History and Characteristics of Direct-to-Consumer Advertising in the United States

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Abstract

Direct-to-consumer advertising (DTCA) in which pharmaceutical companies market prescription drugs directly to consumers is legal in only two countries – the USA and New Zealand. This article describes legislative milestones of DTCA development in the USA which have given rise to the current legal framework.

The article shows the cultural background for DTCA expansion, outlining the fight of patients' associations for better access to information about therapy and drugs and change in perceiving the role of the patient in the health care professional-patient relations. It presents arguments supporting the producers' right to advertise their products.

Direct-to-consumer advertising in the USA is a controversial subject. Although based on only limited data, the existing research gives arguments both in favor and against direct-to-customer advertising. The article also presents the EU policy towards DTCA, considering the consequences of the existing DTCA ban in the EU.

Key words: drug advertisements, DTCA, patients, pharmaceutical marketing

Siowa kluczowe: reklama leków, leki na receptę, pacjenci, marketing farmaceutyczny

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Introduction

Only in two countries in the world, the USA and New Zealand, the law authorizes direct advertising of prescription drugs to consumers (DTCA – direct-to-consumer advertising) [1]. Such advertising entails that prescription drugs can be promoted in popular media, such as television, radio, newspapers and magazines as well as on billboards, via mail or leaflets [2].

The definition of DTCA does not include ads published on drug manufacturers' websites because such information is searched independently by consumers. Nor does it subsume materials that patients receive from the company e.g. by calling their hotline or by post. The concept of DTCA does not cover promotional information published in medical journals because there the target group are healthcare professionals [2].¹

It is on an everyday basis that American citizens are 'bombarded' with advertisements of prescription drugs that are to cure their high cholesterol, diabetes, depression, pain and many other conditions [3]. The development of this form of advertising has been made possible, among other things, due to the establishment of patients and consumers associations demanding that patients be allowed active participation in making health decisions and that there be improved communication between the patient and medical staff [3]. This evolution supported the arguments of DTCA proponents as advertising was to provide patients with information about diseases and their treatment [1]. Although it has been over thirty years since the publication of first advertisements, this issue remains controversial. Advantages and disadvantages of DTCA are widely discussed in the literature [4, 5].

One can only speculate to what extent DTCA contributes to the fact that the drug market in the United States is the largest in the world -41.8% of the world's drugs are purchased there. It is also worth noting that as many as 56% of new drugs (launched between 2006 and 2010) were sold in the US [6].

The aim of this article is to present and explain how public-directed prescription drugs advertising became legally binding in the United States, and the characteristics of this form of marketing. An analysis of the literature and the milestones leading to the current legislation will be presented, as well as the cultural conditions that enabled DTCA. Both positive and negative aspects of this solution will be shown. Finally, the EU approach on the introduction of such advertising in Europe will be demonstrated.

1. History of prescription drugs advertising

In the early twentieth century there were only a few effective drugs on the US market and the patients themselves opted for one or the other [7]. At that time the roles of the doctor who prescribed medication and the pharmacist who dispensed it were not so strictly separated, and virtually all the drugs could be obtained both by prescription and without it.

In 1905, the American Medical Association (AMA) appointed the Council on Pharmacy and Chemistry, which established standards for drugs and evaluated them [3]. The aim of the council was to advocate the use doctor-prescribed drugs, avoiding ineffective self-prescribed medication. The AMA encouraged medical journals not to publish drug ads aimed at laymen, and doctors not to prescribe medicine whose advertising is addressed to the public. Self-treatment was perceived as a threat to the medical profession. The AMA's guidance led to the fact that over the years the only 'ethical' advertising was considered to be that addressed directly to physicians [3].

The aim of the first federal drug regulation in 1906 was to discourage people from self-medicating, but at the same time to encourage drug manufacturers to give consumers accurate drug information (e.g. medicines could not be marked in a confusing or misleading way, the presence and quantity of dangerous substances was to be indicated) [3].

In 1938, the Food, Drug and Cosmetic Act (FDCA) was introduced, which gave the federal Food and Drug Administration (FDA) the right to exercise supervision over food, drugs and cosmetics [2]. The Act was the result of over a hundred deaths caused by the drug called Elixir sulfanilamide. Since then the consent of the FDA had to be obtained before placing the medicament on the market. Also, the scope of information to be included in the drug leaflet was extended. In addition to the drug name and composition, they were to include directions for use [3].

