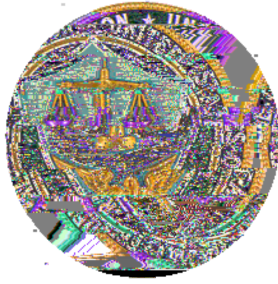

Federal Trade Commission

Enforcement Strategies in the Health Care Industry

Remarks of J. Thomas Rosch[1]
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[1] The views stated here are my own and do not necessarily reflect the views of the Commission or other Commissioners. I am grateful to my attorney advisor Holly Vedova for her invaluable assistance preparing this paper.

2

I. Macro Issue – Is Universal Health Care a Good Idea?

Most developed countries provide universal health care to their citizens, as do many developing nations. The United States is the only wealthy, industrialized nation that does not provide universal health care.[4] Right now, government health care is provided to just over a quarter of the U.S. population through health care programs for the elderly, disabled, military service families and veterans, children, and indigents.[5] Health care spending in the U.S. is estimated to be approximately 15% of GDP, the highest in the world.[6] About 84.2% of U.S. citizens have some form of private health insurance coverage.[7]

My wife and I were beneficiaries of universal healthcare in the U.K. Our son was born there, and we got free milk and a note from the Queen! So I start the discussion here with at least a neutral attitude toward universal healthcare. However, one of the main issues in considering the merits of universal health care is how to pay for it, and the debate about that issue in the U.S. is muted. Countries that provide universal health care coverage usually do so through legislation, taxation, and regulation. There are a multitude of ways to pay for universal insurance – patients may or may not have to pay for some expense out of pocket, and the amount dictates how much revenue must be raised via taxes. Any out of pocket costs by consumers may

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[4] Insuring America's Health: Principles and Recommendations, Institute of Medicine at the National Academies of Science, 2004-01-14, *available at:* <http://www.iom.edu/CMS/3809/4660/17632/17732.aspx>.

[5] Income, Poverty, and Health Insurance Coverage in the United States: 2006, U.S. Census Bureau, issued August 2007, at 18, [hereinafter U.S. Census Bureau Health Insurance Coverage Report] *available at:* <http://www.census.gov/prod/2007pubs/p60-233.pdf>.

[6] The World Health Report 2006 – Working Together for Health, World Health Organization, at 184, *available at:* <http://www.who.int/whr/2006/whr06_en.pdf>.

[7] U.S. Census Bureau Health Insurance Coverage Report at 18.

also be reimbursed by the government and paid for by increased taxes.

When health care services are extremely expensive, and there is high consumer demand, the government may not be able to foot the bill for everyone. So one way or another, rationing will result. There are three ways to ration health care. First, rationing can occur through the restriction of services if a patient is over a certain age, as is the case, as I understand it, in some

some basis other than means. This is not something that we in the U.S. are used to.

As I said at the outset, our current system of allowing market forces continue to govern choice means that cost and quality assurance are of paramount concern. This has created some vexing problems in three other health care areas more specific to antitrust that I will now turn to.

II. Joint Contracting by Competing Physicians

Both physicians as well as health plans are under tremendous pressure to improve the quality of services they provide. This creates tension between the two. Who should decide what services should be provided, and at what cost? This is a debate that has been going on in the U.S. ever since the advent of managed care. Physicians sometimes feel that they are at the whim of powerful health insurers who dictate the provision of health care. In response to this perceived "unlevel playing field" non-integrated groups of competing physicians in the past have gotten together to jointly contract with health plans, in an attempt to "level the playing field." The biggest pitfall here is the *per se* rule against price fixing and rules against group boycotts.[8] This type of conduct has been a longstanding problem for law enforcement officials here in the U.S. and there are numerous enforcement orders against physician groups throughout the U.S.[9]

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[8] Arizona v. Maricopa County Med. Soc'y, 457 U.S. 332 (1982).

