



OTC Medications, Advertising and the Public Health: A US Perspective

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Introduction

The designation “over the counter medication” and “nonprescription medicines” have somewhat different meanings throughout the world. Generally, they reflect products that meet the definition of a drug, are self-limiting in their therapeutic consequences, have nominal or controllable side effects, and are used for diseases and conditions that can be self-recognized. The use of OTC medications is characterized by a highly favorable risk-benefit.

OTC or nonprescription medicine are intended to be distinct from a more potent set of drug products—usually designated “prescription medications”—for which the intervention of a health care professional is deemed essential prior to use. WFPMM carefully distinguishes its mandate by focusing on responsible self-medication and making clear that this does not mean self-prescribing. This distinction is critical to the public health and regulatory positioning of OTC products.

Depending on a country’s drug regulatory program, the marketing approval, labeling, and distribution of OTC medications can be lightly or heavily controlled. The same is true of consumer advertising of OTC products.

The purpose of this paper is to examine the relationship of OTC medications, advertising, and the public health. Particular attention is given to how this relationship has evolved in the US and the strengths and weaknesses of the US approach.

OTC MEDICATIONS AND THE PUBLIC HEALTH

OTC medications meet an important public health need in the treatment of relatively common and easily recognizable conditions. The number and burden of these conditions—headache, fever, cough, cold, allergic reaction, skin irritation, inflammation, heartburn, indigestion, constipation, insect bites, and many others—is almost incalculable.

The Nonprescription Drug Manufacturers Association (US) summarizes the benefits of OTC medications as follows:

Self-medication with nonprescription medicines, the most common form of health care in the United States, is safe, effective, dependable, and affordable – and one way Americans can exert more control over their own health care. (emphasis added).

To these five characteristics there is at least one additional characteristic: in many countries, OTC medications are readily accessible to individuals with common medical problems without waiting for a health care professional or a separate trip to a pharmacy.

The evolution of two classes of drugs—OTC and prescription—reflects both the ubiquity of conditions that can be treated by OTC medications and the safety with which self-medication can occur. For the OTC class, these six descriptive characteristics define an optimum public health solution for the medical conditions for which OTC products are used:

- safe,
- effective,
- dependable,
- affordable,
- accessible, and
- promotes individual autonomy in an appropriate matter.

Generally speaking, prescription medications are more potent, likely to present risk even when used properly, and are for more serious diseases that require professional diagnosis. From a public health standpoint, their use is only justified in conjunction with medical advice from a health care professional. Consequently, prescription drugs are primarily promoted by communications to health care professionals.

In contrast, public knowledge about OTC medications is an integral part of their ability to contribute to the public health. Knowledge about self-medication and OTC products is particularly important to realizing the benefits of accessibility and individual autonomy.

High levels of public awareness also contribute significantly to affordability. According to NDMA, developers and marketers of OTC products produce an estimated 125,000 to 300,000 OTC products in the US (including a variety of sizes, dosage forms, and

strengths) because they know that they will be able to convey product advantages to a substantial population. The result is a vigorous competition for consumers that exerts strong downward price pressures and increases the affordability of self-medication products.

ADVERTISING AND THE PUBLIC HEALTH

Notwithstanding these seeming advantages of public awareness through advertising of OTC medications, public health professionals are often seen as being hostile to advertising.

Sometimes the objection rests on a general belief that consumers cannot responsibly use health information contained in advertisements. Under this view, even if companies advertise responsibly, there is still too large a potential for consumers to misunderstand or misuse the information they receive.

Other times, the objections are based on concern that commerce and public health are innately at cross-purposes. In this view, advertisements are designed to create demand, not education, and therefore companies that advertise do so only in their own self-interest and can not be expected to act responsibly.

Although the prevailing trend in the US is to promote greater personal autonomy in health care decision making, these types of objections are not unknown in the United States. There are consumer advocates who trust neither consumer nor product companies to engage in an honest dialogue about health matters.

Nonetheless, the overall US experience of public health and advertising has been quite positive. To those who argue that consumers are too often misled, the experience of health care advertising has been to the contrary. For example, in 1992 the Heller Research Group reported the following findings from a consumer survey they had done for the NDMA (US):

- Almost seven in 10 respondents said, if at all possible, they prefer to fight symptoms without taking medications.
- Close to nine in 10 consumers said they know medication should only be taken when absolutely necessary.

(Self-Medication in the 90s: *Practices and Perceptions (May 1992)*)

This strongly supports the contention that advertising has been appropriate and has not created a headlong rush of consumers to buy products that they do not need or cannot handle properly. Rather, I believe that the sophistication of American consumers about health matters is a result of advertising, not as some would have it, a precondition of allowing advertising to occur.

The other objection also deserves attention: are public health goals and corporate goals opposite? Again, the US advertising experiences does not support this view.

For example, the creation of immediate product demand is not the only corporate goal that can be served by advertising. Among other things, advertising can be used to:

- Create awareness about a particular medical problem and the availability of a remedy,
- Develop consumer brand or corporate loyalty that transcends immediate purchasing decisions, and
- Direct consumers to the physician or pharmacist for advice.

Even when a primary goal of an advertisement is the creation of immediate product demand, it is usually consistent with public health goals because the advertising directs the consumer to a product that resolves their health concern in a safe and effective manner.

THE US APPROACH TO REGULATING THE ADVERTISEMENT OF OTC MEDICATIONS

While OTC advertising is less heavily regulated in the United States than in some other countries, it is still subject to several levels of review and is one of the most scrutinized forms of advertising in the US.