Before 1951 whether the drug was sold without a prescription (such drugs in the US were called OTC – 'over the counter') or by prescription (RX – 'prescription only') depended on the drug manufacturer. Only sometimes did the FDA indicate medications which should be issued only on prescription, when they were considered potentially dangerous. The lack of clear rules gave rise to confusion among both patients and pharmacists. In 1951, the FDCA was amended and a definition of RX drugs was created. Medicines that were potentially toxic, had harmful actions, complicated dosing, or were dangerous if taken without medical supervision, were to be issued only by prescription. The introduction of this distinction has significantly increased the number of prescription drugs. This move has strengthened the position of the AMA that it be qualified medical personnel that keep watch over what drugs the Americans are taking. Pharmaceutical companies ceased to direct their ads to ordinary people, focusing mostly on physicians [8].

In 1952, further amendments were introduced to the FDCA. It was required that the manufacturer of the drug provide evidence of the safety and efficiency of the drug – only then could it be promoted. Ads were to inform about both risks and gains from taking the medication. The FDA was also given the possibility of jurisdiction over drug advertising [8].

In the 1960s, 90% of marketing expenses were allocated to the promotion addressed to doctors – the remaining 10% on advertising in hospitals and directed to pharmacists. This move was in direct opposition to that of thirty years earlier, when the companies incurred heavy investments in advertising addressed to the public [3].

In subsequent years, the significance and prestige of the medical profession were increasing. Doctors were becoming better educated and specialized. There was a growing disparity between their knowledge and that possessed by the average patient. At that time it was common practice not to inform patients about the diagnosis and treatment. In the late 1960s, spending on prescription drugs amounted to 83% of all drugs spending incurred by the Americans [3].

In 1969, the FDA determined the final regulation on prescription drugs ads. They were: 1) not to be false or misleading, 2) to maintain the correct balance between medication risk and gains (*fair balance*), 3) to contain facts that are significant from the point of view of using the advertised product, 4) to contain information about the most common risks of taking the drug (*brief summary*) [9]. These regulations did not affect public-addressed prescription drugs advertising, but only that directed to healthcare professionals.

Until the mid-1980s US pharmaceutical companies focused mainly on doctors as their core customers, and trained armies of medical sales representatives that would offer them mugs, notepads, conference fees and other things [10]. In the 80s, the policy changed favourably for pharmaceutical companies [2]. At the time, the idea of 'managed care' was being developed, aimed at reducing costs and increasing the efficiency of care. The patient was to take a greater part in the decision-making process regarding their treatment, also have an impact on the drugs they were prescribed, which were to be more modern, newer, better functioning rather than simply the ones chosen by their doctor after they had dinner with a pharmaceutical representative [10]. Organizations of patients and consumers were being formed, demanding better information about treatment. They became the driving force of DTCA. In order for such advertising to take effect, pharmaceutical companies had to properly educate patients and prepare them to talk with the medical staff, the same aim - better education - had the patient's organisations [3]. While the companies tried to give patients

In the early 1980s, some drug manufacturers started to change their marketing approach, directing their attention towards ordinary citizens. At the beginning it was not so much advertising as social campaigns. For example, Pfizer began the 'Partners in Health Care' campaign, which drew attention to the consequences of untreated diabetes, tonsillitis, hypertension or arthritis. However, no drugs were mentioned. Only the name of the company was visible, with the hope that patients would ask about the company's drugs at their local clinic [3]. In 1981, the Reader's Digest published an advertisement of Merck's pneumococcal vaccine, Pneumovax [8]. The advertising machine started rolling.

When advertising of prescription drugs was being regulated in 1969, there was still no advertising for prescription drugs directed to the public, and so the first marketing campaigns were not subject to any restrictions. Initially, the legislators favoured DTCA and hoped that the regulations they created within advertising aimed at medical professionals would be sufficient to protect ordinary consumers. However, in 1983 the FDA heard some criticism - it was feared that DTCA would cause, among other things, the patients to exert influence on the authorized professionals to write out prescriptions for unnecessary drugs, causing an increase in drug prices [3]. In 1985, after conducting a survey among patients and a public debate, in which lobbying pharmaceutical companies pointed to the educational importance of these ads, the FDA published the Federal Register, where it declared that the 1969 regulations are sufficient to protect consumers. This greatly popularized the printed advertising of prescription drugs directed to ordinary people [2].

Still, in the early 1980s, most companies avoided DTCA. According to the 1984 survey, a large part of company managers felt that such advertising would harm the doctor-patient relations, confuse the minds of ordinary people and lead to an increase in drug prices. Also, associations of doctors and consumers did not support this form of advertising. Between 1985 and 1990, at least twenty-four products were promoted in this way [3].

