

Direct-to-Consumer Communication

*An Analysis of the Current Environment in the USA and Europe**

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Die direkt an den Kunden gerichtete Werbung für verschreibungspflichtige Medikamente, das so genannte „Direct-To-Consumer-Advertising“ (DTCA), das derzeit nur in den USA und Neuseeland erlaubt ist, gilt als kontrovers diskutiertes Thema. Fürsprecher halten es für eine nützliche Form der Patientenkommunikation, die die Rolle der Patienten stärkt und diesen mehr Wissen verschafft. Sie behaupten, dass eine früher gestellte Diagnose, Behandlung und eine striktere Einhaltung der Medikamenteneinnahme langfristig zu einer besseren Gesundheit führe und die Krankenhauskosten senke. Gegner befürchten jedoch, dass DTCA den unangemessenen und unnötigen Bedarf und Gebrauch von verschreibungspflichtigen Markenmedikamenten fördern, negative Auswirkungen auf die Arzt-Patienten-Beziehung haben und zu erhöhten Ausgaben für Medikamente führen und damit Gelder für die Forschung und Entwicklung mindern werde. Seit die United States Food and Drug Administration 1997 entschied, die Auflagen für die direkt an Patienten gerichtete Werbung verschreibungspflichtiger Medikamente in Massenmedien zu lockern, haben die Pharmafirmen ihre jährlichen Ausgaben für DTCA von US \$ 790 Mio. 1996 auf fast \$ 2,5 Mrd. 2001 verdreifacht. Kürzlich hat das Europäische Parlament – im Zuge der Neuordnung der pharmazeutischen Gesetzgebung – den Vorschlag zur Lockerung des geltenden DTCA-Verbots in Europa zurückgewiesen. Die derzeitige Debatte dreht sich darum, wie die Patienten am besten Informationen über verschreibungspflichtige Medikamente erhalten können, ohne die bereits engen Budgets der Krankenkassen in den Ländern mit gesetzlicher Krankenversicherung zusätzlich zu belasten.

Keywords: Arzt-Patienten-Beziehung, Direct-to-Consumer-Werbung, Arzneimittelbudget, öffentliche Gesundheitsvorsorge, Gesundheitswesen, Patienteninformation, Pharma-Gesetzgebung

1. Introduction

Globalization, consolidation, and consumerization are three major trends driving the drug manufacturing industry today. These trends impact key marketing objectives to increase demand for medical products, to build strong brands, and to outperform the competition. Increasingly, direct communication with consumers – who may also be patients – is applied to meet these objectives. In the United States, the term “direct-to-consumer” communication in the healthcare field was first introduced in the early 1980s. Synonymous with the expression DTC advertising (DTCA), it is defined as paid advertising and promotion of prescription drugs – especially new and innovative products – by the man-

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ufacturer to the end consumer. DTCA is designed to complement marketing strategies and pharmaceutical promotion activities such as those directed at physicians, pharmacists, other healthcare professionals, and health insurances.

DTCA has evolved beyond simple media commercials into a sophisticated healthcare marketing communications discipline. As such, it employs target audience analysis, strategy development, positioning and key messages. These are conveyed to the patient through numerous channels including mass media (print, radio, television), Internet, E-mail, direct mail, outdoor advertisement and other unique marketing venues. Paid drug advertisements using DTCA run the gamut from disease awareness campaigns to direct comparative marketing between several products. They can be distinguished from "Public Service Announcements" (PSA), which are brief announcement broadcasts on radio or television stations distributed as a public service. There is no charge for the broadcasts; however, the service is typically reserved for not-for-profit organizations.³

Due to the nature of their products, the pharmaceutical industry has been subject to much heavier marketing and advertising restrictions than most other industries. Legal only in the United States and New Zealand as of now, DTCA is currently being reviewed by regulatory bodies in the European Union and Canada, where supporters of DTCA are exerting increasing pressure on authorities to relax their ban on DTC marketing of prescription drugs.

This review article will describe the evolution of DTCA in the United States and provide insights on the financial, medical and societal impact it has had on the general public as a whole and patients in particular. Also, a summary of the arguments used by DTCA supporters and opponents is presented by discussing the claimed benefits and disadvantages within the framework of the United States experience since 1997. Data from numerous U.S. consumer and physician surveys is presented as described in the published literature to date. The concurrent legislative review and debate of DTCA in Europe will be addressed. Finally, the discussion suggests ideas to further the debate.

It is important to note that empirical DTCA data from consumer and financial surveys conducted in Europe either by the government, private media or corporate organizations is currently not available. Therefore, a summary of the pros and cons of the impact of DTCA in Europe cannot be demonstrated. Only one European survey, which was conducted by an American research institution, reveals the extent to which European consumers feel about DTCA. Results of this survey are included in this article.

2. History and Forms of DTCA in the United States

This section will review the evolution of DTCA in the U.S. as well as the various classifications and appeal types of DTC ads.

2.1 The Evolution of DTC Advertising (DTCA)

The Department of Health and Human Services is the United States government's principal agency for protecting the health of all Americans. One of its operating divisions is

³ Media Guidelines: Black Journalists Association of Southern California, 2003. These guidelines are governed by the Federal Communication Commission based on Code of Federal Regulations Title 47.

the U.S. Food and Drug Administration (FDA), which is responsible for regulating drugs and medical devices, among others.

In 1962, the Federal Food, Drug, and Cosmetic Act⁴ was amended and transferred the responsibility for regulating the promotion and advertising of prescription drugs from the Federal Trade Commission to the FDA. The 1962 Act did not explicitly define what constituted advertising. The language specified only that statutory requirements for advertising⁵ could not be applied to those within the definition of labeling. Consequently, the FDA viewed anything which did not fall within the definition of labeling as advertising. Labeling included the medical indication of the drug, adverse side effects, contraindications, warnings and precautions, pharmacology and dosage information. It was characterized as any written, printed, or graphic matter on or accompanying a drug sponsored by the manufacturer, packager, or distributor. The 1962 Act did not address physician-focused promotion versus direct-to-consumer oriented promotion. Hence, DTCA as such was never explicitly illegal in the U.S.⁶

Up until 1983, prescription drug promotion was directed solely at healthcare practitioners, pharmacists, health insurance providers, and federal and state government agencies. To ensure a steady demand for their products, pharmaceutical companies' traditional marketing strategies included print advertisements in medical journals, visits to physician offices and hospitals by sales representatives, distribution of free samples, and promotion at conferences. Rooted in the learned intermediary doctrine⁷, the medical specialist – not the drug manufacturer – was primarily responsible for communicating relevant benefit and risk information about prescription drugs to a patient.⁸

In the early 1980s with a gradual rise in public health awareness, pharmaceutical companies also discovered the end consumer – the patient – as a new target audience for promotional information. Promoting prescription drugs directly to this new target audience evolved into DTCA in the United States. One of the first attempts at DTCA through television was in 1983 for the arthritis pain medication Rufen® by Boots Pharmaceuticals, Inc., encouraging consumers to discuss the product with their doctor and emphasizing its cost savings.⁹

By late 1983, the FDA was becoming increasingly concerned that the alleged benefits and risks of advertised drugs were not balanced, possibly misleading consumers. The agency requested that the pharmaceutical companies voluntarily halt their DTCA campaigns in order to examine the ramifications of this promotion. Specifically, the agency wanted to look at the regulatory guidance in place at that time as well as to evaluate the impact on the health of the American public.

After a series of research programs and public hearings, and following pressure by AIDS patient support organizations, who lobbied for more information to be distrib-

⁴ Federal Food, Drug, and Cosmetic Act of 1938.

⁵ 21 CFR §202.1 Prescription Drug Advertising regulation requires that advertisements must not be false or misleading, must reveal material facts, and must present a fair balance between effectiveness and risk information.

⁶ Reuters Business Insights, 2000.

⁷ The term "Learned intermediary" was introduced to pharmaceutical products liability law in 1966 and provides that manufacturers of prescription drugs and medical devices discharge their duty of care to patients by providing warnings to the prescribing physicians.

⁸ Sterling Drug v. Cornish, 1966.

⁹ Shuler, 1984.

uted to AIDS patients and the general public about the disease, the FDA lifted the voluntary moratorium in 1985. It declared that the 1962 Act still sufficiently regulated the emerging field of DTCA promotional activity in a manner that effectively safeguarded the consumer. The FDA would apply the same standards of advertisements targeting physicians to DTCA, namely to provide full disclosure of information with a fair balance of benefits and risks in addition to a brief summary¹⁰ of the FDA-approved drug package insert.¹¹

Over the next 12 years, DTCA for prescription drugs would grow steadily and be applied to a broad range of media, including cable television, radio, print, direct mail and the emerging Internet. If a company desired to promote a drug name in combination with its medical indication, it was mandated to provide a major product statement detailing all side effects and contraindications within the commercial – an unrealistic requirement given the 30 or 60-second format of mass media advertisement spots.

