Everything Old is New Again: Health Care and Competition in the 21st Century

Prepared Remarks of

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Thank you for inviting me to address the 7th Annual Competition in Health Care Forum. Chicago is a singularly appropriate location for this forum – particularly the 7th such forum. The 7th Circuit Court of Appeals, which has issued a series of seminal opinions in health care antitrust, is located just a few miles from here. One can track many of the major developments in health care antitrust in the last few decades simply by listing the names of 7th Circuit cases, including *Indiana Federation of Dentists*, ¹ *Ball Memorial Hospital*, ² *Hospital Corporation of America*, ³ *Schachar*, ⁴ *Wilk*, ⁵ *Rockford Memorial Corporation*, ⁶ *Marrese*, ⁷ *Sanjuan*, ⁸ *Marshfield Clinic*, ⁹ and *In re Brand Name Prescription Drugs Antitrust Litigation*. ¹⁰

Chicago is also an appropriate place to discuss antitrust and the professions because it is the home to professional organizations representing physicians, surgeons, dentists, hospitals, and lawyers. Each of these professions and professional organizations has been involved in important antitrust cases – some initiated by the Commission and others by private plaintiffs. ¹¹ The antitrust cases brought against these organizations transformed the market for professional services and played important roles in the

¹ Indiana Fed'n of Dentists v. FTC, 745 F.2d 1124 (7th Cir. 1984), rev'd, 476 U.S. 447 (1986).

² Ball Mem'l Hosp. Inc., v. Mutual Hosp. Ins., Inc., 784 F.2d 1325 (7th Cir. 1986).

³ Hospital Corp. of Am. v. FTC, 807 F.2d 1381 (7th Cir. 1986).

Schachar v. American Academy of Ophthalmology, Inc., 870 F.2d 397 (7th Cir. 1989).

Wilk v. American Med. Ass'n, 895 F.2d 982 (7th Cir. 1990); Wilk v. American Med. Ass'n, 719 F.2d 207 (7th Cir. 1983).

United States v. Rockford Mem'l Corp., 898 F.2d 1278 (7th Cir. 1990).

Marresse v. American Academy of Orthopedic Surgeons, 977 F.2d 585 (7th Cir. 1992).

Sanjuan v. American Bd. of Psychiatry and Neurology, Inc., 40 F.3d 247 (7th Cir. 1994).

Blue Cross & Blue Shield United of Wisconsin v. Marshfield Clinic, 65 F.3d 1406 (7th Cir. 1995).

In re Brand Name Prescription Drugs Antitrust Litigation, 288 F.3d 1028 (7th Cir. 2002); In re Brand Name Prescription Drugs Antitrust Litigation, 186 F.3d 781 (7th Cir. 1999); In re Brand Name Prescription Drugs Antitrust Litigation, 123 F.3d 599 (7th Cir. 1997).

See, e.g., American Med. Ass'n, 94 F.T.C. 701 (1979), aff'd, 638 F.2d 443 (2d Cir. 1980), aff'd by an equally divided court, 455 U.S. 676 (1982) (physicians); Wilk v. American Med. Ass'n, 719 F.2d 207 (7th Cir. 1983) (physicians, surgeons, hospitals); Goldfarb v. Virginia State Bar, 421 U.S. 773 (1975) (lawyers); Boddicker v. Arizona State Dental Ass'n, 549 F.2d 626 (9th Cir. 1977) (dentists). For a comprehensive review of antitrust health care cases brought by the FTC, see Health Care Services and Products Division, FTC Antitrust Actions in Health Care Services and Products, available at http://www.ftc.gov/bc/hcindex/hcupdate020118.pdf>.

development of antitrust law. These cases also had a powerful impact on public attitudes toward competition and the professions.

I will talk this afternoon about several subjects, including the nature of the current health care marketplace, the importance of competition in health care, the kinds of anticompetitive behavior the Commission is seeing, the agency's enforcement and research agenda, its efforts to protect and promote quality and efficiencies, and the Commission's various initiatives in health care since I became Chairman 17 months ago. First, though, I wanted to spend a few minutes on the title of my talk.

My speech this afternoon is titled "Everything Old is New Again: Health Care and Competition in the 21st Century." As most of you know, I'm a recovering law professor. Law professors typically use colons in the titles of their articles and speeches. Law professors also routinely explain the significance of their titles, especially why they unify, synthesize, clarify, and otherwise illuminate the subject. My aim is more modest; my title simply reflects several points I want to emphasize about the health care marketplace and the Commission.

First, as a nation we are seeing dramatic premium increases for health care coverage of a sort not experienced for almost a decade. During the mid-1990s, many believed that managed care had solved the problem of ever-increasing health care costs. That assessment was unduly optimistic. The recent cost increases helped make health care a live issue on the legislative and policy agenda. The Commission will confront

Jon R. Gabel et al., *Job Based Health Benefits in 2002: Some Important Trends*, 21 HEALTH AFF., Sept.-Oct. 2002, at 143; Bradley C. Strunk et al., *Tracking Health Care Costs*, Health Affairs Web Exclusive (Sept. 26, 2001), available at http://www.healthaffairs.org/WebExclusives/Strunk Web Excl 92601.htm>.

novel fact patterns and legal issues as the private sector develops new strategies to address these cost increases, while simultaneously ensuring access and high quality.

Second, the Commission continues to see a wide variety of overt anticompetitive behavior in health care, along with some new variants. The Commission continues to bring cases against physicians alleging price fixing – much like those brought by the agency during the last 20 years – although several of the new cases involve an unprecedented number of doctors and consultants, who coordinated the conduct under the guise of assisting in negotiations with payors.

Conversely, the Commission's pharmaceutical docket reflects a new variation on an old theme. The Commission has brought cases against branded and generic pharmaceutical companies that have engaged in a variety of forms of alleged anticompetitive conduct. Pharmaceutical cases account for the majority of the Commission's antitrust resources devoted to health care and a sizeable percentage of the Bureau of Competition's budget. The agency also spent a great deal of time this year preparing an empirical study of the performance of the Hatch-Waxman Amendments. The report of this study included concrete recommendations to address the possibility of future abuse of the Hatch-Waxman framework. These efforts have had far-reaching consequences; about two weeks ago, the President announced that the Food and Drug Administration would take regulatory action to curb the most important problem the Commission's study identified. To

In 1996, less than 5% of new competition investigations involved pharmaceuticals, while in 2001, the percentage of new investigations involving pharmaceutical products was almost 25%.

