INFLUENCE ON CONSUMER BEHAVIOR: THE IMPACT OF DIRECT-TO-CONSUMER ADVERTISING ON MEDICATION REQUESTS (STUDY CASES FOR GASTROESOPHAGEAL REFLUX DISEASE AND SOCIAL ANXIETY DISORDER TREATMENT IN UNITED STATES)

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Abstrak: Sebuah survei yang menggunakan 68 pertanyaan melalui internet yang digunakan untuk menentukan dampak dari *televised direct-to-consumer advertising* (DTCA) pada konsumen yang diprakarsai perubahan pengobatan penyakit *gastroesophageal reflux* (GERD) dan *sosial anxiety disorder* (SAD). Dari 427 responden, 10% pasien GERD yang melihat DTCA dan 6% pasien SAD yang melihat DTCA melaporkan bahwa mereka kemudian memulai percakapan dengan dokter mereka. Hampir setengah dari responden, 47,4% untuk GERD dan 40% untuk SAD, melaporkan bahwa perubahan dalam terapi terjadi sebagai akibat langsung dari diskusi dengan dokter. DTCA melalui televisi untuk kedua golongan obat dapat memiliki dampak yang signifikan pada pasien yang memulai dalam hal permintaan resep.Reaksi terhadap DCTA untuk obat resep memang beragam. *Proponent* berpendapat bahwa hal itu menyediakan konsumen dengan informasi tentang pilihan pengobatan, dan mungkin membantu untuk meningkatkan kesadaran masyarakat, dan akibatnya pengobatan, penyakit serius seperti diabetes, hipertensi, atau depresi. Di lain pihak,mereka juga khawatir bahwa DCTA tidak tepat dapat meningkatkan permintaan pasien yang spesifik, dan umumnya mahal, agen, dan bahwa permintaan ini mungkin memiliki efek negatif pada praktek medis dan pada hubungan dokter-pasien. Isi iklan yang ditujukan untuk dokter telah diteliti, tetapi mereka ditujukan untuk pasien telah kurang mendapat perhatian. Tujuan penelitian ini adalah untuk membangun pesan yang sedang diterima oleh masyarakat dari DCTA. Berdasarkan sampel kecil, DTCA yang melalui televisi untuk obat yang digunakan untuk mengobati GERD dan SAD dapat memiliki dampak yang signifikan pada kedua pasien yang diprakarsai atas permintaan resep dan praktek resep dokter dan dapat mengakibatkan perubahan terapi untuk penyakit ini.

Kata Kunci: DCTA, Perilaku Konsumen, Persepsi, *Brand value*

Background

The first direct-to-consumer advertisement for aprescription drug appeared in *Reader's Digest* in 1981in USA. Over the next few years, other suchadvertisements were published, and the US Food andDrugs Administration (FDA) became worried thatlittle was known about the potential effect of suchadvertisements on the public.

Consequently, in 1983,the FDA initiated an advertising moratorium while itstudied the issues and considered the regulatoryoptions. Although they concluded that "direct tothe public prescription advertising was not in thepublic interest," the FDA lifted the moratorium in1985 because of concerns about freedom of speechand a general consensus that regulations alreadyin place were sufficient to protect the consumer.After the moratorium had been lifted, directto-consumer advertising was permitted providedthat the advertisements met certain criteria;specifically, that they presented true and balancedinformation about the side-effects of the drugs,and their contraindications and effectiveness.The FDA monitors compliance with these criteria.

However, prior approval of drug advertisements is notrequired.Reaction to direct-to-consumer advertisements forprescription drugs is mixed. Proponents argue that itprovides consumers with information about treatmentoptions, and might help to increase public awareness,and consequently treatment, of serious diseases suchas diabetes, hypertension, or depression. Opponents,however, are worried that direct-to-consumeradvertisements might inappropriately increase patientdemand for specific, and generally costly, agents, andthat this demand might have a negative effect onmedical practice and on the physician-patientrelationship.Over the past few years, investment in direct-toconsumeradvertising in this field has risen, and nowexceeds US$1 billion Concurrently,many pharmaceutical companies have reduced theamount spent on direct-to-physician advertising,which suggests a tactical shift in their focus fromphysicians to patients. Last year, for example, drugcompanies spent more on advertisements innewspapers and popular magazines than they did inmedical journals ($685 million *vs* $473 million,respectively) (www.imshealth.com accessed on Aug25, 1999).

The content of advertisements aimed atphysicians has been researched, but those aimedat patients has received less attention. Our aimwas to establish what messages are being receivedby the public from direct-to-consumeradvertisements. Although such advertisements forprescription drugs only appear in the USA andNew Zealand, the lessons drawn from theAmerican experience might be of relevance in theUK, where the debate over this type ofadvertisement is just beginning.

Direct to consumer advertising (DTCA) of prescription medicines is a hotly debatedtopic: in the United States and New Zealand, the only countries where it is fullyallowed; as well as the European Community, Canada and Australia whereregulatory changes to ease current restrictions are being or have recently beenconsidered. Medicines agencies and governments in these countries are examiningand reporting on the issue frequently. Those governments that already allow DTCAhave continued its use, though with additional restrictions, after their most recentreviews (Meek, 2001a; Meek, 2001b).

Direct-to-consumer advertising (DTCA) is a controversial topic among health careproviders, professional organizations, and pharmaceutical manufacturers.Advocates state that DTCA empowers patients with the information needed to morefirmly grasp control of their own health care decisions (Bonaccorso & Sturchio,2002; Calfee, 2007; Holmer, 1999, 2002) and helps patients initiate conversationswith their physicians about sensitive health topics that they otherwise may have beenunable to broach (Calfee, 2007; Donohue, 2006; Kravitz et al., 2005). On the otherhand, critics of DTCA say that it increases health care costs and leads to

conflictbetween the provider and the patient (Aikin, Swasy, & Braman, 2004; Kravitzet al., 2005; Mintzes et al., 2003; Robinson et al., 2004; Spence, Teleki, Cheetham,Schweitzer, & Millares, 2005; Weissman et al., 2004). The vast majority of governments have decided to ban or heavily regulate DTCA due to lack of evidence thatit is truly beneficial to the patient and other health care team members. Theirconcerns center around its potential as a catalyst for increased medication prescribingand health care costs, with the United States and New Zealand being the onlyexceptions to these stiff regulations (Auton, 2006; Brownfield, Berrnhardt, Phan,Williams, & Parker, 2004; Mintzes et al., 2002).

The billions of dollars that pharmaceuticalcompanies spend annually on advertising in the United States are staggering,with an increasing amount of the funds being designated for television campaigns(Rosenthal, Berndt, Donohue, Frank, & Epstein, 2002). In 2006, a total of 12 billionadvertising dollars were spent by the pharmaceutical industry, with 40% of that figureearmarked for DTCA (IMS Health, 2007). The drug companies typically concentratetheir advertising efforts on a select few patent-protected products that havemild side effects and are used to treat chronic health conditions that patients alreadymay feel comfortable self-treating (Findlay, 2002; Rosenthal et al., 2002; UnitedStates General Accounting Office [USGAO], 2002). Research has shown that theclasses of medications most heavily advertised are antidepressants, antihistamines(i.e., used to treat allergies), antihyperlipidemics (i.e., used to lower cholesterol),nasal sprays, and proton pump inhibitors (i.e., used to reduce gastric acid and treatcondition such as gastroesophageal reflux disease or GERD; Rosenthal et al., 2002).

These five classes account for approximately 60% of all DTCA dollars spent(Rosenthal et al., 2002).One forward-thinking study conducted by Bell, Kravitz, and Wilkes in 1999used a phone survey of 329 California patients to measure the actual influence thatDTCA has on the patient–physician interaction. The authors found that 19% ofpatients had asked for a prescription as a result of viewing DTCA and 35% soughtmore information from their health care providers regarding a DTCA medication.This study did not attempt to determine or isolate the effect of any particular typeof DTCA the patient may have encountered, such as television, print, radio, orInternet.The influence of DTCA on the patient–physician relationship also was studiedby Mintzes and colleagues, who administered a patient–physician paired survey to78 physicians and 1,431 patients in doctors' offices in Sacramento, California, andVancouver, British Columbia, to capture data regarding the influence of DTCAon consumer behavior and its impact on physician prescribing (Mintzes et al.,2002; Mintzes et al., 2003). The authors reported that patients who requested aDTCA medication from their doctors were more likely to receive one or morenew prescriptions than those patients who did not discuss advertised medications(Mintzes et al., 2003). Of the 12% of respondents who actually requested a medicationfrom their physician, 42% of the requests were for an advertised medication(Mintzes et al., 2002). Again, this study, as well as several others (Datti & Carter,2006; Murray, Lo, Pollack, Donelan, & Lee, 2004; Robinson et al., 2004), did notfocus on televised DTCA exposure, but rather examined the influence of other typesof advertising viewed.

To the best of the authors' knowledge, this is the only study in the publishedliterature that conducted Internet-administered survey research to attempt topinpoint the effect of advertising specific to television. Television

advertisementviewing influences consumer behavior for products other than pharmaceuticals,and it is reasonable to assume that the average of 16 hours a year that consumersview televised DTCA is going to be influential on patient attitudes and behaviorsas well (Brownfield et al., 2004). This study endeavors to discover the specificinfluences of television DTCA and seeks insight from a targeted population byutilizing the Internet for data collection.

The conclusions of these national agency reviews, as well as those by specialisedanalysts such as Barbara Mintzes from the University of British Columbia, is that theevidence for either the positive or negative effects of DTCA on health outcomes isinsufficient. Increases in medicines use are self-evident consequences ofadvertising. Interpretations of the limited studies on whether consumers and healthsystems benefit from this change are polarised. Indeed the New Zealand policyreview on DTCA reported to its Minister (Ministry of Health, 2001):

Despite concerns about the quality and interpretation of the evidence, there areareas where there is little disagreement between the parties. DTCA undoubtedlyincreases medicine enquiries by consumers to prescribers, and subsequentprescribing to consumers. It is more commonly used for high cost, newermedicines, targeted at long-term use by large populations (NIHCM, 1999, Rosenthalet al, 2002). It has met with limited enthusiasm from government, professionalsand consumers and been the subject of public controversy and governmentresponses in a number of instances involving questions of advertising standardsand/or safety (HAI, 2001a, b).

DTCA usually occurs as a component of much wider scale, longer term and lessvisible marketing and public relations plans, involving the media, medical andcommunity opinion leaders, researchers and clinicians, community organisationsand patient groups (NIHCM, 2000, Rosenthal et al, 2002). Integrated marketingcampaigns involving components directed at professionals, consumers andpayers/formulary managers have been described as the way of the future (Scrip,2000).

The movement to DTCA across many countries reflects internationalpharmaceutical companies responding to competitive pressure as both health careproduct providers, and important industry partners to governments. Discovery ofnew chemical entities has slowed and the requirement to maintain revenuesexpected of the industry has forced greater emphasis on ways to boost salesthrough marketing. The rise of consumerism is also cited as a factor, making itmore effective for patients to influence their doctors than in the past (Meek, 2001,pp.4-6). DTCA may also be seen by pharmaceutical marketers as a way ofovercoming attempts by health care systems to limit doctors' prescribing - by usingconsumers to drive demand (Pharmaceutical Marketing, 2001).