[9] *See, e.g.,* In the Matter of San Juan IPA, Inc., Docket No. C-4142 (consent order issued June 30, 2005), *available at:* <http://www.ftc.gov/opa/2005/07/fyi0548.htm>; In the Matter of White Sands Health Care System, L.L.C, Docket No. C-4130 (consent order issued Jan. 11, 2005), *available at:*
<http://www.ftc.gov/opa/2005/01/fyi0504.htm>; In the Matter of Piedmont Health Alliance, Inc.,
Docket No. 9314 (consent order issued Oct. 1, 2004), *available at:*
<http://www.ftc.gov/opa/2004/10/fyi0457.htm>; In the Matter of Southeastern New Mexico Physicians IPA, Inc., Docket No. C-4113 (consent order issued Aug. 5, 2004), *available at:* <http://www.ftc.gov/opa/2004/08/fyi0445.htm>; In the Matter of California Pacific Medical Group, Inc., Docket No. 9306 (consent order issued May 10, 2004), *available at:* <http://www.ftc.gov/opa/2004/05/fyi0431.htm>; In the Matter of Carlsbad Physician

What are the options for competing physicians who wish to collectively negotiate their fees? There are several. First, competing physicians can *merge* their practices into a single entity whereby the physicians are employed by the entity. Aside from financial integration which I will discuss in a moment, this may be the best means for physicians to increase efficiencies and negotiate fees as a group without running afoul of the antitrust laws. There are no price fixing issues associated with physicians in a group practice, because they are no longer competitors, but instead are employed by the same entity.[10] An antitrust issue that can arise is if the market in which the merging physicians compete is already concentrated, so that the merger will give the merged entity market power. In that situation, the merger is analyzed as any other merger. The enforcement agencies would look to see whether the merger is likely to substantially lessen competition in the relevant market by engaging in coordinated interaction or unilaterally exercising of market power; whether there are entry barriers; and whether there are merger specific efficiencies that would outweigh the anticompetitive effect.[11] In the U.S. we have not had to bring many challenges to physician mergers, probably because many physicians prefer to stay in small, specialized practices.

Second, instead of a complete integration of their practices, competing physicians can

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Association, Inc., Docket No. C-4081 (consent order issued June 20, 2003), *available at:* <http://www.ftc.gov/opa/2003/06/fyi0339.shtm>.

[10] *See* Copperweld Corp. v. Independence Tube Corp., 467 U.S. 752, 771 (1984).

[11] *See* Business Review Letter from Acting Assistant Attorney General Joel I. Klein, U.S. Department of Justice, Antitrust Division, to Donald H. Lipson, Esq., Tallman, Hudders & Sorrentino, dated July 7, 1997, *available at:* <http://www.usdoj.gov/atr/public/press_releases/1997/1180.htm> (stating that proposed gastroenterologists merger was likely to lesson competition in the market for gastroenterology services).

financially integrate in part and avoid summary condemnation for joint pricing. There are various different means by which physicians can financially integrate their practices. Some examples are described in the FTC and U.S. Department of Justice Statements of Antitrust Enforcement Policy in Health Care, though these do not exhaust the possibilities:[12]

(1) an agreement by the physician group to provide services to an MCO at a "capitated" rate;

(2) an agreement by the group to provide designated services or classes of services to an MCO in return for a predetermined percentage of premium or revenue from the plan;

(3) use by the group of significant financial incentives for its physician participants, as a group, to achieve specified cost-containment goals.

(4) agreement by the group to provide a course of treatment that requires the substantial coordination of care by physicians in different specialties offering their services for a fixed, predetermined payment, and where the costs of that course of treatment for any

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[12] U.S. Dep't of Justice & Fed. Trade Comm'n, Statements of Antitrust Enforcement Policy in Health Care (1996), *reprinted in* 4 Trade Reg. Rep. (CCH) ¶ 13,153 (Sept. 5, 1996) [hereinafter 1996 Statements].

[13] *Id.*13

contracting on the basis of clinical integration.[16]

III. Competition by Physician Owned Specialty Hospitals

In the U.S., in the last two decades we have seen the emergence of specialty hospitals that offer a select set of specialized treatments instead of the broader selection of acute care offered at full service hospitals. This is an area in which I had experience as a litigator when I was in private practice, and I can tell you that the issues involved are complex, with no easy answers.

On the one hand, specialty hospitals are a new type of competition for pre-existing full service hospitals, and new competition is usually a good thing. On the other hand, specialty hospitals are often owned by referring physicians, and that raises a host of ethical and fiduciary duty concerns that complicates the competition issues. Furthermore, whether for good or naught, specialty hospitals take profit away from full service hospitals, and that creates complications too.

The pitfalls that arise are threefold. First, physician referrals of patients from a full service hospital where the physician has admitting privileges to a specialty hospital in which they have an ownership interest can raise ethical issues surrounding the physicians' fiduciary duty to their patients. This is due to the financial incentives created by the physicians' ownership interest in the hospital – they stand to profit from their investment in the hospital by the referral, separate and apart from the quality of care provided to the patient. For example, it is argued that these hospitals may offer only the most expensive procedures – *e.g.*, heart surgery.

