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Market-testing Healthcare: Managed Care, Market Evolution and the Search for Regulatory Principles

The growing costs of healthcare as a percentage of GDP in the industrial countries are causing considerable problems for these economies, but any attempt to change the existing healthcare system in any given country is usually accompanied by hefty political debate. A system needs to be found that rations healthcare efficiently and effectively, and which is also politically acceptable. The following article examines recent changes in the healthcare systems in the UK and USA and discusses the extent to which they meet these criteria.

With 30 per cent of the OECD's GDP projected to be spent on healthcare by 2030, numerous member states are attempting to market-test healthcare by tying demand and supply to fixed-price, prospective contracts. Hence, the 2003/4 Bush Administration's Medicare bill offered $500 billion prescription drug benefits to motivate pensioners to join for-profit health maintenance plans that manage costs by substituting closed budgets for fee-for-service arrangements. The same year, German healthcare reforms proposed sickness funds to pool chronically ill patients in specialised disease management programmes, replacing itemised reimbursement by global budgets. Finally, the reforms of the UK National Health Service (NHS), intended to improve the system's overall capacity to respond to patient needs, employed fixed-price performance contracts to stimulate competition in primary and hospital care. In each case, determining cost-effective therapies as a condition for coverage amounts to "managing care" and continues to raise concerns about the legitimacy and contestability of results and standards. Governance concerns related to treatment guidelines, patient rights and the legal status of various stakeholders are covered elsewhere.[1] This article deals with market reactions to regulatory changes and vice-versa.

Following a brief introduction to healthcare systems and the convergence towards "managed care", this paper focuses first on the most recent developments in the UK NHS and the transformation of US managed care towards what President Bush, in his 2006 State of Union address, called "consumer-driven healthcare". This is followed by a discussion of US antitrust rationales for curbing specialty hospitals and upholding apparently anti-competitive settlements between generic and branded drug producers.

From the Convergence towards "Managed Care" to the Common Loss of Cost Control

For healthcare markets to ensure efficient and equitable supply,[2] demand-side and supply-side distortions have to be overcome. On the demand side, insurance contracts blur the link between consumers' price and treatment cost and thereby may artificially fuel demand; they may involve a screening of enrollees based on risks (rather than income) or result in differentially priced or otherwise uneven coverage. On the

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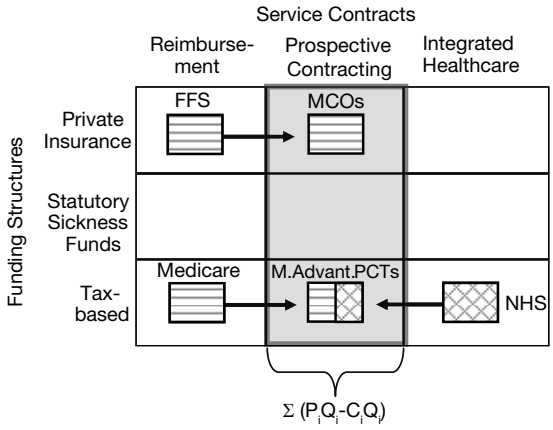
[1] For a review see R. Boscheck: Healthcare Reforms and Governance Concerns: The Cases of the United States, the United Kingdom, and Germany, in: INTERECONOMICS, Vol. 40, No. 2, 2005, pp. 75-88; and R. Boscheck: Healthcare Rationing and Patient Rights, in: INTERECONOMICS, Vol. 39, No. 6, 2004, pp. 310-313.

[2] For a review see M. Rothschild, J. E. Stiglitz: Equilibrium in Competitive Insurance Markets, in: Quarterly Journal of Economics, Vol. 90, 1976, pp. 629-649; J. P. Newhouse: Reimbursing Health Plans and Health Providers, in: Journal of Economic Literature, Vol. 34, No. 3, 1996, pp.1236-1263.

Figure 1
Convergence towards Prospective Contracting



supply side, patients' and payers' difficulties in judging the need for and the quality of treatment may trigger "supplier-induced" services, unwarranted premium-priced therapies, or conversely, the unjustified exclusion from vital cures. Countries apply different means of healthcare governance to regulate patient access and provider and payer performance. Figure 1, sorting arrangements based on types of funding method and supply contract, offers a first, albeit crude, perspective. No OECD country fits neatly into any one class, and no category, by itself, warrants any *a priori* judgment on healthcare performance.

