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COMPETITION ISSUES IN THE DISTRIBUTION OF PHARMACEUTICALS

Contribution from the United States

-- Session III --

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COMPETITION ISSUES IN THE DISTRIBUTION OF PHARMACEUTICALS

-- United States --

Introduction

1. The U.S. Federal Trade Commission and the Antitrust Division of the U.S. Department of Justice are pleased to provide this paper in response to the OECD's call for contributions to the Global Forum on Competition Roundtable regarding competition issues in the distribution of pharmaceuticals.

2. The Federal Trade Commission (FTC or Commission) and the Antitrust Division (collectively, the Agencies) are the federal government enforcers of U.S. competition laws. In addition, the Agencies seek to influence competition policy and promote competitive practices through study of markets and marketing practices (including conducting workshops and publishing reports); through advocacy of competition policy to the U.S. Congress and other governmental bodies considering adopting laws and regulations; through providing formal and informal guidance to businesses; and through briefing, as *amicus curiae*, of questions that arise in non-Agency litigation that implicate competition policy or the competitive workings of specific markets in important ways.

3. Competition in the distribution of pharmaceuticals is critical to ensure an adequate and reliable supply of affordable drugs of acceptable quality. The U.S. pharmaceuticals distribution system is multi-tiered and complex, and competitive restraints may arise at any point in that system. The FTC in particular has applied various tools—study, competition advocacy, and enforcement—to maintain and foster competition throughout that distribution system. In this paper, we first summarily describe the U.S. pharmaceuticals distribution system. We then identify some of the ways in which the Agencies have applied competition policy and enforcement tools to that system. In concluding, we highlight an emerging issue in pharmaceutical distribution that the Agencies are currently studying.

1. The U.S. Pharmaceuticals Distribution System

4. A report by the Kaiser Family Foundation described the U.S. pharmaceutical distribution system as follows:[1]

> *[P]harmaceuticals originate in manufacturing sites; are transferred to wholesale distributors; stocked at retail, mail-order, and other types of pharmacies; subject to price negotiations and processed through quality and utilization management screens by pharmacy benefit management companies (PBMs); dispensed by pharmacies; and ultimately delivered to and taken by patients.*[2]

5. All prescription pharmaceuticals sold in the U.S. (regardless of where they are manufactured) must be approved by the U.S. Food and Drug Administration (FDA), which determines whether

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[1] *See* Kaiser Family Foundation, Follow The Pill: Understanding the U.S. Commercial Pharmaceutical Supply Chain (March 2005) (Kaiser Report).

[2] Kaiser Report, *supra,* at 1.

pharmaceuticals meet safety and efficacy requirements.[3] Manufacturers produce branded and generic pharmaceuticals, which they generally sell to wholesalers, sometimes to pharmacies, hospital chains, and health plans, and rarely to consumers.[4] Manufacturers distribute their products through pharmaceutical wholesalers and through self-warehousing chain pharmacies. Brand manufacturers may stimulate demand for their products through marketing directed at physicians, PBMs, and health plans, and through advertising and purchase assistance programs directed at consumers.[5]

6. Wholesalers purchase drugs from manufacturers and distribute them to pharmacies, hospitals, and other health care facilities. In addition, they may compete in the provision of a variety of services, including the repackaging of pharmaceuticals, the provision of disease management services, and the operation of drug buy-back programs.[6] Large drug wholesalers also contract with generic drug manufacturers for certain retail pharmacies, particularly the smaller chains and independents that may lack the scale to negotiate effectively on their own. Following a period of consolidation, there are three large, national drug wholesalers, as well as a handful of smaller, regional ones.

7. PBMs manage the pharmacy benefit component of employers' health care plans, either by contracting directly with the employer or by contracting with the employer's health insurance provider. PBMs assist third-party payors to manage pharmaceutical costs, for example, by determining which pharmaceuticals will be covered by the payor, how much a pharmacy will be compensated for a sale to covered persons, and how much cost covered persons will have to bear. PBMs typically use formularies both as a tool in negotiating discounts and rebates from manufacturers and as a means of steering covered persons to lower cost alternative therapies. In addition, they establish networks of pharmacies that may gain preference in return for discounted pricing. Almost all PBMs seek to lower the cost of pharmaceuticals to payors and covered persons by providing mail-order services, which may enable the use of automated dispensing processes, increase generic or therapeutic substitution, and promote prescription compliance and disease management by covered persons.[7] There are nine significant competitors and a large fringe of smaller PBMs that serve U.S. employers and insurance companies. [8]

8. Most Americans obtain prescription medications at retail pharmacies. Pharmacies include independents and chain pharmacies, pharmacies in supermarkets and other retail outlets, mail-order pharmacies (which typically are operated by PBMs), long-term care pharmacies (which provide packaging and other services to long-term care facilities and similar settings), and specialty pharmacies (which

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[3] *See* http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/WhatWeDo/UCM121592.pdf.

[4] Kaiser Report, *supra*, at 4.

[5] Kaiser Report, *supra*, at 4.

[6] Kaiser Report, *supra*, at 9.