See Generic Drug Entry Prior to Patent Expiration: An FTC Study (July 2002), available at http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf>.

See Food and Drug Administration, Applications for FDA Approval to Market a New Drug: Patent Listing Requirements and Application of 30-Month Stays on Approval of Abbreviated New Drug Applications Certifying That a Patent Claiming a Drug is Invalid or Will Not be Infringed, 67 Fed. Reg.

Third, from a more personal perspective, the Commission has been pounding the health care antitrust beat since the Supreme Court established in *Goldfarb* that there was no "learned professions exception" to the antitrust laws. ¹⁶ Indeed, even before the Supreme Court's 1975 decision in *Goldfarb*, the agency established a task force to investigate occupational regulations in several industries, including health care. I was proud to play a role in launching that effort as an assistant to the Director of the FTC's Policy Planning Office, my first job at the Commission. As Chairman, I can assure you that the FTC will continue to address anticompetitive conduct in health care. In this task, the FTC is aided by its partners at the Department of Justice and the state attorneys general.

Fourth, in addition to antitrust, the Commission also has an important consumer protection role in the market for healthcare goods and services. Miracle cures and snake-oil are far older than the Commission, but the rise of the Internet and cross-border marketing has simultaneously increased the rewards and decreased the costs and risks of defrauding people. Deceptive and unfair marketing practices are far too common in health care. The Commission has undertaken several important initiatives in this area, including Operation Cure.All, which challenged deceptive and unsubstantiated health claims for serious illness. ¹⁷ The FTC has also focused its attention on purveyors of

^{65448 (}Oct. 24, 2002), available at <<u>http://www.fda.gov/OHRMS/DOCKETS/98fr/102402b.htm</u>>. See also Statement of Federal Trade Commission Chairman Timothy Muris on the FDA's Proposals to Improve Consumer Access to Lower-Cost Generic Drugs (Oct. 21, 2002), available at <<u>http://www.ftc.gov/opa/2002/10/murisfda.htm</u>>.

See Goldfarb v. Virginia State Bar, 421 U.S. 773 (1975). For a historical perspective on the Commission's involvement in health care, see Carl F. Ameringer, Federal Antitrust Policy and Physician Discontent: Defining Moments in the Struggle for Congressional Relief, 27 J. HEALTH, POLITICS, POL'Y & L. 543 (2002).

See Operation Cure.All: Introduction, available at http://www.ftc.gov/bcp/conline/edcams/cureall/index.html; Bogus Cancer Care Guru Settles FTC Charges, (Oct. 28, 2002), available at http://www.ftc.gov/opa/2002/10/walker.htm.

anthrax tests and weight loss products when those products do not perform as advertised. 18

A more general consumer protection problem in health care is the relative scarcity of information about cost and quality. Without good information, transaction costs and uncertainty increase dramatically. Consumers have great difficulty obtaining the goods and services they desire. The Commission has been a strong voice for allowing competition to deliver truthful and accurate information to consumers, and has long supported the voluntary disclosure of truthful non-deceptive information by market participants. Nobel Laureate George Stigler once observed that advertising is "an immensely powerful instrument for the elimination of ignorance." Studies by the Bureau of Economics have confirmed that advertising provides a powerful tool to communicate information about health and wellness to consumers – and the information can change people's behavior. ²⁰ Two months ago, the FTC staff responded to a request by the FDA for comments addressing whether its regulations, guidelines, policies, and practices comply with the First Amendment. These staff comments outlined the empirical evidence on the benefits to consumers from the free flow of truthful and nondeceptive commercial information.²¹ These actions exemplify the Commission's commitment to consumer empowerment through information.

See Tipping the Scales? Weight Loss Ads Found Heavy on Deception (Sept. 2002), available at http://www.ftc.gov/bcp/conline/features/wgtloss.htm; FTC Announces First Two Enforcement Actions Against Purveyors of Bioterrorism Defense Products (Feb. 27, 2002), available at http://www.ftc.gov/opa/2002/02/vitalraw.htm.

George J. Stigler, *The Economics of Information*, 69 J. POLIT. ECON. 213 (1961).

See Pauline Ippolito & Jan Pappalardo, Advertising, Nutrition & Health: Evidence from Food Advertising 1977-1997, FTC Bureau of Economics Staff Report (Sept. 2002), available at http://www.ftc.gov/opa/2002/10/foodads.htm.

FTC Staff Provides FDA With Comments on First Amendment Commercial Speech Doctrine (Sept. 22, 2002), available at http://www.ftc.gov/opa/2002/09/fdacomment.htm.

Much remains to be accomplished in this area of the law to ensure that the market for health care goods and services operates efficiently. If I surveyed the public about whether they had better information about their last purchase of health care services or their last car, we all know what the answer would be. Information about the cost and quality of a wide array of cars is readily available from car manufacturers, dealers, car and consumer magazines, and friends and neighbors. The Internet provides a powerful tool to tap such information and reduce the costs of buying a vehicle. Trying to get similar information about health care goods and services is far more difficult, although there have been some promising recent developments.

Finally, and most important, although there is plenty of misinformation and misapprehension about the role of the Commission and the application of the antitrust laws to the health care marketplace, the FTC's basic task remains the same as it has always been. The Commission works to ensure that the approximately 15% of our nation's GDP devoted to health care, amounting to about \$1.3 trillion per year, is spent in robustly competitive markets. Aggressive competition promotes lower prices, higher quality, greater innovation, and enhanced access. More concretely, in health care, competition results in new and improved drugs, cheaper generic drugs, treatments with

Of course, the quality and reliability of the information that is obtained is a separate matter. *See* Jane E. Brody, *The Hazards of Point-and-Click Medicine*, N.Y. TIMES, Aug 31, 1999, at F1.

See Arnold M. Epstein, Public Release of Performance Data: A Progress Report From the Front, 283 JAMA 1884 (2000); Stephen F. Jencks, Clinical Performance Measurement – A Hard Sell, 283 JAMA 2015 (2000); Daniel R. Longo, et al., Consumer Reports in Health Care: Do They Make a Difference in Patient Care?, 278 JAMA 1579 (1997); Eric C. Schneider & Arnold M. Epstein, Influence of Cardiac-Surgery Performance Reports on Referral Patterns and Access to Care: A Survey of Cardiovascular Specialists, 335 NEW ENGL. J. MED. 251 (1996).

