

## Does Pharmaceutical Advertising Contain Accurate Promotional Statements?

Villanueva P, Peiró S, Librero J, Pereiró I. Accuracy of pharmaceutical advertisements in medical journals. *Lancet* 2003;361:27–32.

### Study Overview

**Objective.** To determine if the promotional claims made in pharmaceutical advertisements are supported by literature cited in advertisements.

**Design.** Cohort study.

**Data collection.** All advertisements for antihypertensive medications and lipid-lowering medications were reviewed in 6 leading Spanish medical journals published in 1997. Advertisements were selected for further review if they had at least one bibliographic reference. Promotional statements in the selected advertisements were categorized as claims of efficacy, safety, convenience, and cost. For each referenced clinical trial, the study type, funding source, and endpoints were recorded.

**Main outcome measures.** 2 pairs of investigators rated each advertisement for accuracy based on a review of the bibliographic reference cited in the advertisement. Disagreements were settled by a third pair of reviewers, which consisted of one person from each of the previous groups.

**Main results.** 264 unique advertisements for antihypertensive and 23 unique advertisements for lipid-lowering medications were identified in the 6 journals. 1 out of 31 antihypertensive and 1 out of 7 lipid-lowering advertisements contained a promotional statement that referenced other literature, providing 125 referenced promotional claims in total. 23 out of 125 (18%) promotional statements were supported by monographic or unpublished data that could not be retrieved by the authors. 79 out of 125 (63%) references were from journals with a high impact factor, and 82% of the retrieved literature referred to randomized clinical trials. In 45 out of 125 (44.1% [95% confidence interval, 34.3–54.3]) promotional statements, the reference did not support the statement because the statement recommended the drug in a patient population not studied by the trial.

**Conclusion.** Promotional statements made in drug advertisements often reference high-quality clinical trials, but claims are frequently not supported by the trial findings.

### Commentary

The Federal Food, Drug, and Cosmetic Act requires promotional statements made in pharmaceutical advertising within the United States to be accurate and truthful [1]. This regulation is designed to protect consumers and physicians alike from misleading marketing practices. This article reports that many recent promotional statements for antihypertensive and lipid-lowering drugs are not supported by the referenced literature, primarily because the advertisers applied study results to a population of patients not included in the trial. If accepted at face value, these statements may lead to prescribing of medications of unproven benefit or even proven to have no benefit.

Compared with a previous review of pharmaceutical advertisements [2], the majority of advertisements referenced highly regarded clinical trials published in high-impact journals. Drug advertisements now cater to a sophisticated physician audience and such references lend credibility to the promotional claim. Omitting or misrepresenting the limitations of these trials, particularly the inclusion and exclusion criteria, makes for a subtle error that can only be detected on close examination of the original manuscript. Drug marketing does affect prescribing habits [3], and promotional information on new drugs is often more widely disseminated than the original data. Ideally, physicians would research promotional claims, but the reality is few have time to do so. Responsibility for advertisement accuracy rests primarily with the manufacturer, but it is time that both regulatory agencies and journals that publish these advertisements become more vigilant. A similar survey of English journals would clarify how extensive the problem has become; it is unlikely that English advertisements are free from these sorts of errors.

### Applications for Clinical Practice

Statements made in drug promotional literature may be inadequately supported by the evidence. Whenever possible, an independent drug reference should be consulted when making treatment decisions.

—Review by Josh F. Peterson, MD, MPH

### References

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2. Wilkes MS, Doblin BH, Shapiro MF. Pharmaceutical advertisements in leading medical journals: experts' assessments. *Ann Intern Med* 1992;116:912-9.
3. Caudill TS, Lurie N, Rich EC. The influence of pharmaceutical industry advertising on physician prescribing. *J Drug Issues* 1992;22:331-8.

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