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# Pharmaceutical advertisements' accuracy in medical journals

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**Background** The pharmaceutical business uses bibliographical references to clinical trials that support their medications in their marketing because to the impact of the rapidly expanding evidence-based medicine movement on physicians' prescribing practices. Our goal was to determine whether the promises made in ads regarding the cost, convenience, safety, and effectiveness of antihypertensive and lipid-lowering medications were supported.

**Methods** All advertising for lipid-lowering and antihypertensive medications with at least one bibliographical reference that were published in six Spanish medical journals in 1997 were evaluated. In order to determine whether the studies cited to support the advertising messages supported the relevant claims, two pairs of investigators independently examined the ads.

**Findings** We found 23 distinct ads for lipid-lowering medications and 264 different ads for antihypertensive medications. A total of 125 promotional claims with references were obtained by recording at least one reference in 31 advertising in the antihypertensive group and at least one reference in every seven advertisements in the lipid-lowering group. Of the 125 references, 79 (63%) came from journals with a high impact factor, 84 (82%) came from randomized clinical trials, and 23 (18%) references from monographic works and unpublished data on file could not be obtained. The reference did not support the promotional statement in 45 claims (44.1%; 95% CI 34.3–54.3), most often because the slogan suggested the medicine in a patient group that was not evaluated in the study.

**Interpretation** Even though these statements are supported by bibliographical references to randomized clinical studies published in respectable medical publications and appear to be evidence-based, doctors should exercise caution when evaluating advertising that make claims about a drug's increased efficacy, safety, or convenience.

## Introduction

For almost a century, there has been debate concerning the veracity and utility of medication advertisements in medical journals.<sup>1</sup> Discussions have centered on the commercials' worth, their educational value and moral implications, and any possible conflicts of interest resulting from the money they bring in.<sup>2,3</sup> Advertisers have come under fire for making false or deceptive claims; omitting negative effects and other information that is crucial for prescribing; extending the indications or making exaggerated claims; applying one standard for developed nations and another

for developing nations; reinforcing prejudices based on gender, ethnicity, or occupation; and unethical implications. The use of bibliographical references to support advertising messages has also come under fire for citing extremely low-quality evidence (4–9), including references from unpublished or in-press material (8,9), published in journal supplements (often with promotional attributes and not always peer-reviewed), or taken from conference abstracts (sometimes with unapproved indications).

The pharmaceutical business is using bibliographical references in drug marketing more often than before, in line with the increasing acceptance of evidence-based medicine. The highest level of scientific evidence is found in randomized clinical trials or systemic reviews of the top trials. Therefore, quotes that are used to scientifically support the efficacy, safety, or other favorable qualities of the treatment being advertised typically come from these trials. In order for manufacturers to thrive in a setting where there is fierce competition among medications in the same therapeutic group, references to randomized clinical studies are particularly common in the advertising of antihypertensive and lipid-lowering medications.<sup>12, 13</sup> The pharmaceutical industry has started a number of multicenter randomized clinical trials with big patient populations and substantial financial resources to examine the use of statins, angiotensin inhibitors, and calcium-channel blockers. In fact, using clinical trials is now a key marketing tactic due to shifts in publishing habits. Randomized clinical trials are frequently used to produce data that can be published regarding a potential or actual benefit of a medication. over its competitors.<sup>13</sup> The data can then be used to improve the product's position in the market. Thus, we aimed to assess whether bibliographical references in advertisements supported the promotional claims being made.

### Material and methods

In order to determine whether the bibliographical references provided in ads for antihypertensive and lipid-lowering medications in six Spanish medical publications in 1997 validated the claims stated in the commercials. We chose medical magazines that are widely read by cardiologists and general practitioners, who are the target audiences for the advertising of antihypertensive and lipid-lowering medications. These journals, which featured both peer-reviewed and non-peer-reviewed publications, catered to a variety of target audiences, as evidenced by the subjects of the published original papers or reviews. They comprised a variety of publications with varying rankings, some of which were obtained by subscription and others of which were free. The Spanish Societies of Family Physicians and Cardiologists published two periodicals as official publications.