These informational difficulties are not unique to health care. Similar informational impediments affect the markets for most professional services, including lawyers.

less pain and fewer side effects, and treatments offered in a manner and location consumers desire.²⁴

The Commission does not have a pre-existing preference for any particular model for the financing and delivery of health care. Such matters are best left to the marketplace. What the Commission does have is a commitment to vigorous competition in both price and non-price parameters. The FTC supports initiatives to enhance quality of care and ensure the free-flow of information because such initiatives benefit patients. The staff issued a favorable opinion to one such initiative, MedSouth in Denver, involving clinical integration, ²⁵ and the staff is currently considering other requests for guidance. The FTC recently closed an investigation in which physician collaboration resulted in a substantial degree of market concentration because the parties demonstrated that considerable efficiencies resulted, notably dramatic improvements in the quality of care. There is great flexibility for health care providers to develop and implement novel financing and delivery arrangements without running afoul of the antitrust laws, although, not surprisingly, the FTC draws the line at anticompetitive conduct.

Simply stated, there is no inherent inconsistency between vigorous competition and the delivery of high quality health care. Theory and practice confirm that quite the opposite is true – when vigorous competition prevails, consumer welfare is maximized in health care and elsewhere in the economy. Interference with competition is far more likely to decrease consumer welfare than increase it. As the Supreme Court observed in *Indiana Federation of Dentists*, such interference necessarily and improperly preempts

See, e.g., Frank R. Lichtenberg, Are the Benefits of Newer Drugs Worth Their Cost? Evidence From the 1996 MEPS, 20 HEALTH AFF., Sept.-Oct. 2001, at 241.

Letter from Jeffrey W. Brennan, Assistant Director, Bureau of Competition, to John J. Miles, Ober, Kaler, Grimes & Shriver (Feb. 19, 2002) (staff advisory opinion re: MedSouth, Inc.), available at http://www.ftc.gov/bc/adops/medsouth.htm.

"the working of the market by deciding... that customers do not need that which they demand."26

So much for my title. Let me now address in greater detail the issues that bring us here today. As Bob Pitofsky, my good friend and immediate predecessor as Chairman, noted in a speech he gave five years ago, "in health care as in no other area, there appears to be a recurring need to return to first principles, and to talk about why competition and antitrust enforcement make sense." As Bob correctly observed in the very next sentence of his speech, it is one of the singular ironies of work at the Commission that even "as markets have become more competitive and our antitrust analysis more sophisticated, and even as policy makers rely more and more on competition as a useful tool for improving the delivery of health care, the question continues to be raised: is competition a good idea in this context?"²⁸

My perspective, both as Chairman of the FTC and as an academic, is that competitive markets systematically outperform all alternative forms of distribution. Problems in the market are always a matter of concern, and the Commission exists to address a variety of such problems. A comparative institutional perspective makes clear, however, that every arrangement for delivering goods and services is imperfect.²⁹ It is a classic nirvana fallacy to assume that because markets are not perfect, a market-replacing

²⁶ Indiana Fed'n of Dentists v. FTC, 476 U.S. 447, 459 (1986). See also Robert Pitofsky, Prepared Statement of Federal Trade Commission Concerning H.R. 1304 (June 22, 1999), available at http://www.ftc.gov/os/1999/9906/healthcaretestimony.htm ("The collective judgment of health care professionals concerning what patients should want can differ markedly from what patients themselves are asking for in the marketplace."). Of course, the presence of insurance complicates the picture, because the availability of coverage creates moral hazard problems by lowering the marginal cost of consuming particular health care services.

Robert Pitofsky, Thoughts on Leveling the Playing Field in Health Care Markets, National Health Lawyers Association Twentieth Annual Program on Antitrust in the Health Care Field, Washington, D.C., (Feb. 13, 1997), available at http://www.ftc.gov/speeches/pitofsky/nhla.htm.

²⁹ See Neil K. Komesar, Imperfect Alternatives: Choosing Institutions in Law, 1994 ECONOMICS AND PUBLIC POLICY 204 ("Bad is often best because it is better than the available alternatives.").

alternative necessarily will be better.³⁰ Unfortunately, such reasoning prevails far too often in discussions of health policy – a fact that helps explain the continuing need to return to first principles.

Whenever one encounters a market problem, the correct response is to correct the market imperfection, and then allow the market to work. The wrong response is to assume the market cannot work and regulate it out of existence. Consider for a moment your reaction if someone told you that cars were too important a product to be left to the vagaries of the market. There are many reasons there might be failures in the markets for new and used cars. Cars are an infrequent purchase. Pricing is far from transparent, particularly if you are leasing or have a trade-in. Quality is difficult to discern, particularly in used cars. There are so many options and models, it is hard to make meaningful comparisons among different manufacturers. Yet, despite these potential problems, we rely on the market – backstopped by some modest safety and disclosure regulations and a limited products liability regime – to deal with millions of discrete purchase and sale transactions every year.

The Performance of the Health Care Market

Of course, health care and cars are not identical, but the differences are not as large as some people assume. What is known about the performance of the health care market along the relevant dimensions of cost, quality, and access?

Cost is obviously the most easily noticeable factor for many people. The total amount spent on health care in the United States is about \$1.3 trillion per year.³¹ Federal,

alternative real institutional arrangements.")

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See Harold Demsetz, Information and Efficiency: Another Viewpoint, 12 J.L. & ECON. 1, 1 (1969) ("The view that now pervades much public policy economics implicitly presents the relevant choice as between an ideal norm and an existing 'imperfect' institutional arrangement. This nirvana approach differs considerably from a comparative institution approach in which the relevant choice is between

state, and local spending accounts for 45% of the total; private insurance and other private spending accounts for 40%; and consumer out-of pocket spending accounts for 15%. The amount spent on health care rose substantially during the 1970s and 1980s but stabilized during most of the 1990s at around 13.5% of GDP.³² The last few years have seen the return of dramatic cost increases, some attributable to increased utilization and some attributable to increased prices.³³ Hospital care just surpassed pharmaceuticals as the key driver of increased health care costs.³⁴

The \$1.3 trillion spent by Americans on health care every year purchases a wide array of medical goods and services. Approximately 32% goes to in-patient hospital care. That figure has declined substantially over the past twenty years, as outpatient care has increased and hospitalization rates and lengths of stay have declined. Only 22% is spent on physician and clinical services, although physicians affect a far larger percentage of total expenditures on health care. Prescription drugs account for about 9%, a figure that has increased substantially over the past decade. The remaining 37% is split between long-term care, administrative, and other expenditures.

