SUBJECT: H331-A/14 END-OF-LIFE CARE – USE OF PLACEBOS IN

SUBMITTED BY: Bureau of Osteopathic Clinical Education and Research

REFERRED TO: Committee on Professional Affairs

RESOLVED, that the Bureau of Osteopathic Clinical Education and Research recommend that
the following policy be REAFFIRMED as AMENDED:

H331-A/14 END-OF-LIFE CARE – USE OF PLACEBOS IN

The AOA approves the attached position paper on Use of Placebos for Pain Management in
End-of-Life Care and will be updated according to the current literature. 2004; 2009; reaffirmed
as amended 2014

USE OF PLACEBOS FOR PAIN MANAGEMENT IN END-OF-LIFE CARE

The placebo effect of medication can be a significant resultant action of any prescription.
However, the substitution of a placebo in place of effective pain medication has been widely
recognized as unethical, ineffective and potentially harmful. A number of
organizations have advised against the use of placebo substitution, including the American Pain
Society, Agency for Healthcare Policy and Research, World Health Organization, the
Healthcare Facilities Accreditation Program, Joint Commission on Accreditation of Healthcare
Organizations, Education on End-of-Life Care Project (co-sponsored by the American Medical
Association), American Nursing Association, and the American Society of Pain Management
Nurses.

This white paper describes the literature and rationale in support of the AOA’s position on the
controversial subject of the use of placebos for pain management in terminally ill patients.

I. Definition of Terms
A. Placebo, placebo substitution, placebo effect and nocebo response

A placebo is a substance presumed to be pharmacokinetically inert. Placebo substitution
means the substitution of a physiologically inactive substance for a comparison with the
physiologically active substance. Placebo effect is the positive psychosomatic response
of an individual to a treatment; in contrast, the nocebo response is a negative
psychosomatic response to a treatment. The placebo effect is an important adjunct in
the treatment of symptoms. The alleviation of symptoms has an inherent positive
psychological component; patients who perceive their symptoms to be relieved by the
treatment and trust in their treating physician’s treatment plan and/or prescription for
the symptom relief are more likely to obtain relief. 

Placebo responses are necessary for controlled clinical trials in which the patient is
informed that a placebo may indeed be utilized. Physiologic responses to placebo can be
pleasant or unpleasant to the patient. An unpleasant effect attributable to administration
of a placebo is called a “nocebo response”. A pleasant effect is called a “positive
placebo response”. It has been noted that, “a positive placebo response simply speaks
to the strength of an individual’s central control processes (i.e., mind) to recruit their
descending inhibitory system to block pain. The trained osteopathic physician knows
that pain relief occurs both in the mind and in the body.” The basis of the placebo
effect in a therapeutic physician-patient relationship also involves good communication
skills as well as listening to the patient.

To summarize, a placebo is a type of treatment, necessarily used in controlled clinical
trials, that has no inherent physiological action yet is designed to mimic a therapy with a
known active physiologic effect. Positive changes resulting from placebo administration
would be due to expectations of success by the patient. Thus, the use of placebo effect
is based on the patient’s perception of the role of the placebo agent with symptom
relief. The placebo response may be enhanced with a positive patient-physician
relationship.

B. Addiction, substance abuse and dependence, tolerance, withdrawal and pseudo-
addiction.

Some physicians inappropriately justify using placebo in pain management to avoid
“addicting” the patient. Addiction, as defined by the American Academy of Pain
Medicine, is a primary, chronic, neurobiologic disease, with genetic, psychosocial,
and environmental factors influencing its development and manifestations. It is
characterized by behaviors that include one or more of the following: impaired control
over drug use, compulsive use, continued use despite harm, and craving.” Actually, it is
rare for a person to develop an addiction to pain medications.

Substance abuse is defined as psychological and physical dependence on substances.
Some physicians are concerned that prescribing narcotics may lead to substance abuse
and therefore may attempt to use a placebo to assess whether the patient truly requires
narcotics for pain relief. However, there is no scientific basis for using placebo in the
assessment of the patient in pain who has or may have the potential for a substance
abuse. The Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-
V), lists definitive criteria for diagnosis of psychological and physical dependence
on substances. This text categorizes “Substance-Related Disorders” but does not utilize
the term addiction; further, nowhere in the DSM-V is placebo administration utilized
with criteria for diagnosing various forms of substance abuse. Substance dependence is
defined as a cluster of cognitive, behavioral and physiological symptoms. The essential
feature of a substance dependent individual is continuous use of the substance despite
significant substance-related problems, such as deleterious effects on occupation,
relationships, health, and others.

Physicians may become uncomfortable with requests for increased dosages of pain
medications, fearing that a patient is manifesting a substance-related disorder. A better
understanding of the concepts of tolerance, physical dependence, physiological
dependence withdrawal symptoms and pseudo-addiction, may help physicians
understand and more effectively treat these patients.

Tolerance represents a markedly diminished effect that can occur with continued use of
most medications; the degree depends upon the daily dose and length of use. The need
for medication titration, either due to development of tolerance or to incomplete
responsiveness, is a part of routine medical care. Tolerance occurs due to compensatory
changes in receptors and/or increased clearance resulting from induction of various
metabolic pathways. The problem of tolerance should therefore be anticipated as a possible outcome in prescription pain medications.

Withdrawal is defined by the DSM-V as a maladaptive behavioral change having physiological and cognitive concomitants, which occurs when blood or tissue concentrations of a substance decline in an individual who had maintained prolonged use of the substance, frequently inappropriately. Examples of withdrawal include the onset of seizures or delirium tremens in a newly abstinent alcohol chemically dependent individual.