The vertical axis identifies the three principal sources of healthcare finance, which differ in terms of coverage, choice, degree of risk selection and the process of fund allocation: *private insurance* charges premia typically based on age and health status at time of enrolment; *statutory sickness funds* pool occupational risk classes, have premia that are independent of individual health risk, and draw payroll taxes into dedicated funds governed by social partners; *tax-based healthcare systems* use centrally or de-centrally collected funds subject to political decisions. All three mechanisms may involve co-payment depending on the type of service rendered. The horizontal axis lists medical supply arrangements that differ in terms of payer-provider relations and degree of patient choice. *Reimbursement* facilitates complex contracting between multiple payers and providers as well as patient choice (rather than cost control). *Prospective contracting* limits the catalogue of eligible suppliers to a small number of pre-qualified providers willing to accept cost containment based on budgets, funding caps and fixed price-contracts. *Integrated healthcare* combines funding and service provision in one organisation in an attempt to internalise uncertainties arising from costs and contractual complexities.

Analysing the original healthcare reform projects pursued by President George W. Bush and Prime Minister Tony Blair shows the US and UK systems set to converge towards cost-effective prospective contracting. In both cases, however, actual market developments led to quite different outcomes and call for policy adjustments.

UK Healthcare Reform – Original Intent and Status 2006

A tax financed, integrated system, the UK's NHS links public sector providers with self-employed general practitioners (GPs), who are compensated based on a mix of fee-for-service and capitation and act as "gatekeepers" for non-emergency hospital services. Strict enforcement of budget limits helped to contain national healthcare expenditure to 7.6% of GDP in 2001, a level much lower than in other northern or central European countries. But it also caused understaffing and waiting lists and positioned the UK in terms of capacity and perceived – not actual – quality close to the bottom of the OECD. Responding to this, most recent reforms, spearheaded by Prime Minister Tony Blair, try to use markets to improve services while centrally containing costs.

More specifically, GPs, as independent contractors, were led to form regional primary care groups (PCGs) and own and operate so-called primary care trusts (PCTs) offering community health services including chronic disease management and managed self-care. Hence, the role of the GP changed from being a gatekeeper to being part of an integrated service provider under annual agreements and budgetary responsibility with health authorities. To expand the range of services on offer, new contracts for general practitioners offered pay rises of up to 50% from 2004 onwards. Next, to address capacity and efficiency concerns in non-ambulatory healthcare services, top-performing hospitals were selected to operate as autonomous, locally run "foundations" permitted to raise private finance and set staff pay. In addition, hospital consultants, typically maintaining private offices while being paid by the NHS, were offered more lucrative contracts in return for accepting tighter government control over their working practices.

Markets reacted. From 1997 to 2005, the NHS headcount swelled by over 300,000 to nearly 1.4 million, including 80,000 additional hospital and community nurses and 31,000 additional hospital administrators. During that period, the number of hospital consultants increased by 49%. Next, primary care services reorganised: top practices turned into franchise operations to compete head on with global players such as US United Health or GlaxoSmithKline disease management operations; private diagnosis and treatment centres (DTCs) were set up to offer walk-in ambulatory care – from speedy analytical procedures to day-surgery. In May 2006, for instance, Care UK won a contract to run a practice for 4000 patients employing three GPs and seven nurses. Competition and performance pay also transformed hospital services; as of spring 2006, hospital revenues are closely tied to the number of services rendered and patients have a choice of four acute hospitals for outpatient appointments and operations.

But results are mixed – at best. Markets give choice, stimulate and sort out practice innovations and cut the number of patients waiting over six months for an operation from 12,000 in 1997 to 3000 in 2006. Today, 31 of the 32 NHS trusts holding foundation status report a combined surplus of £20 million. Still, only 15 out of 26 health targets, established by the ministerial committee on NHS reform, have been achieved so far. Official productivity statistics, tracking annual changes in the health service output-to-input ratio from 1999 to 2004, vary between -1.5% and 1.6% subject to the format of input calculation or the weighting of case mixes.[3] What is worse, in 2005-6, the NHS accumulated a deficit of £536 million, more than twice its shortfall of the previous period, and a total debt in the hospital sector of £1.1 billion. Even though the Department of Health admitted to overspending £610 million on new contracts for nurses, consultants and GPs, with budgets caps and after all permissible adjustments, the system could react only in one way: in April 2006, the NHS announced 7000 jobs to be cut. Capacities will be tighter once again.[4]

Curiously, in mid 2006, two years prior to the official completion date of NHS reform, the UK public debate unites Tories and traditional Labour in rejecting the Blair reform agenda as principally flawed. For the first group, it adds "layer upon layer of bureaucracy", for the second it amounts to "privatisation by stealth". And yet there are obvious parallels to other UK regulatory reform experiences where the combination of underestimated efficiency potentials and performance incentives caused "overshooting".[5] In this particular case, it resulted in the stimulation of supplier-induced services and fee-for-service contracts. Unconstrained markets beating performance targets cause the loss of central cost control. Put differently, UK reforms unwittingly generated a situation similar to the one encountered by the USA just prior to the beginning of its managed care journey.