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[16] *See* Commissioner J. Thomas Rosch, Clinical Integration in Antitrust: Prospects for the Future, Remarks Before the American Health Lawyers Association, ABA Antitrust Section and ABA Health Law Section, 2007 Antitrust in Health Care Conference, Washington, D.C., September 17, 2007, *available at:* http://www.ftc.gov/speeches/rosch/070917clinic.pdf.

Or, these hospitals may order more expensive procedures than most patients need. In short, it is argued that inevitably profit motives incentivizes cream skimming or cherry picking (referral of the most profitable patients to the physician-owned hospital). That in turn may lead to litigation by a full service hospital, alleging that it is the victim of unfair competition.

Alternatively, a full service hospital may also try to control the cream skimming problem by eliminating the privileges of the physicians who refer to specialty hospitals, or removing those physicians from staff. It may also create "quotas" for these physicians. These actions can also lead to litigation, this time by the referring physicians against the full service hospital. In one litigated case I was involved with several years ago, a full service hospital devised a formula to determine whether the physicians who were referring patients to their specialty hospital were violating their fiduciary duty to their patients. The formula limited the number of referrals of insured patients physicians could make. The issue in the litigation ultimately came down to a question of fairness, and it was a vexing question. The case ended up settling.

Second, even in situations where physician owners of specialty hospitals do not engage in self dealing, full service hospitals sometimes claim that specialty hospitals leave the lion's share of the most costly obligations, such as emergency care and uninsured care/charity care, to the full service hospitals, which taxpayers may ultimately have to finance. Some even go so far as to argue it increases the overall cost of health care.[17]

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[17] *See* Improving Health Care: A Dose Of Competition, A Report by the Federal Trade Commission and Department of Justice, July 2004, Chapter 3, VIII, *available at:* <http://www.ftc.gov/reports/healthcare040723/healthcarerpt.pdf> [*hereinafter* Health Care Report]. This report is based on a series of hearings the U.S. Federal Trade Commission and Antitrust Division of the Department of Justice conducted on competition in health care. *See also* U.S. General Accounting Office, GAO-04-167, Specialty Hospitals: Geographic Locations, Services Provided and Financial Performance, at 1, (2003) (Report to Congressional Requesters), *available at*: <http://www.gao.gov/new.items/d04167.pdf>.

What are the options? In 2003 the U.S. Congress imposed an 18-month moratorium during which physician investors in new specialty hospitals could not refer Medicare patients to those hospitals.[18] The moratorium lapsed in June 2005, but Congress then directed the Department of Health and Human Services (HHS) to develop a plan for dealing with physician investment in specialty hospitals. Although there have been new proposals for further legislation like the 2003 moratorium, the issue is still contentious.

One option suggested is a ban on specialty hospitals. But that may stifle innovation and efficiency. Some believe that physician ownership yields higher quality care at a lower cost, and that physician owned facilities are better able to react to new ideas and patient needs. It is also argued that it may be more cost effective for a specialty hospital to add innovative medical technology and equipment that might otherwise be too expensive for a full service hospital.

A second option suggested is to impose compulsory sharing of charity care burdens, either by the mandatory provision of emergency care, or mandatory contributions through Medicare/Medicaid guidelines.

Still another option suggested is for payors, public and private, to put a cap on specialty hospital charges. Changes to the Medicare reimbursement system may also help, to the extent the current reimbursement system encourages cherry-picking of patients.

I should note that this discussion raises a broader public policy issue of the advisability of cost shifting and cross subsidies in hospital pricing that I don't mean to get into here. (That issue

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[18] Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) § 507.

is thoroughly covered in Chapter three of the Commission's Health Care Report.[19]) So putting aside the broader public policy issue, I don't know which of these options is best. The only firm conclusion I've reached is that full service hospitals should not be saddled with the full burden of charity care costs. That is simply not fair. There should be some mechanism to ensure that specialty hospitals carry their share of the burden.

