient/GP provider choices.[1598] The CMA considered this to be a reasonable assumption to apply in the healthcare setting, since one distinguishing feature of healthcare markets is that patients cannot perfectly observe the quality of the service that they will receive before they experience the service. In supporting its main assumption, the CMA further took into account findings from the academic literature demonstrating that the higher the proportion of patients a GP refers to a particular provider, the more likely it is that future patients will be referred by that GP to that provider. Applying this method of analysis, the CMA identified 19 specialties where the parties seemed to be close competitors.[1599]

Applying a similar analysis in the *Heatherwood* case, the CMA concluded that HWPH was not FPH's closest competitor in any specialty and FPH was HWPH's closest competitor for a limited number of specialties for which other NHS providers also competed strongly.[1600] In reaching its conclusion the CMA particularly considered the absence of significant third - party competition concerns and the support from a large number of third parties, mainly CCGs, patient groups and other NHS providers.[1601] Hence, the CMA held that there was not a realistic prospect that the merger would give rise to SLC in relation to *competition in the market*.[1602] In the *Chelsea* merger case where the CMA examined whether the merger between Chelsea and Westminster NHS Foundation Trust (CWFT) and West Middlesex University NHS Trust would reduce quality competition in elective, non-elective, inpatient and outpatient services and specialized services in West London, the

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[1596] *Ibid*, 35-36.
[1597] *Ibid.*, para 6.132.
[1598] *Ibid.*
[1599] *Ibid.*, 6.142.
[1600] Heatherwood and Wexham Park Hospitals NHS Foundation Trust, *supra* n. 1536, at para 10.
[1601] *Ibid.*, para 84.
[1602] *Ibid.*

CMA also measured closeness of competition under an analogous methodology. In this case the CMA concluded that the parties were differentiated either in terms of the scope and level of specialization or the geographic areas from where each party drew its patients for different specialties.[1603] Because of this assessment, the CMA concluded that the merger would not give rise to a realistic prospect of a SLC in the relevant markets.[1604]

The methodologies applied by the CMA in these cases for assessing closeness of competition is primarily based on the assumption that GPs and patients can immediately assess and understand providers' changes in quality which may not necessarily be the case. More than that, even if GPs were immediately able to understand that a hospital has reduced its quality on the basis of its rating, GPs may still advise their patients to receive services from the same provider because of their patients' relationship with a specific health consultants. This is the reason why GPs' referrals may not always reflect providers' closeness of competition with regards to all dimensions of quality.

- ***Competition for the market***

As noted, in its merger assessment, the CMA examines not only the merger's impact on quality competition in the market but also on quality competition *for the market*. When assessing the merger's impact on competition *for the market*, the CMA's approach is quite lenient. This is because in all cases, in shaping its assessment, the CMA exclusively relies on commissioners' views that competition for the market either does not exist or does not contribute to quality improvements. In the *Bournemouth* merger case, for example, the CMA examined whether the merger would be likely to lead to reduced competition in relation to services which commissioners may change or reconfigure, as the merger would reduce the number of potential suppliers.[1605] Based on information provided by the commissioners, the CMA did not find that the merger would be likely to give rise to SLCs in relation to the market for elective, non-elective, community or specialized services.[1606] Interestingly, the commissioners told CMA that they *would be reluctant to procure services via competitive processes to increase*

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[1603] Anticipated Acquisition of Chelsea and Westminster NHS Foundation Trust of West Middlesex University NHS Trust, *supra* n. 1586, paras 62-108.
[1604] *Ibid.*, 4.
[1605] CC's Bournemouth and Poole merger decision, *supra* n.1547, para 60.
[1606] *Ibid.*, 6.320.

*quality*, *noting the potential for destabilizing suppliers*.[1607] The commissioners explained that if an existing supplier was providing services at an acceptable level, they would not be likely to use the potential for change of supplier as a tool to improve quality further.[1608] If quality fell below an acceptable level, they said, they would initially work with the supplier to try to resolve this.[1609] If they had to reconfigure to address quality concerns, it would be a last resort and it would be unlikely that the incumbent supplier would be in a good position to win the tender.[1610] Taking these observations seriously into consideration, CMA concluded that the level of quality at which services would be opened up to competition would not be significantly affected by the merger, and so the constraint on quality would be also unchanged.[1611] In its assessment the CMA further took into account that in relation to elective and non-elective services, the award of contracts in competitive situations had occurred rarely and that the parties had, in recent years, rarely bid against each other.[1612]

In the *Ashford* case, the CMA again assessed the merger's impact on competition for the market in relation to (a) competition to provide Surrey-wide community services (b) competition to provide other discrete community services contracts.[1613] In its assessment of the likely effects of the merger on competition to provide community services, the CMA considered the history of tenders for community services in the area, commissioners' plans for tenders in Surrey in the future and whether the parties would be likely to compete in relation to such tenders. In respect of the Surrey-wide community services commissioners considered that the merged hospitals would be likely to face competition from a number of other bidders.[1614] In relation to tenders for discrete community services, the CMA also held that the merging parties were unlikely to be at an advantage compared with other bidders and that there would be competition from a number of other bidders.[1615] Therefore, the CMA considered that the merger would not reduce competition for the market.[1616]

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[1607] *Ibid.,* 6.317.
[1608] *Ibid.*
[1609] *Ibid.*
[1610] *Ibid.*
[1611] *Ibid.*
[1612] *Ibid.*, 6.320.
[1613] Ashford and St Peter's and Royal Surrey County., CMA's report, *supra* n. 1444, 10.9-10.40.
[1614] *Ibid.*, 10.19.
[1615] *Ibid.* 10.31-10.32.
[1616] *Ibid.*

In the *Heatherwood* merger case[1617], the CMA again considered whether the merger might lead to reduced competition in relation to NHS (i) elective or non-elective services commissioned by CCGs and (ii) specialized services commissioned by NHS England Specialized Commissioning. Based on third party responses, that the NHS Bracknell and Ascot CCG were the only CCGs where the merging parties were the two leading providers of NHS hospital services as well as that there were a number of other NHS providers with a similar range of services, the CMA concluded that the envisaged merger would not limit competition for the market.[1618]

In the *Chelsea case* the CMA also considered whether the Merger might lead to reduced competition in relation to NHS (a) elective or non-elective services commissioned by CCGs and (b) specialized services commissioned by NHS England Specialized Commissioning. Considering the tender data submitted by the parties not showing any material overlap between them in bidding for tender services and that the relevant local CCGs replied to the CMA that the parties did not compete with each other for tendered contracts, the CMA concluded that there were no concerns as to the merger's impact on competition *for the market*.[1619]

### 2.1.3 Assessing countervailing factors: efficiencies, entry and expansion, countervailing buyer power

While mergers can harm competition and thereby adversely affect patients, they can also give rise to efficiencies that make the merged provider a more effective competitor if, for example, the merger itself gives the merging providers incentives to increase quality of services or reduce prices.[1620] Indeed, if these merger-specific efficiencies are large and timely enough, they can enhance rivalry and prevent a merger giving rise to an SLC.[1621] Efficiencies that do not enhance rivalry can also be taken into account as *relevant customer benefits*, provided that they are likely to arise within a reasonable period.[1622] Measuring, however these efficiencies is not an easy task. This is because all the relevant information the CMA may need in order to verify these claimed efficiencies is usually

[1617] Heatherwood and Wexham Park Hospitals NHS Foundation Trust merger case, *supra* n. 1536.
[1618] *Ibid*, 4.
[1619] Anticipated Acquisition of Chelsea and Westminster NHS Foundation Trust of West Middlesex University NHS Trust, *supra* n. 1603, paras 19-22.
[1620] CMA's Guidance, *supra* n. 1494, para 6.70.
[1621] *Ibid.*
[1622] *Ibid.*

held by the merging parties.[1623] For the CMA to give weight to efficiency arguments, the latter must have compelling evidence that such efficiencies not only result directly from the merger itself, but also that they will be timely, likely and sufficient to prevent an SLC from arising.[1624] The CMA may also take the view that a merger may not lead to SLC on the basis there will be constraints post – merger, such as entry and expansion, or countervailing buyer power. In assessing whether these factors are substantial constraints post - merger, the CMA takes into account quality. Indeed, as the CMA states, in order for entry or expansion to be a constraint post -merger, it is necessary that (a) other providers can profitably begin or expand activity in response to a reduction in quality or increase in price by the merging providers and (b) patients or commissioners would be willing to switch to those providers in sufficient numbers to make the quality reduction or price increase by the merged provider unprofitable.[1625] When assessing potential countervailing buyer power the CMA also considers whether the Commissioners would be likely to have the ability to prevent the merged provider from reducing quality or increasing price by switching or threatening to switch to another provider or otherwise constrain the merged provider.[1626] Since in most of cases the CMA accepted the merger on the basis there is no SLC, the CMA has not substantially assessed either qualitative efficiencies or other countervailing factors in its assessment.