[7] Kaiser Report, *supra*, at 14; Letter from James Cooper, Acting Director, Office of Policy Planning, Federal Trade Commission, *et al*., to Hon. James L. Seward, n.2 (March 31, 2009), *available at* http://www.ftc.gov/sites/default/files/documents/advocacy_documents/ftc-staff-comment-honorable-james-l.seward-concerning-new-york-senate-bill-58-pharmacy-benefit-managers-pbms/v090006newyorkpbm.pdf. *See generally* Federal Trade Commission, Pharmacy Benefit Managers: Ownership of Mail-Order Pharmacies (Aug. 2005), *available at* http://www.ftc.gov/reports/pharmacy-benefit-managers-ownership-mail-order-pharmacies-federal-trade-commission-report.

[8] *See* "Statement of the Federal Trade Commission Concerning the Proposed Acquisition of Medco Health Solutions by Express Scripts, Inc." (April 2, 2012), *available at* http://www.ftc.gov/sites/default/files/documents/closing_letters/proposed-acquisition-medco-health-solutions-inc.express-scripts-inc./120402expressmedcostatement.pdf.

specialize in more costly and complex therapeutic agents, such as injectables and biologics). Large pharmacies, mail-order pharmacies, and specialty pharmacies may purchase directly from pharmaceutical manufacturers, performing their own wholesale distribution functions.[9] There are two large national chain pharmacies, a few smaller national chain pharmacies, national chains of general retailers with pharmacies, regional grocery chains with pharmacies, and a large number of independent pharmacies that continue to fill the majority of prescriptions.[10]

9. Competition in pharmaceutical distribution may be limited or encouraged at each level of the distribution chain. Competition is complicated by the fact that the insurer or employer who pays for pharmaceuticals generally has little influence over what is prescribed, the prescriber ordinarily does not bear the costs of the pharmaceuticals prescribed, and the ultimate consumer, the patient, typically has little influence on either the pharmaceuticals prescribed or the prices he will pay for them.

2. Competition Policy and Enforcement Tools

2.1 Workshops and Reports

10. The Agencies use research and market reports to protect and promote competition in pharmaceutical distribution. For example, the current U.S. pharmaceutical distribution system at the pharmacy level was significantly influenced by a January 1979 FTC Report entitled Drug Product Selection. The Report concluded that state anti-substitution laws that prohibit pharmacists from dispensing a lower-cost generic drug for a prescription written for a brand name unduly restricted price competition for multisource prescription drugs and imposed unwarranted costs on consumers. The Report further advised that the repeal of anti-substitution laws would produce significant consumer benefits without compromising the quality of health care. The Report proposed that states facilitate pharmacists' selection of drug products therapeutically equivalent to, but less expensive than products prescribed by brand name by adopting a model statute, the Model Drug Product Selection Act.[11]

11. Five years later, all states had enacted laws allowing pharmacists, when filling a prescription for a specific branded drug, to dispense an equivalent generic version unless the prescribing physician instructs otherwise. In 1985, staff of the FTC's Bureau of Economics followed up the FTC's earlier recommendation by examining the economic impact of state drug product selection laws in its report, Generic Substitution and Prescription Drug Prices: Economic Effects of Drug Product Selection Laws.[12] The staff found that generic substitution on eligible prescriptions rose after the passage of these laws, and that generic substitution reduced consumer expenditures.[13]

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9 Kaiser Report, *supra*, at 10.

10 2012 Rx sales by pharmacy chain are *available at* http://drugstorenews.com/powerx-players-profiles-kings-retail-pharmacy.

11 Drug Product Selection Report January 1979, *available at* http://www.bookprep.com/book/mdp.39015008517792.

12 Alison Masson and Robert L. Steiner, Federal Trade Commission, "Generic Substitution and Prescription Drug Prices: Economic Effects of Drug Product Selection Laws" (Oct. 1985*), available at* http://www.ftc.gov/reports/generic-substitution-prescription-drug-prices-economic-effects-state-drug-product-selection.

13 *Id.*

12. The Commission also concluded that the 1984 Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act[14] increased generic drug entry, but that two provisions governing generic drug approval prior to the brand drug's patent expiration (the 180-day generic exclusivity and the 30-month stay of generic approval provisions) were susceptible to anticompetitive strategies. In July 2002, the FTC issued a report summarizing a lengthy study of allegedly anticompetitive agreements between brand and generic drug companies that took advantage of one or the other of the two provisions. The report recommended limitations and clarifications of those two provisions to mitigate the possibility of abuse that deters more generic drug availability.[15]

13. In July 2004, following 27 days of joint hearings, an FTC workshop, and independent research, the FTC and the Antitrust Division issued a report examining competition issues in health care generally, including markets relating to prescription drugs. One issue examined was whether direct-to-consumer advertising by pharmaceutical manufacturers posed any competitive concerns; the Report concluded it did not.[16]

14. In August 2005, the FTC published a report examining whether the use of vertically integrated mail-order pharmacies in PBM pharmacy benefit plans led to higher costs for the PBM's customers. The report addressed a number of practices alleged to raise the costs to PBM customers, including higher pricing at mail order than retail pharmacies, lower rates of generic substitution by the mail order pharmacies, and dispensing of expensive repackaged drugs. The report did not find evidence of harm to customers from the vertical integration, and generally found that use of the mail-order pharmacies was cost effective for plans and their members.[17]

