

Lies, damned lies, and marketing: an editor's lament

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Overview

Many of the articles published in the ICC COLUMN have emphasized the plight that respiratory patients around the world have in obtaining satisfactory access to appropriate medications and health care. Two main problems have been identified. The first involves the high costs that prevent many patients from obtaining care (1). The second involves the difficulty to determine whether or not new medications, diagnostic procedures, and treatments actually do benefit patient outcomes. This paper provides an editor's perspective on how the marketing activities of proprietary organizations make it difficult to assess published clinical research that is intended to determine the value of treatments. Some of the data mentioned in this article have been previously published and referenced in the ICC COLUMN (2) and in another publication (3).

Perspective

I first became a medical editor with the American Medical Student Association's journal *New Physician* when I was a first year medical student in 1968. Since all the editors for the journal were medical students, few of us had experience with medical research. Because we didn't print scientific articles, we didn't get into too much trouble. We would write about the usual complaints and vicissitudes of medical school, current events at the school, and other topics that students found interesting. I wrote about how my favorite poet (John Keats) was influenced by his education as a physician (4). As I would later learn, the real problems and controversies in medical publishing arise around the reports of the value of proprietary therapies.

Later in medical school when I became an editor of *Northwest Medicine*, a general medical journal, I was

slightly better prepared since I was doing laboratory research and had some grounding in the diseases of the various organ systems. However, I had little clinical experience. When my editor asked me to review an article about the use of oral estrogen for post-menopausal symptoms (mainly those related to vasomotor instability) submitted by a local Ob/Gyn physician, the article seemed very straight-forward to me. All the women in the study had the symptoms, and all of them had a favorable response to the medication. I didn't realize it at the time, but this study, based on one doctor's selected cases from his practice with only short-term follow-up, was woefully inadequate to make any clinically reliable and useful statement about the treatment. The author hadn't made adequate inquiries relating to side effects; he hadn't used a randomized, controlled approach, and he hadn't done any long term follow-up. This was the beginning of my education about how difficult it is to conduct a meaningful clinical trial and how proprietary groups and even physicians use suspect research to market themselves.

After further training in internal medicine, doing research at the National Institutes of Health, and publishing a number of scientific papers, I became the Director of the Division of Scientific Affairs at the *Journal of the American Medical Association (JAMA)*. Supervising the recruitment and review of the major scientific studies published in the largest medical journal in the world opened my eyes to the complex issues of assessing the validity of various kinds of medical studies that were conducted under different circumstances and for different purposes. When I arrived at the *Journal*, I thought that by dealing with the most famous and respected physician scientists and soliciting the submission of their most interesting clinical trials that I would be sure to publish useful, reliable research. I later

found that this was not always the case.

Later, as the Vice President for Medical Affairs and Programming for the US Lifetime Television Network in 1983, I was in charge of the editorial review and approval of the first television commercials for physicians that aired on US national television. The protocol for these commercials was dictated by the US Food and Drug Administration (FDA), but the drug and device companies that developed the commercials, working with their advertising agencies, were relentless in their efforts to promote the values of their products and to minimize the liabilities. These television commercials were couched in technical medical language and were intended for practicing physicians, but the programs and the commercials were on an open cable network, and for each program that had 50,000 physician viewers, there would be about 10 million consumer viewers, and after watching the commercials, these consumers were strongly motivated to ask their physicians about the drug they had seen advertised in the commercials and to demand a prescription. The continual efforts by industry to mislead physicians and their patients clearly often led to bad patient outcomes.

Eventually, the FDA approved commercials specifically intended for consumers for airing on non-physician-directed programs, and this became the major drug marketing activity that drug companies employed for many years. Most physicians strongly believe that these direct-to-consumer (DTC) commercials greatly damage patient-physician relationships and harm patients by pushing them to demand drugs that are not appropriate for them and which are far more expensive than other suitable drugs. Increasingly, I became concerned about the subtle forms of biased marketing and promotion I saw in medical communications (5). No matter which communications medium is employed, whether it is TV, print, internet, lecture, or drug representative, the same problems with proprietary marketing contaminating the messages arise.

