

No. 07-5439

IN THE

Supreme Court of the United States

RALPH BAZE, ET AL.,

Petitioners,

v.

JOHN D. REES, ET AL.,

Respondents.

**On Writ of Certiorari to the
Supreme Court of Kentucky**

**BRIEF OF *AMICI CURIAE* CRITICAL CARE
PROVIDERS AND CLINICAL ETHICISTS IN
SUPPORT OF PETITIONERS**

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INTEREST OF *AMICUS CURIAE*¹

Amici curiae are physicians, professors of medicine, clinical ethicists, and other health care providers who specialize in critical care medicine, medical ethics, and end-of-life care. *Amici curiae*, each of whom is listed below, respectfully submit this brief to provide the Court with a medical ethics perspective on the use of pancuronium bromide, the second of the three-drug protocol used by the Commonwealth of Kentucky for carrying out lethal injections.

Dr. Robert D. Truog is Professor of Medical Ethics and Anesthesiology (Pediatrics) at Harvard Medical School and a Senior Associate in Critical Care Medicine at Children's Hospital Boston.² Dr. Truog is an expert in the ethical issues that arise in anesthesia and critical care, and the author of national guidelines for providing end-of-life care in the intensive care unit. Dr. Truog serves as the Director of Clinical Ethics in the Division of Medical Ethics and the Department of Social Medicine at Harvard Medical School; a member of the Harvard Embryonic Stem Cell Research Oversight Committee; and a member of the Harvard University Faculty

¹ Pursuant to this Court's Rule 37.3, the parties have consented to the filing of this brief. Pursuant to this Court's Rule 37.6, *amici curiae* state that no counsel for a party authored this brief in whole or in part, and no counsel or party made a monetary contribution intended to fund the preparation or submission of this brief. No person other than *amici curiae* or their counsel made a monetary contribution to its preparation or submission.

² Each *amicus curiae* submits this brief in his or her individual capacity. All of *amici curiae*'s organizational and professional affiliations noted in this section are for identification purposes only.

Committee of the Edmond J. Safra Foundation Center for Ethics. He received The Christopher Grevnik Memorial Award from the Society of Critical Care Medicine for his contributions and leadership in the area of ethics.

Dr. Jeffrey Burns, MD, MPH is the Chief of the Division of Critical Care Medicine at Children's Hospital Boston; the Edward & Barbara Shapiro Chair of Critical Care Medicine; and an Associate Professor at Harvard Medical School. Dr. Burns co-authored national guidelines for providing end-of-life care in the intensive care unit.

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Dr. Marion Danis, MD is Head of the Section on Ethics and Health Policy in the Department of Bioethics in the Clinical Center of the National Institutes of Health as well as the Chief of the Bioethics Consultation Service at the Clinical Center.³ Her publications include *ETHICAL DIMENSIONS OF HEALTH POLICY* published by Oxford University Press.

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³ Dr. Danis's submission of this brief reflects her personal views; it is not a reflection of the policies of the National Institutes of Health or the United States Department of Health and Human Services.

member of the Harvard Ethics Leadership Group; and a faculty member for the annual Harvard Bioethics Course. She is a co-author of a New England Journal of Medicine article regarding pharmacologic paralysis and the withdrawal of mechanical ventilation at the end of life.

Dr. Bernard Lo, MD is Professor of Medicine and the Director of the Program in Medical Ethics at the University of California San Francisco. He chaired a national Expert Panel to Develop Clinical, Ethical, and Policy Recommendations Regarding Care Near the End of Life. Dr. Lo is the author of the textbook *RESOLVING ETHICAL DILEMMAS: A GUIDE FOR CLINICIANS* and over 190 academic papers on medical ethics, palliative care, and end-of-life care.

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Program in Trauma, Emergency, and Critical Care at Sunnybrook Health Sciences Centre; Professor of Medicine at the University of Toronto; and Affiliate Professor of Medicine at the University of Washington. He has served on numerous professional society committees for the American Thoracic Society, including the Bioethics, Critical Care Long Range Planning, Health Policy, and Critical Care Program committees.

