

Commentary

The Effect on Social Welfare of a Switch of Second-Generation Antihistamines from Prescription to Over-the-Counter Status: A Microeconomic Analysis

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ABSTRACT

Background: The US Food and Drug Administration (FDA) recently held a meeting to determine whether the status of second-generation antihistamines (SGAs) should be switched from prescription (Rx) to over-the-counter (OTC) status.

Objective: This article provides a conceptual microeconomic framework for addressing issues regarding the impact of such a switch on social welfare.

Methods: A review of the economic literature on Rx-to-OTC switches was conducted. Relevant articles published in English between 1990 and 2001 were identified through searches of ABI Info, EconLit, PsychInfo, MEDLINE, CANCERLIT, AIDSLINE, and HealthStar, as well as a general Internet search for statements in the press or on the FDA Web site. The search terms used were *Rx, prescription, OTC, over-the-counter, second-generation antihistamines, nonsedating antihistamines, first-generation antihistamines, and sedating antihistamines*. Microeconomic models focusing on consumer surplus were employed to determine the potential price response and social-welfare implications of a switch of SGAs to OTC status.

Results: Unlike the agents involved in previous Rx-to-OTC switches, SGAs are still under patent protection. Economic theory suggests that a firm that is protected by a patent will price aggressively. The market for OTC SGAs is likely to be more elastic due to a lack of insurance coverage for OTC products; hence, drug manufacturers would be likely to charge a lower price if SGAs were sold OTC. However, a lower price does not necessarily guarantee an improvement in social welfare; the net impact is determined by whether the increase in consumer surplus outweighs the deadweight loss (losses of consumer and producer surplus not transferred to other parties). Additionally, the assumption of a price reduction would be called into question if there were inequalities in marginal costs between the Rx and OTC markets. In this situation, the postswitch price might increase or not be reduced significantly.

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Conclusions: It is uncertain whether granting OTC status to SGAs would be cost saving to society, particularly as these drugs are patent protected. The social-welfare implications of such a switch would depend heavily on pricing strategies and consumer behavior. Further analyses are needed to determine how both factors influence social welfare; only then can the costs and benefits of a switch be understood completely.

Key words: Rx-to-OTC switch, second-generation antihistamines, social welfare, consumer surplus, deadweight loss, patent. (*Clin Ther.* 2002;24:701-716)

INTRODUCTION

On May 11, 2001, the Nonprescription Drugs Advisory Committee (NDAC) and the Pulmonary-Allergy Drugs Advisory Committee (PDAC) of the US Food and Drug Administration (FDA) jointly hosted a public meeting to review a Citizens' Petition first submitted in July 1998 by a health care insurer, Blue Cross of California (a subsidiary of WellPoint Health Networks).¹ This petition requested that the second-generation antihistamines (SGAs) fexofenadine hydrochloride,* loratadine,[†] and cetirizine hydrochloride[‡] be switched from prescription (Rx) to over-the-counter (OTC) status.

Antihistamines have been the mainstay of treatment for seasonal allergic rhinitis for many years. First-generation antihistamines (FGAs) such as diphenhydramine and promethazine offer symptomatic re-

lief but have undesirable sedating properties. The 3 SGAs provide symptomatic relief and have been shown to be safe and efficacious, with fewer sedating and anticholinergic effects compared with FGAs.²⁻⁴ Currently, SGAs are available in the United States by prescription only.

Because the WellPoint petition marked a departure from standard practice—it is one of the few instances in which a party other than a drug manufacturer has requested an Rx-to-OTC switch—the FDA meeting received much attention and reaction from the press, consumer groups, medical societies, and professional associations, as well as from the pharmaceutical industry. The only other recent instance of an Rx-to-OTC switch initiated by a party other than a drug manufacturer was in 1983, when the FDA initiated the switch of metaproterenol to OTC status; however, later that year the drug was returned to Rx status because of physician concerns about its toxic effects.⁵

According to the 1962 Kefauver-Harris amendments to the Food, Drug and Cosmetic Act (written in 1938 to regulate drug quality), a product to be sold OTC must be shown to be both safe and effective when used without the supervision of a health care practitioner.⁶ Under current regulations, a new drug can be sold OTC if the FDA approves an application establishing the safety and efficacy of the drug when used OTC.⁶ In nearly all instances, such drugs are marketed first as Rx medications. After sufficient postmarketing data have been collected to indicate the drug's safety and effectiveness without physician intervention, the drug may be switched to OTC status. Alternatively, a drug can be sold OTC if its ingredients are included in a previous OTC monograph specifying the OTC labeling for the drug.