Quality presents a more variable picture. At its best, American health care is *the* best in the world. Our markets for innovation in pharmaceuticals and medical devices are second to none. People from all over the world come to the United States to receive cutting-edge treatments from physicians using the most sophisticated technology available. American know-how has made it possible for millions of people with health problems to live productive, pain-free lives.

See Centers for Medicare & Medicaid Servs., U.S. Health Care System, available at http://www.cms.gov/charts/series/sec1.pdf>, page 6.

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³² *Id*. at 3.

Id. at 5. See also Strunk, supra note 12.

³⁴ *Id.*

Nevertheless, health care quality varies tremendously without regard to cost, source of financing, and patient preferences. Local practice norms play a significant role; in health services research circles, experts believe that "geography is destiny" in determining the care one receives. The Institute of Medicine reports on medical error and patient safety attracted wide attention, but several decades of health services research literature documents pervasive quality shortcomings, whether one considers acute care, chronic care, or preventative care. The safety attracted wide attention and patient safety attracted wide attention, but several decades of health services research literature documents pervasive quality shortcomings, whether one considers acute care,

On the access side, approximately 65% of the under-65 population, or roughly 177 million Americans, obtain health insurance through their employers.³⁷ Most employees of large and medium-sized corporations are offered employment-based coverage, although not all choose to purchase it. Dependents of employees can usually obtain coverage through the working member of the family.³⁸ Employment-based coverage is much less available to those who work in certain industries (e.g., agriculture, retail, and food service), temporary and part-time employees, and those who work for

Dartmouth Atlas of Health Care in the United States, Chapter 7, available at http://www.dartmouthatlas.org/98US/chap-7-sec-1.php ("The reality of health care in the United States is that geography is destiny. The amount of care consumed by Americans depends more on where they live – the local supply of resources and the prevailing practice style - than on their needs or preferences")

See, e.g. Institute of Medicine, Crossing the Quality Chasm: A New Health System for the 21st Century (2001); Institute of Medicine, To Err Is Human 16 (1999); Mark A. Schuster, Elizabeth A. McGlynn, and Robert H. Brook, How Good Is the Quality of Health Care in the United States? 76 Milbank Quarterly 517 (1998); Mark R. Chassin, Robert Galvin & The National Roundtable on Health Care Quality, The Urgent Need to Improve Health Quality, 280 JAMA 1000 (1998); Paul D. Cleary & Susan Edman-Levitan Health Care Quality: Incorporating Consumer Perspectives, 278 JAMA 1608 (1997); Robert H. Brook, Managed Care is Not the Problem, Quality Is, 278 JAMA 1612 (1997).

See David A. Hyman & Mark Hall, Two Cheers for Employment-Based Health Insurance, 2 YALE J. HEALTH, POL'Y, L. & ETHICS 23, 26 (2001). It is an oversimplification to equate access with whether one has insurance. The absence of coverage, however, has a substantial impact on how many medical services one receives, how timely the services are provided, and the dollar value of those services. See Jack Hadley, Sicker and Poorer: The Consequences of Being Uninsured (May 10, 2002) http://www.kff.org/content/2002/20020510/may10pres.pdf. But see Helen Levy and David Meltzer, What Do We Really Know about whether Health Insurance Affects Health?, JCPR WORKING PAPER 275 (Jan. 24, 2002) http://www.jcpr.org/wpfiles/levy_meltzer.pdf.

See Hyman & Hall, supra note 37, at 26. As employment-based health insurance coverage has evolved toward increased cost sharing in recent years, fewer employees have elected to cover family members through such insurance.

small businesses.³⁹ Medicare, Medicaid, and other governmental programs cover approximately 75 million Americans. Approximately 40 million Americans are uninsured in any given year. Relatively few Americans are chronically uninsured, however, and the uninsured do have some access to medical care, including emergency care.⁴⁰

For access, the most significant development of the last decade was the rise and decline of managed care – particularly of the more restrictive forms of managed care. In 1988, almost 80% of people with health insurance had traditional indemnity coverage. The most recent figures indicate that only about 5% of people with health insurance still have indemnity coverage. Preferred provider organizations, which accounted for 11% of the coverage market in 1988 now have 52% of the coverage market. Point-of-service plans, which did not even exist in 1988, have 18% of the coverage market.

Antitrust Enforcement Initiatives

Let me now take a few minutes, and describe recent enforcement initiatives by the Commission and the Department of Justice.

Pharmaceuticals

As I noted previously, pharmaceuticals represent a significant (and rapidly growing) percentage of the money spent on health care and on health care competition

44 *Id.*

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Id.; James Maxwell, Peter Temin & Saminaz Zaman, *The Benefits Divide: Health Care Purchasing in Retail Versus Other Sectors*, 21 HEALTH AFF., Sept.-Oct. 2002, at 224.

Access to emergency care is ensured by the Emergency Medical Treatment and Active Labor Act, 42 U.S.C. § 1395dd.

See James C. Robinson, *The End of Managed Care*, 285 JAMA 2622 (2001); Debra A. Draper et al., *The Changing Face of Managed Care*, 21 HEALTH AFF., Jan.-Feb. 2002, at 11.

See Gabel, supra note 12, at 148.