### 3. Assessing the customer benefits

As noted, where the CMA believes at the end of a Phase 1 assessment that it is or may be the case that the merger results or may be expected *to result in an SLC*, the CMA has a discretion to clear the merger where any relevant customer benefits in relation to the creation of the relevant merger situation concerned outweigh the SLC concerned and any adverse effects of the SLC.[1627] The CMA takes into account relevant customer benefits also in the context of a phase II assessment. *What are the customer benefits that actually matter to the CMA?*

The CMA's answer to this core question is straightforward. As the CMA's Guidance clarifies, relevant customer benefits are limited to be benefits in the form of: *(a)* lower prices, higher

[1623] *Ibid.*, 6.71.
[1624] *Ibid.*
[1625] *Ibid*, 6.74.
[1626] *Ibid.*
[1627] *Ibid.*, 7.3.

quality or greater choice of services or goods in any market in the UK, or *(b)* greater innovation in relation to such services or goods.[1628] Such benefits, among others, may include: Higher-quality services through implementing a particular model of care, higher-quality services through service reconfiguration, higher-quality services through increased consultant or staff cover, higher-quality services through access to equipment, greater innovation through research and development and greater ability to attract funding for research and development, financial savings.[1629] As the Guidance underlines, whether or not any of these benefits constitute relevant customer benefits will need to be assessed on a case-by-case basis.[1630]

The customer benefits have to be merger specific. In making this assessment, the CMA considers whether the customer benefit is likely to occur in any event (for example, if the benefit was in any event likely to arise through a commissioner-led reconfiguration) and whether the merging providers would have the ability and incentive to achieve the benefits independently or through arrangements, such as another merger, that do not give rise to competition issues.[1631]

The CMA also considers whether it believes the benefits are likely to be realized. To this end, the CMA reviews implementation plans.[1632] The burden of proof the merging parties have to meet in order to secure that their alleged benefits are considered *customer benefits* is quite high. As the Guidance states, the more detailed and advanced the implementation plans are, the more persuasive they are likely to be.[1633] The merging providers' incentives to implement the benefits are also relevant to the likelihood of implementation.[1634] When considering incentives, the Guidance also stresses, the CMA also takes into account the competitive constraints post-merger.[1635] For the more extensive benefit proposals (accident and emergency reconfiguration), the CMA expects that for each benefit the merging providers put forward, they should be able to demonstrate that the proposed customer benefits are likely to occur and that they have taken the first in a series of steps, namely: (a) they

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[1628] *Ibid.*, para 7.12.
[1629] *Ibid.*, para 7.12, see also Monitor's guidance with regards to customer benefits: 'Supporting NHS providers: Guidance on Merger Benefits', 13-19. Both CMA and Monitor refer to the same type of benefits.
[1630] *Ibid.* 7.14.
[1631] *Ibid.*, para 7.17.
[1632] *Ibid.*, para 7.18.
[1633] *Ibid.*
[1634] *Ibid.*
[1635] *Ibid.*

have determined what the preferred proposal is (b) they have discussed plans with clinicians (c) they have developed a model of care by engaging with clinicians of the merging providers, relevant commissioners, as well as any clinical experts and any relevant advisory group as appropriate (d) they have produced an assessment of the clinical advantages (and any dis-advantages) as well as a robust assessment of the financial or economic viability of the plans.[1636]

In order for the CMA to decide not to refer a merger to Phase 2 on the basis of the relevant customer benefits, it must believe that any such relevant customer benefits concerned *outweigh* the SLC and any adverse effects of the SLC in all affected markets.[1637] Interestingly, the CMA underlines that the relevant customer benefits need not necessarily arise in the market(s) where the SLC has arisen.[1638] It is therefore open to the merging providers to show that sufficient relevant customer benefits might accrue in one market as a result of the merger that would outweigh the finding of an SLC in another market(s).[1639] Weighing up the benefits against the adverse effects on patients involves consideration of the facts and circumstances of an individual case.[1640] In exercising its discretion to decide whether the claimed relevant customer benefits are such as to outweigh the SLC concerned and any adverse effects of the SLC, the CMA, the Guidance says, has regard both to the magnitude of the benefits and the probability of them occurring, and sets this against the scale of the identified anticompetitive effects and the probability of them occurring.[1641] The more powerful and more likely the anticompetitive effects of the merger, the greater and more likely the relevant customer benefits must be to meet and overcome such concerns.[1642]

Since in most of the examined cases, the merger was cleared because the CMA assessed that there was no SLC, the CMA has not discussed in many cases whether the merger would yield relevant customer benefits. This however does not imply that the merging parties do not raise the claim that their merger will yield customer benefits. In the *UCLH* merger case, for example, the merging parties submitted that following the transaction, patients receiving neurosurgery treatment

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1636 *Ibid.*, 7.21.
1637 *Ibid.*, 7.24.
1638 *Ibid.*
1639 *Ibid.*
1640 *Ibid.*, 7.26.
1641 *Ibid.*
1642 *Ibid.*, 7.27.

at UCLH who would previously have been treated at the RFH will receive a higher quality of service. In providing its advice, Monitor claimed that this potential benefit does not constitute a relevant customer benefit because the treatment of neurosurgery patients at UCLH rather than the RFH is unlikely to be dependent on the transaction.[1643] However, in light of the CMA's conclusion that there was no realistic prospect of a SLC, the CMA did not examine the alleged benefits in substance.

In the *Ashford* case,[1644] the merging parties alleged that their proposed merger would create important customer benefits. They classified these under three proposals: (a) extended access to consultant-led or nurse-led care in gastroenterology, stroke, interventional radiology, neurology, specialist diabetes (b) development of a cancer diagnostic and treatment centre at Ashford Hospital (c) improved management of neonatal services.[1645] In evaluating these benefits, Monitor concluded that extending access to consultant-led care in gastroenterology, stroke and interventional radiology services should be taken into account as relevant patient benefits.[1646] These relevant patient benefits all relate to improving access to a service, and in particular extending access to senior clinicians.[1647] According to the Monitor, improved access to a consultant out of hours and at weekends is a clinically significant service improvement in these specialties, each of which provides emergency care for acutely ill patients.[1648] Again, in this case, since the CMA found that the merger would not lead to SLC in any of the examined specialties, the CMA did not examine the mergers' proposed benefits in substance.[1649]

In the *Bournemouth* case, the merging parties insisted that the merger would create substantial customer benefits in five clinical areas: maternity; cardiology; haematology; A&E and

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[1643] Transfer of neurosurgery services from the Royal Free London NHS Foundation Trust to University College London Hospitals NHS Foundation Trust, Monitor's advice to the Office of Fair Trading under Section 79(5) of the Health and Social Care Act 2012, 3-4.
[1644] Ashford and St Peter's and Royal Surrey County, *supra* n. 1444.
[1645] Monitor's advice to the Competition and Markets Authority on the merger benefits of the proposed merger of Ashford and St Peter's Hospitals NHS Foundation Trust and Royal Surrey County Hospital NHS Foundation Trust, 5.
[1646] *Ibid.*,
[1647] *Ibid.*
[1648] *Ibid.*
[1649] *Ibid*, 3.14.