Companies opting to mention only one criterion – the brand name or the indication of the drug – were permitted to disclose only a brief summary describing side effects, contraindications and effectiveness. Most companies promoting their prescription drugs through mass media opted for this second format. However, it became apparent that this version of DTCA was confusing and not informative to consumers, resulting in patients requesting the wrong products from the wrong physicians for conditions they did not have. Acknowledging the need for clarification, the FDA held a public hearing in October 1995 and requested comments on DTC promotion with suggestions how the guidelines could be improved.

On August 8, 1997, the FDA published a draft guidance, which clarified existing prescription drug promotion requirements for paid broadcast advertisements directed at the general public mentioning both the drug brand name and the health condition, and which used consumer-oriented broadcast media including television, radio and telephone communication systems.¹²

Sponsors of paid broadcast advertisements are in compliance with FDA regulations if they include a *major statement* in audio or audio plus visual on the product's most important health risk information in consumer-friendly language. In addition, the advertisement must provide a *brief summary* of the approved package labeling information or, alternatively, make *adequate provision* for dissemination of this labeling information within the broadcast presentation. A sponsor is in compliance with fulfilling the adequate provision requirements if the advertisement references an alternative source where the consumer can obtain the package labeling information. These sources include an operating toll-free telephone number, an Internet web site, a print advertisement in a consumer magazine or the comment that a pharmacist or physician may provide additional product information.

In August 1999, after a two-year review period, the FDA reaffirmed its new policy and finalized the 1997 guidance. In addition, the agency committed at that time to tracking both consumer and physician attitudes about DTCA. Surveys were conducted in 1999 and 2002. Results of these surveys will be reviewed in this article.

10 21 U.S.C. 352(n).

11 Reuters Business Insights, 2000.

12 FDA Guidance, 1997.

2.2 FDA Regulatory Action of DTCA

The FDA has power to stop any pharmaceutical promotional campaign if the agency feels that an advertisement does not meet the guidance requirements. The FDA also has the power to retract a product from sale, prosecute a manufacturer, and require the manufacturer to inform consumers and physicians about its inadmissible claim. From August 1997 to August 2002, the agency issued 88 regulatory letters, mostly because benefits of the drugs were overstated and the risks minimized.¹³ The Law requires pharmaceutical companies to submit advertisements to the FDA for clearance concurrently to the dissemination of the campaign; however, 95 percent of sponsors of DTC prescription drug ads voluntary submit them in advance to ensure compliance with FDA regulations.¹⁴

In response to questions whether the FDA's oversight authority has been effective concerning DTCA, several Members of Congress requested the U.S. General Accounting Office (GAO)¹⁵ to review the public health agency's practices. The GAO determined in October 2002 that the FDA overall is effective to review and monitor pharmaceutical advertising and ensure their compliance with federal guidelines.¹⁶

The agency was found to have, however, two shortcomings. The GAO found that the FDA could not provide sufficient documentation to verify that pharmaceutical companies sent copies of all advertisements. Secondly, GAO criticized a new U.S. Department of Health and Human Services (HHS) rule that all regulatory letters notifying a company of an infraction must be reviewed by the FDA's legal office, known as the Office of the Chief Counsel. The GAO found that this new rule has increased significantly the number of days it takes the FDA to notify pharmaceutical companies of a violation. The GAO recommended in its report to Congress that the internal review process be shortened to improve its monitoring system of DTCA. As a result, FDA has pledged to review all regulatory letters within 15 days.

2.3 Classification Types of DTCA

In the United States, there are three classes of paid DTC advertisements – health-seeking, reminder, and product-specific ads – each with different objectives as well as restrictions for disclosing the product brand name and/or the underlying medical condition.¹⁷

- *Health-seeking* ads provide information about a medical condition like symptoms and causes. The sponsor is not allowed to mention a specific brand name; hence, no drug risk information needs to be disclosed. However, the name of the pharmaceutical manufacturer can be provided. This form of promotion increases public aware-

13 Ostrove, 2001.

14 Baylor-Henry, 2002.

15 The U.S. General Accounting Office is the audit, investigative arm of the U.S. Congress. GAO examines the use of public funds, evaluates federal programs and activities, and provides analyses, options, recommendations, and other assistance to help the Congress make effective oversight, policy, and funding decisions.

16 GAO Report, 2002.

17 Federal Register Vol. 60, pages 42581-42583.

ness of a health condition and may lead to early detection and treatment. It also may make the consumer more conscious of available treatment options.

- In *Reminder* ads only the drug's brand name is disclosed. The medical condition for which the drug is used is not mentioned. This type of promotion reinforces brand awareness and may remind a patient to refill a prescription and be compliant with the treatment instructions. It also can increase curiosity and encourage consumers to ask their healthcare provider about the promoted drug.
- *Product specific* ads are legally allowed to mention a drug's brand name in combination with the health condition that requires the medicine. As such, they have to meet the 1997 FDA guidance requirements, namely to include a major risks statement and a brief summary or adequate provision for the package labeling information. Product-specific ads both reinforce a brand and create awareness about a treatment option, which makes this type of DTC advertisement the most frequently chosen one by sponsors.

2.4 Appeal Types of DTCA

The purpose of paid advertising, in general, is to make potential consumers aware of a product or service and to motivate them to take an action, which is communicated through key messages. In the case of DTCA, key messages are designed to appeal to four major consumer emotions including control, fear, freedom, and self-fulfillment.¹⁸

- *Control* ads urge patients to assume control over their health and motivate them to seek medical advice on the benefits of the advertised drug. It is generally used in DTCA promoting prescription drugs to treat chronic conditions like diabetes or asthma.
- *Fear* advertisements aim to alert patients to a potential health problem like increased cholesterol levels and their impact on heart failure risk. They encourage consumers to seek immediate physician advice. Consumers will remember the brand name while talking to their doctor. However, incorporating too much or too intense fear in an ad can scare consumers away.
- *Freedom* ads encourage patients to liberate themselves from a disease and are generally applied for acute illnesses like depression or social anxiety. They urge patients to ask their doctor about a specific drug.
- Lastly, *self-fulfillment* advertisements urge consumers to fulfill a personal need and appeal to an altered life-style. Products for conditions like insomnia, smoking cessation or sexual dysfunction use this appeal form.

3. DTCA Impact on U.S. Patients and on Society

The 1997 FDA guidance on DTCA of prescription drugs has had a significant and far-reaching effect on the American public health system and society at large including patients, healthcare professionals, health insurance companies, pharmaceutical and biotech companies, as well as the broadcast media and advertising professionals. DTCA has changed the way in which drug companies strategically market their newly approved medicines, and how the U.S. consumer receives education on medical conditions and information about specific drugs.

18 Oglivy, 1987.

Since the guidance was issued, multiple consumer and physician surveys have been conducted in the U.S. to assess the impact of DTCA on patient and physician behavior and attitudes. The results of these surveys, including two FDA consumer surveys, one FDA physician survey and a *Prevention Magazine* survey, indicate that the debate on the effects of DTCA is far from over. DTCA is credited for empowering patients with information, while sharply criticized for contributing to overall escalating U.S. healthcare expenditures. Table 1 summarizes what DTCA is credited for, both positively and negatively.

Table 1: Arguments Supporting and Rejecting DTCA in the USA

Claimed Benefits of DTCA	Claimed Harmful Effects of DTCA
Reduces long-term costs associated with undertreatment of certain conditions.	Leads to unsustainable pharmaceutical expenditures.
Improves patients' and public awareness about unfamiliar medical symptoms and conditions.	Misleads patients if advertisement is unbalanced in disclosing benefits versus side effects.
Prompts patients to talk to their doctors for the first time about a particular ailment.	Promotes drug solutions for problems that could be solved by a lifestyle change.
Serves a patient's basic right to be informed about all possible treatment options.	Increases frequency of doctor visits and workload of physicians to reeducate patients.
Empowers patients to be more involved in decisions about their healthcare.	Leads patients to pressure their doctors to prescribe unnecessary or inappropriate drugs.
Heightens consumer awareness of the inherently risky nature of virtually all prescription drugs.	Damages the doctor-patient relationship.
Improves patient compliance with a prescribed regimen.	Encourages unrealistic patient expectations that there is a drug for every condition.
Encourages health professionals to keep up with current prescribing information.	Medicalizes conditions common to human existence (e. g., hair loss, menopause).

The next sections will review these claimed effects of DTCA as established through results from nationally representative consumer surveys and empiric research published in peer-reviewed journals. Specifically, findings on DTC spending and healthcare expenditures as well as the impact of DTCA on public awareness of medical conditions, patient behavior, patient-doctor relationship, and drug compliance are presented. Information on whether DTCA has impacted patients' health outcomes in a beneficial or adverse manner, however, is not available in the United States at this time. Additional consumer surveys will have to be conducted to provide this data.

