

Evidence-Based Advertising? A Survey of Four Major Journals

David R. Gutknecht, MD

Background: Pharmaceutical advertisements are an important means of bringing drug information to physicians. Most advertisements are intended only to raise awareness, though there are those that do seek to persuade through presentation of research findings. Researchers have questioned the quality of the research reported in advertisements and wonder whether these advertisements would lead to improper prescribing.

Methods: A consecutive 6-month sample of advertisements in 4 general medical journals, 3 from the United States and 1 from Canada, were reviewed to determine how research results are presented in pharmaceutical advertisements.

Results: During this time there were 187 distinctive advertisements, with 43 data presentations in the 33 advertisements that contained quantitative research results. These results were examined using a critical appraisal worksheet. References to randomization and blinding were found in less than one half of the 43 data presentations. *P* values were frequently provided, but confidence intervals and references to power and number needed to treat were not provided in any of the advertisements.

Conclusions: Descriptions of research in pharmaceutical advertisements were brief and incomplete, and they inconsistently provided the basic design and statistical information needed to judge the results reported. More detail could make these advertisements more meaningful to critical readers. (J Am Board Fam Pract 2001;14:197–200.)

Pharmaceutical advertisements are an important means of bringing drug information to physicians.^{1,2} The quality of pharmaceutical advertising has been criticized, however, by a number of investigators. Wilkes et al³ studied 109 advertisements by sending them to reviewers who were asked to judge the advertisements according to criteria that required expert opinion and subjective conclusions. The reviewers believed that 92% of the advertisements were potentially noncompliant with standards set by the Food and Drug Administration. They also believed that 44% of the advertisements would lead to improper prescribing if physicians had no other information on which to act. One fourth of the advertisements in the survey by Wilkes et al incorporated statistics in the written text, and reviewers believed that these statistics were based on inadequate studies in 30% of cases.

The availability and quality of supporting scientific articles were assessed in several other studies.

Mindell and Kemp⁴ found in a survey of 10 consecutive issues of the *British Medical Journal* that only two fifths of advertisements cited published, peer-reviewed material, whereas Smart and Williams⁵ in a similar review found that only 22% of advertisements cited randomized controlled trials.

Although most advertisements are intended only to raise awareness, some, such as those described above, do seek to persuade through presentation of research findings.⁶ Readers of such advertisements who want to judge the soundness of this research for themselves have several options. They can review original peer-reviewed publications, review proprietary information from company files, read product monographs, or study the advertising copy itself to see how the research is described. For many busy physicians, this last approach might be the only one that time pressures will permit.

I reviewed the copy in pharmaceutical advertisements from four general journals to see how often quantitative research results were presented and whether those presentations included references to certain elements of study design and statistics necessary for readers to draw basic conclusions about the validity and applicability of the results reported.

Submitted, revised, 16 November 2000.

From the Department of General Internal Medicine (DRG), Geisinger Medical Center, Danville Pa. Address reprint requests to David R. Gutknecht, MD, Department of General Internal Medicine, Geisinger Medical Center, Danville, PA 17822.

Methods

Issues of four general-interest medical journals published in the first and third weeks of January through June 1999 were reviewed. These journals included *The Journal of the American Medical Association*, *The New England Journal of Medicine*, the *Annals of Internal Medicine*, and the *Canadian Medical Association Journal*. All distinctive pharmaceutical advertisements were selected. Those citing numerical data from controlled clinical trials, and presumably seeking to influence readers through provision of that evidence, were categorized as "evidence-based." Advertisements were then analyzed using a checklist modified from the "Worksheet for Using an Article About Therapy" available at the Evidence-Based Medicine Web site sponsored by the University of Alberta. This guide asks readers to look for randomization, blinding, statistical significance, and other evidence of sound research. To make the analysis as objective as possible, those questions in the original guide that required subjective responses were eliminated. The guide was also modified through the addition of a few questions particularly pertinent to pharmaceutical advertisements.