emergency surgery.[1650] More specifically, concerning maternity services, the merging hospitals claimed that the merger would allow them to build a new maternity unit.[1651] For cardiology, the hospitals claimed that the merge would help them to combine cardiology rotas which would mean that patients at Poole would have access to a cardiologist 24/7, which they did not have.[1652] For haematology, the parties claimed that the merger would provide them with the opportunity to consolidate the level 3 haematology services at Poole hospital, with a 'spoke service' at Bournemouth hospital.[1653] The parties claimed that this investment would allow them to improve quality and outcomes for patients. The parties further claimed that the merger would enable a reconfiguration of A&E services which would result in better A&E consultant cover.[1654] According to the parties if A&E were reconfigured, then emergency surgery would be consolidated on the major injury A&E site, allowing that site to have a dedicated emergency theatre 24/7.[1655] The CC also examined the following benefits: potential financial savings; merger-avoided costs; merger-enabled investments; balanced portfolio of services and cost savings to commissioners.[1656] To evaluate these claims, the CC assessed whether the acclaimed benefits could be considered *benefits to patients* and whether these benefits met the statutory test for relevant customer benefits.[1657] The CC made clear that this test required the proposed benefit to be a benefit to customers in the form of lower prices, higher quality, greater choice or greater innovation.[1658] This test also required that the benefit would accrue within a reasonable period as a result of the merger and that the benefit was merger specific. To make its assessment, the CMA examined the merging parties' detailed plans and proposals. In line with Monitor's advice, the CC did not find that any of the benefits put forward by the parties met the statutory test for relevant customer benefits.[1659] As to the first benefit, the creation of the maternity unit, the CC concluded that the parties did not have a clear plan for the new maternity unit. The CC also disregarded the parties' proposed benefits as to the hematology services as it believed that it did not have sufficient confidence that the merged entity would proceed

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[1650] CC's Bournemouth and Poole merger decision, *supra* n. 1547, at 9.6.
[1651] *Ibid*,
[1652] *Ibid.*
[1653] *Ibid.*, para 69.
[1654] *Ibid*, 72(d).
[1655] *Ibid*, para 9.112.
[1656] *Ibid.*, para 72.
[1657] *Ibid.*
[1658] *Ibid*, para 71.
[1659] *Ibid*, para 72.

with the reconfiguration of the services. The CC also rejected the last claimed benefit, the reconfiguration of A&E services, since it considered that the parties did not have a detailed model of care.[1660] Not finding that any of the parties' proposals would be likely to result in relevant customer benefits within the meaning of the HSCA 2012 the CC ended up prohibiting the merger.[1661]

## 4. Evaluating the CMA's approach *as a whole*: What are the aspects of quality the CMA considers in its merger assessment?

The previous section aimed to discover whether and to what extent the conflicting objectives between the actors involved in the assessment of NHS mergers, notably, the CMA and Monitor, may *transform* CMA's merger analysis with regards to NHS FTs. To adequately examine this question, the previous section analyzed how CMA defines and assesses healthcare quality in the multiple stages of its merger assessment. This section shines a light on the following questions: *Does Monitor's or CCGs' commitment to ensure continuity and access to NHS services impact CMA's assessment of NHS mergers? Does the CMA transform its merger analysis so that it takes these non - competition concerns into account? And if yes how*?

To begin with, in contrast with the US approach, the CMA is clear about the dimensions of quality it actually integrates into its assessment. These according to the Guidance as well as the analyzed merger cases are: (a) clinical factors, such as infection rates, mortality rates, ratio of nurses or doctors to patients, equipment, best practice, and (b) non-clinical factors such as waiting times, access, cleanliness and parking facilities. In addition, acknowledging that competition law does not apply in a vacuum the CMA has issued a special Guidance under which NHS mergers are in fact assessed and examined. Interestingly, unlike the US approach, this Guidance seems to reflect the notion *that health is special.* Indeed, when the CMA assesses whether a hospital merger may lead to SLC it examines both the potential adverse effects for patients/and or commissioners arising from a loss of competition and (b) the benefits of a merger for patients and commissioners. Above all, as the Guidance underlines, the CMA aims to ensure that the merger is *in the overall interest of patients.*

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[1660] *Ibid.*
[1661] *Ibid*, para 76.

Additionally, acknowledging the special character of health, the Guidance states that in assessing the mergers the CMA takes into account not only third parties' views that are actively involved in healthcare provision, such as the commissioners' and healthcare regulators', such as Monitor's and CQC's but also the specific regulatory framework that applies for healthcare. In other words, it seems that the Guidance offers a merger framework under which the opinions of medical professionals (commissioners), health regulators and antitrust enforcers as to how healthcare quality is evaluated and achieved can be actually considered *as a whole*.

More than that, both Monitor and the CMA are straightforward as to the merger's benefits that can in fact be considered *relevant customer benefits*: These are: (a) lower prices, higher quality or greater choice of services or goods in any market in the UK, or (b) greater innovation in relation to such services or goods. Examples of such benefits include: Higher-quality services through implementing a particular model of care, higher-quality services through service reconfiguration, higher-quality services through increased consultant or staff cover, higher-quality services through access to equipment, greater innovation through research and development and greater ability to attract funding for research and development, financial savings. Additionally, the burden of proof the merging parties have to meet in order to convince Monitor and the CMA that their benefits are relevant customer benefits is not low. Indeed, to meet the required burden of proof, they do have to provide detailed plans as to how they envision to translate these alleged benefits into reality.

Are these, however, the only dimensions of quality or the only customer benefits the CMA takes into account in its assessment? Surely, the answer should be negative. This is because *indirectly* the CMA also integrates in its assessment other non - competition concerns, such as continuity and access. *How does the CMA perform this task*?

I argue that the above analysis of the case law demonstrates that the CMA has found the way to integrate these non - competition concerns into its assessment without performing the difficult task of balancing health policy objectives, such as continuity and access, against the restriction of choice and competition for either patients or commissioners. It has also found the way to take into account the objective of continuous access to NHS services without either *widening the notion of consumer welfare* so that it encompasses both competition and non - competition objectives,

such as equity and access, or explicitly stating that a competition law framework aiming to ensure quality should not disregard the wider objectives of the sector at which it applies.

*Under what mechanisms then has the CMA managed to consider in its assessment these non - competition concerns*? Through three main mechanisms I claim. The first one, as noted, is by integrating in its assessment the views of various authorities that their main objective is not to ensure competition. Indeed, to assess an NHS merger, the CMA gathers and considers evidence from various sources including Monitor, NHS England, the CQC and CCGs. As the Guidance illustrates, the CMA considers these authorities' views in choosing the appropriate counterfactual, [1662] in assessing whether the merging parties have incentives to compete[1663] and whether the merger's alleged benefits are relevant customer benefits.[1664] Because NHS England, CCGs and Monitor are particularly considered about the financial stability of the NHS FTs and their ability to provide continuous services, to the extent a merger is alleged to be necessary for the merging parties' financial stability, these authorities fully support the merger. The *Heatherwood* merger[1665] case uncovers my point. In this case the merging parties claimed that the proposed merger was necessary for their financial stability. In providing its advice pursuant to section 79(5) of the HSCA 2012, Monitor stated that in light of HWPH's sustainability, quality and management issues, the merger *appeared as the best available solution to the problems* at HWPH and the most likely way of achieving the necessary improvements to services for patients. Monitor clarified that the merging parties had faced significant sustainability, quality and management issues for a long time and had been subject to numerous regulatory interventions. Without performing a rigorous assessment of the costs and benefits of all potential solutions, Monitor said that the proposed acquisition was likely to deliver a quicker and more sustainable solution to these issues *than further regulatory intervention by Monitor could achieve*. Thus to the Monitor, the failure of the regulatory framework to ensure the continuity of the NHS services in fact meant that the merger should be accepted. Not surprisingly, CCGs, some competing NHS providers, patients, and local representatives also supported the merger. These parties specifically referred to FPH's ability to deal with management issues at HWPH and the wider clinical and financial issues faced by the trust, the opportunity for FPH to increase scale and thus be better able to deal with the

