Position Statement on
Use of Placebos in Pain Management

The American Society for Pain Management Nursing (ASPMN) holds the position that placebos should not be used by any route of administration in the assessment and/or management of pain in any individual regardless of age or diagnosis. ASPMN supports the use of placebos only in Institutional Review Board (IRB) - approved clinical trials.

Definition:
A *placebo* is defined as any medication or procedure that produces an effect in patients resulting from its implicit or explicit intent and not from its specific physical or chemical properties (Bok, 1974). Placebos often take the form of sugar pills, saline injections, miniscule doses of drugs, or sham procedures designed to be void of any known therapeutic value. In contrast, the *placebo effect* is a perceptible, measurable consequence of receiving a placebo that may have a healing or harmful effect. Positive placebo effects may include symptom reduction or improvements in physiological parameters (e.g., blood pressure) and are believed to be due to mind-body or interpersonal (e.g., attitude and intent of caregiver) factors (Arnstein, 2003). Negative placebo effects, ranging from minor discomforts to life-threatening complications, have also been associated with placebo use and are cited in the research literature (Benedetti et al., 1998; Lavin, 1991; Turner, Deyo, Loeser, Von Korff, & Fordyce, 1994; Wolf & Pinsky, 1954).

Informed consent is the voluntary process by which a fully informed individual (or surrogate representative) participates in making choices about health care. Informed consent for the administration of placebos (in approved clinical trials) can be provided by a mentally competent patient/representative who understands: what the placebo is; what alternative treatments are available; and the risks, benefits, and uncertainties specific to both the placebos and alternatives (Brody, 1998). Informed consent is obtained from participants who are 1) told of the study's design, potential benefits, and risks or burdens, 2) fully understand the information provided, including alternatives, and 3) agree to participate in the study voluntarily without coercion (Casarett, Karlawish, Sankar, Hirschman, & Asch, 2001).

Background:
Pain is a complex, multidimensional phenomenon with physical, emotional, social, and spiritual aspects (Ferrell, 1995). Pain is universal in prevalence but uniquely subjective in experience. Health professionals and family members consistently underestimate the presence and intensity of a patient's pain (Cohen-Mansfield, 2002; Marquie et al., 2003; Singer, Gulla, & Thode, 2002; Solomon, 2001). For these reasons, assessments of pain should be based, when possible, on the patient's self-report (McCaffery & Pasero, 1999). Behavioral and observational indices are reserved for use in non-verbal or non-communicative patients who are unable to convey their perception of pain (Malviya, Merkel, Shayevitz & Voepel-Lewis, 1997; Griffie, Kovach, Muchka, Noonan, & Weissman, 2002).

One of the ways that pain is erroneously assessed and improperly treated is in the administration of placebos outside the context of an IRB-approved research study. Placebos administered in

this manner are often intended to discredit the patient's report of pain or discomfort and cast doubt on its validity. It is actually the deceptive use of placebos that defies the precept of truth-telling.

In 1996, the Oncology Nursing Society (ONS) issued a position statement against the use of placebos in managing cancer pain (ONS, 1996). This position was endorsed by twenty-seven other professional organizations including the American Nurses Association (ANA) (1996). Within a year, the American Society of Pain Management Nurses (1996) published its first position statement opposing the deceptive use of placebos, regardless of age or diagnosis. In 2000, the American Medical Association (AMA) established strict guidelines that limited the use of placebos in medical and surgical patients to well-designed, IRB-approved clinical trials (AMA, 2001)

Patients with pain, and their families, have a right to expect that the therapies provided are based on rational, scientifically valid evidence (Wall, 1993), and delivered in a context of mutual respect, trust, and truth-telling (ANA, 2001). Whether well-intentioned or punitively directed, placebo use without consent compromises the therapeutic relationship between patients and healthcare providers. It erodes the necessary environment of trust, and serves to defy the precepts of truth-telling, informed consent, and respectful care (Coggins, 2000).