*Trademark: Allegra® (Aventis Pharmaceuticals, Bridgewater, New Jersey).

†Trademark: Claritin® (Schering Corporation, Kenilworth, New Jersey).

‡Trademark: Zyrtec® (Pfizer Inc, New York, New York).

In its petition, WellPoint made both safety and economic arguments in support of an Rx-to-OTC switch of the SGAs.⁷ A key assumption behind WellPoint's conclusion of cost savings was that there would be a significant price reduction in SGAs after the switch; this assumption was based on observed pricing scenarios for histamine-2 (H_2)-receptor antagonists before and after their switch to OTC status.⁸ However, in the case of the H_2 -receptor antagonists, the switch was proposed by the respective manufacturers near the time of patent expiration. A distinct feature of the proposed Rx-to-OTC switch of SGAs is that all 3 drugs named in the WellPoint petition are still under patent protection. Therefore, economic conclusions based on the assumption of a price reduction analogous to that seen in the Rx-to-OTC switch of H_2 -receptor antagonists would appear to be erroneous. Additionally, the social-welfare implications of a possible forced switch of a patent-protected drug are uncertain.

The purpose of this article was to take a microeconomic approach to the potential effects on social welfare of an Rx-to-OTC switch of SGAs. This included an overview of microeconomic theories relating to social welfare, along with a brief review of the economic literature on Rx-to-OTC switches and an exploration of the social-welfare implications of such a switch with respect to SGAs. Relevant articles published in English between 1990 and 2001 were identified through searches of ABI Info, EconLit, PsychInfo, MEDLINE, CANCERLIT, AIDSLINE, and HealthStar, as well as a general Internet search for statements in the press or on the FDA Web site. The search terms used were *Rx*, *prescription*, *OTC*, *over-the-counter*, *second-generation antihistamines*, *nonse-*

dating antihistamines, *first-generation antihistamines*, and *sedating antihistamines*.

MATERIALS AND METHODS

In microeconomics, social welfare is usually discussed in the context of "consumer surplus," defined as the value consumers receive from a commodity beyond what they have paid for it.⁹ As shown in Figure 1, under a market structure of perfect competition, consumer surplus, corresponding to the price level P_0 , is illustrated by the area AP_0B . In this example, a price reduction will contribute to an increase in consumer surplus. Line AD represents the market demand curve of a commodity. If competition between manufacturers reduces the price from P_0 to P_1 (and increases the quantities consumed from Q_0 to Q_1), this price reduction will generate an increase in consumer surplus, as measured by the area P_0BCP_1 in the figure.

The majority of economic evaluations of Rx-to-OTC switches have followed the above logic. Specifically, these studies have argued that after a drug is switched to OTC status, usually close to or immediately after patent expiration, competition between manufacturers will lower prices, which in turn will result in a higher consumer surplus.¹⁰⁻¹³ For example, Temin¹⁰ addressed the costs and benefits associated with an Rx-to-OTC switch using the example of 0.5% topical hydrocortisone lotion, which was switched to OTC status in the United States in 1979. This author estimated consumer surpluses for 1980 and 1981 of \$236 million and \$482 million, respectively, and corresponding net benefits of \$212 million and \$433 million. Ryan and Yule¹¹ reached similar conclusions about OTC topical hydrocortisone, which was introduced in the United Kingdom in 1987.

