

community has devised the *active placebo*. An active placebo is a placebo with properties that mimic the symptoms or side effects, for example dry mouth, or sweating, that might otherwise reveal whether any given subject is in the study drug group or placebo group (13,14).

VI. SUBJECTS IN THE PLACEBO ARM MAY RECEIVE BEST SUPPORTIVE CARE OR PALLIATIVE CARE

Best supportive care (BSC) and palliative care are treatments used in the context of clinical trials, as well as outside of clinical trials, for example in a hospice. Typically, best supportive care and palliative care include pain control, emotional support, and efforts to maximize health-related quality of life. These types of care may include treatments intended to maximize quality of life, pain control, antibiotics, analgesics, anti-emetics, and treatment of coughs (15).

The National Consensus Project for Quality Palliative Care, an organization that devotes itself to promoting palliative care, provides a definition of palliative care. This definition, in part, is: “Palliative care is operationalized through effective management of pain and other distressing symptoms, while incorporating psychosocial and spiritual care with consideration of patient/family needs, preferences, values, beliefs, and culture” (16). The above organization focuses its efforts on disorders, such as Alzheimer’s disease, Parkinson’s disease, dyspnea, multiple sclerosis, heart failure, and cancer, in the context of people in the final months or weeks of life.

The definitions of best supportive care and of palliative care are sometimes not clearly set forth in medical publications. Zafar et al. (17,18) suggest that the medical writers ensure that these types of care be detailed in any publications or reports. Prof. R.L. Schilsky (19) finds that:

[m]ost palliative care experts feel that PC [palliative care] is a component of cancer care from the time of diagnosis until death, and encompasses essentially all aspects of medical and psychological management directed at symptom control and improving QoL. Best supportive care does the same but the term often refers to palliative care applied primarily when active anti-cancer treatment is no longer being applied. Thus while newly diagnosed patients being treated with curative

¹³ Schulz KF, Chalmers I, Altman DG. The landscape and lexicon of blinding in randomized trials. *Ann Intern Med.* 2002;136:254–259.

¹⁴ Moncrieff J, Wessely S, Hardy R. Active placebos versus antidepressants for depression. Cochrane Database of Systematic Reviews 2004, Issue 1. Art. No.: CD003012. DOI: 10.1002/14651858.CD003012.pub2.

¹⁵ Zafar SY, Currow D, Abernethy AP. Defining best supportive care. *J Clin Oncol.* 2008;26:5139–5140.

¹⁶ National Consensus Project for Quality Palliative Care. *Clinical Practice Guidelines for Quality Palliative Care*, 2nd ed. Pittsburgh, PA, 2008.

¹⁷ Zafar SY, Currow D, Abernethy AP. Defining best supportive care. *J Clin Oncol.* 2008;26:5139–5140.

¹⁸ Cherny NI, Abernethy AP, Strasser F, Sapir R, Currow D, Zafar SY. Improving the methodologic and ethical validity of best supportive care studies in oncology: lessons from a systematic review. *J Clin Oncol.* 2009;27:5476–5486.

¹⁹ Schilsky RL. E-mail of October 10, 2010.