

## **Pharmaceutical Advertising in Korea, Japan, Hong Kong, Australia, and the US:**

### **Current Conditions and Future Directions**

#### **Hye-Jin Paek**

Department of Advertising, Public Relations, and Retailing  
Communication Arts and Science  
Michigan State University  
East Lansing, MI 48824  
USA  
Tel: (1) 517-355-2314  
Email: [paekh@msu.edu](mailto:paekh@msu.edu)

#### **Hyegy Lee**

Department of Advertising, Public Relations, and Retailing  
Communication Arts and Science  
Michigan State University  
East Lansing, MI 48824  
USA  
Tel: (1) 517-355-2314  
E-mail: [leehyegy@msu.edu](mailto:leehyegy@msu.edu)

#### **Carolus L. C. Praet**

Otaru University of Commerce  
3-5-21 Midori, Otaru  
Japan  
Tel: (81) 134-27-5349  
Email: [praetcar@res.otaru-uc.ac.jp](mailto:praetcar@res.otaru-uc.ac.jp)

#### **Kara Chan**

Department of Communication Studies  
Hong Kong Baptist University  
Kowloon Tong  
Hong Kong, China  
Tel: (852) 3411-7836  
E-mail: [karachan@hkbu.edu.hk](mailto:karachan@hkbu.edu.hk)

#### **P. Monica Chien**

School of Tourism  
Department of Business, Economics and Law  
The University of Queensland  
Brisbane, 4072 QLD  
Australia  
Tel: (61) 7-3346-8717  
E-mail: [m.chien@uq.edu.au](mailto:m.chien@uq.edu.au)

**Jisu Huh**

School of Journalism & Mass Communication  
University of Minnesota  
Murphy Hall 338, 206 Church St. SE  
Minneapolis, MN 55455  
USA  
Tel: (1) 612-626-5527  
Email: [jhuh@umn.edu](mailto:jhuh@umn.edu)

**Glen T. Cameron**

School of Journalism  
Health Communication Research Center  
University of Missouri  
239 Walter Williams  
Columbia, MO 65201  
USA  
Tel: (1) 573-882-6883  
Email: [CameronG@missouri.edu](mailto:CameronG@missouri.edu)

Abstract

The pharmaceutical industry has become one of the major industries worldwide as a result of increased efforts to reduce mortality and morbidity, the technological development of medical facilities and treatment, and the aging of the population. But because this product category is so closely associated with public health, pharmaceutical advertising has been strictly regulated by government agencies and monitored by the medical community, public health officials, and researchers. The complex issues involving multiple stakeholders raise the need for more open discussions among practitioners and researchers worldwide. In particular, the current global recession may intensify this pressure because of the economic benefits direct-to-consumer advertising (DTCA), which refers to advertising for prescription (Rx) medicines, provides. Taking account of these developments, this paper attempts to address the important and timely issue in global settings by providing an overview of regulations, studies, and practices in pharmaceutical advertising in the important Asian Pacific countries—Australia, Hong Kong in China, Japan, and South Korea—in addition to the US, one of the two countries where DTCA is allowed. Specifically, the following four issues are addressed in each of the five countries: (a) The current state of pharmaceutical advertising for domestic and global products in each panelist's country; (b) social, cultural, and regulatory issues that are relevant to pharmaceutical products and their ads; (c) empirical research on consumer perceptions and responses to pharmaceutical advertisements; and (d) future directions for research and practice. In so doing, this paper is expected to stimulate further discussions among policy makers, researchers, and practitioners, with regards to pharmaceutical advertising, health communication and policy, and relevant strategic communications in global health care settings.

Key Words: Pharmaceutical Advertising, Direct-to-consumer advertising (DTCA), Over-the-counter Advertising (OTCA), Public Health, Global Strategic Communication

**Acknowledgment**

This manuscript is based on a special theme session that was presented at the American Academy of Advertising-Asia Pacific Conference in Brisbane, Australia, on June 9, 2011. Paek proposed the session and originated the concept of the paper. Cameron served as a discussant in the session and wrote concluding remarks in this paper. The other authors, who made presentations for their respective countries as panelists in the session, are listed in the order in which each country was discussed in the paper.

**Pharmaceutical Advertising in Korea, Japan, Hong Kong, Australia, and the US:  
Current Conditions and Future Directions**

**1. Introduction**

**by Hye-Jin Paek**

Trends toward healthy lifestyles and consumer health concerns are a global phenomenon. The pharmaceutical industry has become one of the major industries worldwide as a result of increased efforts to reduce mortality and morbidity, the technological development of medical facilities and treatment, and the aging of the population (Auton, 2006). Its total expenditure in the world market was estimated at USD 663.50 billion (about 722 billion KRW) with the annual growth of 6.1% (IMS Health, 2007). According to *Advertising Age* (2010), twelve pharmaceutical companies are ranked as top 100 global marketers. These include Procter & Gamble Co. [1], Pfizer [5], Johnson & Johnson [6], GlaxoSmithKline [18], Merck & Co. [23], Eli Lilly and Co. [47], Bristol-Myers Squibb Co. [49], Bayer [55], Novartis [68], Sanofi-Aventis Group [71], Abbott Laboratories [72], and Boehringer Ingelheim [81]. In 2010, pharmaceutical product categories were tenth in ad spending, with 1.79 billion USD spent in the first quarter of 2010—a 3.6% increase compared to the first quarter of 2009. Thus, pharmaceutical advertising has been identified as the key driving force behind a successful launch of pharmaceutical products worldwide (IMS Health 2007). This worldwide growth and impact offer a compelling

reason for why it is important to understand how pharmaceutical advertising is practiced and regulated worldwide. But it is certainly not the only reason.

Existing research has also shown that pharmaceutical advertising serves as an important source of public health information, and that it exerts a significant influence on consumers' product choice and behavior (Lee, Salmon, & Paek, 2007). But because this product category is so closely associated with public health, pharmaceutical advertising has been strictly regulated by government agencies (e.g., FDA and FTC in the US) and monitored by the medical community, public health officials, and researchers. For instance, one type of pharmaceutical advertising is advertising for prescription (Rx) medicines, often called direct-to-consumer (DTC) advertising. DTC advertising refers to any promotional effort by a pharmaceutical company to present prescription drug information to the general public through consumer-oriented media (Pierpaoli, 1986; also Wilkes et al., 2000).

However, the definition is not always as clear as it sounds.<sup>1</sup> That is, three types of prescription drug advertisements aimed at the public can be distinguished (e.g., FDA, 2010; Gardner, Mintzes, & Ostry, 2003; Lyles, 2002): (a) *product claim* advertisements, which promote a specific product and include both the product name and specific therapeutic claims; (b) *reminder* advertisements, which provide the name of a product without containing or suggesting its use; and (c) *help-seeking* advertisements, which inform consumers of new but unspecified treatment options for diseases or conditions and encourage consumers to consult their doctor regarding treatment options. Help-seeking ads may include a drug company's name and may also provide a telephone number or website address where consumers can find additional information.

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<sup>1</sup> This paragraph originally appeared in the section authored below by Carolus L. C. Praet on pharmaceutical advertising in Japan. It was relocated here to preserve overall coherence.

When it is said that DTC advertising is currently allowed only in two countries worldwide, the US and New Zealand, only the first two categories of DTC advertising are applied. In this paper, we define DTC advertising in this narrow term unless specified otherwise.

There has been a heated debate on allowing DTC advertising, characterized by a sharp contrast between its proponents and opponents (see Lee et al., 2007). Proponents emphasize the role of DTC advertising as a source of consumer health information that empowers patients in the doctor-patient relationship and enables them to influence their doctors' prescription decisions. By contrast, opponents address concerns about safety, increased costs, interference with the doctor-patient relationship, and drug abuse. Furthermore, there has been growing criticism that DTC advertising fails to inform consumers about proper drug usage and potential misuse, and that it overstates advertised drugs' efficacy. Such criticism has been intensified by the market withdrawal of heavily advertised drugs such as Vioxx due to serious side effects and health problems. In this social atmosphere of alarm toward the potentially detrimental impact of heavy DTC advertising on consumers, the counterbalancing view is often neglected. That view is that "consumers have been empowered with additional information to the "level the field" with the health care community, contributing to more efficient doctor-patient exchanges" (Beltramini, 2010, p. 574).