A broader consideration of the DTCA policy context is also required. The transnationalnature of the industry is demonstrated in the current concerted effortacross many jurisdictions to reduce regulatory controls around advertising ofprescription medicines. Recent decisions by the European Union andrecommendations of a review in Australia now show similar direction of movement.The industry is also important to national economies: Charles Medawar hasdescribed the concern at high levels of government in Europe about a threatenedexodus of pharmaceutical companies to the USA, based on industry

claims of“external constraints and pressures” and “hostile” market conditions such astighter regulation, price controls and increased emphasis on drug evaluation (SocialAudit, 2002).

The proponents and lobbyists for DTCA extend beyond health product and serviceproviders to include advertising agencies, public relations and media (includingmagazines, newspapers, radio and television) with obvious interest in thesubstantial expenditure and activity in advertising medicines. Advertisingstrategies currently being used in Australia are similar to those for other productssubject to advertising restriction or prohibition: creating indirect references to theproduct through general awareness campaigns by the product promoter; linkedmedia campaigns using print, television and the internet; the use of sponsorship;and creating associations between product packaging and marketing campaignimages and colours.

Responses to DTCA in other countries reflect different aspects of Australia’scomprehensive approach to medicines policy. Proponents and opponents'arguments touch on safety and quality, access through direct and subsidised coststo consumers, judicious, safe and appropriate medicines use, and industryconsiderations. It is therefore important that the forms of DTCA in Australiacurrently occurring and proposed be considered within the National MedicinesPolicy framework.

Objective

The objective of this study is to determine the impact that DTCA has on consumerinitiatedmedication changes for the treatment of GERD and SAD.

The Development of DTCA Across Countries

The most comprehensive recent literature review on DTCA was conducted byBarbara Mintzes of the Health Policy Research Unit at the University of BritishColumbia (Mintzes 2001, Vol 2). Mintzes’ review of the literature forms part of alarger report funded by Health Canada of the health system impacts of DTCA. Thereport is publicly available on the University website.Mintzes’ review gives comprehensive analysis of the international evidence onDTCA, and charts its development in the United States and New Zealand (Mintzes2001 Vol 2. pp. 22-31). As these two countries represent the only fully developedmodels of DTCA, they illustrate many of the issues involved. They each show arapid rise in DTCA in a short period of time, boosted by regulatory relaxation.Public and professional concern in both countries has prompted ongoing inquiry andreview over twenty years, though with little new contribution to the evidencebase.

It is important to note that in both the US and New Zealand, legislation has neverspecifically prohibited advertising prescription medicines to consumers. In each,take-up of the opportunity for DTCA has only occurred within the last twenty years.In both countries expenditure on DTCA and the number of products has acceleratedrapidly in recent years.United StatesDTC advertisements in the US can be classified into three types, useful for broadlyconsidering the scope of this form of advertising. “Help seeking” ads are ones inwhich people are alerted to a condition or disease, informed a treatment isavailable and encouraged to see their doctor. A company name can be used.“Reminder” ads give the name of the medicine, but not the disease or conditionand are designed to build brand name recognition. “Product

claim" ads name abrand and its intended use and, unlike the other categories must meet morestringent requirements for presentation, summaries of information and contacts forfurther information (NIHCM, 2000, p.14).In the US, only one prescription medicine was being advertised in 1981; by 1989, 21companies were advertising 30 products. Throughout that decade DTCA wasprincipally about disease states and did not mention specific product names(Mintzes 2001 Vol 2. pp. 22-31).An early DTCA campaign for benoxaprofen led to 500,000 prescriptions in a fewmonths. The product was subsequently withdrawn following deaths from liverfailure, prompting the US Food and Drug Administration to call a voluntarymoratorium in 1983 to research DTCA and any legislative options required. Theadvertisements were already subject to regulatory action because ofunsubstantiated claims for its use in the treatment of arthritis (Mintzes 2001 Vol 2.p.7).

At a 1984 FDA symposium on DTCA the head of the Drug Advertising Branch statedthat the major conclusions of the symposium were that virtually no-one was infavour of DTCA, it would serve no educational purpose and would be veryexpensive. Despite this, it was seen as inevitable and driven by the vestedinterests of advertising agencies (Mintzes 2001 Vol 2. p.8).Even members of the US pharmaceutical industry were opposed to DTCA in 1984.At one industry symposium, 80% of executives were opposed, based on concernsabout product liability, increased costs of marketing and lower profitability. Oneindustry director noted that if companies thought their product was appropriate forOTC type marketing, they should apply for it to have OTC status (Mintzes 2001 Vol2. p.7).

The FDA moratorium ended in 1985, without any new or changed legislation. It wasconsidered that DTCA could be regulated in the same way as advertising to healthprofessionals. Total expenditure on DCTA grew from US$35M in 1987 to US$695M in1996, with nearly 80 products being advertised by that time (Mintzes 2001 Vol 2.p.8).

In 1995 the FDA held further consultations, in an environment where industry wasnow much more supportive and active in using DTCA. A key regulatory identified by industry by that time was the requirement for a summary of labellinginformation to be included in "product claim" advertising, which made TVadvertising difficult. Most had got around this requirement by only using"reminder" ads, which mention the product name, but make no health claims. Theregulatory basis was that these were allowed in advertising to health professionals,however FDA noted that consumers found such ads unclear about what conditionthe product treated (Mintzes 2001 Vol 2. pp. 8-9).

In 1997, the FDA issued a draft guidance, removing the requirement for thelabelling summary, and replacing it with a statement of the product's major risksand providing sources of further information including toll free numbers, websitesand simultaneous print DTC ads in doctors offices, libraries and stores (Mintzes2001 Vol 2. p.9).

This change led to further growth in DTCA with a move in expenditure totelevision; the growth in total DTCA expenditure accelerated to over US$1.1 billionin 1998 and $US2.5 billion in the year 2000 (NIHCM, 2000, p.3). In 2000 itaccounted for just under 16% of total spending on promotion (Rosenthal et al,2002). US television viewers are reportedly exposed to an average of nine DTCAslots a day (Lancet, 2002).The evidence shows a move to "reminder" and

"product claim" advertisementsrather than "help seeking" ads as regulation has relaxed. Of the total spent onDTCA in 2000 in the United States, 85% was spent on brand name advertising, whilethe remainder was spent on disease state advertising (NIHCM, 2000, p.11).New ZealandMintzes' review shows New Zealand experienced growth in DTCA similar to the USin the short period from its beginning circa 1995. Only 10 products were advertisedin the period 1996 –1999, but 46 were advertised in the period 1999 –2000 (Mintzes2001 Vol 2. pp. 22-31).

A major concern in New Zealand has been the direct to consumer advertising ofsubsidised medicines with consequent impacts on demand and costs. Pharmac, theagency responsible for subsided medicines, noted that 20 of the productsadvertised in 1999-2000 were in this category. Attempts to ban DTCA of subsidisedmedicines were unsuccessful.Public concern about the campaign for orlistat (a medicine for weight loss) led to apolicy review in 2000-01; additional concerns were raised when an asthmamedication (montelukast) was promoted with an offer of one month's freemedication (thereafter the cost to the consumer being $118 per month). A currentanti-smoking medicine campaign offers to pay for the first visit to the GP (personalcommunication, 2002).Pharmac expressed major concerns to the policy review in which it called for DTCAto be banned (Mintzes 2001 Vol 2. pp. 22-31).

The New Zealand Ministry of Health discussion paper canvassed the arguments forand against DTCA and proposed 4 policy options, from the industry self regulatingstatus quo to a complete ban (Ministry of Health 2000).The discussion paper argued "for" and against" cases about DTCA, that it:

- Improves/does not improve some people's access to information
- Raises/does not raise fiscal pressures
- Damages/preserves-enhances the doctor-patient relationship
- Encourages/does not encourage medicalisation.

Despite the history of DTCA and obvious concern among stakeholders, the reviewpaper noted that evidence to support these arguments was limited, and this wasconfirmed in the subsequent policy advice to the Minister (Ministry of Health,2001). The decision of the NZ Government after this review was to retain DTCAbut introduce some new restrictions, for example, on pharmaceutical companysponsorship of events (Ministry of Health, 2001).

In December 2003 the Australian and New Zealand governments signed a treaty tocreate a single agency regulating the registration and promotion of drugs,complementary health products, and medical devices. While this will still allow forAustralia and New Zealand to maintain different policies on DTCA of prescriptionmedicines, the New Zealand Minister for Health was reported in early 2004 to beseeking approval from the New Zealand cabinet for the adoption of commonstandards with Australia on the marketing of medicines, as a way of instituting aban on advertising prescription-only drugs directly to consumers (Burton, 2004).Work in Australia and New Zealand is now (April 2004) well progressed for thedevelopment of a single Trans-Tasman regulatory authority to replace theTherapeutic Goods Administration and a new Trans-Tasman advertising code toreplace the Australian Therapeutic Goods Advertising Code. PHARM has providedinput to these initiatives and supported the proposed maintenance of existing lawscovering DTCA in Australia.

The European Community

The introduction of DTCA was under active consideration in Europe in 2002. It wasproposed that DTCA be allowed in relation to drugs for three conditions for a fiveyearperiod after which a review will occur. Reports from the EC were conflictingabout whether the trial would allow DTCA by companies only in response torequests from patients, or whether it would allow broader advertising (HAI, 2002).

In October 2002 the European Parliament rejected the proposal.As in Australia, more indirect forms of promotion, such as disease awarenesscampaigns, have been a feature of the European scene for some time.

Canada

In Canada regulations permit some forms of DTCA – disease awareness advertisingthat does not mention a product, and advertisements that mention the productname but not the condition for which it is used. However, many Canadians areroutinely exposed to DTCA as much of the cable and satellite television access is toUS stations, governed by US regulations.

DTCA in the Australian context

Australia differs from each of the other jurisdictions in having a comprehensiveNational Medicines Policy (NMP) (Commonwealth of Australia, 2000). The NMPmandates consideration of quality use and equitable access, as well as themaintenance of a responsible and viable pharmaceutical industry; providing anopportunity for partnership approaches to DTCA with a goal of maximising benefitsand minimising harm for all stakeholders. The framework of the NMP also providesa useful environment for testing the outcomes of medicines promotion forgovernment, industry, providers and consumers.DTCA also has a major bearing on another arm of the NMP – access to affordablemedicines – to the extent that it increases demand for new expensive medicinesthus putting additional pressure on the viability of the PBS and/or some consumers'ability to afford higher co-payments.Much of the claim for DTCA is about harnessing the obvious commercial selfinterestand technical knowledge of the company in the service of improved QUMthrough better-informed consumers (Bonaccorso and Sturchio, 2002). Much of thecounter-claim is about potentially poorer use of medicines through medicalisationand lack of awareness of the full range of products available. Carefully designedstudies within comprehensive analysis of the marketing campaign and consumerresponses would assist in determining effects and ensuring efforts are directed tothe best possible outcomes for all stakeholders.

The Current State of DTCA in Australia

Advertising of medicines is governed by the Therapeutic Goods Act and twoindustry codes of practice: the co-regulatory Therapeutic Goods Advertising Codewhich covers promotion to the public of over-the-counter and complementarymedicines, and the self regulatory Medicines Australia Code of Conduct. The lattercontains a section on Communications with the Public, which covers such mattersas media statements, general media articles and patient education (MedicinesAustralia 2003).In January 2003, a new edition of Medicines Australia's Code of Conduct becameeffective. In relation to communications with the public, it

contains new clausescovering media releases about named prescription products and about companyinvolvement in patient support programs.In December 2003, the Australian Competition and Consumer Commission grantedauthorisation of Edition 14 of the Code subject to conditions requiring MedicinesAustralia to:

- Undertake greater monitoring of pharmaceutical company promotionalactivities; and
- Publish full details of all breaches of the Code on its website (ACCC, 2003).

