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September 13, 2016

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Re: The Accreditation Council for Graduate Medical Education's (ACGME's) Common Program Requirements for Resident Duty Hours in the Learning and Working Environment; and the Individualized Comparative Effectiveness of Models Optimizing Patient Safety and Resident Education (iCOMPARE) and Flexibility in Duty Hour Requirements for Surgical Trainees (FIRST) Trials

Dear Dr. Nasca:

Public Citizen, a consumer advocacy organization with more than 400,000 members and supporters nationwide, and the American Medical Student Association (AMSA), representing more than 40,000 physicians in training, are writing to:

(1) Inform you about today's release of the results of a national poll conducted in July that demonstrated that Americans overwhelmingly oppose any weakening of the current 16-hour shift limit for first-year residents (interns) and support a similar cap on upper-level residents' work shifts;
(2) Strongly urge you to maintain the ACGME's 16-hour cap for interns and to extend the 16-hour cap to all residents; and
(3) Reiterate our call for the 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 and FIRST trials, respectively.

Overwhelming majority of American public favors a 16-hour shift limit for all residents; evidence of harm to residents and patients from shifts longer than 16 hours

The just-released results of a new national public opinion poll of 500 likely voters — commissioned by Public Citizen and conducted by Lake Research Partners on July 20-24, 2016, indicate that the vast majority (86 percent) of the American public is opposed to lifting this 16-hour cap for interns (see enclosed report). Indeed, the poll showed that the public favors, by a similarly overwhelming majority (80 percent), the implementation of 16-hour maximum shift

durations for *all* residents. The margin of error for the poll is +/− 4.4%. The results were entirely bipartisan and consistent with those of a similar poll published in 2010.[1]

As documented by Public Citizen in its report, the public's commonsense approach also is fully justified by the evidence on the risks of long resident work shifts without sleep on the safety of both residents themselves and their patients. A substantial body of literature shows that sleep deprivation due to excessively long work shifts increases the residents' risk of motor vehicle accidents,[2,3,4] depression,[5,6,7] and needle-stick and other injuries that can expose residents to bloodborne pathogens.[8,9] Depriving medical residents of sleep also exposes their patients to an increased risk of medical errors,[10] which can lead to patient injury and death.

As you know, in 2009, the Institute of Medicine (IOM) issued a report calling for a significant reduction in the hours that interns and all other residents were required to work.[11] The IOM determined that the evidence linking sleep deprivation with preventable medical errors and illness and injury to residents was sufficient to warrant a reduction in work hours. For this reason, the IOM recommended in its report that *no* residents be allowed to work shifts of longer than 16 consecutive hours.

In response to the IOM's findings and considerable public pressure, the ACGME tightened work-hour restrictions in 2011. Unfortunately, the ACGME implemented the 16-hour shift limit only for interns, allowing other residents to work 28-hour shifts. Still, the 2011 rules were an improvement over the 30-hour shifts allowed for all residents since 2003.[12]

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[1] Blum AB, Raiszadeh F, Shea S, et al. US public opinion regarding proposed limits on resident physician work hours. BMC Med. 2010 Jun 1;8:33. doi: 10.1186/1741-7015-8-33.

[2] Barger LK, Cade BE, Ayas NT, et al. Extended work shifts and the risk of motor vehicle crashes among interns. *N Engl J Med*. 2005;352(2):125-134.

[3] Marcus CL, Loughlin GM. Effect of sleep deprivation on driving safety in housestaff. *Sleep*. 1996;19(10):763- 766.

[4] Ware JC, Risser MR, Manser T, Karlson KH. Medical resident driving simulator performance following a night on call. *Behav Sleep Med*. 2006;4(1):1-12.

[5] Sen S, Kranzler HR, Krystal JH, et al. A prospective cohort study investigating factors associated with depression during medical internship. *Arch Gen Psychiatry*. 2010;67(6):557-565.

[6] Berkoff K, Rusin W. Pediatric house staff's psychological response to call duty. *J Dev Behav Pediatr*. 1991;12(1):6-10.

[7] Gottlieb DJ, Peterson CA, Parenti CM, Lofgren RP. Effects of a night float system on housestaff neuropsychologic function. *J Gen Intern Med*. 1993;8(3):146-148.

[8] Parks DK, Yetman RJ, McNeese MC, et al. Day-night pattern in accidental exposures to blood-borne pathogens among medical students and residents. *Chronobiol Int*. 2000;17(1):61-70.

[9] Ayas NT, Barger LK, Cade BE, et al. Extended work duration and the risk of self-reported percutaneous injuries in interns. *JAMA*. 2006;296(9):1055-1062.

[10] Landrigan CP, Rothschild CM, Cronin JW, et al. Effect of reducing interns' work hours on serious medical errors in intensive care units. *N Engl J Med.* 2004;351(18):1838-1848.

[11] IOM (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-sleep-supervision-and-safety.

[12] Accreditation Council for Graduate Medical Education (ACGME). The ACGME's Approach to Limit Resident Duty Hours 12 Months After Implementation: A Summary of Achievements. http://www.acgme.org/portals/0/pfassets/publicationspapers/dh_dutyhoursummary2003-04.pdf.

Those attacking the ACGME's current resident work-hour restrictions argue that the limits increase medical errors by increasing the frequency of patient handoffs between medical residents. However, as documented by Public Citizen in its report presenting the results of the poll, there is no valid evidence from well-designed studies to support these assertions. In fact, the most rigorous trial to date of the effects of different work shift lengths found that reducing first-year residents' shifts to 16 hours or less actually *reduced* the frequency of serious medical errors despite an increase in the frequency of patient handoffs.[13] It should be remembered that the ACGME instituted the 16-hour limit for interns because of its own conclusion that interns "**make more errors when working longer consecutive hours.**"[14]

Now is not the time to backtrack and allow residents to work longer hours. The ACGME instead should strengthen patient and medical resident safety by, among other measures, expanding the current 16-hour cap on work shifts to all residents. As revealed in the Public Citizen/Lake Research Partners poll, 80 percent of Americans support such action.