[1662] CMA Guidance, *supra* n 1494, para 6.11.
[1663] *Ibid.*, 6.50.
[1664] *Ibid.*, 722.
[1665] Heatherwood and Wexham Park Hospitals NHS Foundation Trust merger decision, *supra* n.1536.

increasing pressure faced by NHS FTs, and the provision of better services and better quality outcomes for patients locally. The *UCLH* case also illustrates my point. In this case, the parties submitted that absent the merger the appropriate counterfactual was the unplanned cessation of neurosurgery at RFH for reasons of clinical safety. The CMA rejected the view that the proposed counterfactual was the appropriate one. However, considering the commissioners' views that the proposed merger would actually improve quality, the CMA concluded that there would be sufficient choice of remaining neurosurgery providers post-transaction to mitigate any competition concerns arising from the transaction. In assessing these mergers *why do commissioners and Monitor adopt a lenient approach as to the merger's anticompetitive concerns? And most importantly, why does the CMA integrates their lenient approach into its analysis*?

Both Monitor and CCGs are responsible for ensuring access to NHS services. Surely, Monitor is also responsible for preventing anticompetitive behaviour. However, since Monitor exercises its regulatory powers in a continuous manner, it should not be expected that Monitor will adopt its decisions in the vacuum. My analysis demonstrated that the commissioners never challenge mergers for an additional reason: because they actually do not believe that competition promotes quality or contributes to the objectives they pursue. Recalling commissioners' views regarding the impact of the above analyzed mergers on *competition for the market*, it is quite obvious that commissioners do not believe in the dogma that the more the providers in the relevant market, the better the quality. Commissioners' approach is not surprising. The commissioners are doctors and as the previous chapter clearly indicated, doctors do not believe in the value of choice. This is perfectly reflected in the *Bournemouth* case where the commissioners in exposing their views as to the merger's impact on competition for the market, they did not hesitate to spell out *that they would be reluctant to procure services via competitive processes to increase quality noting the potential for destabilizing suppliers.* This is understandable. Commissioners have to ensure that all parts of the population have access to healthcare services irrespective of their ability to pay for them. Hence, if they had to tradeoff between continuity and competition, they would opt for continuity. Commissioners in line with the medical perspective on ensuring quality, they believe that collaboration and choice in fact improves health outcomes and not vigorous competition. This is why in the same case the commissioners also alleged that if a supplier was providing services at an acceptable level, they would not be likely to use the potential for change of supplier as a tool to improve quality further. Alternatively, they said, if quality fell below an acceptable level, they would work with the supplier to solve the issue. *Why, does*

*however CMA allow these actors' views to substantially impact on its analysis?* For two reasons I think: first because CMA would be unwilling to apply competition law in a way that disregards the objectives of the UK health system, such as access and continuity. Second, because healthcare sector is a highly sensitive politically sector.

The second mechanism under which, the CMA takes into account in its assessment non-competition concerns is by taking the view that especially with regards to non-elective services parties' incentives to compete on quality are zero. Indeed, in most analyzed merger cases, when assessing the merger's impact on the market of non - elective services, the CMA insisted that due to the regulatory framework at which NHS Trusts operate, the latter do not have incentives to compete on quality. Arguably, when the CMA assesses parties' incentives to compete in the market of non-elective services the CMA constantly repeats that (a) due to the 30 per cent marginal rate tariff, the parties do not have financial incentives to attract additional non - elective referrals (b) patients do not choose their provider when they need emergency care. In light of these concerns, the CMA easily ends up concluding that in the market of non - elective services parties do not have incentives to attract patients and compete on quality. Hence, the merger will not lead to SLC.

In the elective services market, the CMA's approach is different. With respect to these services, the CMA consistently claims that providers have incentives to compete and attract patients since in these markets patients and GPs exercise choice, they exercise choice on the basis of providers' quality and providers have incentives to increase patients' volume since this market is more profitable. Consequently, in these markets, it is more probable that the CMA will conclude that a merger may lead to SLC. However, even when the CMA examines the merger's impact on competition in these markets, the CMA rarely ends up concluding that the merger is likely to reduce providers' incentives to compete on quality. In most cases, the CMA concludes that the parties will face in any case competitive constraints and therefore the risk of SLC is low. Nonetheless, even in the market for elective services, the CMA could support the view that the merging parties do not in fact compete on quality. This is because CMA's assumptions that patients and GPs do exercise choice and that they do take into account quality when they exercise this choice does not fully reflect health care market's reality. As noted in Chapter II, patients cannot easily shape their choice when they choose healthcare providers. Patients do want choice. Nonetheless, they rely on GPs advice when they have to make a choice. This is because patients would be able to choose providers on the

basis of quality only if they had the knowledge to fully assess and compare all dimensions of quality of different healthcare providers. This, however, would require that patients have advanced medical knowledge which surely is not the case. Doctors of course can assist their patients in choosing healthcare provider since they have the scientific knowledge to judge the quality of different healthcare providers. However, as I have already showed, doctors do not necessarily devote time to this task. They help their patients to choose but they do so either on the basis of the patients' personal experiences or the relationships they have with specific healthcare consultants. This means that even in the market for elective services, choice does not necessarily drive quality. Therefore, even in these markets CMA could conclude that providers do not have the incentives to compete on multiple dimensions of quality and therefore clear the proposed merger.

The third mechanism under which the CMA takes non-economic concerns into account is by translating health policy objectives, such access, into dimensions of quality that the Guidance allows the CMA to take into account. This is the approach that was applied by the CMA in the *ECLH* case where in fact the CMA instead of explicitly stating that it examined the merger's impact on patients' access to hospital services, the CMA stated that it examined the transaction's impact on *travelling time for patients*.[1666] In other words, in this case, instead of raising the question of whether the transaction would impact on patients' access, it in fact asked whether the transaction *would increase patients' travelling time*.

By arguing that the CMA has found the way to integrate in its analysis health policy objectives, such as access, *indirectly*, I do not aim to claim that these objectives should not enter the equation. In contrast, I take the view that if a competition assessment completely disregarded these objectives, these objectives may be considerably harmed. I claim though that competition authorities, such as the CMA, should assess and integrate these objectives into their analysis in a more transparent way. The CMA, for instance, should either integrate these objectives into the definition of *customer benefits* or it should balance them against harm to competition. Surely, this analysis is not an easy one. However, this analysis would ensure transparency and accountability. More importantly, if CMA adopted this approach, its analysis would not send the signal to the

[1666]Acquisition by University College London Hospitals NHS Foundation Trust (UCLH), *supra* n. 1525, para 60.

healthcare providers that 'the closer you are to bankruptcy, the more welcome you are to merge'. Therefore, it would protect also CMA's reputation. More than that, an alternative approach would also ensure that healthcare providers' incentives to improve the efficiency of their services, is not substantially reduced.

## 5. Conclusion

This chapter indicated that the regulatory framework under which NHS FTs operate, incentivize them to merge. Indeed, in light of the serious financial difficulties they face, this might be the only way NHS FTs can reduce the risk of exiting the market. The continuous reduction in the NHS budget, the reduced tariff they receive for emergency care and the high standards of quality they have to meet to ensure their license are factors that contribute to their financial distress. Acknowledging that absent most of the proposed mergers, the merging parties would be unable to ensure their financial stability, the CMA assesses NHS mergers in a way that facilitates their clearance. As this chapter illustrated, the CMA performs this task by indirectly integrating continuity in its assessment. *Is this a wise choice*? I claimed that this choice is not a wise one since it sends to NHS FTs the message that 'the closer you are to bankruptcy, the more welcome you are to merge'. I also claimed that to the extent competition authorities, such as the CMA, decide to take health policy objectives into account, they should do it in a way that is transparent. The CMA, for example, should explicitly state in its guidelines or guidance either that these objectives are considered relevant customer benefits or that these objectives can weigh harm to competition. In my view this approach would not only ensure accountability and transparency but it would also protect the competition authority's reputation. More than that, an alternative approach would not substantially reduce NHS FTs' incentives to compete.

