Objective: To evaluate the accuracy and scientific evidence supporting product claims made in print advertisements within otolaryngology journals.

Design: Cross-sectional survey with literature review and multiple-reviewer evaluation. Fifty claims made within 23 unique advertisements found in prominent otolaryngology journals were selected. References to support the claims were provided within the advertisements or obtained through direct request to the manufacturer. Five academic otolaryngologists with distinct training and geographic practice locations reviewed the claims and supporting evidence. Each physician had substantial experience as an editorial reviewer, and several had specific training in research methodology and scientific methods.

Results: Of the 50 claims, only 14 were determined to be based on strong evidence (28%). With regard to the supporting references, 32 references were published sources (76%), while 3 references were package inserts and/or prescribing information (7%). Interobserver agreement among the reviewers overall was poor; however, when 3 or more of the reviewers were in agreement, only 10% of the claims were deemed correct (n=5). Reviewers also noted that only 6% of the claims were considered well supported (n=3).

Conclusion: Advertisers make claims that appear in respectable journals, but greater than half of the claims reviewed were not supported by the provided reference materials.


PHARMACEUTICAL PRODUCT and medical device advertisements are ubiquitously found in medical journals across medical specialties and subspecialties. Manufacturers purchase these advertisements to build product awareness and increase market share among a targeted community of physicians likely to use their product and/or equipment. Journals benefit from advertising revenues as a means to offset the high costs of publication.

Advertisers print claims about product function and efficacy in an attempt to persuade clinicians to prescribe and use their products. To support these claims, advertisers regularly cite references to data within print advertisements, including randomized controlled trials, data on file, presentations, and expert opinions. Many authors have raised the possibility that some promotional material and advertisements may be misleading.1,8

This issue is not a new one: a committee on pharmaceutical advertising convened by the New York Academy of Medicine in 1962 raised questions of pharmaceutical advertising.9 It has been demonstrated that physicians commonly use information obtained in journal advertisements as a source for drug and device education, which directly affects prescribing habits.3,10 Since up to 80% of medical expenditures can be affected by physician prescribing behavior,11 manufacturers of drugs and medical devices have strong economic motivation to influence physicians through advertisements.

Interestingly, no claim validation is required prior to initial publication; the process of validation begins at the same time an advertiser publishes the claim.12 Only then are claims and supporting materials submitted to the US Food and Drug Administration (FDA) Division of Drug Marketing, Advertising, and Communicating.
tions. This group is charged with overseeing and approving all materials dispersed by pharmaceutical and device manufacturers. Unfortunately, there is no authority to require companies to submit materials prior to publication, and so unverified information is allowed to circulate to the public while the validation process occurs. Furthermore, according to a 2006 inquiry by the US Government Accountability Office, regulatory letters that were dispersed by the agency were essentially ineffective in preventing misleading information from being published.13

Approximately 70 000 publications advertising drugs and medical devices in all specialties were submitted to the FDA for review in 2007, which was up from 40 000 in 2003.14 This dramatically increased number raises questions whether the FDA can keep pace and thus whether the published claims are valid.14,18,15,16 Because so many clinicians rely on information gleaned from advertisements as a type of continuing medical education, and in fact use it to stay abreast of new innovations and therapies,17-20 the information being presented to them must be accurate, reliable, and valid.

To our knowledge, a formal review of the reliability of advertisement information dispersed to otolaryngologists has not been reported in the literature. The paucity of scientific review in this area is unfortunate, given the ubiquity of some otolaryngologic procedures, such as the insertion of tympanostomy tubes and tonsillectomy, which are frequent targets of otolaryngologic advertising.21

### METHODS

Claims used in this study were selected from advertisements appearing between January 2007 and July 2008 in Annals of Otology Rhinology and Laryngology, Archives of Otolarangology—Head and Neck Surgery, Laryngoscope, and Otolaryngology—Head and Neck Surgery. All drug and medical device advertisements from these journals with 1 or more claims were extracted. A claim was defined as any assertion about product performance that impacted patient care or physician practice. If a specific advertisement appeared more than once among the journals, the duplicate advertisements were not included. If a drug or product had 2 distinct advertisements with separate claims, then both were separately included in the study.