⁴³ *Id.*

⁴⁵ *Id.*

policy enforcement. Because of innovation, a growing number of medical conditions can now be treated more effectively with drugs and drug therapy than with hospital stays and surgery. The development of new drugs is risky and costly, which obviously raises the prices of branded prescription drugs. The availability of generic versions of branded drugs has had a substantial impact on prices.⁴⁶

In the Hatch-Waxman Amendments to the Food, Drug and Cosmetic Act,

Congress sought to balance innovation and greater market access – the former protected
by patent rights, and the latter protected by competition from generic drug products. ⁴⁷

Although Hatch-Waxman has numerous technical provisions, the basic framework is
fairly straightforward. Branded drug manufacturers must file information with the FDA,
specifying the patents that claim the drug products they intend to market. ⁴⁸ Once the
drug product is approved, the FDA lists the patents in an agency publication widely
known as the Orange Book. ⁴⁹

Studies of the pharmaceutical industry indicate that the first generic competitor typically enters the market at a significantly lower price than its branded counterpart and gains substantial market share from the branded product. *See* David Reiffen & Michael Ward, *Generic Drug Industry Dynamics* (Feb. 2002), available at http://www.ftc.gov/be/workpapers/industrydynamicsreiffenwp.pdf. Subsequent generic entry typically brings prices down even further. *Id.* The policies of many health plans, both public and private, which require generic substitution whenever possible, accelerate this trend.

Drug Price Competition and Patent Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended at 21 U.S.C. § 355 (2000)). Prior to Hatch-Waxman, a generic drug manufacturer could not commence the process of obtaining FDA approval until all patents on the relevant branded product had expired because doing so would have constituted patent infringement. In practice, this meant that the FDA approval process extended the term of the branded manufacturer's patent. The Hatch-Waxman Amendments represented a compromise solution to this problem, balancing an expedited FDA approval process (speeding generic entry) against additional intellectual property protections (to ensure continuing innovation). On the balance struck in Hatch-Waxman between innovation and greater market access, see, e.g., Abbott Labs. v. Young, 920 F.2d 984, 991 (D.C. Cir. 1990) (Edwards, J., dissenting) (citations omitted) (Hatch-Waxman "emerged from Congress's efforts to balance two conflicting policy objectives: to induce brand-name pharmaceutical firms to make the investments necessary to research and develop new drug products, while simultaneously enabling competitors to bring cheaper, generic copies of those drugs to market.")

Of course, branded pharmaceuticals for the treatment of the same disease or condition compete with one another as well, and generic and branded pharmaceuticals compete with other forms of treatment.

The filing is technically called a "New Drug Application" or NDA.

The official title of the book is "Approved Drug Products with Therapeutic Equivalence."

A generic drug manufacturer wishing to enter the market with a generic version of a branded drug must provide the FDA with certain information, including certifications regarding each patent listed in the Orange Book. ⁵⁰ A "Paragraph IV certification" asserts that the patent in question is invalid or not infringed and that the generic applicant seeks entry prior to the patent's expiration. If a patent holder brings an infringement suit against the generic applicant, the filing of that suit triggers an automatic 30-month stay of FDA approval of the generic drug. ⁵¹ Unless the patent litigation is resolved in favor of the generic drug manufacturer, it cannot enter the market during this period.

Hatch-Waxman also provides 180 days of marketing exclusivity to the first generic drug manufacturer that files its application with the FDA and receives approval to market a particular generic drug prior to the expiration of the branded drug's products. ⁵²

After the 180 days, the FDA is free to approve subsequent generic applicants, assuming other regulatory requirements are met.

Although many branded and generic manufacturers have acted in good faith, others have allegedly attempted to "game" this system, securing greater profits for themselves without providing a corresponding benefit to consumers. The Commission has attacked such alleged conduct with cases brought against both branded and generic drug manufacturers. The Commission's first generation of pharmaceutical litigation focused on agreements between branded and generic drug manufacturers that allegedly delayed the entry of generic drugs. These agreements settled patent infringement

The filing is technically called an "Abbreviated New Drug Application" or ANDA. The purpose of the ANDA is to establish the bioequivalency of the generic drug with the branded drug.

If the patent holder does not bring suit within 45 days, the FDA must approve the ANDA immediately, if other regulatory conditions are fulfilled.

The 180-day period is calculated from the date of the first commercial marketing of the generic drug product or the date of a court decision declaring the patent invalid or not infringed, whichever is sooner.

manufacturer. Although settlement of patent infringement litigation can be efficient and pro-competitive, certain agreements can delay generic entry by "parking" the 180-day marketing exclusivity provided by the Hatch-Waxman Amendments. The Commission has aggressively targeted such alleged agreements and obtained consent judgments in two such cases. ⁵³ In a third case, the Commission entered a consent judgment against one firm ⁵⁴ and the case against the other two respondents is currently pending before the Commission. ⁵⁵

The Commission's second-generation pharmaceutical cases involved unilateral action by branded drug manufacturers. The Commission alleged that improper Orange Book listing constituted anticompetitive abuse of the Hatch-Waxman process by creating the possibility of obtaining unwarranted 30-month stays of FDA approval of generic drug products. ⁵⁶ Such conduct raises *Noerr-Pennington* issues, which the Commission has also addressed through an amicus filing in the BuSpar case. ⁵⁷

See Abbott Lab., Dkt. No. C-3945 (May 22, 2000) (consent order), available at http://www.ftc.gov/os/2000/03/abbot.do.htm; Geneva Pharm., Inc., Dkt. No. C-3946 (May 22, 2000) (consent order), available at http://www.ftc.gov/os/2000/03/genevad&o.htm; Hoechst Marion Roussel, Inc., Dkt. No. D-9293 (May 8, 2001) (consent order), available at http://www.ftc.gov/os/2001/05/hoechstdo.pdf>.

See Schering Plough Corp., Dkt. No. D-9297 (Apr. 2, 2002) (consent order as to American Home Products).

See Schering Plough Corp., Dkt. No. D-9297 (June 27, 2002) (initial decision), available at http://www.ftc.gov/os/caselist/d9297.htm.

See Biovail Corp. Dkt. No. C-4060 (Oct. 2, 2002) (consent order).

The Commission filed an amicus brief in *In re Buspirone*, 185 F. Supp. 2d 363 (S.D.N.Y. 2002), a pivotal case involving allegations of fraudulent Orange Book listing practices. In opposing Noerr immunity, the Commission successfully argued that submitting patent information for listing in the Orange Book did not constitute "petitioning" the FDA and that, even if it did, various exceptions to Noerr immunity applied. The district court subsequently issued an order denying Noerr immunity and adopting much of the Commission's reasoning.