# Conclusions

## 1. A short travel to the thesis' main findings

This doctoral thesis posed and examined the question of how healthcare quality concerns can be integrated into a competition law analysis. To answer this question and build its claims this study did not rely on the usual heuristic on which competition authorities usually rely on when they assess to what extent a specific transaction or agreement impacts on quality, that in general more competition improves quality. On the contrary, by examining how healthcare markets actually work, what their limits are, and how healthcare quality is defined and assessed not only from antitrust but also from health policy and medical professionals' perspectives, this doctoral thesis developed three important arguments: first, it claimed that the introduction of competition in medical and hospital markets may not necessarily improve all facets of healthcare quality. On the opposite, the thesis demonstrated that the introduction of procompetitive regulation in hospital and medical markets may substantially harm essential facets of healthcare quality, such as safety, acceptability, equity. Second, it argued that considering the special characteristics of the healthcare markets, regulation may not necessarily protect all facets of healthcare quality, such as equity and acceptability. Third, it showed that the main actors involved in the provision of healthcare, mainly healthcare providers, medical associations and GPs, acting either as gatekeepers or purchasers of healthcare services (or else commissioners) may engage in anticompetitive agreements aiming to ensure that essential facets of healthcare quality are in fact protected. The commissioners for example may agree with the GPs when they act as gatekeepers to boycott specific hospitals that do not meet their own specified standards of healthcare quality. They may also agree to buy more elective care from NHS hospitals that offer also high risk non – elective services in poor disadvantaged areas so that these hospitals can cross subsidize their more costly non elective services. It also showed that hospitals that operate in a competitive environment may attempt to ensure their financial stability and improve the quality of their services by pursuing mergers that inevitably restrict competition, choice and create market power.

In dealing with these potential competition problems, this thesis demonstrated that the question of how quality is defined and assessed in the context of a competition analysis in the healthcare sector is central. As Chapter II of this thesis highlighted, competition authorities would be unable to adequately examine and assess the competition problems that arise in light of the reality that the pursuit of competition in hospital and medical markets may contradict with essential facets of healthcare quality, unless they posed and addressed a fundamental question first: *how should we define and assess quality in healthcare*? *What are the facets of healthcare quality that we commit to take into account in our analysis?*

Importantly, this thesis delved into this research question by examining the notion of healthcare quality not only through the lenses of antitrust, but also through the lenses of medicine and health policy. What this thesis found and demonstrated is that while the notion of quality from antitrust perspective mainly relates to the concepts of choice, competition and innovation, the notion of quality from health policy perspective mainly relates to the notions of equity, access, safety, acceptability effectiveness, continuity. This thesis further indicated that while medical professionals mainly believe that quality will be the result of the medical process and the protection of professionalism, competition authorities actually believe that quality will be improved only to the extent vigorous competition in the healthcare market place is maintained. Additionally, this study indicated that while competition authorities generally believe that the more the market participants, the higher their incentives to improve the quality of their services, health policy makers insist that in certain cases less competition and not more may lead to quality improvements.

Having explored how the notion of healthcare quality can be actually defined and assessed from medicine, health policy and antitrust perspectives, this study then identified three different models under which competition authorities may actually assess how a specific anticompetitive agreement or hospital merger may impact on healthcare quality. These are: (a) the *market approach* under which competition authorities may define quality in healthcare strictly as *choice, variety, competition and innovation*. Undoubtedly, this approach is in line with the central mantra of competition policy that the more the players in a market, the higher the quality of the services they offer; (b) the *European approach* under which competition authorities *may extend the notion of consumer welfare in healthcare* so that it encompasses not only the notions of efficiency, choice, innovation, but also the wider objectives and values European health systems in fact pursue (c) the *UK model* under which

competition authorities may cooperate with health authorities when they assess the impact of a specific transaction on healthcare quality. In the context of this model, as applies in the UK, mergers between NHS FTs are assessed not only through the lenses of competition law but also through the lenses of medicine and health policy. This is because, as the last chapter of this doctoral thesis demonstrated, when the CMA examines the impact of an NHS merger on healthcare quality, it integrates in its merger analysis the views of purchasers of healthcare services, or else commissioners, as well as the opinion of Monitor, the main economic regulator in the UK that is responsible not only for preventing anticompetitive behaviors in the healthcare sector but also for protecting the effectiveness, quality and continuity of NHS services. More than that, the CMA also integrates in its merger analysis the opinion of CQC, the main regulator in the UK responsible for ensuring that healthcare providers meet specific standards of healthcare quality. Under this regime, when the CMA examines an NHS merger, unlike the FTC that in applying *the market approach* mainly examines how a hospital merger may impact on prices, the CMA focuses its analysis on how the envisaged merger may impact on quality. In doing so, the CMA applies a specific merger regime that explains how CMA assesses quality, what are the quality factors that actually takes into account and how it integrates in its merger analysis third parties' opinions, such as the commissioners', and Monitor's advice on the merger's potential customer benefits. The CMA has adopted this quality focus merger regime as under the UK health system, healthcare providers compete on quality and not on prices.

This doctoral thesis' hypothesis was that the *under the market approach* competition authorities might fail to protect the notion of healthcare quality as a *whole*. The thesis tested this hypothesis by using as a case study the US antitrust approach in medical and hospital markets. The thesis chose to examine this case study not only because in the US healthcare services are mainly governed by the market principles but also because US antitrust in general remains faithful to the dogma that social policy objectives should be excluded from the antitrust agenda.

The thesis tested its hypothesis in Chapters III and IV. Chapter III examined how the FTC and the US Courts take into account quality when they assess breaches of competition law by medical associations claiming that their anticompetitive behaviour is necessary for the protection of healthcare quality. Chapter IV examined how the FTC and the US Courts take into account healthcare quality when they examine hospital mergers. These chapters underlined that when the US

antitrust enforcers and the Courts examine and assess how and to what extent an agreement or merger may impact on quality, they constantly tell the story that *healthcare is not special*. Since their antitrust analysis relies on this belief, in the majority of the cases it reflects the notion that *as in other markets, more competition will ensure quality*. This does not in any case imply that the FTC and the US Courts do not examine the quality claims or justifications that are brought by medical associations or hospitals. On the contrary, they do examine them. Nonetheless, in examining these quality claims, the US Court's and the FTC's approach is rather *narrow*. Chapter III for example showed that the medical associations' quality claims enter into the equation only as long as they take the form of a market failure defense. Hence, the possibility of integrating into their antitrust analysis a quality claim that is structured as a *public safety* defense is simply excluded. In identifying the shortcomings of this approach Chapter III pointed to three important issues. First, it underlined that this approach completely disregards the fact that in healthcare markets patients do not necessarily have the knowledge and the ability to make decisions that improve their welfare. Second, it underlined that this narrow approach disregards the fact that healthcare markets are pervaded by negative externalities and that the US antitrust enforcers and the Courts by limiting their analysis to the impact of a specific restriction of competition to the number of choices that are available for consumers, they simply omit to consider the costs to the overall society unsafe choices create. Additionally, this chapter also inspired by Donabedian's argument that the pursuit of healthcare quality cannot be achieved if not all functions of a health system commit to the quality goals the health system as a whole pursues, illustrated that since doctor's commitment to protect quality is highly linked with their commitment to professionalism, an antitrust policy that aims to adopt *a holistic approach* to healthcare quality should not disregard this facet of the notion. In seeking alternative solutions, this chapter proposed that the US antitrust enforcers and the Courts should evaluate and assess quality claims not only on the basis of the way they are constructed, as market failure defenses or public safety justifications, but also on the basis of the risks to healthcare quality, as a multidimensional concept, each particular case raises. This alternative approach might not necessarily transform the antitrust enforcers' findings in the examined cases. However, it would ensure that antitrust enforcers and medical associations do not constantly try to impose their own views on what the main dimensions of healthcare quality are and how they should be protected.