US Healthcare – From Managed Care to Consumer-driven Health Care

Table 1 tracks the transformation of the US healthcare system over the last 10 years as an interaction of different players along the extended healthcare business system – from the pharmaceutical and device industry, drug distribution, and health plans to hospitals, specialists and general practitioners to employers and employees. Three phases may be distinguished.

- *1995-1999*:[6] US employers, encouraged by the tax treatment of insurance premia to offer health plans, cover around 85% of the American working population and their dependants. Yet, throughout the 1990s, a combination of low-cost competition, relative labour surplus, high healthcare costs and severe rate increases not only caused firms to reduce benefits for workers as well as retirees, but also to replace conventional fee-for-service plans by cost-optimised managed care contracts. Traditional insurance companies, learning to manage care through either the acquisition of health maintenance organisations (HMOs) or their key personnel, extended their market share through mergers, premium discounts or participation in the then still less cost-focused Medicare market. The resulting scale gave bargaining leverage in exacting rate concessions from healthcare providers. Seeing their

[3] For a discussion see also http://www.reform.co.uk/website/pressroom/bulletinarchive.aspx?o=83.

[4] "Blot on the landscape", in: The Economist, 8 June 2006.

[5] D. Helm, T. Jenkinson: Introducing Competition into Regulated Industries, in: D. Helm, T. Jenkinson (eds.): Competition in Regulated Industries, 1998, Oxford University Press, pp. 1-22. For earlier but rather similar discussions see J. M. Keynes: (1927) Liberalism and Industry, in: J. M. Keynes: Collected Writings, Vol. XIX, 1927, pp. 644-646; I. Bussing: Public Utility Regulation and the So-called Sliding Scale, New York 1936, Columbia University Press.

[6] Reviewers set slightly different time lines. See R. Boscheck: Healthcare Reforms and Governance Concerns: The Cases of the United States, the United Kingdom, and Germany, op. cit.; P. B. Ginsburg et al.: A Decade of Tracking Healthcare System Change, CSHSC 2006; Medicare Payment Advisory Committee: Variations and Innovation in Medicare, June 2003.

Table 1
From Managed Care to Consumer-driven Healthcare

	1995-1999	1999-2003	2003-200?
Pharma/Device	Disease & Device Management	Patent Disputes & Financial Settlements	Hatch-Waxman Review Supreme Court Decision
Distribution	Pharmacy Benefit Managers (PBMs)	Pharmacy Benefit Managers (PBMs)	Consolidation
Health Plan	Consolidation; Marketshare Race	Abolition of Authorisation/ Capitation; PPOs	Consumer-driven Plans, Administrative Controls
Hospitals	Integrated Delivery Systems (IDSs), Mergers	Joint Hospital-Physician Contracting, Mergers	Retailing services FTC: 'Roll-Back' Reviews
Specialist	Specialist Networks	New Medical Arms Race Single-Specialty Hospitals	Single-Specialty Hospitals – Medicare Reimbursement
GP	Gatekeeper	Loss of Gatekeeper Function	Networked
Employer	Labour Surplus	Labour Squeeze & Media Pressure	Buy-down of Service Levels
Employee	Cost Reduction	Concerns about Quality & Wrongful Denial	Patient Cost Sharing

margins squeezed, numerous hospitals reacted by entering the insurance business to offer integrated delivery systems, consolidated through acquisitions, or tied-up GPs and specialists in physician-hospital organisations (PHOs) to jointly negotiate plans. Similarly, physicians entered independent practice associations (IPAs) as well as specialist groups. With the gateways to markets tightening, many pharmaceutical and device suppliers integrated forward. Some offered fixed-priced treatment-outcomes as disease and device management packages; others took over pharmacy-benefit managers (PBMs), a new form of bulk-buying pharma distributors that rank alternative drug-device combinations in terms of efficacy and price.[7] In sum, during the second half of the 1990s, the USA's shift towards managed care, driven by employers and plan providers, triggered a chain reaction of horizontal and vertical coordination to ensure fixed price-commitments, control costs and market choice. But the situation did not last.

- *1999-2003*: By the turn of the century, specific cost saving practices and cases of abuse had sufficiently alienated providers and patients to trigger regulatory and market reactions against them. Class-action suits drew on common-law theories of breach of contract, fraud and nondisclosure to invalidate the entire range of cost containment methods. Employers reacted to media pressure and contracting labour markets by moving away from tight plan management. In the process, original, integrated-staff HMOs, employing full-time medical professionals to strictly enforce treatment guidelines, lost out to more arm's-length preferred-provider organisations (PPOs) offering more patient choice albeit at higher and increasing costs. In 2003, these new networks together enrolled more than 70% of all insured US employees, but with largely dismal financial results. Shifts in bargaining power in favour of informed and price-sensitive payers had slowed premium growth at a time of rapidly rising, non-controllable costs. Even though the broad-based elimination of authorisation requirements and capitation had reduced the demand and pay for primary-care physicians, mergers, broadening provider networks and the perception of tighter capacities gave hospitals and specialists an occasion to increase rates.[8] At the same time, both groups began to diversify into ancillary diagnostics and screening services as well as ambulatory surgery, stepping up the level of non-price competition in a re-emerging and costly medical arms race. Insurers either consolidated further or exited the market. In sum, the backlash against managed care, driven by employers and employees, shifted the power from plans to providers.