3.1 DTCA Spending and Healthcare Expenditures in the U.S.

There has been widespread concern among U.S. politicians, researchers, health insurers, consumer groups and labor unions as well as state and federal agencies that pharmaceutical companies are spending more money on DTCA than on research and development (R&D). Also of concern is that DTCA may be inducing significant and potentially inappropriate demand for some drugs, putting further pressure on healthcare budgets. Several analysis have been performed to help address these questions and put the total spending on DTCA into better context. In particular, a recent U.S. General Accounting

Office (GAO) report is one of the first and most recent analysis to address these concerns. Also, a National Institute for Health Care Management Foundation study and a Harvard School of Public Health study will be reviewed.

Expenditures for prescription drugs have grown in the last decade at an average annual rate of 18 percent, accounting now for more than 10 percent of the 2001 U.S. healthcare budget of \$ 1.4 trillion. Between 1993 and 2001, U.S. spending on retail prescription drugs increased from \$50 billion to \$ 155 billion and is projected to further rise to \$ 212 billion by 2004, which makes it the fastest growing component in the healthcare budget.¹⁹

The central forces behind this steep rise are numerous, including an increase in the number of new medicines being approved and marketed; an increase in the total number of prescriptions being written by physicians; a shift to the use of more innovative, costlier drugs; a growing population using more medicines, especially the elderly; an increase in insurance coverage for pharmaceuticals; better compliance for existing and new drugs; and a growing demand for new medications by patients.

The 2002 GAO report found that U.S. pharmaceutical companies spent about \$ 30.3 billion on R&D compared to \$ 19.1 billion on promotional activities, including \$ 2.7 billion on DTCA, in 2001. Spending on DTCA grew, however, at a faster rate than R&D (145% and 66%, respectively) between 1997 and 2001. More than 80 percent of promotional spending is targeted to physicians, accounting for about \$ 17 billion.²⁰ Providing physicians with free samples of drugs constitutes the bulk of the funds used to target physicians- about \$ 10.5 billion.²¹

A study released in 2001 by the National Institute for Health Care Management Foundation²² examined the 50 most heavily advertised prescription drugs. These drugs generated retail sales worth \$ 41.3 billion in 2001, or about a quarter (27%) of the total \$ 155 billion spent on retail prescription drugs in that year.²³ Nearly 100 percent of pharmaceutical companies' DTCA budgets was spent promoting these 50 drugs. The study further concluded that these drugs accounted for \$ 9.94 billion or 47.8 percent of the \$ 20.8 billion rise in prescription drug sales between 1999 and 2000. Retail sales revenue for these 50 drugs rose 32 percent for the one-year period, compared with a 14 percent increase for about 9,850 other prescription drugs on the U.S. market.

In July 2001, the U.S. Senate Subcommittee on Consumer Affairs, Foreign Commerce, and Tourism held a public hearing on DTCA of prescription drugs. According to a written testimony by an economist and resident scholar at the American Enterprise Institute for Public Policy Research²⁴, there was little evidence that recent increases in medication expenditures were caused by prescriptions issued inappropriately by physicians.²⁵

19 Levit, 2002.

20 GAO Report, 2002.

21 Herper, 2003.

22 The National Institute for Health Care Management Foundation – founded by the managed care organization BlueCrossBlueShield – is a non-for-profit organization that conducts research, policy analysis and educational activities on a range of healthcare issues.

23 Findlay, 2001.

24 The American Enterprise Institute for Public Policy Research – a Washington, DC-based think-tank – covers economics and trade; social welfare; government tax, spending, regulatory, and legal policies; U.S. politics; international affairs; and U.S. defense and foreign policies.

25 Calfee, 2001.

The increases in drug utilization seemed to be driven primarily by the fact that health-care organizations, physicians, and patients found many of the newer drugs to be very valuable. According to the author, this is not to say that DTCA would not increase sales for advertised brands. However, the evidence suggested that prescribing decisions are dominated by the physician's advice, which may involve non-drug therapy, a generic prescription, or an over-the-counter drug recommendation, as alternatives to prescribing the advertised brand. The author also indicated the existence of strong evidence that many of the most effective drugs were underused, rather than overused. The testimony concluded that the public debate should focus on how to pay for more extensive drug therapy, rather than on how to curtail it.

A February 2002 report by the Harvard School of Public Health analyzed the expenditures on various types of promotional activities targeting healthcare professionals versus the consumer in relation to sales of prescription drugs over a five-year period (see Table 2).²⁶

Table 2: Spending on DTCA versus Promotion to Professionals, 1996 through 2000

	1996	1997	1998	1999	2000
Direct-to-Consumer Advertising**					
Television*	220	310	664	1,127	1,574
Print and other*	571	759	652	721	893
Total*	791	1,069	1,316	1,848	2,467
Percentage of Sales+	1.2%	1.5%	1.6%	1.8%	2.2%
Promotion to Professionals***					
Office-based promotion*	2,458	2,785	3,386	3,607	4,038
Hospital-based promotion*	552	579	671	713	765
Journal advertising*	459	510	498	470	484
Free samples*	4,904	6,047	6,602	7,230	7,954
Total*	8,373	9,922	11,157	12,020	13,241
Percentage of Sales+	12.9%	13.8%	13.7%	11.8%	11.8%
Total Promotional Efforts*	9,164	10,991	12,473	13,868	15,708
Total Sales*	64,993	71,837	81,523	101,971	112,200
Percentage of Sales****	14.1%	15.3%	15.3%	13.6%	14.0%

* U.S. \$ spending in millions

** Data on DTCA spending were obtained from IMS Health and Competitive Media Reporting.

*** Data on promotion to professionals were collected from IMS Health.

**** The percentage of sales was computed using industry sales estimates by the Pharmaceutical Research and Manufacturers of America.

Overall, promotional expenditures grew by 70 percent from \$ 9.1 billion in 1996 to \$ 15.7 billion in 2000. Of the monies spent in 2000, approximately 84 percent or \$ 13.2 billion was allocated to target healthcare professionals. In contrast, only about 17 percent or \$ 2.5 billion was spent on DTCA. However, this number increased significant-

ly from the \$ 791 million spent in 1996, one year prior to the 1997 FDA guidance. A seven-fold growth in television advertising expenditures accounts for this increase.

As a percentage of sales, total promotional expenditures remained fairly constant at about 14% between 1996 and 2000. This means that it took the same proportional effort to promote drugs in order to reach companies' sales targets, which grew from \$ 65 billion in 1996 to \$ 112 billion in 2000.

The increase in absolute spending on DTCA represents a shift in the particular combination of marketing tools used rather than an increase in the intensity of the total promotional effort as a percentage of sales. This, however, may reflect the success of DTCA in generating increasing sales, especially of high-priced drugs. Similar conclusions were reached by the GAO in its 2002 report, which included updated figures for overall promotional spending in 2001.²⁷

The Harvard report also assessed the different therapeutic classes of the most heavily promoted prescription drugs using DTC marketing.²⁸ Unlike promotion to health-care professionals, which is inclusive for almost all brand name drugs, spending on DTCA targeting patients is concentrated on a few products.

In 2000, the largest percentage (60%) of DTCA spending was focused on 20 out of nearly 9,500 prescription drugs approved for the U.S. market (Table 3). These 20 medicines fall within a wide variety of therapeutic drug classes including antidepressants, antihistamines, antihyperlipidemics and anti-inflammatory drugs.

These therapeutic drug classes typically have strong earning potential because they meet one or more of the following market conditions including (i) high prevalence of the underlying medical condition; (ii) chronic nature of medical condition, requiring long-term treatment; (iii) lower side effect profile with fewer or less severe symptoms; and (iv) no competing generic drug.

The effectiveness of DTCA spending can be inferred in the next sections, which address patients' awareness of specific medical conditions, patient behavior, changes in the patient-physician relationship and compliance with drug treatment.

3.2 Impact of DTCA on Public Awareness of Medical Condition

The need to reach out to consumers alerting them about symptoms of undiagnosed conditions with a call to seek medical attention has been acknowledged by many health authorities, health professionals and consumer organizations, including the U.S. Centers for Disease Control and Prevention²⁹ (CDC), the American Diabetes Association and the International Osteoporosis Foundation.

To date, no empirical data exists to support the claim that DTCA has met this need. However, epidemiological evidence has shown a substantial underdiagnosis of many of the major diseases for which effective treatments exist, including arthritis, hypertension, diabetes, osteoporosis, depression, and childhood asthma. Even after diagnosis, these diseases are massively undertreated.³⁰ This failure to treat – together with non-compli-

27 GAO Report, 2002.

28 Rosenthal, 2002.

29 The Centers for Disease Control and Prevention is an agency of the Department of Health and Human Services responsible for developing and applying disease prevention and control, environmental health, and health promotion and education activities.