The Commission has also scrutinized agreements among manufacturers of generic drugs not to compete against one another. The Commission has brought one such case and will pursue others as the facts warrant. ⁵⁸

Physicians

In the past year, the Commission has reached settlements with five groups of physicians for allegedly colluding to raise consumers' costs. Three of the cases are in Denver; one is in Napa; and one is in Dallas-Fort Worth. The number of physicians involved ranged from eight in Napa to more than twelve hundred in Dallas-Fort Worth. To resolve these matters, the physicians agreed to refrain from engaging in similar conduct in the future, to take certain measures to ensure compliance with the consent judgment, and, in one instance, to dissolve the organization through which the physicians conducted their alleged anticompetitive activity. In three of the cases, the FTC also obtained relief against the consultants who were involved in coordinating the alleged collusive conduct. On

Those who would justify such conduct suggest that it is necessary to counter the monopsony power of insurers. A recent *American Medical News* editorial referred to the

See Consent Order Resolves Charges That Biovail and Elan Agreement Unreasonably Restrained Competition In Market for Generic Anti-hypertension Drug (June 27, 2002), available at http://www.ftc.gov/opa/2002/06/biovailelan.htm.

See, e.g., System Health Providers, Dkt. No. C-4064 (Oct. 24, 2002) (consent order); R. T. Welter & Assocs., Inc. (Professionals in Women's Care), Dkt. No. C-4063 (Oct. 8, 2002) (consent order); Physician Integrated Servs. of Denver, Inc., Dkt. No. 4054 (July 16, 2002) (consent order); Aurora Associated Primary Care Physicians, L.L.C., Dkt. No. 4055 (July 16, 2002) (consent order); Obstetrics and Gynecology Medical Corporation of Napa Valley, No. C-4048 (May 14, 2002) (consent order).

In addition to these enforcement efforts, this year, the FTC staff also has filed comments with three state legislatures opposing legislation that would allow physician collective bargaining. FTC Staff Opposes Ohio Bill To Allow Physician Collective Bargaining (Oct. 21, 2002), available at http://www.ftc.gov/opa/2002/10/physicians.htm; FTC Staff Opposes Washington State Proposal to Allow Physician Collective Bargaining (Feb. 14, 2002), available at

http://www.ftc.gov/opa/2002/02/washphys.htm; FTC Staff Opposes Alaska Proposal to Allow Physician Collective Bargaining (Jan. 31, 2002), available at

http://www.ftc.gov/opa/2002/01/alaskaphysicians.htm.

"competition of physician Davids against health plan Goliaths," and suggested that federal antitrust enforcement has "unfortunately favored the big guys." Yet the AMA's own data indicates that insurer market concentration is not a problem in either Denver or Dallas-Fort Worth – the markets which accounted for four of the five physician price-fixing cases brought by the Commission in the past year. In the Denver market, the AMA has calculated that the combined HHI for HMOs and PPOs is 1,336. In the Dallas-Fort Worth market, the AMA has calculated that the combined HHI for HMOs and PPOs is 1,377. Thus, even the AMA's data does not suggest excessive payor concentration in the markets where the Commission has identified collusive physician conduct. Bluntly stated, this conduct had everything to do with physician self-interest and little or nothing to do with insurer monopsony power.

The alleged conduct I have described is naked price fixing, plain and simple. Such conduct is summarily condemned under the antitrust laws, because it has no procompetitive justifications. Of course, it does not follow that all collective conduct is problematic, even though some physicians suggest that the antitrust laws prevent them from delivering high quality care. The antitrust laws actually provide a considerable degree of flexibility in dealing with efficiencies and quality, as long as the conduct in question is, on balance, pro-competitive and the efficiencies derive from the challenged conduct. If anything, competition law has played a major role in ensuring the delivery of

Editorial, *It's about time: Insurers facing antitrust scrutiny*, AMERICAN MED. NEWS, Oct. 14, 2002, available at http://www.ama-assn.org/sci-pubs/amnews/amn-02/edsa1014.htm.

American Medical Association, Competition in Health Insurance: A Comprehensive Study of U.S. Markets, at 13 (Nov. 2001). The AMA did not calculate an HHI for Napa Valley. The Horizontal Merger Guidelines treat an HHI of 1300 as at the low end of a moderately concentrated market. United States Department of Justice and Federal Trade Commission, 1992 Horizontal Merger Guidelines, available at http://www.ftc.gov/bc/docs/horizmer.htm ("the spectrum of market concentration as measured by the HHI into three regions that can be broadly characterized as unconcentrated (HHI below 1000), moderately concentrated (HHI between 1000 and 1800), and highly concentrated (HHI above 1800)").

high quality care, by assuring consumers a range of different health care products and services, empowering purchasers to define quality for themselves, and improving access through price competition.

Quality is obviously an important part of the competitive mix when purchasing health care, and competition law does not hinder the delivery of high quality care. The Commission is always willing to consider arguments about how a particular transaction or conduct will improve quality, and it will pay close attention to such arguments in weighing the competitive implications. Moreover, because quality is so important in health care, we should err on the side of conduct that promises to improve patient care.

Clinical integration that increases quality of care is one example of permissible pro-competitive collective conduct. As I mentioned earlier, the staff recently issued an advisory opinion to MedSouth on this issue. The physicians proposed an innovative form of clinical integration that would allow them to treat patients more effectively. The staff concluded that the collective negotiation of fees was reasonably related to the physicians' clinical integration and quality objectives, even though there was no financial integration. As I also mentioned previously, the Commission recently closed an investigation in which physician collaboration resulted in a substantial degree of market concentration because the group demonstrated that considerable efficiencies resulted, including dramatically improved quality of care.

Collaborative conduct of this sort does not violate the antitrust laws, because there are substantial pro-competitive benefits. However, if a group has no justifications for its price fixing, the inquiry ends and the conduct is summarily (and appropriately) condemned by the antitrust laws.

Hospitals

As you already know, in the last eight years the Commission and Department of Justice are 0 for 7 in hospital merger cases. ⁶³ Obviously, the template for trying hospital merger cases that was used with such great success in the 1980s and early 1990s no longer works. Although some have suggested the Commission should just fold its tent and ignore hospital mergers, I do not believe that response is acceptable.