- *2004-200?*: At present, with healthcare costs again growing at an accelerated rate, employers refocus on cost savings. But instead of going back to tightly managed care, new contracts increase patients' share of the costs through higher deductibles, co-payment and co-insurance. These so-called

[7] R. Boscheck: Healthcare Reform and the Restructuring of the Pharmaceutical Industry, in: Long Range Planning, 1996, pp. 629-642.

[8] See B. C. Strunk et al.: Tracking Health Care Costs in: Health Affairs, 21 June 2005.

consumer-driven plans typically involve an employer-paid healthcare-reimbursement account and an employee-paid top-up and offer patients information on providers, prices and qualities. They are based on the assumptions that, in general, Americans are over-insured, consumers will spend their *own* healthcare dollars more wisely, and that "feeling the price-pinch" will improve health behaviour. They are also expected to benefit US employers by reducing the average health insurance premium by 2 to 3% annually.[9] In a parallel development, conventional health plans apply re-established administrative controls such as authorisation requirements for high-price, and in particular ancillary, services,[10] or pay-for-performance contracts with service providers.[11] Their margins remain tight as healthcare providers, above all hospitals and specialists, continue to grow bargaining power with scale or segment dominance,[12] and GPs attempt to leverage networks and opportunities for collective bargaining. Upstream of the extended healthcare business system, the pharmaceutical industry just "has been given a break" by the Supreme Court upholding market entry agreements between branded and generic drug producers, which will impact healthcare costs.

In sum, by mid 2006, consumer-driven healthcare, the new focal point of US managed care, settles the consumer with the opportunity and risk of optimising his or her global healthcare budget. Criticised for "down-streaming" the risk to patients, one may, alternatively, interpret the concept as delegating decisions to consumers for optimal market benefits. Yet, next to obvious concerns regarding consumer sovereignty in healthcare markets and the legal limits to enforcing patient rights, one may wonder whether patients as payers can truly resist a rebounding supplier drive. While in the UK similar supply-led developments are ultimately curbed by NHS budgetary limits and policy controls, the more market-based US system requires more competitive checks and balances. But, as will be explained below, US healthcare markets and competition law may not be ready to deliver the necessary restrictions.

[9] S. Trude, J. M. Grossman: Patient Cost-Sharing Innovations, Promises and Pitfalls, CSHSC, Issue Brief No. 75, January 2004.

[10] G. P. Mays et al.: Managed Care Rebound? Recent Changes in Health Plans' Cost Containment Strategies, in: Health Affairs, 11 August 2004.

[11] T. Bodenheimer et al.: Can Money Buy Quality? CSHSC, Issue Brief No. 102, December 2005.

[12] L. P. Casalino et al.: Growth of Single-Specialty Medical Groups, in: Health Affairs, Vol. 23, No. 2, 2004, pp. 82-91.

US Antitrust Enforcement in Healthcare – Markets beyond Regulation?

Seen by many analysts to signal a revival of antitrust scrutiny in healthcare, a 2003 joint report by the US Federal Trade Commission and the Department of Justice[13] focused on three main topics: (a) the licensing and joint contracting of physicians; (b) the impact of consolidating hospital networks on group purchasing, labour contracting, plan-provider bargaining, and the bundling and pricing of services; (c) the pricing, distribution and advertising of pharmaceuticals and the competition between branded and generic drugs. Yet, developments in two key areas suggest that the recovery of antitrust is far from complete.

Checking Hospital Market Power

According to Centres for Medicare and Medicaid Services (CMS), payments to hospitals for inpatient care currently account for approximately 31% of the $1.7 trillion in US healthcare spending; 60% of this amount is paid by the federal and state governments.[14] Although hospitals are typically categorised as publicly-owned, non-profit or for-profit private entities, distinctions are blurred as many non-profit hospitals own for-profit institutions and for-profit systems manage non-profit and publicly owned facilities. Grouping hospitals based on the level and complexity of the care from primary to quaternary can also be misleading as institutions are not restricted to offering only the services associated with one category. Irrespective of the type of classification that is used, however, the majority of hospitals face a shortage of nursing staff and other hospital personnel, increased regulatory requirements, payer demands for information, as well as rising cost of liability premiums and prescription drugs. But do these pressures alone explain recent increases in hospital rates?

