DEREGULATING DIRECT-TO-CONSUMER MARKETING OF PRESCRIPTION DRUGS: EFFECTS ON PRESCRIPTION AND OVER-THE-COUNTER PRODUCT SALES*

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Abstract

This paper examines the impact and interrelationships between direct-to-consumer (DTC) and physician-oriented marketing on the sales composition of the prescription (Rx) and over-the-counter (OTC) versions of antiulcer and heartburn medications. To understand better the implications for competition of the 1997 Food and Drug Administration's policies regarding DTC marketing, as well as recent Rx-to-OTC switch approvals, we also examine the relationship between order-of-entry effects and marketing intensities. We find spillover effects of marketing for Rx drugs on same-brand OTC versions of the drugs. We also find that the ratio of cumulative marketing intensity (cumulative marketing efforts divided by cumulative sales) in the OTC segment increases monotonically with order of entry. Our regression results show that various marketing demand elasticities depend on order of entry. Our findings document the importance of nonprice competition in the OTC drug market and suggest that the recent deregulation of Rx DTC marketing enhances rivalry and facilitates competition.

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I. Introduction

The effects of marketing efforts on consumer choice and well-being have long been controversial among economists, marketing analysts, and public policy makers. Classic debates include the following: Do marketing efforts generate informational and educational value for consumers, which enables them to make more informed choices? Do marketing efforts exploit informational asymmetry between producers and consumers, increase perceived product differentiation, and induce inefficient rent-seeking behavior by producers? Or do both of these effects hold, varying by product and stage in the product life cycle?[1] These issues are at the heart of current debates concerning the welfare effects of recent regulatory changes at the U.S. Food and Drug Administration (FDA) regarding direct-to-consumer (DTC) marketing for prescription (Rx) drugs.[2]

In 1997, the FDA clarified guidelines on DTC marketing of Rx drugs that allow manufacturers to place both the drug's name and the condition that the drug treats in an advertisement without requiring manufacturers to include all the additional safety and efficacy information that are traditionally found in the product insert.[3] Prior to this change, whenever a drug's brand name appeared in an advertisement, such detailed product insert information was required as well.

Recent years have also seen an acceleration in the number of Rx-only to over-the-counter (OTC) (Rx-to-OTC) switches that have been approved by the FDA.[4] In the 14-year period between 1976 and 1989, the FDA approved 39 Rx-to-OTC switches (about 2.8 per year), but between 1990 and 1996,

[1] See, for example, Federal Trade Commission, Advertising for Over-the-Counter Antacids: Final Staff Report and Recommendations (1983); Mark A. Hurwitz & Richard E. Caves, Persuasion or Information? Promotion and the Shares of Brand Name and Generic Pharmaceuticals, 31 J. Law & Econ. 299 (1988); Keith B. Leffler, Persuasion or Information? The Economics of Prescription Drug Advertising, 24 J. Law & Econ. 45 (1981); Richard L. Schmalensee, The Economics of Advertising (1972); and Richard L. Schmalensee, Product Differentiation Advantages of Pioneering Brands, 72 Am. Econ. Rev. 349 (1982).

[2] See, for example, Ronald S. Bond & David F. Lean, Sales, Promotion, and Product Differentiation in Two Prescription Drug Markets: Staff Report of the Bureau of Economics of the Federal Trade Commission (1977); Marcel P. Gemperli, Rethinking the Role of the Learned Intermediary: The Effect of Direct-to-Consumer Advertising on Litigation, 284 JAMA 2241 (2000); Jane E. Henney, Challenges in Regulating Direct-to-Consumer Advertising, 284 JAMA 2242 (2000); Alison J. Huang, The Rise of Direct-to-Consumer Advertising of Prescription Drugs in the United States, 284 JAMA 2240 (2000); National Survey of Consumer Reactions to Direct-to-Consumer Advertising, Prevention Mag. 8 (1999); Meredith Rosenthal *et al.*, Demand Effects of Recent Changes in Prescription Drug Promotion, in 6 Frontiers in Health Policy Research (Alan M. Garber & David M. Cutler eds. 2003); and Michael S. Wilkes, Robert A. Bell, & Richard L. Kravitz, Direct-to-Consumer Prescription Drug Advertising: Trends, Impact and Implications, 19 Health Aff. 110 (2000).

[3] Manufacturers are required to direct the audience to another source (for example, a toll-free number or a Web site) to obtain additional safety and efficacy information.

[4] For FDA comments on switches, see Tamar Nordenberg, Now Available without a Prescription, FDA Consumer Magazine (1996) (http://www.fda.gov/fdac/features/996_otc.html).