30 Schuster, 1998.

Table 3: Top 20 Drugs in Terms of DTCA Spending in 2000*

Brand	Name of Drug	Indication	Manufacturer	DTCA Spending**
1	Vioxx	Arthritis	Merck	161
2	Prilosec	Ulcer/Reflux	AstraZeneca	108
3	Claritin	Allergy	Schering-Plough	100
4	Paxil	Anxiety/Depression	GlaxoSmithKline	92
5	Zocor	High cholesterol	Merck	91
6	Viagra	Erectile dysfunction	Pfizer	90
7	Celebrex	Arthritis	Pharmacia/Pfizer	79
8	Flonase	Allergy	GlaxoSmithKline	78
9	Allegra	Allergy	Aventis	67
10	Meridia	Obesity	Abbott Laboratories	65
11	Flovent	Asthma	GlaxoSmithKline	63
12	Pravachol	Allergy	Bristol-Myers Squibb	62
13	Zyrtec	Allergy	Pfizer	60
14	Singulair	Asthma	Merck	59
15	Lipitor	High cholesterol	Pfizer	59
16	Nasonex	Allergy	Schering-Plough	53
17	Ortho-Tri-Cyclen	Oral contraceptive	Ortho-McNeil	47
18	Valtrex	Genital herpes	GlaxoSmithKline	40
19	Lamisil	Toenail fungus	Novartis	39
20	Prempro	Hormone replacement therapy	Wyeth	38
All 20 combined*				1,451
Total Percentage of Industry Spending on DTCA on Top 20 Drugs				58.8%

* Data on DTCA spending by branded drug were obtained from Competitive Media Reporting.

** U.S.\$ spending in millions.

ance – leads to a considerable social burden of otherwise avoidable morbidity and mortality.

A report by the CDC in October 2002 suggests an underdiagnosis of arthritis-related conditions. Following a national telephone survey among 212,000 U.S. adults, the agency adjusted its prevalence estimates to approximately 70 million affected U.S. adults, a 63 percent increase from the estimated 43 million cases in 1997.³¹ The survey reflects, in part, a real rise in arthritis connected to the aging of the baby boomers³²; but it also shows the impact of a revised set of self-report questions with a better description of arthritis-related symptoms. The report concluded that increased intervention efforts, including early diagnosis and appropriate clinical and self-management are needed to reduce the impact of arthritis and chronic joints symptoms. It is of interest to note that two of the 20 most promoted prescription drugs using DTCA – Vioxx and Celebrex – treat this inflammatory condition. However, currently no data exists

³¹ CDC, 2002.

³² The baby boomers represent a U.S. generation born between 1946–1964.

that allows drawing an inference between promotional activities and increased arthritis diagnosis.

Other examples for the importance of improved consumer awareness are diabetes and osteoporosis. The American Diabetes Association estimates that of the 17 million people in the U.S. with diabetes, only two-thirds are diagnosed and treated. With obesity emerging as a new U.S. epidemic and serious public health problem, this number is prone to grow.³³ According to a report by the International Osteoporosis Foundation presented to the European Commission in 2001, osteoporosis is a silent epidemic that is overlooked, underdiagnosed and undertreated. This disease is affecting millions of Europeans causing human suffering and taking a heavy economic toll.³⁴

3.3 Impact of DTCA on Patient Behavior

Numerous consumer surveys on patient behavior have been conducted to assess issues like general awareness for prescribed drugs, discussions initiated by patients with their doctors about an advertised drug, recall ability, request for advertised prescription drug and what sources patients use to obtain additional drug information. The most comprehensive consumer surveys include the 1999 and 2002 surveys commissioned by the FDA, a series of surveys by *Prevention Magazine* between 1997 and 2000, and a 2001 survey by the Kaiser Family Foundation.³⁵

In 1999 and 2002, the FDA conducted national telephone surveys of about 1,000 adults about their attitudes towards DTCA with the goal of gauging the following trends: (i) public awareness of DTCA; (ii) general recall ability of DTCA information; (iii) source and nature of follow-up healthcare information; (iv) impact of DTCA on frequency of physician visits; (v) as well as on the patient-physician relationship from the consumers' perspective³⁶. In addition, the 2002 survey assessed the impact of DTCA on prescribing patterns by healthcare professionals. Results from questions asked in both the 1999 and 2002 surveys are averaged below, if data were similar.

- Public awareness of paid drug advertisements was high (77%).
- Television was the dominant distribution channel of information (96%), followed by magazines (71%), grocery/pharmacy (41%), newspapers (31%), radio (30%), mail (20%), and the Internet (13%).
- Consumers equally recalled information on risks and benefits from TV ads (89%), followed by how to get more information (86%), and who should not take the drug (85%). Information on how to take the drugs (35%) and overdosage (12%) were least recalled.
- DTCA led less than half of respondents to seek additional information (48%).³⁷ These were most interested in information on side effects (61%), followed by interactions with other drugs (17%), dangers of the drug (13%), whether it would work

³³ American Diabetes Association, 2002.

³⁴ International Osteoporosis Foundation, 2001.

³⁵ The Henry J. Kaiser Family Foundation is a non-profit, independent national health care philanthropy dedicated to providing information and analysis on health issues to policy makers, the media, and the general public.

³⁶ FDA Consumer Surveys, 1999 and 2002.

³⁷ This information was not asked in the 1999 FDA survey.

or help (11%), effectiveness (10%), appropriateness (10%), benefits (10%), indication/uses (9%), and cost (4%).

- The top source for more information was physicians (86%), followed by pharmacists (51%), reference books (39%), nurses (37%), friend or relative (35%), toll-free phone number (17%), magazine (17%), and newspaper (8%). Of interest is the growth in the Internet from 1999 (18%) to 2002 (38%).
- Of the patients who asked a doctor for a prescription drug in general, less than half (43%) received one. However, if they requested a specific brand of prescription drug, a majority of the patients' requests were honored (69%).
- Among consumers who went to the doctor expecting a prescription, a majority asked about a specific drug (68%). The main reason patients expected a prescription was because they had received a previous prescription for the same condition (63%). A very small percentage of patients said an ad on TV or the radio (6%) or an ad in a magazine (4%) made them expect their doctor to prescribe a drug for them.

Since 1997, *Prevention Magazine* also has tried – through annual consumer survey of approximately 1,200 nationally representative U.S. adults – to gauge consumers' attitudes and behavior in relation to DTCA. Among the magazine's objectives are to determine (i) general awareness and effectiveness of DTCA and (ii) source and nature of consumer information besides DTC promotion. The major difference between the *Prevention Magazine* survey and other consumer surveys is that it asked respondents about what they could recall from 10 specific prescription drug ads.³⁸ This process is called "aided recall" and may help demonstrate the effectiveness of DTCA to reach its target audience. The 2000 results of the latest survey are put in context of a five-year trend.³⁹

- A large majority of Americans have seen or heard a prescription drug ad (80%). This figure increases among consumers who already take a prescription drug (85%). Nearly all Americans (91%) said they had seen or heard one of the 10 specific drug ads.
- Consumers pay attention to DTC ads for both themselves and for others. The majority of consumers (62%) who talked with their doctor about a promoted drug did so because they learned something about a prescription medicine for a family member or friend.
- Including risk information in DTC ads may actually encourage patients to ask their doctor about the drug. Patients were more likely to talk to their physicians about a promoted drug if they thought the DTC ad did an excellent job (53%) versus a fair or good job (27%) in disclosing risk and side effect information.
- Of the consumers who had seen a DTC ad, only a quarter (26%) asked for a specific brand.
- Of those patients who asked for a prescription, the majority (71%) received the requested drug. The rest received no prescription at all (19%) or a prescription for a different drug (10%).
- Physicians often mentioned non-drug therapies such as diet and exercise to patients when asked about advertised medicines (50%).

³⁸ The 10 drugs used in the aided recall test represented those drugs with the highest advertising expenditures for 1999 and the first five months of 2000. They are, in order of highest expenditure, Claritin, Lipitor, Xenical, Vioxx, Premarin, Celebrex, Buspar, Glucophage, Evista and Avandia.

³⁹ Slaughter, 2001.

DTCA is not the only or the best way to inform the public about medical conditions or how to treat them, but it is beginning to make a small impact, according to the survey. Specifically, public understanding about which drugs treat specific conditions is on the rise, especially among those who suffer or are at risk for these conditions. In 1999, most people suffering from health problems could only identify two out of 13 medicines to treat their conditions; in 2000, they recognized indications for five out of 10 drugs.

In November 2001, the *Kaiser Family Foundation* released a Web-based poll of 1,900 U.S. adults on prescription drug advertising.⁴⁰ It was designed to address the (i) general responses to prescription drug ads; (ii) extent of specific ads encouraging people to seek treatment or additional information; (iii) possibility to educate the public about health conditions and treatment options; (iv) success in communicating information about drug side effects and sources for additional information; and (v) public perception of prescription drug ads.

