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if price is mismeasured, so is the dependent variable, but then their formula the coefficient becomes $(\beta + 1)(\sigma - 1)$, and the implied $\sigma = 1.2$ is even s credible.

'Aging of lines": Once popular restaurants lose customers over time. We ld bring in new ones and make an adjustment for their superiority. But then, ne time later, the chefs are hired away and the old restaurants regain their re. Will we come back to the same level? How?

A major finding is that if one allows for the changing mix of import goods s leads to lower estimates of their income elasticity. That makes sense, but v low "should" the import income elasticity be? Can one really explain ng world trade just by the reduction in transport costs and the rising quality raded goods? I find the notion that traded goods have higher income elastic- s quite plausible. The explicit "bias" adjustment to the price index that fol- /s is, however, more problematic. But the advice to collect more data is ely right!

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The Roles of Marketing, Product Quality, and Price Competition in the Growth and Composition of the U.S. Antiulcer Drug Industry

Ernst R. Berndt, Linda T. Bui, David H. Lucking-Reiley, and Glen L. Urban

7.1 Introduction

The introduction of Tagamet into the U.S. market in 1977 marked the beginning of a revolutionary treatment for ulcers and the emergence of a new industry. What distinguished the products of this new industry was their ability to heal ulcers and treat preulcer conditions pharmacologically on an outpatient basis, thereby substituting for traditional, and costly, hospital admissions and surgeries. Tagamet, known medically as an H_2-receptor antagonist, promotes the healing of ulcers by reducing the secretion of acid by the stomach.

A striking feature of the antiulcer market is that it has sustained growth in sales (quantity, not just revenue) for over fifteen years and still shows no sign of slowing. New prescribing habits have clearly diffused to an ever increasing number of physicians. Today there are a total of four H_2-receptor antagonists: Tagamet, Zantac, Pepcid, and Axid. Zantac is now the United States' (and the world's) largest-selling prescription drug, having estimated worldwide sales in 1992 of about $3.5 billion. Moreover, Tagamet is also among the ten top-selling prescription drugs in the United States.[1]

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1. One hundred powerhouse drugs (1993, S1). Incidentally, Tagamet ranks 7th, Pepcid 17th, Prilosec 25th, and Axid 61st in terms of U.S. sales. In terms of world sales, Tagamet is 7th, Pepcid 22d, Prilosec 49th, and Axid 67th.

his paper we attempt to explain the growth and changing composition of ntiulcer drug market. Although we examine the impacts of pricing and ct quality, we devote particular attention to the role of firms' marketing s. We distinguish between two types of marketing: (1) that which concen- on bringing new consumers into the market ("industry-expanding" ad- ng), and (2) that which concentrates on competing for market shares hese consumers ("rivalrous" advertising). Note that of these two types, t-expanding advertising has particular economic importance in a new t, because no matter how potentially beneficial is the new product, it can ate no consumer's surplus until consumers have been informed about the roduct and have been induced to experiment with it.

others have done, we estimate the effects of industry-expanding advertis- sales. However, we also examine how the effectiveness of this socially cial type of advertising varies with market structure. We exploit two First, in the earliest years of the market when Tagamet was a monopoly ct all of the Tagamet advertising was, by definition, market-expanding. d, the timing of entry is largely exogenous in this industry, for patent tion ensures that firms cannot enter until their research laboratories de- a new molecule that has the desired impact and until approval for use is by the U.S. Food and Drug Administration (FDA).

also analyze factors affecting the market shares earned by the limited r of firms in this market. A principal theme is that the patent and pioneer ages to Tagamet were overcome by Zantac, the second entrant, through but effective marketing efforts, especially efforts that interacted with parent existence of more favorable side-effect profiles than Tagamet's. ver, Zantac's relative price, although higher than Tagamet's, declined ntially over time. Thus, evidence from this industry suggests that while rriers to entry from patent and first-mover advantages are considerable, e not insurmountable.

empirical analysis is based on an unusually rich and detailed data set. ning with the introduction of Tagamet in July 1977, we have obtained ly data, for each of the products in this market, on quantity and average f sales (separately for the retail drugstore and hospital markets); market- forts (minutes of detailing by sales representatives to physicians, and sional medical journal advertising); and product-quality information, in- g side-effect profiles, efficacy, dosage forms, and indications for which duct had received approval from the FDA.