Following a previously established protocol, and after a pilot trial of the review procedure with advertisements that were not included in the study, two pairs of reviewers (PV and IP, and JL and SP) independently reviewed the articles referenced in the advertisements to see whether they supported the publicity claim. When the reviewers disagreed, the articles were reviewed again by a third pair of reviewers with one person from each of the previous groups (PV and SP). The reviewers judged that a claim was supported by the reference when the publicity slogan could be supported by the study, even in instances where the study itself was of very poor quality, and when only quotes from the introduction or discussion were cited. The reviewers judged that an advertising claim was not supported by the reference if a false statement was made in a claim that clearly could not have been derived from the study referenced; the advertising claim had no relation with the study referenced; the patients of the study differed greatly from the target patients in the advertisement, including cases in which effects seen only in animals or in vitro were transferred to human beings, explicit reference was made to an indication in patients who were excluded from the study; the study did not include an analysis of a particular subgroup; or the advertising claim exaggerated the efficacy of the product.

We also compiled information about the financial source of the studies (the pharmaceutical industry, government, non-profit organisations, mixed financing, not stated); the design (randomised or other); the journal (included in the first 20 positions on the basis of their impact

factor in the 1996 science citation index for general, internal, or cardiovascular medicine, and others); and the outcome of the study referenced, including clinical endpoints (eg, mortality, infarcts, re-admissions, etc), surrogate endpoints (decrease in arterial pressure or lipid concentrations), and pathophysiological endpoints (regression of atheroma plaques, changes in arterial diameter, etc). The advertising messages were classified as either claims of efficacy (with improved outcomes), safety (reduction in adverse effects), convenience (ease of administration, improved dose, etc), or cost (low price, better cost-effectiveness ratio).

First we described the references cited, indicating the journal that had published the article, the design of the study, its source of funding, etc. Then we described the characteristics of the promotional claims and calculated the proportion of promotional claims that were not supported by the corresponding reference. A further analysis was made to detect any association between the type of drug analysed, the journal publishing the advertisement, or the type of promotional slogan. Finally, where the reviewers thought a claim was not supported by the bibliographical reference, the reasons were described. To test statistical significance, we used 95% CIs of proportions estimated by the binomial exact method. All the analyses were made using the STATA statistical package, version 6.0.

### Role of the funding source

The sponsor of the study had no role in study design, data collection, data analysis, data interpretation, or in the writing of the report.

### Results

In 1997, the six journals published a total of 13 601 pages in 134 issues and 11 supplements. Table 1 shows the journals' characteristics. Advertisements covered a total of 3861 pages (28.4% of the journals; range 8.1–39.5); 20.4% of the pages were for 264 different antihypertensive advertisements, and 4.4% for 23 different lipid-lowering advertisements. We identified 264 different advertisements for antihypertensives, 31 with references, containing a total of 73 promotional claims with bibliographical references; and 23 different advertisements for lipid-lowering drugs, seven with references, containing 52 promotional claims with bibliographical references (figure 1). In 95 advertisements (76.0%), the reference supported a claim of efficacy, in 24 (19.2%) safety, in five (4.0%) convenience, and in one (0.8%) cost. Of the references identified, we could not retrieve 23 (18.4%) because they corresponded to monographic studies, non-indexed journals, or non-published data on file. Of those retrieved, 79 (63.2%) references had been published in journals of general, internal, or cardiovascular medicine that were

	<i>Atencion Primaria</i>	<i>Fomacion Medica Continuada</i>	<i>Jano</i>	<i>Medicina Clinica</i>	<i>Hipertension</i>	<i>Revista Española de Cardiología</i>
Journal name						
Abbreviated title	<i>At Primaria</i>	<i>Form Med Cont</i>	<i>Jano</i>	<i>Med Clin (Barc)</i>	<i>Hipertension</i>	<i>Rev Esp Cardiol</i>
Target audience	GPs	GPs	All	General and internal medicine	GPs and cardiologists	Cardiologists
Peer reviewed	Yes	No	No	Yes	No	Yes
Included in Medline	Yes	No	No	Yes	No	Yes
Included in science citation index	No	No	No	Yes	No	No
Subscription	Payment or membership benefit	Payment	Free	Payment	Free	Payment or membership benefit
Issues per year	19+2S	10	44+1S	40+1S	9+1S	12+6S
Circulation (copies by issue)	10 457	11 311	39 535	7589	19 885	3681
Pages per year	2767	1032	4860	2146	834	1962
Pages with drug advertisements/year*	853 (30.8%)	222 (21.5%)	1920 (39.5%)	264 (8.1%)	224 (26.8%)	378 (19.3%)
Pages with AHT advertisements†	170 (19.9%)	37 (19.6%)	164 (8.5%)	39 (14.7%)	211 (94.2%)	165 (43.6%)
Pages with LLD advertisements‡	49 (5.7%)	17 (7.6%)	43 (2.2%)	12 (4.5%)	7 (3.1%)	40 (10.6%)
Pages with AHT advertisements and references‡	46 (27.0%)	11 (29.7%)	30 (18.3%)	14 (35.9%)	95 (45.0%)	68 (18.0%)
Pages with LLD advertisements and references‡	12 (24.5%)	3 (17.6%)	2 (4.6%)	0	1 (14.3%)	5 (12.5%)