References for the selected claims were noted and compiled. References were defined as materials cited in support of the information or claim in the advertisement. Cited references were categorized as journal articles, data on file (eg, unpublished company documents), meeting abstracts or presentations, and prescribing information (eg, package inserts or Physicians’ Desk Reference entry). For references not identifiable through a literature search using PubMed, 3 attempts were made to contact manufacturers via telephone and/or e-mail to request the supporting data for the advertised claims.

Five board-certified otolaryngologists served as reviewers of the database consisting of the selected advertisements, cited references, and study data sheets. One reviewer was a subspecialty trained otologist/neurotologist; 1 was fellowship trained in head and neck oncology; 1 was fellowship trained in rhinology; and 2 were general otolaryngologists with extensive experience and training. The reviewers were asked to classify claims and rank the level of evidence and appropriateness of cited references. Claims and references were classified into 4 categories according to a modified version of the system created by Loke et al:1: (1) unambiguous clinical outcome, (2) vague clinical outcome, (3) emotive or immeasurable outcome, and (4) nonclinical outcome. Reference evidence level was ranked, and an appropriateness score was determined (Figure). Evidence level was defined as 1 of the following: (1) unverified; (2) irrelevant reference (readily available but did not support the claim); (3) Nonscientific reference (supported the claim but was not a meta-analysis or randomized control trial [RCT]); (4) limited research-based evidence (included at least 1 supportive and adequate scientific study); and (5) moderate–strong reference (included at least 1 supportive, relevant, high-quality RCT or multiple supportive, adequate or high-quality studies). Finally, reviewers rated the validity of the claim based on the available material and the confidence that they would use the statement in their practice (Figure).

Weighted $k$ coefficients were calculated for each pair of raters answering each question using Fleiss-Cohen weights thus producing coefficients equivalent to intraclass correlation coefficients. The equivalences across all rater pairs were tested, and the overall weighted $k$ was calculated for each question. When low $k$ scores were obtained, gradings of responses were assessed by a consensus of 3 or more reviewers on a specific score.

### RESULTS

Within the 76 journal issues sampled, 370 advertisements were identified. These included a total of 887 claims, of which 367 were referenced (41%). Of the 370 advertisements identified, a total of 77 unique advertisements were included for sampling, which yielded 154 unique claims and 58 associated references for our general pool. Of note, among the 77 advertisements, 50 contained claims, while 27 advertisements served as product placement or awareness advertisements. A range of 1 to 10 claims per advertisement was noted, with an average of 3 claims per advertisement.

Within the 77 unique advertisements, 50 claims were randomly sampled. With regard to subspecialty representation of these claims, head and neck oncology (32%,
n = 16), pediatrics (30% n = 15), and rhinology (28% n = 14) were heavily represented vs otology (10% n = 5) and facial plastic surgery (n = 0). Most of the advertisements sampled dealt with surgical device promotion (58% n = 29) rather than drug promotion (42% n = 21). Within the pool of selected advertisements, 42 unique literature references were cited, of which 76% were to published scientific articles (n = 32), 7% to package inserts (n = 3), 7% to data on file (n = 3), 5% to presentations (n = 2), and 5% to nonscientific articles (n = 2).

Interobserver agreement among reviewers was slight to poor (Table 1). The overall weighted $\kappa$ is reported for question 4 because no difference existed between weighted $\kappa$ coefficients across rater pairs. However, pairs differed significantly for questions 3 and 5 ($P = .002$ and $P < .001$, respectively), and so overall weighted $\kappa$ values are not reported. The consensus scores of more than 3 reviewers on an assessment varied by question, with an overall range of 48% (question 3) to 84% (questions 1 and 5).