Legal Tenets:
The concealed use of placebos carries the risk of liability for fraud, malpractice, breach of contract, and the violation of informed consent requirements. Attorneys from different parts of the country have concurred that placebos violate informed consent and their use constitutes both medical negligence and deception that no court would excuse (Fox, 1994). This premise has been tested in the courts, awarding $15 million to the estate of Henry James, a 71-year-old bone cancer patient who was given placebos instead of opiates for pain. Unfortunately it was too late to award anything to Mr. James, who died with severe unmanaged pain (Brider, 1991; Shapiro, 1996).

Ethical Tenets:
The ethical principle of beneficence (the duty to benefit another) obliges healthcare professionals to manage pain and provide humane care to all patients. Both professional organizations and accrediting agencies have echoed this mandate. The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) states that patients have the right to appropriate assessment and management of pain (JCAHO, 2001; Berry & Dahl, 2000). The American Medical Association's Principles of Medical Ethics (2001) have been adapted by the American Pain Society (1996) to apply to all clinical disciplines, and state that "a healthcare provider shall deal honestly with patients and colleagues, and strive to expose those healthcare providers deficient in character and competence or who engage in fraud or deception." In addition to veracity (truth-telling), other ethical principles such as fidelity (faithfully performing a duty) and justice (providing a comparable level of care to all patients) may be violated by placebo use. The concealed use of placebos directly conflicts with these rights and norms of professional behavior.

The rationale for placebo administration on the grounds that it does no harm (nonmaleficence) ignores the risks associated with uncontrolled pain. The undertreatment of pain is widespread and well substantiated (Agency for Health Care Policy and Research [AHCPR], 1992; Allcock, McGarry, & Elkan, 2002; Anderson et al, 2000; Bernabei et al., 1998; Breitbart et al., 1996; Cleeland et al., 1994; Cleeland, Gonin, Baez, Loehrer, & Pandya, 1997; Desbiens, Mueller-

Rizner, Connors, Wenger, & Lynn, 1999). The potential harm caused by inadequately managed pain includes delayed healing (Cooper, 1990; Houldin, Lev, Prystowsky, Redei, & Lowery, 1991; Pokela, 1994; Puntillo & Weiss, 1994; Weiner & Rudy, 2002); interference with independent function (Cooper, Tate, Yassi, & Khokhar, 1996; Gronblad, Hurri, & Kouri, 1997; Lindstrom, Ohlund, & Nachemson, 1995; Robbins, 1994); diminished quality of life (Ferrell, 1995; Simmonds & Claveau, 1997); increased morbidity and mortality (Rosenfeld et al., 1996; Ben-Eliyahu, Liebeskind, Page, & Yirmiya,1993; Miaskowski & Sutters, 1997) and higher healthcare costs (Grant, Ferrell, Rivera & Lee,1995).

Respect for the dignity of patients and their right to self-determination is a central ethical tenet of the American Nurses Association's (2001) *Code for Nurses*. Patients have a moral and legal right to receive accurate, complete, and understandable information in order to make informed decisions. Nurses are not only justified in refusing to participate in placebo use outside the context of an IRB-approved clinical trial, they are morally obliged to protect patients from potential harm and deceptive practices (Tucker, 2001). As in the case of Henry James, nurses can be held fiscally liable for administering placebos to patients with pain (Shapiro, 1996).

Recommendations:

1) Establish policies to ensure that no patient will receive a placebo unless it is in the context of an IRB-approved clinical trial. For example the policy could state: It is the policy of [name of organization] to prohibit the administration of placebos unless it is done within the context of an IRB-approved clinical trial. The policy should include at least the following elements:
    - Mechanisms of reporting if policy is violated by a prescriber or clinician, including notification of the appropriate supervisor/managers.
    - The appropriate venue(s) where violations of the policy will be discussed (e.g., Ethics Committee, Risk Management, Quality Assurance, Utilization Management, Credentialing Departments).
    - Actions taken to censure those who prescribe and/or administer placebos, including penalties for repeated violations.
    - Rationale for not administering placebos based on current literature, position papers, policies, codes of professional behavior, JCAHO standards, and evidence-based clinical practice guidelines.
    - Protection of those who refuse to administer and those who report the use of placebos outside the context of an IRB-approved clinical trial.
2) Health professionals should be informed that despite a valid written order (even with informed consent), that administering a placebo outside the context of an IRB-approved clinical trial is prohibited. Institutional procedures for informing the prescriber and supervisor about the inability to execute an order to administer placebos without IRB-approval should be detailed.
3) To establish these policies and procedures, involve key stakeholders such as:
    - Pharmacy and Therapeutics Committee
    - Ethics Committee
    - Risk Management/Legal Department
    - Quality Assurance and Utilization Management professionals
    - Credentialing Departments
4) Clinical Practice Committees (or equivalent committees addressing the clinical practice of nurses, pharmacists and physicians).

