

Re: In the Matter of the Accusation against Harold Luke MD

**AMICUS BRIEF IN SUPPORT OF THE REQUEST FOR RECONSIDERATION**

Case No.: 09-2002-140142

OAH No.: L2004050401

This amicus brief is submitted on behalf of the **American Academy of Pain Management, American Society of Pain Educators, Compassion & Choices, Citizen Advocacy Center, Southern California Cancer Pain Initiative, Ira Byock, M.D., Robert Brody, M.D., Prof. June L. Dahl, Prof. Barry Furrow, Margo McCaffery, MS, RN, FAAN, Chris Pasero, MS, RN, FAAN, Russell Portenoy MD, Lawrence J. Schneiderman, M.D., David Weissman, M.D., and Miles J. Zaremski, J.D.** All amici are described in the appendix.

Amici urge the Board to give careful consideration to the pending Request for Reconsideration in the above referenced matter. Our view, based upon the opinions of distinguished experts who have reviewed the records, discussed the matter with Dr. Luke, and testified that Dr. Luke's care of his terminally ill patient comported with modern principles and practices of pain management, is that it would be a serious error to punish Dr. Luke for his efforts to relieve the pain and suffering of his patient. As advocates for good pain and symptom management of terminally ill patients, we are greatly concerned about the potential for a case where the clinician acted to relieve pain and suffering and then faces punishment for this conduct to set back our mutual efforts to encourage good pain management.

Patients in California and other states are routinely undertreated for pain. This problem has been widely recognized and documented in the medical literature. In a seminal medical study of end of life care, researchers found that 50% of all patients who died during hospitalization "experienced moderate or severe pain at least half of the time during their last 3 days of life."<sup>1</sup>

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<sup>1</sup> SUPPORT (Study to Understand Prognoses and Preferences for Outcomes and Risks of Treatments) Principal Investigators, *A Controlled Trial to Improve Care for Seriously Ill Hospitalized Patients*, 274 JAMA 1591, 1594 (1995). See also, A. Jacox, D. Carr, and R. Payne, *New Clinical-Practice Guidelines for the Management of Pain in Patients with Cancer*, 330 N. Engl. J. Med. 651 (1994) (pain associated with cancer is frequently undertreated); David Joranson et al, *Opioids for Chronic Cancer and Non-Cancer Pain: A Survey of State Medical Board Members*, Federation Bulletin: the Journal of Medical Licensure and Discipline, 79 (4):15-49 (1992) (reporting on studies that reflect "that adequate pain control is not being achieved in a significant portion of patients, and that patients often do not receive analgesics to match the severity of their pain", notwithstanding that pain can be

Elderly patients are particularly vulnerable to insufficient pain treatment. A recent study in the Journal of the American Medical Association found that up to 40% of cancer patients in nursing homes are not appropriately treated for pain. In addition, 26% of those experiencing pain did not receive any pain medication, and 16% were given over-the-counter pain relievers like aspirin or acetaminophen for their pain.<sup>2</sup>

At the same time, it is well established that only perhaps 10% of dying patients have conditions in which alleviation of pain is truly difficult or impossible.<sup>3</sup> One repeatedly identified cause of this problem is physician concern that prescribing controlled substances will invite regulatory agency oversight.<sup>4</sup> Other factors inhibiting adequate pain treatment

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well-controlled for more than 85% of all cancer patients.) A comprehensive overview of the literature documenting the problem of undertreatment of pain is found in: Ben Rich, *A Prescription for the Pain: The Emerging Standard of Care for Pain Management*, 26 William Mitchell L. Rev. 1(2000). The systematic undertreatment of pain has been officially recognized by the Agency for Health Care Policy and Research (AHCPR), a division of the U.S. Department of Health and Human Services. AHCPR, *Acute Pain Management: Operative or Medical Procedures and Trauma. Clinical Practice Guideline* ("half of all patients given conventional therapy for their pain—most of the 23 million surgical cases each year—do not get adequate relief.")