AHT=antihypertensive drugs. LLD=lipid-lowering drugs. S=supplements. \*Number of pages (proportion of these pages in journal). †Proportion of

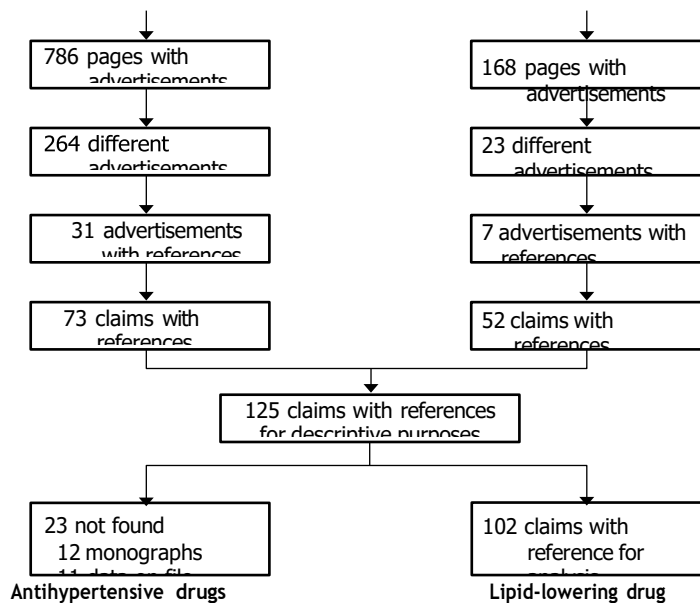


Figure 1: Number of pages of advertisements and claims with references in the study

ranked in the first 20 positions of the science citation index on the basis of their impact factor; the remaining 23 references were from other journals (only one was a Spanish-language journal). In total, 19 (15.2%) references cited abstracts or papers published in journal supplements. The journals most frequently referenced were *Circulation* (22 references, 17.6%), *The New England Journal of Medicine* (18 references, 14.4%), and *The Lancet* (11 references, 8.8%). Of the 102 references that were retrieved and reviewed, 84 (82.3%) were from randomised clinical trials and 18 (17.7%) from studies based on other designs, including reviews and non- original research. 41 studies (40.2%) had been financed by the pharmaceutical industry and another 22 (21.6%) cited the pharmaceutical industry as a cofinancier; eight (7.8%) corresponded to studies financed by government or non-profit organisations; the remaining 31 (30.4%) did not state their source of funding. The outcomes included in our analysis were clinical endpoints in 44 papers (43.1%), surrogate endpoints in 38 (37.2%), and physiopathological endpoints in 20 (19.6%).

Table 2 shows examples of the classifications for judging that advertising claims were not supported by the reference. The bibliographical reference did not support the promotional statement in 45 (44.1%; 95% CI 34.3–54.3) of the 102 promotional claims analysed (table 3). Such an association was seen more frequently in advertisements for antihypertensive drugs (68.6%) than in advertisements for lipid-lowering products (19.6%). The accuracy of the claims was not associated with the journal in which the advertisement was published, or with the types of promotional messages. Most claims that were not supported by the reference (20, 44.4% of non-supported claims) recommended the drug in a patient group other than that studied in the trial. In another 15 claims, the advertisement transferred results from studies in high-risk groups to the general patient population; four claims focused on specific populations (eg, elderly people or patients with diabetes) that had been either excluded or not analysed in the study referenced; one claim transferred results that had been obtained in vitro or in

