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Honorable David Michaels, Ph.D., M.P.H.
Assistant Secretary of Labor for Occupational Safety and Health
Department of Labor
Occupational Safety and Health Administration
200 Constitution Avenue NW
Washington, DC 20210

Dear Dr. Michaels:

This letter is in response to the recent denial of the second petition[1] (the first having been sent in 2001) of Public Citizen and co-petitioners calling on the Occupational Safety and Health Administration (OSHA) to assume responsibility for, and enact a standard, regulating medical resident work hours. In denying our petition, the Obama administration has rehashed the same discredited Bush-era arguments of nine years ago, when our first petition was rejected on almost identical grounds. OSHA has, once again, opted out of its legal obligation to protect residents from excessive work hours, deferring instead to a largely unaccountable private entity, the Accreditation Council for Graduate Medical Education (ACGME).

A. The Obama administration's response mirrors Bush-era denial of Public Citizen's 2001 petition

Our petition in 2001 was filed as a result of the long-standing failure of the ACGME to protect resident physicians from the consequences of excessive hours on the job. When OSHA denied the petition one year later, the ACGME still had no universal duty hour limits in place. OSHA was confident that the ACGME's newly proposed guidelines (implemented in 2003 and not in force at the time of the first denial), and the enforcement tools at its disposal, would be sufficient to address the problem, as it stated in its 2002 letter rejecting our petition (attached):

> "Since the time you submitted your petition to OSHA, the ACGME has endorsed a report calling for greater limits on resident duty hours, including administrative changes strengthening the systems for ensuring hospital compliance with the new working hour requirements … **OSHA believes that the ACGME and other**

> **entities are well-suited to address work-duty restrictions of medical residents and fellows.**" [emphasis added]

Where the Bush administration based its confidence in the ACGME on the pending 2003 guidelines, the Obama administration is now relying on the new 2011 rules, stating in its recent letter (attached):

> "OSHA also recognizes that ACGME regulates duty work hours for resident physicians since ACGME is the organization responsible for the broader accreditation process and oversight of the medical residents' sponsoring institutions … **[The] new duty hour standards along with the new enforcement mechanisms that took effect in July 2011 provide an opportunity for ACGME to take meaningful steps to protect the health of resident physicians within the context of their overall residency experience."** [emphasis added]

Thus, the Obama administration continues the Bush-era belief in the ACGME as the appropriate entity to discharge what is actually OSHA's legal responsibility because of unwarranted, unrealistic hopes that it will do a good job.

B. ACGME "progress" since Public Citizen's first petition

Over the past decade, it became increasingly clear that the faith placed by the Bush administration in the ACGME was misplaced. The 2003 guidelines adopted shortly after the denial of our petition were patently insufficient to address the dangers of long hours, as was made clear in a 2009 Institute of Medicine (IOM) report that called for much safer work-hour limits.[2] In addition, ACGME enforcement of its own duty hour rules remained woefully inadequate.

In a nationwide, validated survey in 2003-04 of 4,015 interns, 84% reported hours of work in violation of the 2003 ACGME standards.[3] This number far exceeds ACGME-disclosed rates of violations reported by resident physicians and residency programs, indicating both that the ACGME's enforcement has been ineffective and that widespread underreporting exists (as confirmed in the recent IOM report).[4] As long as ACGME relies on resident self-reports as its primary means of ensuring compliance with its rules, pervasive underreporting by residents will hinder any meaningful enforcement.

It is worth pointing out that the ACGME is a private organization that primarily represents residents' employers rather than the residents themselves. The ACGME board of directors includes members from the American Hospital Association and the Association of American Medical Colleges, both of whom represent the interests of teaching hospitals,[5,6] the very employers under whom residents work. These member

organizations appoint a total of eight representatives to the board, while only two of the approximately 30 positions on the board are reserved for resident representatives.[7]

C. OSHA again placing faith in ACGME

By deferring to the ACGME, the Obama administration is choosing to ignore the organization's track record, relying instead on the new ACGME work-hour limits implemented in July 2011 in response to the IOM report.[8] However, these new work-hour rules serve as yet more evidence of the need for federal oversight.

The updated guidelines, while acknowledging the danger of extremely long shifts and restricting interns to no more than 16 continuous hours, inexplicably continue to permit upper-level residents to work up to 28 hours. As we stated in our petition, there is no scientific basis for this guideline, as human beings do not suddenly acquire the ability to work safely for 12 additional hours after completing one year of training. The ACGME also maintained its 2003 policy of permitting programs to average the 80 hour/week duty hour limits over the course of a month, thereby continuing to allow residents to work 100 or more hours on any given week. These, among other dangerous guidelines, prompted Public Citizen and its co-petitioners to again request that OSHA fulfill its legal responsibility to protect resident physicians from harm.