Meanwhile, ads for over-the-counter (OTC) drugs are also subject to these criticisms. OTC drugs are medications that can be purchased at a pharmacy, grocery, or convenience store without a prescription to treat the symptoms of common colds or pains (Berry, 2001). The Food and Drug Administration (FDA) has determined that these medications have medical benefits for common ailments and are safe for general consumption. But similar criticisms apply to OTC advertising that is potentially misleading and deceptive (Sansgiry, Sharp, & Sansgiry, 1999).

Public health organizations and activists have highlighted the prevalence of misuse and abuse of OTC drugs, which can lead to side effects and health problems as serious as the ones caused by illegal drugs (e.g., The National Youth Anti-Drug Media Campaign). In 2009, an advisory committee recommended that the FDA place new restrictions on acetaminophen, which is the generic name for the pain relief ingredient found in many OTC branded products such as Tylenol, Excedrin, and numerous cold medicines. The reason was that acetaminophen could potentially cause liver failure and even death (Foxhall, 2009). This public recommendation could imply that more restrictions are to come on OTC products and their advertising. In addition, advertising practitioners and researchers will face more challenges as market environments change drastically and consumers become increasingly skeptical and distrustful of pharmaceutical advertising. This skepticism may differ in degree from one country to another (Diehl, Mueller, & Terlutter, 2007), but it will nevertheless exist.

In conjunction with the pharmaceutical industry's growing market and advertising, these complex issues involving multiple stakeholders raise the need for more open discussions among practitioners and researchers worldwide. In particular, even though the examples and debates described above focus on the U.S. case, the size of the pharmaceutical industry's global market calls for a better understanding of that market's many participants. For example, Asia has become a rapidly emerging market for the pharmaceutical industry (Epstein, 2007). The current global recession may intensify this pressure because of the economic benefits DTC advertising provides, which is clearly the case in Korea. Taking account of these developments, this paper attempts to address the important and timely issue in global settings by providing an overview of regulations, studies, and practices in pharmaceutical advertising in the important Asian Pacific countries—Australia, China with a particular emphasis on Hong Kong, Japan, and South

Korea—in addition to the US. While a stricter sense of DTC advertising (that mention product names) is not allowed in these Asian countries, the help-seeking and disease awareness types of advertising appear present or become more viable as a broader form of DTC advertising.

Specifically, the following four issues are addressed in each of the five countries: (a) The current state of pharmaceutical advertising for domestic and global products in the panelist's country; (b) social, cultural, and regulatory issues that are relevant to pharmaceutical products and their ads; (c) empirical research on consumer perceptions and responses to pharmaceutical advertisements; and (d) future directions for research and practice.

These four issues are discussed for each country in the following sections. First, Korea's pharmaceutical advertising is discussed along with the recent heated debates about permitting DTC advertising. Second, in the case of Japan, thorough economic and market analyses are provided and problems are noted concerning the unclear definitions of DTC advertising.

Third, Hong Kong, China's case is discussed based on reviews of empirical research on consumer perceptions of and responses to pharmaceutical advertising. Fourth, the case of Australia represents a unique situation because it neighbors New Zealand, one of the two countries that allow DTC advertising by law. In particular, it illustrates one example of subtle prescription drug promotion, as well as the growing concern about how this promotion occurs on the Internet.

Lastly, as one of the largest pharmaceutical advertising markets and a mecca of DTC advertising, the US case provides useful information on historical changes in regulation, empirical research, and current states and future directions with regards to DTC and OTC advertising.

This paper ends with a commentary put forward by the internationally renowned strategic communication scholar, Dr. Glen Cameron. In particular, he points out several key challenges, directions, and trends for future research and urges the relevant academic community to develop a more pointed and constructive program of research in the DTC advertising domain in particular and in the health advertising domain in general.

Taken together, this paper is expected to stimulate further discussions among policy makers, researchers, and practitioners, with regards to pharmaceutical advertising, health communication and policy, and relevant strategic communications in global health care settings.

## **2. Pharmaceutical Advertising in South Korea**

**by Hyegyu Lee**

### *Pharmaceutical Market*

The South Korean pharmaceutical market ranks tenth-largest in the world, estimated at worth around KRW13,917 billion (US\$12.4 billion) in 2011, a 5.3% increase on the previous year. Business Monitor International (BMI, 2011) estimates that market in 2015 will reach KRW 17,576 billion (US\$17.58 billion) in consumer prices. Prescription drugs account for 80% of the total. This phenomenon is due mainly to an increasing population of the elderly, and the prevalence of cancer and chronic diseases. In addition, Koreans tend to prefer physicians for medical assistance, even for minor ailments. Data show that Koreans visit physicians 11.3 times per year on average, much exceeding the OECD average of 6.8 times (BMI, 2008).

Accordingly, large multinational companies marketing original prescription drugs such as Sanofi-Aventis, GSK and Pfizer have dominated the marketplace, occupying the top rankings in

prescription drug sales. Although South Korea boasts around 250 pharmaceutical manufacturers, most of those have focused on generic products and over-the-counter (OTC) drugs (신범수, 2009).

In South Korea, annual per-capita spending on OTC items currently hovers around US\$45; this is less than Japan's comparative US\$60-plus, but more than Hong Kong's US\$34 (BMI, 2011). BMI (2011) expects Korea's OTC market to expand from US\$2.4 billion in 2010 to US\$2.6 billion in 2011, due to increase in Korea's aging population, removal of certain prescription drugs from the reimbursement list, and increased self-medication.

#### *Pharmaceutical Advertising Environment*

Traditionally, Koreans largely have depended on physicians and pharmacists for their medical decisions. Physicians have developed a paternal approach towards patients, and the latter generally have accepted this well (신동원, 2000). The paternal approach also applies in the relationship between pharmacists and patients. A survey by Korea Institute for Health and Social Affairs shows that more than 74% of purchases of cold medicine are made based on pharmacists' consultation; advertising influences only 5.6% of purchases (강신국, 2009).

Nevertheless, the advertising market for OTC products seems promising. The Korea Pharmaceutical Association estimates that advertising spending by major pharmaceutical companies will be some KRW170 billion, exceeds their research and development (R&D) spending of KRW140 billion (송대웅, 2004). The Korean Pharmaceutical Manufacturers Association reported that OTC advertising increased 21% in 2010 compared to 2009 (김길원, 2011).

Key drivers of South Korea's OTC advertising market are identifiable from social, cultural, and regulatory perspectives. Apart from the expectation that increases in Korea's aging

population will have a corresponding increase in medication spending, there is a cultural trend towards self-diagnosis and self-medication. A Nielsen study (2007) indicates that 35% of Korean consumers purchased OTC medicine they always previously had. Moreover, currently, the Korean government also is trying to modify extant regulations so that an increased range of OTC products will be available in convenience stores as well as in pharmacies (김경식, 2009); if this modification is implemented, self-medication without consultation with pharmacists could increase significantly.

### *Regulation of Pharmaceutical Advertising*

Currently, the Korean Pharmaceutical Affairs Law (KPAL) strictly regulates advertising of OTC drugs, and prohibits provision of information to the public about prescription drugs. Examples of such constraints are that a brand name should not be incorporated into an advertising song about OTC drugs, and that before-and-after drug use comparison advertisement is prohibited (황은하, 2008). As in many other countries, direct-to-customer (DTC) advertising is strictly prohibited in Korea. However, KPAL does not explicitly set restrictions of industry-funded disease awareness campaigns. Recently, a few pharmaceutical companies sponsored medical associations to launch diseases awareness advertising, evoking debates over its compliance to KPAL: Examples are an anti-smoking campaign sponsored by Pfizer that markets Champix (aid to tobacco cessation) and a cervical cancer prevention campaign by Merck Sharp and Dohme that markets Gardasil (cervical cancer vaccine) (이동근, 2008).