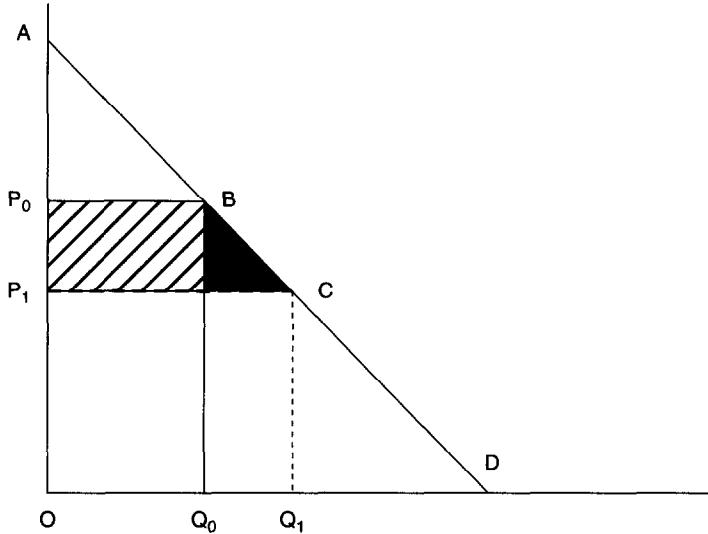


Figure 1. Consumer surplus under a market structure of perfect competition. P = price; Q = quantity; D = demand.

H₂-receptor antagonists have been studied extensively in the economic literature on Rx-to-OTC switches. The first OTC H₂-receptor antagonists became available shortly after the patent expiration on Tagamet® (GlaxoSmithKline, Research Triangle Park, NC) in 1994. Andrade et al¹⁴ looked at the impact of the switch on patients with chronic dyspepsia. Using a managed-care database for the 1-year periods before and after H₂-receptor antagonists received OTC status, the authors concluded that the switch was cost saving for the managed-care plan. A somewhat different conclusion was reached by Kalish et al,¹⁵ who designed a decision-analytic model to compare costs associated with an initial episode of dyspepsia between 2 classes of H₂-receptor antagonists—those that had recently been switched to OTC status and those available by prescription only. Their findings suggested that differences in health care

costs between the 2 classes of drugs were negligible, from both the societal and managed-care perspectives.

Other drugs and drug classes studied in the economic literature of Rx-to-OTC switches have included loperamide,¹¹ nasal sprays for the common cold,¹⁶ and vaginal antifungal agents.¹⁷ A summary of these articles is provided in the table.

As discussed earlier, the majority of economic articles on Rx-to-OTC switches have concluded that such switches are cost beneficial (or cost saving) and economically desirable for society or payers. However, it is worth noting that previous economic studies of Rx-to-OTC switches in the United States have shared a significant similarity—the switch was usually proposed by the manufacturer of an Rx drug as its patent was nearing expiration. In fact, some authors have argued that the Rx-to-OTC switch is a strategy used by manufacturers to preempt generic compe-

Table. Summary of studies of previous switches of drugs from prescription (Rx) to over-the-counter (OTC) status. All studies were retrospective database analyses, unless otherwise noted.

Reference	Drug (Year of Switch)	Country	Economic Perspective	Conclusions
Temin ¹⁰	Topical hydrocortisone (1979)	US	Third-party payer (government)	Consumer surplus: \$236 million (1980); \$482 million (1981) Net benefit: \$212 million (1980); \$433 million (1981) Consumer surplus and net financial benefit realized in years immediately after switch
Ryan and Yule ¹¹	Topical hydrocortisone (1987)	UK	Third-party payer (government)	Negligible change in no. of prescriptions immediately after switch 1.1 million OTC packets sold immediately after switch Sales of OTC packets led to consumer benefits of £2.0-£2.2 million between 1987 and 1989
Ryan and Yule ¹¹	Loperamide (1983)	UK	Third-party payer (government)	No. of prescriptions reduced by 280,000 (1985) and 549,000 (1987) after introduction of OTC alternative Net benefit of switch, £2.0 million
Lundberg and Isacson ¹⁶	Nasal cold spray (1989)	Sweden	Third-party payer (government)	Reduction in physician visits by 2%, 1988-1994 Savings on physician visits of SKr 500,000 in same period No. of prescriptions fell by 10.6 prescriptions/100 persons in same period Sales of prescription nasal decongestants declined by SKr 315,887 in same period

(continued)

Table. (Continued)

Reference	Drug (Year of Switch)	Country	Economic Perspective	Conclusions
Gurwitz et al ¹⁷	Vaginal antifungal agents (1990)	US	Third-party payer (managed care)	No. of prescriptions fell by 6.42 prescriptions/100 female managed-care plan members after introduction of OTC alternative Annual savings of \$42,528 in medication costs realized No significant reduction in no. of physician visits
Kalish et al ^{15*}	H ₂ -receptor antagonists (1994)	US	Third-party payer (managed care) and societal	Negligible differences in health care costs between Rx and OTC drugs for treatment of initial episode of dyspepsia
Andrade et al ¹⁴	H ₂ -receptor antagonists (1994)	US	Third-party payer (managed care)	Annual savings of \$187,212 in medication costs for chronic treatment (vs initial episode) realized by managed-care plan No. of prescriptions fell by 1.5 prescription/chronic user after introduction of OTC alternative No significant reduction in no. of physician visits

US = United States; UK = United Kingdom; H₂ = histamine-2.