Some advertisements cited multiple aspects of a trial or quoted more than one trial. In those cases, each individual "evidence-based claim," or "data presentation," was analyzed. Only advertising copy was examined. References were not consulted, and accompanying monographs were not examined.

To validate my assessments, two independent observers, a professional statistician and an experienced clinician interested in evidence-based medicine, used this worksheet to analyze a subset of 10 advertisements. Overall, agreement was excellent, with the exception of the two questions that dealt with absolute and relative change. Accordingly, those questions were dropped from the analysis.

Results

The four journals reviewed contained 187 distinctive advertisements. Thirty-three were "evidence-based" and provided 43 data presentations for analysis (Table 1).

The findings on analysis of these 43 presentations are displayed in Table 2. Of these presentations, 37% and 47% documented randomization and blinding, respectively; few confirmed that all subjects were accounted for, and none made ex-

Table 1. Evidence-Based Advertisements in *The Journal of the American Medical Association*, *The New England Journal of Medicine*, the *Annals of Internal Medicine*, and the *Canadian Medical Association Journal*, January–June 1999.

| Findings | Number |
|---------------------------------|--------|
| Distinctive advertisements | 187 |
| "Evidence-based" advertisements | 33 |
| Individual data presentations | 43 |

plicit statements about comparability of groups or treatments. (For these measures, all advertisements provided either positive affirmation or left the reviewer to guess. None explicitly stated that these qualities did not characterize the studies cited.) *P* values were supplied in three fourths of the presentations, but an explicit statement of number needed to treat was found in none of the advertisements. Confidence intervals were also cited in none of the data presentations, and none made reference to the power of the study cited. Because the applicability of data to practice might depend on whether a head-to-head drug comparison was done, the nature of the comparison reported was accordingly reviewed. One half of the comparisons were of drug to drug and one half were of drug to placebo.

Table 2. Research Descriptions in Data Presentations in Pharmaceutical Advertisements Published in *The Journal of the American Medical Association*, *The New England Journal of Medicine*, the *Annals of Internal Medicine*, and the *Canadian Medical Association Journal*, January–June 1999.

| Indicator | Percent |
|--|---------|
| Random assignment specified | 37 |
| All accounted for, or intention to treat, specified | 7 |
| Blinding specified | 47 |
| Comparability of groups specified | 0 |
| Comparability of treatment, save intervention, specified | 0 |
| <i>P</i> value given | 77 |
| Confidence intervals given | 0 |
| Number needed to treat explicitly stated (if pertinent) | 0 |
| Power mentioned (if pertinent) | 0 |
| Drug-to-drug comparison made | 51 |

Discussion

Pharmaceutical advertisements are primarily promotional. Relatively few contain research results, and there is disagreement about whether those that do should be held to the standards of peer-reviewed publications. There is also debate about the degree of responsibility for advertising content that journal editors should bear. Critics in the United Kingdom have argued that advertising copy should be as rigorous as clinical publications,^{4,5} whereas others have insisted that pharmaceutical advertisements and scientific articles have fundamentally different purposes and that independent editorial review of advertisements is impractical.⁷

Advertisements, however, are not only promotional but also sometimes educational, as the pharmaceutical industry admits and even insists.¹ Why should research not be properly presented, especially as busy physicians might not have time to seek out original references and must rely on the advertisements themselves? Advertising copy cannot contain all the methodologic and statistical detail found in original reports, but it can, in very brief terms, confirm that the research cited meets basic criteria for validity, significance of results, and applicability to the reader's practice. As interest in evidence-based medicine grows, it is likely that an increasing number of journal readers will be skilled in critical appraisal. Advertisers who want to reach this segment of their readership will do well to consider and address their expectations.

The results of this survey suggest that those expectations are not currently being met. Pharmaceutical advertisements in the four general journals reviewed gave inconsistent attention to presenting basic descriptors of sound comparative trials. Explicit confirmation of randomization and blinding was only sometimes found, and references to confidence intervals, power, and the number needed to treat were not provided at all.