15. The FTC examined potential competition issues presented by expected entry of follow-on biologics into the distribution chain in a Roundtable workshop on November 21, 2008,[18] and in an FTC report in June 2009.[19] The FTC conducted a public workshop on February 4, 2014, entitled Follow-On Biologics: Impact of Recent Legislative and Regulatory Naming Proposals on Competition. The purpose of the workshop and subsequent study is to collect additional and updated information concerning the expected entry of biosimilars and interchangeable biologics into the pharmaceutical distribution chain and how certain legislative proposals and naming conventions may affect follow-on biologics competition.[20]

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14 For a more in-depth description of the Hatch-Waxman Act, *see generally* http://www.fda.gov/newsevents/testimony/ucm115033.htm.

15 Generic Drug Entry Prior to Patent Expiration: An FTC Study (July 2002), *available at* http://www.ftc.gov/sites/default/files/documents/reports/generic-drug-entry-prior-patent-expiration-ftc-study/genericdrugstudy_0.pdf.

16 Improving Health Care: A Dose of Competition, *available at* http://www.ftc.gov/reports/improving-health-care-dose-competition-report-federal-trade-commission-department-justice.

17 Pharmacy Benefit Managers: Ownership of Mail-Order Pharmacies, *supra*, at 7.

18 November 2008 Roundtable: Competition Issues Involving Follow-on Biologic Drugs, *available at* http://www.ftc.gov/news-events/events-calendar/2008/11/emerging-health-care-competition-and-consumer-issues.

19 Emerging Health Care Issues: Follow-on Biologic Drug Competition, *available at* http://www.ftc.gov/reports/emerging-health-care-issues-follow-biologic-drug-competition-federal-trade-commission-report.

20 Notice of December 10, 2013 Workshop to Explore Competition Issues Involving Biologic Medicines and Follow-On Biologics; Request for Comments, *available at* http://www.ftc.gov/policy/federal-register-notices/public-workshop-follow-biologics-impact-recent-legislative.

2.2 Antitrust Law Enforcement

2.2.1 Pharmaceutical Manufacturers

16. The Commission has been active in bringing competition enforcement actions at the pharmaceutical manufacturer level. In the last five fiscal years, the Commission has brought enforcement actions against 19 mergers in the branded and generic pharmaceutical sectors (*e.g.*, Novartis/Alcon, Merck/Schering Plough, Pfizer/Wyeth, Teva/Barr, Teva/Cephalon, Actavis/Warner Chilcott, Watson/Actavis, Mylan/Agila).

17. In pharmaceutical product markets, price generally decreases as the number of generic competitors increases. Accordingly, the reduction in the number of suppliers within each relevant market has a direct and substantial effect on pricing. When the first generic version of a drug enters the market, it typically competes by selling at a discount to the branded drug. At that point, the brand typically loses most of its sales to the generic version. During the period in which only one generic product is available, the price for the branded product acts as a ceiling above which the generic manufacturer cannot price its product. In most cases, once additional generic versions of the drug enter the market, competition among the generic competitors drives generic pricing down further. Prices continue to decrease incrementally with the entry of the second and each subsequent generic pharmaceutical competitor. With multiple generic firms competing, the retail price of a generic drug is an average of 75% lower than the retail price of a branded drug.[21]

18. Generic drugs may be launched upon the expiration of the branded product's patents or before expiration. If the generic company intends to launch its product before the expiration of the branded product's patents, it must notify the FDA and certify that its product does not infringe the branded company's patent or that the branded company's patents are invalid. Under the Hatch-Waxman Act, this is referred to as a Paragraph IV certification. A Paragraph IV certification typically leads to patent infringement litigation between the generic company and branded company. The first company to file a Paragraph IV Abbreviated New Drug Application (ANDA) has the right to market its generic drug exclusively for a period of 180 days. No other firm, even those that subsequently submit Paragraph IV ANDAs, may enter the generic market until after the conclusion of this period. The prospect of earning higher profits as the only firm marketing a generic version of a drug for 180 days provides an incentive to defend against the patent infringement claims brought by the brand drug manufacturer. Thus, the firm with exclusivity usually takes the leading role, and invests the greatest resources, in pursuing these cases.[22]

19. One example of antitrust enforcement to protect competition at the drug manufacturer level is the merger enforcement action involving Actavis and Warner Chilcott in the fall of 2013. Actavis's proposed acquisition of Warner Chilcott posed competition concerns in four separate drug markets. In one of those markets, both companies were the only two significant competitors of one generic oral contraceptive. In three other drug markets (two oral contraceptives and one osteoporosis treatment), Warner Chilcott sold branded drugs and Actavis was likely to be the first generic supplier to compete with those brands. As a condition of approving the merger, the FTC required Actavis to sell all of its rights and assets related to its generic versions of all four drugs and to supply generic versions of two of those drugs to an unrelated generic competitor for a specified period. Finally, the FTC required Actavis to relinquish its claim to first

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21 *See* Drug Pricing: Research on Savings from Generic Drug Use, U.S. General Accounting Office, GAO-12-371R, Jan. 31, 2012, p.1 *available at* http://www.gao.gov/products/GAO-12-371R.