This may be an area in which the Commission might consider a challenge to physician or hospital practices under Section 5 of the FTC Act, which prohibits "unfair methods of competition."[20] Section 5 can be used to challenge conduct that violates the antitrust laws – the Sherman Act and the Clayton Act – but it also may be used to challenge conduct that may not amount to a violation of the Sherman Act and Clayton Act, but rather conflicts with the basic policies of those laws.[21] Many of the disputes surrounding specialty hospitals are over issues of

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[19] In discussing the impact of specialty hospitals on uncompensated/charity care, the U.S. FTC and Department of Justice Health Care Report recommends that governments should reexamine the role of subsidies in health care markets in light of their inefficiencies and potential to distort competition. Health Care Report, *supra* note 12, Executive Summary Recommendation 3, page 23. The Health Care Report also recommends that the U.S. Congress and state legislatures should consider whether direct subsidies for desired conduct are advisable. Health Care Report, *supra* note 12, Chapter 3, page 40.

[20] The U.S. FTC and Department of Justice Health Care Report states that, "[i]f there is specific evidence of anticompetitive conduct by individual providers or provider collusion in response to marketplace developments [such as market entry by a specialty hospital, among other things], the Agencies will aggressively pursue those activities." Health Care Report, *supra* note 12, Executive Summary, page 28, 9th Observation.

[21] *See* F.T.C. v. Brown Shoe Co., 384 U.S. 316, 321 (1966) ("[t]his broad power of the Commission is particularly well established with regard to trade practices which conflict with the basic policies of the Sherman and Clayton Acts even though such practices may not actually violate these laws. . ."); F.T.C. v. Sperry & Hutchinson Co., 405 U.S. 233, 239 (1972) (stating that the FTC Act "its legislative history, and prior cases compel an affirmative answer" to the questions of (1) whether "§ 5 empower[s] the Commission to define and proscribe an unfair competitive practice, even though the practice does not infringe either the letter or the spirit of the antitrust laws?" and (2) whether "§ 5 empower[s] the Commission to proscribe practices as

fairness, and arguably are not straightforward antitrust violations; that fits within my own view of a potential Section 5 case.

Is it an "unfair method of competition" for physic.1 T2 2dT*oeFMd.0 poc.1 and thesal Speciahty Hosptiv

unfair or deceptive in their effect upon consumers regardless of their nature or quality as competitive practices or their effect on competition?"); F.T.C. v. Ind. Fed'n of Dentists, 476 U.S. 447, 454 (1986) (observing that the standard for "unfairness" under the FTC Act is, "by necessity, an elusive one, encompassing not only practices that violate the Sherman Act and the other antitrust laws, but also practices that the Commission determines are against public policy for other reasons.").

[22] Heartland Surgical Specialty Hospital, LLC v. Midwest Division, Inc., 527 F.Supp. 2d 1257 (2007 D.C.D.K.).

market. Specifically, Heartland Surgical Specialty Hospital alleged that the full service hospital defendants were concerned about Heartland's effect on their profitability and orchestrated a group boycott of Heartland by the MCO defendants. There are allegations of a variety of communications and meetings between and amongst the competing full service hospitals and competing MCOs relating to the alleged boycott. The U.S. District Court for the District of Kansas dismissed the defendant MCOs' motion for summary judgement, allowing the trial to proceed on the basis of a Sherman Act Section 1 theory of a conspiracy to boycott, and also dismissed all but one of the defendant full service hospitals' motions for summary judgment.[23] The case ended up settling.

IV. Joint Buying of Drug and Health Services Through Large PBMs

Pharmacy Benefit Managers (PBMs) administer drug benefit programs for employers and health insurance carriers.[24] They contract with health insurance providers and self insured employers to provide managed prescription drug benefits. Roughly 95% of patients in the U.S. with a drug benefit receive the benefits through a PBM. In the U.S., the PBM industry has evolved from one of numerous, small claims processing firms to a more concentrated industry with comprehensive service offerings. They negotiate discounts and rebates from pharmaceutical manufacturers, contract with retail pharmacy networks to provide drugs to patients, establish drug formularies to encourage patients to use less expensive drugs, and provide drug utilization oversight.

PBMs can be enormously efficient. However, many, if not most of the efficiencies they

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[23] *Id.*

[24] For an overview of the U.S. PBM industry, *see* Health Care Report, *supra* note 12, Chapter 7, Section IV.