Undoubtedly, Chapter's IV research findings lead to similar observations and conclusions. This chapter illustrated that the FTC and the US Courts have not provided sufficient weight to

quality arguments. This, again, does not in any case imply that the US antitrust enforcers do not assess them. It mostly implies that price concerns and not quality concerns dominate antitrust enforcers' merger analysis in hospital markets. As Chapter III, Chapter IV pointed to the shortcomings of the US Court's and antitrust enforcers' narrow approach as to how healthcare quality is attained in hospital markets. First and foremost, Chapter IV demonstrated that antitrust enforcers' narrow *market approach* does not allow them to integrate into their analysis the voices of healthcare quality researchers indicating that in specific cases less competition and not more may lead to quality improvements. It further showed that their narrow approach as to how healthcare quality is improved in hospital markets may disincentivize the merging parties from bringing quality of care to the heart of the merger analysis. Additionally, it may also disincentivize health policy researchers from developing research on the relationship between hospital mergers and quality improvements. *Indeed, why should healthcare quality researchers invest in researching the relationship between clinical integration, consolidation and healthcare quality as long as their findings would not in fact transform how the US antitrust enforcers assess and examine quality considerations in hospital merger cases?* Most importantly, since when the US antitrust enforcers and the Courts assess a merger's impact on healthcare quality, they keep retelling the story that *the Clayton Act contains no healthcare exemption* and that antitrust laws apply to hospitals in the same manner that they apply to all other sectors of the economy, they do not closely examine the merger's impact on the health objectives their health system *as a whole* pursues. In other words, their analysis is not in line with Donabedian's core argument that healthcare quality can be protected *as a whole* only to the extent it is assessed at all levels at which healthcare actually takes place.

Surely, the US market approach's advantages should neither be underestimated nor disregarded. Indeed, an antitrust analysis that is based on the belief that vigorous competition will necessarily improve quality and that quality should strictly be defined as choice, innovation and competition is an analysis that is easy to be applied. This is because such an analysis does not require the antitrust enforcers to expand their understanding of how healthcare quality should actually be protected and achieved in the healthcare sector when they assess a specific agreement's or merger's impact on quality. More than that, it does not require the antitrust enforcers and the US Courts to integrate into their analysis the views of health policy researchers or medical professionals on how healthcare quality improvements are achieved in hospital and medical markets. In other words, their approach is not only easy to be applied but it is also not costly. This is because under

the *US market approach*, the enforcement of competition law in the healthcare sector does not require higher costs. Undoubtedly, the market approach also ensures deterrence. This is because to the extent health policy goals or the non - economic facets of healthcare quality do not become part of the antitrust analysis, medical associations or hospitals have low incentives to enter into agreements or attempt to pursue transactions that may in fact mask their self - interest or their desire to weaken price or quality competition. This is because the burden of proof that they actually have to meet in order to convince the US antitrust enforcers and the Courts that a specific agreement or merger is in fact necessary for the protection of healthcare quality is high. More than that, an approach that in fact remains faithful to the assumption that quality equals to choice and competition ensures that the antitrust enforcers and the Courts do not apply competition law in healthcare in a way that reflects their personal preferences or political ideologies on how healthcare should be distributed. In other words, the *US market approach* also ensures transparency and accountability.

Considering the shortcomings of the *US market approach* the thesis then made a step forward and asked: *Should competition authorities attempt to widen the definition of quality in healthcare so that it encompasses also the perspectives of other actors in healthcare, such as medical professionals and health policy makers on how healthcare quality is protected and achieved? Should they expand the definition of healthcare quality so that it is also in line with the policy goals their health systems pursue?* Considering that as Chapter V demonstrated, EU health systems operate on the basis of specific principles and values, such as equity, solidarity, safety, access, the thesis chose to call this model, *the European approach*. In attempting to identify how and to what extent the *European approach* may in fact be applied by Competition Authorities in the EU, Chapter V asked: *Can competition authorities take these objectives into account under EU competition law? And, if yes, how?* To adequately examine this question, this chapter first identified how conflicts in fact appear between the goals of choice and competition and health policy goals, such as equity, access and safety when procompetitive regulation is introduced in health systems and how these conflicts may in fact incentivize main actors in healthcare to engage in anticompetitive agreements with an eye to protect the notion of healthcare quality *as a whole*. To this end, Chapter V used as a case example the procompetitive regulation that has established the choice and competition model for healthcare provision in the UK since the early 1990s. This chapter highlighted that the main actors in healthcare in the UK, such as the purchasers of healthcare services, healthcare providers or the GPs in pursuing their role as gatekeepers may enter into anticompetitive agreements or decisions in order

to protect the goals of equity, safety and acceptability, essential dimensions of healthcare quality. This chapter demonstrated that these objectives may be taken into account in the context of article 101 TFEU both on the basis of the Commission's *more economic approach* and the Court's *more pluralistic approach*. In reaching this conclusion, this chapter examined some seminal European cases in which the European Commission and the EU Courts integrated in their 101 TFEU analysis non - competition goals, such as professional integrity, solidarity, the protection of the environment or the protection of employment. This chapter argued that in line with the Commission's more economic approach in the *CECED* or in the *Meca - Medina* cases, competition authorities may incorporate into their analysis health policy objectives and goals, such as equity by translating these objectives into *a wider notion of efficiencies*. Considering for example the effect of health on labour productivity, savings and school education, competition authorities may take the view that access to healthcare has an economic value as such and therefore although a specific agreement may restrict choice and competition, it should be exempted on the basis of article 101(3) as it protects equity and therefore impacts positively on economic progress. They may also follow an alternative approach: they may choose to translate equity gains into efficiency improvements by widening the notion of efficiencies in healthcare. They may for instance take the view that in healthcare the notion of efficiencies encompasses also the notion of distribution efficiency in *Donabedian* terms, which actually requires the distribution of care among different classes of patients in a way proportionate to expected improvements in health. Competition Authorities may also integrate into their analysis health policy objectives, such as equity, by adopting the European Court's pluralistic approach with regard to article 101(1) and 101(3) TFEU. In line, for example, with the Court's approach in the *Albany* or *the Wouters* cases, competition authorities may hold that the protection of equity is a legitimate objective and its protection requires that a specific agreement that restricts choice but protects equity should be exempted from the application of competition law on the basis of article 101(1) TFEU. In line also with the Court's wider approach in the *GlaxoSmithKline v. Commission* case, competition authorities may integrate the non - economic facets of healthcare quality into their analysis by widening the interpretation of the notion 'technical and economic progress' in the context of article 101(3). This chapter did not only delve into the question of *how* under EU competition law the multiple facets of healthcare quality can be taken into account. In addition to this, it also made an important normative claim: it argued that competition authorities should consider health policy objectives in their competition assessment, because if they omitted to do so, their competition assessments would lose their legitimacy in the sense that they would not match the substantive goals

of their societies that have democratically decided to operate on the basis of specific principles and values, such as equity and accessibility in healthcare.

