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June 13, 2013

The Honorable Kathleen Sebelius
Secretary
Department of Health and Human Services
200 Independence Ave. SW
Washington, DC 20201

RE: Censorship of an Expert Within the National Institutes of Health Who Holds Views Contrary to Those of NIH Leadership Regarding the Surfactant, Positive Pressure, and Oxygenation Randomized Trial

Dear Secretary Sebelius:

Public Citizen, a consumer advocacy organization with more than 300,000 members and supporters nationwide, is deeply troubled to learn that the National Institutes of Health (NIH) has silenced an expert within the agency who has previously raised serious concerns about the ethics of clinical trials with designs that are very similar, if not identical, to that of the Surfactant, Positive Pressure, and Oxygenation Randomized Trial (SUPPORT study) involving extremely premature babies.

Dr. Charles Natanson, Senior Investigator and Chief of the Anesthesia Section in the NIH Clinical Center's Critical Care Medicine Department, was invited by Bloomberg BNA to co-present a continuing legal educational (CLE) webinar in July regarding the SUPPORT study. Also invited to participate in the webinar are Dr. Michael Carome, Director of Public Citizen's Health Research Group, and Dr. Arthur L. Caplan, a bioethicist at the New York University Langone Medical Center.

Dr. Natanson is one of the world's leading experts on how to safely design clinical trials testing titrated therapies in critically ill patients where death is one of the primary endpoints, as was the case with the SUPPORT study. He is one of the most published authors on this topic[1,2,3,4,5,6] and

[1] Deans KJ, Minneci PC, Eichacker PQ, Natanson C. Defining the standard of care in randomized controlled trials of titrated therapies. *Curr Opin Crit Care.* 2004;10(6):579-82.
[2] Deans KJ, Minneci PC, Suffredini AF, et al. Randomization in clinical trials of titrated therapies: Unintended consequences of using fixed treatment protocols. *Crit Care Med.* 2007;35(6):1509-1516.
[3] Minneci PC, Eichacker PQ, Danner RL, et al. The importance of usual care control groups for safety monitoring and validity during critical care research. *Intensive Care Med.* 2008;34(5):942-947.
[4] Deans KH, Minneci PC, Klein HG, Natanson C. The relevance of practice misalignments to trials in transfusion medicine. *Vox Sang.* 2010;99(1):16-23.
[5] Deans KJ, Minneci PC, Danner RL, et al. Practice misalignments in randomized controlled trials: identification, impact, and potential solutions. *Anesth Analg.* 2010;111(2):444-450.
[6] Deans KJ, Minneci P, Eichacker PQ, et al. Walk a mile in whose shoes? *Anesth Analg.* 2010;111(2):576-577.

has spoken about it at numerous conferences around the world. NIH is very familiar with his expertise in this regard. Dr. Natanson recently spoke publicly at international conferences about design problems related to the SUPPORT study and other similar studies that raise serious ethical concerns with respect to the protection of human subjects.

Bloomberg BNA recently asked NIH to allow Dr. Natanson to participate in the July CLE webinar on the SUPPORT study, and NIH denied the request. This denial was communicated to Bloomberg BNA by NIH Public Affairs Specialist Renate Myles, who stated that "we are declining participation in the webinar at this time due to a forthcoming public meeting announced by [the Department of Health and Human Services] HHS: http://www.hhs.gov/ohrp/ on IRB process for trials randomizing participants within the standard of care."

We are dismayed by the hypocrisy that NIH has sought to gag a renowned expert such as Dr. Natanson, who has identified serious concerns about the ethics of the study design used in the SUPPORT study, while at the same time allowing other NIH officials the freedom to speak publicly about the study as long as their positions are favorable to the NIH party line. Indeed, just last week, with full knowledge of the same forthcoming public meeting referenced above, the NIH Director and two senior colleagues, including the director of the NIH institute that funded the SUPPORT study, published a commentary article on the topic in the *New England Journal of Medicine.* This article defended the ethics, design, and consent procedures of the SUPPORT study and contested the findings by the Office for Human Research Protections that the study's consent forms failed to disclose the risks of the research, including the possible increased risk of death, to the parents of the subjects.[7]

This concerted effort by NIH officials to publicly promote a one-sided, biased defense of the study and to suppress an alternative viewpoint voiced by a well-informed NIH expert ultimately undermines the mission and integrity of the agency. As one of the premier academic institutions in the world, NIH should welcome and encourage the full and free expression of diverse ideas rather than engage in unacceptable censorship of its own physician scientists.

The fact that HHS plans to convene a public meeting to discuss issues related to the SUPPORT study is a flimsy excuse for preventing an expert such as Dr. Natanson from discussing that study in a public academic forum.

We encourage you to immediately investigate NIH's policies regarding participation of agency scientists in legitimate public forums and direct NIH to stop censoring experts who have well-reasoned, evidence-based critiques of the SUPPORT study or any other NIH-funded research.

[7] Hudson KL, Guttmacher AE, Collins FS. In support of SUPPORT — A view from the NIH. *N Engl J Med.* Published online June 5, 2013. DOI: 10.1056/NEJMp1306986.

Thank you for your attention to this important matter.

Sincerely,

Michael A. Carome, M.D.
Director
Public Citizen's Health Research Group

Sidney M. Wolfe, M.D.
Senior Advisor and Founder
Public Citizen's Health Research Group

cc: Dr. Francis Collins, Director, NIH
Dr. Alan E. Guttmacher, Director, Eunice Kennedy Shriver National Institute of Child Health and Development