Type	Claim (literal translation)	Reference (literal)	Reasons for non-support
False	"The only AII antagonist with data	Pitt B, et al. <i>Lancet</i> 1997;	The study used various endpoints, of which overall mortality was a

statement	for reduction of mortality"	349: 747–52.	secondary endpoint, to compare losartan with captopril. The study did not show any differences in any of the primary endpoints; the reduction in mortality in the losartan group was not significant ( $p=0.07$ ); the comparison group was given captopril and not placebo.
Absence of relation	"Low incidence of side-effects" effects.	Lee CR, Bryson HM. <i>Drugs</i> 1994; 48: 274–96.	The study quoted reviewed the pharmacodynamic and pharmacochemical properties of lacidipin and not the adverse
Generalisation from groups of patients to overall population	"Raises survival rate of heart failure"	SOLVD investigators. <i>N Engl J Med</i> 1991; 325: 293–302.	The trial included patients with symptomatic heart failure and low ejection fractions. In fact, another randomised clinical trial by the same group in asymptomatic patients showed no significant differences in survival.
Explicit indication for specific groups of patients	"From now on, many elderly patients will have peace of mind and lead safer lives. Because [RM] is the only ACEI with a diuretic adapted to the renal conditions of the elderly patient with hypertension"	Fernandez M, et al. <i>Hypertension</i> 1994; 23 (suppl): I207–10.	The treatment group consisted of 17 patients, 11 of whom were younger than 58 years, and six of whom were between 58 and 69 years of age. The investigators did not assess renal function (although it did exclude "kidney failure"), or safety in elderly patients.
Transfer of results to humans	"The blockage exerted by valsartan on the AT1 receptor antagonises the effects of angiotensin II, resulting in a selective anti-hypertensive effect, preventing the appearance of side-effects like coughing."	Criscione L. <i>Br J Pharmacol</i> 1993; 110: 761–71.	This review included only in-vitro and animal assessments. Prevention of coughing is a supposition based on an action mechanism that has not been shown in human beings.
Exaggeration of efficacy	"You will need to treat fewer patients to save a life: SAVE (captopril) 24, AIRE (Ramipril) 18, TRACE (Trandolapril) 13."	Kober L, et al. <i>N Engl J Med</i> 1995; 333: 1670–76. Pfeffer, et al. <i>N Engl J Med</i> 1992; 327: 669–77. The AIRE investigators. <i>Lancet</i> 1993; 342: 821–28.	The populations in these studies are not comparable. In their discussion, the authors of the TRACE study highlighted the differences in designs and populations when comparing with the SAVE and AIRE studies, and pointed out that they were not comparable.

RM=registered mark. SAVE, AIRE, TRACE, and SOLVD are acronyms of clinical trials. AII (angiotensin II antagonists) and ACEI (angiotensin-converting enzyme inhibitors) are acronyms of antihypertensive therapeutic drug groups.

Table 2: Examples of non-supporting claims

	Total	Number of claims not supported	95% CI
<b>Drugs</b>			
Antihypertensive	51	35 (69%)	54·1–80·9
Lipid-lowering	51	10 (20%)	9·8–33·1
<b>Journal*</b>			
<i>At Primaria</i>	61	29 (48%)	34·6–60·7
<i>Form Med Cont</i>	18	11 (61%)	35·7–82·7
<i>Jano</i>	34	17 (50%)	32·4–67·6
<i>Med Clin (Barc)</i>	19	12 (63%)	38·6–83·7
<i>Hipertension</i>	38	25 (66%)	48·6–80·4
<i>Rev Esp Cardiol</i>	25	15 (60%)	38·7–78·9
<b>Promotional slogan</b>			
Efficacy	84	36 (43%)	32·1–54·1
Safety	15	6 (40%)	16·3–67·7
Convenience	3	3 (100%)	29·2–100·0
Total	102	45 (44%)	34·3–54·3

\*The totals add up to more than 102 because some claims appeared in more than one journal.

Table 3: Characteristics of non-supported claims

animals to human beings. In ten advertisements (21·3% of non-supported claims), the publicity exaggerated the results reported; in nine (19·1%), false statements were made, corresponding mostly to claims of risk reduction that had not been significant in the research referenced. Finally, in six advertisements (12·8%), the work referenced had no relation to the promotional claim.