2. Development of DTCA

In the late 1980s and early 90s, the pharmaceutical industry adopted more aggressive marketing and began increasing investments in DTCA. This change was caused i.a. by the economic recession and changes in the health care system. Moreover, American doctors were losing public trust [3]. Patients wanted to be better informed about their treatment and its possibilities, and the development of technology, also the Internet, meant that it was becoming increasingly easy. DTCA spending in the mass media grew rapidly, in 1991 amounting to USD 55 million, in 1995 to the staggering 363 million [3].

In 1997, after several years of discussions with the pharmaceutical industry and a public debate, the FDA is-

sued guidance for the industry (Draft Guidance for Industry: Consumer-Directed Broadcast Advertisements) [2]. Changes were introduced which somewhat loosened the restrictions imposed on the pharmaceutical companies advertising prescription drugs. The new regulations allowed that in selected types of advertising (e.g. TV commercials where only the name of the drug was presented) be included only the main risks associated with the drug (major statement), rather than its common risks (brief summary), which was previously required. However, the ads needed to present information about where full information of these risks were to be found (adequate provision) – e.g. telephone hotline, fax number, website [2]. The pharmaceutical companies responded with a dynamic growth of investment in TV advertising, and a lowered interest in print advertising [8].

Along with changes in the law, pharmaceutical companies were increasing their spending on prescription drugs advertising in the media. In 1996, it amounted to 0.7 billion USD, in 2006 reaching the record 5.41 billion USD – since then the expenditure has been steadily falling, in 2012 reaching 4.16 billion USD [11].

Since 1999, the FDA began to examine the impact of DTCA by conducting large surveys among physicians and patients. In a report published in 2004, the FDA states that the ads seem to increase treatment awareness, motivate to ask questions to health workers and to ask better-informed questions. However, the studies also pointed to a poor understanding of the risks associated with the use of the drug. The final conclusions of the FDA pointed to both good and bad aspects of advertising directed to the public [1]. In 2004, 2009 and 2012 the FDA came up with additional guidelines on DTCA, addressed to the industry [12].

In the United States there are occasional calls to ban DTCA. However, the most simple argument that manufacturers should not be prohibited from advertising their own product, is sufficient to silence such appeals [5].

Currently, there are three categories of DTCA ads. These are: defining advertising product (*product claim ad*), advertising reminding of the product (*reminder ad*) and advertising for seeking help (*help-seeking ad*) [5].

Ads defining the product include the product name, indicate its application and report safety and performance. When considering regulations for these cases of DTCA, two forms of communication should be distinguished. The first type being the ads printed in newspapers, magazines and periodicals, and the second – ads broadcast in mass media, via radio, television and telephone communication systems [13]. Internet-based ads are yet another category. Researchers point to the need for additional regulation on prescription drugs advertised on the Internet [5].

Printed ads must include information about the most common risks of taking the drug (*brief summary*), i.e. all side effects, contraindications, warnings, precautions and side effects. In their 2004 guidelines, the FDA encourages companies that they avoid using difficult, medical language, as it was often practiced before, but consumerfriendly vocabulary, so that the warnings and the most important dangers and side effects of the drug could be easily understood. The printed ads must also contain the statement: "You are encouraged to report negative side effects of prescription drugs to the FDA. Visit MedWatch or call 1-800-FDA-1088" [13].

Broadcast advertising must include a statement about the key risks (*major statement*), presented in a clear, understandable and neutral form [13]. It is therefore more constrained than printed advertisements. This entails that broadcast advertising must refer the patient to the relevant source (*adequate provision*), where they can find at least the most common risks of taking the drug (*brief summary*) – e.g. printed advertising, the Internet, doctor or pharmacist.

Reminder ads include the name of the drug, but not its application. It is assumed that the patient knows what the drug is and does not need to be repeated that information. This type of advertising cannot be used for drugs that have warnings on the package [14].

These advertisements describe the disease or condition but do not mention a specific drug which can be applied to a given ailment. For example: 1) people are shown who constitute the group, which might take a given drug; 2) some symptoms are shown, e.g. a runny nose, sneezing, red or watery eyes; 3) individuals with such symptoms are encouraged to talk with their doctor; 4) information about the drug manufacturer and its website are provided [14].

Although not as popular as in the case of other goods, product placement in popular TV series and films is another form of drug promotion [15]. Since it is increasingly popular, the need to regulate such advertising is being pointed out [16].

