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April 11, 2013

Richard B. Marchase, Ph.D.  
Vice President for Research & Economic Development  
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AB 720E  
701 20th Street South  
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Dear Dr. Marchase:

We understand from several media reports published in the past 24 hours that you have spoken to a number of reporters and made misleading, out-of-context statements responding to Public Citizen's April 10 letter to Secretary of Health and Human Services Kathleen Sebelius in which we condemned the unethical conduct of the Surfactant, Positive Pressure, and Oxygenation Randomized Trial (SUPPORT).<sup>1</sup>

The following are examples of statements attributed to you:

*The New York Times*: [Marchase] said that a similar group of infants born around the same time in the same hospitals who did not participate in the study, but were eligible, died at higher rates than those in the low-oxygen group. Those infants were not a control group in the study, but **were similar to those in the study group**, he said; **they had a 24 percent mortality rate, compared with a 20 percent mortality rate for the infants in the low-oxygen group** [emphasis added].<sup>2</sup>

*Bloomberg News*: **The infants who participated in the study were less likely to die than babies at the same institutions who weren't in the trial**, regardless of how much oxygen they received, Marchase said yesterday in a statement. The mortality rates were also lower than expected based on historical levels, he said.<sup>3</sup>

*USA Today*: In a statement, university's vice president for research Richard Marchase said although slightly more babies who received lower-dose oxygen in the study died,

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<sup>1</sup> Carome MA, Wolfe SM. Letter to Secretary of Health and Human Services Kathleen Sebelius regarding the SUPPORT Study. April 10, 2013. <http://www.citizen.org/documents/2111.pdf>.

<sup>2</sup> Tavernise, S. Study of babies did not disclose risks, U.S. finds. The New York Times. April 10, 2013. <http://www.nytimes.com/2013/04/11/health/parents-of-preemies-werent-told-of-risks-in-study.html?ref=health&r=0>. Accessed April 11, 2013.

<sup>3</sup> Edney A, Cortez MF. Parents not informed of premature babies at risk in study. Bloomberg News. <http://www.bloomberg.com/news/2013-04-10/parents-not-informed-premature-babies-at-risk-in-study.html>. Accessed April 11, 2013.

those **death rates still were lower than was usual for premature babies getting standard care at the time.**<sup>4</sup>

The impact of your statements has been to lead some reporters to believe and write that the SUPPORT babies had a lower death rate than a “similar group of infants.”

These statements are misleading, as a paper published by the SUPPORT study investigators in the March 2012 issue of the journal *Pediatrics* makes clear.<sup>5</sup> The *Pediatrics* article, entitled *Enrollment of Extremely Low Birth Weight Infants in a Clinical Research Study May Not Be Representative*, compared key baseline demographic and clinical factors for the 1,316 premature babies enrolled in the SUPPORT study (enrolled babies) to those of 3,054 premature babies at the SUPPORT study hospitals who were eligible for the study but did not enroll (non-enrolled babies). Important data from the *Pediatrics* paper demonstrates that the non-enrolled babies overall were sicker and more at risk of death than babies in the SUPPORT study. That data, excerpted from tables 1 and 2, is presented in the table below:

Table: Comparison of Baseline Clinical Variables for Enrolled and Non-enrolled Babies

<b>Variable</b>	<b>Enrolled Babies (N = 1,316)</b>	<b>Non-Enrolled Babies (N = 3,053)</b>	<b>Unadjusted P-value</b>
<b>Prenatal antibiotics</b>	78.1%	65.4%	<.001
<b>Antenatal Steroids (any)</b>	96.2%	84.4%	<.001
<b>Antenatal steroids (full course)</b>	71.7%	49.4%	<.001
<b>APGAR score &lt;3 at 1 minute</b>	24.4%	31.9%	<.001
<b>APGAR score &lt;3 at 5 minutes</b>	4.4%	8.4%	<.001
<b>Intubated in the delivery room</b>	63.6%	75.8%	<.001
<b>Surfactant given in delivery room or neonatal intensive care unit</b>	82.5%	86.5%	<.001
<b>Chest compressions in delivery room</b>	5.9%	9.7%	<.001
<b>Epinephrine in delivery room</b>	3.1%	6.0%	<.001

For each of the above baseline variables, there was a statistically significant difference between the enrolled and non-enrolled babies. Thus, the two groups were not “similar.” More important,

<sup>4</sup> Officials: Baby study didn't fully disclose risks. USA Today. April 10, 2013.

<http://www.usatoday.com/story/news/nation/2013/04/10/premature-baby-study/2072281/>. Accessed April 11, 2013.

<sup>5</sup> Rich W, Finer NN, Gantz MG, et al. Enrollment of extremely low birth weight infants in a clinical research study may not be representative. *Pediatrics*. March 2012;129(3):480-484.

the differences overall predicted a less favorable outcome for the non-enrolled babies in comparison to the enrolled babies. Thus, the fact that the non-enrolled babies had a higher mortality than the babies enrolled in the SUPPORT study was expected.

Indeed, the stated purpose of the *Pediatrics* paper was to compare the outcomes for the SUPPORT study babies and the non-enrolled babies, given that the two groups *differed* in many important ways at baseline. And the authors concluded that the significant outcome differences (including mortality) were likely due to these differences in baseline characteristics.

Your use of data intended to highlight the *differences* between these two groups of babies and to try to claim that (a) the two groups of babies were *similar*; and (b) the non-enrolled babies had a higher death rate, is misleading. Your conclusion that enrollment in the study resulted in better survival is invalid and unsupported by the scientific evidence.

Statements such as those attributed to you in the news articles quoted above mislead reporters and the public. These statements have misled reporters just as the egregious deficiencies in the consent forms misled the parents of the premature babies enrolled in the SUPPORT study with regard to the purpose, nature, and risks of the research.

We urge you to heretofore refrain from making similarly misleading statements and issue an updated statement to the media clarifying your comments to correct your prior statement and accurately inform the public.

Thank you for your attention to this matter.

Sincerely,

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

Sidney M. Wolfe, M.D.  
Director  
Public Citizen's Health Research Group

cc: Ray L. Watts, M.D., President, University of Alabama at Birmingham (UAB)  
Anupam Agarwal, M.D., Interim Senior Vice President of Medicine and Dean of the School of Medicine, UAB