The survey concluded that drug advertising on television effectively prompted viewers to seek out more information both about the advertised drug and about the condition it treats. However, the advertisements were less successful at conveying drug risks and where to obtain additional information. What follows is a brief outline of some of the survey's major findings:

- Among the 30 percent of participants who spoke to their doctors about the viewed ad, 44 percent received a prescription for the drug.
- After viewing specific drug ads, about four in 10 adults were very or somewhat likely to talk to their doctor about the advertised drug (37%) and/or talk to their physician about the medical condition mentioned (40%).
- When asked for a self-assessment of how much they learned from viewing specific ads, most (70%) replied little or nothing about the health condition, and a majority (59%) said they knew little or nothing more about the drug.
- While people who had just viewed a specific drug ad were not always able to recall the specific side effects mentioned, they were more likely to consider them as serious compared to people asked about DTC ads in general.
- Half (49%) did recall that the ad mentioned getting more information from a doctor or pharmacist, but 40 percent were not able to recall where else to find this information (toll-free phone number, web site, or magazine).
- Lastly, many adults (84%) felt the ad did a good or excellent job of telling them about the condition covered in the ad, the medicine's potential benefits (72%), and who should take it (66%). Fewer said the same about the side effects (52%) and directions for using the medicine (47%).

3.4 Impact of DTCA on Patient-Doctor Relationship

Critics of DTCA worry that prescription drug promotion increases the frequency of doctor visits and workload of physician to reeducate patients. It is also believed that DTCA may lead patients to pressure their physician to prescribe unnecessary or inappropriate drugs and result in a damaged doctor-patient relationship.

A large majority of consumers in the 1999 and 2002 FDA surveys reported favorable assessments of their talks with their doctors and encountered no resentment or other un-

⁴⁰ Kaiser Family Foundation, 2001.

favorable reaction.⁴¹ Most respondents said their doctor welcomed their questions (87%), reacted as if those questions were an ordinary part of a visit (77%), and proceeded to discuss the drugs with the patient (83%). Only four percent said their physician seemed angry or upset.⁴² Eighty-five percent of respondents were satisfied or very satisfied with their discussions with physicians about advertised drugs. Finally, 62 percent agreed or strongly agreed that DTCA helped them have better discussions with their physicians.

In April 2002, the National Medical Association⁴³ released a survey of 900 African-American physicians acknowledging the importance of drug ads in raising awareness among African-American patients about medical conditions and treatment options.⁴⁴ The majority of respondents believed that DTCA increases and improves communication between physicians and patients. It concluded that improved marketing to minority communities could prove beneficial to African-American patients.

The survey's findings are especially important in light of two reports published in 2002 on the healthcare of minority Americans. The Commonwealth Fund⁴⁵ report found that minority Americans lag behind on healthcare quality measures and are more likely to have communication problems with their doctors than Caucasians.⁴⁶ A study released by the Institute of Medicine⁴⁷ showed that racial and ethnic minorities receive lower quality healthcare even when their insurance and income are the same.⁴⁸

Physicians, however, historically have not favored DTCA. The American Medical Association conducted a survey of its members in 1984 and found that a large majority (84%) opposed prescription drug advertising in general. Thirteen years later, sentiments had not changed. In 1997, a survey of the American Academy of Family Physicians' members showed that a large majority had negative feelings about print (80%) and broadcast (84%) advertisements.⁴⁹

Results from a 2002 FDA survey of 500 physicians indicate for the first time a possible shift in this mentality.⁵⁰ While physicians said that patients were asking more questions about prescription drugs over the last five years, a majority of physicians (53%) felt no pressure at all to prescribe any drug during the patient visit, while only four percent said they felt very pressured. Furthermore, more than half of physicians (53%) reported that DTCA contributed to having a better discussion with patients with a large percentage of patients (73%) asking thoughtful questions, which correlates to the findings in the FDA consumer surveys. Fewer but still a considerable percentage of physicians thought patients were more aware of treatment options due to DTCA (42%).

41 FDA Consumer Surveys, 1999 and 2002.

42 Data are averaged from the two FDA surveys.

43 The National Medical Association is the oldest and largest medical organization in the U.S. representing interests of patients and physician of African-American descent.

44 National Medical Association, 2002.

45 The Commonwealth Fund is a private foundation that supports independent research on health and social issues.

46 Leatherman et al., 2002.

47 The Institute of Medicine – as part of the National Academy of Sciences – provides advice concerning health and science policy to the government, the corporate sector, and the public.

48 IOM Report, 2002.

49 Mitka, 2003.

50 FDA Physician Survey, 2002.

Many physicians, however, acknowledged that DTCA does cause some problems in their patient relationships. Most physicians reported having to spend time correcting misperceptions from the ads (41%), especially when patients think that the drugs work better than they do (75%). About a quarter of physicians said they had to explain to patients that they did not need the drug or have the condition the drug treats (26%). Lastly, physicians felt some pressure from patients when asked to prescribe a specific brand name drug (54%).

Overall, two out of five physicians (40%) reported that DTCA had a positive impact on their patients and practice. The rest reported either no change (28%) or a negative impact (30%).

It is important to note that some physicians criticized the results of the FDA physician survey for being too positive.⁵¹ Sarah Walker, M.D., president of the American College of Physicians-American Society of Internal Medicine said she felt the results did not mirror her clinical experience because patients often pressured her to prescribe certain drugs. Sidney Wolfe, M.D., director of the Public Citizen's Health Research Group⁵², suggested that pharmaceutical companies' efforts to target physicians is paying off. By raising awareness of a particular drug through free samples, physicians are more likely to give them to patients. He further suggests that physicians are less likely to recommend cheaper or generic drugs as a result.⁵³

3.5 Impact of DTCA on Drug Compliance

Poor communication and misunderstandings between patient and physician are known to lead to sub-optimal health outcomes through medication error or non-adherence to a long-term treatment plan. Several reports reviewed for this article offer conflicting data whether patients showed increased compliance of drug regimen after seeing or hearing a DTC ad.

In the 2002 FDA survey of physicians, DTCA was found to increase some patients' compliance. A small majority (54%) of physicians said paid drug advertising increased chances that a patient used the medication properly, while a smaller percentage (33%) said it influenced whether patients adhered to their drug regimen.⁵⁴ Conversely, an average of 36 percent of physicians said DTCA had no affect at all on patients' compliance.⁵⁵

The 2000 Prevention Magazine survey offers, however, a different explanation of the impact of DTCA on compliance. Despite increased spending on DTCA by pharmaceutical companies since 1997, the percentage of U.S. citizens taking prescription drugs has stayed relatively the same. The number of prescriptions being written and the total amount being spent on these prescriptions, however, has increased. Therefore, the survey hypothesizes three scenarios (i) overall, people are taking more drugs; (ii) people are

51 Mitka, 2003.

52 Public Citizen's Health Research Group is a national, nonprofit consumer advocacy organization to represent consumer interests in Congress, the executive branch and the courts.

53 Mitka, 2003.

54 FDA Physician Survey, 2002.

55 Data were averaged for two specific questions in the 2002 FDA survey on proper use of medication and adherence to treatment regimen that were used to determine whether DTCA increased compliance.

taking more expensive drugs; or (iii) people are being more compliant with their drug regimens, especially those who take medication for chronic conditions like allergies.⁵⁶

The survey further states that physicians play an important role in whether patients follow their treatment regimen. Physicians who spend time talking to their patients about the side effects both serious and non-serious of advertised prescription drugs resulted in 22 percent of patients to be more likely to take their medication.

4. DTCA in Europe

In the European Union, pharmaceutical companies are regulated by the European Commission's Directorate General-Enterprise. The European Agency for the Evaluation of Medicinal Products works closely with the Enterprise Directorate-General to formulate policy and oversee the safety of pharmaceutical products in the European Union. All proposed legislation governing pharmaceuticals must be reviewed and approved by the European Parliament and the Council of Ministers.

While some non-branded advertisements that mention a medical condition but do not include a specific treatment are allowed, promotion of pharmaceutical drugs or DTCA is not permitted in Europe at this time. The reasons for this are many, including fears that increased demand for certain drugs may adversely impact healthcare budgets in countries with universal healthcare coverage; the patient-physician relationship may be compromised; pharmaceutical companies who produce the drugs will not be impartial about benefits and risks in advertisements; and lastly, the question of liability can not be answered.

This section describes the ongoing discussion by E.U. politicians to ease the rules and present views from opposing parties. Due to the lack of empirical data analyzing the benefits and disadvantages of DTCA in Europe, a direct comparison with information from the U.S. is not feasible at this time. However, results of one consumer survey by *Prevention Magazine* from 2000 of European citizens in four E.U. countries and one E.U.-candidate country may provide insight into how Europeans view DTCA.

