

Is Prescribing Placebos Ethical?

By ACSH Staff — October 1, 1998

Yes

by Kenneth E. Legins

In 1903 Mark Twain wrote of Christian Science: "The power which a man's imagination has over his body to heal it or make it sick is a force which none of us is born without. The first man had it, the last one will possess it." The power of the mind over the body is often indisputable, even among the staunchest defenders of the scientific method. The biologic effect of hope or faith, which scientists sometimes refer to as the placebo effect, is little understood in the medical community.

At Stanford University 86 women with metastatic breast cancer were divided into two groups. In one, the patients were encouraged to examine their fear of dying and to take charge of their lives. The patients in the other group (the control group) were given no such support. The support-group patients evidently were in less pain than were those in the control group and, to the surprise of the researchers, lived on average 18 months longer.

The Harvest Moon Festival is an important tradition in the Chinese-American community. Some health professionals noted that the death rate in this community decreased by 35 percent before the festival and increased by 35 percent subsequently. The greatest changes in mortality were among older women, who were responsible for the festive rituals. There were no noticeable changes in mortality among non-Chinese-American neighbors. Researchers have noted a similar phenomenon among Jewish men, whose duties during Jewish holidays are considerable. It seems that elders can somehow postpone death until they have fulfilled their obligations.

Biological effects of the mind come not only from psychological interventions and from the presence of certain environmental factors but also from the double-blind experimental administration of placebos methods, preparations, and substances whose effects are either not pharmacologic or not specific to any of a patient's health problems. Drug companies routinely compare the effects of newly developed drugs and "sugar pills" inert, putatively inactive imitations of the newly developed pharmaceutical. On average, 10 percent of patients who receive "sugar pills" in double-blind trials report salutary and/or adverse effects. Placebos can have occasional healthy effects in many patients, especially those with anxiety, depression, pain, colds, and symptoms apparently of mental origin. For example, in a study of the effects of supplementary calcium on depression, 28 percent of the control group reported a subsidence of depression after using a prescribed placebo.

Reportedly, patients have even become "addicted" to placebos: According to an Internet paper* by Ben Z. Krentzman, M.D., one patient ingested 10,000 placebo units in one year; another had a

compulsive desire to take placebo tablets, tended to increase the "dose," couldn't stop taking the "medicine" without psychiatric help, and suffered "abstinence syndrome" when deprived of its classic characteristics of drug addiction.

Scientific research on endorphins hormones the body produces that are conducive to pain relief has suggested possible mechanisms for the placebo effect. Endorphins are closely related to hormones released by the anterior lobe of the pituitary gland. These hormones influence growth, lactation, and skin pigmentation and participate in hormonal cycles that effect varied physical and psychologic functions.

Granted, using placebos therapeutically requires extraordinary caution: First, how placebos affect the mind remains to be elucidated. Second, therapeutic placebo use entails deceit, which can seriously impair the doctor-patient relationship (which alone can have a strong placebo effect). Third, the physician may misconstrue a salutary placebo effect as evidence that the patient's illness is wholly or largely a neurosis. Fourth, there is no legitimate program for health professionals that focuses on how and when to use placebos and on how to judge their effects. Fifth, there are no standards for managing possible aftereffects of placebo administration i.e., for dealing with any consequences of learning that a health problem and/or relief from it was "all in one's head." But the dearth of information on the placebo effect and the need for caution do not negate the legitimate findings of clinical researchers and should not rule out or automatically render unethical all therapeutic placebo uses by clinicians. For example, most of the patients that physicians in private practice initially see are former patients of other physicians who, in placebo fashion, may have prescribed as "tonics" vitamin supplements and/or similarly given vitamin B12 injections to those patients. Patients thus treated may have derived subjective benefits from the treatment and may become upset, distrustful, and/or secretive or even fall ill if their new physician does not follow suit. Eliciting a placebo effect a health improvement that results from the attempt to modify disease rather than from the specific treatment does not require deception. Provided the treatment is harmless and the physician has described it honestly to the patient, placebo use in such circumstances as those outlined above is not unethical; indeed, it may prevent alienating the patient toward biomedicine. Moreover, such a situation may afford an opportunity to moderate a potentially harmful practice excessive ingestion of certain dietary supplements, for instance.