D. OSHA's dubious current justifications for inaction

The Obama administration's justifications for its denial of our most recent petition are, as with the Bush administration before it, based on irrelevant arguments that do not address the issue at the core of our request: that medical residents are employees and are, therefore, clearly under OSHA's jurisdiction and entitled to all of the protections that are afforded to other workers. In fact, in its denial letter, OSHA agrees with this claim. However, it then goes on to list a series of arguments that do not in any way negate this central premise of OSHA protection.

1. *"Resident" and "student" are not mutually exclusive designations*

In its letter, OSHA concedes the central point that residents are, in fact, employees but evades the implications of this acknowledgment by rehashing the "residents as students" argument:

> "Although it is clear that they are employees, and therefore covered by the Occupational Safety and Health [OSH] Act of 1970, resident physicians are also students since they receive training critical to their professional education."

We do not see the point of emphasizing that residents are also students. OSHA does not contend that residents' dual status as students excludes them from the OSH Act's

protections and presents no reason why their role as students somehow provides them any protections against workplace injury that justifies the agency's failure to act.

As it turns out, OSHA's belated acknowledgment of residents' status as employees (they made no such mention in their 2002 denial letter) has already been confirmed by the National Labor Relations Board (NLRB). In a 1999 decision, the NLRB determined that resident physicians are primarily employees, not students, stating: "That they [house staff] also obtain educational benefits from their employment does not detract from this fact [that they are employees]. Members of all professions continue learning throughout their careers." The NLRB concluded that "house staff are employees … and … are therefore entitled to all the statutory rights and obligations that flow from our conclusion."[9]

OSHA also fails to mention how enforcing safe work-hours would interfere with the education residents receive as students. The question of whether new work-hour rules would adversely impact resident education is a reasonable one, but even here, the evidence seems to be in favor of such rules. A systematic review of studies exploring this question found that, in nine out of 14 studies, educational outcomes did not change with reduction or elimination of shifts greater than 16 hours. In four out of 14 they actually improved. In only one out of 14 studies did any measure of education worsen (and that particular measure was a subjective rating by senior physicians).[10] Regardless of the true outcome, however, resident safety takes precedence over education, and programs must find ways to adapt (as they did in 2003) to accommodate both concerns.

2. *Patient safety is another red herring*

OSHA once again justifies its denial of our petition on the grounds that the issue "goes beyond the occupational safety and health of the residents and impacts patient safety and quality of care." However, OSHA does not elaborate any further on this, choosing to ignore the significant body of literature presented in our recent petition supporting the common sense notion that patients are better cared for by well-rested residents than those forced to stay awake after long shifts.[11,12] In addition, handoff of patient-care duties between shifts is addressed extensively in the 2009 IOM report, with detailed recommendations (such as standardized handoff protocols) that can be easily adopted by hospitals to minimize the chance that patient safety would be compromised by the process.[13]

Furthermore, the grounds for our petition clearly centered on the safety and health of residents, and only mentioned patient safety in passing, explicitly stating that this issue was beyond the scope of the petition and OSHA's jurisdiction. All of the evidence presented in the petition, in the form of peer-reviewed studies documenting that long work hours represented a serious occupational hazard, referred to resident — not

patient — health. And again, we are not aware of anything in the OSH Act that prohibits the enactment of a standard if the standard would also incidentally benefit nonworkers.

3. *OSHA inaction in other industries does not justify inaction in this case*

In its denial letter, the Obama administration did differ in one respect from its predecessor by adding a novel, but similarly immaterial, justification. What we asked for in the petition were regulations specifically targeted to a single group of workers (resident physicians). In its denial of our request, OSHA seems to claim that, since workers in multiple industries suffer from work-related fatigue, the agency cannot issue standards protecting workers in *one* industry. In other words, OSHA is effectively saying that it will never issue a standard that would protect one group of workers unless all workers are protected. This is an alarming precedent, and one unique to OSHA given that other agencies within the federal government have long instituted work-hour regulations precisely for those sectors where worker fatigue can also be dangerous to the general public.

For over a century (dating back to 1907), in fact, the federal government has recognized the importance of regulation of work hours in transportation and other industries. Under the jurisdiction of the Department of Transportation, work-hour limits and rest-period requirements for the highway, aviation, railroad, and maritime industries have been established.[14] In addition to serving as an acknowledgment by OSHA of its comparative inaction on this topic across multiple industries — including professions that, like medical residency, impact public safety — this argument lacks logic. The agency's neglect of workers in other industries should not serve as an argument against protecting medical residents. After all, in its letter, OSHA refers to residents as being "in a unique situation" due to their educational requirements and the impact of their work on nonemployees (patients). Therefore, at the very least, this is reason enough to prioritize resident work hours over other workers.