*Study used a decision-analytic model.

tition.¹⁸⁻²⁰ Once generic products enter the market, generic competition is known to lower the average price of a drug^{21,22}; consequently, the price reduction that has been observed after a switch is likely to be the result of generic competition after patent expiration. This raises 2 questions: what would happen to the price of SGAs if they were to be switched while still under patent protection? Even more important, what are the social-welfare implications of such a switch?

According to microeconomic theory, while a product has patent protection, the manufacturer tends to price aggressively (“monopoly behavior”).²³ Figure 2 depicts the pricing behavior of a patent-holding firm and the social-welfare implications of such behavior. As shown, a patent holder focusing on maximizing profits will produce at the level at which its mar-

ginal cost (MC) equals marginal revenue (MR), but will charge as high a price as the market will support (ie, in reference to the market-demand curve represented by line AD). The patent holder will produce Q_M units of commodity and charge P_M for each unit.

Economists have pointed out that this profit-maximizing behavior causes a distortion in resource allocation,⁹ also illustrated in Figure 2. If the market in the figure were perfectly competitive, the output level and price charged would be Q_C and P_C , respectively, and a consumer surplus of ACP_C would be realized. However, under the pricing strategy of the patent holder in this model, the consumer surplus is AP_MB ; some of the consumer surplus that would have occurred in a competitive market structure (ie, P_MBEP_C in the figure) is now transferred from the

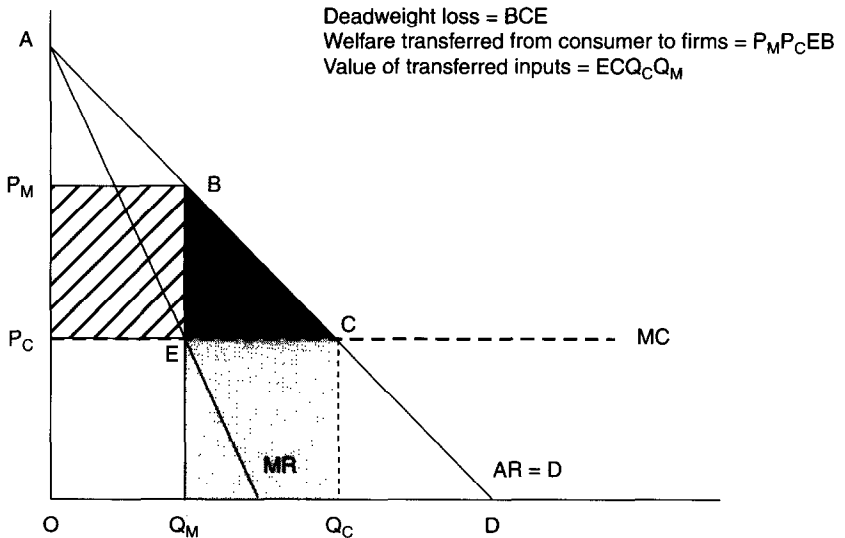


Figure 2. Pricing behavior of patent holders and its social-welfare implications. P = price; M = monopoly; C = competition; Q = quantity; MR = marginal revenue; MC = marginal cost; AR = average revenue; D = demand.

consumer to the firm, whereas the remainder (ie, BCE) becomes a deadweight loss to society. Therefore, in addition to considering consumer surplus, discussions of the potential social-welfare implications of an Rx-to-OTC switch of the patent-protected SGAs must consider the change in deadweight loss before and after the switch.