In 2001 the Review of Drugs Poisons and Controlled Substances Legislation usefullydescribed the purpose of requiring a prescription for a medicine (Galbally, 2001.p.37):

By requiring that a prescription be obtained for the medicine, the intention isto overcome the consumers' lack of knowledge and understanding to:• Diagnose the condition from which he or she is suffering;

- *Determine the most appropriate treatment; and*
- *Use the product safely and effectively.*

Galbally notes that restrictions on advertising "… are not intended to depriveconsumers of information about medicines …". They incorporate the provision ofinformation through a 'learned intermediary': the doctor and pharmacist(Galbally, 2001. p.87). The Review notes later that arguments for DTCA are basedon the assumption that doctors will act as a "… perfect gatekeeper (with) up-todateknowledge, a capacity to evaluate promotional material and to communicateabout the treatment with patients" (Galbally, 2001. p.90).

Despite the existence of laws at State, Territory and Commonwealth level thatexplicitly prohibit any person publishing an advertisement about a prescriptionmedicine, the Review noted these limits were being tested in 2001:

A number of advertisements highlighting a disease state withoutmentioning a product or the company that sponsored the advertisementshave been brought to the Review's attention. The advertisements andsurrounding public relations activities have ensured that most people wereaware which product was being advertised. The advertisements did notbreach the advertising regulations and the industry association was unableto deal effectively with the situation particularly where the companieswere not members of the association.

Citing this and other concerns to stakeholders, the Review concluded that selfregulationor co-regulation of the advertising of prescription medicines using acode of practice would be unlikely to achieve the necessary controls. However, itproposed allowing government to solicit advertisements as part of a disease stateeducation strategy and to allow advertising of prices, the distribution of ConsumerMedicine Information and disease state advertisements according to codes ofpractice, with adequate safeguards to prevent unscrupulous suppliers exploitingthe advertisements (Galbally, 2001. p.92-3).

DTCA and QUM

DTCA and judicious use, including the consideration of non-medicine optionsDTCA may promote the use of medicines more prominently than non-medicinealternatives. The evidence based on expenditure and market development alone isthat DTCA works in promoting demand. Indeed, it has been described as "thewonder drug for the pharmaceutical industry itself" because of its ability to affectpatient demand and, in turn, prescribers' behaviour (Hoffman and Wilkes, 1999).Mintzes notes that well designed studies of information content in DTCA have foundtheir information quality to be poor, with factual inaccuracies and inadequatebalance of benefit and risk information. Over half of the 1998 US broadcast adsviolated US regulations (Mintzes 2001 Vol 2. p.iv).US pharmaceutical consulting firm Scott-Levin has described the effect of brandadvertising. It reported in 1998 that visits to doctors for heavily advertisedconditions rose 11% compared to a 2% increase in total office visits in the periodJanuary and September. Visits for high cholesterol rose 26% (Scott-Levin 1998b).In another release by the same company, a spokesman reported:

"DTC is not only raising consumer awareness of available treatmentoptions, it is driving patients to their physicians to further discuss theseoptions, with these same patients frequently requesting a specificmedication by name. Physicians are also honouring these drug requests".

The research showed requests for loratidine (antihistamine) were honoured 86% ofthe time and for pravastatin (lipid lowering) 93% of the time (Scott-Levin, 1998c).Mintzes has identified and analysed 22 consumer surveys on DTCA reported in theperiod 1991-2001. While there are considerable variations and limitations insample and methodology, a number of findings are suggested by this evidence(Mintzes 2001, Vol 2. pp.32–52).In US random sample surveys, DTCA prompted between 20 and 30 percent ofconsumers to speak to their doctor about a medicine. Up to 10% of these directlyrequested a medicine and over 80% of these received it. Up to half of theconsumers in one survey indicated they would switch doctors if they did notreceive a prescription they requested.This may be a particular concern under the Galbally proposals (Galbally, 2001.p.93), where government is encouraged to solicit advertising from companies aspart of disease state advertising. Consumers' capacity to choose based on normalsources of objective information may be severely compromised where multiplesources of information are mobilised, coordinated and resourced by thepharmaceutical company.

There is concern about the 'medicalisation' of minor or self-limiting conditions as aproduct marketing strategy (Moynihan, Heath and Henry, 2002). This involvescoopting medical and consumer advocates in large-scale strategies to promote thesponsors' medicine for an otherwise "under-treated" condition. In this instanceDTCA can promote large-scale uptake of medicines that would otherwise be usedsparingly, if at all. It leads to the development of new health expenditures byconsumers, governments or both.

DTCA and appropriate selection, when a medicine is chosen as the best therapyMintzes notes one report by PHARMAC in New Zealand, where brand promotion of asteroid inhaler for asthma (fluticasone) was associated with substitution of thisproduct for a less expensive but therapeutically equivalent

beclomethasoneinhalers (Mintzes 2001, Vol 2. p. vi).The availability of Consumer Medicines Information (CMI) as approved objectiveinformation about a medicine may assist appropriate use. However, interpretationof the CMI is envisaged to take place in consultation with an independent "learnedintermediary" and in an environment of peer and community support based onobjective evidence.CMI cannot assist appropriate selection by consumers as it is product specific anddoes not provide comparative drug information. DTCA is also product specific. Thefull range of therapies available are not all advertised, with bias towards newerand more expensive therapies. DTCA is unlikely to provide consumers withobjective comparative drug information to assist them with appropriate selection.

There also may be risks from overuse of medicines and/or sharing resulting fromDTCA, given the persuasive and credible nature of advertising, the limited brandmarketing objective and the risk of consumers not pursuing or finding sufficientobjective information through other channels.DTCA and safe and effective useA significant consideration in DTCA in the Australian context is the role of thescheduling of medicines. Galbally notes that scheduling reflects the level ofprofessional advice and counselling necessary to overcome the informationasymmetry between the consumer and sponsor of the product. The level ofrestriction is based on the hazardous properties of the substances and the risksassociated with supplying and using products containing them (Galbally, 2001.p.33).

A consistent finding across the US surveys on DTCA and replicated in New Zealand isthat consumers regard the existence of medicine advertisements as an indication ofgovernment-approved safety and low risk. A 1999 FDA survey found that more thanhalf of the respondents could not explain what prescription-only meant and onequarter thought that only the safest medicines could be advertised to the public.Galbally (2O01) considered that there was enough anecdotal evidence to concludethat at least some consumers equate advertising with safety and this creates "particularly risk-laden situation" especially where the provider fails to providenecessary counselling and CMI (p.90).

Similarly, there are consistent survey findings that consumers overestimate thequality and scope of information in DTCA. For example, a New Zealand survey ofwomen assessed their responses to an advertisement for Cyproterone. Forty-fivepercent thought the ad gave them enough information on whether to take themedicine and 27% thought it clearly stated the risks and benefits. The only risk statement was:

"Diane-35 has a similar side effect profile to other oral contraceptives.Some women should not use Diane-35".

Cyproterone is associated with serious risk for liver toxicity, higherthromboembolic risks than other oral contraceptives and has been restricted fromuse as a contraceptive in Europe. A coplaint about the advertisement wassubsequently upheld."Prevention" magazine surveys in the US in 1998 and 1999 found that whilerespondents were increasingly aware of the advertisements, many were unaware ofwhat conditions they treat. Mintzes notes (2000, v.2 p.39):
Most people who were aware of ads for a drug and had the conditionremained unaware of the drug's indication. These results suggest that inmany cases DTCA is

more successful in stimulating brand recognition thanin conveying information about conditions for use such as the drug'sindication.

There have been several instances of extensive DTCA and promotion leading tosignificant uptake by consumers, with subsequent concerns about and/orwithdrawal of the medicine (HAI, 2001b; Mintzes 2001, Vol 2. pp.32–52)). This maybe a particular problem without good adverse event reporting and in a regulatoryenvironment where fast track processes enable market availability without fullsafety data.DTCA as a contributor to medicines educationEducation and information is an essential part of the National Medicines Policy andin particular the Quality Use of Medicines. Industry is an important contributor toresearch and development, professional and consumer education and information.It benefits from appropriate use, through the capacity to enhance markets andprofitability through addressing under-use and in reduced product liability(National Medicines Policy 2000, p.7).

A typical statement of the educational claims for DTCA is a quote from a VicePresident of Marketing for Zeneca Pharmaceuticals:

DTCA allows ethical pharmaceutical companies to educate patients on therange of options that are available to help them manage their diseasestates. Since companies are expected to and in fact should always promotethe safe use of products, education should provide the foundation for theoverall communication programme. (In Meek, 2001, p.19)

As noted earlier, well-designed studies of information content in DTCA have foundtheir information quality to be poor with factual inaccuracies and inadequatebalance of benefit and risk information (Mintzes 2001 Vol 2. p.iv).In discussing the question of whether DTCA improves consumer access toinformation, the New Zealand Ministry of Health discussion paper noted that theirmedicines agency MedSafe found just 33% compliance with DTCA regulation byprescription medicines advertisements in 1998 and only two thirds compliance in1999 (Ministry of Health 2000). The discussion paper comments:

The record of the industry in New Zealand has caused concern. Medsafe'sFebruary 2000 examination of non-compliance suggests that the status quoDTCA position is unlikely to guarantee a medicines advertising environmentthat, on balance, will provide either net health benefits or, at least, anabsence of net health costs in terms of information transfer.

This comment, similar to that of Galbally about the capacity for regulation ofadvertising by the industry in Australia (Galbally, 2001. p.92-3), raises questionsabout how pharmaceutical companies perform in publicly agreed education andinformation partnerships with other stakeholders.Medicines education as a vehicle for DTCADirect-to-consumer advertising is just one channel in the marketing mix formedicines and typically occurs together with marketing to doctors and samplegiveaways (National Institute for Healthcare Management, 2000, p.5). Ultimately,consumers pay for medicines promotion (Hoffman and Wilkes, 1999). In

the US in2000, DTCA at US$2.6 billion added to the US$4 billion spent on physician officedetailing and over US$8 billion retail value spent on samples (NIHCM, 2000, p.4).

DTCA has raised significant concern among professionals. Over half of USphysicians surveyed by the pharmaceutical consulting company Scott-Levin in 1998said their attitude to DTCA was negative. More than half disagreed that DTCA "is areliable source of information; over 60% disagreed with the statement "DTC givesthe public information it can't get anywhere else" and "it's an objective source ofinformation" (Scott-Levin, 1998a).Australia also provides a number of avenues for medicines promotion, informationand education, including advertising to prescribers in professional journals,sponsorship of professional organisations, events and meetings, medicines detailingto doctors by company sales representatives and the provision of free "samples"through that representative system. It is also now commonplace to use medialaunches for promotion to the public through news and current affairs publications;and direct to consumer advertising such as the unbranded examples cited byGalbally above, with links to internet sites, patient groups and further productinformation.

A Cochrane review shows that mass media approaches influence health servicesutilisation and can have an important role in both encouraging the use of effectiveservices and discouraging those of unproven effectiveness. The reviewers statethat the evidence supports the importance of ensuring that reporting in the laymedia correctly represents best available knowledge (Grilli R et al, 2002).