### Discussion

The pharmaceutical industry in general, and large international companies in particular, have kept abreast of developments in the evidence-based medicine movement, and have tried to incorporate the movement's tenets into their promotional strategies. In Spain, one pharmaceutical company registered the expression "medicina basada en la evidencia" (the Spanish translation of evidence-based medicine) as a promotional trademark. Although the relation between the pharmaceutical industry and evidence-based medicine is complex, some factors have suggested that the relation between the two is two-way. On the one hand, because of legal requirements that must be met before a drug can be placed on the market, most products are tested in randomised clinical trials to show their efficacy, at least in terms of surrogate endpoints. Data generated in these trials can then be used for promotional purposes. On the other hand, only large pharmaceutical companies have the resources to finance the large trials necessary to measure results that are otherwise difficult to detect (ie, a reduction in death through primary prevention with lipid-lowering drugs). Since physicians have access to evidence of efficacy only after a company has financed a trial, the companies that can do so have a competitive advantage over those that cannot. As the effect that randomised clinical trials have on prescribing behaviour grows, the greater the advantage for the pharmaceutical company in possession of the data. Thus, the original intention of the evidence-based medicine movement—to use the knowledge obtained from randomised clinical trials to improve therapeutic decisions—is becoming a promotional strategy used by the pharmaceutical industry. This strategy is also used in the prescription marketplace, in which several so-called me-too drugs (similar to others already on the market) compete for the same patient population, and pharmaceutical companies need to develop aggressive campaigns to change prescribers' habits, and to distinguish between almost identical products (eg, angiotensin inhibitors and statins).<sup>13</sup> Under these circumstances, clinical research becomes part of a race to obtain results to support the market position of a drug,<sup>14</sup> and publishing the results of a randomised clinical trial also provides a reference from a prestigious medical journal for reinforcement of sales. Occasionally the journal's image is used to reinforce the credibility of the product (figure 2)—a practice the owners of the brand image should monitor very closely.

Although inclusion of bibliographical references in advertisements does not seem to be generalised in Spanish medical journals (only 33·6% of the antihypertensive drug and 13·7%

of lipid-lowering drug advertisements included citations), our findings suggest that companies finance randomised clinical trials and report their results as part of their marketing strategies.

We have seen an increase in the number of randomised clinical trials and in the number of high quality journals referenced, compared with earlier studies.<sup>4–7</sup> We have also shown that this practice is especially prevalent in specific types of drugs, such as lipid-lowering products, where the seven advertisements with references, all of them for statins, contained almost as many references as the 31 advertisements for antihypertensive drugs. These findings for varying use of data generated from randomised clinical trials depending on the type of drug being promoted corroborate those of earlier studies that showed infrequent use of bibliographical references to promote diuretic drugs or  $\beta$  blockers.<sup>12</sup> However, our results, by contrast with those of other studies, suggest that most of the references accompanying advertisements were from randomised clinical trials published in journals with a high impact factor. Furthermore, the quality of the data and of the publishing journal does not seem to

Figure 2: Drug advertisements that use the image of *The New England Journal of Medicine* and *The Lancet*

lead to greater truthfulness in advertising, suggesting that use of



these references simply forms part of an advertising strategy used to reinforce the credibility of the drug by associating it with the prestige of a randomised clinical trial or a journal.<sup>7–9</sup> Such reinforcement of a drug's prestige probably explains why so few references are taken from Spanish journals, which are considered much less prestigious than English-language ones. Furthermore, when the bibliographical reference did not support the advertising claim, the most common reasons were very misleading: results from studies done in patients with specific characteristics (postinfarct, severe ventricular failure, etc) had been automatically transferred to the population at large; alternatively, results were applied to specific categories of patients (diabetic patients, elderly people, women, patients with specific comorbidities) when these patients had in fact been excluded from the study (even when analysis of these subgroups had shown results that were not significantly different from the controls). Assessment of the truthfulness of the promotional claims is complex and beyond the aim of this study: every one must be considered as a research question, and the randomised clinical trials themselves would have to be systematically reviewed to see whether the question is in fact answered. Thus, in our review, some of the claims could be correct, although they are not supported by the

accompanying bibliographical reference, whereas others could be incorrect, yet supported by papers of poor methodological quality or references to parts of the papers that did not allow us to draw a conclusion as to their truthfulness.