begin in section 7.2 by providing background information on ulcers and reatments. Then in section 7.3 we present an overview of data trends. scribe the growth of the antiulcer market, as well as the pricing and ing behavior of the various market participants. We move on in section develop an econometric framework for modeling the growth of the anti- ndustry. In particular, we examine the effects of "informative" or market- ling marketing efforts on industry sales. In section 7.5 we report findings

from an analogous attempt to model factors affecting market shares earned by the various products in this industry. Here we examine in particular the roles of rivalrous marketing, product quality, order of entry, and price competition. Finally, in section 7.6 we offer some concluding observations and suggestions for future research. The paper also includes a data appendix.

7.2 Background on Ulcer Treatments

Peptic ulcer disease occurs in 10–15 percent of the U.S. population.[2] Ulcers located in the stomach proper are termed gastric ulcers, while those in the duodenum (the bulb connecting the stomach to the small intestine) are called duodenal ulcers. A related nonulcerous condition is gastroesophageal reflux disease (GERD), which occurs in the esophagus. What the three conditions have in common is that they involve inflammation of tissue in the digestive tract that is exacerbated by the presence of the body's naturally occurring gastric acid. GERD and duodenal ulcers have roughly the same rates of occurrence in the U.S. population, whereas gastric ulcers are about one-fourth as likely. The incidence of ulcers in adult males is about twice that in adult females and appears to be most common in individuals twenty to fifty years old.

Ulcers have a long history of clinical treatment. There is evidence that already in the first century A.D., coral powder (calcium carbonate, an antacid) was used to relieve symptoms of dyspepsia (see Fine, Dannenberg, and Zakim 1988). Early in the twentieth century, conventional medical wisdom conformed to the notion "no acid, no ulcer." As a result, until the 1970s recommended treatments sought to neutralize gastric acid and often consisted of hourly feedings of milk and/or antacids, as well as a dietary reduction of acidic food and drink. If ulcers persisted, surgery was undertaken. It is worth noting that while antacids such as Maalox and Mylanta neutralize gastric acid, they do not decrease the rate of gastric secretions (they may in fact increase them). Moreover, the required dosages of antacids are typically quite large, side effects can be considerable, and adverse interactions with other drugs are not uncommon. As a result, with antacids patient compliance can be problematic.

An alternative ulcer treatment involves acid suppression with anticholinergics, such as Pro-Banthine and atropine. Anticholinergic agents decrease acid secretion by inhibiting receptors for the hormone acetylcholine in the acid-producing cells of the stomach lining. However, these agents cause considerably unpleasant reactions, because acetylcholine is involved in a number of biochemical processes other than the secretion of gastric acid, and anticholinergics tend to be nonselective. The side effects of dry mouth, blurred vision, urinary retention, abnormally rapid heartbeat, and drying of bronchial secretions are particularly frequent.

2. The material in this section is taken in large part from Scouler (1993) and the references cited therein. Also see Fine, Dannenberg, and Zakim (1988) and McKenzie et al. (1990).

977 a revolutionary form of antiulcer drug was introduced to the United , known as an H_2-receptor antagonist.[3] H_2-receptor antagonists act by ng the histamine-2 (H_2) receptor on parietal cells in the lining of the ch—cells that produce gastric acid. Histamine-2 is one of three "messen- olecules" (along with gastrine and acetylcholine) that can stimulate the tion of acid by the parietal cells. By blocking the receptor for H_2 (and, the anticholinergic drugs, avoiding any interference with other biochem- ocesses), an H_2-antagonist can decrease overall acid concentration in the ch. H_2-antagonist healing rates are very high. A four- to six-week treat- eriod, for example, is associated with a healing rate of 70–80 percent ients suffering from duodenal ulcers.

thKline was the first pharmaceutical company to introduce an H_2- nist in the U.S. market (in August 1977), and they dubbed it Tagamet emical name is cimetidine). Thereafter three companies followed suit— with Zantac (ranitidine) in June 1983, Merck with Pepcid (famotidine) ober 1986, and Lilly with Axid (nizatidine) in April 1988. Each of these $_2$-antagonists is a slightly different chemical entity. Tagamet's patent pro- could not prevent entry by such therapeutic substitutes.