Medicines Australia's Code of Conduct says that promotion in patient associationpublications is regarded as promotion to the public, but does not cover otherrelationships with and sponsorship of patient support groups. The ConsumersHealth Forum has guidelines for consumer organisations about industry funding ofconsumer education and a group of companies has similarly developed guidelinesfor partnerships with consumer organisations (CHF, 2001, Tasker et al 2002).Neither has any formal status at present.Concerns have been raised in Australia about both the primary motivation andmethods used in several examples of such campaigns by pharmaceuticalcompanies. Campaigns for medicines use in baldness, irritable bowel syndrome,social phobia, osteoporosis and erectile dysfunction have been shown to usesophisticated marketing and promotion plans involving raising awareness of thecondition and their product through the cooption of medical opinion leaders,distribution of background media stories, development of foundations and lobbygroups. Much of this activity includes promotional and monetary incentives forparticipants such as grants, donations, meetings, conferences and prizes(Moynihan, Heath and Henry, 2002).Moynihan et al suggest that such campaigns skew appropriate consideration oftreatment options:

… within many disease categories, informal alliances have emerged,comprising drug company staff, doctors and consumer groups. Ostensiblyengaged in raising public awareness about under diagnosed and undertreated problems, these alliances tend to promote a view of theirparticular condition as widespread, serious and treatable. Because these"disease awareness" campaigns are commonly linked to companies'marketing strategies, they operate to expand markets for newpharmaceutical products. Alternative approaches … are played down orignored.

DTCA proponents argue that advertising is just one channel in a variety ofinformation available to consumers (Bonaccorso and Sturchio 2002):

… consumers and patients are already inundated with myriad sources ofhealth information. The real question is how to ensure that people haveaccess to the best quality of information they need, when they need it.Direct to consumer advertising is just one channel by which healthinformation reaches consumers.

However, the comprehensive marketing approaches described above are ones inwhich many channels of information are influenced by the pharmaceuticalcompany, including sources known to strongly affect consumer behaviour: media,professional opinion leaders and the learned intermediary required by regulation,the prescriber. When other sources of information such as charitable, communityand consumer organisations are also recruited as part of the promotional goal, thechannels available to the consumer seeking balanced and objective informationmay be further reduced.This has implications for Galbally's proposal whereby government actually solicitsDTCA for disease state campaigns (Galbally, 2001. p.93). Governments' motives inmedicines policy have been called into question by industry who note that costcontainmentmay be a primary motivating factor, as with any payer (Bonaccorsoand Sturchio 2002). However Australia's National Medicines Policy also reflects acommitment to achieving optimal health outcomes as well as economic objectives(National Medicines Policy, 2000. p.1).

DTCA and the Internet

The Internet is becoming increasingly important as a source of health informationand, judging by the extent it is being used for this purpose, it is also responding toa huge unmet desire for health information among consumers. In the US, it hasvariously been estimated that between 57% and 75% of Internet users have used itto obtain health information (Pew Internet and American Life Project 2000). Also,that 5% of people who use the Internet on a typical day use it to find healthinformation and 25% of searches through search engines involve health relatedissues. About 41% of Americans polled say that material they found on their mostrecent online health search affected decisions about whether they should go to thedoctor, how to treat an illness or how to question a doctor.In Australia the Therapeutic Goods Advertising Code governs advertising on theInternet of complementary medicines and OTCs directed at Australian consumers.Advertising to Australian consumers of prescription products through the Internetwould breach the Medicines Australia Code of Conduct. However, internationalaccessibility to overseas-based Internet sites means that Australian consumersreceive DTCA from these sources.

A US study found that the majority of consumers feel it is difficult to distinguishbetween commercial and independent sites, identify the source of onlineinformation or determine whether the information has been reviewed or approvedby experts (Internet Healthcare Coalition 2000). Again, Australian consumers arelikely to face similar difficulties.In February 2004, Australia and the

United States completed negotiations on a FreeTrade Agreement (FTA) between the two countries. Medicines are a component ofthe draft agreement (Department of Foreign Affairs and Trade, 2004). In draftannexure 2-C, Clause 6 reads:

Dissemination of Information.Each Party shall permit a pharmaceutical manufacturer to disseminate tohealth professionals and consumers via the manufacturer's Internet siteregistered in the territory of a Party, and on other Internet sites registeredin the territory of a Party linked to that site, truthful and not misleadinginformation regarding its pharmaceuticals that are approved for sale in theParty's territory as is permitted under each Party's laws, regulations andprocedures, provided that the information includes a balance of risks andbenefits and encompasses all indications for which the party's competentregulatory authorities have approve the marketing of the pharmaceuticals.

This clause has led to some discussion about whether this would allow DTCA inAustralia. Australian officials' advice is that the phrase *"as is permitted undereach Party's laws, regulations and procedures"* ensures that current Australian lawprohibiting DTCA will apply. In addition a statement from Medicines Australia(2004) on this concern regarding the FTA states:

The FTA text articulates that any marketing and advertising to consumersmust comply with existing laws. Current Australian law stands thatadvertising direct to consumers by industry is prohibited. The prescriptionmedicines industry accepts and supports this Government legislation. It isnot seeking to have this law overturned.

DTCA in NESB communities

When considering the current and potential impact of DTCA, the multiculturalnature of Australian society must be take into account. In the 1996 Census, 41.1%of the total Australian population had at least one parent born overseas, and 13.3%had been born in a Non English speaking (NES) country. Australians speak 193languages and 15.1 % speak a language other than English at home (MulticulturalAffairs Unit, 1997: fact file 5). The cultural and linguistic diversity of Australia'spopulation is associated with certain challenges in relation to the use of medicines.First, the use of medicines is associated with various cultural beliefs and practices.Second, language barriers limit access to health information and health servicesespecially for recent arrivals.There is no research or other material that addresses issues with regard to DTCA toconsumers from NESB. It is evident that there is both a lack of and a great needfor culturally and linguistically appropriate information about medicines and theiruse. Ethnic media are important sources of health information among various NESBcommunities (NSW Multicultural Health Communication Service, 1999).Recently, the private sector has shown interest in the 'ethnic market' andmulticultural advertising and marketing flourish (Department of Immigration andMulticultural Affairs, 1997). There are about 110 newspapers and magazinespublished in 31 languages as well as various ethnic radio and television programsincluding SBS and community programs.The ethnic press is often privately owned and published on a shoestring budget,therefore financial benefits from possible DTCA could be welcomed by the ethnicpress.The

ethnic media does constitute an important means of delivery of healthinformation to various NESB communities and as such might attract attention ofpharmaceutical manufacturers in the case of the legalization of DTCA. While itmay have some attractions as a way of addressing the information deficit amongNESB consumers, the benefits of the 'information' provided by such advertisingwould be somewhat questionable as noted earlier.

In summary, DTCA raises a number of concerns when considered from theperspective of the Quality Use of Medicines and the National Medicines Policy.

1. There is clear evidence that DTCA increases consumer demand formedicines from prescribers, and that prescribing of the advertisedmedicines increases as a consequence. This is the obvious and intendedoutcome of DTCA.
2. Extensive prescribing of newer medicines as a result of DTCA overseas hasled to significant problems in cases where the medicine is subsequentlyfound to have serious side effects or adverse consequences for health. Thisraises important public health considerations as well as questions of liabilityfor medicines' promoters.
3. DTCA strategies frequently overstate medicines' benefits and minimise risksand side effects. This may undermine the judicious use of medicines andthe consideration of non-medicine options, and the ability to makecomparative choices where a medicine is deemed appropriate.
4. While DTCA is prohibited in Australia, its use is growing and the current selfregulatoryindustry Code of Conduct has been unable to prevent thisoccurring. Australia should not allow DTCA to become established bydefault, given the major impacts evident in overseas jurisdictions.
5. DTCA is being directed to subsidised as well as non-subsided prescriptionmedicines, with obvious implications for the Pharmaceutical BenefitsScheme.
6. The proponents of DTCA extend beyond the medicines' producers, toinclude advertising, public relations and media companies who stand tobenefit significantly from this expenditure. There is a potential conflict ofinterest between the media's role as a public information provider and itsrole as a vehicle for advertising and promotion.
7. DTCA occurs as part of more comprehensive marketing strategies directedto the media, prescribers, medical and health experts. Communityorganisations are increasingly being engaged in such campaigns and someappear to be set up by pharmaceutical companies for this purpose.
8. The effect of such comprehensive and indirect marketing means thatconsumers' capacity to obtain independent advice on medicines is limitedand they may be unaware of these influences on apparently independentsources such as prescribers, the media or community organisations.
9. Government engagement in pharmaceutical company sponsored awarenesscampaigns may further reduce the availability of independent informationto consumers.

Consumers Perception, Value and Price

Key intangibles assets such as brand value (or brand equity), product diffferentiation, and goodwill are the outcomes of investment in advertising. It's generally believed that advertising contributes to the creation of brand value. Mizik and Jacobson (2003) argue that brand based advertising can create a comparative advantage for firms through its ability to differentiate the firm's product. The brand can be a formidable barrier to imitation, as brand equity is difficult for competitors to copy, becoming an effective entry deterrence strategy. Industry observers and analysts note that many companies continue to emphazise brand building activities.

While brand value creation is generaaly regarded as a "good thing", we need to have more concrete measures of brand appropriation (i.e. extracting profits from brand value). Merely knowing the effect of brand value on purchase intent (Cobb-Walgren, Ruble, and Donthu 1995) is inadequate; rather we need to understand the financial consequences of brand value (Chu and Keh 2006; Mizik and Jacobson 2003). According to Keller, "To practicing managers, it is especially important to develop better measures that are able to directly relate marketing activity to actual performance".

There has been a steady stream of reserach studying the financial impact of advertising and brand value. Specifically, prior studies examine the contemporaneous association between advertising expenses and accounting and stock market returns (Erickson and Jacobson, 1992), advertising expenses and market value of the firm (Chauvin and Hirschey 1993), advertising and perceived quality (Moorthy and Zhao 2000), perceived quality and firm value (Aaker and Jacobson 1994), brand attitude and firm value (Aaker and Jacobson 2001), branding strategy and firm value (Rao, Agarwal, and Dahlhoff 2004), and brand value and firm value (Barth et al, 1998; Kerin and Sethuraman 1998; Simon and Sullivan 1993).

There are two issues about advertising. First, it has been shown that advertising has an important pass-through effect on branding. Advertising influence value creation in a firm by acting as an appropriation mechanism to build brand names and erect market barriers deterring competitor entry. The key role of advertising in a firm's communication strategy in creating brand equity is realized through the promotion of ideas, goods, or services. In a practical sense, brand equity represents the added value the product garners as a result of past investment in the marketing activity for a brand. Despite the argument for this relationship, however, to date the literature has not explicitly examined the joint effects of advertising and brand value of firm performance.

Second, firms spend large amounts annually on advertising and brand value creation with the expectation of reaping returns in the future. As such, it is important to examine not only the contemporaneous effect of advertising or brand value on firm performance, but also their lagged effects.

The information value of advertising and brand value

According to Low and Mohr: " To be sure, advertising is vital to brand equity. However, advertising, per se, is not sacre cow that should necessarily be part of every year's marketing allocation. Monies should be allocated to advertising only if it has a clearly defined role within that year's strategy for meeting a brand's goal".

There have been numerous tudies, hovewer, on individual effect of advertising on the persistence of profits (e.g Mueller 1990), implying that excess returns erode more slowly for firms that advertise heavily. For example, Chauvin and Hirschey (1993) provide evidence that advertising expense has a positive influence on the market value of the firm. They suggest that spending on advertising can be viewed as a form of investment in intangible assets with positive effects on future cash flows. When Erickson and Jacobson (1992) control for endogeneity between discretionary expenditures and profitability, however, they find that advertising generates substantially lower accounting and stcok market returns than indicated in previous research. In a recent study Chu and Keh (2006) investigate the effect of advertising, promotion and RnD expenses on brand value creation. They find that these lagged expenses yield diminishing returns to brand value.