22 *See supra* note 14. The FTC has been very active in pursuing enforcement actions involving agreements between brand and generic drug manufacturers that allegedly manipulated certain provisions of the Hatch-Waxman Act to delay generic entry. A description of those enforcement actions is beyond the scope of this paper.

filer marketing exclusivity for generic versions of two of the drugs to preserve the incentives of other generic companies then challenging the relevant Warner Chilcott patents.[23]

20. A second example of antitrust enforcement at the manufacturer level is the September 2013 merger action involving Mylan and Agila. In eleven generic injectable pharmaceutical markets, Mylan and Agila were two of only a few current or likely future competitors. This was a concern not only because prices generally decrease as the number of competing generic suppliers increases, but because these injectable generic products are highly susceptible to supply disruptions caused by the inherent difficulties of producing sterile liquid drugs. Recent manufacturing problems have made it difficult for customers to obtain sufficient quantities, and contributed to price increases, of several generic injectable products affected by this transaction. The complaint alleged that by reducing the number of competitors in these markets, the acquisition as originally proposed would eliminate important competition and likely lead to higher prices. Under an Order resolving FTC concerns, Mylan must divest all eleven generic injectable drugs.[24]

2.2.2 Insurance Companies and PBMs

21. The Commission has been active in reviewing a number of significant mergers in the PBM area, including most recently the Medco/Express Scripts and PCS/Caremark transactions. In addition, the Commission has investigated vertical transactions between PBMs and chain pharmacies, such as the merger of CVS Pharmacy and Caremark Rx, Inc., and PBMs and pharmaceutical manufacturers, such as the Merck/Medco merger.

22. In 2012, the Commission completed an 18-month investigation to determine whether the merger of two of the three largest PBMs, Medco Health Solutions and Express Scripts, might result in competitive harm in the provision of PBM services to large private employers and other plan sponsors. The Commission concluded that anticompetitive effects for PBM services to employers were unlikely because at that time, there were at least nine additional competitors in the provision of these services, including health-plan owned PBMs. The Commission analyzed bid data produced by the parties and other PBMs and determined that Medco and Express Scripts were not particularly close competitors, and thus that anticompetitive price effects were unlikely to result from the merger. Further, coordination was unlikely in this market as pricing for PBM services and other contract terms are difficult to compare among competitors. The investigation showed that market allocation was also unlikely given that a significant competitor, CVS/Caremark, maintains a large retail pharmacy and therefore has different incentives than Medco/Express Scripts, making it unlikely that the two firms would allocate markets. Similarly, smaller PBMs and health plan-owned PBMs have little incentive to participate in an allocation scheme as these firms had recently repositioned themselves to compete more successfully for employer business. Moreover, coordination among so many firms would be extremely difficult. Finally, the merger would produce a firm with a smaller share of retail pharmacies' sales (29%) than is ordinarily considered necessary to exercise monopsony power, and there was no evidence that the merger would result in reduced output for pharmacy services.[25]

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23 *See generally* http://www.ftc.gov/enforcement/cases-and-proceedings/cases/2013/12/actavis-inc-warner-chilcott-plc-matter.

24 *See generally* http://www.ftc.gov/enforcement/cases-and-proceedings/cases/2013/12/mylan-inc-corporation-agila-specialties-global.

25 *See* http://www.ftc.gov/news-events/press-releases/2012/04/ftc-closes-eight-month-investigation-express-scripts-incs.

23. In 2007, the FTC investigated CVS Corporation's acquisition of Caremark Rx, Inc. At the time of the merger, CVS was a large pharmacy chain with a small PBM, PharmaCare, while Caremark was a large PBM but had no retail pharmacies. Due to the limited nature of any horizontal overlap, and no clear evidence of potential harm from the creation of the vertical relationship, the FTC took no enforcement action. However, even when the Agencies do not challenge a merger, they continue to monitor the combined firm's conduct and address any competitive problems. Shortly after the merger, and in response to several complaints, the FTC conducted an investigation to determine whether CVS Caremark engaged in unfair methods of competition under Section 5 of the FTC Act, or made acquisitions in violation of Section 7 of the Clayton Act. After a thorough and comprehensive competition review, the Commission determined that no additional action was warranted.[26]

2.2.3 Pharmaceutical Wholesalers

24. The Commission has investigated and taken action against mergers in the pharmaceutical wholesaler market. These matters include the litigated matter against Cardinal Health and McKesson. In this case, the Commission authorized staff to file separate motions in federal district court to block the mergers of the nation's four largest drug wholesalers into two wholesale distributors of pharmaceutical products. The Commission charged that Cardinal's proposed acquisition of Bergen Brunswig Corporation and McKesson Corporation's proposed acquisition of AmeriSource Health Corp. would substantially reduce competition in the market for prescription drug wholesaling and lead to higher prices and a reduction in services to the companies' customers—hospitals, nursing homes and drugstores—and eventually to consumers.[27] Two separate motions for preliminary injunctions were filed in the U.S. District Court for the District of Columbia March 6, 1998. On July 31, 1998, the District Court granted the Commission's motions enjoining both proposed mergers.[28] The parties abandoned their respective merger plans soon after the decision.