In recent years, there also have been movements to relax DTC advertising restrictions. In 2008, Korean law changed to allow advertising prescription drugs effective against communicable epidemic diseases. With this change, in 2009 the first TV commercial aired; this was for the Merck Sharp & Dome's of prescription diarrhea vaccine RotaTeq (이영수, 2009).

This relaxation evoked debates over the further allowance of direct-to-consumer (DTC) advertising in Korea

### *Debate over DTC Advertising*

Introduction of DTC advertising has been debated in recent years in Korea (박동준, 2009) and a clear division exists between proponents and opponents. Many of the former support DTC advertising for economic reasons. The Korean Ministry of Strategy and Finance in 2009 announced a possibility of relaxing the strict restrictions on drug advertising (박동준, 2009), and more recently, the Korean Communication Commission (KCC), the South Korean media regulation agency, proposed allowing DTC advertising to enlarge the advertising market (김현철, 2011).

Such movements have been criticized by DTC advertising opponents such as the Ministry of Health and Welfare, physicians' and pharmacists' societies, and civic organizations. DTC advertising critics argue that prescription drug advertising will lead to its misuse and/or overuse, price increases, and consequent negative impact on public health (김현철, 2011).

Despite these dichotomic voices from various organizations, however, not many arguments based on valid research evidence have been presented, nor any systematic overview of the clinical and economic impact of DTC advertising in Korea. Hence there has been no properly-informed debate on the pros and cons of DTC advertising.

Of concern is whether drug advertising educates or misleads consumers (Shin & Moon, 2005). Information conveyed via DTC advertising may fill an educational gap for current or potential patients—e.g., increasing disease awareness, earlier disease detection and better compliance with medical care. For example, a survey among Korean women showed that since

RotaTeq was advertised, awareness and knowledge of disease and its causes increased seven-fold, from 12% in 2007 to 82% in 2009 (이영수, 2009).

On the other hand, however, DTC advertising information may be inaccurate or unbalanced considering that its purpose, from an advertiser's perspective, is to promote a drug, but not to educate the public, and thereby to increase inappropriate and unnecessary use of medication. Furthermore, even when the information is accurate or balanced, consumers may misperceive or miscomprehend the information, thereby may decide wrongly. In particular, such risks might be higher for lifestyle drugs such as those for obesity, male-pattern hair loss or erectile dysfunction, for use of which consumers tend to make their own decision before or without consulting with doctors. Supporting this possibility, physicians have reported that they often receive consumers' request for prescription of such drugs (조필현, 2006; 이호갑, 2001).

As implied in cases described above, the DTC advertising effect might differ depending on product categories. Chang, Lee, Kim, and Lee (2008) report that older Koreans showed their desire to participate in making treatment decisions equally with physicians in cases such as common colds or hypertension, but less so in cases of congestive heart failure. In the RotaTeq ad evaluation survey (이영수, 2009), most respondents indicated they would follow physician's advice when deciding the use of product, suggesting that DTCA advertising would not pressure physicians to prescribe inappropriate medications in such product categories.

Taken together, we may conclude that DTC advertising could be a double-edged sword, the net consequences of which could benefit the public in some instances but harm that public in others. This controversial aspect calls for systematic and comprehensive review of pertinent issues, not only from clinical and economic perspectives but also from the perspectives of

various stakeholders such as healthcare professionals, consumers and the pharmaceutical industry.

#### *Future Perspectives*

The Korean government has strongly regulated drug promotion including advertising. Nevertheless, the current movement suggests that relaxations in laws governing this area may occur in the future.

As for OTC drugs, advertising has significant role in creating and maintaining their market in Korea. Moreover, it is supposed that marketers will increase spending on advertising, as an increase of self-medication is expected. Allowing DTCA, at least for some product categories or in limited media platforms, is anticipated.

Despite current and prospective changes in the pharmaceutical advertising environment, limited knowledge is available on the role of pharmaceutical advertising, not only from a public health perspective but also from a marketing perspective. More research is necessary concerning the central question of whether pharmaceutical advertising is beneficial to consumers and, if so, in what ways.

### **3. Pharmaceutical Advertising in Japan**

**by Carolus L. C. Praet**

#### *Pharmaceutical Market*

Japan's pharmaceutical market is the second largest in the world and accounted for 11% of global pharmaceutical sales in 2009. Data for 2009 indicate that Japan's expenditure per head of the population on pharmaceuticals was only second to that of the US (VFA, 2010). With

Japanese aged 75 years or older accounting for 28% of drugs consumption (Hodgson, 2008), the rapid aging of Japan's population is expected to drive the growth of the country's healthcare and pharmaceutical markets (Economist Intelligence Unit, 2005; Hodgson, 2008). The Japanese pharmaceutical market grew by 2.5% in 2009 to reach a value of \$66.9 billion (Datamonitor, 2009).

*The prescription drug market.* Japan's prescription drug market value is ten times that of its over-the-counter (OTC) market (Health Policy Bureau, 2008). In recent years, the Japanese government has reduced entry barriers for foreign pharmaceutical firms. While Japanese firms still dominated the market with a combined market share of 63% in 2003, recently the market share of foreign companies has grown. As a result, Pfizer, Roche (Chugai), Novartis and Merck (MSD) have now entered the Japanese top 10 of pharmaceutical companies (Mahlich, 2007)

In order to reduce rising healthcare costs, Japan's Ministry of Health, Labor and Welfare (MHLW) has started to actively promote the use of generic drugs to increase the volume market share of generic drugs from 17% in 2007 to 30% by 2012 (Hodgson, 2008; Wan, 2009; Yakuji Handbook, 2010). As a result of MHLW's policies, the volume share of generic drugs increased to more than 20% in 2009 (Yakuji Handbook, 2010). The limited size of the generics market in Japan stands in stark contrast with the relatively large volume share of generics in the pharmaceutical market of other major economies such as the USA (63%) and European countries such as Germany (56%) and the UK (59%) (Hodgson, 2008). One of the main reasons for this phenomenon is that Japan's national healthcare insurance system limits the patient's financial contribution or co-payment to a maximum of 30% of the retail price of prescription drugs. For people aged over 75, the burden is only 10% of the actual retail price. The system covers both branded drugs and generic drugs and consequently most patients have little financial incentive to

demand the generic version of a drug. In addition, the Japanese public tends to perceive generic drugs as being of inferior quality compared with brand-name drugs. In order to change the poor image of generic drugs and promote them as cost-effective and safe, the Japanese government is trying to educate the public through advertising and educational activities (Wan, 2009).

Three factors are expected to increase the market share of generic drugs in Japan in the near future: (a) the governmental push to lower the costs of the healthcare system by promoting prescription of generic drugs, as described above; (b) the so-called ‘2010 problem’, the expiring of patents on many prescription drugs in 2010; and (c) the recent entry by manufacturers of brand-name drugs –such as Pfizer– into the Japanese market for generic drugs, which will likely cause competitors to follow.

*The OTC drug market.* The Japanese OTC market value was \$6.27 billion in 2008 and was projected to remain stable at \$6.28 billion in 2009 (Yakuji Handbook, 2010). In contrast with prescription drugs, there are no retail price controls on non-prescription medicines in Japan (JSMI, 2004).

As part of its push to reduce the costs of the healthcare system, the government has also been promoting self-medication among consumers. Based on a revision of the Pharmaceutical Affairs Law (PAL), a new classification system of OTC drugs was introduced in June 2009. OTC drugs are now classified into three classes based on their risk level. Class one OTC drugs are those that are deemed to have the highest health risk, whereas class three drugs have the lowest risk (Yakuji Handbook, 2010).

For many OTC drug categories, Japanese consumers tend to be very brand loyal. Therefore, domestic companies that have established brands continue to hold a majority share of the market,

although foreign companies are expected to increase market share in new product categories (Euromonitor International, 2010).

