Editors-in-Chief Statement Regarding Published Clinical Trials Conducted without IRB Approval by Joachim Boldt

March 2, 2011

To our readers:

Landesärztekammer Rheinland-Pfalz (“LÄK-RLP”), the State Medical Association of Rheinland-Pfalz, Germany serves as the Institutional Review Board (IRB) for clinical research at Klinikum Ludwigshafen, where Dr. Joachim Boldt’s recent research was conducted. LÄK-RLP has completed a careful evaluation of the status of IRB approval for research conducted by Dr. Boldt dating back to 1999 and determined, to the best of its ability, the status of IRB approval for 102 articles published by Dr. Boldt.

Table 1 lists 89 articles for which LÄK-RLP was unable to verify IRB approval. Table 2 lists 11 articles for which LÄK-RLP was able to verify IRB approval. Table 3 lists 2 articles for which LÄK-RLP determined that IRB approval was not necessary.

The undersigned Editors-in-Chief of medical journals affected by these findings will retract the articles in our respective journals that are listed in table 1. Formal retraction notices will appear in each journal.

The retraction of the articles in Table 1 for lack of IRB approval means that the research was unethical, and that IRB approval for the research was misrepresented in the published article. It does not mean that the research results per se are fraudulent. Klinikum Ludwigshafen has commissioned an investigating committee to systematically assess the veracity of the findings presented in Dr. Boldt’s articles against patient and laboratory records. We will communicate to our readers any finding of data fabrication, falsification, or misrepresentation identified by the investigating committee at Klinikum Ludwigshafen.

We, the undersigned Editors-in-Chief, on behalf of our Editorial Boards, affiliated societies, and publishers, extend our appreciation to LÄK-RLP for their review of the status of IRB approval for Dr. Boldt’s research and to the investigating committee at Klinikum Ludwigshafen for their ongoing review of his research findings.

On behalf of our respective journals,

Lars S. Rasmussen
Editor-in-Chief, Acta Anaesthesiologica Scandinavica

Steven M. Yentis
Editor-in-Chief, Anaesthesia
Hugo Van Aken
On behalf of the Editorial Board, Anästhesiologie Intensivmedizin Notfallmedizin Schmerztherapie

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

James C. Eisenach
Editor-in-Chief, Anesthesiology

Charles S. Reilly
Editor-in-Chief, British Journal of Anaesthesia

Donald R. Miller
Editor-in-Chief, Canadian Journal of Anesthesia/Journal canadien d'anesthésie

Joseph E. Parrillo
Editor-in-Chief, Critical Care Medicine

Bernd Zwissler
On behalf of the Editorial Board and his CoEditor-in-Chief, Rolf Rossaint, Der Anästhesist

Martín R. Tramèr
Editor-in-Chief, European Journal of Anaesthesiology

Massimo Antonelli
Editor-in-Chief, Intensive Care Medicine
March 2, 2011

Joel A. Kaplan
Editor-in-Chief, *Journal of Cardiothoracic and Vascular Anesthesia*

Jorg Wiltrang
Editor-in-Chief, *Journal of Cranio-Maxillo-Facial Surgery*

George B. Stefano
Editor-in-Chief, *Medical Science Monitor*

Davide Chiumello
Editor-in-Chief, *Minerva Anestesiologica*

Wolfgang R. Mayr
Editor-in-Chief, *Vox Sanguinis*
Table 1: Articles without evidence of IRB approval as determined by LÄK-RLP

**Acta Anaesthesiologica Scandinavica**

**Anaesthesia**

**Anästhesiolgie Intensivmedizin Notfallmedizin Schmerztherapie**
- Triem JG, Röhm KD, Boldt J, Piper SN. [Comparison of a propofol-based anesthesia regimen using optimised-target-controlled-infusion (OTCI) and manually-controlled infusion (MCI) technique]. Anasthesiol Intensivmed Notfallmed Schmerzther. 2006;41:150-5

**Anesthesia & Analgesia**

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**Acta Anaesthesiologica Scandinavica**


**Anaesthesia**


**Anästhesiolgie Intensivmedizin Notfallmedizin Schmerztherapie**

- Triem JG, Röhm KD, Boldt J, Piper SN. [Comparison of a propofol-based anesthesia regimen using optimized-target-controlled-infusion (OTCI) and manually-controlled infusion (MCI) technique]. Anasthesiol Intensivmed Notfallmed Schmerzther. 2006;41:150-5

**Anesthesia & Analgesia**

Boldt J, Brosch Ch, Röhm K, Lehmann A, Mengistu A, Suttner S. Is albumin administration in hypoalbuminemic elderly cardiac surgery patients of benefit with regard to inflammation, endothelial activation, and long-term kidney function? Anesth Analg. 2008;107:1496-503


**Anesthesiology**


**Annals of Thoracic Surgery**


**British Journal of Anaesthesia**


Boldt J, Suttner S, Brosch C, Lehmann A, Mengistu A. Influence on coagulation of a potato-derived hydroxethylstarch (HES 130/0.42) and a maize-derived hydroxethylstarch (HES 130/0.4) in patients undergoing cardiac surgery. Br J Anaesth. 2009;102:191-7


Piper SN, Röhm KD, Boldt J, Faust KL, Maleck WH, Kranke P, Suttner SW. Inspired oxygen fraction of 0.8 compared with 0.4 does not further reduce postoperative nausea and vomiting in dolasetron-treated patients undergoing laparoscopic cholecystectomy. Br J Anaesth. 2006;97:647-53


**Canadian Journal of Anesthesia/Journal canadien d'anesthésie**


Critical Care Medicine


Der Anästhesist


European Journal of Anaesthesiology


**Intensive Care Medicine**


**Journal of Cardiothoracic and Vascular Anesthesia**


**Journal of Cranio-Maxillo-Facial Surgery**

**Medical Science Monitor**


**Minerva Anestesiologica**


**The Thoracic and Cardiovascular Surgeon**


**Vox Sanguinis**

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Table 3: Articles that do not require IRB approval as determined by LÄK-RLP