After more than 50 years of being a medical editor and seeing many examples of irreconcilable, contradictory evidence for almost every medical point of view, I have identified a number of perspectives that help me to assess the believability of medical research and to reject hidden marketing and promotion that distort the truth and harm patients. Physicians are usually better trained to critique medical research, but patients also need to understand and analyze medical research findings at some level. Otherwise they will be victimized by commercial interests masquerading as impartial scientists and clinicians. I hope

that you will find the following perspectives on published clinical trials helpful and that you will assist your patients in obtaining safe and effective therapies at reasonable prices.

- ❖ Clinical trials with negative results are not usually published, and access to this information is limited if the studies were conducted by proprietary companies that control the data. This means that physicians must look critically at the positive studies they encounter in various publications since the downside that the treatments have will usually be concealed.
- ❖ If a drug or device company conducts studies, the methodology of the studies will be designed to optimize the occurrence of a favorable result for their product, and the information from the study that is reported will be selected to achieve this result. The same is true of studies conducted by medical specialty organizations whose members will benefit financially from the acceptance of a procedure or treatment that they perform. By looking carefully at the methodology, the side effects, the patient population studied, the group that funded the study, the payments the authors of the study received from the sponsor, and other features of the study, you can assess whether or not it is relevant for your patients and also whether or not it should be believed.
- ❖ Many ineffective drugs with serious side effects are sold because proprietary companies did not publish their own studies that show lack of efficacy and complete information about all side effects. Their marketing and the presentations of their sales representatives about these drugs to physicians emphasize a rosy, one-sided picture of the treatment. Drug representatives are not reliable sources of information about therapy.
- ❖ Most regulatory agencies look only at the non-inferiority of a new drug being tested compared with another already-approved drug in order to approve the new drug's use. In view of the unreliability of company-conducted drug studies, this is not a good guarantee that the new drug will be useful in your practice. Many regulatory agencies ignore the availability of equally effective drugs that are available at much lower cost in considering new drugs even though cost is often the deciding factor for patients' ability to purchase a medication. Physicians should consult their patients and include cost as a factor in deciding whether or not to prescribe a drug for an individual patient. Usually, there will be a much

less expensive option that will be equally effective compared to new, branded drugs. Physicians should be cautious about introducing new drugs into their practices when long experience with other well tested medications is available. New drugs seldom look as good as they are initially marketed, two years after their introduction.