However, with 3 main players (the manufacturers of the 3 patent-protected SGAs), the SGA market is akin to an oligopoly. In the present analysis, use of a price-aggressive, monopolistic model to examine the potential consequences of a switch allows isolation of consumer surplus and deadweight loss along with a graphic representation of market dynamics. Therefore, a monopoly model of a single SGA patent holder has been used to characterize the hypothetical collective behavior of the category of SGA patent holders. Readers interested in learning more about the behavior of pharmaceutical companies in oligopolistic markets are directed to Comanor,²⁴ Lu and Comanor,²⁵ and Mullins.²⁶

RESULTS

As mentioned, pricing of SGAs in the OTC market is likely to remain aggressive after a switch from Rx to OTC status. In such a scenario, there are 2 uncertainties. First, will the price of SGAs be reduced after the switch? Second, what are the social-welfare implications of the switch? Both questions can be addressed using standard microeconomic theory.

To evaluate the impact of the switch on the price of SGAs, it is important to understand differences in the demand for SGAs before and after the switch. Health insurance is known to increase demand

and make consumers less price sensitive (ie, it decreases the elasticity of demand). Indeed, findings from the RAND Health Insurance Experiments indicate that use of both Rx and OTC drugs increased as cost sharing (ie, the out-of-pocket proportion) decreased.^{27,28} Because most health insurance plans do not cover OTC products, consumers become financially responsible for the full list price of an OTC drug rather than simply the copayment component of an Rx drug. If SGAs were switched to OTC status, the consumer's cost-sharing proportion would increase from the copayment required by his or her health plan to a 100% out-of-pocket expense. Consequently, the demand curve for SGAs in the OTC market after the switch would be more elastic than the existing curve for SGAs in the Rx market. What pricing strategy would a patent holder aiming to maximize profits employ when faced with a more elastic OTC market compared with the less elastic Rx market?

Assuming equal marginal costs in both the Rx market before the switch and the OTC market after the switch, Figure 3 illustrates the pricing behavior of manufacturers in these markets. AD represents the market demand for a product in the Rx market, whereas A'D' represents the market demand for SGAs in the OTC market. Because of insurance coverage for Rx drugs, demand in the Rx market is less elastic than in the OTC market (ie, AD is steeper than A'D'). Microeconomic theory suggests that a profit-maximizing patent holder will charge a higher price in a less elastic market and a lower price in a more elastic market; therefore, the price of the OTC drug after the switch (P_{OTC}) will be lower than that of the Rx drug before the switch (P_{Rx}). It should be noted that in this discussion, "price" refers to

