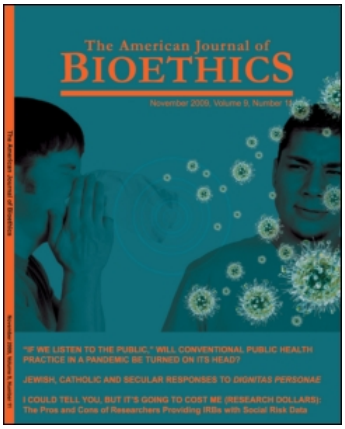

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Placebo Is Far From Benign: It Is Disease-Mongering

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Placebo Is Far From Benign: It Is Disease-Mongering

Alain Braillon, Hôpital Nord

The placebo effect was first described at the end of the 18th century, when Benjamin Franklin and Antoine Lavoisier investigated Franz Mesmer's magnetic healing techniques. Nowadays, scientific analysis separates the placebo effect into the response to three components: 1) assessment and observation of subjective outcome, 2) therapeutic ritual, and 3) a supportive patient-practitioner relationship (Kaptchuk et al. 2008). New methods are used to highlight neurobiological evidence and showed the activation of specific brain regions after administration of a placebo. This is not surprising: it is the result of a psychosocial effect based upon the subject's expectation.

This scientific analysis is verbiage for marketing. Pragmatically, the placebo effect is simply a belief. Placebos do nothing. Placebos do not affect health outcomes such as mortality and morbidity. Placebos do not have powerful objective clinical effects: the subjective patient-reported alleviation is small, observed in only one third of the subjects and only under certain conditions (if you slip a placebo into a person's drink, it does not work). The effect, if any, rapidly wears off and it cannot be distinguished from reporting biases. One of these biases is well known in psychology: the *Hawthorne effect*.

Placebo is Latin for "I will please"; the doctor's duty is not to please but to help. Sadly, in too many cases, we would like to help more the patient but we cannot. The numerous successes of medical science have not changed our duty since the 16th century when Ambroise Paré claimed that the physician's duty was to "occasionally cure, often relieve, and always console." There is no need for placebos to provide reassurance, comfort and hope. Several skills are pivotal in the physicians' relationships with their patients: take time; be open and listen; remove barriers; let the patient explain; share authority; be committed . . . placebo cannot replace them.

Today in the real world, despite continuous progress in health and longevity more and more people are worried about their health with unreasonable fear and irrational

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expectations. A placebo is a dangerous tool. Resorting to a placebo to get rid of a troubling patient can delay the proper diagnosis of a serious medical condition. It also jeopardizes the doctor-patient relationship, which is based on trust. Lying to the patient is a serious breach of confidence and it risks a backlash. Moreover placebos strengthen medical arrogance and infantilize people.

In 1923, Jules Romains wrote a comedy: "Knock or the Triumph of Medical Science" in which, thanks to frightening graphs, an inventive village doctor succeeds in turning the robust inhabitants into confirmed hypochondriacs (Bamforth 2002). It has a name: "disease-mongering". By defining vague symptoms as an entity requiring a treatment healthy people are converted into patients (Braillon and Bernardy-Prud'homme 2008). They need explanation and reassurance that promote autonomy, not to be given faith in a non-existent disease and crackpot medicine: 'Be strong and of good courage, there is nothing wrong with you". Why do so many doctors avoid telling people the truth? Oncologists have learnt how to do it for more serious conditions.

In order to respect the informed consent principle, some physicians say that the prescription is inert when they prescribe a placebo (Tilburt et al. 2008). By doing so, they fall from magic into insanity: they reduce the second component of the placebo effect.

Homeopathic preparations may be the most common used inert placebo. Across Europe the situation differs from country to country. In the United Kingdom, the vast majority of primary care trusts have cut funding for homeopathic preparations and the number of prescriptions for these remedies dropped from 83,000 in 2005 to 49,300 in 2007, despite an increase in the number of prescriptions for medical treatments overall. No one seems to have noticed an increase in mortality or in morbidity. In France much of the cost of homeopathic remedies is reimbursed under the mandatory National Health Service scheme and everything is done to increase the faith in the remedy. The high price increases the subjective effect (Waber et al. 2008). For example, the homeopathic preparation of ginkgo biloba costs 0.53 € per day while captopril for hypertension costs 0.33 € per day (diuretics are even cheaper). On a volume basis, homeopathic preparation of ginkgo biloba is 175 € per liter; however, no effect can be observed. In 2007, the French Medicine Agency (Afssaps, France]) issued a national official warning to pharmacists and doctors after a mix-up in the labeling of two homeopathic preparations by the company: "Vials labelled Ginkgo biloba mother tincture contain Equisetum arvense mother tincture and vice-versa . . . between May and October" (Dcscience 2007). There were no claims, nor reports for a decreased efficacy or adverse effects due to this mix-up.

More seriously, some placebos are not inert. Money-hungry quacks supply various minerals, herbs, and 'natural' products that must not be considered as placebo. They might contain junk ingredients that are dangerous, as confirmed by many reports. No changes since Fleurant, a money-hungry apothecary, who supplied unicorn's horn to the "Imaginary Invalid" (Molière 1673). The second case is a new emerging challenge: the inappropriate use of true medications to satisfy anxious patients or parents expecting treatment be given to their child (Tilburt 2008). A national campaign "Antibiotics are not automatic" was necessary to cut the incredible antibiotic overuse in France (Sabuncu et al. 2009). The use of true medications as placebo only exposes to adverse effects, nothing else.

In my view, placebos must be restricted to clinical trials and then only to measure the 'nuisance' effects in the experimental setting. Even here their use is very limited: the Helsinki Declaration stressed that new therapies must be tested against the current standard of care, not against placebos. Again, placebo is far from benign. Recently a clinical trial investigated the effect of etanercept for the treatment of alcoholic hepatitis (Boetticher et al. 2008). Etanercept was compared to a placebo rather than the standard care despite that the American Society of Gastroenterology states that "corticosteroids should be used in patients with severe alcoholic hepatitis in whom the diagnosis is certain" (McCullough and O'Connor 1998). Corticosteroids have a proven efficacy against mortality in this condition: pooling data from all published studies shows that corticosteroids allow a risk reduction in mortality (five patients need to be treated with corticosteroids to prevent one death). The etanercept trial with its placebo arm was not scientifically justified and again had serious adverse effects.

An ethical debate is not necessary for placebo. Just ask yourself, "Whose interests are served?" and just remember that, "You must provide effective treatments based on the best available evidence." ■

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