4.1 Pending Review of European Pharmaceutical Legislation

Historically, due to legal restrictions,⁵⁷ prescription drug information and promotional materials in the European Union were directed only at physicians, pharmacists and other healthcare professionals. Consumers could access that material only if it was bundled with all available treatment options as part of an unbranded disease-awareness effort. Patient-oriented drug promotion for over-the-counter drugs on the other hand is legal.⁵⁸

Currently, the European Commission is debating a liberalization of the drug advertising rules.⁵⁹ In July 2001 – as part of a package of draft amendments for a wide-range

56 Slaughter, 2001.

57 Council Directive 1989/552/EEC prohibits television advertising of prescription-only products. Council Directive 1992/28/EEC regulates advertising medicinal products for human use.

58 Council Directive 1992/28/EEC allows Over-the-counter (OTC) marketing directly to consumers; however, it curtails an excessive and ill-considered OTC promotion including free samples.

59 The European Commission is responsible to initiate draft legislation, present legislative proposals to the European Parliament and the Council, and implement approved legislation.

reform of the European Pharmaceutical Legislation⁶⁰ – the Enterprise Directorate-General⁶¹ introduced a proposal to relax the rules of the Advertising Directive⁶² that ban DTC information or advertisement of prescription drugs to European patients.⁶³ In November 2001, the Commission submitted its proposal to the European Parliament⁶⁴ for final vote on October 22, 2002. The Parliament's President referred it to the Committee of the Environment, Public Health and Consumer Policy⁶⁵ for review and recommendations by early October 2002.

Aimed to ensure the availability of accurate and more patient-oriented information, the revised Advertising Directive included a pilot program that would allow drug-developing companies during a five-year trial period to promote medicines for three specific conditions. These include AIDS, diabetes, and chronic respiratory problems such as asthma. The Commission chose these three medical areas because they have two commonalities: they all are chronic or long-term care diseases or conditions, and there has been a significant demand for information from patients who suffer from the conditions.⁶⁶

The Commission's intention was not to legalize unsolicited DTCA for prescription drugs, but rather to enable patients and consumers to request information directly from industry about their condition and available treatment options. The aim was to address the current practice of European patients who access information about their diseases and medicines on the Internet through web sites provided by non-European, mostly American companies. This puts consumers without Internet access and English language skills at a disadvantage. Also, many drugs are marketed differently outside of Europe. As a result, information on those drugs may be misleading and possibly harmful to European patients.

Under the proposed rules, the European Agency for the Evaluation of Medicinal Products⁶⁷ (EMEA) would have significant regulatory authority to monitor and approve the content of consumer-oriented information. EMEA also would be required to work with the Commission, the Member States, industry and patient groups to harmonize guidelines covering media and content. The pharmaceutical industry would have to adopt principles of good conduct as well as self-regulatory control procedures.

⁶⁰ Proposal for a Directive of the European Parliament and of the Council amending Directive 2001/83/EC on the Community code relating to medicinal products for human use.

⁶¹ The Enterprise Directorate-General is the Commission's division with special responsibility for promoting European business.

⁶² Advertising regulations contained in Articles 86 to 88.

⁶³ European Report 2611, 2001.

⁶⁴ The European Parliament with its 626 members shares legislative power with the Council and plays a decisive role in budget approvals.

⁶⁵ The Committee on the Environment, Public Health and Consumer Policy is responsible to review legislative proposals on environment, public health, food safety and consumer protection issues.

⁶⁶ European Commission, IP/01/1027, Brussels, 18 July 2001.

⁶⁷ The EMEA – similar to the U.S. FDA – is responsible for approving drugs and monitoring drug safety.

4.2 *Heated Debate*

Since the initial publication of the Commission's proposal in July 2001, criticism has grown with strongly divergent views from different stakeholders, including consumer groups, healthcare provider associations, and governmental authorities.

The European Consumers' Organization⁶⁸ and the European AIDS Treatment Group⁶⁹ expressed concerns about potential health risks and excessive demand for prescription drugs, which may lead to an explosion of healthcare costs. The UK pressure group Social Audit claimed that the proposed new rules do not make an adequate distinction between DTC information and DTC advertising⁷⁰. Health Action International Europe⁷¹ argued that the proposed rule changes would lead to increased costs for prescription drugs, lack of impartial information and compromised public health. They also would promote the medicalization of normal life.⁷²

In March 2002, representatives from academia, drug regulators, consumer groups and the pharmaceutical industry met in Brussels to discuss the draft Advertisement Directive. The ensuing debate resulted in one astounding clarification – hardly anyone involved would admit to supporting the proposal. The Commission's proposal stated that the DTC recommendations were based on expectations expressed by patients' groups. However, at the conference, the agency's spokesperson could not name a single patient group that had supplied a written request for the legislative change.

Additional confusion could be found within the specific language chosen in the proposal, namely the exact definition and differentiation of non-promotional information versus advertisement. Another issue of contention was the proposal's limitation to only three disease areas. Unrelated patient groups claimed that restricting the information pilot study to only these disease areas was unfair and inadequate because patients suffering from other diseases have exactly the same informational needs.⁷³

The Standing Committee of European Doctors and the Pharmaceutical Group of the European Union – representing European physicians and pharmacists – in a joint statement claimed that DTCA of prescription drugs could not lead to a direct purchase by consumers since the physicians writing the prescription serve as gatekeepers. But it would be unreasonable to permit the establishment of a situation where patients would pressure physicians to prescribe only highly priced, advertised medicines.⁷⁴

Elsewhere in the European Union, the Dutch inspectorate of health has claimed that even the most limited use of DTC information boosts unnecessary medical consultation. Following a recent three-month campaign for a nail fungus treatment – which neither carried the company nor the product name – physician office visits for this condition rose from an average of two per month per doctor to 20 patients per week per doctor. Dutch general practitioners were recently asked to boycott the drug manufacturer in a

68 The European Consumers' Organization is a Brussels-based federation of 34 independent national consumer organizations from the EU, accession and EEA countries.

69 The European AIDS Treatment Group is a pan-European organization advocating for the interests of people living with HIV/AIDS.

70 European Report 2650, 2002.

71 Health Action International Europe is a network of 150 consumer health groups.

72 Health Action International Europe Report, 2001.

73 Cassels, 2002.

74 Pharmaceutical Group of the European Union, 2002.

letter to the journal of the Royal Dutch Medical Association, *Medisch Contact*.⁷⁵ The Dutch health ministry announced it would vote against relaxing rules as proposed by the Commission.

The European Federation of Pharmaceutical Industries and Associations (EFPIA)⁷⁶ adopted an agnostic approach to the debate. Claiming that it did not ask directly for legalizing DTCA, it limits itself to agreeing on a set of guidelines it has created for its members' use of the Internet to provide patients with information on their products.

4.3 Current Ruling to Date

On October 9, 2002, the Committee of the Environment, Public Health and Consumer Policy released a report accepting the Commission's proposal; however, it included its own amendments. The Committee also asked to be consulted again should the EC intend to amend the proposal substantially or replace it with another text.⁷⁷

The controversial, year-long debate around relaxing the DTC ban is reflected in the amendments made by the Committee to the Commission's proposed version of articles 86, 87 and 88 – the Advertisement Directive. It provided a lengthier definition of information versus advertising of medicinal products. *Information* shall include objective reports on the composition, action, quality, indication, contraindication, adverse reactions as well as the results of market canvassing activity.⁷⁸ *Advertisement* shall include any form of door-to-door marketing, market canvassing activity or inducement designed to promote the prescription, supply, sale, consumption or awareness of the availability of medicinal products.

The Committee *rejected* the draft proposal by the Enterprise Directorate-General to establish a five-year pilot project allowing drug companies to provide DTC information on three medical conditions by completely deleting the relevant regulatory language.⁷⁹ The Committee's report provided commentary by numerous members justifying this drastic amendment. Arguments ranged from being discriminatory to people with other diseases, the possibility of an increase of patient demand for specific, generally costly drugs and an overall increase in drug use, to an adverse effect on medical practice and on doctor-patient relations.

The draft proposal also was viewed as a first step towards legalizing DTCA. The lack of estimates for the impact on health insurance budgets and the open question of liability also were raised. The pharmaceutical industry's inability to provide impartial information could result in a misleading of the public. Lastly, the proposal did not provide a manner in which patients can receive comprehensive information about different treatment options.

However, the Committee recognized the needs of patients and consumers to be able to obtain accurate, understandable, reliable and non-promotional information on the range of treatment choices, including medicines. In a new amendment⁸⁰, the Committee

⁷⁵ Sheldon, 2002.

⁷⁶ EFPIA represents views of about 2,000 pharmaceutical companies conducting research, development and manufacturing of medicinal products for human use in Europe.

⁷⁷ Report to European Parliament, 2002.

⁷⁸ Article 86, Paragraph 1, introductory sentence.

⁷⁹ Article 88, Paragraph 2.