With regard to the classification of advertisement claims, 56% were found to be unambiguous clinical outcomes (n = 28), while 18% were deemed to be vague outcomes (n = 9). Consensus was unable to be reached for 16% of the claims reviewed (n = 8).

Supporting claims contained some level of research-based evidence in 48% of the advertisements (n = 24), while 18% were nonscientific, irrelevant, or unreferenced claims (n = 9). Reviewers were unable to reach consensus when grading the level of evidence in 34% of the claims (n = 17).

References supported associated claims in 34% of the advertisements reviewed (n = 17), while 12% of the claims actually had references that contradicted part or all of the statement (n = 6). Consensus could not be reached for 52% of the claims reviewed (n = 26).

With respect to the questions regarding accuracy and validity, it was found that 10% of the claims were deemed correct (n = 5), while 50% were could not be assessed (n = 25). When asked if the accompanying references provided enough support for the claim to be used in daily practice, our panel determined that just 6% of the claims were well supported (n = 3), whereas 58% of the claims were unsupported by the reference materials provided (n = 29).

**COMMENT**

Our findings within the otolaryngology literature are similar to those found in studies of advertiser claims within other medical and surgical specialties. Assurances of data and claim validity by the pharmaceutical industry to professionals and government agencies help to alleviate some of the pressures placed on these firms. In response to previous work raising questions and doubts about advertising, industry officials formed the International Federation of Pharmaceutical Manufacturers and Associations as an attempt to standardize internal and self-review. Membership in the organization requires that manufacturers provide “accurate . . . substantiated . . . and ethical” advertisements. Unfortunately, the discordance between reviewers in this study as well as in other well-documented studies illustrates that much work still needs to be done to ensure that valid information is distributed.

According to the Pharmaceutical Research and Manufacturers of America annual industry review, industry trends show that spending on promotions targeting physicians increased from $3.9 billion to $7.2 billion, or about 9% annually from 1997 to 2005. Furthermore, a recent study based on publicly available data illustrates that the pharmaceutical industry spends almost twice as much on promotion as it does on research and development. Despite this staggering growth in advertising to physicians by pharmaceutical companies, the FDA resources have not increased in proportion to the demands. In the latest budget appropriated by the Office of Management and Budget, the FDA received a 6.7% increase in spending, but the agency’s recent problems have called into question the effectiveness of these allocated resources.

Given the multitude of concerns that exist about the FDA’s inadequate funding and the pharmaceutical companies’ advertising inaccuracy, others have begun scrutinizing the drug and medical device industry. For example, investigators have shown that 44% to 50% of the statements made in sampled advertisements are poorly supported by the scientific evidence provided. In the present study, while 68% of the sampled claims were noted to be supported by moderate to strong research evidence (n = 34), we showed that 58% of the claims sampled were not supported by the provided reference materials (n = 29). In a study by Lankinen et al, not a single claim was found to be supported by strong scientific evidence. These data call into question the physician practice of accepting advertiser claims and allowing them to influence patient care without investigating the level of the supporting evidence.

A few sampled claims are listed in Table 2. As illustrated by these representative examples, most claims were considered unsupported by our review group. Although we experienced relatively low interobserver agreement among the 5 reviewers, consensus of 3 or more was noted for 84% of the claims (n = 42). It is important to
the claims were deemed “unambiguous clinical” out-
classification scale. Compared with our study in which 50% of
pharmaceutical advertisements using a similar classifi-
formed a review of all studies examining the quality of
means is representative of all otolaryngologic advertise-
the advertiser.
the observers will not have the knowledge assumed by
the observer might compromise the eventual data, in that
observer believes something to be true, he or she might
viewer opinion regarding the validity of the claim. If an
duced interobserver consistency might be due to re-
riences of our reviewers might account for this, but given
ability in reviewer responses. The varied research expe-