In terms of nonexperimental clinical use, placebos are perhaps best defined as a means of either (1) eliciting an indefinite or nonspecific favorable effect on the health of a patient, or (2) weaning a patient, more or less nonpharmacologically, from ingesting a therapeutically ineffective preparation whose side effects are adverse or whose long-term use is risky. Physicians who use placebos therapeutically must do so no less carefully and honestly than they use pharmaceuticals. To dismiss all therapeutic uses of placebos as unethical is to mishandle something that is intrinsic to the practice of medicine.

Kenneth E. Legins, M.P.H., is a health writer and a health communications specialist for the World Health Organization.

YES

Under certain circumstances it would be ethical, and even desirable, to prescribe placebos.

In medicine, a placebo is defined as a substance used against a condition that has no known pharmacologic susceptibility to it. There is an important distinction between pure and impure placebos. Pure placebos, such as sugar or starch, are completely inert. Impure placebos are drugs without any known salutary pharmacologic effect on the conditions for which they are being used.

Placebos can be used therapeutically or as substitutes for pharmacologic agents in controlled trials of drug efficacy. Virtually no one would dispute the morality of using placebos in drug trials in which patients have given informed consent and would not be harmed by the discontinuance of an active medication. But is it ever ethical to use a placebo therapeutically?

Those who object to the prescribing of placebos should be aware that the placebo *effect* is ubiquitous in clinical medicine. From time immemorial, those whose calling was to heal others have observed that many persons get significant physical and emotional relief solely from encountering a physician, shaman, or faith healer. As Dr. Howard Brody stated in "The Lie that Heals: The Ethics of Giving Placebos" (*Annals of Internal Medicine*, July 1982), "[T]he placebo effect pervades much of medical practice even when no placebo has been used."

When a patient has seen a physician for an upper respiratory infection, has received a prescription only for an over-the-counter drug, and has taken the medicine, often some of the relief the patient experiences results not exclusively from the pharmacologic action of the drug but also, as Brody stated, from "the emotional support of the doctor-patient relationship, the doctor's confirmation and legitimization of the illness, and the reassurance that the symptoms do not represent something more serious than a bad cold."

How often do physicians order harmless tests "unnecessarily" solely to lessen a patient's anxiety and "justify" such orders as necessary to "rule out" various forbidding diagnostic possibilities? In combination, such testing and the physician's attention and reassurances contribute ethically to the pervasive and useful placebo effect. "Placebo" traces to a Latin expression for "I shall please." Trying to please "worried well" patients (who constitute a large proportion of the patients of internists in private practice) through reassurances whenever it is appropriate is an integral part of clinical medicine.

American physicians almost never use pure placebos completely inert substances to treat patients. I cannot recall ever having done so in 30 years of practice, and I would venture that finding a pharmacist willing to provide such a placebo would be difficult. The vast availability of impure placebos in the United States has made the necessity of ordering a pure placebo rare in this country. Thus, it is specifically the prescribing of impure placebos i.e., the prescribing of pharmacologic agents not for their pharmacologic effects but rather for a placebo effect that is common.

That a physician would even consider prescribing a placebo is explainable by documentation that pure placebos work 30-40 percent of the time. Numerous studies published in peer-reviewed psychiatric and other medical journals have attested placebos' ability to reduce or eliminate pain

and even to affect body chemistry for example, by lowering blood glucose in diabetics or by lowering serum cholesterol. Moreover, various placebo (sham) surgical procedures have significantly mitigated abdominal pain and angina pectoris.

The dominant argument against prescribing placebos is that deliberately misrepresenting as a medicine that should better the patient's condition pharmacologically a preparation of no substantial intrinsic utility against that patient's condition is immoral. Those who criticize the prescribing of placebos further claim that it deteriorates the physician-patient relationship and that it reinforces the erroneous and harmful notion that there is a pill for every complaint.

But is the placebo such a cheat? Consider the following scenario. A pharmaceutical company carries through trials of a new drug. This drug is inexpensive and, according to the experimental data, has no significant side effects; does not interact with other drugs; can be taken safely during pregnancy and nursing; and can benefit 35 percent of patients with these complaints: head, chest, or abdominal pain; air hunger resulting from an inability to breathe deeply; fatigue; and lightheadedness. Later research makes known that this drug works by causing a release of endorphins in the patient, and that these endogenous pain relievers are responsible for the moderation of the aforementioned complaints. The package insert states in boldface: "Use of this drug for the above indications is warranted only after a careful history has been taken and appropriate diagnostic tests have been performed to rule out identifiable medical or surgical conditions that may require other forms of treatment." I doubt very much that there would be any scientific, medical, or ethical opposition to the marketing of this drug. Indeed, the drug's properties would make it an important part of any general practitioner's armamentarium. And knowledge of how the drug works would validate it to ethicists.