Summary:
Placebo use for the assessment and/or treatment of pain, including the evaluation of response to pain treatments, constitutes fraud and deception. Placebo use in this manner is associated with substandard assessment and treatment of pain. Therefore, the American Society for Pain Management Nursing adamantly opposes the use of placebos. Professionals are urged to refuse to administer placebos and institutions are advised to establish policies that prohibit their use outside the context of an IRB-approved research study.

Written by: Candace C. Coggins, MS, MA, CARN, NP; Paul Arnstein, Ph.D, RN; Sal Leahy, RN, MSN

July 2004

References

Agency for Health Care Policy and Research (AHCPR). (1992). *Acute pain management: Operative or medical procedures and trauma clinical practice guideline*. (Publication No. 92-0032). Rockville, MD: Author.

Allcock, N., McGarry, J., & Elkan, R. (2002). Management of pain in older people within the nursing home: A preliminary study. *Health and Social Care in the Community, 10*(6), 464-471.

American Medical Association. (2001). *Principles of medical ethics.* Retrieved June 1, 2003, from http://www.ama-assn.org/ama/pub/category/2512.html

American Nurses Association. (2001). *Code of ethics for nurses with interpretive statements.* Washington, DC: American Nurses Publishing.

American Nurses Association & Oncology Nursing Society. (1991). *Use of placebos for pain management in patients with cancer*. [Position statement]. Retrieved June 1, 2003, from http://nursingworld.org/readroom/position/social/scpain.htm

American Pain Society. (1996). *Ethical principles of the American Pain Society*. Retrieved June 1, 2003, from http://www.ampainsoc.org/about/ethics.htm

American Society of Pain Management Nurses. (1996). *Use of placebos for pain management* [Position statement]. Pensacola, FL: Author.

Anderson, K.O., Mendoza, T.R., Valero, V., Richman, S.P., Russell, C., Hurley, J., DeLeon, C., Washington P., Palo, G., Payne, R., Cleeland, C.S. (2000). Minority cancer patients and their providers: Pain management attitudes and practice. *Cancer*, *88*(8), 1929-1938.

Arnstein, P. M. (2003). The placebo effect. In E. Leskowitz (Ed.), *Complementary and alternative medicine in rehabilitation* (pp. 149-160). New York: Churchill Livingstone.

Benedetti, F., Amanzio, M., Baldi, S., Casadio, C., Cavallo, A., Mancuso, M., Ruffini, E, Oliaro, A., Maggi G. (1998). The specific effects of prior opioid exposure on placebo analgesia and placebo respiratory depression. *Pain*, *75*(2-3), 313- 319.

Bernabei, R., Gambassi, G., Lapane, K., Landi, F., Gatsonis, C., Dunlop, R., Lipsitz, L., Steel, K., Mor, V. (1998). Management of pain in elderly patients with cancer. SAGE Study Group. Systematic Assessment of Geriatric Drug Use via Epidemiology. *Journal of the American Medical Association*, *279*(23), 1877-1882.

Berry, P.H., & Dahl, J.L. (2000). The new JCAHO pain standards: Implications for pain management nurses. *Pain Management Nursing, 1*(1), 3-12.

Bok, S. (1974). The ethics of giving placebos. *Scientific American*, *231*(5), 17-23.

Brider, P. (Ed.). (1991). Jury says neglect of pain is worth $15 million award. *American Journal of Nursing*, *91*(1), 11.

Breitbart, W., McDonald, M.V., Rosenfeld, B., Passik, S.D., Hewitt, D., Thaler, H., & Portenoy, R.K. (1996). Pain in ambulatory AIDS patients, I: Pain characteristics and medical correlates. *Pain*, *68* (2-3), 315-321.