<<http://www.ahcpr.gov/clinic/medtep.acute.htm>>. See also Jamie H. Von Roenn, *Physician Attitudes and Practice in Cancer Pain Management*, 119 ANN. INTERNAL MED. 121, 121 (1993) (A survey of doctors treating patients with cancer found that 86% of the respondents "felt that the majority of patients with pain were undermedicated.")

<sup>2</sup> Roberto Bernabei et al., *Management of Pain in Elderly Patients with Cancer*, 279 JAMA 1877, 1879 (1998).

<sup>3</sup> See *supra* n.1, Jacox, Carr, and Payne (cancer pain can be relieved for up to 90 % of patients.); American Pain Society, *Treatment of Pain at the End of Life: A Position Statement from the American Pain Society*, (visited May 30, 2000) <<http://www.ampainsoc.org/advocacy/treatment/htm>>. ("Well-trained clinicians can provide adequate pain relief for more than 90% of dying cancer patients")

<sup>4</sup> See "Breaking Down The Barriers to Effective Pain Management," Recommendations to Improve the Assessment and Treatment of Pain in New York State, Report to the Commissioner of Health, January 1998 (Hereinafter NY Report); Institute of Medicine, *Approaching Death, Improving Care at the End of Life*, at p. 191, 197 (National Academy Press) (1997) (laws designed to prevent diversion of drugs such as triplicate prescriptions and limits on the number of medication dosages prescribed are burdensome and deter legitimate prescribing of opioids to patients at the end of life); David Joranson, *State Medical Board Guidelines for Treatment of Intractable Pain*, American Pain Soc. Bulletin, Vol. 5, No. 3 (May/June 1995, at 2 (citing California study reflecting that physicians avoid prescribing controlled substances including "triplicate" drugs for patients with intractable pain for fear of discipline by the medical board); Robyn S. Shapiro, *Health Care Providers' Liability Exposure for Inappropriate Pain Management*, 24 J. Law, Med. & Ethics 360, 363 (Winter 1996) (identifying fear of legal penalties, especially disciplinary action, as one of the most important reasons health professionals undertreat pain. Citing California survey revealing that 69% of

described in the medical literature include the fear that strong pain treatment will hasten death.<sup>5</sup>

It is not uncommon for physicians to be investigated for prescribing controlled substances in amounts that other caregivers perceive as excessive. In this case it was a nurse's concern about the magnitude and rate of the escalation of the morphine administration immediately prior to the patient's death that initiated inquiry. However, experts in this case testified that Dr. Luke's care comported with modern standards of care governing management of pain and other distressing symptoms in a dying patient. Dr. Luke testified that his intention was to relieve the patient's pain and distress. The physician's intention ought not be second-guessed.

California is among the most progressive states in attempting to improve pain care. The state legislature passed an Intractable Pain Treatment Act in 1990. It provides that "[n]o physician or surgeon shall be subject to disciplinary action by the board for prescribing or administering controlled substances in the course of treatment of a person for intractable pain." In 1994 the MBC provided all California physicians with a copy of the clinical guidelines for pain management issued by the U.S. Agency for Health Care Policy and Research, and adopted a policy statement encouraging aggressive pain care.<sup>6</sup>

Subsequently, the MBC adopted an official guideline regarding pain management, which specifically identifies failure to adequately manage pain as "inappropriate prescribing."<sup>7</sup> In explicitly making undertreatment of pain a type of inappropriate prescribing, the MBC has expressly recognized that this is a form of professional misconduct, and, thus, is subject to the full range of sanctions. In 1997 the California legislature passed the Pain Patient's Bill of Rights.<sup>8</sup> This law provides, in pertinent part, that "[a] patient suffering from severe chronic intractable pain has the option to request or reject the use of any or all modalities to relieve his or her severe chronic intractable pain."<sup>9</sup>

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physicians stated that the potential for disciplinary action made them more conservative in their use of opioids in pain management).

