October 28, 2010

To our readers:

In December 2009 *Anesthesia & Analgesia* published the manuscript “Cardiopulmonary Bypass Priming Using a High Dose of a Balanced Hydroxyethyl Starch Versus an Albumin-Based Priming Strategy” by Joachim Boldt, Stephan Suttner, Christian Brosch, Andreas Lehmann, Kerstin Röhm, and Andinet Mengistu (*Anesthesia & Analgesia* 2009; 109: 1752-1762). Shortly following publication the Journal received several letters from concerned readers that the variability in the cytokine assay was too low to be believed. Upon reviewing the results, we concurred with that assessment. We also believed that the variability in blood gas results reported in the paper was too low to be believable.

After several months of inquiries we determined that Professor Boldt’s institution, Klinikum Ludwigshafen, had no Institutional Review Board. Instead, IRB review and ethical oversight of research conducted at Klinikum Ludwigshafen is the responsibility of Landesärztekammer Rheinland-Pfalz (“LÄK”), the Rheinland State Medical Board. In May I sent a request for review to LÄK, explaining my concerns about the veracity of the report published in *Anesthesia & Analgesia*.

On October 25th I received notification from LÄK about their findings. Professor Boldt’s manuscript describes IRB review, written informed consent, prospective randomization, and a follow-up questionnaire. LÄK determined that there was no IRB approval, no written informed consent, no randomization process, and no follow-up questionnaire as described in the study. These are very serious misrepresentations in Professor Boldt’s manuscript. As a result, the entire manuscript is compromised, and is hereby retracted.

The primary concern investigated by LÄK was whether the data in the manuscript were fabricated. Fabrication is easy to disprove by providing original research data (e.g., patient medical records, laboratory records, disk files from research equipment) to demonstrate the validity of the report. Despite having several months to collect such data, Professor Boldt has not provided LÄK with any original research data to refute the allegation of data fabrication. LÄK has not reached a conclusion that the data were fabricated. This is still an open question, and LÄK is continuing its investigation.

Based on the findings of LÄK, the report published in *Anesthesia & Analgesia* is fraudulent. Numerous representations in the manuscript are untrue. It is possible that the study was never performed at all. If the study were performed as reported, then that would represent a profound violation of research ethics, as there was no IRB approval or written informed consent.
Professor Boldt has published more than 200 manuscripts in the peer reviewed medical literature. A shadow has been cast over that body of work based on a determination that the report published in *Anesthesia & Analgesia* is fraudulent. In the coming months and years we will work with LÄK to determine the veracity of all reports by Professor Boldt published in *Anesthesia & Analgesia*.

Editorial comments to accompany this retraction will appear in the March 2011 issue of *Anesthesia & Analgesia*. However, our responsibility to our readership, and to the patients we care for, requires our immediately sharing the findings of the inquiry by LÄK with our readership and the academic community, and our immediate retraction of the manuscript.

*Anesthesia & Analgesia* is uncompromising in its commitment to scientific integrity. When credible evidence of misconduct is brought to our attention, our commitment to the scientific record, to our readers, and to the patients our readers care for requires that we pursue all such allegations until a determination has been made.

I appreciate the dedication to academic integrity demonstrated by Landesärztekammer Rheinland-Pfalz in pursuing their investigation into the veracity of a report published in *Anesthesia & Analgesia*. They have been exceedingly helpful and forthcoming at every step. I have absolute confidence that LÄK will work with the Journal to review the veracity of the manuscripts published by Professor Boldt in *Anesthesia & Analgesia* and restore the integrity of the published scientific record.

Sincerely,

Steven L. Shafer, MD  
Editor-in-Chief  
*Anesthesia & Analgesia*