Barth et al. (1998) examine the association between Financial World magazine's brand value estimates and equity share prices of firms owning the brands. They estimate the association between the brand value estimates and share prices, controlling for equity book value and net income. They also estimate the association between year-to-year changes in brand value estimates and annual share returns, controlling for net income and change in net income. They find that brand value estimate provide significant explanatory power for share prices incremental to advertising expense, operating margin, growth, and market share. Brand value estimates are also significantly positively related to share prices after controlling for recognized brand assets and analyst' earnings forecasts.

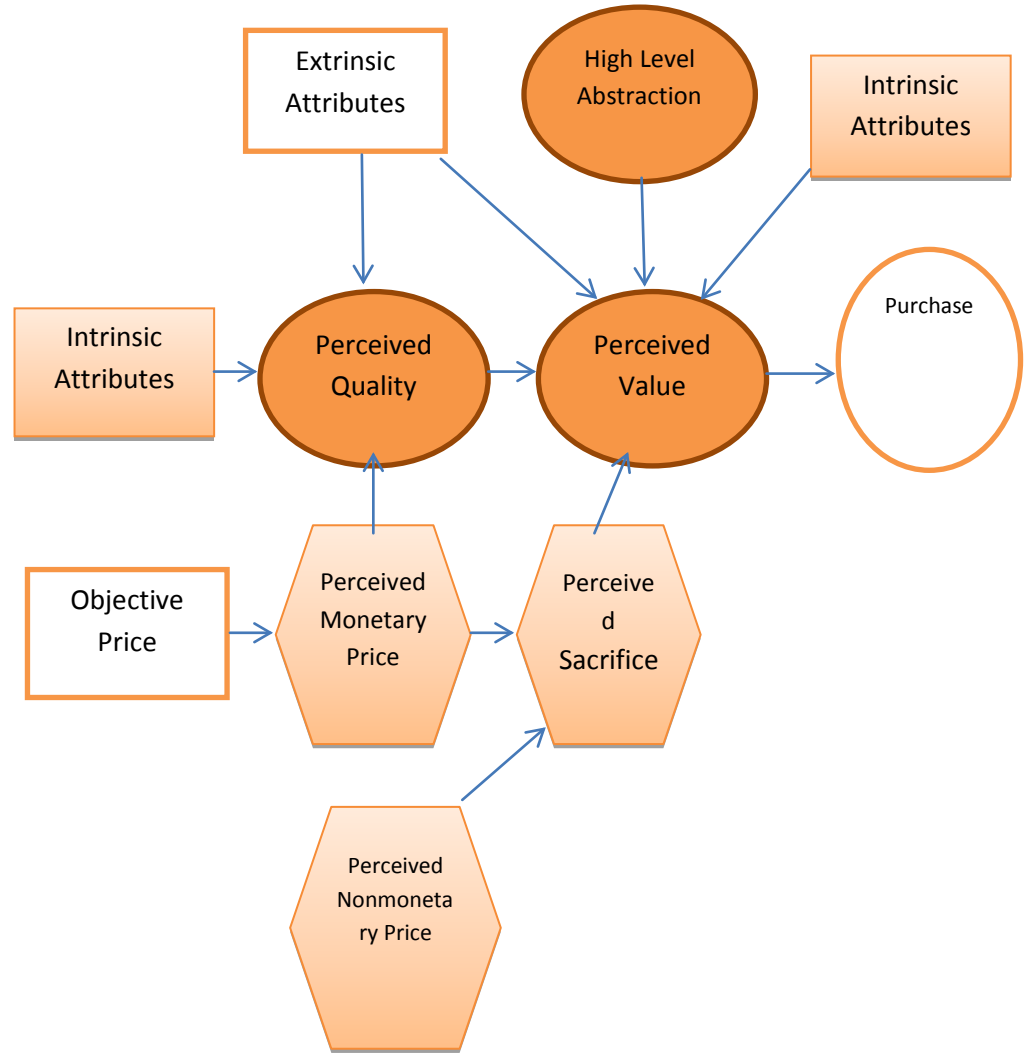
Prior research has also examined the effects of perceived quality, brand attitude, consumer attitude and brand value estimates on contemporaneous return or market value (Barth et al 1998; Kerin and Sethurahman 1998).

The Concept of perceived quality

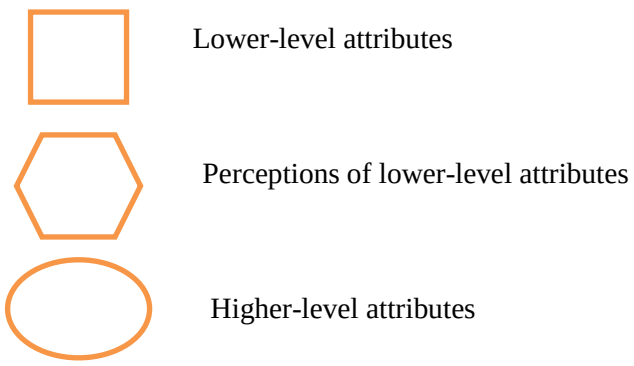
Quality can be defined broadly as superiority or excellence. By extension, perceived quality can be defined as the consumer judgement about a product's overall excellence or superiority.

Perceived quality is

- Different from objective or actual quality.
- A higher level abstraction rather than a specific attribute of a product.
- A global assessment that in some cases resembles attitude
- A judgement usually made within a consumer's evoked set



A means-end model relating Price, Quality and Value



The concepts of perceived price

From the costumer's perspective, price is what is given up or sacrificed to obtain a product. This definition is congruent with Ahtola's (1984) argument against including monetary price as a lower level attribute in multiattribute models because price is a "give" component of the model, rather than a "get" component. Defining price as a sacrifice is consistent with conseptualizations by other pricing researchers (Chapman 1986; Mazumdar 1986)

Levels of consumer attention, awareness, and knowledge of prices appear to be considerably lower than necessary for consumers to have accurate internal reference prices for many products (Dickson and Sawyer 1985). Another recent study indicates that price awareness differs among demographic groups, the greatest levels of awareness being in consumers who are female, married, older, and do not work outside the home (Zeithaml and Berry 1987). Attention to prices is likely to be greater for higher priced packaged goods, durable goods, and services than for low priced, but other factors in the categories –complexity, lack of price information, and processing time required- may interfere with accurate knowledge of prices. An additional factor contributing to the gap between actual and perceived price is price dispersion, the tendency for the same brands to be priced differently across stores or for products of the same type and quality to have wide price variance (Maynes and Assum 1982)

Full price models in economics (e.g. Becker 1965) acknowledge that monetary price is not only sacrifice consumers make to obtain products. Time costs, search cost, and physic costs all enter either explicitly or implicitly into the consumer's perception of sacrifice. If consumers cannot find products on the shelf, or if they must travel distances to buy them, a sacrifice has been made. If consumers must expend effort to assemble durable products or time to prepare packaged goods, and if this time and effort does not provide satisfaction to the consumer in the form of recreation or a hobby, a sacrifice has been made. Research ini economics, home economics, and marketing supports the proposition that other costs –time, effort, search, psychic- are salient to consumers (Down 1961; Gronau 1973; Leibowitz 1974; Leuthold 1981; Linder 1970; Mabry 1970; Mincer 1963)

The Price-Quality Relationship

Price reliance is a general tendency in some consumers to depend on price as a cue to quality (Lambert 1972; Shapiro 1968,1973). The body of literature summarized by Olson (1977) is based on the assumption that a general price-perceived quality relatinship exists. Despite a multitude of experimental studies on the topic, however, the relationship has not surfaced clearly except in situations where methodological concerns such as demand artifacts (Sawyer 1975) could offer alternative explanations for the results (Monroe and Krishnan 1985; Olson 1977). Monroe and Krishnan (1985) concluded that a positive price-perceived quality relationship does appear to exist despite the inconsistency of the statistical significance of the research findings. They also noted, however, that multiple conceptual problems and methodological limitations compromised previous research.

Many empirical studies have produced results that conflict with Monroe and Krishnan's assessment of a positive relationship. In several studies 9Ftiedman 1967; Swan 1974), overall association between price and perceived quality is low. Other

studies show the relationship to be nonlinear (Peterson 1970; Peterson and Jolibert 1976), highly variable across products being judged (Gardner 1971). Other research, summarized by Olson (1977), shows that price becomes less important as a quality indicator when other product quality cues, such as brand name (Gardner 1971) or store image (Stafford and Enis 1969), are present.

Both Peterson and Wilson (1985) and Olshavsky (1985) argue that the emphasis in price-quality syudies should not be on documenting the general price-perceived qualityrelationship, but on the conditions under which price information is likely to lead to an inference about product quality. One possibility is that some individuals rely heavily on prices as a quality signal whereas others do not. Peterson and Wilson sorted respondents into groups on the basis of their having a price-reliance schema and confirmed in an experiment that "schematics" perceive a stronger relationship between price and quality than "aschematics."

Consumers appear to depend more on price as a quality signal in some product categories than in others. One explanation for this variation may be differences in price-objective quality relationships by category. Another explanation may be price variation in a category. Still another category-specific contingency is quality variation: in categories where little variation is expected among brands, price may function only as an indication of sacrifice whereas in categories where quality variation is expected, price may function also as an indication of quality.

The concept of perceived value

In the means-end chains, value (like quality) is proposed to be a higher level abstraction. It differs from quality in two ways. First, value is more individualistic and personal than qualityand is therefore a higher level concepts than quality. Second, value (unlike quality) involves a tradeoff of give and get components. Though many conceptualizations of value have specified quality as the only "get" component in the value equation, the consumer may implicitly include other factors, several that are in themselves higher level abstractions, such as prestige and convenience.

Consumers sacrifice both money and other resources (e.g. time, energy, effort) to obtain products and services. To some consumers, the monetary sacrifice is pivotal: some supermarket shoppers will invest hours clipping coupons, raeding food advertising in the newspaper, and travelling to different stores to obtain the best bargains. To these consumers, anything that reduces the monetary sacrifice will increase the perceived value of the product. Less price-conscious consumers will find value in store proximity, because time and effort are perceived as more costly.

How carefully do consumers evaluate these components of products in making assessments of value? To judge from the product category of beverages, cognitive assessment is limited. Rather tahn carefully considering prices and benefits, most respondents depends on cues –often extrinsic cues- in forming impressions of value. These value triggers were present regradless of the way consumers defined value. Many consumers who defined value as low price reported using a coupon as a signal to low price without actually comparing the reduced price of the couponed brand with the prices of the other brands, or they reported that "cents-off" or "everyday low prices" signs or aprivate label brand triggered the value perception.

Holbrook and Corfman (1985) maintain that value perceptions are situational and hinge on the context within which an evaluative judgment occurs. This view may help explain the diversity of meanings of value. Value meant different things at each of these points. At the point of purchase, value often meant low price, sale, or coupons. At the point of preparation, value often involved some calculation about whether the product was easy to prepare and how much the consumer could obtain for what she/he paid.

As Olshavsky (1985) suggested, not all consumers want to buy the highest quality item in every category. Instead, quality appears to be factored into implicit or explicit valuation of a product by many consumers (Dodds and Monroe 1985; Sawyer and Dickson 1984). A given product may be high quality, but if the consumer does not have enaogh money to buy it (or does not want to spend the amount required), its value will not be perceived as being as high as that of a product with lower quality but a more affordable price.