- ❖ Doctors are often deceived by studies that indicate a treatment has a P value of <0.05 (a significant difference) associated with some biologic change observed in patients following its use. The change may be a statistical or laboratory fluke; it may not be a clinically meaningful effect; it may not be relevant for the patient population that is usually treated; it may be the only one of 20 studied variables that had a statistically significant P value on the basis of chance, or it could be the result of falsified data. P values relating to treatment effects on surrogate measures are statistical findings that do not necessarily tell you if the treatment will improve patient outcomes or treat the patient's disease. Patients should not continue to take a medication if follow-up has not shown that it produces the desired clinical response and that side effects of the drug are more damaging than the benefit. It is a tragedy to put a patient on an expensive drug for the remainder of their life when it does not improve their outcome, or worse, when its side effects cause harm.
- ❖ Scientific evidence concerning medications is constantly being manipulated and misrepresented to deceive the public about the benefits of medications in order to advance the financial interests of the company that funds the research and profits from the medication's use. False and misleading advertising and other forms of marketing occur in all areas of commerce, and health care is no exception. Ask yourself if those who promote a procedure or treatment have a conflict of interest that could impair their objectivity in recommending it for your patients, and if they do then disregard their advice. In capitalist countries, the penalties for distributing misleading information are much less than the financial benefits from swindling and harming patients, which fuels such damaging behavior.
- ❖ The companies seeking approval for a drug or device can manipulate the decisions of a regulatory agency if the agency (such as the US FDA) receives its funding from the companies that it regulates. When the agency is controlled by the political party in power, and its politicians receive payoffs from the companies that are regulated, the politicians will pressure the agency take actions on medications and devices based on political expediency, not scientific merit. This frequent political manipulation requires physicians to be skeptical and cautious in using new drugs, procedures, or treatments.
- ❖ Physicians should not participate in medical education that is developed or funded by the companies or organizations that produce or market treatments that are covered in the educational materials and which financially benefit them. The information will be biased, and if you follow it, it will harm your patients.
- ❖ The primary reason that the integrity of medical science and medical practice in many countries is in question is because the medical scientists and the physicians receive payments and other bribes from industry, which they usually do not disclose to their patients or to the public. Among most human beings, the appearance of conflict of interest is, in fact, a real conflict of interest. Experience shows that physicians who have conflicts of interest in their practices act to benefit their commercial benefactors at the expense of their patients. This violates their professional oaths; their fees become more important to them than their patients.
- ❖ Because most new drugs are no better than available older drugs, most new drug studies promote unnecessary new medicines. Nevertheless, the new drugs are heavily promoted, and this fosters large, unnecessary costs to health care systems and patients. These costs deplete resources for overall public health, which leads to increased overall mortality and morbidity. Most clinical reviews of treatments focus on drug treatments and ignore other health approaches to disease, particularly public health measures that tend to compete with physicians' medical practices. Prevention and public health is neglected because it does not generate profit for the proprietary commercial health care industry that controls the health care system.
- ❖ Some governments have programs such as the "sunshine act" in the US that obligate drug companies to reveal how much money and to whom they pay physicians. However, the websites for the public to access this information are very difficult to use, and because the multi-national corporations can

funnel these pay-offs to physicians through national operating companies in countries that do not require disclosure of such information, it is possible to conceal payments to physicians who act as paid marketers for industry products. At the very least, patients and physicians should inquire whether or not physicians' they deal with receive payments from industry. For articles about treatments published in the medical literature, one should check the article's disclosure statement (generally at the end of the article or on the journal's website) for information about financial conflicts of interest by the authors.

- ❖ The variables that are studied in clinical trials of treatments are often unimportant for health or for assessing patients' clinical outcomes; however, companies market statistically significant results of such data as if it obligates physicians to use their product. They do not mention study results that are unfavorable unless required to by regulatory groups. For example, the new anti-coagulants in most cases are hundreds of times more expensive than generic warfarin, and warfarin is as effective, as the new agents in most of the studies. But if a single study leads to a statistically significant superior result of a new anti-coagulant over warfarin, the marketers of the new drug trumpet "Drug A better than Warfarin" in all their ads. The fact that other studies do not achieve these results is not mentioned. They also do not mention that the new anti-coagulants have no agent available to reverse their effects in the event of the common bleeding complications, or the fact that if the new drug is stopped it may greatly increase the risk of stroke in the patient, unlike warfarin, or the fact that new agents are marketed to promote the idea that they can be used without monitoring INR levels even though some of the new drugs would provide greater benefit to the patient if they were monitored! This information is concealed from patients and physicians. It indicates that new drug marketing is false and misleading and that their marketing focuses on increasing market share and not optimizing patient outcomes! The ages of the patients studied in clinical trials of new drugs are often not the relevant ages of patients who should be studied for treating the disease for which the drug is being evaluated. The purpose of this patient selection is to improve the effects and minimize the side effects of the drug. Many drug studies are done in third world countries where there may be important differences in the patients and the physicians who are involved in the studies that may influence the results. Many proprietary companies perform the clinical drug trials that drug companies are required to submit for approval. There are serious conflicts of interest in the supervision of such studies by these companies working for industry. Companies involved in drug trials often delay or refuse to release data for independent analysis. When any of these issues is present in the studies conducted on a new drug, physicians would do well not to use it until independent data confirm the benefits that the company's studies claims.
- ❖ The marketing of new drugs emphasizes their health benefits, but in their marketing they often ignore or minimize their side effects or complications. Many of these side effects are so serious that they can lead to drug discontinuation or patient death, but such side effects may be buried in the lengthy product information and couched in medical or technical jargon that patients and many physicians do not understand. In DTC TV ads side effects are often rattled off rapidly at the end of the commercial as if they are of trivial importance.
- ❖ Pills do not usually prevent diseases nor do they cure chronic diseases. Often they don't influence the disease process they are being used to treat. Most new therapies simply provide lifelong amelioration of disease. Unfortunately, they often also cause severe side effects that are much worse than the disease itself. Physicians are so used to writing prescriptions for patients that they often ignore hygienic measures that can prevent and benefit chronic diseases more than pills. Marketers often ignore preventive medicine since it may deprive them of customers. Physicians can do their patients a great favor by convincing them to implement a healthy life style without adding the burden and expense of another drug prescription.
- ❖ Clinical studies will often report only short-term data from treatments when these data show results that are better than long-term treatment data even though most patients will need long term treatment for their disease.
- ❖ Medical media will not usually cover negative studies about a drug therapy if they receive funding from the makers of the medication because their funding of PR releases, sponsorship for their work, and access to drug company information will be terminated.

