

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
ANESTHESIA AWARENESS CAMPAIGN, INC.
AS AMICUS CURIAE
IN SUPPORT OF NEITHER PARTY**

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INTEREST OF *AMICUS CURIAE* AND SUMMARY OF ARGUMENT¹

The Anesthesia Awareness Campaign, Inc. (“AAC”) is a non-profit organization founded in 1998 that is dedicated to helping victims, providing education, and working to prevent anesthesia awareness. Anesthesia awareness, also called intraoperative awareness or conscious paralysis, is the phenomenon of being mentally alert while supposedly under full general anesthesia. In some instances, victims are able to feel excruciating pain but are unable to communicate their awareness because they are paralyzed by a neuromuscular blocker. The AAC was founded by Carol Wehrer who, having received general anesthesia and been paralyzed by a neuromuscular blocker, was conscious and aware when her eye was surgically removed.

The AAC’s mission is “to prevent patients (even one) from experiencing anesthesia awareness and its consequences through education, prevention, and empowerment by replacing ignorance or fear with knowledge.” The AAC’s Board of Directors includes medical professionals and anesthesiologists as well as Ms. Wehrer. The AAC has worked with the Joint Commission on Accreditation of Healthcare Organizations (“JCAHO”) on raising awareness about this medical complication. JCAHO consulted with the

¹ 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 preparation of this brief. No person other than *amicus curiae*, its members, or its counsel made a monetary contribution to its preparation or submission. The parties have consented to the filing of this brief and their written consents are being filed today with the Clerk.

AAC when drafting JCAHO's 2004 Sentinel Event Alert Issue 32 on preventing and managing cases of anesthesia awareness.

The AAC takes no position on the requirements of the Eighth Amendment. However, because the execution protocol at issue in this case carries a risk for anesthesia awareness, the AAC believes that it is essential for the Court to be fully informed about three things. First, anesthesia awareness is a real and recognized medical complication. Second, when anesthesia awareness occurs, it can produce severe physical and psychological pain, particularly when general anesthesia is combined with a neuromuscular blocker that prevents patients from communicating with care providers. Third, the AAC and the medical community have identified safeguards that can—indeed, must—be must be employed whenever general anesthesia is used, in order to minimize the risk of such devastating consequences. These safeguards include refraining from the use of neuromuscular blockers except when absolutely medically necessary; using reliable monitoring of anesthetic depth by an anesthesia professional; avoiding intravenous-only administration of anesthesia; and having trained anesthesia professionals administer the general anesthesia. Each of these points is more fully developed below.

ARGUMENT

I. Anesthesia Awareness Is a Real and Widely-Recognized Medical Complication.

Anesthesia awareness has been recognized as a potential medical complication since as early as

1846.² In 1960, the pioneer medical study on the incidence of awareness under general anesthesia was published.³ Anesthesia awareness is reported to occur in between 0.1% and 0.9% of general anesthesia cases—and those are cases where anesthesia is typically administered by a trained and licensed anesthesia professional.⁴ Thus, at a minimum, awareness occurs in one out of every one thousand cases of general anesthesia, equaling some 26,000 occurrences of anesthesia awareness each year in the United States.⁵

Anesthesia awareness may occur even where the patient is not paralyzed by use of a neuromuscular blocker. For purposes of this brief, however, the AAC focuses on cases of anesthesia awareness where patients receive both anesthesia and a neuromuscular blocker that prevents them from indicating to the surgical team that they are aware despite the general anesthesia.

² See M.M. Ghoneim, *Awareness During Anesthesia*, in *Awareness During Anesthesia* 1, 3 (M.M. Ghoneim ed., 2001).

³ See Claes Lennmarken & Gunilla Sydsjo, *Psychological Consequences of Awareness and Their Treatment*, 21 *Best Practice & Research Clinical Anesthesiology* 357, 358 (2007).