An example of a drug product placement is the film titled *The Sixth Sense*, where Zoloft by Phizer is presented. Also, in the *Scrubs* TV series, the NuvaRing by Organon was shown. Sometimes a famous person suffering from an illness speaks favourably in the popular media about a drug they use [15].

A regulation of the placement of pharmaceutical products is a challenge currently faced by the FDA. The applicable law does not solve the problems arising in this sphere, which can lead to many abuses. [15]

3. DTCA – advantages and drawbacks

Prescription drugs advertising directed to the public raises many dilemmas. Allowing such advertising certainly affects the patient-doctor relations. Researchers suggest both positive and negative effects of such advertising.

DTCA proponents are of the opinion that these ads help educate patients, give them control over their own health and help maintain it [4, 5]. Thanks to providing the patient with knowledge about their disease and its treatment, they **facilitate discussion between the medical staff and the patient**. Patients may engage in discussions regarding the treatment of their disease, ask for a particular drug and find out whether it is suitable for them.

Most physicians (53%) agree that DTCA advertising is useful because it facilitates discussion with the patient. Seventy-three percent of respondents said that it allows patients to ask more informed questions [17]. Doctors believe that patients' questions about a certain drug have a positive or neutral impact on the visit. One-third of American adults has discussed some drug with a doctor, and 10% of them received the drug they asked for [18]. As many as 63% of oncology nurses believe that DTCA promotes dialogue with the patient [2].

Ads encourage patients to contact the medical personnel. If patients experience any symptoms mentioned in the advertisement, or think they are at a risk of developing an illness, they can go and see their doctor or nurse, which could save their lives. This is particularly important in diseases such as hypertension or elevated cholesterol, which are slow and 'silent' killers.

In the years 1998–1999, drugs for allergies were actively promoted. At this time, there was an increase in related visits, from 13–14 million to 18 million [19]. The 2004 FDA survey also indicated that 27% of Americans were attracted by the ad and consequently arranged an appointment with their doctor to talk about the disorder, which they had never discussed before [5]. Ads can help diagnose diseases whose symptoms the doctor has not noticed, and the patient – alarmed by advertising – informs the doctor.

Ads make it more likely that patients take their prescribed medications. Studies consistently show a small but statistically significant improvement in the use of drugs by those 'exposed' to DTCA. This is because the ads remind us of taking the medicine [5]. There are also studies indicating that patients watching DTCA play a more active role in caring for their health and follow the rules of medication more conscientiously. One of them, conducted by pharmaceutical companies, indicated that patients with diabetes, depression, increased cholesterol, arthritis or allergy were more likely to continue treatment after 6 months if themselves they asked the doctor about the drug after seeing the ad, than if the drug was prescribed by the physician [4].

DTCA remove the stigma of people suffering from a medical condition. There are certain diseases that seem shameful to people – e.g. depression or erection problems. Ads make us familiar with these topics, showing that others also have such problems. A 1997 survey among people calling the number shown in television advertising on genital herpes showed that after seeing the ad 45% of these people decided to go to the clinic in the next three months [5].

The negative consequences of DTCA are also extensively presented in the literature. Usually, when considering the considerable **increase in drug prices** in the United States, two reasons are mentioned. The first is the possibility of prescription drugs advertising directed to the public. The second is the lack of a formal policy of controlling drug prices in the United States. Pharmaceutical companies typically advertise the most expensive drugs and most do not mention their cheaper counterparts [19].

Advertising creators are accused of **misleading con**sumers, inventing new diseases and exaggerating the benefits related to the use of drugs. A common accusation is that relevant information is omitted [5, 20]. An analysis of television commercials of Frosch's drugs and those of other companies seems to suggest that despite the claim that drug advertising serves an educational function, it provides a very limited amount of information about the causes of disease and groups of people at risk. People who have lost control over their emotional, social and physical life as a result of not taking any medication are usually depicted. The importance of a healthy lifestyle is minimised [20]. It is often suggested that health improvement is the result of taking the drug, or at most, a combination of taking the medication and lifestyle changes, not the lifestyle change only [21].

Prescription drugs advertising directed to the public leads to an improper prescription of drugs. It may happen that the patient really wants to get the advertised drug, and the practising professional is unable to convince them that it is inappropriate for them, and gives out the desired prescription under pressure, which can lead to extremely negative consequences. There are also patients who, thanks to advertising, learn to mimic the symptoms so as they are issued a prescription for the drug they need. [5]

In the opinion of some, DTCA is also a threat to doctor-patient relations. Ads for prescription drugs can cause a loss of confidence in the medical personnel. In one of the studies cited by Ventola, more than half of the patients were disappointed when they did not get the drug they requested [5].