Accordingly, last summer, the Commission established a new merger litigation task force. ⁶⁴ The task force will screen targets, select the best cases, and develop new strategies for trying the m. The merger task force will also take a hard look at which strategies worked and which did not in the prior hospital merger cases.

In addition, the Commission is in the midst of a retrospective study of consummated hospital mergers. The Bureaus of Economics and Competition are evaluating the effects of hospital mergers in several cities. The agency will announce the results of these studies regardless of the outcome. If the studies find efficiencies associated with some or all of the mergers, the staff will say so. If, on the other hand, the studies indicate that the mergers were anticompetitive, then Commission will carefully consider whether administrative litigation is appropriate. Whether or not there is an appropriate remedy will obviously influence the Commission's analysis of whether to pursue such a proceeding.

In either event, the agency will obtain useful real-world information, allowing the Commission to update its prior assumptions about the consequences of particular

See Thomas L. Greaney, Whither Antitrust? The Uncertain Future of Competition Law in Health Care, 21 HEALTH AFF., Apr.-Mar. 2002, at 185, 186.

See Federal Trade Commission Announces Formation of Merger Litigation Task Force (Aug. 28, 2002), available at http://www.ftc.gov/opa/2002/08/mergerlitigation.htm.

transactions and the nature of competitive forces in health care. In *California Dental*, the Supreme Court emphasized the importance of relying on real-world empirical evidence, instead of hunches, guesswork, and theoretical predictions. The retrospective study represents an effort to meet this challenge. To the extent ex post data reveal a real problem in some of these mergers, that data may bolster the Commission's position the next time it seeks a preliminary injunction against a proposed merger in federal district court.

Insurers

Competition must be maintained at all levels of health care if consumers are to receive the full benefit of the nation's antitrust laws. Historically, purchasers have been subject to less searching scrutiny under the antitrust laws than sellers. ⁶⁶ As then-Judge and now-Justice Stephen Breyer once observed, when Congress enacted the Sherman Act, its focus was on prices that were too high, not too low. As such, Judge Breyer asserted that "courts should be cautious – reluctant to condemn too speedily – an arrangement that, on its face, appears to bring low price benefits to the consumer." ⁶⁷

Of course, there are concrete dangers associated with monopsony power – although structural features beyond purchaser concentration are necessary for the exercise

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California Dental Ass'n v. FTC, 526 U.S. 756, 776-781 (1999). Although the professional context of the dispute in California Dental was an important factor for the majority, a fuller evidentiary record would have revealed that the restraints in question were likely anticompetitive. See Timothy J. Muris, California Dental Association v. FTC: The Revenge of Footnote 17, 8 SUP. CT. ECON. REV. 265 (2000). Unfortunately, the 9th Circuit Court of Appeals dismissed the case without allowing the Commission to submit additional evidence. See FTC Dismissed California Dental Case (Feb. 15, 2001), available at http://www.ftc.gov/opa/2001/02/cdadismisspr.htm.

To be sure, the relevant statutes do not differentiate in any way between buyers and sellers, and there are sound economic reasons for applying similar scrutiny to monopoly and monopsony practices. *Kartell v. Blue Shield*, 749 F.2d 922, 931 (1st Cir. 1984).

of monopsony power.⁶⁸ When monopsony power exists, the correct response is to address it directly, rather than to rely on physician collusion to create countervailing power. Indeed, relying on seller collusion to address buyer monopsony risks the worst of all worlds, as monopolistic sellers and monopsonistic buyers both act in their own interest to the detriment of patients.

The increasing consolidation of the health insurance market and the possible development of monopsony power have not escaped the attention of the antitrust agencies. Of course, the McCarran-Ferguson Act complicates enforcement in this area because it largely exempts the "business of insurance" from federal antitrust scrutiny. ⁶⁹ The Commission also labors under several distinct disadvantages in addressing anticompetitive conduct by purchasers. In many geographic markets, non-profit firms have a major position in the purchasing side of the health care market. The Commission has limited jurisdiction over nonprofit firms, unless they are merging or operating for the benefit of for-profit members. The Commission is also prohibited by statute from studying the business of insurance without prior approval from two key Congressional committees. ⁷⁰

The Department of Justice primarily has dealt with the financing side of the health care market. The Antitrust Division has made it a priority to scrutinize mergers through which the merged insurer would have sufficient market power to increase prices or reduce quality in the sale of managed care plans in specific geographic areas or to acquire

In addition to a substantial market share, market elasticity of supply and elasticity of demand among non-monopsonist firms must be low. R.D. Blair & J.L. Harrison, MONOPSONY: ANTITRUST LAW AND ECONOMICS (1993).

^{69 15} U.S.C. § 1012(b).

⁷⁰ 15 U.S.C. § 46.

monopsony power over providers.⁷¹ The DOJ also plans to focus on collective or unilateral activity by health insurers that may raise competitive concerns, depending on the insurer's market power and other relevant market conditions. For example, the Department of Justice recently scrutinized the health insurance market in a major metropolitan area for possible evidence of coordination or collusion among managed care plans operating there. 72 The Department of Justice has also investigated "all products" and "most favored nations" clauses in insurance contracts – in some instances forcing insurers to remove them from their contracts when they have a dominant market position and their use raises anticompetitive concerns. ⁷³

The Commission's Research Agenda

As my earlier remarks reflect, the Commission has brought and will continue to bring cases against anticompetitive practices affecting the health care industry. Besides bringing cases, the Commission also conducts studies, holds hearings, and issues reports to Congress and the public. The Commission's deliberative and research capacities are particularly helpful in health care because the agency can study and evaluate the evolving marketplace and selectively intervene when it discovers anticompetitive conduct. The agency also uses its deliberative and research capacities to obtain a broader and deeper understanding of the facts that emerge in enforcement matters. The Commission then uses this understanding to inform its enforcement decisions.

The generic drug study, which I mentioned earlier, exemplifies the latter approach. After initiating several pharmaceutical cases, the Commission conducted a

73 Id.

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Address by Deborah Platt Majoras, available at http://www.usdoj.gov/atr/public/speeches/200195.htm. My remarks concerning the Department of Justice's priorities and activities are based on this speech.

study to examine whether such anticompetitive conduct was limited to the cases already identified. The study also examined the performance of the Hatch-Waxman Amendments more broadly to determine the nature and extent of anticompetitive impediments to generic entry. The study involved gathering information from more than 90 companies and took more than a year to complete. The report was issued in July 2002, and it immediately became the gold standard for what is known about the actual performance of the Hatch-Waxman Amendments. As I noted previously, last month, the President proposed regulations to curb the most important problem the Commission's study identified.