But the attributes of this fictitious drug except perhaps how it works are those of a pure (inert) placebo. Although how pure placebos work remains to be discovered, endorphin release is a plausible explanation. It almost certainly involves an unelucidated mind-body interaction.

Without data that explain how pure placebos work, is there a way in which they can be used ethically? In my opinion, yes. The physician who would consider prescribing a placebo should very carefully investigate the patient's complaints or symptoms and order appropriate diagnostic tests. If the physician is ultimately at least reasonably confident that the patient's health problems do not stem from organic disease, he could offer the patient a pure placebo as a medicinal whose mode of action is uncertain but that has helped a significant number of patients with similar problems.

As Dr. Walter Brown states in "Harnessing the Placebo Effect" (*Hospital Practice*, July 15, 1998), "[T]he clinician might well suggest that the placebo seems to work by stimulating the body's own healing mechanisms. In that fashion the clinician can take advantage of the low cost and safety of placebos and enlist their efficacy for the good of the patient."

On the other hand, using a placebo as a means of learning whether a patient's pain is "real" or "imaginary" is clearly immoral. In any event, such a test would be invalid: For one thing, in many cases placebos can moderate pain whose source is organic disease.

Anyone who thinks that prescribing placebos is unethical should consider that virtually every American physician prescribes impure placebos—A practice more dangerous, prevalent, and

expensive than is prescribing pure placebos. Examples include prescribing antibiotics to treat unambiguously viral respiratory infections, administering vitamin B12 shots to treat fatigue, and prescribing or administering a weak anticancer agent in subtherapeutic doses to treat end-stage cancer.

Although some critics may condemn these common therapeutic uses of impure placebos, I feel that, when impure placebos are put to therapeutic use in patients that physicians have carefully selected, far more good than harm results. Academicians without clinical experience who have never dealt with the frustration of patients with chronic complaints, or with the fear and despair of terminally ill patients tend to be the most strident critics of the therapeutic use of placebos.

While expenditures for various modes of alternative medicine to most forms of which the placebo effect is pivotal rise in the United States, the American medical research community scarcely investigates how pure placebos improve health in normative biomedical settings. It is high time to do so.

ACSH scientific advisor Kenneth M. Prager, M.D., is an Associate Clinical Professor of Medicine at Columbia University's College of Physicians and Surgeons.

No

by Dr. Gary P. Posner

The latter half of this century has witnessed the development of increasingly efficacious pharmacologic agents, dazzling surgical innovations, and technological marvels such as computerized tomography (CT) and magnetic resonance imaging (MRI). Such advances have metamorphosed the practice of medicine from a largely palliative, or symptom-treating, service into a science characterized by precision healing.

Yet a large segment of the American populace seems turned off by modern medicine's efficiency. Increasingly, patients are drawn to products, services, and practitioners termed "alternative," "complementary," or "natural" despite growing scientific evidence that, under properly controlled conditions, such methods almost universally prove inferior to conventional ones. Indeed, research suggests that alt-med methods rarely have beneficial health effects beyond those reasonably categorizable as the placebo effect. In other words, it seems that most alt-med methods lack wholesome effects on patients that are both clear-cut and predictable.

Medical science has yielded means of saving staph-infected limbs, controlling diabetes, installing replacement heart valves (and even hearts), and curing some forms of cancer. When a patient's condition is perilous, dietary supplements, home remedies, and placebos (administered deliberately or unknowingly) cannot, to say the least, effectively replace state-of-the-art modalities.

But many visits to physicians' offices are prompted by self-limited conditions such as the common cold, and treating self-limited conditions is largely futile. One's cold will disappear within seven days if one takes a medicine for it, and within one week if one doesn't. Headaches, insomnia, and many other complaints that are not self-limited are often reasonably ascribable to everyday stress and a psychologic approach to stress is arguably more healthful than a pharmacologic one. Family counseling is often a safer and more effective headache remedy than is a controlled substance.