2.2.4 Pharmacies

25. The FTC has brought several enforcement actions in mergers involving chain pharmacies (Rite Aid/Revco; J.C. Penney/Eckerd; Rite Aid/Jean Coutu) and institutional pharmacies (Omnicare/PharMerica). The *J.C. Penney* matter is illustrative.

26. In late 1996, the Commission and J.C. Penney Company, Inc., the parent company of Thrift Drug, Inc., entered into a consent order requiring Penney to divest 161 drug stores in North and South Carolina. The Commission determined that this divestiture was necessary to maintain a level of competition that otherwise would have been lost as a result of Penney's acquisitions of Eckerd Corporation, which operated numerous drug stores in North and South Carolina, among other states. J.C. Penney, through its wholly-owned subsidiary Thrift Drug, already owned 1,089 drug stores in 17 states, including North and South Carolina. According to the Commission's complaint, the acquisitions would have given Penney a dominant position in the three local markets in the state of North Carolina as well as in the Charleston, South Carolina market. As a result, the FTC alleged Penney would have had the ability to increase prices for the retail sale of pharmacy services to insurers and other third-party payors. The FTC

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[26] *See generally* http://www.ftc.gov/enforcement/cases-and-proceedings/cases/2012/09/cvs-caremark-corporation. Under its consumer protection authority, however, the Commission determined that CVS Caremark misrepresented the price of some Medicare Part D prescription drugs, and ordered the company to pay $5 million in consumer redress.

[27] *See* http://www.ftc.gov/news-events/press-releases/1998/03/ftc-will-seek-block-mergers-nations-four-largest-drug-wholesalers.

[28] *See* http://www.ftc.gov/news-events/press-releases/1998/07/ftc-wins-court-order-blocking-mergers-nations-four-largest-drug.

also alleged that new entry by other firms was not likely to be timely enough or sufficient to offset these anticompetitive effects. The Commission's order required that Penney sell all of the divested stores to a single pharmacy chain to ensure that the buyer had sufficient size and coverage to serve as an alternative to Penney-owned pharmacies for a prescription benefit management firm's retail pharmacy network.[29]

2.3 Competition Advocacy

2.3.1 Legislative Testimony

27. FTC staff, upon request of federal, state, and local government officials, periodically comment on the competitive implications of proposed laws and regulations. In particular, staff seek to assist legislators and regulators avoid consumer harms that would flow from undue restriction of competition at each level of the pharmaceutical distribution chain. For example, FTC staff have looked at direct-to-consumer (DTC) advertising of prescription drugs from both consumer protection and competition perspectives.[30] In summary, staff explained how DTC advertising can catalyze price and quality competition among alternative and new therapies, remind consumers of healthful practices, and enable consumers to better communicate with their physicians; but that untruthful or misleading advertisements can be particularly harmful to consumers. Staff encouraged the FDA to "allow[] pharmaceutical manufacturers greater latitude in their advertising, . . . protect[ing] consumers from deceptive information but not . . . stifl[ing] truthful information that could benefit consumers."[31] In particular, staff opined that "the net benefits of DTC advertisements can be increased by limiting current disclosure requirements," and adjusting disclosure requirements according to the advertising medium used.[32]

28. A second example is in the pharmaceutical benefits industry. Insurers and employee benefit plans have sought to control costs by selectively contracting with pharmacies and limiting, at least to some extent, the ways and places in which covered persons can fill their prescriptions. FTC staff have commented on several legislative proposals that would require health insurers and employee benefit plans: (1) to include in their pharmacy networks any pharmacy that is willing to participate on the terms offered to other network pharmacies; and (2) to enable all covered persons to fill their prescriptions at pharmacies of their choosing.[33]

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29 *See generally* http://www.ftc.gov/enforcement/cases-and-proceedings/cases/1997/03/jc-penney-company-inc-and-thrift-drug-inc.

30 *See* http://www.ftc.gov/sites/default/files/documents/advocacy_documents/ftc-staff-comment-food-and-drug-administration-matter-direct-consumer-promotion/v960001.pdf. *See also* http://www.ftc.gov/news-events/press-releases/2003/12/ftc-staff-provides-fda-comments-direct-consumer-prescription-drug, noting FTC Staff comment to FDA analyzing the overall economic effects of DTC advertising and providing the FDA with a number of suggestions about how its regulatory scheme for DTC advertising could be modified to communicate information to consumers in an easy to understand and accessible way.

31 *Id*. at 4. Staff recommended to the FDA its own approach to the assessment of whether advertising conveys false or misleading claims based on the Commission's Deception Policy Statement, FTC Policy Statement on Deception, Cliffdale Assocs., 103 F.T.C. 110, 174 (1983), Letter from the Commission to Chairman John D. Dingell, Committee on Energy and Commerce, U.S. House of Representatives, Oct. 14, 1983, and the FTC Policy Statement on Advertising Substantiation, 49 Fed. Reg. 30,999 (Aug. 2, 1984), Thompson Medical Co., 104 F.T.C. 648, 839 (1984).