Objective quality versus perceived quality

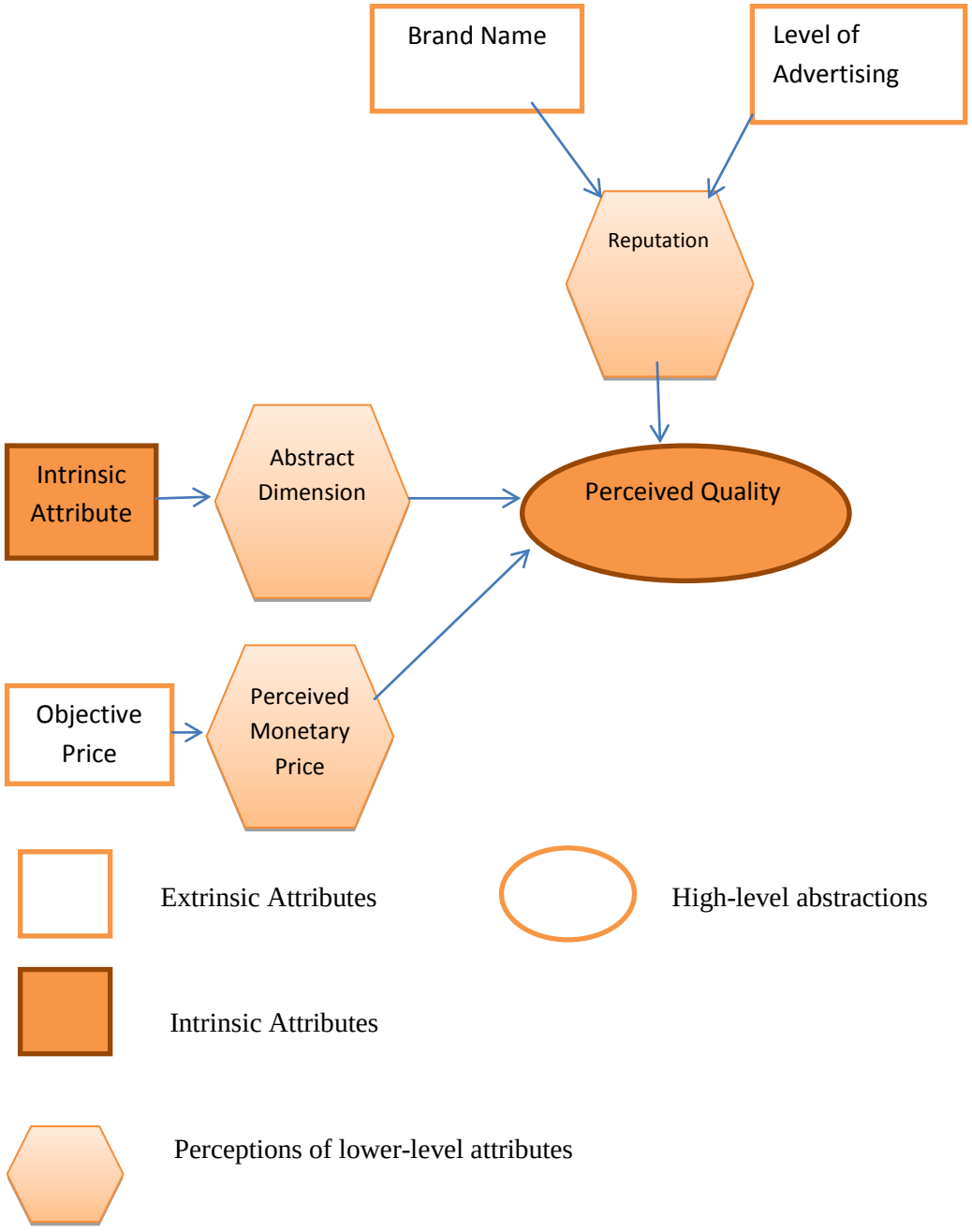
Several reserachers (Dodds and Monroe 1984; Garvin 1983, Holbrook and Corfman 1985) have emphazised the difference between objective and perceived quality. Holbrook and Corfman 91985), for example, distinguish between mechanistic and humanistic quality: "....mechanistic [quality] involves an objective aspect or feature of a thing or event; humanistic [quality] involves the subjective response of people to objects and is therefore a highly relativistic phenomenon that differs betwen judges". "Objective quality" is the term used in the literature (e.g.Hjorth-Anderson 1984; Monroe and Khrishnan 1985) to describe that actual technical superiority or excellence of the products.

As it has been used in literature, the term "objective quality" refers to measurable and verifiable superiority on some predetermined ideal standard or standards. Published quality ratings from sources (such as Consumer Reports) are used to operationalize the construct of objective quality in research studies (Curry and Faulds, 1986).

The term "objective quality" is related closely to –but not the same as- other concepts used to describe technical superiority of a product. For example, Garvin (1983) discusses product-based quality and manufacturing-based quality. Product-based quality refers to amount of specific attributes or ingredients of a product. Manufacturing-based quality involves conformance to manufacturing specification or service standards. In prevailing Japanese philosophy, quality means "zero defects-doing it right the first time." Conformance to requirements 9Crosby 19790 and incidence of internal and external failures are other definitions that illustrate manufacturing-oriented notions of quality.

These concepts are not identical to objective quality because they, too, are based on perceptions. Though measures of specifications may be actual (rather than perceptual), the specifications themselves are set on the basis of what managers perceive to be important. Manager's views many differ considerably from consumer's or user' view. Consumer Reports ratings may not agree with managers' assesment in term of either salient attributes or weights assigned to the attributes. When asked how consumers perceive quality, managers listed workmanship, performance, and form as critical components. Consumers actually keyed in on different components: appearance, cleanability, and durability.

Figure 2. The Perceived Quality Component



To reiterate, perceived quality is defined in the model as the consumer's judgement about the superiority or excellence of a product. This perspective is similar to the user-based approach of Garvin (1983) and differs from product-based and manufacturing-based approaches. Perceived quality is also different from objective quality, which arguably may not exist because all quality is perceived by someone, be it consumers or managers or researhers at Consumer Reports.

Lutz (1986) proposes two forms of quality, "affective quality" and "cognitive quality". Affective quality parallels Olshavsky's and Holbrook and Corfman's views of perceived quality as overall attitude. Cognitive quality is the case of a superordinate inferential assessment of quality intervening between lower order cues and an eventual overall product evaluation (Lutz 1986). In Lutz's view, the higher the proportion of attributes that can be assessed before purchase (search attributes) to those that can be assessed only during consumption (experience attributes), the more likely it is that quality is a higher level cognitive judgement. Conversely, as the proportion of experience attributes incerases, quality tends to be an affective judgment. Lutz extends this line of reasoning to propose that affective quality is relatively more likely for services and consumer nondurable goods (where experience attributes dominate) whereas cognitive quality is more likely for industrial products and consumer durable goods (where search attributes dominate)
Evaluation of quality usually take placein comparison context. Maynes (1976) claimed that quality evaluations are made within "the set of goods which....would in the consumer's judgement serve the same general purpose for some maximum outlay." A product's quality is evaluated as high or low depending on its relative excellence or superiority among products or services that are viewed as substitutes by the consumer. It is critical to note that the specific set of productsused for comparison depends on the costumer's, not firm's, assessment of competing products.

Holbrook and Corfman (1985) note that early phylosophers used the word "quality" to refer to explicit features (i.e. properties of characteristics) of an object as perceived by a subject. Olshavsky (1985) terms this tendency to infer quality from specific attributes "surrogate-based preference forming behaviour" and cites examples of product categories in which a given surrogate is highly associated with quality.

Attributes that signal quality have been dichotomized into intrinsic and extrinsic cues (Olson 1977; Olson and Jacoby 1972). Intrinsic cues involve the physical composition of the product. Intrinsic attributes cannot be changed without altering the nature of the product itself and are consumed as the product is consumed. Extrinsic cues are product-related but not part of the physicalproduct itself. They are, by definition, outside the product. Price, brand name, and level of advertising are example of extrinsic cues to quality.

The intrinsic-extrinsic dichotomy of quality cues is useful for discussing quality but is not without conceptual difficulties. A small number of cues, most notably those involving the product's package, are difficult to classify as either intrinsic or an extrinsic. Package could be consideredan intrinsic or an extrinsic cue depending on whether the package is part of the physical composition of the product (e.g. a dripless spout in detergent or a squeezable ketchup container), in which case it would be an intrinsic cue, or protection and promotion for the product (e.g. a cardboard container for a computer), in which case it would be an extrinsic cue. For

purposes of the model, package is considered an intrinsic cue but the information that appears on the package (e.g. brand name, price, logo) is considered an extrinsic cue.

Though the concrete attributes that signal quality differ across products, higher level abstract dimensions of quality can be generalized to categories of products. As attributes become more abstract (i.e. higher in the means-end chains), they become common to more alternatives. Garvin (1987), for example, proposes that product quality can be captured in eight dimensions : performance, features, reliability, conformance, durability, serviceability, aesthetics, and perceived quality (i.e. image). Abstract dimensions that capture diverse specific attributes have been discussed have been discussed by Johnson (1983) and Achrol, Reve, and Stern (1983). In describing the way consumers compare noncomparable alternatives 9e.g. how they choose between such diverse alternatives as a stereo and a Hawaiian vacation), Johnson posited that consumers represent that attributes in memory at abstract levels (e.g. using entertainment value as the dimension on which to compare stereos and Hawaiian vacations). Similarly, Achrol, Reve, and Stern proposed that the multitude of specific variables affecting a firm in the environment can be captured in abstract dimensions.

Price, brand name, and level of advertising are three extrinsic cues frequently associated with quality in research, yet many other extrinsic cues are useful to consumers. Price, the extrinsic cue receiving the most research attention, appears to function as a surrogate for quality when the consumer has inadequate information about intrinsic attributes. Similarly, brand name serves as a "shorthand" for quality by providing consumers with a bundle of information about product (Jacoby et al 1978; Jacoby, Szybillo, and Busato-Schach 1977). Level of advertising has been related to product quality by economist Nelson (1970,1974), Milgrom and Roberts 91986), and Schmalensee (1978). The basic argument holds that for goods whose attributes are determined largerly during use (experience goods), higher levels of advertising, rather than actual claims made, informs consumer that the company believes the goods are worth advertising (i.e. of high quality). Supporting this argument is the finding that many subjects in the exploratory study perceived heavily advertised brands to be generally higher in quality than brands with less advertising.

Which type of cue –intrinsic or extrinsic- is more important in signaling quality to the consumer? An answer to this question would help firms decide whether to invest resources in product improvements (intrinsic cues) or in marketing (extrinsic cues) to improve perception of quality. Finding a simple and definitive answer to this question is unlikely, but the exploratory study suggest the type of attribute that dominates depends on several key contingencies.

The first contingency relates to the point in the purchase decision and consumption process at which quality evaluation occurs. Consumer may evaluate quality at the point of purchase (buying a beverage) or at the point of consumption (drinking a beverage). The salience of intrinsic attributes at the point of purchase depends on whether they can be sensed and evaluated at that time, that is, whether they contain search attributes (Nelson 1970). Where search attributes are present, they may be important quality indicators. In their absence, consumers depend on extrinsic cues. At the point of consumption, most intrinsic attributes can be

evaluated and therefore become accessible as quality indicators. Consumers depend on intrinsic attributes when the cues have high predictive value (Cox 1962).

