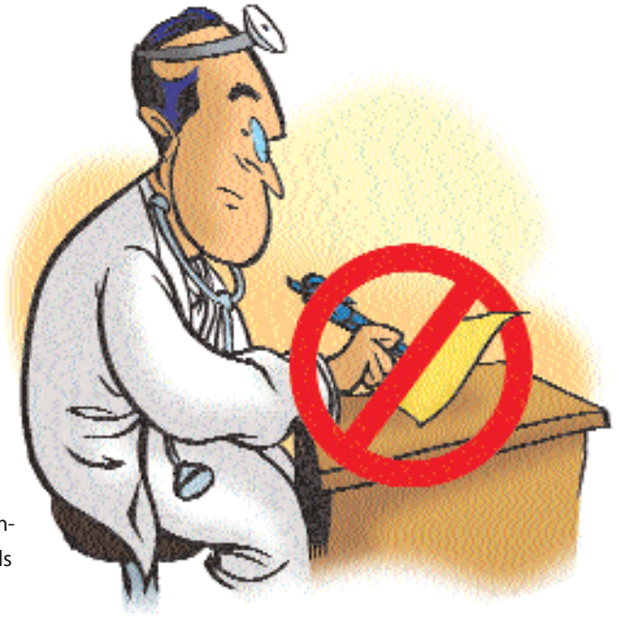
OPINIONS

Information standards



In the November/December issue of PharmaVOICE, we asked if the Food and Drug Administration should consider relaxing its standards for press releases about drug approvals, which currently are almost always considered a promotion. The regulatory agency issued a call for public comment May 16, 2002, after the Supreme Court said FDA restrictions on advertising of compounded drugs violated the First Amendment in Thompson v. Western States Medical Center.

The FDA's regulation of information about off-label use of pharmaceutical products, its blanket prohibition against the dissemination of educational material by pharmaceutical companies and drug makers, and its standards for the release of information about drug approvals may be illegal, according to the Pharmaceutical Research and Manufacturers of America (PhRMA), which represents the country's leading research-based pharmaceutical and biotechnology companies.

Commenting on the FDA's regulation of speech, PhRMA said there should be no uniform prohibition against the dissemination of information about off-label uses found in medical or reference texts.

An off-label rating system

Dissemination of information regarding off-label use has been a hot issue for years. Restriction of valid medical information does not work and encourages companies and individuals to navigate the grey areas of any regulation.

Off-label information distribution could be seen as a win-win situation for physicians, patients, and the industry if textbooks, references, and reprints carried a disclaimer on the front cover. Instead of regulating distribution, encourage appropriate disclaimers that forcefully identify the information as off label. This could be in the form of approved stamping of material much like the rating system for movies or records, which informs the audience about what they are about to see, hear, or read. Significant fines could be imposed for any individual or company not in compliance.

A system such as this would not compromise free speech and valid information exchange but would put this information into appropriate context for the receiver.

Jim Clifford
Co-Chairman
CommonHealth

Both sides of the argument

My opinion is that I understand both sides have an argument, in that the FDA is concerned about how public-release statements may be picked up by the public and they in turn go to their physicians to exert pressure to use the medication for off-label uses.

On the other side, physicians are able to use pharmaceutical products for off-label uses under the abbreviated new drug application procedure, usually in concert with the pharmaceutical company in a one-off clinical trial. I believe that, with accelerated drug approvals with a call for Phase IV programs and proactive risk management, some of these issues may be resolved.

William Van Nostrand
Group President
Dendrite Clinical