Brody, B.A. (1998). *The ethics of biomedical research: An international perspective*. New York: Oxford University Press.

Casarett, D., Karlawish, J., Sankar, P., Hirschman, K.B., Asch, D.A. (2001). Obtaining informed consent for clinical pain research: Patients' concerns and information needs. *Pain, 92* :,71-79.

Cleeland, C.S., Gonin, R., Baez, L., Loehrer, P., & Pandya, K.J. (1997). Pain and treatment of pain in minority patients with cancer. The Eastern Cooperative Oncology Group Minority Outpatient Pain Study. *Annals of Internal Medicine*, *127*(9), 813-816.

Cleeland, C.S., Gonin. R., Hatfield, A.K., Edmonson, J.H., Blum, R.H., Stewart, J.A., & Pandya, K.J. (1994). Pain and its treatment in outpatients with metastatic cancer. *New England Journal of Medicine*, *330*(9), 592-596.

Coggins, C. (2000). Therapeutic use of placebo: Case-specific justification or rhetorical oxymoron? [Letter]. *Journal of Nursing Scholarship*, *32*(2), 115.

Cohen-Mansfield, J. (2002). Relatives' assessment of pain in cognitively impaired nursing home residents. *Journal of Pain and Symptom Management*, *24*(6), 562-571.

Cooper, D.M. (1990). Optimizing wound healing: A practice within nursing's domain. *Nursing Clinics of North America*, *25*(1), 165-179.

Cooper, J.E., Tate, R.B., Yassi, A., & Khokhar, J. (1996). Effect of an early intervention program on the relationship between subjective pain and disability measures in nurses with low back injury. *Spine*, *21*(20), 2329-2336.

Desbiens, N.A., Mueller-Rizner, N., Connors, A.F., Jr., Wenger, N.S., & Lynn, J. (1999). The symptom burden of seriously ill hospitalized patients. SUPPORT Investigators. Study to Understand Prognoses and Preferences for Outcome and Risks of Treatment. *Journal of Pain and Symptom Management,17*(4), 248-255.

Ferrell, B.R. (1995). The impact of pain on quality of life: A decade of research. *Nursing Clinics of North America*, *30*(4), 609-624.

Fox, A.E. (1994). Confronting the use of placebos for pain. *American Journal of Nursing*, *94*(9), 42-46.

Grant, M., Ferrell, B.R., Rivera, L.M., Lee, J. (1995). Unscheduled readmissions for uncontrolled symptoms. A health care challenge for nurses. *Nursing Clinics of North America, 30* (4):, 673-682.

Gronblad, M.M., Hurri, H., & Kouri, J. (1997). Relationship between spinal mobility, physical performance tests, pain intensity and disability assessments in chronic low back patients. *Scandinavian Journal of Rehabilitation Medicine*, *29*(1), 17-24.

Houldin, A.D., Lev, E., Prystowsky, M.B., Redei, E., & Lowery B.J. (1991). Psychoneuro-immunology: A review of literature. *Holistic Nursing Practice*, *5*(4), 10-21.

Joint Commission on Accreditation of Healthcare Organizations (JCAHO). (2001). JCAHO pain standards for 2001. Retrieved June 1, 2003, from http://www.jcaho.org

Kovach, C.R., Noonan, P.E., Griffie, J., Muchka, S., & Weissman, D.E. (2002). The assessment of discomfort in dementia protocol. *Pain Management Nursing*, *3*(1),16-27.

Lavin, M.R. (1991). Placebo effects on the mind and body. *Journal of the American Medical Association*, *265*, 1753-1754.

Lindstrom, I., Ohlund, C., & Nachemson, A. (1995). Physical performance, pain, behavior &

subjective disability in patients with subacute low back pain. *Scandinavian Journal of Rehabilitation Medicine*, *27*(3),153-160.

Marquie, L., Raufaste, E., Lauque, D., Marine, C., Ecoiffier, M., & Sorum, P. (2003). Pain rating by patients and physicians: Evidence of systematic pain miscalibration. *Pain*, *102*(3), 289-296.