32 *Id*. at 4.

33 *See, e.g.*, Letter from Todd J. Zywicki, Director, Office of Policy Planning, Federal Trade Commission, to Patrick C. Lynch, Attorney General, State of Rhode Island, and Juan M. Pichardo, Deputy Majority Leader, Senate of Rhode Island (Apr. 8, 2004) ("RI Letter"), *available at* http://www.ftc.gov/sites/default/files/documents/advocacy_documents/ftc-staff-comment-hon.patrick-

29. In these comments, staff explained that the limiting of networks of health care providers, including pharmacies, arose as a response to the sharply rising costs of health care, and that economic theory and empirical evidence demonstrate that such "selective contracting increases the intensity of competition among providers, which is manifested in lower prices paid by insurers to providers."[34] Further, staff observed, restricting networks may create scale and other efficiencies, further reducing costs. Both of these kinds of cost savings, staff concluded, are likely to be passed on to covered persons, through reduced premiums, lower out-of-pocket costs, or improved services.[35] "By eliminating an important form of competition in the market for pharmaceutical services," staff concluded, these "any willing provider" and "freedom of choice" bills "are likely to undermine the ability of some consumers to obtain the pharmaceutical services they need at a price they can afford. . . . Although the Bills appear intended to broaden access to pharmaceutical services, there is a significant probability they will have the opposite effect."[36]

30. Although, PBMs do not generally distribute drugs, they have important effects on the pharmaceuticals supply chain in the U.S. FTC staff have offered comments on a variety of legislative proposals to regulate some of PBMs' relationships with health insurers, with physicians, and with pharmacies.[37] For example, FTC Staff commented on a New York bill that would impose fiduciary-like obligations on PBMs in their dealings with health plans, requiring PBMs, during contract negotiations and periodically thereafter, to disclose detailed information about their costs, dealings with pharmaceutical manufacturers, pharmacies, and other health plans, and business strategies.[38] Staff observed that "[a]lthough the bill attempts to eliminate perceived conflicts of interest . . . , empirical evidence suggests that those conflicts of interest are not prevalent," and that health plans are sophisticated companies that can and do "protect themselves from potential conflicts of interest in arms-length contracts with PBMs."[39] Moreover, there is no theoretical or empirical basis for believing that purchaser access to sellers' cost data renders markets more competitive.[40] Staff explained that the disclosure requirements might preclude health plans and PBMs from entering into what they deem the most cost-effective agreements for the administration of pharmacy benefits.[41] Further, they might facilitate collusion. "If, for example, pharmaceutical manufacturers know the precise details of rebate arrangements offered by their competitors, then tacit collusion among them may be more feasible."[42] FTC staff also observed that the bill

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c.lynch-and-hon.juan-m.pichardo-concerning-competitive-effects-ri-general-assembly-bills-containing-pharmaceutical-freedom/ribills.pdf, and other letters cited in n.4 of the RI Letter.

34 *Id*. at 4.

35 *Id*. at 4.

36 *Id*. at 7.

37 Moreover, the previously discussed legislative proposals that would restrict health insurer and employee benefit plan practices, such as the use of limited pharmacy networks, seemingly would restrict those same practices when carried out by PBMs under contract with insurers and plans.

38 Letter from James Cooper, Acting Director, Office of Policy Planning, Federal Trade Commission, to New York State Senator James L. Seward (March 31, 2009), *supra*. See also Letter from Maureen K. Ohlhausen, Acting Director, Office of Policy Planning, Federal Trade Commission, *et al*., to New Jersey Assemblywoman Nellie Pou (April 17, 2007) ("New Jersey Letter"); Letter from Maureen K. Ohlhausen, Director, Office of Policy Planning, Federal Trade Commission, *et al*., to Terry G. Kilgore, Member, Virginia House of Delegates (October 2, 2006) ("Virginia Letter"); and Letter from Susan A. Creighton, Director, Bureau of Competition, Federal Trade Commission, *et al*., to California Assembly Member Greg Aghazarian (Sept. 7, 2004), commenting on similar legislative provisions.

39 *Id*. at 2.

40 *Id*. at 6.

41 *Id*. at 4.

42 *Id*. at 5.

would require disclosures to physicians of PBM financial information whenever a "drug switch" is requested. That requirement "may work to chill otherwise cost-effective interchange programs . . . [which] have the potential to increase usage of less expensive, but therapeutically effective, branded drugs or their generic equivalents."[43]

31. FTC Staff also commented on a North Dakota bill that might have prevented a PBM from seeking to switch a prescription from one drug to another that has similar therapeutic effects, but that is pharmaceutically distinct, unless done "for medical reasons that benefit the covered individual."[44] Staff observed that to the extent the bill would "make[] safe and cost-reducing drug substitutions less common, it is likely to increase the cost of pharmaceuticals, which in turn is likely to increase health insurance premiums and reduce the availability of insurance coverage for pharmaceuticals."[45] Moreover, Staff noted, the ban was unlikely to provide countervailing benefits to consumers, because North Dakota already required prescriber authorization prior to therapeutic substitution.