One limitation we experienced, as has been noted by other
spite multiple attempts at contact.
easily acquired. Similarly, we experienced a low rate of
meeting abstracts, presentations, data on file) were not
available 1% of the time, the references for supporting
articles were easily retrieved, other referenced sources (eg,
ticles were easily retrieved, other referenced sources (eg,
In addition, although references to journal ar-
and to provide clear supporting data that can be easily
The need for manufacturers to make only valid claims
implications that can ultimately jeopardize patient care.
accept statements as fact without substantiating the va-
will always be controversy and differences of opinion with
regard to optimal patient treatment, there should not be
disagreement on an objective evaluation of whether a given
reference supports a claim.
In the present study, reviewers had full access to the
available associated reference materials for each se-
lected claim. Unfortunately, owing to time constraints
in the real world of medical practice, readers often blindly
accept statements as fact without substantiating the va-
ability and accuracy of the supporting data. This has strong
implications that can ultimately jeopardize patient care.
The need for manufacturers to make only valid claims
and to provide clear supporting data that can be easily
interpreted by physicians regardless of research experi-
ence is illustrated by these results.
Our study showed that over half of the claims made
in print advertisements within the selected sample were
not sufficiently supported by the provided reference ma-
terials. In addition, disagreement encountered by review-
ers evaluating the same pieces of supporting data calls
into question the clarity of the supporting documents.
With the increasing number of advertisement claims being
submitted to regulatory agencies and the dwindling funds
appropriated to review these materials, it is imperative
that journal editors take a critical look at this important
adjunct in patient care.

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Author Contributions: All authors had full access to all
ment, but it allows for discussion to be generated, and
it highlights some of the inadequacies in the current state
of advertising. A more comprehensive analysis using dif-
ferent sampling methods, additional journals, and addi-
tional years may have yielded different trends.
Third, although we used a rating scale adapted from
a previous study, our low interobserver rating was trou-
bling.11 The low level of agreement further supports the
need for clear and transparent advertising to be pre-
sented. When well-trained and experienced otolaryn-
gologists cannot agree that the presented data support
the advertised claim, we believe that the claims them-

Second, the analysis was limited to 4 journals and ex-
amed only a year and a half of publishing. This by no
means is representative of all otolaryngologic advertise-

understand that a reviewer’s assessment of “not sup-
ported by the evidence” is not intended to judge the va-

With regard to classifying claims, Othman et al25 per-
formed a review of all studies examining the quality of
pharmaceutical advertisements using a similar classifi-

Claim Type  Claim Source Rating
Unambiguous  “_________ is proven to relieve a wide range of seasonal allergy rhinitis symptoms . . . with no impairment or sedation.” Published Supported
Vague “_________ Turbinoplasty technique reduces the risk of complications, such as pain, crusting and osteitis.” Presented at meeting Unsupported
Emotive “_________ Ear Cleansing System generated strong results among chronic ear wax build ups sufferers.” Survey Unsupported
Nonclinical “as compared with electrosurgery or lasers, the ________ allows safer dissection near vital structures.” Data on File Unsupported

Table 2. Examples of Evaluated Claims
the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis. **Study concept and design:** Del Signore and Spiegel. **Acquisition of data:** Del Signore, Murr, Lustig, Platt, Jalisi, and Spiegel. **Analysis and interpretation of data:** Del Signore, Lustig, and Spiegel. **Critical revision of the manuscript for important intellectual content:** Platt, Jalisi, Pratt, and Spiegel. Obtained funding: Spiegel. Administrative, technical, and material support: Del Signore, Platt, Pratt, and Spiegel. **Study supervision:** Jalisi and Spiegel. **Financial Disclosure:** None reported. **Previous Presentation:** This work was presented as a poster at the Combined Otolaryngology Spring Meeting, May 28-31, 2009; Scottsdale, Arizona.

## REFERENCES