McCaffery, M., & Pasero, C. (1999). *Pain clinical manual* (2nd ed.). St. Louis: Mosby.

Merkel, S.I., Voepel-Lewis, T., Shayevitz, J.R., & Malviya, S. (1997). The FLACC: A behavioral scale for scoring postoperative pain in young children. *Pediatric Nursing*, *23*(3), 293-297.

Oncology Nursing Society. (1996). *Use of placebos for pain management in patients with cancer* [Position statement]. Pittsburgh, PA: Author.

Page, G.G., Ben-Eliyahu, S., Yirmiya, R., & Liebeskind, J.C. (1993). Morphine attenuates surgery-induced enhancement of metastatic colonization in rats. *Pain*, *54*(1), 21-28.

Pokela, M.L. (1994). Pain relief can reduce hypoxemia in distressed neonates during routine treatment procedures. *Pediatrics*, *93*(3), 379-383.

Puntillo, K., & Weiss, S.J. (1994). Pain: Its mediators and associated morbidity in critically ill cardiovascular surgical patients. *Nursing Research*, *43*(1), 31-36.

Robbins, L. (1994). Headaches and the immune system. *NHF Head Lines*, *91*, 8.

Rosenfeld, B., Breitbart, W., McDonald, M.V., Passik, S.D., Thaler, H., & Portenoy, R.K. (1996). Pain in ambulatory AIDS patients II: Impact of pain on psychological functioning and quality of life. *Pain*, *68*(2-3), 323-328.

Shapiro, R.S. (1996). Health care providers' liability exposure for inappropriate pain management. *Journal of Law and Medical Ethics*, *24*(4), 360-364.

Simmonds, M.J., & Claveau, Y. (1997). Measures of pain and physical function in patients with low back pain. *Physiotherapy Theory and Practice*, *13*(1), 53-65.

Singer, A.J., Gulla, J., & Thode, H.C., Jr. (2002). Parents and practitioners are poor judges of young children's pain severity. *Academy of Emergency Medicine*, *9*(6), 609-612.

Solomon, P. (2001). Congruence between health professionals' and patients' pain ratings: A review of the literature. *Scandinavian Journal of Caring Science*, *15*, 174-180.

Sutters, K.A, & Miaskowski, C. (1997). Inadequate pain management and associated morbidity in children at home after tonsillectomy. *Journal of Pediatric Nursing, 12*(3), 178-185.

Tucker, K.L. (2001). Deceptive placebo administration. *American Journal of Nursing*, *101*(8), 56.

Turner, J.A., Deyo, R.A., Loeser, J.D., VonKorff, M., & Fordyce, W.E. (1994). The importance of placebo effects in pain treatment and research. *Journal of the American Medical Association*, *217*, 1609-1614.

Wall, P.D. (1993). Reply to E. Leskowitz. *Pain*, 53(1), 115.

Weiner, D.K., & Rudy, T.E. (2002). Attitudinal barriers to effective treatment of persistent pain in nursing home residents. *Journal of the American Geriatrics Society*, *50*(12), 2035-2040.

Wolf, S., & Pinsky, R.H. (1954). Effect of placebo administration and occurrence of toxic reactions. *Journal of the American Medical Association, 155*, 339-341.

Suggested Additional Readings

- Ferrell, B.R., & McCaffery, M. (1996). Current placebo practice and policy. *ASPMN Pathways*, *5*(1), 12-14.
- Goodwin, J.S., Goodwin, J.M., & Vogel, A.A. (1979). Knowledge and use of placebos by house officers and nurses. *Annals of Internal Medicine*, *91*, 106-110.
- Jerome, Groopman, (2004). *The anatomy of hope: How people prevail in the face of illness.* New York: Random House
- Hinnant, D.C. (1995). Institutional policy prevents misuse of placebos. *ASPMN Pathways*, *4*(1), 1, 7.
- McCaffery, M., Ferrell, B.F., & Turner, M.T. (1996). Ethical issues in the use of placebos in cancer pain management. *Oncology Nursing Forum*, *23*, 1587-1593.
- Rothman, K.J., & Michels, K.B. (1994). The continuing unethical use of placebo controls. *New England Journal of Medicine*, *331*, 394-397.

July 2004