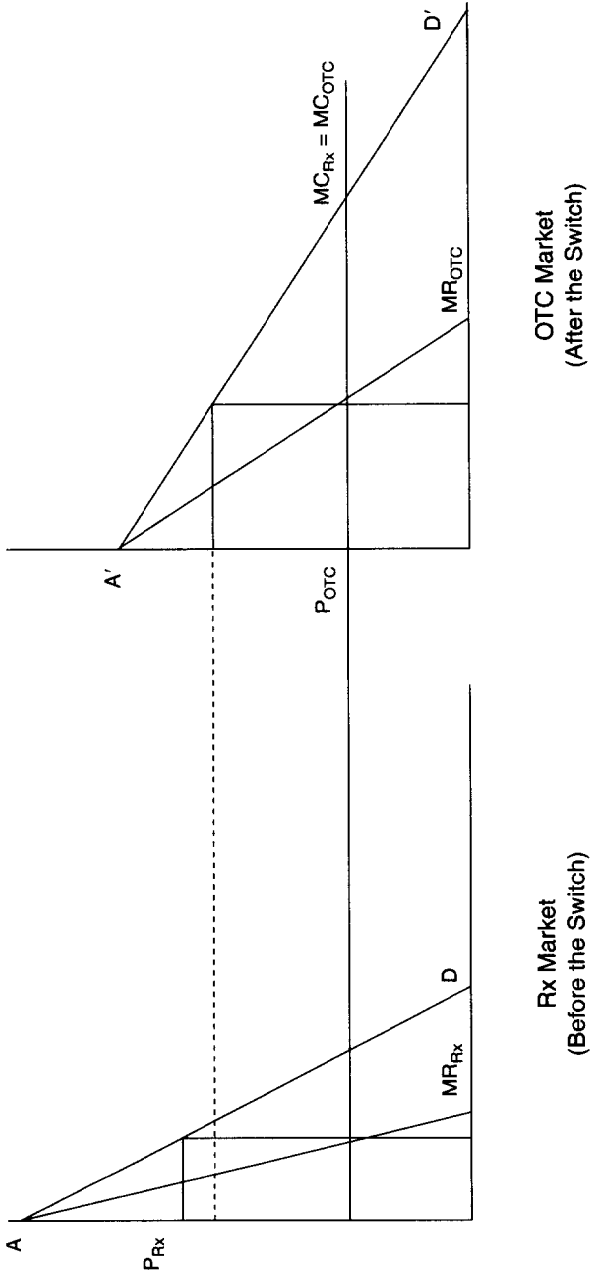


Figure 3. Patent holder's pricing behavior in the prescription (Rx) and over-the-counter (OTC) markets. P = price; MR = marginal revenue; D = demand; MC = marginal cost.

the full price of a drug rather than to its purchase price for consumers. Because of the societal perspective adopted in this analysis, what matters is the full price of a product, regardless of who pays.

Lower prices for SGAs after a switch to OTC status do not necessarily guarantee an improvement in social welfare. Figure 4 compares social welfare in the instance of a patent holder operating in 2 markets—a less elastic market resembling the current Rx market and a more elastic market representing the OTC market after the switch to OTC status. As illustrated, changes in social welfare are determined by variations in 3 areas: consumer surplus retained by consumers (ie, ABP_{Rx} and $A'B'P_{OTC}$), consumer surplus transferred to the patent holder (ie, $P_{Rx}BEP_C$ and $P_{OTC}B'E'P'_C$), and deadweight loss (ie, BCE and $B'C'E'$). Mathematically, social welfare before and after the switch can be expressed using the following equation, in which “Ar” equals “area”:

$$\begin{aligned} & \{Ar(ABP_{Rx}) + Ar(P_{Rx}BEP_C) - Ar(BCE)\} - \\ & \{Ar(A'B'P_{OTC}) + Ar(P_{OTC}B'E'P'_C) - Ar(B'C'E')\} \\ & = \{((Ar(ABP_{Rx}) + Ar(P_{Rx}BEP_C) - Ar(A'B'P_{OTC}) + \\ & Ar(P_{OTC}B'E'P'_C)) - \{Ar(BCE) - Ar(B'C'E')\}) \\ & = \{\text{variations in combined consumer surplus}\} - \\ & \{\text{variations in deadweight loss}\} \end{aligned}$$

If the switch leads to an increase in deadweight loss greater than the increase in the combined consumer surplus, social welfare will be damaged by the switch despite the price reduction. The exact magnitude of change in social welfare will depend on the shape of the demand curve before and after the switch and can be determined only empirically.

Note that the conclusion of a post-switch price reduction relies on an assumption of equal marginal costs in both the Rx and OTC markets. If one assumes instead that the marginal costs after a

switch are likely to increase due to such factors as more intensive direct-to-consumer (DTC) advertising, development of new distribution channels, and production of new packaging, the price of SGAs may actually be increased after a switch to OTC status. (Some may argue that DTC advertising is a fixed cost because a manufacturer’s expenditure on it does not vary by quantity of product sold and, therefore, by sales. It is important to understand that while there is a capital investment component in advertising, this does not mean that advertising costs are fixed. The association between the volume of advertising expenditure and the volume of sales has been analyzed in numerous empirical studies.²⁹⁻³¹)

As illustrated in Figure 4, when the firm’s marginal cost after the switch (MC'_{OTC}) is much higher than its marginal cost before the switch (MC_{Rx}), the price of SGAs after the switch (P'_{OTC}) may be higher than the price before the switch (P_{Rx}). In this circumstance, not only do the social-welfare implications become uncertain, but the assumption of a postswitch price reduction is called into question.