While prospective payment systems under Medicare and their adoption by private payers managed to constrain growth of hospital expenditure until the end of the 1990s, recent analyses predict a 55% to 75% real increase in per capita hospital expenditure up to 2013.[15] Studies abound that link hospital consolidation,

[13] At www.ftc.gov./reports/healthcare/04072healthcarerpt.pdf.

[14] See http://www.cms.hhs.gov.

[15] S. Heffler et al.: Health Spending Projection through 2013, in: Health Affairs 2004 (web-exclusive) at http://content.healthaffairs.org/cgi/content/full/hlthaff.w4.79v1/DC1; and D. Shactman et al.: The Outlook for Hospital Spending, in: Health Affairs, Vol. 22, No. 6, Nov./Dec. 2003.

ostensibly reasoned in terms of efficiency increases and the need to deliver full-fledged, cross-subsidised community services, to the creation of market power for the sole purpose of increasing prices.[16] But regulatory and market controls remain muted.

Whereas in 1979 only 31% of US hospitals were affiliated, by 2001 66.7% of them operated as part of a system with different degrees of financial and operational integration.[17] Weighing potential efficiencies against likely anticompetitive effects, the Federal Trade Commission (FTC) and Department of Justice (DoJ) formulated "safety zones" for presumably innocuous hospital mergers and were initially quite successful in taking legal actions against obvious outliers. However, from 1994 through 2000, at a time of around 900 hospital mergers, both agencies and state antitrust enforcers lost all seven cases they litigated.[18] Courts accepted broader market definitions, offsetting consumer benefits and special community commitments of non-profit organisations. Regulatory controls were basically blocked, but market challengers did not fare much better.

In the second half of the 1990s, a rather new breed of physician-owned single-specialty hospitals (SSHs), focusing mostly on cardiac, orthopaedic and general surgery, had set out to compete with general hospitals and ambulatory surgery centres. Specialists joined an SSH to share capital costs, specialise further within a recognised specialty group, and leverage scale and professional management in dealing with health plans and ever more regulatory environments. Market reception was expectedly mixed.

Advocates argued that SSH – as focused factories – provided higher quality care at, at times, significant price discounts. Critics contended that specialty hospitals fed on self-referral and concentrated on relatively profitable conditions and less severely ill patients. As a result, general hospitals were seen in need to either compensate for the loss of cross-subsidisation by raising the average price of service, sign lower priced full-line supply contracts with plans or suffer a loss; at any rate, their ability to provide emergency care and other essential community services was likely to be impaired. In this situation, some responses of general hospitals seemed justified even if questionable from a competition policy point of view.

Reacting to physicians involved with SSHs, some general hospitals removed their admitting privileges, de-listed them from on-call rotations, or limited their access to operating rooms. In other cases, hospital networks entered into managed care contracts with health plans that precluded the use of any SSH or lobbied regulators to apply certificate-of-need laws to encumber specialty hospital entry altogether. At the height of the "specialty hospital backlash", the Medicare Modernisation Act of 2003 (MMA) imposed an 18 month moratorium on new physician-owned heart, orthopaedic and surgical specialty hospitals. Under the moratorium, physicians may not refer Medicare patients to a specialty hospital in which they have an ownership interest, and Medicare may not pay specialty hospitals for any services rendered as a result of a prohibited referral. Oddly enough, an in-house referral within a dominant hospital network is obviously considered part of a necessarily bundled service as it fetches the full rate. Should regulations shelter dominant, but not naturally monopolistic, players against competitive controls?

And yet, there are signs of change. Since August 2002, a new FTC task force has been in place to establish more robust and narrow market definitions[19] and conduct retrospective assessments of certain hospital mergers. Rather than trying to contest good-faith commitment of merging parties before the act, the new "look back" approach makes use of hard evidence to determine whether the merger has caused smaller hospitals to close, service charges to rise, and whether the efficiencies promised in the Hart-Scott-Rodino filing in fact have been realised. Negative findings can lead to forced divestitures.

In 2005, an FTC administrative law judge ruled that the three-hospital Evanston Northwestern Healthcare (ENH) illegally raised prices after the merger and ordered the system to divest Highland Park Hospital.[20]

[16] M. Katz, C. Shapiro: Critical Loss: Let's Tell the Whole Story, in: Antitrust magazine, spring 2003, pp. 49-56; K. L. Danger, H. E. Frech: Critical Thinking about 'Critical Loss' in Antitrust, in: Antitrust Bulletin, 2001, pp. 340-42.

[17] G. J. Bazzoli: The US Hospital Industry: Two Decades of Organizational Change?, 2003, at http://www.ftc.gov/ogc/healthcarehearings/docs/0305 29bazzoli.pdf.

