Response
To the Editor:

As we have presented, because there are numerous reasons why consent should not be required prior to an evaluation for brain death (BD), Nevada revised its Uniform Determination of Death Act (UDDA) to stipulate that consent is not needed to conduct a BD evaluation.2 Rady et al3 argue that this is constitutionally problematic.

The revisions to Nevada’s UDDA stem from the response of the Supreme Court of Nevada to the case of Aden Hailu, a woman whose father requested continuation of organ support after she was declared brain dead using the practice parameter for determination of BD from the American Academy of Neurology (AANPP).4 The AANPP was originally written in 1995 in response to concerns raised by the authors of the UDDA and was updated in 2010.5 The Court found that organ support should be continued because the hospital did not provide sufficient evidence or expert testimony that the AANPP is the accepted criteria for determination of BD in the medical community. Notably, the Court stated that their ruling was not an attempt to “set in stone certain medical criteria for determining BD,” but rather that it was based on the “undeveloped record before [them].”4

The Nevada Assembly sought to avoid future confusion about the criteria needed to determine BD, so they proposed revisions to their UDDA to clearly state that BD determination in an adult must be made in accordance with the AANPP.2 Additionally, because questions about the need for consent prior to the determination of BD were raised in recent lawsuits in other states, the Assembly specified in the revised UDDA that BD determination is a clinical decision and therefore does not require consent. The determination is not based on “battery” as Rady et al3 claim but rather on a neurologic examination that is similar to, but more detailed than, the routine examination performed multiple times a day on comatose patients around the world.1–3 The AANPP provides: (1) clear instructions about performing the examination and apnea testing, (2) stipulations on how to avoid complications during the evaluation, and (3) indications to abort apnea testing.5

We applaud Nevada for revising their UDDA in response to these recent lawsuits. Although claims have been made that determination of BD in the absence of consent violates a patient’s freedom of religion and privacy, determination of death should not be a negotiated standard or choice.1,6 Nonetheless, determination of whether or not Nevada’s UDDA revision is constitutionally problematic is outside the purview of physicians.

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References
6. Alameda Superior Court Case No. RP 13–707598.
its findings hypothesis generating. However, given the long history of frustrated attempts to identify novel pharmacotherapies for patients with sepsis, efforts to advance the care of critically ill patients should be applauded.

Our concern centers on efforts by the investigators to leverage the lay press and medical education blogs to frame their findings as revolutionary. In a press release filed jointly by Eastern Virginia Medical School and Sentara Healthcare, the study’s lead author Dr Marik states, “my intention was never to discover the cure for sepsis, it just kind of happened by mistake.” This message has been emphasized by Dr Marik on popular medical education blogs (which are read by thousands of trainees and practicing physicians in internal medicine and emergency medicine) stating, “there can be no question of doubt that we have changed the natural history and disease progression of patients with sepsis.”

The leap from retrospective single-center data to unequivocal proclamations of safety and efficacy is a startling one. Aggressive nutritional supplementation in the early stages of critical illness has repeatedly been shown not to benefit patients. Vitamin C supplementation in critical illness has been studied in high-quality trials without any signal of benefit. In a recent multicenter randomized trial of high-protein enteral nutrition enriched with immune-modulating nutrients including vitamin C, patients in the intervention arm actually had increased adjusted mortality at 6 months compared with patients who received standard high-protein enteral nutrition. Arguing, as the study authors do, that high-dose IV supplementation is not only more efficacious but also unquestionably safe ignores high-quality trials of other antioxidant therapy. Glutamine, an amino acid felt to have many of the same immunomodulatory properties as vitamin C, although no better than placebo at moderate doses, increased rates of death when given at high doses.

These studies do not refute Marik et al’s findings. They do, however, highlight the need for caution and humility when extrapolating the results of a single-center study to scores of critically ill patients. Without ingenuity and persistence in the face of repeated failures, medical breakthroughs would not be possible. However, when in the desperate hope for discovery we greet the fantastic with unblinking acceptance, we risk becoming unmoored from the principles that have guided steady advances in the care of critically ill patients.

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We thank Drs Walter and Singer for their comments regarding our study. However, we believe that a number of the quoted statements have been taken out of context or misinterpreted. It is true that we did not expect our therapy to have a dramatic impact on the initial treated patients and we did not expect to see the dramatic impact on mortality that we witnessed vs historical control subjects. Although the standards for applying the term cure are different in the lay press, we were responding to the apparent size of the effect from our intervention. Furthermore, it is true that we believe that the treatment was effective for patients with sepsis. This strong belief was the reason that we applied the term cure are different in the lay press, we were responding to the apparent size of the effect from our intervention. Furthermore, it is true that we believe that the treatment was effective for patients with sepsis. However, we believe that a number of the quoted statements have been taken out of context or misinterpreted. It is true that we did not expect our therapy to have a dramatic impact on the initial treated patients and we did not expect to see the dramatic impact on mortality that we witnessed vs historical control subjects. Although the standards for applying the term cure are different in the lay press, we were responding to the apparent size of the effect from our intervention. Furthermore, it is true that we believe that the treatment was effective for patients with sepsis. This strong belief was the reason that we applied the therapy to additional patients and why we analyzed those results after the fact. We agree that additional well-designed studies are necessary to convince the medical community of the efficacy of this treatment.