In a recent study of Canadian pharmaceutical advertising, Lexchin⁶ examined 130 advertisements in 5 journals and found that 22 reported quantitative changes in clinical outcomes. Thirteen of these advertisements touted relative risk reduction rates, whereas absolute reduction rates were left for readers to calculate by themselves. Lexchin believed that relative risk reductions were favored because physicians have been shown to respond more favorably to data presented that way.⁸ The current

study also sought to determine how often data were presented in terms of relative vs absolute change, but that inquiry was abandoned when a clear lack of observer agreement on these observations became evident. That no conclusions on the relative vs absolute issue could be drawn might be an indication of just how ambiguous advertising presentations can be. Although Lexchin's conclusions can be criticized for lack of validation, his findings, nonetheless, led him to question whether advertisers were in compliance with the provision of the Canadian Pharmaceutical Advertising Advisory Board that "statistics must be presented so as to accurately reflect their validity, reliability, and level of significance."

The current study sought to determine what a critical reader might encounter if he or she were to review drug advertisements with a users' guide in hand. By concentrating only on advertisements with quantitative data and by examining only advertising copy, and not supporting references, this study was more limited than that of Wilkes et al.³ It was also more objective than the study of Wilkes et al, yet broader in scope than the Lexchin investigation, which examined only a few key features of the advertisements reviewed.⁶ The current study involved only a consecutive sample of advertisements, and inferences about all advertisements, of course, cannot be made. The study was also limited by the number of advertisements, there being only so many distinctive advertisements published in general journals during the time of the study. Including advertisements from earlier journals was, however, neither practical nor likely to have changed the findings, because as Lexchin has pointed out, older advertisements are unlikely to contain references to newer concepts such as the number needed to treat.⁶

If claims in advertisements were supported by better descriptions of their supporting studies, would they necessarily be more reliable? Unfortunately, no. Advertisements seek to persuade, and the industry admits they might be biased.¹ Graphs and figures can be misleading, and claims of superiority might be inappropriately based on analyses of undeclared end points.⁹

Most pharmaceutical advertisements do not include data. Instead, they promote their products through slogans, admonitions, and colorful, attention-getting images. Some offer only imagery, with no description of a product at all. Almost 1 in 5

does seek to persuade through presentation of research results. Those data-driven advertisements could have even more impact if they would consistently document randomization, blinding, intention to treat, and the nature and comparability of groups and treatment; present both absolute and relative changes; offer some measure of data precision; and support claims of equivalence with appropriate statistics. Providing information in this way would not guarantee advertising credibility, but it would be a step in the right direction.

References

1. Levy R. The role and value of pharmaceutical marketing. *Arch Fam Med* 1994;3:327–32.
2. Wind Y. Pharmaceutical advertising. A business school perspective. *Arch Fam Med* 1994;3:321–3.
3. Wilkes MS, Doblin BH, Shapiro MF. Pharmaceutical advertisements in leading medical journals: experts' assessments. *Ann Intern Med* 1992;116:912–9.
4. Mindell J, Kemp T. Evidence-based advertising? Only two fifths of advertisements cited published, peer reviewed references. *BMJ* 1997;315:1622.
5. Smart S, Williams C. Evidence-based advertising? Half of drug advertisements in *BMJ* over six months cited no supporting evidence. *BMJ* 1997;315:1622–3.
6. Lexchin J. How patient outcomes are reported in drug advertisements. *Can Fam Physician* 1999;45:1213–6.
7. Fletcher RH, Fletcher SW. Pharmaceutical advertisements in medical journals. *Ann Intern Med* 1992;116:951–2.
8. Bobbio M, Demichelis B, Giustetto G. Completeness of reporting trial results: effect on physicians' willingness to prescribe. *Lancet* 1994;343:1209–11.
9. Kessler DA. Addressing the problem of misleading advertising. *Ann Intern Med* 1992;116:950–1.