

Direct-to-consumer advertising of internationally controlled substances

1. Among the three international drug control conventions, the Convention on Psychotropic Substances of 1971 specifically touches upon the scope of advertising of internationally controlled substances. Article 10 of the 1971 Convention requires that each party shall, subject to its constitutional limitations, prohibit the advertisement of psychotropic substances to the public.¹

2. The term ‘advertisement’ refers not only to public announcements in newspapers and magazines for public consumption, but also to those broadcasted on television or radio or other means. Additionally, it restricts announcements on posters, outdoor displays as well as on those in shop windows intended to draw the attention of the public. However, it does not include announcements in technical journals published specifically for medical practitioners, chemists or pharmacists, or those printed on posters shown at scientific conferences or exhibitions. It also does not cover announcements in commercial literature published exclusively for members of the medical professions or for pharmacists or other licensed traders in psychotropic substances.²

3. Direct-to-consumer pharmaceutical advertising (DTCPA) has become one of the most important types of health communication showing a significant growth in the last few years.³ DTCPA can be defined as an effort (usually via popular media) made by a pharmaceutical company to promote its prescription products directly to consumers.⁴ The idea of DTCPA is not only to inform, educate, and empower the patients, but also to encourage them to contact a clinician. DTCPA promoters claim that it removes the stigma associated with certain diseases and that, from a market perspective, it encourages product competition and lower prices.

4. To date, the United States and New Zealand are the only countries that allow DTCPA to include product claims.⁵ The DTCPA in the United States is under the regulation of the U.S. Food and Drug Administration (FDA) and it requires “Direct-to-Consumer” advertising to provide a balanced presentation of a product’s benefits, risks, and side effects.⁶

5. Since 2000, Canada has experienced an increase in so-called “reminder ads” in which the name of the drug, and the condition it treats has been mentioned - but not in the same advertisement.⁷ The pharmaceutical industry and lobby groups have attempted, unsuccessfully, to overturn bans on DTCPA in Canada and other countries or regions, such as in the European Union (EU). Notably, in 2008, 22 of the 27 EU member States voted against proposed legislation that would have allowed even limited “information to patients” to be provided.⁸

6. Arguments against DTCPA point out that advertising can omit important information. Although “Direct-to-consumer” pharmaceutical advertising is presented as aimed at informing and educating patients, experience shows that it often results in misinformation.⁹

¹ United Nations, Treaty Series, vol. 1019, No. 14956.

² Commentary on the Convention on Psychotropic Substances of 1971, Article 10, Paragraph: 2,

http://www.unodc.org/documents/treaties/organized_crime/Drug%20Convention/Commentary_on_the_Convention_1971.pdf.

³ FDA weighs limits for online ads, Kuehn BM - JAMA (2010 Jan 27; 303(4):311-3); DTC marketing mix: Radio and outdoor ad spending soars, Internet not so much. Pharma Marketing. Available at: <http://pharmamktng.blogspot.com/2010/06/dtc-marketing-mix-radio-outdoor-ad.html>.

⁴ Direct-to-consumer advertising in oncology, Abel GA, Penson RT, Joffe S, Schapira L, Chabner BA, Lynch TJ Jr Oncologist (2006 Feb; 11(2):217-26).

⁵ ProCon.org: Should Prescription Drugs Be Advertised Directly to Consumers? (2017 Nov 12), <https://prescriptiondrugs.procon.org/>.

⁶ According to Virginia State Board of Pharmacy v. Virginia Citizens Consumer Council, Inc., “the Court noted that in cases of commercial speech, such as price advertising, freedom of speech protections apply just as they would to noncommercial speech. Even speech that is sold for profit, or involves financial solicitations, is protected”. Prohibition of DTCPA in the United States would therefore impinge on the constitution and freedom of speech.

⁷ Direct-to-consumer advertising and expenditures on prescription drugs: a comparison of experiences in the United States and Canada: Morgan SG Open Med (2007 Apr 14; 1(1): e37-45).

⁸ Direct to consumer pharmaceutical advertising: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3278148/>.

⁹ Direct-to-consumer advertising in oncology-Abel GA, Penson RT, Joffe S, Schapira L, Chabner BA, Lynch TJ Jr Oncologist (2006 Feb; 11(2):217-26).

7. DTCPA has also been criticized because advertisements for drugs often emphasize drug benefits over risks and promote new drugs before safety profiles are fully known.¹⁰ Based on some opinions, DTCPA contributes to the “medicalization” of natural conditions, cosmetic issues, or trivial ailments leading to an overmedicated society.¹¹ Such advertising can cause inappropriate prescribing in cases where the patient’s request for an advertised drug is clinically inappropriate and the health care provider is unable or unwilling to correct the patient’s perception.¹² It can also negatively influence a patient-clinician relationship, diminishing the patient’s trust in their health care provider’s clinical decisions.¹³

8. Opponents to DTCPA in the United States argue that regulations should be strengthened through legislation, thus minimizing the direct contact between pharmaceutical sales representatives and physicians and prohibiting televised advertisements of drugs.¹⁴

9. DTCPA can also raise costs by promoting expensive “me-too” or “copycat” drugs that might not offer any significant benefits over established and cheaper medications or generics.¹⁵

10. The INCB reminds States Parties to the 1971 Convention of their obligations under Article 10 of the Convention to limit the scope of direct-to-consumer advertising. Where direct advertising to consumers is permissible, it is desirable to ensure that such advertisements are carefully regulated, and that the principles of responsible sharing of truthful and non-misleading information about medicines are applied.

INCB is the independent, quasi-judicial body charged with promoting and monitoring Government compliance with the three international drug control conventions: the 1961 Single Convention on Narcotic Drugs, the 1971 Convention on Psychotropic Substances, and the 1988 Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances.

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¹⁰ FDA weighs limits for online ads. Kuehn BM, JAMA (2010 Jan 27; 303(4):311-3); Shaw A Direct-to-consumer advertising of pharmaceuticals: The DTC advertising debate, ProQuest. (2008 Mar). Available at: www.csa.com/discoveryguides/direct/review4.php/; Drug risks and free speech--can Congress ban consumer drug ads? Shuchman MN Engl J Med. (2007 May 31; 356(22):2236-9).

¹¹ Big bad pharma: an ethical analysis of physician-directed and consumer-directed marketing tactics, Connors AL Albany Law Rev (2009 Sep; 73(1):243-82).

¹² A decade of controversy: balancing policy with evidence in the regulation of prescription drug advertising: Frosch DL, Grande D, Tarn DM, Kravitz RL Am J Public Health (2010 Jan; 100(1):24-32).

¹³ Big bad pharma: an ethical analysis of physician-directed and consumer-directed marketing tactics: Connors AL Albany Law Rev (2009 Sep; 73(1):243-82).

¹⁴ Connors AL, Big bad pharma: An ethical analysis of physician-directed and consumer-directed marketing tactics, Albany Law Rev.

(2009;73(1):243–282); Abel GA, Penson RT, Joffe S, et al. Direct-to-consumer advertising in oncology, Oncologist, (2006;11(2):217–226),

¹⁵ Big bad pharma: an ethical analysis of physician-directed and consumer-directed marketing tactics, Connors AL Albany Law Rev (2009 Sep; 73(1):243-82).