

The Right to Know

**You watch television...
you read the papers... you listen to
the radio... you talk to friends and
relatives... wherever you turn,
there are messages about drugs...
new drugs and old drugs, some that
need a doctor's prescription,
others that don't. And still others
that are the subject of the
Government's "War on Drugs."
Whom to believe? And what to
believe? This booklet is an effort
to bring together much needed,
clear, reliable information
on this often confusing subject.
It has been prepared by a group of
professionals who are dedicated
to the dissemination of truthful
information to health
professionals and to the public.**

The Coalition for Healthcare Communication

The Coalition is a not-for-profit organization representing eleven major communications industry groups engaged in medical publishing, in the development of medical education materials, and in the dissemination of information concerning medical products and services. The Coalition seeks to achieve goals shared by the Food and Drug Administration, the medical community, policy makers, and the American public: to safeguard and ensure the continuous flow of sound medical information.

Why is pharmaceutical marketing necessary?

In the late 19th century, Emerson fostered the idea that “if you’ve built a better mousetrap, the world will beat a path to your door.” That may have been true then, but today, in the 21st century, it may take quite a while until “the world” finds out about your mousetrap, unless you take positive, affirmative steps to let people know about it. Pharmaceuticals and medical devices are, of course, a great deal more complicated than mousetraps. And, when it comes to matters of health, frequently time is of the essence.

In fact, to be of real value as quickly as possible, prescription drugs *must* be marketed! And, because drugs and devices are high-technology products, they require detailed information for appropriate use. There must be an effective transfer of information from the scientists who discovered and developed them to the physicians and other health professionals who will prescribe them to the patients who will consume them. All this must occur in as short a time span as possible, without compromising the need for consumer safety.

The landscape of medical knowledge

Medical information can be found all over the map. It comes from research articles in medical journals and textbooks; published reports of medical meetings, conferences, and seminars; health-related stories in the mass media; advertising messages from pharmaceutical manufacturers; and, of increasing significance, the Internet. Each of these sources has its own rules and, when the focus is on drugs or devices, the information conveyed may vary considerably in style and reliability.

FDA and FTC

The Food and Drug Administration (FDA) monitors advertising claims for prescription drugs and devices. Ads must be balanced, stating clearly when the product may be used, when it must not be used, and when it should be used with caution. The Federal Trade Commission (FTC) oversees ads for nonprescription drugs, foods, and nutritional products, and the FTC does this by requiring substantiation of claims by the advertiser when questions arise.

Confusion may arise when certain prescription drugs become available without a prescription. This happens when a prescription drug has established a track record for safety and effectiveness, and public health officials determine that it may be sold directly to consumers without a doctor’s prescription (“over the counter” as pharmacists say, or “OTC”). Shifting a prescription drug to OTC status saves the cost of a doctor visit for a prescription. However, sometimes only the lowest dose of a drug is accepted for OTC use, while higher doses remain available only with a prescription.

“Dogs bark, cows moo...”

Most people are aware, in a general way, that the FDA is the US government regulator of drugs and devices. The limits and extent of FDA authority over communications, however, are less well understood. As a former FDA commissioner once said, “dogs bark, cows moo, and regulators regulate.” Over the years, with remarkably little resistance from Congress, the FDA has substantially expanded its authority to include virtually every communication from a drug or medical device manufacturer. For a drug, that includes any claims about the conditions (“indications”) for which the drug may be used, its dosage, and its benefits, as well as disclosure of its side effects. Whether the product is advertised to a medical audience or directly to consumers makes no difference; the rules remain the same, although the language may be simplified for the public.

“Off-label” communications and the First Amendment

The FDA takes its responsibility to protect the public very seriously. The FDA reviews and approves the claims that a manufacturer may make about its products in a document called the “package insert” or “labeling.” However, experience has shown that approved labeling often may lag behind current medical research and practices, which may render parts of the official labeling obsolete.

The fact is that once the FDA has approved a drug for any condition, doctors are free to prescribe it as they see fit, even for uses not yet approved by the FDA—the so-called “off-label” or “unapproved” uses. However, under the existing law, the people who may know the most about the drug—the drug manufacturers—are forbidden to communicate about such uses except under very restricted circumstances. Doctors are free to report the results of their off-label use at conferences or meetings and in textbooks or medical journals, but drug manufacturers may not pass those reports along without following an expensive and lengthy review by the FDA.