The Bureau of Economics is also working closely with several outside academics to study quality of care, so the Commission can factor non-price competition into its analysis of future cases. With the assistance of these academics, the Commission is studying the impact of regulation and competition on quality. This research will help provide a sound empirical basis to assess the interaction of competition and health care quality.

The health care workshop held by the FTC on September 9-10, 2002, was also an important part of the Commission's research agenda. The workshop featured presentations by academics, providers, insurers, employers, patient groups, and representatives of the Commission, Department of Justice, and state attorneys general. The workshop had more than a dozen speakers and five panel discussions. The panels focused on clinical integration, payor/provider issues, group purchasing organizations, generics and branded pharmaceuticals, and direct-to-consumer advertising of pharmaceuticals. Each panel presented a broad range of views on each of these subjects

from knowledgeable panelists. Several hundred people attended the workshop. The staff is already using some of the information obtained at the workshop in pending investigations. The workshop also made clear that there is a considerable diversity of views on the appropriate role and priorities for the Commission and other enforcement agencies.

The Commission's research agenda remains a work in progress. I am pleased to announce that the Commission has authorized an extended set of hearings on health care and competition policy, commencing in February 2003 and continuing through the year. The hearings broadly will examine the state of the health care marketplace and the role of competition, antitrust, and consumer protection in satisfying the preferences of the citizenry for high-quality, cost-effective health care. The hearings will examine some of the subjects covered in the September 9-10, 2002, workshop at greater depth, and will also address a broader range of issues. The Department of Justice will co-host the hearings.

Our goals are two-fold. First, we hope to gain a better understanding of the marketplace to inform our enforcement agenda. Second, we will report to Congress and the public on our findings. We are still developing a list of specific topics, but I expect that the hearings will examine hospital mergers, pharmaceuticals, the significance of non-profit status, vertical integration, the boundaries of the state-action and Noerr-Pennington doctrines, monopsony power, and the adequacy of existing remedies for anticompetitive conduct.

The hearings will also consider the implications of the Commission's consumer protection mandate with regard to the performance of the health care financing and

delivery markets. Although the Commission has considerable expertise in dealing with snake-oil, the agency is interested in evaluating whether there is a broader consumer protection role for the Commission, similar to its role in other areas of the economy. Thus, the hearings will consider the disclosure of costs, risks, and benefits by manufacturers of medical devices and pharmaceuticals (both prescription and over-the-counter), and by providers of professional services in connection with advertising and other forms of information dissemination.

Quality will be a major item on the hearing agenda. The hearings probably will devote several days to considering how quality should be factored into an antitrust analysis. Measuring and disseminating information about health care quality raises complex questions. These are obviously subjects on which agencies other than the Commission have considerable expertise. The Commission will be working closely with these agencies during the hearings, and as the agency develops cases, to ensure that the Commission's antitrust analysis fully incorporates these considerations. For example, our recent alleged price-fixing cases did not involve quality issues. There are many more complex issues in the health care market, however, and we need to educate ourselves about them.

Quality also can figure in markets in new ways. Last week, the Institute of Medicine recommended that the federal government should start paying more to providers who deliver high quality services.⁷⁴ To date, such arrangements are uncommon in the private sector and almost unheard of in the public sector.⁷⁵ The hearings

Robert Pear, Study Tells U.S. To Pay More For the Best Medical Care, N.Y. TIMES, Oct. 31, 2002, at 21.

David A. Hyman & Charles Silver, You Get What You Pay For: Result-Based Compensation for Health Care, 58 WASHINGTON & LEE L. REV. 1427 (2001).

accordingly will include some consideration of the comparative competitive effects of explicit and implicit contracts for quality.

As with the workshop held in September, the agency will invite representatives of industry, academia, other branches of government, antitrust practitioners, and patient groups to participate. There will be at least twenty days of hearings, primarily at the Commission's headquarters in D.C. The Commission will prepare an extensive report, which will help ensure that everyone recognizes the significance of the "first principles" alluded to by Bob Pitofsky. The report will also lay out the costs and benefits of various policy options we face as a nation in dealing with health care – a sector of our economy that accounts for 1 in every 7 dollars in the GDP.

Conclusion

From my perspective as Chairman of the FTC, it is somewhat surprising to hear so much skepticism about the application of competition law and policy to health care. Clearly, much remains to be done to explain the benefits of markets, both in theory and in practice, for the financing and delivery of health care and the role of the Commission in ensuring that outcome.

Happily, health care is the area of the economy in which the promise implicit in the creation of the Commission has been most fully met. There are substantial consumer welfare benefits and synergies from creating an agency combining administrative expertise and enforcement authority, addressing antitrust, consumer protection, and competition advocacy. Since 1975, when the Commission sharpened its focus on this area, through six presidents and eight Chairmen, the Commission has maintained a leadership role in implementing competition law and policy in health care.

I was proud to participate in this endeavor at the outset in the Commission's Policy Planning Office. As Director of the Bureau of Competition in the early 1980s, I was proud to play a role in consolidating the Commission's leadership in this area, with cases like *Indiana Federation of Dentists*. As Chairman, I am proud to maintain and extend the Commission's important work.

Vigorous competition can be quite unpleasant for competitors. Indeed, as Judge Easterbrook noted in *Ball Memorial*, "competition is a ruthless process." Yet ruthless competition is exactly what the drafters of the Sherman, Clayton, and FTC Acts mandated when they wrote these three statutory charters of economic freedom. 77

The job of the FTC is to protect competition from those who would interfere with its efficient operation to the detriment of consumers. The Commission's enforcement and research agenda makes me quite confident the agency will successfully meet the challenges of applying competition law and policy to health care. Everything old may be new again, but some things never go out of style.

⁷⁶ Ball Mem'l Hosp., 784 F.2d at 1338.

See, e.g., Northern Pacific Ry. Co. v. United States, 356 U.S. 1, 4 (1958) ("The Sherman Act was designed to be a comprehensive charter of economic liberty aimed at preserving free and unfettered competition as the rule of trade.")