

The Placebo Effect and Its Ethical Implications:
A Review of the Literature
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Abstract

Much has been written on the legal and ethical implications, as well as the efficacy, of placebos, with members of the legal, medical, and psychiatric professions all having contributed to the literature on these issues. This paper reviews a significant portion of that literature in an attempt to determine whether or not placebo treatment is effective and, if it is, whether effectiveness outweighs ethical and potential legal problems surrounding such treatment.

Introduction

The history of placebo is as long and storied as the history of medicine itself. In fact, when you consider some of the medical treatments from the past, many were essentially placebos (Melmed). When translated from Latin, the word *placebo* means "I shall please" (Talbot). The traditional concept of placebos is the sugar pill, but there are many other things that can fall under that umbrella. Even the experts do not agree on a precise definition of a placebo; however, most seem to agree that it is some kind of relatively inert medical treatment (Brody; Nordenberg; Kapp; Brown). Researcher and writer Margaret Talbot also includes false surgeries, with just an incision made, in her definition of placebo. Placebos can do wonders for the human body and its malfunctions—it is well known that 30-40% of the participants in a placebo trial will experience relief from their symptoms (Talbot). The idea of placebo, though, comes along with serious ethical problems. Deception in the medical world has serious ramifications, and placebo prescription often entails that type of dishonesty. One is then led to wonder if the legal and ethical consequences of placebo usage are warranted by its effectiveness and success.

Are Placebos Effective?

One of the central parts of the research question is based on the supposed success of placebos. Howard Brody, M.D., points to Henry K. Beecher's famous 1955 doubleblind study, which established the legitimacy of the placebo effect for the first time in American medicine. Beecher's study showed that 30 to 40% of the participants in any given clinical study would experience positive results from taking a placebo. The F.D.A. also acknowledges the reality of the placebo effect. They will only sanction a drug if it is clearly proven to demonstrate superiority over placebos, which demonstrates the existence of the placebo effect (Lapierre). The effect is not limited to taking a pill, either. Placebo surgeries, in which incisions are made but no procedure is done, have been at times shown to cause more pain relief than subjects who actually received the surgery. Walter A. Brown, a doctor and a researcher, cites a study of patients who received surgery for angina pectoris. One hundred percent of patients who received an incision, but no procedure, reported significant improvement in their breathing. Only 76% of the patients who actually underwent the procedure reported improvement. Brown cites colds, asthma, short-term depression, high blood pressure and heart disease as afflictions that respond positively to a placebo

treatment. However, he also mentions that there are several diseases that will not respond -- such as long-term depression. Legal and medical expert Marshall Kapp also brings up that a placebo treatment can cause adverse side effects, such as nausea, vomiting, or headaches, in five to ten percent of patients. This is an important point because it forces us to see placebos as a true treatment, one that can have both positive and negative effects. The medical community seems to concur that the placebo effect is, for good or ill, real.

The Ethical and Legal Problem

It has been proven that the effects of placebo treatments are significant, but so is the debate that comes along with prescribing (or performing) them. Many issues accompany the prescription of placebos, the first being that of deception. Many medical professionals condemn the use of placebos in medicine. In fact, the AMA outlawed the use of placebos in medicine in its revised ethical policy in 2006 (Harris; Lapierre). Brody writes extensively on the moral dilemma of placebos in his article "The Lie That Heals: The Ethics of Giving Placebos." One of the most significant problems that he and others raise is breaking the bond of trust between doctor and patient (Brody; Harris; Kapp; Nordenburg; Talbot). This can lead to anger or mistrust if patients discover they have been duped. This is especially true in clinical studies. Talbot notes:

Of course, patients are often far from pleased to hear how well their placebos have worked. "Once we did a PMS study where we treated people for a month with placebo and then told people who'd responded what they'd been on," says Karen Weihs, a clinical psychiatrist at George Washington University. "And as it turns out, it's a very difficult thing to confront somebody with. Some people feel insulted, or silly. You're telling them it's all in their mind. We try to frame it positively -- your symptoms aren't so severe that you need medication; your mind has other ways of making you feel better. But that doesn't always help." (Talbot)