#### *Pharmaceutical Advertising Expenditures in Japan*

Reflecting an overall decline in advertising expenditures in 2009, advertising expenditures for pharmaceuticals and medical supplies in the traditional media (newspapers, magazines, radio and television) declined 11.1% from 183.7 billion yen during 2008 to 163.3 billion yen in 2009. The majority of the industry's expenditures went to television (76%), followed by newspapers (12.1%), radio (6.7%) and magazines (5.2%) (Dentsu, 2010).

According to Japan Self-Medication Industry data, total expenditure for over-the-counter (OTC) advertising in 2004 was 176.9 billion yen. The expenditure by media was: television (71.2%), newspapers (16.7%), magazines (6.4%), and radio (5.7%) (JSMI, 2004). Similarly, the majority of direct-to-consumer (DTC) advertising expenditures in 2005 went to television (71.1%), followed by newspapers (16.5%), magazines (6.2%), and radio (6.2%) (Muto, 2008).

In 2008 the top ten spenders on DTC advertising accounted for 75% of total advertising expenditures. Four companies were Japanese, whereas six companies were foreign-affiliated. In fact, this represents a shift away from the traditional foreign dominance of the category toward more active involvement on the part of Japanese companies (Furukawa, 2009).

#### *Regulation of Pharmaceutical Advertising in Japan*

The "Pharmaceutical Affairs Law" (PAL) and the "Standards for Appropriate Advertisements of Pharmaceuticals" (SAAP), a directive issued by Japan's Ministry of Health, Labor and Welfare, regulate the pharmaceutical industry. In fact, PAL only prohibits pharmaceutical advertising that uses false or extravagant claims.

Currently, SAAP prohibits advertisements for prescription-only medicines to the general public. However, disease awareness campaigns, encouraging those with a particular medical condition to consult their doctor, are permitted provided they do not mention specific drug brand names in the advertisements (Iimura & Kuwagata, 2010; Sugahara, 2003).

In January 2011, the Government Revitalization Unit (GRU) in charge of deregulating the Japanese market proposed that the SAAP clause which prohibits DTCA to the general public be abolished from fiscal year 2011. At the time of writing, MHLW had not yet adopted the proposal and it remains unclear whether it will do so in the future. Medwatcher Japan –an NGO that monitors the behavior of pharmaceutical companies and regulatory authorities– strongly criticized the GRU proposal and instead proposed a revision of PAL to the effect that it would prohibit DTC advertising altogether (Medwatcher Japan, 2011). Thus, regulation/deregulation of DTC advertising remains a highly controversial issue in Japanese public discourse.

In fact, legal controls and administrative guidance (in the form of SAAP) play only a relatively minor role in restricting pharmaceutical advertising; the bulk of pharmaceutical advertising regulation takes place at the industry level in the form of voluntary control or self-regulation.

All classes of OTC medicines can be advertised in Japan. However, OTC advertising is subject to strict compliance with regulatory and voluntary controls. The majority of regulations regarding pharmaceutical advertising in Japan are controlled at the voluntary industry code level. The voluntary code stipulates in detail –for each of the three risk level categories of OTC drug and for all media categories– the format and contents of warning messages to be included regarding proper use of the advertised drug. The voluntary code also explicitly stipulates that

comparative advertising for pharmaceuticals is not allowed, but that the comparison with a company's own products is permissible (JSMI, 2004).

In 1974, the OTC medicine industry established a self-regulatory control body called the “Advertising Review Board” (ARB), which holds bi-monthly meetings to post-review OTC advertising carried in television, radio, newspapers and magazines during the previous two months (JSMI, 2004).

#### *Characteristics of Japanese DTC Marketing and Advertising*

Data on DTC advertising—disease awareness and help-seeking campaigns, but excluding corporate advertising—expenditures in the mass media reported by Furukawa (2009) show that expenditures have grown dramatically from 1.1 billion yen in 1999 to 11.6 billion yen in 2008. The amount spent on DTC advertising will likely increase in the future as in 2005 DTC advertising spending by pharmaceutical companies in Japan was only 0.75% of their total marketing budgets, whereas DTC advertising expenditures amount to 21% of DTC marketing budgets in the US (Muto, 2008).

If one uses a narrow definition of DTC advertising as promotion of brand-name prescription drugs, the conclusion would be that DTC advertising is not allowed in Japan. However, if one expands the definition to include help-seeking campaigns—including disease awareness campaigns—aimed directly at the public and which indirectly promote a company's products by linking the company brand to the disease, then DTC advertising is allowed and used in Japan. Thus far, there has been little debate in Japan about the definition of the term DTC advertising, but Furukawa (2009) makes a case for including disease awareness and help seeking campaigns that target the public through the mass media in the definition of DTC advertising. He notes that some Japanese commentators argue that a distinction should be made between (a)

DTC advertising campaigns that mention a product name and (b) disease awareness and help-seeking campaigns, and points out that Japanese media appear to make this distinction as well. However, many Japanese pharmaceutical and advertising industry insiders appear to include disease awareness and help-seeking advertising campaigns –and even corporate advertising– into their definition of DTC advertising (e.g., Muto, 2008).

Based on the above definition of DTC advertising, Furukawa (2009) subdivides help-seeking DTC advertising messages into five types: (a) patient disease awareness/education; (b) increased disease cognition; (c) self-awareness of symptoms; (d) understanding of treatment; (e) encouragement of doctor consultation. He reports that nearly all Japanese DTC advertising TV campaigns broadcast between 2000 and 2008 encouraged patients to seek doctor consultation, often in combination with one or more of the other types of message goal.

As is the case in other countries, marketing of prescription drugs in Japan has been traditionally characterized by a heavy reliance on push marketing through medical representatives (MR) (Furukawa, 2009). Only recently have companies started to complement push marketing with pull marketing by targeting consumers directly through DTC advertising in the form of disease awareness and help-seeking campaigns. The number of DTC ads by generic manufacturers has also been on the increase in recent years (JETRO, 2010). Japanese DTC marketing is characterized by its use of integrated marketing communication campaigns that integrate above-the-line media with below-the-line activities and often feature links to corporate websites or websites specifically designed for the DTC campaign.

One characteristic of Japanese advertising in general (Praet, 2001; 2009) that also applies to pharmaceutical advertising, is the heavy reliance on celebrity endorsement. One reason for this phenomenon specific to pharmaceutical advertising is that pharmaceutical ads are not

allowed by law to make price claims, nor can they appeal to quality of the manufacturing process, superiority claims, specific benefits, or the effectiveness of the drug.

In the case of OTC drugs, one of the few ways to differentiate a product from the competition –apart from differentiation through brand name or packaging– is through image advertising. The use of a specific celebrity allows companies to differentiate their corporate or product brand image from competitors or to appeal to specific target groups. Another reason for this phenomenon is that in Japan, marketers of prescription drugs are not allowed to promote product brand names. As a result, DTC ads tend to rely as heavily as, if not more heavily than OTC ads, on celebrities. As many prescription drug ads (including ads for generic drugs) target older people, the use of older celebrities popular among the elderly is prevalent as an effective means to convey a sense of trust in the company and its products.

#### *Directions for Future Research*

To date, very little –if any– empirical research has been conducted on the characteristics of Japanese pharmaceutical ads. In addition, research needs to address the views of pharmaceutical corporations, advertising professionals, and health care professionals on the use of DTC advertising in Japan. Finally, research on Japanese consumer attitudes toward and perceptions of DTC advertising and OTC advertising is needed.

As discussed above, when discussing DTC advertising it is necessary to distinguish among the three types of advertising and to be explicit in one's definition of the term. Finally, it is also necessary to consider whether corporate advertising by prescription drug manufacturers should be included in a definition of DTC advertising.

#### **4. Pharmaceutical Advertising in Hong Kong, China**

**by Kara Chan**

##### *Overview of Pharmaceutical Advertising*

The Hong Kong pharmaceutical market is attractive, despite a relatively small population and market size. It is the gateway to the world's fastest-growing economy, China, and is in close proximity to many emerging economies. The healthcare system of Hong Kong is of high standard when compared with other countries in the Asia Pacific region (Espicom Limited, 2011). The Hong Kong pharmaceutical market is expected to grow from USD0.9 billion in 2009 to USD1.4 billion by 2014, up from the calculated HKD7.19 billion in 2009 (Hong Kong Business, 2011). The growth in the pharmaceutical market can be attributed to three sources. First, the cut in funding for the pharmaceutical consumption in public hospitals pushed patients to pay for their own medicines. Second, a proposed voluntary health insurance scheme has the potential to improve the breadth of healthcare service and the use of pharmaceuticals. Third, the aging population profile gives rise to a higher need for medicines for chronic diseases (Hong Kong Business, 2011).