32. The North Dakota bill also sought to regulate PBM contracts with pharmacies by prohibiting a PBM from discriminating among pharmacies "on the basis of copayments or days of supply" and requiring that "a contract must apply the same coinsurance, copayment, and deductible to covered prescriptions" to all pharmacies in a network. Staff observed that the bill would prevent use of "benefit plans to encourage participants to use network pharmacies that provide drugs to the plan at a lower cost than other network pharmacies."[46] As a result, plan participants "would be less likely to use low-cost pharmacies than if they had been allowed to share in the cost savings via a lower copayment."[47] And health plans and consumers would miss out on savings that might otherwise have been realized.

33. Some of the legislative proposals seeking to regulate health insurers/employee benefit plans and PBMs would limit use of mail-order pharmacies. For example, the Virginia Letter, *supra*, discusses provisions of the Virginia bill that would prohibit insurers and PBMs from barring access to the pharmacy of the beneficiary's choice, and prohibiting PBMs and health benefit plans from encouraging the use of either preferred provider or mail-order pharmacies via differential copayments or other financial incentives. And a more recent legislative proposal in New York would limit a health plan's ability to steer beneficiaries to a lower cost mail-order vendor of maintenance drugs, via financial incentives or other terms of coverage, whenever a competing retail pharmacy is willing to fill prescriptions at "comparable" prices.[48] Indeed, some states have considered outright bans on inclusion of mail-order pharmacies in payor networks.[49]

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43 *Id.* at 8.

44 Letter from Maureen K. Ohlhausen, Acting Director, Office of Policy Planning, Federal Trade Commission, *et al.*, to Nebraska Senator Richard L. Brown (March 8, 2005), *available at* http://www.ftc.gov/sites/default/files/documents/advocacy_documents/ftc-staff-comment-honorable-richard-l.brown-concerning-north-dakota-h.b.1332-regulate-contractual-relationship-between-pharmacy-benefit-managers-and-covered-entities/050311northdakotacomnts.pdf.

45 *Id*. at 7. As staff observed, the precise meaning of "therapeutically equivalent," as used in the North Dakota bill, is unclear, and so the precise effect of the "for medical reasons" clause was unclear. *See also* the Virginia Letter, *supra*, discussing similar limitations on therapeutic and generic substitution.

46 *Id*. at 6.

47 *Id*. at 6.

48 Letter from Susan S. DeSanti, Director, Office of Policy Planning, Federal Trade Commission, *et al*. (August 8, 2011) to New York State Senator James L. Seward, *available at* http://www.ftc.gov/sites/default/files/documents/advocacy_documents/ftc-staff-comment-honorable-james-l.seward-concerning-new-york-assembly-bill-5502-b-regulate-use-mail-order-pharmacies-health-plans/110808healthcarecomment.pdf. *See also* the New Jersey Letter, *supra*, discussing a provision that

34. Some of the legislative proposals also would ban mail-order pharmacies from payor networks. In replying to requests for comment, FTC staff noted that a recent U.S. General Accounting Office (GAO) empirical study had found that mail-order prices generally were well below the prices offered by retail pharmacies in GAO's sample.[50] FTC staff explained that restricting a health plan's ability to offer favorable treatment to a low cost mail-order pharmacy would undercut pharmacies' incentives to bid aggressively for a share of that health plan's business, and that reducing those incentives is likely to raise the prices that consumers pay for the prescription drugs that their health plans cover. Some cost increases may be passed on to plan beneficiaries in the form of higher out-of-pocket prices. In some cases, health benefit plans may respond to higher costs by reducing the scope of prescription drug coverage, or by eliminating prescription drug coverage entirely. Although these bills may seek to enhance consumers' ability to fill prescriptions at pharmacies of their choice, they would impede health competition between retail and mail-order pharmacies, to the detriment of consumers.

35. The FTC submitted testimony before Congress in 2007 and 2012 regarding bills that would provide antitrust immunity to independent or community pharmacists in their reimbursement negotiations with PBMs.[51] In both cases, the Commission opposed antitrust exemptions that would allow pharmacists to engage in collective bargaining to secure higher fees and more favorable contract terms from health plans. The Commission warned Congress that the proposed exemptions threatened to raise drug prices for consumers and to increase costs to employers who provide health insurance to employees and retirees, without any assurance of offsetting higher quality care. The FTC was concerned that increasing costs to employers could result in reducing or eliminating those benefits.

2.3.2 Staff Advisory Opinions

36. Anticompetitive conduct may be discouraged, and efficient and often procompetitive conduct encouraged, not only through litigation, but through informal consultations and through the Agencies' formal advisory opinion programs, undertaken prior to the requestor's engaging in the conduct.[52] This has been true of conduct in the pharmaceuticals industry, as elsewhere.