Dr. Cynda Hylton Rushton PhD, RN, FAAN is Associate Professor of Nursing and Pediatrics at Johns Hopkins University School of Nursing; chair of Maryland's Council on Quality Care at the End of Life; a faculty member at the Berman Institute of Bioethics; Program Director at the Harriet Lane Compassionate Care Program at Johns Hopkins University and Children's Center; and Co-Chair of the Ethics Committee and Consultation Service at Johns Hopkins Hospital. She was a Kornfeld Fellow in end-of-life, ethics, and palliative care and was awarded the American Association of Critical-Care Nurses Pioneering Spirit Award for her work in advancing palliative care.

SUMMARY OF ARGUMENT

Pancuronium bromide, the second drug in the three-drug protocol used by the Commonwealth of Kentucky, is a neuromuscular blocking agent that paralyzes all muscles under a person's voluntary control. Neuromuscular blocking agents serve narrow functions in clinical medicine. Anesthesiologists use such agents during the induction of anesthesia to insert a breathing tube through the patient's mouth down into the trachea,

and during some surgical procedures to ensure that the patient's body remains completely still. These agents are also used in limited circumstances in the intensive care setting, including, for example, to facilitate the use of mechanical ventilation equipment.

The Commonwealth of Kentucky has asserted that the administration of pancuronium bromide in the lethal injection procedure serves the aesthetic purpose of masking muscle movements such as convulsions or gasps that witnesses may perceive as suffering. The medical community has considered this aesthetic rationale for administering neuromuscular blocking agents in end-of-life care where a terminally ill patient's body may exhibit similar movements after the withdrawal of life support. For a number of reasons, the medical and medical ethics communities have rejected the introduction of neuromuscular blocking agents for this purpose.

Neuromuscular blocking agents possess no sedative or pain-relieving properties and therefore serve no palliative function for a dying patient. At the same time, the use of such drugs brings significant risks to the patient. Neuromuscular blocking agents can paralyze the patient's diaphragm and cause a patient to asphyxiate. In addition, neuromuscular blocking agents can mask the physical signs that doctors look for when attempting to identify whether a dying patient is suffering pain. For example, drugs like pancuronium bromide may suppress the visual signs of acute air hunger associated with the withdrawal of a ventilator, leaving the patient to endure the agony of suffocation in silence and isolation. In light of these risks, the

medical community has concluded that it is medically and ethically inappropriate to use pancuronium bromide or other paralytic agents for aesthetic purposes during the withdrawal of life support.

ARGUMENT

I. PANCURONIUM BROMIDE IS A NEUROMUSCULAR BLOCKING AGENT THAT PARALYZES THE BODY'S VOLUNTARY MUSCLES

Pancuronium bromide is a member of the class of drugs known as “neuromuscular blocking agents.” It is a synthetic derivative of “curare,” a poison used for centuries by indigenous peoples in South America to immobilize prey. See Thandla Raghavendra, *Neuromuscular Blocking Drugs: Discovery and Development*, 95 J. ROYAL SOC'Y MED. 363, 365 (2002); see also Palmer Taylor, *Agents Acting at the Neuromuscular Junction and Autonomic Ganglia*, in GOODMAN & GILMAN'S THE PHARMACOLOGICAL BASIS OF THERAPEUTICS 217, 220 (Laurence L. Brunton et al. eds., 11th ed., 2005). Neuromuscular blocking agents are paralytics. They prevent the body's skeletal muscles—those that a patient can control voluntarily—from contracting.

The process of voluntary muscle contraction begins when the brain sends a signal to a nerve cell, known as a neuron, that is linked to the muscle. See generally Thomas C. Westfall & David P. Westfall, *The Autonomic and Somatic Motor Nervous Systems*, in GOODMAN & GILMAN'S THE PHARMACOLOGICAL BASIS OF THERAPEUTICS 137, 145-153 (Laurence L. Brunton et al. eds., 11th ed., 2005). The signal travels down the neuron and triggers a series of chemical reactions that, in turn, lead to the release of

a neurotransmitter called acetylcholine. *Id.* When it reaches the muscle, acetylcholine docks at specialized receptors and initiates chemical and electrical changes in muscle cells that then cause the muscle to move. *Id.* at 152.