But what if a medical meeting included a presentation and discussion of off-label uses and was supported by a pharmaceutical or device manufacturer? That question brings up the important US Constitutional issue of free speech.

The FDA’s traditional position has been that commercial sponsorship of such discussions would make the speech illegal. In other words, even though the information presented at the meeting was truthful and accurate, such communication would be forbidden because it was supported by a drug company or medical device manufacturer. The Coalition for Healthcare Communication, the Washington Legal Foundation, and many other interested parties protested this policy as an infringement on the rights of doctors and patients to know about the latest medical discoveries and on the rights of manufacturers to speak truthfully about their products.

At present, a compromise prevails. Industry support for and distribution of medical articles and books are acceptable to the FDA, provided any off-label uses are clearly identified and there is no clear pattern of drug company intent to promote the product’s off-label use. To clarify its authority and policies regarding the regulation of health communications, the FDA recently requested that all concerned parties provide their opinions and suggestions on the issue. More changes may be coming soon.

Transparency

In the present, fast-moving climate of innovation, industry support has become essential for many vital academic activities. Not only are medical publishers dependent on the revenue from drug advertisements, but their editorial pages carry the results of the latest drug research. The essential element needed here to protect the integrity of the communications process is *transparency*—that is, a clear statement that discloses any relationship that might suggest a potential conflict of interest or bias.

The current policy for most medical journals mandates that clinical investigators seeking to publish their research must fully disclose before publication whether they receive grants from pharmaceutical companies, own stock in such companies, or have any other meaningful relationship with such companies. The same principle applies to other examples of industry-supported activities as well, such as participation in symposia, meetings, and discussion groups. (It is ironic that many outspoken critics of the drug industry are not required similarly to disclose biases evidenced by their prior research and writings).

Avoidance of conflict of interest is particularly important in continuing medical education (CME). Most physicians, today, are obligated to lifelong learning as a condition of maintaining their professional license. The CME process may take the form of reading certain texts, attending conferences and symposia, and taking self-administered tests. These activities and any materials generated in connection with them, such as videotapes, audiotapes, and booklets, are produced by fully accredited institutions and medical faculty. Topics or speakers may be suggested by industry personnel, but final decisions about faculty and content are the responsibility of the accredited provider. The industry thus maintains an “arms-length” distance from all such activities.

The right to know

It seems like a distant memory, but until about 20 years ago, information about prescription drugs was directed only to health professionals. However, times and customs change. Today, US consumers want to understand the benefits and risks of medical and surgical treatments—and they don’t want access to information blocked by anyone. To be sure, there are wide variations in educational levels and comprehension of healthcare information, and there are considerable differences in just how much or how little an individual patient wishes to participate in decision-making with a physician. Nevertheless, many consumers today are very knowledgeable about their health condition and the management of any problems. For example, some patients with breast cancer or AIDS have been reported to understand nearly as much about their disease as their doctors! These patients are likely to want to read up-to-date information on new developments in the professional literature.

Sources of drug information

The following list provides links to some of the major organizations concerned with the dissemination of truthful drug information. Please note that the Pharmaceutical Research Manufacturers Association website contains its new, voluntary code on marketing practices adopted in July of 2002. Further, the American Medical Association (AMA) website contains the AMA ethical guidelines for physicians.

Accreditation Council for Continuing Medical Education (ACCME)
www.accme.org

American Academy of CME (AACME)
www.academycme.org

Association of Medical Publications (AMP)
www.amponline.org

Coalition for Healthcare Communication
www.cohealthcom.org

Council of Science Editors
www.councilscienceeditors.org

Food and Drug Administration (FDA)
www.fda.gov/

Health on the Net (HON)
www.hon.org

MEDLINEplus Health Information
www.nlm.nih.gov/medlineplus

National Council on Patient Information and Education
www.ncpie.org

Pharmaceutical Research and Manufacturers of America (PhRMA)
www.phrma.org

C O A L I T I O N F O R

Healthcare Communication

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