Placebo-based treatments lack such realities but abound in practitioner "caring" and thus seduce patients. During 15 years of practicing primary care medicine in an HMO-owned clinic, I observed firsthand how patients responded to honest treatment and how they responded to placebo treatment. Although each annual evaluation of the clinic's physicians took into account the medical appropriateness of the treatment the patients received, the "patient satisfaction" factor was more important. After all, patient dissatisfaction due to doctors' unwillingness to prescribe, for example, antibiotics as placebos for patients' colds might prompt a major employer to switch to a different managed-care insurance company. To prevent such losses, the HMO in which I practiced used "How did we do today?" leaflets, which were handed out to patients in the waiting room. These questionnaires were in many patients' hands as they entered the examination room. Doctors who did not grant a patient's request for an antibiotic "cold remedy" prescription risked low marks regarding how "caring" they were and how "satisfying" the patient's visit was and perhaps even regarding how "knowledgeable" they were.

How do patients develop such mistaken beliefs as the necessity of taking antibiotics to treat a cold properly? Primary-care physicians who routinely and "caringly" misstate or exaggerate the conditions of patients with colds (e.g., "It's a good thing you came in today or you might have wound up with pneumonia. Here are some antibiotics.") probably constitute a major source of this misbelief. Many or most primary-care physicians at least occasionally fall back on a convenient ethical compromise that involves prescribing an inexpensive but patient-pleasing antibiotic. Primary-care physicians who care enough to brave the probable consequences might instead briefly discuss with the patient the differences between bacterial and viral infections, likewise discuss why using antibiotics inappropriately is hazardous, and give the patient an educational handout that covers how colds are self-limited and how rest and other "comfort measures" can make a cold more tolerable. But such "renegades" risk losing their patients and their patients' families, friends, and coworkers to practitioners who have no qualms about prescribing placebos and who are thus more "caring."

While one might have hoped that progress in medical research and technology would have obviated the routine prescribing of placebos, bringing the typical American medical visit to a "satisfactory" conclusion might necessitate prescribing one. But what should constitute a "satisfactory" conclusion to a medical visit? And even if prescribing a placebo is necessary to satisfy a patient, is the practice ethical? I would not contend that occasionally prescribing inert placebo tablets to a particularly hypochondriacal patient is unethical. But I do consider unethical the prevailing practice of prescribing antibiotics by which I mean "agents that are effective against particular bacteria but not against viruses" as "antiviral" placebos. For one thing, this practice is contributing mightily to the emergence of resistant bacterial infections, and it is expected that such infections will cause tens of thousands of human deaths in the next decades.

In today's "politically correct" America, a visit to a physician is deemed "satisfactory" only if the patient "feels good" about the visit when he or she leaves the office no matter what standards of medical ethics the physician must shelve or pervert toward that end. In this context, a physician's refusal to provide an antibiotic "cold remedy" prescription to a patient with a cold who has requested such is socially unacceptable and "wrong."

Physicians who frequently prescribe placebos (whether inert or not) differ little professionally from astrologers and "psychic healers." Indeed, such doctoring is arguably less ethical than astrological counseling and so-called psychic healing: Investigating claims of the paranormal has been an avocation of mine for more than a decade. I have concluded that many (perhaps most) astrologers and "psychics" believe in the alleged super- or preternatural influences they cite and sincerely consider false that their satisfied customers are satisfied because of a placebo effect. Scientifically literate physicians who routinely administer or prescribe inert placebos or medicinals or dietary supplements for a placebo effect lack such an excuse.

Medical authorities have issued warnings about the long-term societywide risks of continuing to prescribe antibiotics as placebos. But in view of the competitive pressures of the healthcare marketplace, it appears that nothing short of disciplinary or criminal sanctions will stem the tide. Is the physician who, to stay afloat financially, routinely administers or prescribes placebos doing what is ethical? By society's "politically correct" standards, yes. By the principles of medical science, no.

ACSH scientific advisor Gary P. Posner, M.D. (www.gpposner.com [1]), is a contributing editor to The Scientific Review of Alternative Medicine, a Scientific and Technical Consultant to the Committee for the Scientific Investigation of Claims of the Paranormal (CSICOP), and the founder of the Tampa Bay Skeptics.

NO

by Dr. Michael Kirsch

In the medical research arena, using placebos is not only ethical it's also essential. Placebos enable distinguishing the pharmacologic effects of a drug from subjective improvements the drug has not induced. Thus, drug trials often include a placebo group of patients. Such patients unlike those who receive placebos in everyday office settings receive placebos only after they have given informed consent. There is thus no deception.