Neuromuscular blockers like pancuronium bromide do exactly what their name suggests: they block the nerve signals that cause muscular contraction. See, e.g., Palmer Taylor, *Agents Acting at the Neuromuscular Junction and Autonomic Ganglia*, in GOODMAN & GILMAN'S THE PHARMACOLOGICAL BASIS OF THERAPEUTICS 217, 223 (Laurence L. Brunton et al. eds., 11th ed., 2005). Specifically, these drugs attach to the same receptors that acetylcholine uses to activate the muscle. *Id.* But, unlike acetylcholine, they do not trigger the reactions that cause the muscle to move. *Id.* Instead, the muscle remains still. *Id.* And, because neuromuscular blockers take up the space at the receptor for acetylcholine, they preclude it from activating the muscle. *Id.* It is a game of biochemical musical chairs in which the acetylcholine molecules are left standing. As a result, when a neuromuscular blocking agent is circulating in the body and the brain sends out a signal to activate a voluntary muscle—urging the diaphragm to move and the lungs to breathe, for example—nothing happens. Voluntary muscles are effectively paralyzed, tied down with an internal chemical restraint.

Neuromuscular blocking agents like pancuronium bromide affect only muscle movement. They have no effect at all on consciousness or pain. If neuromuscular blocking agents are used alone, the patient remains completely awake but totally unable to move.

Today, neuromuscular blocking agents like pancuronium bromide are used for limited purposes in clinical medicine. Anesthesiologists use them in the operating room, under careful monitoring, to relax head and neck muscles and ease the insertion of a breathing tube into the patient's trachea. See, e.g., Alex S. Evers et al., *General Anesthetics*, in GOODMAN & GILMAN'S THE PHARMACOLOGICAL BASIS OF THERAPEUTICS 341, 363 (Laurence L. Brunton et al. eds., 11th ed., 2005). They are also used during surgery to immobilize an anesthetized patient. *Id.* Even an unconscious patient may make involuntary or reflex movements in response to stimuli during surgery, such as an incision or tissue manipulation, and such movement can be detrimental. Neuromuscular blockers paralyze the patient and ensure that she does not disrupt the surgery and inadvertently harm herself. Neuromuscular blocking agents also can be used in surgery to relax muscles, which avoids the need to use unsafe levels of anesthesia.

For critically ill patients, neuromuscular blocking agents may be used in a few narrow circumstances. For example, they may be used for brief periods to facilitate endotracheal intubation or for longer periods, "as a last resort," in mechanically-ventilated patients whose condition requires high ventilator settings. John P. Kress & Jesse B. Hall, *Principles of Critical Care Medicine*, in HARRISON'S PRINCIPLES OF INTERNAL MEDICINE 1583, 1584 (Dennis L. Kasper, et al. eds., 16th ed., 2005). By paralyzing the patient, physicians ensure that the machine controls the movement of breathing for the patient and works optimally.

When neuromuscular blocking agents are used in

these specific clinical contexts, “sedative-induced amnesia is mandatory.” *Id.*; see also Brian Gehlbach & John P. Kress, *Pain Control, Sedation, and Use of Muscle Relaxants*, in *PRINCIPLES OF CRITICAL CARE* 165, 175 (Jesse B. Hall, et al. eds., 3rd ed., 2005). This is so because conscious paralysis—where the patient is awake and lucid but wholly unable to move—is terrifying. In other words, neuromuscular blocking agents can cause such profound distress that physicians *must* couple them with amnesiacs, sedatives, and analgesics to ensure that patients remain unaware of the entire experience.

Although neuromuscular blockers serve important purposes in their limited applications, one thing is clear: pancuronium bromide and drugs in its class are extremely dangerous. As a leading textbook on surgery explains,

Neuromuscular blocking agents have no amnestic, hypnotic, or analgesic properties; patients must be properly anesthetized *prior to* and in *addition to* the administration of these agents. A paralyzed but unседated patient will be aware, conscious, and in pain, yet be unable to communicate their predicament. Inappropriate administration of a neuromuscular blocking agent to an awake patient is one of the most traumatic experiences imaginable.

Robert S. Dorian, *Anesthesia of the Surgical Patient*, in *SCHWARTZ’S PRINCIPLES OF SURGERY* 1851, 1858 (F. Charles Brunnicardi, et al. eds., 8th ed., 2005) (emphasis in original).

