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December 16, 2015

Thomas J. Nasca, M.D., M.A.C.P.
Chief Executive Officer
Accreditation Council for Graduate Medical Education
515 North State Street, Suite 2000
Chicago, IL 60654

Re: Individualized Comparative Effectiveness of Models Optimizing Patient Safety and Resident Education (iCOMPARE) Trial and Flexibility in Duty Hour Requirements for Surgical Trainees (FIRST) Trial

Dear Dr. Nasca:

Your December 7 response[1] to our November 19 letter[2] regarding the iCOMPARE and FIRST trials fails to substantively address our major concerns about the trials' serious ethical lapses and instead represents a misleading attempt by the Accreditation Council for Graduate Medical Education (ACGME) to absolve itself of any responsibility for its central role in this unethical research.

Strikingly absent from your response is any acknowledgment of (a) the risks posed by sleep deprivation resulting from excessively long duty shifts to the medical residents — particularly the first-year medical residents — who have been randomly assigned to the experimental groups of both trials; (b) the lack of informed consent of the subjects of the trials; or (c) the serious deficiencies in the scientific design of the trials.

Neither the ACGME's desire to assess the impact of its duty hour standards on patient safety and resident education as part of its upcoming five-year review nor the Institute of Medicine's (IOM's) call for the ACGME to "foster research studies across multiple institutions to examine the effects of duty hour changes and practices" in its report, *Resident Duty Hours: Enhancing Sleep, Supervision, and Safety*,[3] provides a valid justification for conducting such poorly designed, risky research without the informed consent of the subjects. Your reliance on such

[1] Accreditation Council for Graduate Medical Education. Response to Public Citizen and the American Medical Student Association regarding the iCOMPARE and FIRST trials. December 7, 2015. http://www.citizen.org/documents/2285_ACGME_Response.pdf. Accessed December 9, 2015.
[2] Public Citizen and the American Medical Student Association. Letter to the Accreditation Council for Graduate Medical Education regarding the iCOMPARE and FIRST trials. November 19, 2015. http://www.citizen.org/documents/2285.pdf. Accessed December 9, 2015.
[3] Institute of Medicine. *Resident Duty Hours: Enhancing Sleep, Supervision, and Safety*. Washington, DC: The National Academies Press; 2009. http://www.nap.edu/catalog/12508/resident-duty-hours-enhancing-sleepsupervision-and-safety. Accessed December 9, 2015.

ends-justifies-the-means arguments is reminiscent of many other — and in some cases continuing — attempts to justify unethical research over the past century.

You make passing reference to research that "suggests that the additional 2011 duty hour requirements may not have had an incremental benefit in patient safety, and that there might be significant negative impacts to the quality of physician education, professional development, and socialization to the practice of medicine." However, we are not aware of — nor do you offer — any new data that refutes the existing substantial evidence, documented in detail in our letters to the Office of Human Research Protections (OHRP)[4,5] — and sent also to you — on long duty shifts' harmful effects on residents.

You assert that the ACGME waivers were granted only "for the length of each research trial (June 2016 for the completion of the FIRST trial, and July 2017 for the completion of the iCOMPARE trial)." Your characterization of the end dates for the trials is at odds with the documentation provided on the websites established by the trials' researchers. The iCOMPARE trial website explicitly states that the randomized iCOMPARE trial interventions and experiment will end in June 2016.[6,7] Likewise, documentation provided on the website established by the FIRST trial researchers states that the randomized "trial runs through the 2014-2015 academic year."[8]

The trials' websites also make clear that the waivers extend *beyond* the duration of these study periods. The iCOMPARE website states that the ACGME waivers will continue until "at least June 2019"[9,10,11] (or until June 2017, one year after the randomized trial ends, according to another page on the website[12]). The FIRST trial website states that "[h]ospitals within the intervention arm will be granted the ability to relax several current hour requirements during the

[4] Public Citizen and the American Medical Student Association. Letter to the Office for Human Research Protections regarding the iCOMPARE trial. November 19, 2015. http://www.citizen.org/documents/2283.pdf. Accessed December 9, 2015.
[5] Public Citizen and the American Medical Student Association. Letter to the Office for Human Research Protections regarding the FIRST trial. November 19, 2015. http://www.citizen.org/documents/2284.pdf. Accessed December 9, 2015.
[6] iCOMPARE trial information: Executive summary. September 2014. http://www.jhcct.org/icompare/docs/iCOMPARE%20-%20Design%20Summary%20(20140908).pdf. Accessed December 9, 2015.
[7] iCOMPARE: Timeline and upcoming activities for enrolled programs. http://www.jhcct.org/icompare/Timeline.asp. Accessed December 9, 2015.
[8] Flexibility in Duty Hour Requirements for Surgical Trainees Trial — "the FIRST trial": FIRST trial post-randomization frequently asked questions. http://www.thefirsttrial.org/Documents/Post-Randomization%20FAQs%20(Intervention).pdf. Accessed December 11, 2015.
[9] iCOMPARE trial information: Executive summary. September 2014. http://www.jhcct.org/icompare/docs/iCOMPARE%20-%20Design%20Summary%20(20140908).pdf. Accessed December 9, 2015.
[10] iCOMPARE trial information: Frequently asked questions. http://www.jhcct.org/icompare/docs/iCOMPARE%20-%20Frequently%20Asked%20Questions%20(20140908).pdf. Accessed December 9, 2015.
[11] iCOMPARE trial information: Eligibility and program selection. September 2014. http://www.jhcct.org/icompare/docs/iCOMPARE%20-%20Eligibility%20and%20Program%20Selection%20(20140908).pdf. Accessed December 9, 2015.
[12] iCOMPARE: Timeline and upcoming activities for enrolled programs. http://www.jhcct.org/icompare/Timeline.asp. Accessed December 8, 2015.

