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November 19, 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:

Public Citizen, a consumer advocacy organization with more than 400,000 members and supporters nationwide, and the American Medical Student Association, representing more than 40,000 physicians in training, strongly urge the Accreditation Council for Graduate Medical Education (ACGME) to immediately rescind the organization's waivers of most of its 2011 duty-hour standards for internal medicine and general surgery training programs randomly assigned to the experimental groups in the ongoing iCOMPARE trial and the recently completed FIRST trial, respectively.[1]

As discussed in detail in the enclosed complaint letters submitted today to the U.S. Department of Health and Human Services' (HHS') Office for Human Research Protections (OHRP), both trials — neither of which was possible without the ACGME waiving of its current duty-hour restriction — are highly unethical and failed to materially comply with key requirements of the HHS regulations for the protection of human subjects at 45 C.F.R. Part 46. As you can see, we are simultaneously urging OHRP to invoke its authority and immediately suspend the iCOMPARE trial.

Importantly, it seems highly unlikely that trials that involve randomizing resident physicians to the less restrictive flexible duty-hour schedule permitted under the ACGME waivers — with longer shifts and less time off between shifts — could ever be designed and conducted in a manner that would satisfy the Belmont Report's basic ethical principles and the HHS regulations for the protection of human subjects.

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[1] Accreditation Council for Graduate Medical Education. Letter to members of the graduate medical education community regarding the iCOMPARE and FIRST trials. March 13, 2014. http://www.thefirsttrial.org/Documents/2014-03-13%20Nasca%20Letter%20to%20the%20Community%20re%20Multicenter%20Duty%20Hour%20Trials.pdf. Accessed November 17, 2015.

The 2011 work-hour restrictions were put in place because of clear evidence of risk to resident physicians and were in line with the ACGME's mission to improve health care and advance the quality of resident physicians' education.[2] The decision to waive most of the 2011 duty-hour standards, especially those pertaining to shift length and time off between shifts, for these studies is both shocking and deeply disappointing.

Particularly disturbing is the ACGME's apparent disregard of the evidence that justified its appropriate decision in 2011 to increase the restrictions on resident physicians' duty time, including limiting duty periods for PGY-1 residents to a maximum of 16 hours. In explaining its action, the ACGME noted the following with respect to resident health and well-being:[3]

- Resident well-being and an improved balance between residents' professional and personal lives is one area where the body of literature on the effects of common duty-hour limits has produced relatively unequivocally positive findings.
- An anticipated effect of the 2003 standards was improvement in resident mood and quality of life, which has been borne out by several studies across multiple specialties.

The organization similarly noted the following regarding the health and well-being of patients:[4]

> This group of requirements addresses the requests for some flexibility in the standards requested by the community. It takes into account the differences between PGY-1 residents and their more senior colleagues, and the consensus that very junior learners would benefit from a more supported and regulated learning environment. **PGY-1 residents may not have sufficient experience and skills to provide high-quality, safe patient care, while research indicates that under the current standards, this group works the longest hours of any cohort of residents**,. … All differences between first-year and other residents, with exception of home call and 1 day off in 7, are significant (P < .0001). **In addition, PGY-1 residents make more errors when working longer consecutive hours. Entrusting care to residents with inadequate experience is neither good education nor quality, safe patient care. PGY-1 residents must earn the right to remain with patients for 24 continuous hours, through demonstration of the competencies required**, which are best learned under the direct supervision of upper-level residents, fellows, and faculty. The ideal is a first year of education with more protected hours, with hours and responsibilities gradually increasing over the years of residency, and the final year of residency beginning to emulate practice, while still under supervision. [Emphasis added]

We are aware of no new evidence that refutes the evidence on long duty shifts' harmful effects on residents[5] and that would have justified its waivers.

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[2] Accreditation Council for Graduate Medical Education. ACGME Mission, Vision, and Values. https://www.acgme.org/acgmeweb/tabid/121/About/Misson,VisionandValues.aspx. Accessed November 17, 2015.

[3] Accreditation Council for Graduate Medical Education. *The ACGME 2011 Duty Hour Standards: Enhancing Quality of Care, Supervision, and Resident Professional Development*. 2011. https://www.acgme.org/acgmeweb/Portals/0/PDFs/jgme-monograph%5B1%5D.pdf. Accessed November 17, 2015.

[4] *Ibid*.

[5] For a detailed summary of some of these effects, see the section within each attached letter titled "Unacceptable risk for the experimental group resident subjects."

Finally, the ACGME's decision to grant waivers that extend for a full year or more beyond the end of the one-year randomized phase of each trial is outrageous. Publicly available FIRST trial documents indicate that the ACGME waiver for general surgery residency training programs randomly assigned to the experimental arm remain in effect until June 2016, one full year after the randomized phase of the trial ended.[6] Likewise, several publicly available iCOMPARE documents indicate that the ACGME waiver for internal medicine residency training programs randomly assigned to the experimental arm will continue until June 2019, three full years after the randomized phase of the trial will end,[7,8,9] although one document indicates that the waiver will end in June 2017[10] (and it is also unclear, from the publicly available iCOMPARE documents, whether the waivers also apply to control arm programs). It is unethical to allow both resident physicians and patients at hospitals assigned to the experimental groups for these trials to continue to be exposed to a greater-than-minimal-risk experimental intervention after the one-year randomized phase of each trial has been completed and while data analysis is ongoing.

In closing, it is imperative that the ACGME immediately rescind the waivers of most of its 2011 duty-hour standards for the internal medicine and general surgery residency training programs randomly assigned to the experimental groups in the ongoing iCOMPARE trial and the recently completed FIRST trial, respectively. Furthermore, in light of all the concerns highlighted above and in our letters to OHRP, an independent body needs to investigate the process that allowed these inappropriate waivers to be granted in the first place, in the face of the strong evidence of resident and patient harm that caused ACGME to issue the duty-hour standards in 2011.

Thank you for your prompt attention to this urgent matter regarding the health and welfare of physician residents and patients. Please contact us if you have any questions or need additional information.

Sincerely,

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

Deborah V. Hall, M.D.
National President 2015-16
American Medical Student Association

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[6] 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 November 17, 2015.

[7] iCOMPARE trial information: Executive summary. September 2014. http://www.jhcct.org/icompare/docs/iCOMPARE%20-%20Design%20Summary%20(20140908).pdf. Accessed November 17, 2015.

[8] iCOMPARE trial information: Frequently asked questions. http://www.jhcct.org/icompare/docs/iCOMPARE%20-%20Frequently%20Asked%20Questions%20(20140908).pdf. Accessed November 11, 2015.

[9] 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 November 17, 2015.

[10] iCOMPARE. Timeline and upcoming activities for enrolled programs. http://www.jhcct.org/icompare/Timeline.asp. Accessed November 17, 2015.

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Enclosures

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