⁸⁰ Article 88, Paragraph 6 a (new).

suggested that the Commission should present a new proposal following consultation with consumers, patient organizations and other interested parties to address this issue. The new proposal should look specifically at ways in which web sites and telephone hot-lines are or could be used to provide this needed information, while at the same time addressing the question of liability. Particular attention should be paid to solutions that would ensure information is accessible to people with disabilities including the blind and visually impaired.

In a separate amendment⁸¹, the Committee suggested the possibility of urging every national authority within the European Union to establish a web site that functions as a portal and provides objective information on pharmaceutical products and health issues in general. Lastly, it asked for a means to evaluate the overall level and kind of public health benefit resulting from this novel approach to informing consumers. This would allow an assessment of the quality of information as well as its accuracy, dissemination, accessibility and involvement of stakeholders.

The European Federation of Pharmaceutical Industries and Associations called on all Members of the European Parliament (MEPs) to respond positively to the industry's concerns on the key issues for the pharmaceutical industry, Europe's patients and future clinical research. It claimed that Europe will take a step backwards – unless the proposal is changed – instead of moving towards an informed and liberalized society.⁸²

On October 22, 2002, the 626 MEPs voted on the Commission's initial proposal to reform the European legislation for pharmaceutical products. It was the first vote of two readings of the European Parliament under the co-decision procedure.⁸³ The proposal now needs to be endorsed by the E.U. Council of Ministers⁸⁴ before the Parliament may complete its second reading. In its initial vote, the Parliament followed the recommendations of the Committee of the Environment, Public Health and Consumer Policy by rejecting the proposed revision of the Advertising Directive. The Parliament will hold a second and final vote scheduled tentatively for the first half of 2003, until which the European Commission has the opportunity to resubmit a revised proposal on this matter. The legislative adoption within the EU member countries of the final amended regulations will follow sometime in 2004.

In the meantime, some European drug companies already employ DTC outreach tactics within the legal framework by collaborating with patient and caregiver groups and leveraging the Internet to build relationships with those target audiences.

4.4 European Consumer Attitudes about DTCA

While there is limited consumer research in Europe about the merits of DTCA, there are a few studies that demonstrate attitudes of European consumers about DTCA if it were allowed in their country as well as what types of information Europeans seek.

The findings of *Prevention Magazine* in its 2000 International Consumer Wellness

⁸¹ Article 88, Paragraph 7 a (new).

⁸² EFPIA, 2002.

⁸³ The co-decision procedure is the most common legislative procedure placing the European Parliament and the Council on equal footing.

⁸⁴ The Council of Ministers is the embodiment of the EU Member States, whose representatives come together regularly at ministerial level.

Study about European consumers' attitudes towards DTC included results from 4,006 adult consumers from Finland, France, Germany, Poland, and United Kingdom.⁸⁵

About 20 percent of Europeans polled in the survey said that they were aware of DTCA. The French were the most aware of this type of promotion, while Germans were the least aware. If DTCA were allowed in their country, an average of 58 percent said they would discuss an advertised prescription drug with their doctor, with the French (65%) most interested in doing so, followed by the U.K. (62%), Poland (55%), Germany (52%) and lastly Finland (28%). Less than a majority of Europeans (41%) said they would specifically request an advertised drug.

These figures are substantially higher than the U.S. polled adults. However, European consumers are pessimistic about the willingness of their physicians to discuss advertised medicines (24%) and prescribe requested drugs (8%).

These findings may reflect Europeans growing dissatisfaction with their healthcare systems. The survey showed that on average, Europeans reported that they did not receive adequate information from their pharmacist or doctor about the medicine they were prescribed including: the exact condition the medicine is intended to treat (46%); the risks or side effects that the patient might experience (37%); warnings about who should take the medicine (39%); possible interactions with other prescriptions (32%); how much the medicine costs (12%); what to do if you develop side effects or other problems (34%); and lastly how the medicine actually works in the body (28%).

A 2003 study by Cambridge University Health⁸⁶ called "The Informed Patient" Project recently concluded that European patients and citizens' healthcare information needs are not being met.⁸⁷ The objective of the study was to develop guidelines to shape future healthcare policies on how to provide information to European patients in order to:

- Deliver impartial, sound (evidence-based), and accessible information and knowledge support to address the generally inadequate provision to patients/citizens noted today.
- Ensure that such support will mitigate some of the burden for the growing numbers of aged with chronic illnesses on the already constrained healthcare systems across Europe.
- Help patients and healthcare professionals better evaluate treatment choices as medical science and healthcare become increasingly complex.
- Increase transparency and accountability of the healthcare system so that choice and cost-effectiveness are evident.
- Adopt, on an on-going basis, new information and communications technologies such as the Internet and digital TV, so that healthcare operations will promote best practices, adopt new effective treatments and discard ineffective and/or unsafe old treatments.

Following a conference held at Cambridge University in December 2002 with numerous stakeholders including academic, government and industry representatives, a consensus statement was drafted, outlining a four-part initiative:

⁸⁵ Slaughter, 2001.

⁸⁶ Cambridge University Health is the health policy and management center for the University of Cambridge.

⁸⁷ Detmer et al., 2003.

- Create a Framework for the Future. This can be accomplished by convening key stakeholders in the near future to develop the set of initiatives outlined in the Statement.
- Support Implementation. Focus the EU and member state governments and the private sector explicitly on accessibility, availability, and quality of structured information for patients/citizens.
- Co-ordinate the Suppliers of Information. By developing and using agreed standards, promote the effective provision of quality information.
- Leadership and Education. Provide critical support to patient health education and continued professional development.

The consensus statement urges the Commission “to take the lead in moving the agenda forward by building on and co-ordinating existing initiatives into a broader framework, bringing together both private and public sector interests to assist developments for the benefit of patients and the healthcare industry in member states and regions and localities as appropriate.”⁸⁸

5. Discussion

DTC advertising of prescription drugs is generally viewed as the pharmaceutical companies’ preferred vehicle to provide information to the end consumer and create awareness and demand for their products. Numerous consumer surveys conducted among U.S. adults support the notion that DTC promotion of advertising drugs has generally had a positive impact on general health awareness among the American public.

They also show that DTCA is not as perfect or effective as pharmaceutical companies would like them to be. According to a recent survey referenced in Forbes magazine, pharmaceutical ads for prescription drugs are less effective than ads for over-the-counter drugs or nutritional supplements.⁸⁹ DTCA, therefore, is far from substituting public health campaigns, some of which are supported by government agencies and often include television ads. Rather, DTCA is one tool, which combined with others such as information provided by physicians or other sources, including the Internet, is paramount to providing patients with the necessary tools to empower them to be more involved in their own healthcare management.

U.S. consumers are becoming more educated about medical symptoms and related conditions, initiating discussions with their physicians, and are more aware about risk and benefit information. Research supports that when all of these conditions exist, compliance with prescribed treatment plans increases.

While expenditures on DTCA in the U.S. have increased significantly, they still remain insignificant as percentage of total promotional spending. Drugs that received the highest percentage of advertising expenditures often result in higher awareness among consumers, especially those that take the drugs. But the length of time the drug has been in the market and advertised is an important factor in raising awareness about the drug as well as the medical condition the drug is intended to treat. The true answer to whether DTCA is effective will only be known, however, when studies have been conducted to evaluate whether patients experience better health outcomes such as reductions in hos-

⁸⁸ Ibid.

⁸⁹ Herper, M., 2003.

pitalization or reduced morbidity and mortality as a result of DTCA. Such studies have yet to be completed.

What is clear from the U.S. experience is the growing movement and acceptance of patient empowerment, which is often termed patient-centered care or shared decision-making. There is increasing usage of the Internet by patients, physicians, and pharmacists. Patients independently find information about medical conditions, including disease-focused self-diagnosis and assessment tools, in addition to available treatment options. Increasingly, physicians use E-mail as a communication tool with their patients to address their questions and concerns outside the office visit. Health insurers as well as doctors are beginning to employ the Internet as an integral disease management tool, for example, by alerting patients to schedule their next office visit or to maintain a prescribed treatment plan. Doctors also are employing the Internet to submit drug prescriptions to the pharmacist, which safeguards the patient by eliminating legibility mistakes.

These changes are not implemented without effect on consumers and patients, who are increasingly challenging the traditional role of a patient as a passive participant in their own healthcare maintenance. With their access to information and the level of medical sophistication growing, patients are evolving into educated, empowered consumers who are taking an active role in their health, demanding safer, more effective medical solutions. They could also assume stronger activist roles to influence public and regulatory policies. In today's globalized world with the Internet, this wave of change in the U.S. does not have simple boundaries. Approximately 38 percent of European households were linked to the Internet in December 2001, according to the European Commission, and this number continues to grow.

The recent European rejection to relax the DTC ban was inspired by concerns about possible escalating drug costs as well as concerns for physicians' ability to handle increased patient visits and possible pressure to prescribe advertised drugs. The European parliamentarians, however, did not consider improvements within a legalized DTCA framework, namely the ability for the European Agency for the Evaluation of Medicinal Products to provide regulatory authority over pharmaceutical drug advertising.