37. For example, the RX-360 International Pharmaceutical Supply Chain Consortium ("RX-360") — a consortium of pharmaceutical and biotechnology companies — recently sought FTC Staff guidance concerning RX-360's planned joint supplier quality and safety audit programs. Upon review of information provided by RX-360 and its members, FTC staff replied that the audit programs apparently: (1) do not require exchanges of competitively significant information; (2) contain protections to reduce Rx-360 members' ability to use the programs for anticompetitive ends; (3) protect audited firms from concerted

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would prohibit PBMs from using mail-order pharmacy services except on written request of covered persons.

49 *See, e.g.*, the Rhode Island Letter, *supra*.

50 *See* Rhode Island Letter, *supra*, at 31, discussing findings of *Prescription Drug Discount Cards*, U.S. General Accounting Office, GAO-03-912, September 2003, p. 11.

51 Testimony of David Wales (October 18, 2007) re Community Pharmacy Fairness Act of 2007, *available at* http://www.ftc.gov/sites/default/files/documents/public_statements/prepared-statement-federal-trade-commission-concerning-community-pharmacy-fairness-act-2007/p859910pharm.pdf, and testimony of Richard Feinstein (March 29, 2012) re Preserving Our Hometown Independent Pharmacies Act of 2011, *available at* http://www.ftc.gov/sites/default/files/documents/public_statements/prepared-statement-federal-trade-commission-concerning-h.r.1946-preserving-our-hometown-independent-pharmacies-act-2011/120329pharmacytestimony.pdf.

52 The FTC's staff advisory opinion program is described at http://www.ftc.gov/sites/default/files/attachments/competition-advisory-opinions/advop-health.pdf. The Antitrust Division's program is described at http://www.justice.gov/atr/public/busreview/201659c.htm.

misuse of the audit programs; and (4) are intended and likely to promote efficiency, quality, and safety. Accordingly, FTC staff advised, it had no present intention to recommend an FTC challenge to the programs.[53]

2.3.3 Amicus Curiae Filings

38. The FTC seeks to influence the development of competition law not only through its own enforcement, but also by filing briefs as *amicus curiae* in private litigation involving substantial questions of public importance. The FTC's recent amicus brief in *Mylan Pharmaceuticals v. Warner Chilcott* may have a substantial impact on the distribution of pharmaceuticals.[54] Plaintiffs in the *Mylan* case allege that Warner Chilcott maintained a monopoly in the market for Warner Chilcott's drug, Doryx, by suppressing competition from lower-priced generics by making minor non-therapeutic changes to its branded product – a practice known as "product hopping." According to the plaintiffs, each reformulation was intended to, and did, suppress competition from generic equivalents not on the merits of the reformulated products, but through manipulation of the regulatory system. Warner Chilcott moved to dismiss the case, claiming in essence that the introduction of reformulated products is *per se* lawful.

39. Without taking sides on the substantive merits of plaintiffs' claim, the FTC explained how the Hatch-Waxman Act and state generic substitution laws had fostered generic-brand competition, which typically brings prices down radically, and how "product hopping" strategies by the branded product manufacturer can be strategic acts to impede generic substitution, particularly given the regulatory environment and attributes affecting pharmaceuticals markets. For example, prior to facing generic competition, a brand company can introduce a reformulated product and simply withdraw the original product. In such a situation, consumers do not choose the reformulated product based on its merits; instead, the brand forces the switch by removing the product from the market so that there is effectively no longer a market for the original product when a generic would be ready to enter. Accordingly, the FTC argued that plaintiffs' allegations, if proven, are sufficient to establish exclusionary conduct.

3. Conclusion

40. The Agencies will continue to use an array of law enforcement and other tools to maintain and promote competition throughout the pharmaceuticals distribution chain, as this is critical to ensure the availability and affordability of safe and effective drugs for U.S. consumers. Familiar issues will recur, demanding further Agency attention, and new ones will arise. For example, one area of current study is the potential competition that follow-on versions of branded biologic medicines may offer, with attendant consumer benefits. As discussed, in the late 1970s and 1980s, the Agencies significantly contributed to the promotion of competition in the "small molecule" pharmaceutical industry by studying and reporting on generic substitution and the economic effects of drug product selection laws. Similarly, in the biologic pharmaceutical products industry, the Agencies can continue to play a critical role in competition policy by examining, reporting on, and engaging in competition advocacy on such topics as legislative efforts to impede follow-on biologics and regulatory naming proposals for biosimilars and interchangeable biologic drugs.[55]

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53 The advisory opinion is *available at* http://www.ftc.gov/sites/default/files/documents/advisory_opinions/rx-360-international-pharmaceutical-supply-chain-consortium/100916bloomletter.pdf.

54 Federal Trade Commission's Brief as *Amicus Curiae* (November 21, 2012), Civil Action No. 12-3824 (E.D. Pa.), *available at* http://www.ftc.gov/sites/default/files/documents/amicus_briefs/mylan-pharmaceuticals-inc.et-al.v.warner-chilcott-public-limited-company-et-al./121127doryxamicusbrief.pdf.

55 *See* http://www.ftc.gov/system/files/documents/public_events/follow-biologics-workshop-impact-recent-legislative-regulatory-naming-proposals-competition/biologicsagenda.pdf.