⁴ See Richard J. Pollard et al., *Intraoperative Awareness in a Regional Medical System: A Review of Three Years' Data*, 106 *Anesthesiology* 269, 269 (2007) (summarizing findings from prior studies).

⁵ Peter S. Sebel et al., *The Incidence of Awareness During Anesthesia: A Multicenter United States Study*, 99 *Anesthesia & Analgesia* 833, 836–37 (2004).

II. Anesthesia Awareness Can Cause Severe Physical and Psychological Pain.

AAC's participants bear personal witness to the awful physical and psychological injuries that can arise as a result of anesthesia awareness. They were rendered unconscious by anesthesia, only to suddenly find themselves awake and aware but unable to move or call out for help. They were filled with anxiety and panic, they felt pain, and they suffered grievous physical and psychological damage.⁶

Kathleen LaBrie is an AAC participant who received general anesthesia and a neuromuscular blocker for an operation opening both sinus cavities and a deviated septum. She describes her experience as follows:

I'll never forget what happened. I realized something was very, very wrong when I awoke to the grinding and pushing in my nose. I also could hear conversations. I was awake and unable to let anyone know. I really thought I was slowly dying and not one person in that room cared. If anyone wants to know what HELL is like this is it, what happened to me. This was the most horrifying, terrifying, nightmare, living hell of my life. The experience created post-traumatic stress disorder, outbursts of anger for no reason, problems with trust, concentration, and socializing, panic attacks, emotional numbness,

⁶ AAC President Carol Wehrer testified in the trial in this case as to her personal experience with anesthesia awareness, and the transcript of her testimony is set forth in the Joint Appendix at 387–400. Her testimony is also briefly summarized in the Petitioners' Brief at 11.

nightmares, and I am easily startled. I have the feeling of needing to be on guard at all times. It was the worst thing that ever happened to me, and I don't know who I am now. I consider conscious paralysis worse than death

AAC participant Kelly Haapala received general anesthesia and a neuromuscular blocker for a hip-socket joint replacement after a car accident. Ms. Haapala's description of becoming conscious during surgery is as follows:

Halfway into the surgery, I started to awaken. I first couldn't figure out where I was and then as the drugs wore off more, I realized where I was . . . I could feel the tugging and pushing on my left side and slowly the pain began to surface. I kept telling myself it must be a nightmare but the pain was so unbearably severe that I began to worry that my body would not be able to withstand this stress and pain and that I would die! It was as if a hot poker was being jammed into me. . . . I felt like they were killing me and I needed to do anything I could to move and let them know I was awake!

I still have nightmares that this happened to me and even compared to the accident, this is the worst terror that I've ever experienced . . . I have problems with sleeping, problems with trusting, feel like I need to try to make every day for my children and family as good as it can be because I am so scared that our lives together will be taken away.

For someone to ever experience conscious paralysis and be awake during a procedure and

feel the pain like I did, it is just worse than death and is inhumane!

Diana Todd, a participant of AAC who suffered conscious paralysis during hysterectomy surgery, offers this account of her experience:

I was awake, aware, paralyzed, utterly terrified, unable to do anything about it no matter how hard I tried, and I wished I could die. I remember thinking, "Take me now, please take me." This was the most traumatizing experience of my life. It takes away your basic humanity. That kind of terror is cruel beyond description. There is simply no way to adequately describe what it is like to have every single scrap of your own self control stripped away. You can't even scream to relieve the pressure.

Amongst the problems in the aftermath of my trauma, I have nightmares, crippling indecision, fears, panic attacks, some claustrophobia, inability to sleep for long periods, sleep restfully, without a light, or to sleep on a normal schedule, and I am exhausted all the time.

I consider conscious paralysis to be cruel, dehumanizing, unnecessary, and unforgivable.