To address concerns about problems related to patient handoffs, the ACGME should mandate new standards for ensuring that residents are trained on how to implement handoffs in a consistent, standardized, and effective fashion, and require that attending physicians supervise and confirm the adequacy of such handoffs. In its report, Public Citizen summarizes studies published since 2011 that demonstrate the benefits already achieved by standardized handoffs.

The unethical iCOMPARE and FIRST trials

Nearly 10 months ago,[15] Public Citizen and AMSA first called on the ACGME to 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 and FIRST trials, respectively. Both are highly unethical and fail to materially comply with key requirements of Department of Health and Human Services (HHS) regulations for the protection of human subjects. Moreover, these trials, conducted in hospitals throughout the country, are poorly designed and biased by the researchers' desire to create evidence that can be used to support their underlying agenda: to lift the ACGME's 2011 protective limits on resident work hours.[16]

Disturbingly, the ACGME — despite being made aware of the unethical nature of the trials — extended its waiver of some of the organization's current key resident work hour restrictions and

[13] Landrigan CP, Rothschild CM, Cronin JW, et al. Effect of reducing interns' work hours on serious medical errors in intensive care units. *N Engl J Med.* 2004;351(18): 1838-1848.
[14] 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.
[15] Public Citizen and the American Medical Student Association. Letter to the ACGME regarding the iCOMPARE and FIRST trials. November 19, 2015. http://www.citizen.org/hrg2285. Accessed September 12, 2016.
[16] Flexibility in Duty Hour Requirements for Surgical Trainees Trial – "the FIRST trial": Webinar PowerPoint presentation. http://www.thefirsttrial.org/Documents/Flexility%20In%20duty%20hour%20Requirements%20for%20Surgical%20Trainees%20Trial-the%20FIRST%20trial%20webinar.pptx.

provided additional funding to allow the continuation of the FIRST trial for a third academic year beginning July 1, 2016.[17] We have learned that the iCOMPARE trial has been extended for another year as well.[18]

As we noted in our November 19, 2015, letters to the ACGME[19] and to the Office for Human Research Protections,[20] the failures of the FIRST trial and iCOMPARE trial investigators to obtain the informed consent of the residents and patients who are the human subjects of the research violate the Belmont Report's basic ethical principle of respect for persons.[21]

These ethical violations are thrown into sharp relief by the results of the Public Citizen/Lake Research Partners poll for the following question:

> Researchers are conducting an experiment at more than 100 hospitals in the U.S. The hospitals were randomly divided into two groups: In one group, first-year residents are working shifts lasting no more than 16 hours in a row, as currently required by the ACGME. In the other group, first-year residents are allowed to work shifts lasting 28 or more hours in a row without sleep. The researchers want to find out whether patients treated at the hospitals where first-year residents are allowed to work for 28 or more hours in a row are more likely to die or have serious complications compared with patients treated at hospitals where first-year residents work no more than 16 hours in row.
>
> If you were admitted to one of the hospitals participating in this experiment, would you want to be informed if that hospital was assigned to the group where first-year residents are allowed to work shifts lasting 28 or more hours in a row without sleep?

A total of 84 percent of respondents stated that they would want to be so informed, with 78 percent responding "strongly" in the affirmative.

Allowing the continued unwitting enrollment of tens of thousands of patient subjects in the FIRST and iCOMPARE trials, in the face of data showing that the vast majority of the adult public would want to be informed of this experiment if they were admitted to one of the experimental-group hospitals, would constitute an egregious, knowing disregard for the basic ethical principle of respect for persons.

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[17] Accreditation Council for Graduate Medical Education. Letter to members of the graduate medical education community. May 17, 2016. http://www.acgme.org/Portals/0/PDFs/Nasca-Community/NascaLettertotheCommunity-5-17-16.pdf. Accessed September 12, 2016.

[18] Personal communication with residents who have been human subjects in the iCOMPARE trial.

[19] Public Citizen and the American Medical Student Association. Letter to the ACGME regarding the iCOMPARE and FIRST trials. November 19, 2015. http://www.citizen.org/hrg2285. Accessed September 12, 2016.

[20] Public Citizen and the American Medical Student Association. Letters to OHRP regarding the iCOMPARE and FIRST trials. November 19, 2015. http://www.citizen.org/hrg2283 and http://www.citizen.org/hrg2284, respectively. Accessed September 12, 2016.

[21] National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. *Ethical Principles and Guidelines for the Protection of Human Subjects of Research*. April 18, 1979. http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.html. Accessed September 12,2016.

Note that simply informing patient subjects of their involvement in these experiments would not constitute voluntary informed consent as required by HHS regulations and the ethical principles governing human subjects research, nor would it address the other ethical and regulatory lapses related to the design and conduct of these trials that were described in our prior letters. Moreover, the cluster-randomization design of these trials essentially makes it impossible to obtain the voluntary informed consent of all patient subjects enrolled at hospitals assigned to the experimental arms: Subjects would be unable to refuse participation in the trials without leaving the hospital and going to another, which for many seriously ill patients would not be medically feasible.

Requests to ACGME

In conclusion, we strongly urge the ACGME to:

1. Listen to the American public and reject any calls to remove the 16-consecutive-hour limit for interns;
2. Apply the 16-hour cap to all residents, and
3. Rescind its waivers that allow the iCOMPARE and FIRST trials to continue.

We look forward to a prompt reply and to immediate action on our three requests.

Sincerely,

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Enclosure