The lie also deprives patients of the chance to make their own medical decisions and, to some degree, deprives them of their medical autonomy (Kapp). Kapp also worries that accepting this "white lie" as acceptable would encourage and justify other deceptive activities in the medical community, a concern echoed by Michael Kirsh in Nordenberg's article: "In such a world [where placebos are ethically accepted], all of us would be groping for truth in a hall of mirrors" (qtd. in Nordenberg). Talbot also worries that this might lead to negligence by doctors who might be inclined to simply write a placebo prescription and be done with it. This could lead to undiagnosed illnesses. Brody also pointed out that the legitimization of placebos might lead to the notion that one can only be cured by drugs, an idea that the medical community certainly does not want to perpetuate. Also, the charge for the placebo medication is hard to determine because it is just a sugar pill (Brody).

In addition to the ethical and medical problems brought up by placebos, there are several legal problems that could arise (Talbot; Kapp). Kapp points out that there are four main consequences that could arise from the prescription of placebos: fraud, the lack of informed consent, malpractice, and breach of contract. All four are serious and could easily result in lawsuits.

Responses to Ethical and Legal Problems

Much of the literature about placebos offers possible responses to the most serious problems mentioned above. One of the newer and more debated solutions has been to cut out the deception. Talbot, Brown, and Brody all believe that the placebo effect might be just as successful without the deception. Brown suggests presenting the placebo thus:

Mrs. Jones, the type of depression you have has been treated in the past with either

antidepressant medicine or psychotherapy, one of the talking therapies. These two treatments are still widely used and are options for you. There is a third kind of treatment, less expensive for you and less likely to cause side effects, which also helps many people with your condition. This treatment involves taking one of these pills twice a day and coming to our office every two weeks to let us know how you're doing. These pills do not contain any drug. We don't know exactly how they work; they may trigger or stimulate the body's own healing processes. We do know that your chances of improving with this treatment are quite good. If after six weeks of this treatment you're not feeling better we can try one of the other treatments. (Brown)

This idea is still being studied, but has shown promising results so far, with patients still benefiting from the placebo without being deceived. Another solution to the problem of deception in clinical trials, proposed by Lapierre, is to include the possibility that the participant might receive a placebo in the statement of informed consent. Although this only addresses clinical studies, it is still a preventative measure against deception. Lapierre also believes it would keep the placebo effect intact because participants would still be unaware whether they were taking the actual drug or a placebo.

Kapp offers legal rebuttals to all four of the problems that he outlined previously. The first response to allegations of fraud would be that no damage was caused to the patient. Kapp cautions, however, that courts are beginning to look for favorably upon emotional damage, and this would still pose a problem. The second response, to allegations of malpractice, would be that no negligence occurred and the patient was treated in an effective and common way. Therapeutic privilege and a signed waiver are also ways to justify a medical placebo prescription (Kapp).

Conclusion: Ethical Problems vs. the Positive Placebo Effect

While most experts (Brody; Brown; Kapp; Lapierre; Melmed; Nordenburg; Talbot) seem to agree that prescribing false placebos under a total pretense is deceptive and wrong, Talbot, Melmed, Brown, and Brody also stress that a pill or treatment is not the only form of placebo. Often, a physician's care, understanding, and compassion will trigger a response similar to the placebo effect. In the end, Talbot believes, this is the type of doctors we want to see:

Besides, the physician who can marshal a placebo response with her words and manner probably comes closest to what many of us would think of as the profession's ideal -- the kind of doctor who seems wholly committed to our welfare, not the insurance company's; who knows when and how to give us hope, who listens closely but doesn't feel constrained from delivering advice; who knows us because she has taken the time to know us. (Talbot)

Perhaps such medical care—and caring—can indeed “marshal a placebo response,” at least in some patients, whether a placebo is actually administered or not. Nevertheless, for others, more concrete, measurable signs of medical attention may be needed. For these patients, it is worth investigating further the effects of removing the deception from the placebo treatment (Brody; Brown; Kapp; Talbot). Long-term studies, qualitative as well as quantitative, are certainly warranted in that specific area and directed toward answering the question of whether placebo treatments are equally effective when prescribed with patients’ full knowledge and consent.

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