In Hong Kong, there have been pharmaceutical advertisements for a specific kind of diseases in the mainstream media aimed directly at the general public (Diehl, Terlutter, Chan, & Mueller, 2010). Pharmaceutical and health care advertising has increased from 6.4 million in 2009 to 7.7 million US dollars in 2010, hence by 21 percent (admanGo, 2011). The two major advertisers in the pharmaceutical and health care category include Fortune Pharmacal, a local pharmaceutical manufacturer for cold and flu killers, and GlaxoSmithKlith, a global pharmaceutical company manufacturing Panadol and other medicines (admanGo, 2011).

### *Regulations of Pharmaceutical Advertising*

In Hong Kong, pharmaceutical advertising for major diseases (such as tumors, venereal diseases, or diseases of the heart or cardiovascular system) aimed directly at the general public via mainstream media are prohibited under the Undesirable Medical Advertisements Ordinance (Hong Kong SAR Government, 2010). Pharmaceutical advertising for minor diseases (such as common colds, coughs, influenzas, rhinitis, indigestions, headaches, dry skin) are allowed. Pharmaceutical advertising on the broadcast media are further regulated by the Generic Code of Practice on Television Advertising Standards (Hong Kong Broadcasting Authority, 2010a). According to these regulations, selected medical preparations and treatments such as smoking cessation, clinics for the treatment of hair and scalp, pregnancy testing services are prohibited to advertise on the broadcast media. In addition to the kind of diseases to be advertised, the design and the contents of the pharmaceutical advertisements are strictly controlled (Diehl et al., 2010). In order to avoid giving the impression of professional advice and support, presentations of doctors or other medical professionals in the ads are not allowed. Presentations of a patient undergoing treatment, dramatization of ailments, and offensive descriptions of the illness are also banned. Advertisements should not make exaggerated claims with superlative and comparative adjectives such as ‘the most successful’ and ‘quickest.’ Additionally, sales promotions of any kind are prohibited in pharmaceutical advertising (Diehl et al., 2010; Gao, 2005).

### *Consumers' Perception of Pharmaceutical Advertising*

Self-medication is common in Hong Kong. A telephone survey found that over 32 percent of respondents reported that they took over-the-counter (OTC) medicine over the last two weeks (Lam, Tse & Munro, 1989). Self-medication was preferred to consulting a doctor

when respondents perceived the illness as minor. Other reasons for self-medication included convenience, insufficient time to consult doctor, non-availability of doctor, prior knowledge of what to do, and cost saving (Lam, Catarivas, Munro, & Lauder, 1994). A survey revealed that self-medication was illness-specific. Respondents were more likely to self-medicate when suffering from diarrhea, flu and stomachache. Respondents were less likely to self-medicate when they have fever (Chan & Ha, 1997). People concurrently use both traditional Chinese medicine and western medicine but they seem to have different perceptions about these medicines. A focus group study found that interviewees considered traditional Chinese medicine perform better in curing the root of the health problem. However, Chinese medicine was perceived to be slow in action. Western medicine was perceived to be more powerful, but had risky side effects (Lam, 2001).

In general, Hong Kong consumers had positive attitudes towards OTC advertising (Chan & Ha, 1997). They agreed that OTC advertising provide information about new medicine and utilities of individual brands. The major criticisms among Hong Kong consumers of OTC advertising included its economic cost and perceived confusing messages because most ads were very similar. They also perceived that most OTC advertising exaggerated the therapeutic functions of the products. OTC advertising had not been very successful in enhancing buying confidence among Hong Kong consumers. Most of the respondents did not perceive pharmaceutical advertising help them to select the best brand. They did not perceive that brands that advertised more are better (Chan & Ha, 1997). According to a survey, respondents most often sought out information about self-medication from family members and friends. They considered pharmaceutical advertising the second most important source of information about self-medication. Respondents in the middle-aged and the working class tended to rely on

pharmaceutical advertising as a source of information (Lam et al., 1994). A recent study found that Hong Kong consumers' had no difference in skepticism toward advertising of prescription drug and non-prescription drug. The result may be due to the consumers' inability to differentiate between advertising of prescription drug and non-prescription drug (Diehl et al., 2010).

#### *Consumers' Complaints of Pharmaceutical Advertising*

The Hong Kong Broadcasting Authority is responsible to deal with consumers' complaints toward pharmaceutical advertisements broadcast on television and radio. During the period January 2008 to February 2010, the Broadcasting Authority announced its investigation of 40 television commercials of pharmaceutical products being complained by consumers (Hong Kong Broadcasting Authority, 2011). Most of the complaints were about the presence of disgusting scenes or sounds, such as the showing of cleaning sputum, sneezing at a person, or the appearance of black dots on the body. Five complaints were about the substantiation of claims or the possibility of misleading in the advertisements. For example, one complaint that the claim of "all residues would be discharged after taken" by Panadol Reluctance advertisement was unscientific. The Hong Kong Broadcasting Authority obtained the relevant expert advice that the active ingredient of the medicine, paracetamol, is extensively metabolized and its metabolites can be excreted largely in the urine. As a result, the complaint was considered unsubstantiated (Hong Kong Broadcasting Authority, 2010b). Another complaint stated that a woman character in the Coltalin GP Extra (a flu killer) remarked, "for ordinary cold or flu, it is not a must to see a doctor." This remark misleadingly implied that it is not necessary for one to see a doctor when having a cold. However, the complaint was unsubstantiated because the advertisement did not discourage viewers from consulting doctors when ill (Hong Kong Broadcasting Authority, 2008). It was found that the complaints for all 40 pharmaceutical advertisements were unsubstantiated.

It indicates that pharmaceutical advertisers exercise much self-regulation and they have been stringent in making health claims in the broadcast medium.

#### *Debates on Pharmaceutical Advertising*

There are debates in the Hong Kong society over pharmaceutical advertising. On one hand, the trade and the advertisers urged the government to relax restrictions on advertising of restricted drugs (Lam & Smith, 2002). On the other hand, the medical professionals demanded stricter regulations because some pharmaceutical products disguised themselves as health products in the advertisements. The medical professionals worried that misleading pharmaceutical advertisements would induce improper self-medication, cause health hazards and delay proper medical treatment. Taking into account the opinions from the public and the trade, the Undesirable Medical Advertisement Ordinance was amended in 2005. The major amendment is to extend the prohibition/restriction on advertising to six additional groups of claims related to breast lumps, genitourinary system, endocrine system, body sugar/glucose, blood pressure as well as blood lipids/cholesterol (Hong Kong SAR Government, 2010). Nevertheless, to the disappointment of medical professionals, the amended ordinance did not include three types of claims, namely, the regulation of the immune system, the promotion of detoxification and slimming/fat reduction. This may be because the government believes that these claims pose relatively lesser risk to public health (Lam, 2005). The consumers are pressing for the right to be informed, while at the same time expecting the government to step up regulation against misleading claims in pharmaceutical advertising.

#### *Future Directions*

To summarize, the Hong Kong pharmaceutical market is characterized by the concurrent use of both Western and Chinese medicines. As Chinese medicines are increasingly adopted as

preventive health measures, there will be more research on the consumer perception of effectiveness of Western and Chinese medicine. Hong Kong consumers are pressing for informed consumer choice. It is expected that there will be more advertisements on medication of chronic diseases as well as more advertisements for prescribed pharmaceuticals.