<sup>5</sup> Lawrence J. Scheiderman, *The Family Physician and End-of-Life Care*, 45 J. FAM. PRAC. 259 (1997), citing Sidney H. Wanzer et al., *The Physician's Responsibility Toward Hopelessly Ill Patients: A Second Look*, 320 NEW ENG. J. MED. 844-9 (1989).

<sup>6</sup> "Prescribing Controlled Substances for Intractable Pain", policy statement of the MBC adopted May 6, 1994.

<sup>7</sup> "Guideline for Prescribing Controlled Substances for Intractable Pain, Guideline adopted by the MBC July 29, 1994.

<sup>8</sup> Cal Health & Safety Code Sec 124960.

<sup>9</sup> Cal Health & Safety Code Sec 124960 (h).

Where a physician fails to provide adequate pain treatment, he or she is exposed to disciplinary action by the medical board. Indeed, the MBC recently took disciplinary action in a case alleging inadequate pain management. *In the Matter of the Accusation Against: Eugene B. Whitney, M.D.*, Case No. 12 2002 133376.<sup>10</sup> This kind of action is likely to increase as awareness of the problem of inadequate pain management grows and calls for increased board involvement are made.<sup>11</sup>

Numerous organizations have published guidelines and authoritative articles governing pain and symptom management and all exhort clinicians to treat pain and other distressing symptoms in terminally ill patients attentively and aggressively. These include the World Health Organization,<sup>12</sup> the American Pain Society,<sup>13</sup> the American Medical Association,<sup>14</sup> the Agency for Health Care Policy and Research ("AHCPR"),<sup>15</sup> the Federation of State Medical Boards,<sup>16</sup> and the Joint Commission on Accreditation of

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<sup>10</sup> The Tomlinson case is discussed in detail in Kathryn Tucker, *Medico-Legal Case Report and Commentary: Inadequate Pain Management in the Context of Terminal Cancer - The Case of Lester Tomlinson*, 5 PAIN MEDICINE, 214-217 n.2 (June 2004).

<sup>11</sup> See, e.g., Kathryn L. Tucker, "Medical Board Corrective Action With Physicians Who Fail to Provide Adequate Pain Care," *J. Med. Licensure and Discipline*, vol. 87, n. 4, pp. 130-131 (2001). The growing interest in the medical board community in addressing clinician failure to provide adequate pain management is exemplified by the prominent place the subject took at the 2002 annual conference of the Citizen's Advocacy Center, held in San Francisco in Nov. 2002, and the conference of the Federation of State Medical Boards, held in Chicago in April 2003.

<sup>12</sup> World Health Organization, *Cancer Pain Relief* (1986).

<sup>13</sup> American Pain Society. *Quality Improvement Guidelines for the Treatment of Acute Pain and Cancer Pain*, 274 JAMA 1874 (1995).

<sup>14</sup> W.T. McGivney et al., *The Care of Patients with Severe Chronic Pain in Terminal Illness*, 251 JAMA 1182 (1984).

<sup>15</sup> Acute Pain Management: Operative or Medical Procedures and Trauma Clinical Practice Guideline (visited 5/31/00) <<http://www.ahcpr.gov/clinic/medtep.acute.htm>>. Agency for Health Care Policy and Research (AHCPR), Clinical Practice Guideline No. 9: Management of Cancer Pain, Publication 94-0592(1994).

<sup>16</sup> Model Guidelines for the Use of Controlled Substances for the Treatment of Pain, 85 FED'N BULL: J. OF MED. LICENSURE AND DISCIPLINE 84 (1998) ("principles of quality medical practice dictate that...people...have access to appropriate and effective pain relief...The Board encourages physicians to view effective pain management as a part of quality medical practice for all patients with pain, acute or chronic, and it is especially important for patients who experience pain as a result of terminal illness.")