DISCUSSION

Brass⁶ provided a general overview of the regulatory history, as well as the pros and cons, of Rx-to-OTC switches. This author listed several potential benefits to the switch: increased access to effective drugs; decreased frequency of visits to physicians; reduced health care costs; and increased patient autonomy and education. In addition, Brass noted several areas of concern: inaccurate self-diagnosis; delayed or suboptimal treatment of a serious condition; risks associated with inappropriate drug use; redistribution of health

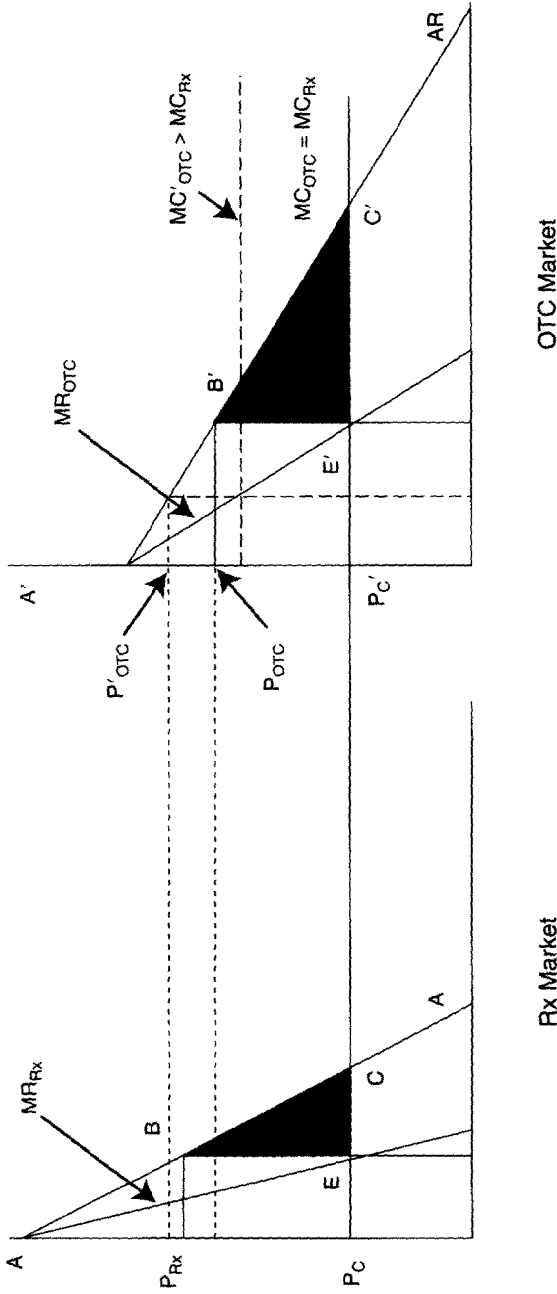


Figure 4. Deadweight loss: social welfare in the case of a patent-holder operating in 2 markets—a less elastic market resembling the current prescription (Rx) market and a more elastic market representing the over-the-counter (OTC) market after a switch to OTC status. P = price; MR = marginal revenue; MC = marginal cost; AR = average revenue.

care costs; and a diminished physician role in patient care. With the exception of patient autonomy and education, all benefits and concerns mentioned by Brass are raised in the discussion of an Rx-to-OTC switch of SGAs.

After the FDA hearing on May 11, 2001, the majority of members of the NDAC and PDAC panels voted in favor of the switch of the SGAs to OTC status. According to WellPoint's petition, SGAs, like FGAs, should be classified as GRAS/ GRAE (generally recognized as safe and effective). Indeed, an evidence report submitted with the WellPoint petition indicated that the 2 types of antihistamines have comparable efficacy and that the most significant adverse events associated with the FGAs (ie, sedation, impairment while driving, and life-threatening cardiac arrhythmias) are rarely observed with the SGAs.³²

During discussions leading up to the final vote, however, groups ranging from trade associations to physician societies questioned Wellpoint's safety argument. In a joint letter, the American Academy of Allergy, Asthma and Immunology (AAAAI) and the American College of Allergy, Asthma and Immunology (ACAAI) emphasized the critical role of the physician in patient care.³³ The letter stated that eliminating physician intervention could have drastic consequences for patients with allergic rhinitis; that misuse of SGAs (ie, abuse, overuse, or underuse) would be more likely without physician advice, which would inevitably result in increased health care costs; and that more significant comorbidities, such as asthma, sinusitis, or otitis media, could be missed in the absence of physician visits. Similar concerns were raised by the American Academy of Otolaryngology–Head and

Neck Surgery,³⁴ as well as by several independent physicians.^{35–37} Both the societies and physicians expressed the opinion that a switch would be likely to lead to poorer health outcomes in instances of misdiagnosis or undermanagement of comorbid conditions. Subsequently, such cases could be expected to overburden the health care system and increase costs.