Pseudo-addiction is the term used to describe the behavior of a patient in pain who is receiving an insufficient amount and/or an inappropriate dosing frequency of administration of the prescribed pain medication. In an effort to obtain relief, the patient in pain would request more frequent and/or increased medication. Such “drug seeking behavior” has been deemed as “proof” of “addiction.” The reason for such requests is frequently that the patient is under-dosed, receiving too little of the medication and/or too long a delay between doses of the pain medication. In such instances, the patient receives inappropriate pain relief, which is not an appropriate criterion of a substance-abusing patient according to the DSM-V.

II. Legal Considerations in the Use of Placebos in Pain Management

While there are no specific laws governing the use of placebos in any circumstance, there is a considerable amount of legislation regarding a patient’s right to pain management. There are several state statutes that address this issue, some of which are based on the Federation of State Medical Boards’ Model Guidelines for the Use of Controlled Substances for the Treatment of Pain. This document clarifies that legislative statutes accepting these guidelines understand the ongoing increased scientific knowledge of pain management, and thus have no need to modify legislation as the science of pain management changes. This document does not mention placebo usage.

The American Bar Association (ABA) adopted a resolution concerning the promotion of pain management in all patients with chronic pain. This resolution states, “…that the American Bar Association urges federal, state and territorial governments to support fully the rights of individuals suffering from pain to be informed of, choose, and receive effective pain and symptom evaluation, management and ongoing monitoring as part of basic medical care, even if such pain and symptom management may result in analgesic tolerance, physical dependence or as an unintended consequence shorten the individual’s life.” Placebo substitution for active pain medicine without informed consent on the part of the patients clearly violates the nature and substance of the ABA’s position. Additionally, in two Supreme Court decisions regarding the right to assisted suicide, the court promoted the right of individuals to appropriate palliative care and pain management.

While there is little case law concerning tort or administrative findings against physicians for inadequate pain management, this is likely to change in the near future. The main barrier to malpractice claims for inadequate pain management is use of the customary local standard to determine what constitutes ordinary care. The courts are steadily moving away from this standard to a national standard which uses clinical guidelines as the determinant of ordinary care. This is seen in the decision in the case of Nowatske v. Oserloh, where the court stated, ”should customary medical practice fail to keep pace with development and advances in medical science, adherence to custom might constitute a failure to exercise ordinary care…”
Guidelines developed by the Agency for Healthcare Policy and Research, now the Agency for Healthcare Research and Quality (1), the American Pain Society, (7) as well as the Joint Commission on Accreditation of Healthcare Organizations as (20) are good examples of sources the courts are using to determine ordinary practice. These guidelines do not support the use of placebo in any fashion except in approved research studies when the appropriate patient informed consent has been obtained. Therefore, the physician thus cannot justify the use of placebo for pain management by attempting to diagnose “addiction” or with support from any of the above regulatory agencies. (1, 13, 17)

Furthermore, under California’s elder abuse statute, a physician was successfully sued by the deceased’s family for inadequate pain management at the end of life. (22)

III. Adverse Effects of Placebo Use

Pain is a universal experience and is subjective by nature. Despite the common colloquialism, “I feel your pain,” no individual can truly experience another’s pain. There are no laboratory tests or consistently reliable physical findings for assessment of pain. Patient self-report remains the gold standard for pain assessment. (14) Use of a placebo in place of an effective pain medication for attempting to determine whether the patient at end-of-life is really in pain is under no circumstances appropriate.

There is a concern if a physician deceives the patient and substitutes a placebo treatment in the place of a known effective treatment without informing the patient. Deception has no place within the therapeutic relationship and is counter-productive. A physician may counsel a patient that “this treatment may be effective in treating your condition,” but evidence-based medicine cannot guarantee a treatment outcome.

In this era of informed consent, deception of the patient poses many problems, including erosion of the trust individuals and society as a whole have for physicians. There are methods of using placebos and the placebo effect that do not involve deceit, e.g., clinical trials or the use of placebo as one of the trial agents for neurolytic block. This one narrow exception uses the placebo trial as part of the treatment selection for neurolytic blockade, a highly specialized procedure performed by a few skilled pain management physicians with appropriate informed consent.

Substituting placebo for accepted forms of pain treatment is under-treatment of the condition. Under-treatment of pain, as detailed in the American Bar Association’s 2000 report, is an ongoing problem. (22) While there have been reports of placebo efficacy in pain management, placebo control of pain occurs in fewer patients and for shorter duration than active pain treatments. (24, 26) It has also been argued that the prescription of an ineffective placebo in place of effective pain medication can act as a “suicidogen,” whereby an individual in pain who is given inadequate medication for relief may be prompted to hasten his/her death. (11) In the clinical setting, substitution of a placebo for an active pain medication, even with the consent of the patient, is clinically suspect because better treatment alternatives exist and there are risks associated with the use of placebos. It is therefore inappropriate to substitute a placebo for a medication known to be effective in the treatment of a patient with the verified pain of a terminal illness.

Additionally, placebos are associated with side effects (25) and potentially precipitate hyperalgesia or withdrawal in patients previously treated with pain medications.

IV. Summary
Exquisite management of end-of-life pain is a medical imperative. Use of a placebo in place of known effective pain medication for determining whether the patient is really in pain is under no circumstances appropriate. Use of placebos does not meet the accepted criteria to diagnose substance abuse, commonly referred to by some physicians as “addiction.” There is no medical justification for the use of placebos to assess or treat pain at end of life.

The only appropriate use of a placebo is in approved clinical research with informed consent.

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Explanatory Statement:
Striking out statement on page 2 (lines 20-21) and corresponding reference. All remaining references
have been checked and revised editorially.

ACTION TAKEN _____________________

DATE ______________________________