20 switches occurred (about 3.3 per year). Between 1994 and 1996 alone, the FDA approved 10 Rx-to-OTC switches, including Children's Advil, Children's Motrin, Orudis KT, and Actron for pain relief; Femstat 3 for treating vaginal yeast infection; Pepcid AC, Tagamet HB, Zantac 75, and Axid AR for heartburn; and Rogaine for promoting hair growth. Many of today's leading selling OTC products had an Rx heritage. For example, OTC medications such as Advil, Motrin IB, Benadryl, and NyQuil were originally Rx-only drugs that switched to OTC status in the 1980s.[5] The increase in approvals of Rx-to-OTC switches reflects in part the impact of those advocating greater consumer choice, self-medication, and consumer empowerment. It also likely reflects manufacturer incentives as embodied in the Waxman-Hatch Act of 1984, which in some cases permits an additional 3 years of marketing exclusivity for previously Rx-only products whose new approved efficacy indications involve an OTC formulation.

The clarified DTC advertising guidelines provide manufacturers even greater inducements for Rx-to-OTC switches. Specifically, by marketing the Rx version of a drug directly to consumers while it is still under patent protection, a producer may be able to exploit spillovers to its subsequent OTC version, particularly when marketing signals quality and translates into long-lived brand-name equity. Hence, DTC marketing of a branded Rx product may have long-term effects on the subsequent success of Rx-to-OTC switches.

In this paper, we examine recent DTC marketing efforts and Rx-to-OTC switches involving the H_2-antagonist class of drugs, which treats a wide variety of gastrointestinal disorders including duodenal and gastric ulcers, hypersecretory conditions, acid indigestion, and heartburn. These top-selling Rx medications all switched from Rx to OTC in 1995–96—Pepcid to Pepcid AC, Tagamet to Tagamet HB, Zantac to Zantac 75, and Axid to Axid AR. The Rx version of Tagamet lost patent protection in 1994, as did Rx Zantac in 1997, Rx Pepcid in 2001, and Rx Axid in 2002. For some of these drugs, DTC advertising has been used for both the Rx and OTC formulations.

In this paper, we first assess whether order-of-entry effects, documented to be strong in the H_2 Rx market, are also present in the H_2 OTC segment and examine whether there is any carryover of order of entry from the Rx

[5] For further discussion, see Davina C. Ling, Advertising, Competition, and Prescription-to-Nonprescription Drug Switches in the US Antacid Market (unpublished Ph.D. dissertation, Massachusetts Inst. Tech., June 1999); Barbara Hesselgrave, Will Managed Care Embrace Rx-to-OTC Switches? Drug Topics, June 2, 1997, at 13; Robert McCarthy, OTCs: The Wild Card in Cost-Effectiveness, 17 Bus. Health 33 (1999); Mickey C. Smith, Rx-to-OTC Switches: Reflections and Projections, Drug Topics, July 20, 1998, at 70; Bruce Stuart & James Grana, Are Prescribed and Over-the-Counter Medicines Economic Substitutes? A Study of the Effects of Health Insurance and Medicine Choices by the Elderly, 33 Med. Care 487 (1995); and Elyse Tanou & Thomas M. Burton, More Firms "Switch" Prescription Drugs to Give Them Over-the-Counter Status, Wall St. J., July 29, 1993, at B1.

to the OTC markets.[6] Next we consider the role of DTC marketing, as well as traditional physician-oriented "detailing" marketing, on the sales composition of the OTC H_2s and of the Rx H_2s. Finally, we assess whether there are any significant interactions between the Rx and OTC DTC marketing efforts for a brand.

As best we can determine, the research we report here is the first systematic empirical examination of the impact and interrelationships between DTC marketing on Rx and OTC versions of "sunset" branded pharmaceuticals facing Rx patent expiration.[7] Our research integrates data from various sources, such as Rx drug sales and marketing data from IMS Health, scanner OTC data from Information Resources, Incorporated (IRI), as well as DTC marketing data from Leading National Advertisers. We begin with a historical overview of regulatory and other factors affecting the Rx and OTC H_2-antagonist products.

II. Background

As early as the 1800s, patent medicine advertisers were the largest patrons of newspaper advertising.[8] The modern distinction between Rx and OTC drugs began with the 1938 Federal Food, Drug, and Cosmetic Act, which defined different labeling guidelines for Rx and OTC drugs. Under the 1938 act, even though the authority over the labeling of both Rx and OTC drugs was given to the FDA, control over drug marketing remained with the Federal Trade Commission. The 1962 Kefauver-Harris amendments to the Federal Food, Drug, and Cosmetic Act gave the FDA its current responsibility for monitoring Rx drug promotional materials. The 1962 amendments outlined basic requirements for Rx marketing: Rx promotional materials cannot be false or misleading; they must provide a "fair-balance" coverage of risks and benefits of using the drug; they must provide a summary of contraindications, side effects, and effectiveness; and they must also meet specific guidelines for readability and size of print.