The FDA had counseled the committee that in reaching its decision, it should not take the “cost of therapy or reimbursement by health insurers” into account³⁸ but should consider only each drug's safety profile.³⁹ Thus, the committee's decision was to be based solely on whether the drug was safe and sufficiently well tolerated to be sold without a prescription. Despite this focus on clinical issues, one economic concern provoked intense debate both during and after the FDA hearing: the financial consequences for consumers of the switch of SGAs to OTC status. According to WellPoint, giving SGAs OTC status would make the products more accessible to patients, creating a cost saving for society. The AAAAI and ACAAI, on the other hand, felt that OTC status would actually discourage the use of SGAs.³³

Many patients pay minimal copayments for these drugs, which are usually covered under insurance formularies. If patients are forced to pay the full cost, many may opt for cheaper but less effective and more dangerous alternatives. Before the hearing, an article in the *Washington Post*⁴⁰ pointed out that if the SGAs are sold OTC, patients may have to pay wholesale prices of close to \$70 instead of the typical \$10 to \$15 copayment. Meanwhile, with this transfer of costs to consumers, managed-care groups would save nearly \$45 million annually.⁴⁰

In letters to the FDA,^{41,42} members of the public expressed 2 sides of the argument. Some viewed a potential switch as “liberating”; the trend toward deregulation and efforts to contain health care costs in recent years may be driving this opinion. On the other hand, many consumers were disturbed by managed-care groups’ attempts to shift health care costs to consumers.

As mentioned earlier, the examples used in the present analysis are simplified versions of reality. For ease of graphic representation, the manufacturers of the 3 SGAs were considered as a single patent-holding entity. These examples point out the limitations of attempting to project the economic consequences of an Rx-to-OTC switch of SGAs from the experience with previous switches. The existence of discounting and various forms of competition in the real world make the pricing strategies of firms in the SGA market complex and highly variable, adding to the difficulty of projecting the impact of a switch on social welfare. The effect on social welfare of a switch in the oligopolistic SGA market will probably fall between that in a monopolistic market (as was assumed in our study) and that in a perfectly competitive market (as was assumed in many previous studies), as will the postswitch price.

Economic projections are further complicated by the current availability of FGAs in the OTC market. Although both FGAs and SGAs can be used to treat allergic rhinitis, the 2 classes of drugs are considered heterogeneous commodities. Therefore, if SGAs were to be switched to OTC status, 2 types of substitution would occur in the OTC market: substitutions within the SGA class and substitutions between the SGA and FGA classes.

Thus, in addition to considering the price elasticity of the demand for SGAs in the OTC market, economic analyses of the effects on demand of an Rx-to-OTC switch will also need to consider the cross-price elasticity between the FGA and SGA classes. The exact magnitude of the impact of a switch on social welfare must be determined empirically, which will be possible only when we have more complete knowledge of the demand for SGAs. Without a better understanding of consumers’ behavior in the SGA market, it is premature to draw any conclusions about whether the proposed switch of SGAs to OTC status will benefit or harm the social welfare.

CONCLUSIONS

Policymakers must recognize that decisions regarding a switch of Rx medications to OTC status are public health decisions. FDA actions concerning an Rx-to-OTC switch in a class of pharmaceutical products are likely to have many economic and clinical implications.

This article used a simplified microeconomic framework to demonstrate that an Rx-to-OTC switch of SGAs may not be cost saving to society, as was projected by WellPoint. A switch will affect not only consumers’ demand, but also manufacturers’ pricing strategies. In the case of an Rx-to-OTC switch of SGAs, prediction of the social-welfare implications is made more difficult by the fact that these products are still under patent protection. Because the net impact of a switch is determined by whether the increase in consumer surplus outweighs the deadweight loss, the impact of an Rx-to-OTC switch of SGAs would depend heavily on pricing strategies and consumer behavior.

Further analyses, including empirical estimates of the demand for SGAs and assessments of the impact of a switch on vulnerable populations (eg, Medicare, Medicaid, uninsured), are needed to determine how these 2 factors will influence social welfare. Only then can the costs and benefits of a switch be fully understood.

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