[18] California v. Sutter Health Sys., 84 F. Supp. 2d 1057(N.D. Cal.); FTC v. Tenet Healthcare Corp., 17 F. Supp. 2d 937 (E.D. Mo. 1998); United States v. Long Island Jewish Med. Ctr., 983 F. Supp. 121 (E.D.N.Y. 1997); FTC v. Butterworth Health Corp., 946 F. Supp. 1285; United States v. Mercy Health Services, 902 F. Supp.968 (N.D), Iowa 1995; FTC v. Freeman Hosp., 911 F. Supp. 1213 (W.D. M o.); Inre Adventist Health Sys., 117 F.T.C. 224 (1994).

[19] For a discussion see R. Boscheck: Healthcare and Antitrust, forthcoming.

[20] The not-for-profit system challenged the decision before the full commission. A ruling is expected by 17 May 2007.

Payers provided daunting evidence: in 2000, Evanston Northwestern a.o. raised prices to UnitedHealthcare's HMO by 52% at its Evanston facility and Glenbrook (Ill.) Hospital and 38% at Highland Park and raised its rates to UnitedHealthcare's PPO by 190% for Evanston and Glenbrook and 20% for Highland Park.[21] The administrative law judge rejected alternative remedies suggested by ENH and was not concerned about the consequences of the "unscrambling of the eggs". Even though the case is still under review by the full commission whose decision can also be appealed, US hospital networks are preparing to defend the competitive impacts and pro-competitive justifications of their recent mergers. They also better be ready to face revitalised market-tests.

In August 2006, the CMS announced that specialty hospitals will be allowed to re-enter Medicare.[22] The policy shift has been linked to a recent study,[23] commissioned by the CMS, which compared thirteen physician-owned specialty hospitals with acute-care competitors in terms of physician referral patterns, clinical quality, patient satisfaction and community benefits. The results show that physicians did, in fact, refer more of their patients to their own facilities than to competing hospitals. But clinical care was at par, patients were very satisfied and specialty hospitals provided more community benefits than their not-for-profit competitors when taxes were taken into account. One may expect the strengthening of specialty hospitals, together with the revival of regulatory scrutiny, to provide a check on hospital market power. In another important healthcare area, however, recent court decisions may well end up damaging consumer welfare.

Reviewing Hatch-Waxman – Making Drug Supplies Contestable or Collusion Look Good?

According to the US Government Accountability Office, "(p)rescription drug spending as a share of national health expenditures increased from 5.8 percent in 1993 to 10.7 percent in 2003 and was the fastest growing segment of health care expenditures".[24] In 2001, the USA spent $140.6 billion on pharmaceuticals, three times more than a decade earlier, chiefly due to an increase in drug utilisation, increased retail prices and the more intensive use of more expensive drugs. During the same period, the annual R&D spending in the pharmaceutical industry swelled from $8 billion to $30 billion. By 2004, the average drug development cost per compound, pre-approval, was estimated to be around $1.4 billion and the average new drug required $0.5 billion sales to earn a return just above the industry cost of capital.[25]

Patents provide incentives for companies to undertake risky research by temporarily excluding followers from competing away supra-normal profits; they also entail the disclosure of information that may allow others to circumvent the original functional mechanism and thereby stimulate innovation and diffusion. The 1984 Hatch-Waxman Amendments to the Food, Drug and Cosmetic Act (FDC Act),[26] regulating the generic drug approval process, lowered barriers to competition and product prices significantly. But the law also created incentives for branded and generic producers to settle patent disputes in ways that may delay the entry of generics and reduce consumer welfare.

The FDC Act offers generic drug producers an Abbreviated New Drug Application (ANDA) upon demonstrating that their new drugs are "bioequivalent" to the approved pioneer product and after providing "Paragraph IV" certifications that assert that any patent surrounding the original compound is either invalid or not infringed. Once the information is filed, the patent holder has 45 days to bring an infringement suit, which automatically delays the FDA's ANDA approval and hence the generic's chance to reach the market by 30 months. If the patent holder does not bring suit, the ANDA may be immediately approved. The first successful filer of an ANDA containing "Paragraph IV" certification is granted a 180-day period of exclusivity, calculated from the day of the first commercial marketing of the generic drug, during which no second ANDA filer may enter the market. In the prevailing in-

[21] The system is said also to have raised prices to Humana in 2000 by nearly 60%; Aetna by 15%; and Cigna's HMO by 15% to 20%, and 30% to its PPO. Private Healthcare Systems saw a 40% increase by the Evanston and Glenbrook hospitals. See M. Taylor: Antitrust watchdog, in: Modern Healthcare, Vol. 36, No. 26, 26 June 2006.

[22] CMS: Addressing Specialty Hospitals, Report on Medicare Compliance, 14 August 2006.