- ❖ A company can falsify the results of clinical trials with their new drugs, particularly in cases where such clinical trials are too expensive to repeat. Even in the unlikely case that such falsification of clinical trial data is discovered, companies can blame the hoax on lower level scientists or agents working for them. Top company executives are never held personally liable for such falsification. The profits realized from the sale of inappropriate drugs are much greater than any fine that would be levied for false claims or mislabeling. Falsification of study data is a very profitable activity. Marketing and PR activities can confuse and reframe the criminal activity so that physicians and the public do not blame the company and soon no longer remember that it occurred.
 - ❖ Independent medical news that accurately reports on serious flaws in medical care is rare because the companies that produce medical news depend on the medical industry and physician organizations for their revenue. If a news story criticizes any aspect of health care delivery, it will be greeted by angry rebuttal and rationalizations, as well as retributions against the news source. As a result, investigative journalism concerning problems or issues in health care rarely takes place, and the truth about most industry crimes cannot be obtained. Marketing and promotion by the health care industry has replaced serious analysis of the appropriateness of health care practices in most medical communications. Since the hard questions concerning medical care are not asked in public communications, those who are involved in the practice of medicine must ask the hard questions themselves. A skeptical view of medical news coverage of medical procedures and therapies—especially new ones, is the safest attitude to have.
 - ❖ Many drug trials include procedures, patient exclusions, and interactions with health care personnel that never occur in medical practice. Physicians should read the full materials and methods section of published clinical trials that are of interest to them to see if the studies are relevant to their patient population. Industry sponsored clinical trials are not conducted as therapy is done in real life medical practice, and the results of clinical trials may not be relevant to everyday practice. Complex statistical analyses such as “intention to treat” in a randomized controlled trial may also limit the understanding of how the results of the clinical trial can be interpreted.
- The marketing of the product studied in the clinical trial will attempt to generalize the positive results of the trial far beyond the specifics of the actual trial. Don't be deceived! Positive results in a well-designed trial should be obvious at a glance!
- ❖ Only 13% of new drugs involve new drug mechanisms; the rest are me-too drugs. They are marketed by trying to focus on some aspect of the drug's action that is more prominent (sometimes only a small amount more) than the other drugs in its class. Such differences are not usually of clinical significance, but the marketers try to deceive physicians into believing that the new drug is better than the other drugs that work the same way by identifying a “statistically significant difference” on some parameter so that patients and physicians will accept the much higher cost of the new, branded drug.
 - ❖ Commercial distortion of the results of drug studies by industrial sponsors harms patients, interferes with good medical care, and wastes money from the limited funds available for health care. Both physicians and patients should carefully evaluate the outcomes and cost-effectiveness of medical therapies and procedures.
 - ❖ Public health measures and improvements in the social and physical environment have raised life expectancy by 25 years during the past century. Medical care is only responsible for five of those years. Patients and physicians need to remember the importance of preventive medicine and the social and physical environment's role in health. Pills and procedures have limited value in public health. Clinical trials don't mention, and marketing and promotion of trial results don't reveal, that poor overall fitness is the biggest health risk for patients.
 - ❖ Through the power of marketing, the health care industry can create the perceived need for patients to spend money for unnecessary therapy. The health care industry medicalizes such normal human phenomena as menopause, aging, social discomfort, and death. Patients are coerced into paying for drugs that are marketed to ameliorate normal processes. At the far extreme of this medicalization, patients are hijacked from their families as they approach death and become captive victims of intensive medical overtreatment in the hospital. Such futile care represents the majority of medical expense for their whole lives. This occurs in the final few months of the end-of-life with little or no benefit and enormous expense and harm.