## **5. Pharmaceutical Advertising in Australia**

**by P. Monica Chien**

### *Pharmaceutical Market and Advertising*

The pharmaceutical industry is one of Australia's major innovators and also the second largest exporters behind automotive vehicles, parts, and accessories (Medicines Australia, 2010). The pharmaceutical trade makes a significant contribution to the nation's economy as it generates in excess of AUD\$11 billion in revenue annually (IBIS World Industry Research Report, 2011). It is estimated that Australia will be the fifth largest pharmaceutical market in the Asia Pacific region in 2016 (Espicom Business Intelligence, 2011). Recently, research has shown that the impact of global financial crisis caused Australian consumers to reassess their shopping habits (Nielsen Media Research, 2010). This trend presents a new challenge for the pharmaceutical industry as shoppers are looking for value, resulting in frequent promotional activity and price deflation for over-the-counter medicines.

As the Australian pharmacy trade has recorded strong annual growth, pharmaceutical industry represents the 15th largest advertising category in Australia (Nielsen Media Research, 2010). In the 12 months to September 2010, pharmaceutical companies recorded an estimated spending of AUD\$217.5 million on mass media advertising, although this figure included both

disease awareness advertising and OTC advertising (Nielsen Media Research, 2010). Currently, the top ten pharmaceutical advertisers in main media are GlaxoSmithKline Australia, Reckitt Benckiser, Wyeth Australia, Johnson & Johnson, Sanofi-Aventis Consumer Health Care, Health World, Novartis Australia, Swisse Health Products, Schering Plough, and Pfizer, representing more than half of all advertising spending in Australia (Nielsen Media Research, 2010).

High levels of advertising spending have been linked to increased public awareness of health or medical conditions, which in turn, may cause consumer anxiety and induced purchase (Donovan, 1999; Jones & Mullan, 2006). Indeed, the OTC categories in Australia such as anti-inflammatories and rheumatics, wound care and gastrointestinal treatments have experienced sales increases over the past year as a result of growing media exposure (Nielsen Media Research, 2010). This trend implies that DTC advertising may also contribute to expectations about the benefits of drug treatments and lead to increased pharmaceutical expenditures by consumers, if it becomes lawful.

#### *Regulation of Direct-to-Consumer (DTC) Advertising*

Advertising of medicines in Australia is governed by the Therapeutic Goods Act and two industry codes of practice: the co-regulatory Therapeutic Goods Advertising Code by the Therapeutic Goods Administration and the self-regulatory Medicines Australia Code of Conduct (Australian Government Department of Health and Ageing, 2007; Hall, Jones, and Iverson, 2009). The former covers promotion of OTC and complementary medicines to the public, whereas the latter contains a section of Communications with the Public which covers matters such as media releases about named prescription products, general media articles, and patient education (Medicines Australia, 2010).

However, given the physical proximity and close economic relations between Australia and New Zealand, the legality of DTC advertising in its neighbouring country has significant implications for Australia (Vitry, 2004). There has been speculation that a common regulatory drug agency may be eventuated, such as the development of a Trans-Tasman regulatory scheme for therapeutic products (Hall, Jones, & Hoek, 2011). Moreover, the Free Trade Agreement (FTA) between Australia and the USA, in which medicines are a key component of negotiation, provided another impetus toward less regulation in Australia (Australian Government Department of Health and Ageing, 2007). The new clause gave pharmaceutical manufacturers permission to disseminate information directly to health professionals and consumers via the manufacturers' web sites (Mackenzie, Jordens, Ankeny, McPhee, & Kerridge, 2007). This has resulted in a relaxation of the ban on Internet DTC advertising and led to some discussion about review of DTC advertising legislation in Australia (Toop, 2006).

#### *Current Advertising Issues*

Although DTC advertising is currently banned in Australia, there is a growing concern about the subtle use of prescription drug promotion. The Australian Consumers' Association has shown some of the tricks used by pharmaceutical companies to circumvent the current regulations (Toop, 2006). The most common strategy is to use disease awareness advertising (DAA) as a disguise. Pharmaceutical company-sponsored DAA is designed to promote disease awareness and to provide treatment information without mentioning the name of a drug, but may include the company information or logo (Hall et al., 2011; Miller & Waller, 2004). For example, in an extensive advertising campaign for *Orlistat* (a medication produced by Roche), the public was told the story of "Linda" who took an "innovative approach" to lose weight (Vitry, 2004). Although the advertisements did not mention the name of a prescription medicine, concurrent

mailings about the “Xenical Lose Weight Gain Life Program” were sent to doctors with the company’s logo and reproductions of consumer advertisements. Similarly, a variety of late-night infomercials have been developed that combine depiction of a health condition and an exhortation to the viewer to “ask your doctor about new treatments” (Mackenzie et al., 2007). These un-named product advertisements have evaded the limits of the law, by masquerading as community education or disease awareness campaigns (Hall & Jones, 2007).

Other communication strategies often used by pharmaceutical companies include (a) email spam; (b) the use of emotional appeals or celebrity endorsements to promote consumer awareness of conditions (e.g., Pfizer indirectly promoted a drug for erection problems by using ads featuring the legendary soccer player Pele to urge men to consult a doctor); (c) sponsorship of journalists to attend pharmaceutical conferences overseas or journalism awards; (d) funding non-profit organizations and their disease awareness programs (e.g., the Arthritis Foundation encouraged arthritis patients to talk to their doctors about an exciting new treatment following Celebrex’s donation of AUD\$250,000); and (e) using alternative promotional channels such as posters, product packaging and branded merchandise (e.g., hairdressers wearing capes branded by Novo Nordisk were involved to increase the sales of a topical preparation of oestradiol) (Glatter, 2004; Hall & Jones, 2008; Hall et al., 2011; Hoek, 2008; Mackenzie et al., 2007; Vitry, 2004).

Increasingly, consumers’ active use of the Internet in searching out health care information has rendered communication control almost impossible (Mackenzie et al., 2007). Australian consumers can readily access web sites that are either sponsored by pharmaceutical brands or linked to drug company web sites. International accessibility means that overseas based websites are outside the Australian jurisdiction and thus do not breach the Medicines

Australia's Code of Conduct (Australian Government Department of Health and Ageing, 2007). Meanwhile, since the Code of Conduct relies on consumers' complaints, it presents a number of loopholes that allow pharmaceutical companies to subvert the ban (Vitry, 2004). For example, Sanofi-Synthelabo's advertisement of hypnotic zolpidem was seen by thousands of travellers as it circulated through the Qantas in-flight magazine, until a complaint was lodged and the company was fined AUD\$50,000 (Vitry, 2004).

#### *Research on DTC Advertising Effects*

Because DTC advertising does not exist in Australia, research on its effects has been either sporadic or hypothetical. In an exploratory study, Miller and Waller (2004) identified four issues related to consumer attitudes toward DTC advertising: (a) information, (b) quality, (c) credibility, and (d) price. The authors indicated that while respondents did not have a strong feeling for or against DTC advertising, appropriateness of DTC advertising was found to depend on the type of medicines being advertised. Whereas ads for antidepressants and respiratory steroids were perceived by respondents as inappropriate, ads for anti-obesity, cholesterol reducers, antihistamines, analgesics and smoking cessation were deemed acceptable (Miller & Waller, 2004). Future research needs to identify the mechanisms that underlie consumer perception of appropriateness, in order to provide input for the development of advertising for both DTC and OTC medicines.

More recently, Hall et al. (2011) studied Australian consumers' responses towards disease awareness advertising and compared these with New Zealand consumers' perceptions of DTC advertising. Despite differences in the types of advertising, respondents believed that disease awareness advertising and DTC advertising not only generated awareness of disease and treatment options, but also improved discussions with their doctors. However, many consumers

in New Zealand felt confused by the information in DTC advertising and agreed that most people lacked the technical knowledge to judge the benefits and risks associated with an advertised product. Similarly, Australians found disease awareness advertising to be often confusing and difficult to understand. These findings may alarm Australian policy makers and consumer advocates as pharmaceutical brands embedded in the disease awareness programs may implicitly influence consumer behavior. Results of Hall et al.'s (2011) study supported previous research findings on DTC advertising's ability to mislead consumers (e.g., Jones & Mullan, 2006) and implied the possibility of advertising miscomprehension.