[23] D. Burda: A bottom-line debate: opposition to doc-owned hospitals comes down to money, in: Modern Healthcare, Volume 36, No. 12, 20 March 2006.

[24] General Accounting Office: Prescription Drugs: Price Trends for Frequently Used Brand and Generic Drugs from 2000 through 2004, Aug. 2005.

[25] Marakon Associates: Crisis? What Crisis? A fresh diagnosis of Big Pharma's R&D Productivity Crunch, presentation 2004.

[26] Congress passed the Hatch-Waxman Amendments to the Food, Drug and Cosmetic Act (FDC Act) in 1984. Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L.Ko. 98-417,98 Stat 1585 (1984) (codified as amended 21 U.S.C. §355 (1994)).

terpretation of the Hatch-Waxman Amendments, the first filer can substantially delay the commencement of the exclusivity period.[27]

A review of all relevant patent litigation initiated between 1992 and 2000, found that generics prevailed in 73% of the disputes; in the cases of Prozac, Zantac, Taxol and Plantinol alone, bringing generics to market before patent expiration saved US consumers more than $9 billion.[28] For brand-name manufacturers and generic producers, it would be clearly more lucrative to settle patent disputes, agree to defer entry and share the avoided profit loss. But a presumption is no proof. Between 1992 and 1999, eight out of fourteen settlements involved payments from the brand-name manufacturer to the generic first filer. All cases were investigated by the FTC and its learning was passed on to Congress. As a result, the 2003 Medicare Modernisation Act amended the Hatch-Waxman Act to ensure that patent settlement agreements are filed with the FTC and the Department of Justice and that only one 30-month stay per branded product can be granted. But courts seem unwilling to follow the Commission's presumption that financial settlements pay for deferred entry, are anti-competitive and should be illegal *per se*.

In 2003, the FTC considered that Schering-Plough Corporation, Upsher-Smith Laboratories, Inc., and American Home Products had settled patent litigation on terms that included substantial payments by Schering to its potential rivals in return for agreements to defer introduction of low-cost generic substitutes for Schering's prescription drug K-Dur20. Regarding these provisions to be unfair methods of competition, the FTC entered an order that would bar similar conduct in the future. The Eleventh Circuit set aside the Commission's decision finding that "a payment by the patentee, accompanied by an agreement by the challenger to defer entry, could not support an inference that the challenger must have agreed to a later date in return for such payment".[29] The Commission sought but was denied a *certiorari* review by the Supreme Court in June 2006.[30]

Both courts were apparently swayed by an economic analysis, prepared on behalf of Schering-Plough Corporation, of the "perhaps dramatically socially counterproductive" consequences of a *per se* condemnation of financial agreements under conditions of uncertain market entry and significant litigation costs. It argues that financial agreements may be necessary for settling patent disputes, where incumbents and entrants hold different expectations on the patent's remaining market value, the probability of litigation success and the likelihood of third party entry.[31] Where such settling the dispute results in entry earlier than with litigation, consumer welfare *may* be improved. But the question is, how does one know when litigation results would have otherwise occurred, and whether pre-entry arrangements do not shape post-entry conduct? The supporting analysis in the Schering case is far from formulating a needed *rule of reason*.[32] There is a danger that conditional economic arguments are interpreted in ways that could even make collusion look good rather than as contributing towards identifying bright line, efficient rules, i.e. principles that allow for efficient law enforcement while limiting the costs of taking wrong decisions. Also, considering financial settlements illegal *per se* may be a rough guideline but in some high profile cases it has in fact sped up rather than delayed litigation and entry.

In 2001, Eli Lilly rejected an offer by Barr Laboratories to settle a patent dispute over Prozac in exchange for $200 million and Barr's commitment not to produce a generic version of the drug until 2004, when Lilly's patent was set to expire. Sidney Taurel, Lilly's CEO, "felt that settling violated antitrust laws

[27] Leibowitz points out that a second filer will only be able to overcome the generic bottleneck if a court decides that the patent supporting the 180-day exclusivity period is invalid or not infringed. This however requires that the brand-name company sues the subsequent ANDA filer and thereby allows it to obtain a favourable court decision. If the branded product manufacturer does not do this, generic entry may be forestalled. See J. Leibowitz: Barriers to Generic Entry, prepared Statement of the FTC before the Special Committee on Aging of the US Senate, 20 July 2006.

[28] Federal Trade Commission: Generic Drug Entry Prior to Patent Expiration: An FTC Study, at http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf.

[29] J. Leibowitz, op. cit., pp. 15-16.

[30] Federal Trade Commission: Petition for a Writ of Certiorari, FTC v. Schering-Plough Corp., No. 05-273 (June 26, 2006) (denying cert, petition); Schering-Plough Corp. v. F.T.C., 402 F.3d 1056 (11th Cir. 2005); Schering-Plough Corp., No. 9297, 2003 WL 22989651 (F.T.C.) (Dec. 8, 2003) (Commission decision and final order).