Extrinsic cues are posited to be used as quality indicators when the consumer is operating without adequate information about intrinsic product attributes. This situation may occur when the consumer :

- Has little or no experience with the product
- Has insufficient time or interest to evaluate the intrinsic attributes
- Cannot readily evaluate the intrinsic attributes

In other situation, intrinsic product attributes indicating quality are simply too difficult for the consumer to evaluate.

Cost Effectiveness and Direct to Consumer Advertising

Cost effectiveness asks the question: Is the additional health gained from an intervention sufficient to justify the societal costs incurred? Gains are often measured using some form of a "QALY", a Quality Adjusted Life Year. Analysts calculate the cost per QALY gained, and if that ratio is below a threshold, then the treatment is considered "cost effective", while if it is above, then the treatment is not cost effectives. One suggested rule of thumb is that treatments below $50,000 per QALY gained are considered very cost effective and treatments below $100,000 per QALY gained are cost effective (Ubel et al, 2003).

To think about the cost effectiveness of DTC advertising, it is necessary to frame the question by describing the intervention. We may view the intervention as the advertising itself, or as the prescription drug that is consumed in response to the advertising. However, in either scenario, the costs calculated and the gains accrued will be identical.

At first blush, the answer to the question of the cost effectiveness of prescription drug advertising appears obvious. The cost effectiveness of DTC will be a function of the cost effectiveness of the advertised drugs, which are generally well established as being cost effective. For example, three of the top ten advertised drugs in 2006 were in the class of medications known as "statins", which are highly effective and generally considered to be safe (Shepard et al, 1995). Overall, research indicates that targeted statin therapy for the primary prevention of cardiovascular events can be cost effective (Pearson, 2000). For example, Glasziou (2003) estimated that the discounted long term cost per life year gained for Pravastatin in Australia to be $10,938. This includes a 22% reduction in mortality over six years, and a 20% decline in hospitalization costs for all vascular events.

Can these cost effectiveness ratios be applied to individuals who consume the drug due to DTC advertising? One obvious difference is the additional cost of the advertising itself, which increases costs and may thereby decrease the cost effectiveness ratio. However, *if the price of the drug does not change*, then advertising will only reduce the profit per unit for the manufacturer (unless average production costs decrease because of increased output), and not change cost effectiveness ratio. This argues that if the drug is cost effective, and advertising does not affect the price, then the consumption of advertised drugs is necessarily cost effective. However, this simple analysis ignores several additional issues that may also have an impact.

From an economic welfare perspective, the desirability of advertising depends on the trade-off between potentially increased market prices and reduced

search costs. Higher prices will benefit producers at the expense of consumers, while reduced search costs will benefit consumers by lowering the true cost of the product (Stivers and Tremblay, 2005). Thus the first critical issue is the effect of DTC advertising on the price of the advertised drugs. If consumers simply pay more for the same drugs or switch from a low priced drug to an equivalent higher priced drug (e.g., from a generic to a name brand), then social welfare is not enhanced and the cost effectiveness is diminished.

Second, many observers are concerned that advertising of drugs will lead to many patients seeking prescriptions which they may not need (a concern reviewed in detail further on in the paper). Normally, economics would argue that, so long as consumers are willing to pay the price associated with the visit, this is not a concern. The complication is that the visit to the physician's office is typically paid for by insurance, not the patient, so that there is moral hazard in consumption of physicians' services. The drug advertising thus creates a negative externality for the insurer (which is often the government) creating economic inefficiencies. From a cost effectiveness perspective, the "false positive" visits – visits to the physician seeking an inappropriate medication – increase the total cost of the "true positives" who appropriately receive the prescription. Thus an increase in visits seeking a prescription which is not, after professionalassessment, needed, will result in lower cost effectiveness for persons seeking a prescription due to an advertisement they viewed than for those diagnosed in more traditional ways.

Third, there may be a difference in patient characteristics between individuals on whom the cost effectiveness ratio was calculated and those seeking treatment in response to a prescription drug advertisement. Cost effectiveness ratios often depend on the clinical characteristics of the treated population. For example, although research indicates that targeted statin therapy for the primary prevention of cardiovascular events can be cost effective (Pearson, 2000), the higher the risk of a cardiovascular event, the lower the cost per QALY. Thus, because men have a higher underlying risk of cardiovascular events, statin therapy for a 58 year-old men costs $48,100 per QALY gained but $94,400 per QALY gained for a woman of the same age Blake (2003). So if individuals responding to drug advertising are systematically different from a more "typical" patient population, then the standard cost effectiveness ratios for those patients will also be different. The remainder of the paper is organized around these three issues: the impact of advertising on prices, the impact on other (non-drug) providers and evidence regarding differences in patients who seek treatment due to drug advertising.

The Impact of DTC Prescription Drug Advertising on Prescription Drug Prices, Spending and Utilization

One of the key debates has been the issue of the impact of DTC advertising on drug spending. Studies of the question have consistently found that DTC advertising is associated with increases in spending on prescription drugs (see Table 4). This is true both pre-1997 (Basara, 1996; Stern, 1994) and post-1997 (Gilbody, Wilson and Watt, 2005). But the reason for the increase in spending is less clear.

Prescription drug spending could increase as a result of DTC advertising in one of three ways. The advertising could lead to higher prices for advertised drugs; it could lead to increased utilization of drugs; finally, it might lead to substitution from less expensive to more expensive drugs for the same condition. The

implications of these three effects are quite different. If increased spending is due to higher prices, then this suggests that the primary impact of DTC advertising is to create a more inelastic demand for particular drug products, which is not necessarily welfare enhancing. Conversely, if the primary effect is to increase utilization, then the welfare impact will be driven by the value of the drug (assuming no selection effects). If the effect is caused by substitution to more expensive drugs in a class, then the welfare effects will depend on whether any increased benefits of the advertised drug relative to the previously utilized drug are cost effective.

In a 2002 review of the literature, the GAO concluded that the majority of the increased spending was due to increased utilization, not due to higher prices (GAO, 2002). GAO reports that between 1999 and 2000, utilization for the most heavily advertised drugs increased by 25%, while prices rose by 6%. For drugs that were not heavily advertised, utilization increased by 4% and prices by 9%. A similar finding is reported by Berndt (2001) and in a review by Vogel, Ramachandran and Zachry (2002). One contrary finding was reported by Calfee, Winston and Stempski (2002), who examined statin use before and after the 1997 change in FDA DTC advertising regulations change, and found no evidence that advertising effected prescription demand, number of pill, revenues or market shares. However, this study linked national data to national prescriptions, rather than using more specific market-by-market data.

This issue is strongly related to the question of whether DTC advertising tends to expand market shares for individual products or whether DTC advertising expands the overall market for the class of drugs. If DTC advertising expands individual product's market share, at the expense of their competitors, then DTC advertising will tend to make the demand for the advertised product less elastic, allowing sellers to charge higher prices. The welfare effects of this change would depend on the relative merits and prices of the advertised drug and substitutes. However, to date, most evidence suggests that DTC advertising expands overall market size, rather than individual product market share. Ling, Berndt and Kyle (2002) find that DTC advertising for prescription drugs does little for individual products' market share, but instead expands the overall size of the market; this is in contrast to the over-the-counter DTC advertising, where the opposite result held. Similarly, Donohue and Berndt (2004) report that DTC advertising for antidepressants had little impact on drug choice, but increased the probability that an individual diagnosed with depression received antidepressant treatment. Both studies attribute the lack of impact of DTC advertising on particular drug's market share to the physician acting as the patient's agent. Berndt et al (1995) found a more mixed result in an early (using pre-1997 data) study of H2-antagonists (such as Tagamet and Zantac), with DTC advertising effecting both market share and market size.

Bradford et al (2006), in a study of local and national DTC advertising for the COX-2 inhibitors Vioxx and Celebrex, found that Vioxx advertisement increased Vioxx prescriptions and had a smaller effect on Celebrex prescriptions, while Celebrex ads only increased Vioxx prescriptions and had no effect on Celebrex sales. This study then is consistent with the idea that that patients respond to advertisements and that there is significant spillover between drug advertisements. Similarly, Donohue et al (2004) used a commercial claims database to show that DTC advertising for depression medications significantly increased the

probability of a depression medication being dispensed for those diagnosed with depression during an outpatient visit.

However, Zachry et al (2002) reports that the effect of DTC advertising on utilization varies by drug type. DTC advertising had no impact on the number of prescriptions written or diagnoses for benign prostatic hypertrophy or antihypertensives. For antilipemics (Zocor), every $1000 spent on DTC yielded 32 new diagnoses and 41 antilipemic prescriptions. Of the 41 antilipemic prescriptions, 23 were for Zocor.

Overall, the advertising demand appears to be relatively inelastic. A Kaiser Family Foundation study found that every 10% increase in DTC advertising lead to a 1% increase in prescription drug spending (Rosenthal, et al, 2003; KFF, 2003). The authors estimate that this indicates that every $1 spent on DTC advertising yields $4.20 in additional sales. More recently, Iizuka and Jin (2005) find that a $28 increase in monthly DTC advertising leads to one patient visit within 12 monthsii.

Externalities Associated with DTC Advertising

Physician groups have been very vocal in their opposition to DTC advertising of prescription drugs because of concerns about changes in the doctor-patient relationship and because of fears that advertising may lead to many patients seeking unneeded treatments. In contrast, consumers like DTC advertising. Murray et al (2004) report that 47% of consumers hold the view that DTC advertising is either good or very good and only 19% hold the view that it is bad or very bad (Murray et al, 2004). Three quarters of patients think DTC advertising increases their awareness of new drugs, and most (58%) felt the ads provided sufficient information to allow the consumer to decide whether to discuss the drug with their doctor (Aikin, Swasy and Braman, 2004). Women, in particular, felt more in control during their visit to the doctor (Murray et al, 2004).

Despite the official opposition of physician's groups, individual doctors are not as opposed. The FDA found that 41% of doctors believed that DTC advertising led to benefits, while 18% believed it led to problems (Aikin, Swasy and Braman, 2004). 73% of physicians agree or strongly agree that DTC advertising helps educate and inform patients, and 67% agree or strongly agree that it helps the physician have better discussions with the patient (Weissman et al, 2004). Some patients report that doctors acted as if they were being challenged when the patient brought up an advertised drug (Murray et al, 2004). However, the FDA found that 90% of patients reported that doctors welcomed their questions (Aikin, Swasy and Braman, 2004).

This may be because scheduling a visit to a doctor specifically in response to a DTC advertisement is rare; the FDA reports that only four percent of patients made a visit to a physician with the primary purpose of asking about an advertised drug. More commonly, patients asked about an advertised drug during an already scheduled visit (Aikin, Swasy and Braman, 2004; Murray et al, 2004). Potential patients typically respond to the advertisements by talking to their doctor about the advertised drug. Overall, fourteen percent of survey respondents discussed a health concern with their doctor as a result of a DTC advertisement. Consumers understand that the materials are promotional, and seek their doctor's advice about the appropriateness of particular medications; however, the advertising increases

awareness of treatment possibilities (Young et al, 2005). Only six percent of patients expected to receive a prescribed medication during a physician visit because of DTC advertising (Aikin, Swasy and Braman, 2004). When patients ask for a prescription drug they have seen advertised, doctors generally respond by doing something, although they often do not prescribe the requested drug. Physicians prescribed the DTC advertised drug 39% of the time, a different drug 22% of the time and took no action 18% of the time (Weissman et al, 2004).