The Federal Trade Commission (FTC) has the broadest mandate to oversee and act against deceptive trade practices in commerce, including advertising. It has the primary jurisdiction over OTC advertising, although it does consult with the Food and Drug Administration (FDA). FDA has jurisdiction over the labeling of OTC medications and the labeling and advertisement of prescription drugs.

Among the prominent features of FTC oversight of OTC advertising are:

- no pre-publication review (i.e., enforcement, if any, occurs after publication);
- advertisements must generally conform to the standard of “truthful and not misleading;”
- advertising language and the FDA approved labeling need not be identical;
- warnings and full disclosure are not required (i.e. statement such as “read the label carefully before use” and “follow label directions for proper use” are sufficient, and
- comparative advertising is encouraged if it otherwise meets all standards.

In a 1992 article on Nonprescription Drugs and the Regulation of Advertising, James D. Cope, President of the NDMA (US) articulated the three basic regulatory standards that FTC applies in determining whether an advertisement for an OTC medication is “truthful and not misleading.”

- Reasonable Basis/Prior Substantiation. Under this policy, OTC product claims, express or implied, must be supported by adequate substantiation. To meet this test, there must be a reasonable basis for the claim. FTC often looks to FDA for advice on whether a reasonable basis exists.
- Deception. Under this policy, FTC looks to whether a consumer might be misled or deceived under ordinary circumstances.
- Unfairness Policy. Under this policy, FTC looks to whether a trade practice, including an advertisement, is likely to cause substantial injury to consumers. This is a fairly subjective test and is most often applied in support of allegations made primarily on the basis of deception or inadequate substantiation.

In addition to FTC activities, companies that advertise OTC products are subject to private litigation from competitors under the Lanham Act. Also, most states have consumer protection laws that allow enforcement actions that parallel those available to the FTC and the FDA. Usually, the state attorney general is the focal point for such activities.

It will be noted that the governmental controls over OTC advertising are substantial, but not as intrusive as they might be, given the need to protect the public health. This reflects the partial protection that commercial speech enjoys under the US Constitution’s First Amendment protection of free speech. The relative lack of government intrusiveness is also a result of extensive voluntary self-regulation by the media, advertising and OTC industries.

It is beyond the scope of this article to fully describe the matrix of self-regulation of OTC advertising that protects the public health and minimizes the need for government regulation. The elements can be summarized as follows:

- NDMA Code of Advertising Practices. The Nonprescription Drug Manufacturers Association (US) has had a voluntary advertising code since 1934. It has been updated a number of times and is closely followed by most companies.
- NAD/NARB. The Council of Better Business Bureaus and the National Advertising Review Board (created by the advertising industry) have developed a process by which complaints about the truth and accuracy of advertisements are investigated and voluntarily adjudicated.

- Television Network Advertising Clearance. The television networks usually request submission of story boards and review claim substantiation prior to accepting advertising.
- Individual Company Review. For practical, as well as legal, regulatory and scientific reasons, companies are diligent about assuring the truthfulness of any of their OTC advertising, In addition, they know that their competitors will be scrutinizing their advertisements and can bring a private lawsuit under the Lanham Act.

STRENGTHS AND WEAKNESSES OF THE US APPROACH

In the United States, OTC medications are widely promoted through consumer-directed advertising. This has created an enormous and growing market characterized by:

- comparatively low prices (advertising costs are fully absorbed not additive);
- high consumer awareness levels of when and how to use products;
- very high satisfaction levels among customers;
- almost no safety problems; and
- support for self-medication among health professionals.

As has been stated previously, this system appears to serve the public health needs of the United States in an exemplary fashion. Its strengths are based on how it simultaneously protects the public health and is well-suited for the American approach to product communications.

As it operates in practice in the United States, there are few, if any, weaknesses to the American system of OTC advertising. There are occasional complaints that the system promotes overuse of medications, allows irresponsible communications to occur, and is too reliant on consumer sophistication. None of these arguments can stand up to much scrutiny.

Prescription drugs are distinct from OTC products. The relative freedom accorded to OTC advertising in the US and a number of other countries is closely tied to the characteristics of OTC medications, as distinct from prescription medications. As the Heller study cited above makes clear: consumers try to avoid all medications and use OTC products only when absolutely necessary. Further, it can be argued that where OTC medications are widely available and there is a broad public knowledge of OTC medications, it is less likely that consumers will demand or utilize prescription medications inappropriately.

Societal commitment to public communications, including commercial speech, provides a net benefit despite the risk of irresponsible communications. There is an assumption that communications should be promoted. The unique way in which the FTC operates is a by-product of this commitment, as is the lack of mandated pre-publication government review.

In the US, the benefit to the public health of open communications about OTC products has been demonstrably greater than any harm created by irresponsible acts. While differences in culture and government structure have required different approaches in other countries, the public health benefit of open communication and industry self-regulation appears to be constant across societies that share this commitment.

There is a value to greater self-care and personal autonomy, regardless of the sophistication of consumers. American consumers have become more knowledgeable about health care, largely as a result of public education campaigns and advertising. However, allowing OTC product advertising prior to such conditions was never treated as very risky, because of the high safety profile and self-limiting nature of OTC products. I believe this is true in a number of other countries.

CONCLUSION

The purpose of drug regulatory systems is to protect and expand the public health. This includes both protecting consumers from harm and assuring them access to the products and information they need to be healthy.

OTC advertising, as regulated and practiced in the United States, meets both these tests. Self-regulation has been largely successful and post-publication enforcement by government has been needed only occasionally and has been effective in resolving issues.

The advantages of this approach have been multiple, including wide availability of safe and effective products at highly competitive prices. However, the applicability of the US OTC advertising system, or elements of it, to other countries is at least partially dependent on: the countries' approaches and traditions for assuring the public health and on the existence of stringent self-regulation by industry.