Normal deaths taking place with friends and family are made impossible as the medical industry piles on confiscatory health care that bankrupts the patient and their family. As a related activity, the medical industry creates previously non-existent diseases and markets the treatments for these non-diseases. For example, social anxiety, which can be a normal response of human beings to certain encounters with others, is labeled social anxiety disorder by predatory psychiatrists. They treat it with dangerous, powerful psychoactive drugs that numb patients into believing that their normal experiences aren't happening. Finally, medical marketing achieves its most degrading level with DTC marketing in which emotional presentations in a video commercial try to convince patients to believe that drug therapy will cure their symptoms. These therapies are never curative, and they often introduce serious side effects that are disclosed only briefly and in a dismissive manner. This mass manipulation of gullible patients represents a reprehensible form of exploitation by the medical industry. After decreasing in recent years, DTC marketing has increased in the past year by 21%.

- ❖ It is always worthwhile when reading a clinical trial report to explore who provided the funding, who determined the need for the study, who designed and conducted the study, and who published the results of the study. If a drug company or a medical specialty organization is responsible then the study is almost certainly a marketing activity, intended to profit the instigator. Since the instigator typically has a positive result that is desired, and has many ways of bringing about the desired result by manipulating the study, it is not surprising that published investigation of study results by drug companies versus those by independent investigators have found that studies done by drug companies of their own drugs are four times more likely to show positive results than studies by independent investigators. A similar trend is seen by studies by specialty organizations trying to show that procedures that are done by their own specialty are beneficial. Physicians should also be aware that drug studies that are done by specialists in special clinical trial facilities do not give the same results as using the therapy in real life medical practice.
- ❖ Advertisements of medical industry products in all media try to deceive people into believing that their product will preserve youth, mind, and beauty. This marketing objective is easily established in video or in pictorial ads by showing young, happy, attractive actors who seldom resemble the age, state of mind, and physical appearance of actual patients. Yet the viewers of the ads are easily convinced that the ads reflect reality.
- ❖ Many drugs such as Premarin were widely prescribed for decades before their full range of carcinogenic and other health risks became known. This is another argument to resist the deceptive advertisements that are used to establish the use of expensive, new branded drugs. Time will usually reveal whether or not a new medication is beneficial.
- ❖ Physicians and patients should be aware that medical industry marketing and propaganda is ubiquitous on social media, on websites intended for physicians (such as MedPage and Medscape), and on many other internet sites. The funding by industry for this marketing is seldom disclosed or easy to find on the site. Most internet information about medicine is unreliable and should be ignored. There are sites that are impartial and do not have conflicts of interest, but it is hard to locate them and to document their credibility.
- ❖ Drug regulators such as EMEA in Europe and FDA in the US and the experts that they convene as their advisory committees are often on drug company payrolls. For the FDA, the whole agency is dependent on drug company payments for its existence. The recently departed FDA Commissioner, Dr. Margaret Hamburg, believes that having advisors who have conflicts of interest is acceptable and necessary. She was political appointee of an administrator and a Congress consisting of members who almost all receive political bribes from the drug and device companies that are regulated by FDA. It is not surprising that the people in the US spend more money on health care than any developed country in the world and yet have the worst public health.
- ❖ Bribes from drug companies to physicians are not rare occurrences. In the US a study showed that 95% of US physicians received bribes. In some cases they were just free samples of medications or free lunches, but often the physicians were treated to expensive vacations or given many thousands of dollars for giving lectures or participating in advisory boards or clinical trials. This almost universal acceptance of conflicts of interest among physicians indicates