II. IT IS MEDICALLY AND ETHICALLY INAPPROPRIATE TO INTRODUCE NEUROMUSCULAR BLOCKING AGENTS LIKE PANCURONIUM BROMIDE IN END-OF-LIFE CARE

At the end-of-life stage, a physician's focus turns from curing or restoring health to ensuring patient comfort during the dying process. The physician has an obligation to provide care that relieves pain from physical, emotional, social, and spiritual sources.

This stage of patient care also brings with it special issues that relate to easing the distress of family members. Although the needs of the patient are, and must be, the physician's primary focus, a family-centered approach is often particularly important in end-of-life care. Families need to be informed of the patient's situation, supported in their grieving process, and assured that their loved one is not in pain.

This last need raises particular challenges because of the physical process the body undergoes at the end-of-life stage. When patients are nearing death, their bodies may twitch or convulse, or they may gasp loudly as if trying to breathe. Although these physical reactions are a normal part of the dying process, family members often interpret them as signs of suffering and may ask clinicians to stop these movements.

The medical ethics community has carefully evaluated the extent to which neuromuscular blocking agents may be administered to a dying patient to mask these physical signs and to ease the distress of family members. Established guidelines for critical care physicians, as well as the overwhelming consensus in the medical community,

provide that the introduction of neuromuscular blocking agents like pancuronium bromide in the dying process for this aesthetic purpose is both medically and ethically inappropriate. See, e.g., Robert D. Truog, et al., *Recommendations for End-Of-Life Care in the Intensive Care Unit: The Ethics Committee of the Society of Critical Care Medicine*, 29 CRIT. CARE MED. 2332, 2344 (2001).

From a clinical perspective, administering a neuromuscular blocking agent to a terminal patient is inappropriate because there is no medical justification for the drug. In the end-of-life care setting, a physician's role is to relieve fully the patient's pain and suffering. Because neuromuscular blocking agents possess no sedative or analgesic properties, they do not produce actual comfort but only the appearance of comfort. Without a rationale linked to patient comfort, there is no medical reason for introducing neuromuscular blocking agents in a patient's dying process.

The administration of paralytic agents in the end-of-life context is inappropriate also because it introduces unacceptable risks of extreme pain and distress. As noted above, neuromuscular blocking agents paralyze the body's muscles, including the diaphragm and other muscles needed for breathing. Their administration to a dying patient therefore can cause that patient to suffocate to death.

In addition, neuromuscular blocking agents like pancuronium bromide can mask the signs of severe pain. When a patient is paralyzed, he is unable to display any of the behavioral cues that allow a physician to assess his pain levels. See *id.* at 2345. For example, the presence of a neuromuscular blocking agent will suppress the visual signs of acute

air hunger associated with the withdrawal of a ventilator as well as other signs of pain and suffering. *Ibid.* When the attending physicians cannot identify these signs of suffering, they cannot administer the further sedatives or analgesics that are needed to ensure the patient's comfort.

Other tools available for assessing pain, moreover, are insufficient substitutes for the patient's behavioral clues. For example, monitoring a patient's blood pressure or heart rate may give some sign of the patient's level of comfort, but these tests can be unreliable due to the physiologic instability of dying patients. Without physical signs such as grimaces or gasps, physicians, the most highly trained of a patient's caregivers, may be unable to provide an acceptable level of palliative care to their patients.

In light of these concerns arising from the administration of neuromuscular blocking agents, the Ethics Committee of the Society of Critical Care Medicine has concluded, consistent with the consensus in the medical community, that the risks to the patient are too great to justify administering neuromuscular blocking agents for the aesthetic purpose of easing family members' distress. See *ibid.* The standard of care instead requires doctors to communicate with family members about the convulsions or gasps that are part of the dying process and to treat any signs of pain and suffering with analgesics or sedatives. These conversations mitigate family distress without the severe risks to patient comfort associated with the use of neuromuscular blocking agents.

CONCLUSION

Because neuromuscular blocking agents serve no palliative function for a dying patient and pose severe risks to patient well-being in the end-of-life care setting, it is medically and ethically inappropriate to administer these drugs for aesthetic purposes.

Respectfully submitted,

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