Arguably, the European approach's merits are many. First and foremost, as Chapter V of the thesis indicated, EU competition law offers a flexible framework under which the notion of healthcare quality can be taken into account *as a whole*. Indeed, both under article 101(1) and article 101(3) the values this notion encompasses can be integrated. Nonetheless, while in the context of article 101(3) the parties of the agreement have the burden to prove that although their agreement restricts competition, it is necessary for the protection of the goals of equity, safety or acceptability, under article 101(1) competition authorities have the burden to prove that this agreement pursues a specific legitimate objective and its protection requires exemption from the application of competition law. Furthermore, while in applying article 101(3) the parties of the agreement would have to meet the standards of a strict proportionality test in order to be exempted from the application of article 101 TFEU, competition authorities in applying the *Wouter'* s or the *Meca - Medina* approach would have to meet a proportionality test much less demanding. Arguably, to the extent healthcare quality dimensions are examined on the basis of article 101(3) deterrence is enhanced. This is because in this case, the parties of the agreement would have to perform the task of translating the health policy objectives their anticompetitive agreements pursue into efficiencies. Undoubtedly this task is not an easy one. Therefore, the parties' agreement would have the incentives to argue that their agreement meet the conditions of article 101(3) only to the extent the objectives their agreement in fact pursues have an economic value. Indeed, as Chapter V of this thesis indicated, the Commission in applying its more economic approach with regards to article 101 TFEU would not in any case exempt an agreement on the basis of article 101(3) if it aimed to protect objectives that cannot be translated into efficiencies. More than that, the parties would have to prove that they are unable to protect the non - economic facets of healthcare quality in a way less restrictive to competition. Again, meeting this condition of the article 101(3) test is not an easy task. Nonetheless, applying article 101(3) in cases where the parties of an agreement claim that they have agreed to restrict competition and choice in order to protect essential dimensions of healthcare quality entails an important risk: that this agreement may not be exempted from the application of article 101 TFEU just because the objectives it aims to attain contribute to efficiency only indirectly. Hence, I argued that in cases where the economic dimension of a non - competition concern is not

evident enough, the application by competition authorities of the Court's more pluralistic approach may be more appropriate.

Surely, the European Approach also suffers from shortcomings. First and foremost, under this approach competition authorities would have to perform the difficult task of balancing the goals of competition and choice against health policy objectives and goals that they may not necessarily have the knowledge to assess and evaluate. Indeed, the antitrust enforcers' task is to ensure vigorous competition, not to assess whether access to affordable and high quality healthcare is in fact restricted. Additionally, competition enforcers, experts and scholars do not necessarily agree as to the extent to which non - competition goals can and should enter the antitrust agenda. Therefore, absent a specified framework or guidance issued by the competition authorities explaining how and under what conditions health policy goals or the non - economic facets of healthcare quality should become part of the antitrust analysis, the application of competition law in the healthcare sector may lead to considerable discrepancies. While some authorities may stick to the notion that non - competition goals should not enter into the equation, others may insist that the healthcare sector is a special one and as a result competition law should be applied in this sector in way that does not disregard its objectives. Inevitably, these diversified views between competition authorities in Europe as to how and to what extent health policy objectives may transform competition analysis in the healthcare sector may lead to further discrepancies as to the extent to which non - competition goals should be taken into account in the context of an article 101 TFEU analysis in other sectors as well, such as education or the environment.

Chapter VI examined the *UK model* under which competition authorities cooperate with multiple regulators and actors in healthcare in order to ensure that their analysis does not disregard the goals of their health systems. In the context of this model, the CMA applies a specific competition regime when it assesses a competition restriction's impact on healthcare quality. In applying this model, when the CMA examines whether and to what extent a merger between NHS FTs may restrict competition, it integrates quality concerns in all stages of its merger analysis: when defining the relevant geographic market, when assessing the SLC and also when evaluating in cooperation with Monitor, the Commissioners and the CQC the merger's potential customer benefits. This chapter identified the main pros and cons of this model. This chapter asked: *Can the cooperation of these multiple authorities ensure that healthcare quality in the merger assessment of NHS FTs is*

*actually taken into account as a whole?* To adequately answer this question this chapter first examined the specific merger regime under which the CMA assesses a merger's impact on quality competition. This chapter showed that in contrast with the *US Market approach*, the CMA is clear about the quality dimensions that it actually considers in its merger assessment. These are clinical factors, such as infection rates and mortality rates, as well as non - clinical factors such as waiting times. This chapter further indicated that the CMA and Monitor, again in contrast with the *US Market Approach* are straightforward as to the merger's benefits that can in fact be considered *relevant customer benefits* and therefore outweigh restrictions of competition. In sum, these can be lower prices, higher quality, and greater innovation in relation to NHS services.

This chapter indicated that although the continuity of health services and the financial stability of the NHS FTs are not considered *relevant customer benefits* as defined by the Enterprise Act of 2002, the CMA has found the way to consider these objectives in its merger assessment *indirectly* and without performing the difficult task of balancing health policy objectives, such as continuity and access to healthcare services against the restriction of choice and competition for either patients or commissioners. This chapter identified three mechanisms under which CMA attains this goal: (a) by integrating in its merger assessment the views of authorities that their primary objective is not to ensure competition, but to protect the continuity of NHS services. As noted, these authorities are mainly Monitor, and the commissioners; (b) by taking the view that in the relevant market of non - elective services, due the regulatory framework at which NHS FTs operate and the low financial incentives these entities have to attract patients, they lack incentives to compete; (c) by translating health objectives, such as accessibility, into quality dimensions, such as traveling time. In brief, the CMA acknowledging that absent most of the proposed mergers, the merging parties would be unable to ensure their financial stability and the continuity of their services, assesses NHS mergers in a way that facilitates their clearance.

*What are the mains pros and cons of the UK approach?* Undoubtedly, the *UK model's* main advantage is that it offers a framework under which the opinions of medical professionals acting as commissioners, health regulators and antitrust enforcers as to how healthcare quality is achieved and improved *can be actually considered as a whole*. Indeed, in acknowledging that competition law does not apply in vacuum, the CMA integrates in its analysis the voices of all actors responsible for ensuring that the competitive forces in the UK healthcare sector do not undermine essential dimensions of

healthcare quality. Nonetheless, this approach also suffers from shortcomings. Arguably, CMA's approach with regards to mergers between NHS FTs reflects the notion that 'the closer you are to bankruptcy, the more welcome you are to merge'. Such an approach not only harms the competition authority's reputation but most importantly weakens NHS FTs' incentives to operate efficiently. Since they know that their potential financial failure will not force them to exit, their incentives to improve the efficiency of the services they offer are low. Second, the methodology under which CMA takes non - competition goals into account, such as access and the continuity of NHS services, lacks transparency. This chapter proposed that if CMA's goal is to take these objectives into account, then it should explicitly state in its merger specific regime either that these objectives are considered relevant customer benefits or that they can weigh harm to competition. Although this analysis is not an easy one, it would ensure transparency, accountability and most importantly it would not send the signal to the competing NHS FTs that the weaker you are the more welcome you are to merge. Therefore, deterrence would be also enhanced.

## 2. Integrating healthcare quality *as a whole*: *Mission impossible?*

The thesis' main findings lead us to the conclusion that in general healthcare quality concerns can be integrated into a competition analysis under all three specified approaches: the *European approach*, the *UK approach* and the *US Market Approach*. This of course does not imply either that under all these identified models, all dimensions of healthcare quality can be actually taken into account *as a whole* or more importantly that these dimensions can be balanced against harm to competition. Indeed, under the *US Market Approach* such a task cannot be performed. This is because, as the US Courts and the FTC constantly repeat, the Sherman and the Clayton Acts contain no healthcare exceptions. Obviously, as this thesis demonstrated, under the narrow *US market approach* health policy objectives, such as equity and access, cannot be integrated into a competition law analysis. In other words, the thesis' hypothesis was confirmed.