Some type of regulatory framework, preferably with multiple stakeholder input, could ensure a stronger, more transparent relationship between government and pharmaceutical companies. In addition, the voices of patient advocacy groups could be heard better and put into context with what types of information patients want, the information that pharmaceutical companies could provide and information that contributes to patient concordance in sync with evidence-based medicine.

Pharmaceutical companies - which perhaps have the best information on the drugs they make and are legally accountable for any claims - could work with regulatory authorities as well as non-governmental organizations to develop guidelines that enable companies to provide patients with suitable and approved communication, including information and advertising, in order to educate consumers about their goods and services.

A joint public-private partnership also could help the European Commission, Parliament and Council of Ministers better address concerns of escalating healthcare costs. Different payment and cost structure proposals could be evaluated by all involved. For example, patients could be better informed on budgetary implications of their demand for a particular promoted drug as well as the appropriate use, misuse, and over use of the medicinal intervention. Once armed with this information, patients could make their own decision whether to incur their own costs for a preferred prescription drug. Health literacy activities that place in context the value of prevention, detection, and treatment

of disease and health outcomes could add, rather than detract, from overall health spending.

European legislators and regulators face significant challenges in balancing a patient's right to be informed with fiscal responsibility. They are right to be concerned about accepting DTCA as it exists in the U.S. However, Europeans can use data available from U.S. consumer and physician surveys to learn both the advantages and disadvantages of DTCA – and develop suitable guidelines that are not American but distinctly European – in content, execution and delivery.

It is unclear if the European Union and the national health authorities will be able to provide its approximate 375 million citizens with the right solution to meet their medical needs and civic rights for complete information before EU enlargement in 2004. It would greatly benefit all Europeans – currently within the EU and those awaiting to join – if a resolution to the debate between medical information and advertising were resolved. Increased patient e-literacy and mobility across Europe emphasize the need for an early outcome to the debate on DTCA in Europe.

Regardless of the regulatory situation around DTCA in Europe, the *informed patient* – an individual who visits the doctor's office armed with questions about the advantages of one drug over another and is prepared to ask for the best treatment – is becoming increasingly the norm throughout the U.S. This trend will eventually emerge in Europe as patients begin to demand that physicians allow them to become more involved in the decision-making process about fundamental issues affecting an integral part of their lives – their own health.

In addition, European patients are increasingly looking to the Internet for more information about their condition. At this point, most healthcare information sources on the Internet are American or English-language web sites, where the most up-to-date products and news on the latest research published in medical peer-reviewed journals can be found. It should be a high priority of the European Union to use the Internet to provide comprehensive medical information in multiple languages to harmonize access to quality healthcare for all of its citizens.

Finally, scientific progress in health will continue to advance at an expanding pace. It is in everyone's interest for each of us to be better informed patients. Further developing a framework that promotes the optimal common currency – effective health communication – to advance public health is of utmost importance.

References

- American Diabetes Association (Oct. 2002): Facts & figures on diabetes; www.diabetes.org/main/info/facts/facts.jsp.
- Baylor-Henry, M. (Mar. 2002): Personal conversation with this former FDA employee involved in 1997 guidance clarification.
- Calfee, J. (July 24, 2001): Written testimony before the Senate Subcommittee on Consumer Affairs, Foreign Commerce, and Tourism for Public Hearings on Direct-to-Consumer Advertising of Prescription Drugs; American Enterprise Institute; www.aei.org/ct/ctcalf010724.htm.
- Cassels, A. (Apr. 2, 2002): Push for consumer drug ads gets cool reception in Europe; Canadian Medical Association Journal; 166 (7): 946.
- Centers for Disease Control (Oct. 25, 2002): Prevalence of self-reported arthritis or chronic joint symptoms among adults – United States, 2001; Morbidity and Mortality Weekly Report 51(42): 948 – 950.

- Detmer, D., Singleton, P., MacLeod, A., Wait, S., Taylor, M. and Ridgwell, J. (2003): The Informed Patient: Study Report; Cambridge University Health; www.jims.cam.ac.uk/research/health/health_f.html.
- EFPIA (Oct. 15, 2002, Press release): Revision of the EU Pharmaceutical Legislation: EFPIA urges MEPs to support pharmaceutical research for the benefit of patients; www.efpia.org/3_press/20021015.htm.
- European Report 2611 (July 17, 2001): Pharmaceuticals: Commission presents its proposal for new EU rules; www.eisnet.be.
- European Report 2650 (Jan. 12, 2002): Pharmaceuticals: Confusion over drug advertisement proposal; www.eisnet.be.
- FDA Consumer Survey (1999 and 2002): Attitudes and behaviors associated with DTC promotion of prescription drugs; Center for Drug Evaluation and Research, Division of Drug Marketing, Advertising, and Communications; www.fda.gov/cder/ddmac/dtcindex.htm.
- FDA Guidance (Aug. 8, 1997): Guidance for Industry: Consumer-directed broadcast advertisements; www.fda.gov/cder/guidance/index.htm.
- FDA Physician Survey (2002): Direct to Consumer Advertising of Prescription Drugs: Preliminary Survey Results (Jan. 13, 2003): Center for Drug Evaluation and Research, Division of Drug Marketing, Advertising, and Communications; www.fda.gov/cder/ddmac/dtcindex.htm.
- Findlay, S. (Nov. 20, 2001): Prescription drugs and mass media advertising, 2000; National Institute of Health Care Management; www.nihcm.org.
- GAO Report to Congressional Requesters (Oct. 28, 2002): GOA-03-177; Prescription drugs – FDA oversight of Direct-to-Consumer advertising has limitations; www.gao.gov/new.items/d03177.pdf.
- Health Action International Europe Report (Dec. 2001): Direct-to-consumer prescription drug advertising – The European Commission's proposal for legislative change; www.haiweb.org.
- Herper, M. (May 2, 2003): Prescription Drug Ads Are No Blockbusters; Forbes online; www.forbes.com.
- International Osteoporosis Foundation (Dec. 4, 2001): Osteoporosis in the European Community: a call to action; www.osteofound.org/publications/pdf/eu_report.pdf.
- Institute of Medicine IOM Report (Mar. 20, 2002): Unequal Treatment: Confronting Racial and Ethnic Disparities in Health Care. www.nap.edu/books/030908265X/html/.
- Kaiser Family Foundation (Nov. 29, 2001): Understanding the effects of DTC prescription drug advertising; www.kff.org/content/2001/20011129a/.
- Leatherman, S. et al. (Apr. 2002): Quality of Health Care in the United States: A Chartbook; Commonwealth Fund Report 520; www.cmwf.org/programs/pub_highlight.asp?id=736&pubid=520&CategoryID=3.
- Levit, K. et al. (Jan./Feb. 2002): Inflation spurs health spending in 2000; *Health Affairs* 21(1): 172 – 181.
- Media Guidelines: Black Journalists Association of Southern California, 2003; www.nabj.org.
- Mitka, M. (Feb. 19, 2003): Survey Suggesting That Prescription Drug Ads Help Public Is Met With Skepticism; *Journal of the American Medical Association* 289: 827.
- Ogilvy, D.; Ogilvy on Advertising, Mar. 1987 Edition; New York: Vintage Books.
- Ostrove, N. (July 24, 2001): FDCH Congressional testimony to the Committee on Commerce, Science and Transportation; Division of Drug Marketing, Advertising and Communications, US FDA.
- Pharmaceutical Group of the European Union (2002); Press release, www.pgeu.org.
- Report to European Parliament on amending Directive 2001/83/EC (Oct. 9, 2002): by the Committee on the Environment, Public Health and Consumer Policy; www2.europarl.eu.int/omk/sipade2?L=EN&OBJID=5317&LEVEL=3&MODE=SIP&NAV=X&LSTDOC=N.
- Reuters Business Insights (March 2000): The Evolution of DTC Marketing across key pharmaceutical markets; www.reutersbusinessinsight.com.
- Rosenthal, M. et al. (Feb. 14, 2002): Promotion of prescription drugs to consumers; *New England Journal of Medicine* 346(7): 498 – 505.

- Schuster, M. et al. (1998): How good is the quality of health care in the United States?; *Milbank Quarterly* 76: 517 – 563.
- Sheldon, T. (Aug. 17, 2002): Dutch GPs call for ban on Novartis products; *British Medical Journal* (325): 355.
- Shuler, J. (Sep. 1984): Liz Moench: Taking Boots Directly to Consumers; *Pharmaceutical Executive* 4: 22-29.
- Slaughter, E. et al (2001): Survey on Wellness and Consumer Reaction to DTC Advertising of Rx Drugs (2000-2001); *Prevention Magazine*, Vol. 1; U.S. Report with International Perspectives; Emmaus: Rodale.
- Sterling Drug v. Cornish, 370 F.2d 82, 85 (8th Circuit decision, 1966).