[31] See R. D. Willig, J. P. Bigelow: Antitrust policy towards agreements that settle patent litigation, in: The Antitrust Bulletin, fall 2004, pp. 655-698. The authors point out that their research was begun in connection with work performed on behalf of Schering-Plough Corporation. For a contrarian view see C. Shapiro: Antitrust Analysis of Patent Settlements between Rivals, in: Antitrust, summer 2003, pp. 70-77, but also C. Shapiro: Antitrust Limits to Patent Settlements, in: RAND Journal of Economics, Vol. 34, No. 2, 2003, pp. 391-411.

[32] Rather, it suggests speculating "whether the amount that was found to be paid could, as a matter of plain logic, purchase a significant postponement of competition". See R. D. Willig, J. P. Bigelow, op. cit., p. 678.

and it isn't morally right".[33] Barr won a court ruling and, within two weeks of putting its own anti-depressant on the market, took over 50 per cent of Lilly's sales of Prozac. In the final analysis, US consumers saved an estimated $2.5 billion in line with Hatch's and Waxman's original intent. Yet, with the Supreme Court's decision of 26 June 2006 consumers may see more financial settlements and less generic competition.

Is a Revival of Antitrust Sufficient?

During its evolution from managed care to consumer-driven healthcare, parties across the US healthcare system adjusted first to ensure fixed-price commitments, then to offer a broader choice among providers, and now to enable consumers to optimise their individual healthcare budgets. Throughout the balance of market power shifted in line with competitive success and coordination, but only lately seems to have rekindled regulatory concerns. In their 2003 joint report, the FTC and DoJ committed themselves to vigorously enforcing competition in healthcare markets, relying wherever possible on individual rather than coordinated decisions and markets rather than organised countervailing powers to offset dominance. As the above suggests, there is a need to refine these principles in line with specific contexts and changing market realities; both agencies are inviting inputs. Ultimately, however, consumer-driven healthcare puts patients at the end of a line of coordination decisions that they may or may not be able to assess. What type of competition policy can guarantee that healthcare providers compete on relevant as opposed to merely patient-observable performance parameters and that consumers face proper incentives and have adequate information to take self-responsible decisions? And with all of it in place, would this ensure an efficient, market-tested healthcare delivery or simply overload an emotionally involved but otherwise rationally ignorant consumer?

Options Going Forward – Once Again!

In mid 2006, two years prior to the official completion of the UK NHS reform, the stimulation of supplier-induced services has resulted in a £0.5 billion annual deficit and the need to reverse critical capacity expansions. Unconstrained markets beat performance targets but also central cost control. In the USA, fixed-price performance contracts for providers are being substituted by consumer-managed healthcare budgets; healthcare competition has intensified but focuses on increasing service volume rather than efficiency. Antitrust principles are being reviewed to roll back provider concentration and regulatory gaming, but one may question whether this is sufficient to empower patients as consumers to take adequate, self-responsible decisions. In either country, users and the public at large reject blunt administrative controls and restricted provider choice, characteristic of tightly managed plans. But in either country, payers are confronting affordability problems. But before rejecting prospective contracting as principally flawed, one may wish to recall the fundamental characteristics of its alternatives.

On the one hand, a publicly financed healthcare minimum may provide the foundation on which to establish *decentralised healthcare coordination*, with tax-credits for both employers and employees contributing to health plans, unfettered competition in healthcare and insurance markets subject to harmonised minimum quality standards and vigorous and unbiased antitrust enforcement. On the other hand, a full-fledged publicly financed, *single-payer national health system* requires centrally set payment rates, macro-budgets and micro treatment decisions that rely on outcome data and limited incentive contracts. Whereas in the first case one may doubt whether one can rely on patients acting as sovereign consumers, the second poses the question of how to instil trust in the efficiency of centralised coordination and the innovativeness of cost-centre management.

Put into context, the middle ground, based on *prospective contracting*, may not look too bad. It attempts to delegate treatment decisions to knowledgeable service providers closest to a case, but is clearly hampered by providers' conflict of interest and the lack of regulatory controls. Incentives need to be constantly redesigned to align public interests with private profit motives in ways that limit the need for external monitoring. Still, considering the alternatives, current set-backs in the USA and the UK may be just the price to be paid for ultimately improving the system. Either way, failure is no option. With 30% of OECD GDP projected to be spent on healthcare in 2030, there is an urgent need to find a system that rations healthcare in the most efficient, effective and politically acceptable way.

[33] S. Kirchgaessner, P. Waldmeir: Drug patent payoffs bring scrutiny of side-effects, in: Financial Times, 24 April 2006.