a lack of sensitivity among physicians toward their patients. Organized medicine in the US has made cosmetic statements about limiting industry bribes to physicians, but takes little action against those guilty of flagrant conflicts of interest and gross impropriety.

- ❖ Clinical trials conducted by commercial sponsors are 5.3 times more likely to recommend the new drug being tested than studies by non-profit organizations.
- ❖ A country has the right to decide what medications and devices can be made available to its population and how such medications must be tested. If the country is a democracy then the people should have that right. However, in the US, which is ruled by an oligarchy of powerful corporations and their legislative puppets, their own interests are served and the people are robbed, injured, and exploited.
- ❖ In reviewing the risks and benefits of clinical trials, also consider the data on public health measures that might provide even better patient outcomes at less risk and expense. Does a given study even consider such measures as smoking cessation, weight loss, exercise, diet, and life style?
- ❖ Studies designed by Pharma often use higher doses of their own product in comparing it with lower doses of other drugs to make it seem that their drug is more efficacious. Then, they examine the side effects of their product at its lower dose so that the comparison with the side effects of the other drugs is invalid. It is important to consider the dose response curve of drugs and the relative frequency of side effects at different doses.
- ❖ Drugs should be tested against the best available drugs that are available for the disease being treated and not simply allowed to prove non-inferiority to an inferior drug for approval. Expensive non-inferior drugs should not be approved if better and less expensive drugs are equivalent and available.
- ❖ In diseases such as COPD in which drugs do not alter the course of the disease and medications are approved based on their ability to improve such factors as frequency of infectious exacerbations, quality of life, and exercise tolerance, multiple different medications with different mechanisms are able to achieve some or all of these benefits. COPD patients may benefit from many different medications, and they are often used in combination. However, companies are not required to assess the effectiveness of their product in combination with other products that have known benefits. Such tests should be required to demonstrate a niche for a new COPD medication. This is essential so that patients can receive the maximal benefit from the available drugs at the lowest cost. A recent study revealed that an expensive proprietary inhaled corticosteroid frequently used with bronchodilators did not provide any additional benefit to the bronchodilators alone.
- ❖ Companies often conceal the patient level data from clinical trials they conduct, even from the investigators who conduct the studies for them and who write the scientific reports about the trials that are published. Crucial data may be missing from the final published trials. Negative findings from the trials may be suppressed and never revealed unless data are subpoenaed by government regulatory groups or lawsuits. This is another reason why experienced physicians delay using new drugs until clear evidence of their benefit and absence of serious, unreported side effects are obtained.
- ❖ It has often occurred that a drug company influences medical organizations and their medical journals to provide more favorable assessments of their drugs either in their medical news coverage or in the articles they publish by threatening the organization that it will terminate its advertising and other funding unless they do. Readers cannot unquestioningly accept the truth of published articles concerning medications because of such influences.
- ❖ It is a major conflict of interest for advertising agencies that work to promote and market clients' drugs to purchase companies that perform clinical research and develop "educational materials" for their clients. It creates a powerful motivation for the research group to influence the results of the studies and to transform the educational materials into promotional pieces. Always check to see if financial conflicts of interest exist in the development of supposed scientific materials.
- ❖ An independent academic assessment of US drug ads found that 92% of them contained material that was in violation of FDA regulations. A total of 44% of the drug ads, if acted on by a physician, would lead them to prescribe outside of product labeling. Drug ads often contain biased information.
- ❖ Often, medications have some physiologic result that is viewed as beneficial, but when the medication is used over time it is found to have more serious