Healthcare Organizations ("JCAHO").<sup>17</sup> These guidelines all emphasize the importance of pain management as an element of medical treatment. In addition, the United States Supreme Court spoke, in a pair of celebrated and widely reported decisions issued in 1997, to the right of a dying patient to obtain adequate pain management<sup>18</sup>, with Justice O'Connor stating resoundingly: **Dying patients who are experiencing great pain have a right to obtain medication from their physician to alleviate that suffering even to the point of causing unconsciousness and hastening death.**<sup>19</sup> These decisions were widely discussed in the medical literature.<sup>20</sup>

A physician practicing medicine in the State of California in September 2002, the time when Dr. Luke's care under review was rendered, had been *barraged* with information from the Medical Board, the state legislature, the courts, the medical journals, and the lay and trade press, that it is an essential duty and responsibility to treat pain and other distressing symptoms attentively and aggressively, particularly in the context of end of life care of a dying patient.

A physician who fails to provide adequate, attentive and, if needed, aggressive pain and symptom management faces exposure for disciplinary action and tort liability.<sup>21</sup> Conversely, a physician who provides such care should be recognized as practicing within modern standards of care and should be honored as a model for other clinicians.

A physician who understands his duty and responsibility to treat the pain and other distressing symptoms of his actively dying patient in an attentive and aggressive manner, consistent with that patient's wishes as expressed in an advance directive, and does so, should

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<sup>17</sup> JCAHO, *Comprehensive Accreditation Manual for Hospitals: the Official Handbook (CAMH)* (visited 5/31/00) <[http://www.jcaho.org/standard/pm\\_ac.html](http://www.jcaho.org/standard/pm_ac.html)>.

<sup>18</sup> *Washington v. Glucksberg*, 521 U.S. 702 (1997); *Vacco v. Quill*, 521 U.S. 793 (1997).

<sup>19</sup> *Washington v. Glucksberg*, 521 U. S. 702, 736-737 (1997)(O'Connor concurring).

<sup>20</sup> Robert A. Burt, *The Supreme Court Speaks: Not Assisted Suicide, But a Constitutional Right to Palliative Care*, 337 *New Eng. J. Med.* 1234-36 (1997).

<sup>21</sup> Tort liability for undertreatment of the pain of a dying patient accrued in the widely discussed case of *Bergman v. Chin*, A091386, (Alameda County Superior Court, 2001) (No. H205732-1) available at <http://www.compassionindying.org/bergman/index.php> (last visited July 1, 2005). The *Bergman* case received wide coverage in the local, regional, specialty, and national press. See, e.g., Tanya Albert, *Doctor Guilty of Elder Abuse for Under-Treating Pain*, *AM. MED. NEWS*, July 23, 2001. Mark Crane, *Now you may be liable for under-treating pain*, *MED. ECON.*, September 2001, available at <http://www.compassionindying.org/bergman/medicalecon.pdf> (last visited July 05, 2005); Rebecca Porter, *Failure to Treat Pain is Elder Abuse Jury Finds*, 37 *TRIAL*, No. 9, 87 (Sept. 2001). David W. Shapiro, *Inadequate Treatment of Pain*, 31 *PROF'L. LIAB. NEWSLETTER*, No. 4, May/June (2001). Tom Troy, *New Type of Suit: Pain Treatment*, 23 *NAT'L L. J.* 45 (2001) available at <http://www.compassionindying.org/bergman/nljarticle.html> (last visited July 9, 2005).

not be punished; certainly the draconian sanction of license revocation is beyond the bounds of reasonable corrective action.

Were a serious sanction imposed in this case it would be unjustified. It would irreparably harm this clinician. Moreover, it would send a chilling message to all licensees in this state that it is risky to work to relieve the pain and suffering of a dying patient, putting the comfort of all terminally ill Californians at risk.

Accordingly, amici respectfully urge the Board to reconsider the draconian sanction of revoking Dr. Luke's license.