But doctors who prescribe placebos outside medical research are con artists. If such deception became an accepted therapeutic practice in the field of medicine, it would resurrect professional hubris in a profession threatened on several fronts. Even graver is that it would directly undermine the very keystone of healthcare: the doctor-patient relationship.

A breach of trust can ruin any human relationship, but in medical practice a serious violation of trust, whether the violator is the physician or the patient, can be more difficult to remedy than the illness itself. Such a breach can result, for example, from concealing a serious diagnosis or prescribing a placebo.

Although prescribing placebos therapeutically is always wrong, it is particularly harmful in this time of tumultuous healthcare "reform": Nearly 80 percent of Americans are under managed care, which has rocked the formerly esteemed doctor-patient relationship. Patients complain of physician apathy and accuse HMOs of skimping on their care. Physicians complain about having to see more patients yet receiving less reimbursement. HMO physicians must also observe strict cost controls, struggle with a Byzantine bureaucracy, and get good "grades" on "patient satisfaction." The bonds between physicians and patients are clearly strained. Prescribing placebos leads to severance, not rapprochement.

Doctors immersed in this maelstrom can serve as loyal patient advocates only when the physician-patient relationship is intact. Anything that separates patients and their doctors jeopardizes the profession's capacity for healing. Prescribing placebos would have just this effect.

To prescribe placebos routinely in a nonexperimental setting is to revert to medical paternalism, which patients have properly rejected. Good intentions are no excuse for using placebos therapeutically, which detracts from patients' autonomy. How can a patient give informed consent to nonexperimental placebo administration? How can the prescriber fulfill his or her ethical obligation to inform the patient of the risks and possible benefits of taking the "drug" and of alternatives to taking it? Snake oils and their pseudoscientific relatives should be anathema to physicians.

Prescribing placebos can be a convenient "exit strategy" for doctors treating persons with chronic or intractable symptoms. But it encourages the unhealthy belief that all symptoms have pharmacologic antidotes. Placebos should not be used as substitutes for conversations between doctors and patients, even when such conversing would be difficult.

If the therapeutic use of placebos were legitimized, the public would become aware of the event in short order and be outraged by it. The "take-home" message for patients would be that physicians' trustworthiness is relative. Patients would, in effect, hear from their doctors: "Yes, I know I gave you a placebo last week, but now I am (really) telling you the truth." Without trust, the doctor-patient relationship would be in free fall.

Sanctioning the therapeutic use of placebos would be far-reaching. Suppose some physicians on the healthcare team object to such use on ethical grounds. Would these "conscientious objectors" withdraw from treating the placebo recipient? Would such withdrawal be proper? Would the placebo prescriber try to deceive objecting physicians? Would nurses, pharmacists, and dietitians play along? The American Society of Pain Management Nurses and the Oncology Nursing Society have gone on record against using placebos therapeutically.

Although administering or prescribing placebos to unknowing patients is unethical, otherwise eliciting the placebo effect is not. I do so daily in my gastroenterology practice. Any health improvement in a patient who has been treated only with substances, preparations, or methods of no known ability to affect that patient's condition significantly is reasonably describable as a placebo effect. For instance, many persons "feel better" after but not because of taking an herbal or vitamin supplement.

The distinction between using a placebo dishonestly and relying on the placebo effect is subtle but important. Consider this example of a doctor relying on the placebo effect without straying from candor:

Patient: "Doctor, is there anything you can do for my stomach cramps?"

Physician: "Many patients with your symptoms experience relief by adding fiber to their diet. Hopefully, by making you more regular, we can reduce your cramps."

Patient: "Is there any scientific basis for this?"

Physician: "The studies have been inconclusive, but I've seen many patients in your situation improve just by changing their diet or taking a fiber supplement."

If using placebos therapeutically is ethical and reasonable, shouldn't we encourage judges to render extralegal activist rulings, winegrowers to bottle "placebo" vintages, curators to display masterpiece look-alikes misleadingly, and journalists and newscasters to sanitize news? In such a world, all of us would be groping for truth in a hall of mirrors.

The doctor-patient partnership needs a shot of truth serum, not a saline injection. Sugar pills are bitter medicine. I find them too hard to swallow.

ACSH scientific advisor and freelance writer Michael Kirsch, M.D., practices gastroenterology in Mentor, Ohio.

(From *Priorities*, Vol. 10, No. 4)

Source URL: <https://www.acsh.org/news/1998/10/01/is-prescribing-placebos-ethical>

Links

[1] <http://www.gpposner.com/>