undesirable results. For example, antiarrhythmic medications were found to reduce abnormal heart beats and were frequently used for this ability during the 1980's. Unfortunately, when a study compared patients with arrhythmias who received antiarrhythmic therapy with similar patients who did not receive these medications, it was found that the medications were associated with more deaths. It was estimated that 75,000 lives were lost yearly as a result of their use to suppress the abnormal heart beats. Short-term data can be misleading, particularly when only one drug action is considered.

- ❖ Often, clinical trials use “composite end points” to measure differences between treatments. This means that several factors are included so that if any of them are fulfilled then the treatment is defined as influencing the composite end point. However, composite end points sometimes include both very serious outcomes and very minor ones. This can mask the clinically important effects of drugs and these composite end points are often chosen to mislead doctors to have a more favorable view of the drug being tested. Thus, you may see that a treatment greatly reduces a composite end point but only by reducing a clinically unimportant outcome while the serious outcome (such as death) is unaffected.
- ❖ Remember that 40% of studies on drugs are never published by the sponsoring company; physicians often have to make decisions based on biased evidence. They should not be afraid to doubt published results.
- ❖ When clinical trials involving drug comparisons were examined by impartial scientists, it was found that different conclusions were often reached by both patients and physicians when a study of a drug was widely promoted by the drug company marketing the drug. People believed that the results were more positive for the drug being promoted. Marketing of a drug affects public and professional perception in spite of the scientific evidence.
- ❖ Until recently, an average of about \$1,500 was spent by drug companies each year for every US physician for their “continuing medical education.” These educational materials were effective in increasing sales of the companies’ drugs that were being reviewed. This funding has in recent years been reduced when the serious biases of these “educational communications” became widely known. Even supposedly “scientific” educational materials will

usually be misleading when financial conflicts of interest occur in their development.

- ❖ False clinical studies and misleading drug and DTC ads destroy patient-doctor relationships. A total of 75% of doctors write prescriptions for drugs that patients request even if they don't believe they are appropriate. Patients need to be educated about the downside of DTC ads.
- ❖ Almost all medical device trials are unblinded. However, when sham-treated controls are included in these trials in which benefit was conferred by a procedure, it is often found that the patients who received sham procedures had just as much benefit. The placebo effect, which is thought to account for the benefits experienced in sham-treated patients, is an extremely powerful and often neglected phenomenon. This benefit to sham-treated patients and ineffectiveness of invasive treatment was found recently in the SYMPPLICITY trial involving renal artery denervation by catheter-based ablation. Do not believe unblinded medical device trials! Since patients' subjective responses to therapies are important factors to evaluate their risks and benefits, they should be given considerable weight in the decision of whether or not a treatment, including a placebo treatment, should be used.

The perspectives presented above indicate that in countries where commercial interests dominate medical practice and physicians' freedom to care for their patients is constrained, patients will suffer.

Patients must seek physicians without commercial conflicts of interest who will work with them to obtain health care that is safe, effective, and economical. Physicians must not be deceived by marketing that deceives. Primary care family physicians that provide continuity and comprehensiveness of care and are trained to act as patient advocates are in short supply worldwide, probably because they limit the profitability of for-profit medical organizations that dominate health care.

Although the effect of proprietary marketing and falsification of clinical trials varies from country to country, the effects of financial conflicts of interest will be a constant threat to patient outcomes and the ethical practice of medicine worldwide.

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