Our study was limited by the fact that our results cannot be generalised to other types of drugs, journals, medical specialisations, or countries. The results for drugs whose use has already been established, or for drugs in less competitive segments of the market would differ from those of antihypertensives or lipid-lowering drugs. Rennie<sup>2</sup> states that advertisements are published in two types of journals: peer-reviewed journals, usually owned by societies, obtained by subscription or as a membership benefit, and containing more text than advertisements; and throwaway journals, which physicians receive free of charge, are not peer-reviewed, tend to publish reviews rather than original research, and have a higher proportion of advertisements. This classification is clearly exemplified in the Spanish journals we reviewed, where *Medicina Clínica*, a prestigious peer-reviewed journal, had 8% advertisement pages and *JANO*, which physicians receive free of charge, had 39%; however, *Atención Primaria*, another prestigious peer-reviewed journal from the Society of Family Physicians, had the second largest proportion of pages devoted to advertisements. The journals' different policies about the amount of advertising they accept, and the segmentation of target populations by the pharmaceutical companies probably account for these wide discrepancies. Similar criteria help to explain differences seen between countries, where different regulations governing advertising are also in force. For example, although the regulations controlling advertisement of drugs in Spain are stringent,<sup>15</sup> there is no requirement of fair balance, as in the US Food and Drug Administration regulatory norms.<sup>16</sup> Finally, our study was restricted to only a few journals, and thus has very wide CIs.

Little is known about the effect of pharmaceutical advertising on physicians' prescribing behaviour. Pharmaceutical marketing practices do affect prescribing,<sup>17,18</sup> and whether pharmaceutical advertising, under its different forms, can affect such factors as the appropriateness of the prescription, the presence of adverse effects and pharmaceutical spending has been debated.<sup>19,20</sup> Up to now, various strategies have been proposed and implemented to complement legal regulations: tightening of government regulations for pharmaceutical publications; reinforcement of review procedures by the journals' editors, including peer review of advertisements;<sup>3</sup> implementation of codes of good practices and self-regulation;<sup>21,22</sup> and lobbying, such as the activities done by the Medical Lobby for **Appropriate Marketing group**. The issues we have highlighted have all taken place under the strict regulatory environment that oversees pharmaceutical publications in Spain.<sup>15</sup> Spanish regulations incorporate the 1992 European Directive, and are very similar to regulations of other countries in the European Union. Publishers are required to guarantee the veracity of the text and the truthful reproduction of "quotes, charts and other illustrations extracted from medical journals and other scientific works", and send copies of all advertising published to the health authorities. Sanctions can be imposed upon violation of these rules. The combination of a series of factors, including the large volume of advertising material, the weakness of the inspection procedures, the complex bureaucracy of the sanctioning mechanisms, and the imagination of the advertisers who place claims within the very limits of truthfulness, make it difficult to use these regulations to effectively control advertising. Were the journals themselves to take on the control activities, that would imply a commitment on the part of the editors to print only truthful advertising. Few journals, however, seem willing to take this commitment on board, beyond exerting rudimentary controls to reject offensive or exaggerated advertisements and to publish letters criticising "offending" examples.<sup>2,3</sup> Here, various factors come into play, ranging from the already heavy workload involved in publishing a journal, to fear of losing financial support, reluctance to endorse advertisements with the journal's seal of approval, and awareness that a promotional advertisement is not a systematic review and that physicians are a target audience capable of distinguishing advertisements from scientific evidence. Self-

regulation processes have been used for some time in various countries<sup>21,22</sup> and special bodies have been created to oversee control activities. These organisations have probably helped to correct some abuses, such as those in advertisements comparing different drugs. However, results of some studies<sup>24–27</sup> show that these measures are insufficient, even when publishing policies are combined with self-regulation, as occurs when a journal requires publicity to be submitted for previous review by one of these bodies. Finally, despite the stir caused by some campaigns, lobbying activities have very little overall effect.<sup>28</sup> Overall, the solutions that have been adopted have not been sufficient to tackle the complex issue of pharmaceutical advertising (advertising also has positive aspects and plays a part in rapid distribution of effective drugs). Current control measures seem to buffer Europe, the USA, Canada, and Australia against situations such as those seen in the third world. Furthermore, they help create an environment in which pharmaceutical companies must decide how much they value physicians' confidence in the information they provide. Our results suggest that physicians should continue to be cautious in assessment of advertising claims of greater efficacy, safety, or convenience, even though these claims seem to be supported by bibliographical references to randomised clinical trials published in reputable medical journals and seem to be evidence-based.

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