tac was marketed very aggressively by Glaxo, in partnership with ann-LaRoche, and was also priced at a premium over Tagamet. Detailers epresentatives who call on physicians) emphasized that unlike Tagamet, original dosage required it to be taken four times daily, Zantac needed aken only twice per day. Moreover, Zantac detailers highlighted side- profiles that had accumulated with Tagamet—nausea, diarrhea, drowsi- ecreased sperm count, gynecomastia (swelling of the breasts in males), g interactions.[4] Within eighteen months Tagamet responded to Zantac oducing a twice-per-day version of its drug, but it continued to find n the defensive in terms of alleged side-effect and adverse-interaction . A prolonged rivalry then ensued, first between Tagamet and Zantac in n of new versions whose dosages were but once per day (thereby facili- atient compliance even further), and later including additional competi- m the newly entered Pepcid and Axid, each available with a once-daily regimen.

ldition to side-effect profiles and frequency of dosage, another form ry among the four H_2-antagonists involved FDA-approved treatments tions). Since several distinct types of ulcerous conditions exist, similar oducts can compete on the basis of efficacy for different indications. In ted States, before a drug can be introduced into the market, the FDA ant approval for at least one indication. When Tagamet was originally ed into the U.S. market in August 1977, its approval was for duodenal

met was introduced into the United Kingdom one year earlier, in 1976.
une 1983, Tagamet had registered ten adverse interactions at the FDA. Zantac recorded verse interaction in January 1992.

ulcers; Tagamet was also the first to be approved for duodenal ulcer maintenance treatment (to prevent recurrence of a newly healed duodenal ulcer) in April 1980, and gastric ulcers in December 1982. However, Zantac was the first to obtain approval for the GERD indication (May 1986),[5] and it was not until March 1991 that Tagamet obtained FDA approval for GERD. It is worth noting that once FDA approval for an indication is granted, the manufacturer is permitted to provide promotional and marketing material *only* for approved indications. Thus, even though Tagamet had clinical effects very similar to Zantac's, suggesting that it would probably be effective in the treatment of GERD, Tagamet promotions were not permitted to mention GERD until 1991. Although physicians often prescribe drugs for indications not approved by the FDA (called off-label prescribing), not having FDA approval for an indication which is held by a competitive product may constitute a signficant disadvantage in the marketplace. Hence, even though Tagamet pioneered in the three antiulcer indications, the fact that it lagged behind Zantac in the relatively populous GERD market was of considerable importance.

Today the four H_2-antagonist drugs are frequently viewed as being "... equally efficacious in their ability to suppress acid secretion" (McKenzie et al. 1990, 58), but different in their pharmacological profiles. McKenzie et al. note that Tagamet is "the H_2-antagonist implicated with the most side effects and drug interactions," and that such adverse impacts occur "to a lesser extent" with Zantac. The third and fourth entrants—Pepcid and Axid—appear to have even fewer drug interactions and side effects. What is not yet clear, however, is the extent to which apparent differences in side-effect profiles simply reflect differential lengths of time over which the various drugs have been able to accumulate medical experience.

Modern ulcer medicines are not restricted to H_2-antagonists. One alternative therapy is Carafate (sucralfate), introduced into the United States by Marion Labs in August 1981. Instead of inhibiting acid secretion, Carafate acts by forming a protective coating over the ulcer that in turn promotes healing. While it is relatively free from side effects, Carafate has problems of convenience and compliance, since it must be taken four times per day, always on an empty stomach (before meals). It also acts more slowly than the acid inhibitors in relieving pain. For these reasons, Carafate serves a market niche, being used predominantly for older patients and patients in intensive care.

Another entrant in the antiulcer market is Cytotec (misoprostol), introduced in December 1988. Cytotec has been targeted at ulcers associated with the use of nonsteroidal anti-inflammatory drugs (NSAIDs—pain relievers such as Motrin). Its rather small market niche consists of patients who take NSAIDs chronically and are at greater risk for the development of peptic ulcer disease or complications from peptic ulcers—particularly the elderly, those with previ-

5. Discussions with industry officials suggest that Glaxo actually invented the GERD indication at the FDA.

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