study period *and the year after the study period* (two years total)" [emphasis added],[13] while another part of the website states "The trial runs through the 2014-2015 academic year. However the waiver runs for two years: 2014-2015 and 2015-2016 academic years."[14] Therefore, your assertion that the ACGME waivers were granted only for the length of each research trial cannot be reconciled with the researchers' representations of the duration of both the trials and the ACGME waivers.

Your letter disingenuously attempts to downplay the potential adverse impact of the waivers on both the resident and patient subjects randomly assigned to the experimental groups. While the letter states emphatically that the ACGME "did NOT waive the central requirements for duty hours that have been in place since 2003 … (i.e., 80 hours per week—averaged over four weeks; one day off in seven—averaged over four weeks; and 24-hour in-house call duty no more frequently than every third night)," it makes no mention of any of the provisions that *were* waived. These include the most stringent 2011 duty requirement for first-year residents: the maximum 16 duty hour limit, the elimination of which allowed first-year residents in the experimental groups to work shifts of 28 consecutive hours or more. The ACGME also waived stringent requirements for minimum time off between scheduled duty periods for both first-year and intermediate residents. The near-doubling of maximum duty shift length for first-year residents, thus reverting back to the pre-2011 ACGME standards, and decreased time off between duty shifts poses a substantial risk to the first-year residents (which is not mitigated by any direct supervision) and, as confirmed by the IOM,[15] to patients (regardless of who bears ultimate responsibility for patient care).

Finally, the ACGME seeks to avoid culpability for its decision to grant waivers that allowed these unethical trials to proceed by claiming that the trials were "reviewed by the Institutional Review Board (IRB) of the institution affiliated with each principal investigator" and that "the iCOMPARE trial was funded by the National Institutes of Health (NIH)." But neither IRB review nor NIH funding is sufficient to establish that research is ethical. Moreover, the statement that the FIRST trial underwent IRB review at the institution affiliated with the trial's principal investigator is inaccurate. For that trial, the IRB administrator at Northwestern University made a colossal error by determining that the trial did not involve human subjects research and therefore did not need to be reviewed by the Northwestern University IRB.

We are hardly surprised by the ACGME's response. As an important funder, facilitator, and endorser of the FIRST and iCOMPARE trials, the ACGME no doubt is reluctant to acknowledge that it erred in supporting such unethical research.

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[13] Flexibility in Duty Hour Requirements for Surgical Trainees Trial — "the FIRST trial": Study overview. http://www.thefirsttrial.org/Overview/Overview. Accessed December 8, 2015.

[14] Flexibility in Duty Hour Requirements for Surgical Trainees Trial — "the FIRST trial": FIRST trial post-randomization frequently asked questions. http://www.thefirsttrial.org/Documents/Post-Randomization%20FAQs%20(Intervention).pdf. Accessed December 11, 2015. While this FIRST trial webpage also goes on to confusingly state, "Data collection will continue until June 30, 2016," this is immaterial to the fact that the randomized, *interventional* phase of the trial for which the ACGME waiver was ostensibly sought ended on June 30, 2015.

[15] Institute of Medicine. *Resident Duty Hours: Enhancing Sleep, Supervision, and Safety*. Washington, DC: The National Academies Press; 2009. http://www.nap.edu/catalog/12508/resident-duty-hours-enhancing-sleepsupervision-and-safety. Accessed December 9, 2015.

In light of your flawed response, we renew our call for the ACGME to immediately rescind the waivers of key provisions of its 2011 duty hour standards for the internal medicine and general surgery residency training programs in the iCOMPARE trial and FIRST trials, respectively. We also call your attention to the enclosed letter submitted by the Committee of Interns and Residents, SEIU Healthcare, which endorses and amplifies our complaints to OHRP.

Sincerely,

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Enclosure

cc: Mr. John Duval, Chair, Board of Directors, ACGME
The Honorable Sylvia Mathews Burwell, Secretary of Health and Human Services
The Honorable Karen B. DeSalvo, Acting Assistant Secretary for Health, HHS