[6] See Ernst Berndt *et al.,* Information, Marketing and Pricing in the U.S. Anti-ulcer Drug Market, 85 Am. Econ. Rev. 100 (1995); Ernst Berndt *et al.,* The Roles of Marketing, Product Quality and Price Competition in the Growth and Composition of the U.S. Anti-ulcer Drug Industry, in The Economics of New Goods 277 (Timothy F. Bresnahan & Robert J. Gordon eds. 1997).

[7] For related empirical research on Rx-to-OTC switches, see Peter Temin, Costs and Benefits in Switching Drugs from Rx to OTC, 2 J. Health Econ. 187 (1983); Peter Temin, Realized Benefits in Switching Drugs, 35 J. Law & Econ. 351 (1992); and Ernst R. Berndt, Margaret K. Kyle, & Davina Ling, The Long Shadow of Patent Expiration: Generic Entry and Rx-to-OTC Switches, in Scanner Data and Price Indexes 229 (Robert C. Feenstra & Matthew D. Shapiro eds. 2002). Additional research on order-of-entry effects in Rx pharmaceutical markets is Ernst Berndt *et al.,* An Analysis of the Diffusion of New Antidepressants: Variety, Quality and Marketing Efforts, 5 J. Mental Health & Pol. Econ. 3 (2002).

[8] James Harvey Young, The Medical Messiahs: A Social History of Health Quackery in Twentieth Century America (1967), as cited in Wilkes, Bell, & Kravitz, *supra* note 2.

Since then, Rx drugs have been marketed not only to physicians, but also more directly to consumers. As noted by Ernst Berndt and coauthors,[9] for example, in March 1988 Tagamet Rx launched "Tommy Tummy" and "stomach TLC" DTC marketing campaigns, and soon after Glaxo initiated an extensive television and print DTC effort for Zantac. Under the interpretation of FDA regulations regarding DTC marketing at that time, the marketing was quite restrictive in that if a brand name was mentioned in the advertisement, extensive product-labeling information was required to accompany the advertisement.

These restrictions on DTC marketing were relaxed and clarified in 1997 when the FDA issued new draft guidelines. A manufacturer is now permitted to advertise an Rx drug's name and the condition for which it is indicated without needing to issue as fully detailed a summary regarding the product's side effects and other risks. The FDA requirements for risk disclosure in advertisements may be met if the advertisements contain information on the product's main risks and refer to other sources from which consumers may obtain additional product information and full product labeling. For instance, a prominently positioned toll-free phone number (or Web address) must now be found on the advertisement, which the consumer can use to obtain further information. Usually, there is explicit encouragement for readers and viewers of DTC advertisements to discuss the product with their physicians.

While relatively little is known to date regarding the ultimate impacts of DTC marketing of Rx products on consumer utilization and health status,[10] there is little doubt that relaxation of the DTC restrictions by the FDA has been associated with a very substantial increase in DTC marketing of Rx products. In particular, according to IMS Health, DTC marketing expenditures for Rx medications increased from $1.1 to $2.5 billion between 1997 and 2000.[11]

Both the shift in regulatory regime for DTC advertising and the more favorable regulatory environment for Rx-to-OTC switches are important in explaining recent developments in the H_2-antagonist market. The first H_2-antagonist, Tagamet (chemical name, cimetidine), was introduced in 1977. It revolutionized the treatment of ulcers by allowing pharmacological treatment on an outpatient basis, rather than with expensive inpatient care such as hospital stays and surgeries. Three other H_2-antagonists were launched between 1983 and 1988: Zantac (ranitidine), Pepcid (famotidine), and Axid (nizatidine). The benefits of patent protection, together with successful marketing and the resulting widespread utilization, led to spectacular revenue

[9] Berndt *et al.*, The Roles of Marketing, *supra* note 6.

[10] For an initial and preliminary analysis, see Prevention Mag., *supra* note 2. Also see Wilkes, Bell, & Kravitz, *supra* note 2; and Meredith Rosenthal *et al.*, Promotion of Prescription Drugs to Consumers, 346 New Eng. J. Med. 498 (2002).

[11] IMS Health data can be obtained at http://www.imshealth.com. Also see Rosenthal *et al.*, *supra* note 2.

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