It is important to understand how consumers perceive different elements of DTC advertising and respond to marketing strategies used by pharmaceutical companies so as to determine the persuasiveness of communication. The processes by which consumer-focused outcomes are achieved, and theoretical explanations for them, need to be fully addressed by future studies. For example, consumers' implicit memories for pharmaceutical brands may play a key role in influencing patient's request for a particular drug. Longitudinal studies may be required to understand whether previously encoded brand information implicitly affect present information processing to influence cognition and behavioral intention (Lee, 2002).

#### *DTC Advertising Outlook in Australia*

While an imminent introduction of DTC advertising in Australia is unlikely, there have been active debates over its potential benefits. Advocates of DTC advertising claim that it provides health information to consumers which may encourage early detection of undiagnosed conditions, increases salience of health issues in general, empowers consumers in health decision-making, and improves compliance (Harker & Harker, 2007; Hoek, 2008). However, there are still concerns over the use of DTC advertising, including the profit driven motives of

pharmaceutical companies, the potential for unbalanced information, the creation of a “pill for every ill” mentality, and negative implications on doctor-patient relationships (Finlayson & Mullner, 2005; Hall & Jones, 2007). Proliferation of health information web sites has made policing difficult, if not impossible. The fact that camouflaged DTC advertising is occurring in Australia and the current regulation has been effectively sidestepped suggests that prohibition is, on its own, an inadequate policy (Mackenzie et al., 2007). Clearly, strategies on how best to counteract these drug campaigns beyond legislation are needed to respond to the challenges raised by pharmaceutical marketing in Australia.

## **6. Pharmaceutical Advertising in the U.S.**

**by Jisu Huh**

### *Overview of Pharmaceutical Advertising*

*DTC advertising.* Traditionally, most marketing efforts promoting Rx drugs focused on direct-to-physician advertising in medical journals and personal visits by salespeople. However, changes by the US Food and Drug Administration (FDA) in 1997 to its regulation of DTC advertising were followed by a dramatic increase in the amount of DTC advertising, especially in broadcast media.

DTC advertising became one of the fastest growing advertising categories in the 2000s. In 2006 at the height of spending, DTC advertising spending reached \$5.5 billion and then went down to \$4.8 billion in 2007 and \$4.4 billion in 2008. More recent statistics indicate that DTC advertising spending seems to have been stabilized at the \$4.5 billion level in recent years after two years of sharp declines (Arnold, 2010).

*OTC Advertising.* In 2008, about \$3.6 billion was spent to advertise OTC drug brands and the advertising spending slightly dropped in 2009 to \$3.2 billion (OTC Perspectives, 2010). Among advertising media, television (\$2.0 billion) and magazines (\$834 million) received the lion's share of 2009 ad dollars, followed by the Internet (\$156 million) and radio (\$103 million) (OTC Perspectives, 2010).

#### *Regulation of Pharmaceutical Advertising*

The practice of advertising pharmaceuticals directly to consumers has a long history in the U.S., with many patent medicines advertised in newspapers in the 18<sup>th</sup> – 19<sup>th</sup> centuries. Such practice was unregulated until 1906 when Congress passed the Pure Food and Drug Act, which was directed at regulating product labeling (Schwartz, Silverman, Hulka, & Appel, 2009). In 1938, Congress passed the Food, Drug, and Cosmetic Act (FDCA), providing the framework for contemporary pharmaceutical advertising regulation (Donohue, 2006). In 1951 Congress enacted the Durham-Humphrey Amendments to the FDCA, which created Rx and OTC drug categories (Palumbo & Mullins, 2002). In 1962, Kefauver-Harris Drug Amendments Act transferred jurisdiction of Rx drug advertising from the US Federal Trade Commission (FTC) to the FDA, which remains in effect today (Schwartz et al., 2009). However, the FTC still regulates OTC advertising.

The FTC regulates OTC advertising under section 5 of the Federal Trade Commission Act, which states 'unfair or deceptive acts or practices' as unlawful. The principle is that all advertising should be truthful and not misleading and all claims substantiated (Watts & Wilkenfeld, 1992). The FTC defines deceptive advertising as an ad containing a representation or omission that is likely to mislead reasonable consumers. The omission of or failure to provide material information also constitutes deceptive advertising.

In addition, the FTC's advertising substantiation doctrine requires that all objective product claims, either explicit or implied, should be adequately substantiated. If an ad claims the drug has been proven effective for a particular condition, the company should be able to produce evidence to support the statement. Often, the FTC collaborates with the FDA to determine if there is a 'reasonable basis' for ad claims of OTC drugs (Watts & Wikenfeld, 1992). The FTC considers six factors to determine a 'reasonable basis': (a) type of claim, (b) nature of the product, (c) benefits of a truthful claim, (d) consequences of a false claim, (e) cost of developing substantiation, and (f) amount of substantiation that experts in the field believe is reasonable.

DTC advertising is regulated by both the FDA and the FTC following the same deception doctrine and advertising substantiation doctrine applied to OTC advertising regulation, but the role of the FDA is much more significant for DTC advertising than is the FTC. The FDA rules require all DTC ads mentioning both the advertised brand name and the treated disease to present (a) 'brief summary' of the drug's side effects, contraindications, warnings, and precautions and (b) 'fair balance' between the drug's risks and benefits (FDA/ Department of Health and Human Services, 1985).

In 1997, the FDA loosened its regulation and created new guidelines for broadcast DTC advertising. The new rules required that DTC advertising in broadcast media only need to contain information about 'major risks' instead of a full 'brief summary.' Under the 'major risks' requirement, ads must disclose the drug's major risks and most common adverse effects. Instead of a 'brief summary,' DTC ads may make 'adequate provision' for dissemination of package labelling information by referring consumers to other sources (e.g., toll free number, website, print ads) (FDA, 1999). The FDA issued new draft guidance for print ads in 2004, which focus

on using language and formats that more clearly convey risk information so the consumer is more likely to understand it.

### *Research on DTC Advertising Effects*

The issues surrounding DTC advertising involve questions of public health, health care costs, corporate responsibility, advertising ethics, physician/patient dynamics, and consumers' ability to understand and use medical information. Historically, health care professionals have exhibited negative attitudes toward DTC advertising. Early studies reported the majority of physicians perceived DTC advertising would produce negative outcomes, increase demand for advertised drugs, or raise drug costs, and viewed DTC advertising as a challenge to their authority and were concerned it might undermine the physician-patient relationship. However, as research has accumulated, more positive or mixed views have been reported (for detailed review, see Huh & Langteau, 2007).

Although most physicians do not believe their prescribing practice is affected by DTC advertising, surveys of physicians have provided interesting findings. Murray et al. (2003) found most physicians filled requests for new Rx medicines. Huh and Langteau (2007) demonstrated that while physicians' responses to patients' request for an advertised drug were mixed, greater presumed detrimental effects of DTC advertising predicted refusal of patient requests.

Compared to physicians, consumers have shown more positive attitudes toward DTC advertising. They believe DTC advertising can provide useful drug information and education about new treatments (e.g., FDA, 2004; Huh, DeLorme, & Reid, 2004). Nevertheless, there are indications that consumer views may be moderating, showing increasing skepticism toward DTC advertising and negative perceptions (Spake & Joseph, 2007). Despite the increasingly skeptical views among consumers, DTC advertising has been found to impact consumer behavior and

physician-patient interaction by motivating consumers to seek more information and to initiate discussions with doctors. Some consumers ask their doctors to prescribe advertised brands or change prescriptions (Government Accountability Office [GAO], 2006).

Studies about DTC advertising effects suggest both positive and negative effects on consumers: DTC ads have been found to encourage consumers to talk to their doctors about previously undiagnosed conditions and obtain treatment. However, in some cases, DTC ads are related to: increases in prescriptions for advertised drugs when alternatives may be more appropriate, and cultivating perceptions of disease prevalence (for detailed review, see DeLorme, Huh, Reid, & An, in press).