Nonetheless, in my view, even under the US *market approach* quality considerations can enter the equation as the *CDA* case actually demonstrated. Interestingly, in this case, the Supreme Court did not hesitate to admit that to a certain extent *healthcare markets are special*. Surely, in this case the Supreme Court did not make a step forward by claiming that considering healthcare markets' special facets the US antitrust enforcers or the US Courts should balance restrictions of competition

against improvements to healthcare quality. However, the Supreme Court explicitly said that in applying competition law in healthcare, the US antitrust enforcers should not disregard the special economic features of healthcare markets, such as the market failures that pervade them. Hence, in my view, the *CDA* case offers a more flexible framework under which healthcare considerations can be considered in a competition analysis. To better develop my thinking, I give an example. In the *Teladoc* case, the Texas Medical Board attempted to convince the District Court that telemedicine can lead to poor quality or insufficient care since correct diagnosis necessitates face to face encounter with patient and physical examination. The District Court was not convinced. In fact, by insisting that the Supreme Court has explicitly rejected the notion that improved patient safety is a sufficient justification for a society of professionals to adopt an anticompetitive policy, it rejected the Board's quality justifications fully. If, however, the District Court had examined this claim through the lens of the Court's reasoning in the *CDA* case, the outcome of this case might be different. Indeed, if in this case, the District Court had taken the view that healthcare markets are pervaded by asymmetries of information and that physical examination, especially for certain types of treatment, might in fact be necessary for the correction of this market failure, the District Court might be more willing to examine more closely the Texas Medical Board's safety argument in substance. This example indicates that under the *US market approach*, as applied by the Supreme Court in the *CDA* case, there is some room for the antitrust enforcers to integrate safety claims in their assessment. Nonetheless, this does not in any case imply that all healthcare quality considerations can be taken into account under the *US market approach*, even as it was applied by the Supreme Court in the *CDA* case. This is because under the narrow *US Market Approach*, as already underlined, health policy goals such as equity, cannot become part of the antitrust agenda. The above example shows, though, that some essential facets of healthcare quality, such as safety or effectiveness, may be taken into account by the US antitrust enforcers in the context of the *US market approach*.

The thesis demonstrated that while protecting the multiple dimensions of healthcare quality in the context of the US market approach is a *mission less possible*, under both the *European* and the *UK model* this mission is possible. This is because in my view, what is crucial for the adoption of a holistic approach to healthcare quality is not only the model under which healthcare quality is actually integrated into a competition analysis but also competition authorities' commitment to protect all the dimensions of this notion. I believe that to the extent Competition Authorities commit to respect the principles and values under which their health systems operate, they can in

fact take into account all dimensions of healthcare quality both under the *European* and the *UK approach*. To shine a light on this argument, again I provide an example. Chapter V of this thesis asked: *Should GP's in their role as commissioners be allowed to buy more elective care from NHS hospitals that offer high risk non-elective services in poor rural areas so that these hospitals can cross-subsidize their more costly non-elective services?* In dealing with this question, to the extent competition authorities in Europe commit to integrate this equity concern into their analysis they could in fact perform this task under both the Commission's *more economic approach* and the *Court's more pluralistic approach*. Under the *Court's more pluralistic approach* competition authorities might say that this agreement pursues a legitimate objective, the protection of equity, and therefore should be exempted from the application of article 101TFEU. They may also say on the basis of the Commission's more economic approach that this agreement reduces risks to health safety and therefore it contributes to efficiency or that it promotes distributional efficiency which is part of a wider notion of efficiencies in healthcare. Such equity concerns may also be considered by the CMA when it examines mergers between NHS FTs. Chapter V for example pointed to the issue that childhood asthma incidence is rising in poor urban neighborhoods and asked: *Should, competition authorities be allowed to clear a hospital merger, although it leads to market power in the respiratory services market on the basis it will allow the merged entity to employ the most reputable respiratory specialists? Should this merger be allowed on the basis it will ensure merging entities' financial stability and therefore access to these services to the most vulnerable groups of our society?* Under the *UK model*, Monitor may issue an opinion advising the CMA to accept this merger on the basis that absent the merger the provision of good quality respiratory services for less advantaged groups of our society may be harmed.

This analysis demonstrates that competition authorities in Europe have the tools to take into account the multiple dimensions of healthcare quality irrespective of the model they apply in the context of their analysis. In protecting healthcare quality as a whole what is important is not only the model that they actually apply but competition authorities' commitment to assess an agreement's or a merger's impact at all levels at which healthcare takes place. This means that when competition authorities perform this task, they should also take into account the health policy objectives their systems aim to attain. If they neglected these objectives not only would they run the risk of reaching decisions that may harm these objectives but most importantly they would run the risk of making assessments that they are not legitimate in the sense that they do not respect the special value their societies attach to heath and healthcare. Additionally, as the *US market approach* demonstrated, an

assessment that would exclude from its assessment any non - competition goal, may yield conflicts between medical professionals, health policy makers and antitrust enforcers on how healthcare quality should be pursued and protected. In Donabedian's language this conflict would undermine commitment in achieving healthcare quality as not all functions and institutions in the healthcare system would actually agree on what the main facets of healthcare quality are.

However, it should be, again, noted that competition authorities should take into account the policy objectives of their health systems in a way that is transparent. This means that in cases where they decide that they should accept a restriction of competition in order to ensure a health policy objective they should explicitly state in their analysis (a) what is the goal they want to protect (b) why this restriction is necessary for the protection of this objective. If they balanced non - competition goals indirectly and without explicitly mentioning what exactly they try to protect through this balancing act, then there would be room for competition authorities to integrate into their analysis their ideological or political views on how healthcare should be distributed. Again, their assessment would lack legitimacy. This suggests that if Competition Authorities chose to integrate healthcare quality concerns under the *European Approach* they may have to issue guidance explaining under what conditions and how they balance restrictions of competition against specific facets of healthcare quality. It also suggests that if Competition Authorities chose to integrate healthcare quality concerns into their assessment on the basis of a model similar to the UK one, they should be also explicit on what are the dimensions of healthcare quality they actually protect, and under what conditions they balance them against harm to competition.

## 3. The limitations of this study: proposals for future research

This study claimed that antitrust enforcers should not exclude from their analysis the perspectives of other actors in healthcare on how healthcare quality should be achieved and protected. Nonetheless, in achieving this goal it is crucial that antitrust enforcers are equipped with the tools to evaluate whether a specific restriction of competition is necessary for the protection of healthcare quality. Especially in the case of hospital mergers, it seems that there is a relevant confusion on the conditions under which more consolidation brings quality improvements. Therefore, further research in this field of health quality seems necessary. This is because, if antitrust

enforcers had more sound empirical evidence showing under what conditions a hospital merger may improve quality then they may be more willing to consider merging parties' quality improvement claims. For example, as Chapters I and II of this study indicated, research in healthcare quality has found a relationship between procedure volumes and patient outcomes. Nonetheless, this research finding does not necessarily apply to all surgical procedures. For instance, as Chapter I indicated, regarding pediatric quality of care there are consistent research findings showing that hospitals caring for higher volumes of patients with similar conditions have better adjusted mortality rates.[1667] I claim that if Competition Authorities had consistent findings regarding the relationship of procedure volumes and patient outcomes in other also fields of surgery or medical treatment the antitrust enforcers may be less hesitant to integrate quality claims into their antitrust analysis.

Future research may also be needed on other healthcare markets than the ones this study examined. While this study focused mainly on horizontal restraints in hospital and medical services markets, the issue of healthcare quality has also a central role in other markets, such as the health insurance markets. Additionally, future research may also be necessary on how vertical restraints in healthcare markets impact healthcare quality, e.g. exclusivity agreements between doctors and hospitals, and more importantly how healthcare quality considerations may be taken into account in the context of vertical mergers, e.g. mergers between hospitals and insurance companies or between hospitals and physician groups.

## Concluding Remark

Competition law does not apply in a vacuum. Therefore, competition authorities should take into account the specific objectives of the sector at which competition law applies. If competition authorities in the EU neglected the objectives of their health systems, they would apply competition law in healthcare in a way that disregards that their societies attach specific value to health and healthcare. Undoubtedly, their decisions would lack legitimacy.

Florence, 22nd December 2017

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[1667] J. Mainz, *supra* n. 37, at 526.

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