Visits at the clinic have specific time frames. Discussing advertised drugs is a waste of time. They can stop the doctor from asking the patient some relevant questions about their health and informing them about important preventive behaviours. The medical staff lose time to explain the patient why the touted drug may not be best for them [22]. Some patients may also self-diagnose the disease, which they in fact do not suffer from, and may unnecessarily come to visit.

The above-mentioned negative and positive effects of prescription drugs advertising leave considerable room for doubt. Undoubtedly, DTCA contributed to the increase in the value of the pharmaceutical market in the United States and a growth in sales of innovative, modern drugs. But its good and bad aspects for the patient are still widely discussed in the literature, making it a field for further research.

4. EU approach to DTCA

The EU law prohibits public advertising of prescription drugs [23]. Obviously the large pharmaceutical companies are lobbying to make DTCA advertising legal [24]. They repeat the argument used in the US, arguing that such advertising has a very important role in education regarding the disease and appropriate treatment. So far, however, European leaders have been effectively resisting those pressures. In 2002, during the European Parliament's vote on the admission of DTCA, as many as 494 MPs voted against it, only 42 saying 'yes' [3].

All drug advertising (both OTC and RX addressed to doctors) are subject to various kinds of EU regulations. Drugs are specific products – not only our health, but even our life depends on them, hence the justification to give their advertising more attention. Member states differ in terms of how strictly they approach pharmaceutical marketing. [25]

For example, in Poland, advertising drugs was prohibited [26] until 1993, when public advertising of OTC drugs was allowed [27]. Advertising of OTC drugs caused that there was a fourfold increase in sales in 1994–2001 [28]. In accordance with the European Union law, public advertising of prescription drugs is currently prohibited in Poland [29]. Poland has quite strict regulations regarding pharmaceutical marketing, physicians cannot be visited by medical representatives during their working hours, doctors cannot accept gifts worth over 100 PLN or unrelated to the practice of medicine [25].

Does the ban on advertising prescription drugs mean that the Europeans, including Poles, are less informed about them than the Americans? Pharmaceutical companies will of course argue that it is so. However, despite the ban on advertising prescription drugs, it is required in the EU to provide accurate information about drug products. On the Internet you can find i.a. product characteristics and leaflets, which are attached to the packaging. Therefore, a patient who wants to become acquainted with the possibilities of therapy for some diseases, will have to put more effort into seeking information than the average American but will not be deprived of such a possibility. And the information, thus obtained, will not be in any way considered advertising.

It is worth noting that we are not quite defended against DTCA in the European Union. All fans of the popular *Dr. House* series must recognize the Vicodin brand (Abbott Laboratories) – a popular painkiller prescribed in the USA.

Summary

The aim of the article was to present and explain how it happened that advertising of prescription drugs directed to the public became legal in the United States, and the characteristics of this form of marketing. It is worth quoting a few significant facts related to DTCA. Firstly, it is the cultural factors – the organizations and associations of patients demanding better access to information about treatments and medication; change in the perception of the role of the patient in doctor-patient relations, and in a sense defending freedom, that is, the rights of producers to market their products – all of these factors have aided the development of this form of advertising.

Secondly, this form of advertising has developed in the last three decades. In the last two there has been a very dynamic investment in this form of advertising, and pharmaceutical companies strongly increased their spending on this type of promotion.

Thirdly, advertising of prescription drugs addressed to the public, even though legal in the United States raises a lot of controversy there. Various studies are underway that indicate both positive and negative effects of such a solution. Certainly, the possibility of such advertising affects the entire health care system in the USA – drug prices, choice of prescribed drugs by authorized professionals, and use of drugs by patients. Fourthly, in the United States there are still unresolved legal issues related to DTCA advertising on the Internet and drug product placement in TV series, films, etc. It is a challenge faced by legislators.

Fifthly, advertising products that may affect human health is a very complex issue, which presents a number of ethical and legal challenges both to manufacturers wishing to sell their products with the help of marketing and to state authorities and consumer organizations wanting to defend the best interests of citizens. Despite pressure from various groups, at the moment it is little probable that a ban on DTCA in the US be introduced. Also the EU politicians do not seem to be inclined to revoke the prohibition of this type of advertising.

Note

¹ In the US, medication can be prescribed by physicians, dentists, optometrists, qualified nurses and veterinarians.

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