#### *Research on OTC Drug Advertising Effects*

OTC advertising has been the focus of limited academic study, though extensive proprietary research certainly exists (but for a detailed review of the existing literature on OTC advertising, see DeLorme, Huh, Reid, & An, 2010). But some evidence suggests consumer attitudes toward OTC advertising are generally unfavorable. Diehl et al. (2007, 2008) found less favorable attitudes toward OTC advertising than advertising in general but the survey also found that consumers were less skeptical of OTC advertising than advertising in general. Another study (Mackowiak et al., 1997) reported that pharmacy professionals also viewed OTC advertising unfavorably because they consider the ads to be untruthful and to omit information.

Only two experiments have tested causal links between OTC advertising and consumer responsiveness. Kavanoor, Greweal, and Blodgett (1997) studied effects of ad credibility and ad format (comparative vs. non-comparative) on beliefs, attitudes, and behavioral intention. Though ad credibility did not moderate format effects, comparative/high credibility formatted ads consistently produced the most favorable responses. Wright (1979) tested the effect of

instructions in TV commercials which urged consumers to read in-store warnings about OTC drugs and product packages, and found a message combining a concrete verbal action instruction with a visual of the action produced a short-term increase in package inspection and reading of in-store warning signs.

In addition to micro-considerations, OTC advertising also plays a role in the larger American economy. Market competition and advertising's economic contributions are closely associated, though the jury is empirically out on whether the associations involving OTC drugs are good or bad for the consumer. Proponents argue advertising allows pharmaceutical companies to compete with one another more effectively. Such competition, it is argued, produces new and better OTC medicines, and at competitive prices. Critics counter OTC advertising is anti-competitive, resulting in higher prices, barriers to market entry, and wasteful economic resources. Though the research is not extensive, the evidence is revealing. Ling, Berndt, and Kyle (2002) studied the order-of-entry effects and other outcomes relative to marketing efforts and Rx-to-OTC switching and found that pioneering OTC drug brands enjoy order-of-market entry advantages (e.g., Tylenol, Advil), while first-mover advantages are not insurmountable for later entrants.

#### *Directions for Future Research*

This brief overview of the current state, issues, and research regarding DTC and OTC advertising in the U.S. pharmaceutical market suggests that advertising appears to be a prominent and important driver of the purchase and consumption of pharmaceuticals. Americans are more empowered in their personal health care today than ever before. They seek more knowledge about traditional as well as alternative medicines. Advertising, although intended for profit, appears to play a role in helping fulfill their informational needs. However, advertising in

this public health domain is especially complex compared to other types of consumer advertising and not without challenges.

Nevertheless, there are still many gaps in our understanding of the influence of DTC and OTC advertising on consumers. For example, the following questions remain unanswered: (a) whether DTC advertising is beneficial or harmful to a patient's health; (b) how physicians respond to patients' inquiries about and requests for an advertised drug; and (c) what are the effects of DTC advertising on appropriateness of drug use, compliance with drug instructions, preventative health measures, use of health care services, and changes in pharmaceutical costs.

The OTC advertising literature stream is small, fragmented, and dated. New evidence is needed for the following: (a) ad content characteristics including information/persuasive balance, prevalence of health/non-health claims, and human portrayals; (b) accuracy of product claims and side effects in ads; (c) consumer response to OTC advertising content, including its role in information seeking and decision making for specific OTC drug categories and Rx-to-OTC drug switches; (d) the impact of OTC advertising on patient/health care provider interaction to determine how ads affect advice seeking and giving regarding OTC medications; and (e) advertising's role in the OTC drug market at both the aggregate and product category levels.

A new emerging trend in DTC and OTC advertising that deserves future research attention is the growing advertising on the Internet or digital media. For both Rx and OTC drugs, the Internet stands out as the fastest growing medium for advertising targeting consumers. OTC advertising spending on the Internet increased by 65.5% between 2008 and 2009, while almost all other media ad spending decreased (OTC Perspectives, 2010). A recent forecast predicted that pharmaceutical advertising spending across digital media in the U.S. market would surpass the total ad spend in print in 2010 (OTC Perspective, 2010). DTC advertising has also increased use

of the Internet as an advertising channel (Huh & Cude, 2004; Tripp & Straub, 2001). The increasing use of various online media platforms for pharmaceutical advertising adds another layer of complication to the controversial DTC advertising phenomenon and seems to perplex regulators and public policy makers.

Because incomplete or inaccurate information in DTC and OTC advertising persists, there is a need for programs that educate consumers regarding how to critically assess the quality of information in advertisements aimed at consumers. At the same time, additional training and incentives for health care providers may be needed in order to make sure patients understand all the risks and benefits of new drugs so they can become more informed consumers.

## **7. Concluding Remarks**

**by Glen T. Cameron**

Each of the contributors to this overview of current conditions and research programs about DTC advertising has done an excellent job of adding to the understanding of this specialized subcategory of advertising. The similarities across national settings appear to outweigh the differences, in spite of the fundamental fact that only two countries officially allow DTC advertising.

Because readers can readily make their own comparison-and-contrast analysis of the nationalities represented here, precious editorial space will not be wasted on that endeavor. An attempt will be made to offer some reflections on the important role that the academic advertising community can play in bringing clarity to our understanding and national policies across increasingly pseudo-borders in a now borderless virtual world. This can perhaps best be

done by posing some of the more important questions, including questions that might be considered rhetorical due to the fairly strong convictions of the commentator based on experience founding and developing an active health communication research center over the past decade.

First, a rhetorical question: why would any members of the academic advertising community be proponents of an information control policy? Free information and lively public discourse, even heated public debate, can only lead to a better informed and more robust population engaged in making at least somewhat better health decisions, usually in collaboration with their professional caregiver. My own experience in providing strategic communication research and services for three major health communication grant programs in the United States and South Africa suggests that persuasion knowledge is actually quite sophisticated even among semi-literate populations. The third person effect seems to be at work when policy analysts and mass communication researchers make the assumption that information consumers must be protected from messages. Circumstances are only compounded when the same assumption is made by politicians. Therefore, one important direction for the academic advertising community would be to explore systematically the nature and extent of persuasion knowledge of advertising consumers who may arm themselves to manage health conditions using prescription based medicines, over-the-counter medicines, and traditional herbal remedies. Concomitant with this research would be a clearer understanding of how reactance theory plays a part, whether salubrious or damaging, in the decisions made by consumers. Indeed, one could hypothesize that persuasive messages arguing that information should be suppressed would be the ultimate reactance trigger, evoking threats to personal freedom and autonomy among those being protected from pharmaceutical information. If such information might lead to prevention of

cervical cancer and the reason for suppression involves mistrust of profit motives, then empirical light should be shed on that question but not at the expense of free-flowing consumption of health information. Fewer assumptions, as implied in some of the research reviewed in this article, and more testable questions will invigorate the body of DTC advertising research.

Now, the more genuine question: what lines of inquiry can advertising researchers develop around the world to avoid derivative research? In the coming years, we must avoid conducting studies that force excellent scholarly colleagues such as the co-authors of this manuscript to offer reviews of semi-theoretical, descriptive research. Counterintuitively, the economic catastrophe that has shaken most national economies may provide impetus for a far more pointed and constructive program of research in the health advertising domain. Governmental grant programs and foundation support of research in the United States has recently shifted dramatically toward investigations that clearly lead to changes in health outcomes for large populations, not simply statistically significant findings in small samples, often within intervention and control designed experiments. One can only hope that the same sea change in funded research programs around the world will revolutionize DTC and OTC advertising, as well as traditional medical advertising research.

Although this may mean that less fundamental research on the nature of human communication will be accomplished, it augurs well for those investigators who can inform dissemination and implementation, as well as policy, in the best interests of vast human populations who grapple every day with how best to take care of themselves and their own families. The time is right to move forward from a creditable body of medical advertising research to an even sharper focus on questions that will serve each one of us members of the human family in managing our own health matters.

For this commentator, the clear and thorough review of the current state-of-the-art among health advertising researchers offered in this paper suggests the scholarly foundation is in place for the academic advertising community to develop a thoughtful, inclusive, and more pointed program of research to identify the crucial role of advertising/strategic communication in human health decisions that leads to better health outcomes worldwide.

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