Physicians accommodate patients' requests either because the requested drug was the most effective available or is equally effective to other alternatives; only 5.5% of the time did physicians prescribe a DTC advertised drug despite believing another drug was more effective (Weissman et al, 2004). Doctors considered the advertised drug requested by the patient to be a "very likely" choice 54% of the time (Mintzes et al, 2003). Physicians were more likely to be ambivalent about prescribing non-advertised, but requested, prescription drugs than DTC advertised drugs requested by patients (Mintzes et al, 2002).

Advertising tends to focus on drugs that are newer (Donohue et al, 2007) and targeted at undertreated illnesses (Iizuka, 2004). The FDA found in surveys that among patients who visited a doctor and asked for a prescription drug by brand name, 88% had the underlying condition that the prescription drug seeks to treat (Rados, 2004). Three-quarters of patients who received a prescribed medication after visiting the doctor due to DTC advertising reported feeling much or somewhat better overall (Weissman et al, 2003).

It also appears that DTC advertising may lead to improved quality of care. In one of the clearest examples to date, Kravitz et al (2005) found that consumers' asking providers for advertised drugs led to superior care. In a randomized controlled trial, only 31% of patients presenting with major depression received appropriate depression medications. In contrast, 76% of patients asking for the correct medication received appropriate depression medications, while 53% of patients who asked for a specific (and appropriate) brand name drug received appropriate depression medications. However, Kravitz et al also found that patients presenting with symptoms of adjustment disorder with depressed mood, for whom a depression medication is not clinically indicated, were also more likely to receive a depression prescription if they asked for it.

Selection Effects

Increased utilization from DTC advertising can occur either by new consumers responding to the ad and obtaining prescriptions or by increased usage by those patients who already have a prescription – i.e., increased compliance. In either of these situations, there is the potential for a selection effect whereby the individuals who respond to an advertisement are systematically different from those who do not. There is relatively little evidence about the effect of advertising on compliance and even less on the selection effects among new patients.

The most straightforward way that selection could occur is if those who seek out drugs in response to DTCA are systematically either more or less severe in their illness than the "typical" person who is prescribed the drug. We were unable to locate any published articles that examined this question directly, although there is much speculation that such selection occurs. This is a fruitful area for further research.

However, some individuals may not seek out a new drug in response to DTCA, but instead may either restart existing prescriptions or adhere better to already prescribed drug regimens. Certainly, patient compliance with prescribed medications is a significant public health issue. Dezii (2000) found that 70% of patients do not comply with their prescribed drug treatments, with an annual societal cost of $170 billion, which exceeds total drug expenditures. More than one in ten hospital admissions have been blamed on noncompliance (Col, Fanale and Kronholm, 1990) as well as 125,000 cardiovascular deaths per year (Sullivan, Krelig and Hazlet, 1990). One of the benefits cited for DTCA is improved compliance (Armantier and Namoro, 2006). If this is the mechanism by which DTCA increases demand, then the selection effect becomes dependent on a comparison of patients with high and low adherence rates within drug classes affected by DTCA.

But the evidence regarding the effect of DTCA on compliance is limited and mixed. Donohue et al (2004) found no effect of DTC advertising on compliance with a four month treatment regimen for depression for the advertised drug, but a small effect for the drug class. For statins, Bradford et al (2006) found that patients beginning statin therapy (for which this is a clinical need for uninterrupted treatment and frequent non compliance (Ellis et al, 2004; Abughosh et al, 2004; Theibaud et al, 2007; Pearson et al, 2000)) during months of high DTC advertising were more likely to achieve low-density lipoprotein cholesterol blood-level goals after treatment. Patients beginning treatment in high advertising months (defined as the top quartile of advertising) were 6% more likely to achieve their goals. However, that the effect was only significant for those with the least stringent goals. Finally, Wosinska (2005) found that advertising prior to the initiation of therapy for hyperlipidemic patients leads to higher compliance, perhaps suggesting an interaction between patient motivation and advertising. Also, advertising for any brand drug increases compliance across the drug class, although the effect size is small.

Objective

The objective of this study is to determine the impact that DTCA has on consumerinitiatedmedication changes for the treatment of GERD and SAD.

Methods Instrument Design

A questionnaire consisting of 68 items was used to collect data on patientperceptions of and actions resulting from viewing televised DTCA. The surveyincluded questions about what actions consumers took after viewing DTCA, whatinfluence DTCA had on their prescription-seeking behaviors, and what responsephysicians had to requests from patients for the medications viewed. Questions torespondents about DTCA viewed for specific medications and changes in therapywere posed as independent events. The survey also had items regarding cost ofprescriptions to the consumer, insurance status, number of prescriptions currentlytaking, and demographics. Information regarding the impact of DTCA onconsumer-initiated requests for medications used to treat GERD and SAD andthe outcomes associated with those requests were specifically targeted. GERD andSAD were selected due to the significant amount of advertising dollars allocatedby pharmaceutical companies to market their medications used to treat thesetwo diseases (Atherly & Rubin, 2008; Rosenthal et al., 2002; USGAO, 2002).

Medications included in the survey follow: Nexium, Prevacid, and Protonix forGERD and Paxil, Prozac, and Zoloft for SAD. Two distractor medications wereincluded in the study, Sultin for GERD and Zitsoter for SAD, to establish reliabilityand validity of the author-designed instrument, and ‘‘Other’’ also was provided as aresponse. A small group of colleagues tested the instrument to solicit feedback on thesurvey design and to establish face validity. Changes were made based on thatfeedback prior to finalizing the tool.

Study Participants

The survey was sent to 2,500 e-mail addresses randomly selected from a purchasedlist of AOL, Hotmail, MSN, Road Runner, and Yahoo! accounts of consumers overthe age of 18 residing in the United States, and information was collected for 3months through February 2005. No respondent identifying data was collected,and e-mail addresses were blinded to the authors. Study design was approvedInfluence on Consumer Behavior 453by the University of Louisiana-Monroe Institutional Review Board (IRB).Participation in the survey was considered providing informed consent perIRB approval.

Statistical Analysis

Survey responses and change in therapy were summarized using descriptive statistics.The data were analyzed utilizing the binomial test with Z approximation, frequencycounts, and Crosstabs, using SPSS 13.0 and SAS 8.1. Applying these tests to both theGERD and SAD responses for each medication included in the survey resulted inthree binomial tests.

Results Subjects

Of the 2,500 survey recipients, 487 accessed the provided link and returned aresponse. Of those responses, 60 surveys were eliminated: 51 due to a greater than10% error rate and nine because the respondents resided outside of the United States.The remaining 427 validly executed surveys yielded a 17.1% response rate. Therespondents were 70.0% female, 83.1% White=non-Hispanic, and 82.4% insured.Approximately one-third of those surveyed were between the ages of 18 and 34,and one-fourth were over the age of 50. When asked about their prescription consumption,40.5% of the respondents reported taking no medications, and 24.6%reported taking a medication for which they had seen a television advertisement.Respondents to this survey were broadly reflective of the population ofInternet-mediated health seekers in that they are more likely to be female, educated,and affluent compared with the general population (Dutta-Bergman, 2004; Spooner,Meredith, & Rainie, 2003).

Respondents With GERD

When asked if they were taking a medication for heartburn, 83 respondents(19.4%) answered affirmatively, and when asked to indicate which brand theywere taking, participants selected Prevacid (40), Nexium (26), Protonix (9),and Other (8). No respondents chose the fictitious product, Sultin. When askedif they had viewed DTCA for prescription heartburn medication, an overwhelmingmajority reported seeing advertisements (89.5%), and of those who hadviewed televised DTCA, 10% reported talking with their doctor about the advertisedmedication. Of those patient-

initiated conversations, respondents reportedthat almost half resulted in a change of therapy. Of note, the terms of thechange were not specified in the survey and may have included initiation, deletion,or modification of therapy.

Respondents With SAD

Of the 34 respondents who stated that they were taking a medication used to treatSAD, 58.8% reported using Zoloft, 26.5% reported taking Paxil, and 14.7%454 N. M. Khanfar, H. H. Polen, and K. A. Clausonreported taking Prozac. No respondents chose the fictitious SAD medication(Zitsoter) and no respondents chose Other. Almost 80% of those surveyed reportedseeing a television advertisement for a medication used to treat SAD, and of those80%, 20 respondents reported discussing the advertised product with their physician,which resulted in a change of therapy in eight patients.

Discussion

Television advertising is a proven mechanism for increasing awareness and sales of amultitude of products and services, and the pharmaceutical industry has aggressivelytapped into this resource (Advertising Age, 2008). Of the 427 respondents in this survey,an overwhelming majority reported viewing televised DTCA for the top brandsof GERD and SAD medications. The question is whether the campaigns for thesemedications have been successful in capitalizing on this exposure. According to thissmall self-reported study, the answer is yes, especially for the GERD products. Whileonly 10% of patients who viewed DTCA for GERD medications discussed thoseadvertisements with their physician, almost one-fifth of those patient–physicianencounters ended with a change of therapy. While fewer SAD patients reported seeingDTCA, the ultimate impact was even greater in this patient population. OnceSAD patients were prompted into discussing those advertised medications with theirphysician, 40% reported that it resulted in a change of therapy.

This survey instrumentdid not specifically ask if the change of therapy was made to the advertisedmedication, but it did demonstrate, as reported in previous literature (Mintzeset al., 2002, 2003; Murray et al., 2004; Weissman et al., 2003), that DTCA is capableof provoking a change and directly influencing patient care.The fictitious medications in this survey were included in order to establishreliability and validity of the instrument. While the other medications were recognizedby a large number of those surveyed, fewer than 2% of the respondentsreported seeing a commercial for the fictitious products, and no respondentsreported taking them, thus reinforcing the validity and reliability of the responses.Many diseases, especially those that carry a social stigma with them such asdepression and impotence, are underdiagnosed because of reluctance on the partof the patient to discuss these sensitive topics with their physicians, and, accordingto research, exposure and demystification of these diseases is a possible advantageof DTCA (Calfee, 2007; Donohue, 2006; Kravitz et al., 2005). After viewingadvertisements for DTCA medication, especially those that give details on diseasesymptomatology, patients are more likely to initiate a discussion that potentiallycould lead to an early detection and diagnosis (Calfee, 2007; Findlay, 2002; Holmer,1999; Mintzes et al., 2003). This study showed that 58 out of 427 patients initiated aconversation with their physician that they directly attributed to

DTCA influence.Whether or not this positively impacts pharmaceutical industry profits, it is difficultto assign a dollar figure to an improvement in patient outcomes and physician–patient communication. The debate continues, however, as to whether DTCA helpsor hinders the relationship dynamics between patients and health care providers,and further research should be conducted to establish the long-term causal relationshipbetween patient-initiated discussions due to DTCA and actualized clinicalimprovements in patient outcomes.

Limitations

The study was limited to the mainland borders of the United States and to respondentsresiding in the United States and thus cannot be extrapolated to consumerpopulations in New Zealand or in the European Union where regulations aboutDTCA are being reconsidered. Additionally, this survey was not designed to detectif consumer-initiated changes in therapy were made to the advertised medication oranother agent. Finally, this study was unable to measure what disease-specific orsocioeconomic factors lead to exposure to DTCA being greater in one group(GERD), but yielding greater medication change in the other (SAD).

Conclusion

Based on this small self-reported sample, DTCA via television for medicationsused to treat GERD and SAD can have a significant impact on both patient-initiatedprescription requests and physician prescribing practices and may result in a changeof therapy for these diseases.

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