[25] The Commission also analyzed whether the transaction would give the merged firm market power in the market for the provision of PBM services by national full-service PBMs to large employers. The Commission concluded that there were sufficient remaining independent, full-service PBMs with national scope (Medco, Express Scripts) and significant competition from several health plans and several retail pharmacy chains offering PBM services, that there would be no anticompetitive price increase resulting from the merger.

there was no reason to expect that to lead to a reduction in output.[26]

Thus, the Commission gave PBM buyer power a pass, at least for that transaction, due in part to efficiencies. However, I don't think that means PBM buyer power will never be a concern. In its Caremark RX/AdvancePCS closing statement, the Commission made note of the competition among the remaining competing PBMs, anticipating that competition would remain vigorous, and was likely to cause PBMs to pass on at least some of their cost savings to customers, in order to gain or retain their business.[27] If there comes a point when that competition wanes, PBM buyer power could raise significant concerns.[28] It is hard to say exactly what level of concentration in the PBM industry would reach that point.[29]

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[26] Statement of the Federal Trade Commission, In the Matter of Caremark Rx, Inc./AdvancePCS, File No. 031 0239, *available at:* <http://www.ftc.gov/os/caselist/0310239/040211ftcstatement0310239.pdf>.

[27] *Id.*

[28] Some have raised issue with PBMs' transparency in the rebates they receive from pharmaceutical manufacturers. It is argued that greater transparency in rebates will encourage PBMs to compete more aggressively. *See, e.g.,* Health Care Report, *supra* note 12, Chapter 7, page 16. The Health Care Report concludes that vigorous competition in the marketplace for PBMs should result in the optimal level of transparency. Health Care Report, *supra* note 12, Chapter 7, page 17. In addition, the FTC has commented on various legislative proposals in the PBM industry in the U.S. that would, among other things, impose regulatory requirements re: transparency of rebates, and concluded that such legislation may increase the costs of pharmaceuticals and health insurance. *See, e.g.,* Letter from Maureen K. Ohlhausen, Director, Office of Policy Planning, FTC, to Nellie Pou, Assemblywoman, 35th District of New Jersey, dated April 17, 2007, *available at:* <http://www.ftc.gov/be/V060019.pdf>; Letter from Susan Creighton, Director, Bureau of Competition, FTC, to Greg Aghazarian, California Assembly Member, dated September 7, 2004, *available at:* <http://www.ftc.gov/be/v040027.pdf>.

[29] On a related issue, in 2003 the U.S. Congress requested the FTC to examine whether private-sector health insurers that offer prescription drug coverage pay more for such drugs when using a mail-order pharmacy owned by a Pharmacy Benefit Manager (PBM), as opposed to using a mail-order or retail pharmacy that the PBM does not own. The concern was over conflict of interest with a health insurer's interests and the PBM's incentives – whether PBMs could have incentives to increase costs and generate additional profits through their mail-order pharmacies.

Let me briefly turn to some of the private litigation involving PBMs. A few years ago the United States Circuit Court for the First Circuit held that a PBM network that excluded out of network pharmacies was a procompetitive joint venture offering potential efficiencies such as lower prices and stable long term supply. Stop & Shop Supermarkets Co. v. Blue Cross & Blue Shield.[30] The PBM network allegedly covered 85 percent of reimbursed retail drug purchases. The plaintiff alleged a *per se* violation of Section 1 of the Sherman Act, but both the district court and the First Circuit rejected that approach, based on the procompetitive nature of the PBM joint venture. Another private case had a similar result. In 2005, in North Jackson Pharmacy v. Caremark RX, Inc.,[31] the federal district court declined to apply the *per se* rule to a an alleged agreement among insurers and the PBM with whom they contracted to represent them in assembling retail pharmacy networks as providers of drugs to the insured drug purchasers. The retail drug store plaintiffs alleged that the agreement amounted to an agreement to fix the prices paid to those retail pharmacies for dispensing drugs. The court reasoned that there was a

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The FTC issued a report in September 2005 concluding that, in 2002 and 2003, prescription drug plan sponsors generally paid lower prices for drugs purchased through PBM-owned mail-order pharmacies than for drugs purchased through mail-order or retail pharmacies not owned by PBMs. The report concludes that competition in the PBM industry can afford health insurers sufficient tools to safeguard their interests. Pharmacy Benefit Managers: Ownership of Mail Order Pharmacies: A Federal Trade Commission Report (August 2005), *available at:* <http://www.ftc.gov/reports/pharmbenefit05/050906pharmbenefitrpt.pdf>.

[30] 373 F.3d 57, 63-65 (1st Cir. 2004).

[31] 385 F.Supp. 2d 740 (N.D. Ill. 2005).