Respectfully submitted,

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cc: Via Facsimile and regular mail

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## **Appendix**

### **Organizations Participating as Amici Curiae in Support of the Request for Reconsideration**

#### **American Academy of Pain Management**

The American Academy of Pain Management is the largest Pain Organization in the United States. Academy Membership is 6,000 strong and growing. The Academy provides credentialing, accreditation of facilities, networking opportunities, continuing education, quality publications and an annual clinical meeting. It is the goal of the American Academy of Pain Management to bring together the many professionals who work with individuals in pain and to assist in the creation of quality services for those individuals.

#### **American Society of Pain Educators**

The American Society of Pain Educators is the only national organization committed to healthcare education for pain and its management. The ASPE provides this training for all healthcare professionals and is currently developing a credentialing process for professional pain educators.

#### **Compassion & Choices**

Created in 2005 by the unification of Compassion In Dying and End-of Life Choices, Compassion & Choices supports, educates and advocates for choice and quality care at the end of life. As the oldest and largest choice-in-dying organization in the country, with 9 chapters serving over 5,000 members in California, Compassion & Choices has more than 25 years of experience advocating for comprehensive pain and symptom management for every dying person. C & C's Legal Director served as co-counsel in the *Bergman* and *Tomlinson* cases.

#### **Citizen Advocacy Center**

The Citizen Advocacy Center (CAC), based in Washington, D.C., provides training, research, conferences and networking for health care institutions' public members and consumer representatives. These institutions include professional licensing boards, Quality Improvement Organizations, certifying agencies, and other health care oversight bodies. CAC is working to improve the regulation and oversight of pain care by health care professionals.

#### **Southern California Cancer Pain Initiative(SCCPI)**

SCCPI, founded in 1993, is a nonprofit volunteer interdisciplinary organization made up of physicians, nurses, pharmacists, psychologists, social workers and many other professionals dedicated to the relief of cancer pain. SCCPI works closely with other professional and regulatory agencies to remove barriers to optimum pain relief. SCCPI currently has approximately 2,200 individual members.

**Individual Pain Management/Palliative Care Clinician Amici Supporting the Request  
for Reconsideration**

**Ira Byock, M.D.**

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Dr. Byock has been involved in hospice and palliative care since 1978, during his residency. At that time he helped found a hospice home care program for the indigent population served by the university hospital and county clinics of Fresno, California. He is a Past President of the American Academy of Hospice and Palliative Medicine (1997). Dr. Byock has authored numerous articles on the ethics and practice of hospice, palliative and end-of-life care. His first book, *Dying Well*, has become a standard in the field. He has been an advocate for the voice and rights of dying patients and their families. Dr. Byock was the recipient of the National Hospice Organization's **Person of the Year** (1995), the National Coalition of Cancer Survivorship's **Natalie Davis Spingarn Writers Award** (2000), and the American College of CHEST Physicians **Roger Bone Memorial Lecture Award** (2003).

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Margo McCaffery is a registered nurse and has been an educator and consultant in the care of patients with pain for over 40 years. She is a founding member of the International Association for the Study of Pain and has served on the World Health Organization's Expert Committee on Cancer Pain Relief and Active Supportive Care. She is the co-author of Pain: Clinical Manual.

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Chris Pasero is a registered nurse, educator, and clinical consultant, specializing in pain management for over 15 years. She co-founded the American Society for Pain Management Nursing and served as President and on the Board of Directors of that organization. She is the co-author of Pain: Clinical Manual.

**Russell Portenoy MD**

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Dr. Schneiderman is co-founder of the UCSD Medical Center's Medical Ethics Committee, a member of the American Society for Bioethics and Humanities, the American Society of Law and Medicine, serves on the American Council on Science and Health Board

of Scientific and Policy Advisers, the UCSD Center for Ethics in Science and Technology Leadership Council and on the Editorial Board of the Cambridge Quarterly of Healthcare Ethics. He is co-author of Wrong Medicine: Doctors, Patients, and Futile Treatment and over 160 medical and scientific articles. He teaches, provides ethics consultations, and researches various aspects of end-of-life care.

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