Descriptions of anesthesia awareness in the published medical literature echo these accounts from the AAC. It is well recognized that victims of anesthesia awareness endure "immediate, intraoperative suffering . . . [and that] long-lasting severe mental symptoms may develop."⁷ Medical studies indicate that anesthesia awareness can create "great anxiety

⁷ Lennmarken, *supra* note 3, at 357.

and panic” and terrible sensations of alarm and fright, including “fears of impending death.”⁸ Aware patients may sense pain, pressure, or other stimuli associated with the surgical procedure, but, because of their paralysis, they are unable to notify their physicians.⁹

The following are descriptions of several patients’ experiences with anesthesia awareness detailed in the Moerman study:

Woke up suddenly, feeling intensive pain in the middle of her chest, tried to move backwards and scream but was unable to do so, terrified as if in a nightmare.

Felt intense pain in, and heavy pulling on, her abdomen, heard voices, could not move, felt powerless, tried to warn but was unable to do so, was frightened she might suffer more pain.

Felt and heard being manipulated on his leg, heard drilling and tightening of screws . . . tried to warn anyone but was unable to do so . . . afraid to feel more pain, panicked, thought he might never get out of it and might become comatose.

Felt increasing pain until pain was unbearable . . . wanted to warn anyone but was unable to do so, unable to talk, powerless.¹⁰

⁸ *Id.*

⁹ N. Moerman, B. Bonke, & J. Oosting, *Awareness and Recall During General Anesthesia: Facts and Feelings*, 79 *Anesthesiology* 454, 461–62 (1993).

¹⁰ *Id.* at 460.

It is likewise well documented in the medical literature that the experience of anesthesia awareness while a patient is paralyzed and unable to communicate can traumatize a person: “The realization of consciousness of which operating room staff are evidently oblivious, along with increasingly frenetic yet futile attempts to signal with various body parts, leads rapidly to the conclusion that something has gone seriously wrong,” and can trigger “shock and traumatization.”¹¹ This trauma can cause post-traumatic stress disorder (PTSD) and other serious psychological consequences such as “recurrent nightmares related to paralysis, preoccupation with death, sleep anxiety and initial insomnia.”¹² These acute post-awareness psychological complications underscore the severity of the actual trauma that occurs during anesthesia awareness.

III. Whenever General Anesthesia Is Used, Measures Can—and Must—Be Taken To Minimize the Risk of Anesthesia Awareness.

In light of the increased awareness of the existence and the potentially devastating nature of anesthesia awareness, the JCAHO,¹³ the American Society of

¹¹ See Michael Wang, *The Psychological Consequences of Explicit and Implicit Memories of Events During Surgery, in Awareness During Anesthesia* 145, 147–48 (M.M. Ghoneim, ed. 2001).

¹² *Id.* at 150.

¹³ Joint Commission on Accreditation of Healthcare Organizations, Sentinel Event Alert Issue 32, Preventing, and Managing the Impact of, Anesthesia Awareness (Oct. 6, 2004), available at http://www.jointcommission.org/SentinelEvents/SentinelEventAlert/sea_32.htm [hereinafter JCAHO Alert].

Anesthesiologists (“ASA”),¹⁴ and the American Association of Nurse Anesthetists (“AANA”)¹⁵ have all issued practice advisories for the prevention and management of anesthesia awareness. The AAC strongly believes that any use of general anesthesia must be carried out in accordance with medical practices that can greatly reduce the risk that a person will suffer anesthesia awareness.

First, when general anesthesia is used, a neuromuscular blocker should not be used unless doing so is absolutely medically necessary.¹⁶ One advisory cautions anesthesia professionals to “[a]void muscle paralysis unless absolutely necessary, and, even then, avoid total paralysis.”¹⁷ In one 2007 medical study, each confirmed instance of anesthesia awareness involved the use of a neuromuscular blocker with general anesthesia.¹⁸

Second, a reliable form of anesthesia monitoring should be used on persons under general anesthesia. Such monitoring can track indicators of physiologic

¹⁴ American Society of Anesthesiologists Task Force on Intraoperative Awareness, *Practice Advisory for Intraoperative Awareness and Brain Function Monitoring*, 104 *Anesthesiology* 847 (2006) [hereinafter *ASA Practice Advisory*].

¹⁵ American Association of Nurse Anesthetists, Position Statement 2.12: Unintended Awareness Under General Anesthesia, *available at* www.aana.com (follow “Resources: Practice Documents” hyperlink) [hereinafter *AANA Position Statement*].

¹⁶ See JCAHO Alert, *supra* note 13; ASA Practice Advisory, *supra* note 14, at 850; AANA Position Statement, *supra* note 15, Table II; Ghoneim, *supra* note 2, at 13–14.

¹⁷ JCAHO Alert, *supra* note 13.

¹⁸ Pollard et al., *supra* note 4, at 270.

and motor responses to painful stimuli, such as high blood pressure, fast heart rate, movement, or hemodynamic changes.¹⁹ The ASA recommends anesthesia monitoring by “multiple modalities” and cautions that the “use of neuromuscular blocking drugs may mask purposeful or reflex movements and adds additional importance to the use of monitoring methods that assure the adequate delivery of anesthesia.”²⁰

The AAC believes that brain wave activity monitoring, in addition to monitoring of physiologic and motor responses, is a necessary and important part of monitoring for anesthesia awareness.²¹ The Food and Drug Administration has endorsed this view, finding that an anesthesia professional’s “[u]se of BIS [a medical device that monitors brain wave activity] monitoring to help guide anesthetic administration may be associated with the reduction of the incidence of awareness with recall in adults during general anesthesia and sedation.”²²

Third, avoiding delivery of general anesthesia solely by intravenous means can reduce the chance

¹⁹ JCAHO Alert, *supra* note 13; ASA Practice Advisory, *supra* note 14, at 851, 854; AANA Position Statement, *supra* note 15; Ghoneim, *supra* note 2, at 17.

²⁰ ASA Practice Advisory, *supra* note 14, at 854. See also AANA Position Statement, *supra* note 15.

²¹ Anesthesia Awareness Campaign, Inc., *Suggestions for Improvement in the Anesthesia System*, available at <http://www.anesthesiaawareness.com/improvements.html>.

²² JCAHO Alert, *supra* note 13.

that a person will suffer anesthesia awareness.²³ Instead, it is generally recommended that anesthesia be delivered by both inhalant and intravenous means.²⁴

Finally, general anesthesia should be administered only by trained anesthesiology personnel.²⁵ In a surgical setting, an anesthesia professional administers the anesthesia and remains at the patient's bedside, monitoring real-time indicators to track anesthetic depth. A trained professional helps ensure that patients given general anesthesia receive the appropriate level of medical care to minimize the risk of conscious paralysis.

In the AAC's view, these measures must be employed to minimize the risk that anyone undergoing general anesthesia will suffer the terrible physical and psychological injuries associated with anesthesia awareness.

²³ JCAHO Alert, *supra* note 13; *ASA Practice Advisory, supra* note 14, at 850.

²⁴ See JCAHO Alert, *supra* note 13.

²⁵ See Pollard, *supra* note 4, at 272 ("Clinical anesthesiologists supervising registered nurse anesthetists in the anesthesia care team model of practice delivered all anesthetics in this study."). A fully-trained anesthesiologist must fulfill three years of residency experience, after medical school and a one-year internship. A nurse anesthetist must complete a four-year baccalaureate degree, several years of nursing experience in an acute care setting, and then a master's degree of two to three years.

CONCLUSION

The Court's decision in this case should take into account that any use of general anesthesia entails a significant risk of anesthesia awareness, especially when combined with a neuromuscular blocker; that the experience of anesthesia awareness is often a devastatingly painful one, as the accounts from the AAC's participants show; and that there are methods for minimizing the risk of anesthesia awareness that must be employed in order to avoid the unnecessary imposition of such injuries on any person undergoing general anesthesia.

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