E. OSHA already has the authority under the General Duty Clause to enforce safe resident work hours, but there is no evidence that this authority is being utilized

Our petition asked for a specific standard regulating resident work hours, since such a standard would be the most effective means of ensuring accountability for protection of residents' health. However, even in the absence of such a standard, which OSHA has now twice refused to enact, the agency already has the authority to enforce safe medical resident work hours. Given that OSHA acknowledges that residents are covered under the OSH Act, the agency can simply assert its authority under the General Duty Clause to hold accountable employers that violate the health and safety of their residents.

This is an avenue that has not been pursued to our knowledge,[15] yet it seems to us a necessary and reasonable approach until a formal standard is set. OSHA regularly invokes unofficial standards set by independent organizations (e.g., American Conference of Governmental Industrial Hygienists guidelines) when citing an employer under the Clause[16] and could do the same in this case, referring to the new ACGME rules, at a minimum (but preferably the more protective IOM recommendations), as justification for its enforcement actions.

In its letter, OSHA stated, reasonably, that the agency is "facing significant challenges" and must therefore "prioritize limited resources and cannot move forward on every rulemaking request." We agree that the agency is indeed chronically underfunded by Congress.[17] However, enforcement of resident work hours under the General Duty Clause need not consume more resources. OSHA already conducts more than 100 hospital inspections every year for other reasons.[18] Therefore, the agency could simply instruct inspectors to investigate compliance with IOM work-hour recommendations in the course of the inspection, which would clearly not represent an unreasonable time or resource demand.

F. OSHA must follow through on its pledge to protect resident whistle-blowers

In its letter, OSHA did not mention the General Duty Clause as an avenue of enforcement, instead referring only to the whistle-blower provisions of the OSH Act (29 U.S.C. § 660[c]) as a means of responding to incidents where retaliatory action has been taken by an employer against a resident for voicing concerns about work-hour violations. While insufficient as a sole enforcement tool, whistle-blower protection is yet another reason why OSHA must assume responsibility for protecting residents. The ACGME's monitoring and compliance is based on resident physicians reporting violations in their own programs — yet the ACGME does not provide whistle-blower protection.

However, even with the protection against employer retaliation afforded by OSHA, residents will still have an inherent disincentive to report work-hour violations, as they may fear loss of their program's residency accreditation as a result of their complaint. In addition, the OSHA whistle-blower protection provision applies only in cases where an employee exercises rights under the OSH Act or makes a complaint under the Act. The average resident physician, however, is likely not aware of their rights under the OSH Act, and even those residents who are aware that they can file a complaint with OSHA will likely be discouraged by the agency's general lack of willingness to act on this issue. These points underscore why a proactive enforcement policy under the General Duty Clause is necessary, in addition to one that responds to complaints after the fact.

G. OSHA must act immediately, using its existing authority to protect resident physicians

Unfortunately, the Obama administration, in acknowledging that medical residents are entitled to protections as employees under the OSH Act, and then going on to state that it will not act to protect them as required by the Act, has, as in the case of the Bush administration, demonstrated brazen disregard for the health and safety of 110,000 U.S. resident physicians. OSHA's arguments against acting are irrelevant and serve to divert attention away from the fact that OSHA is explicitly declining to fulfill its legal responsibility in deference to an unaccountable, private body (ACGME) that has consistently demonstrated its inability to protect resident physicians from harm.

As the agency has refused to consider enacting a new standard regulating resident work hours, we call on OSHA to:

1. Begin enforcing safe resident work hours under the General Duty Clause and hold academic hospitals accountable for putting the safety of physicians-in-training, and that of their patients, in harm's way; and
2. Provide data detailing past enforcement actions taken to protect resident whistle-blowers under 29 U.S.C. § 660(c) and elaborate further on how it plans to hold academic medical centers accountable for retaliatory actions against residents in the future.

We look forward to a prompt response to the questions raised in this letter and, most importantly, to our requests for action on this issue.

Sincerely,

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[1] Public Citizen and co-petitioners. Petition to Reduce Medical Resident Work Hours. September 2, 2010. Accessible at: http://citizen.org/Page.aspx?pid=4287

[2] Institute of Medicine. Resident duty hours: enhancing sleep, supervision, and safety (2009). Accessed on October 8, 2011. http://www.nap.edu/catalog.php?record_id=12508

[3] Landrigan CP, Barger LK, Cade BE, Ayas NT, Czeisler CA. Interns' compliance with accreditation council for graduate medical education work-hour limits. JAMA. 2006 Sep 6;296(9):1063-70.

[4] Institute of Medicine. Resident duty hours: enhancing sleep, supervision, and safety (2009). P. 64. Accessed on October 8, 2011. http://books.nap.edu/openbook.php?record_id=12508&page=64.

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[6] Association of American Medical Colleges (AAMC). Accessed on October 4, 2011. https://www.aamc.org/about/.

[7] Accreditation Council for Graduate Medical Education. The ACGME at a Glance. Accessed on October 27, 2011. http://www.acgme.org/acWebsite/newsRoom/newsRm_acGlance.asp.

[8] Nasca TJ, Day SH, Amis ES Jr; the ACGME Duty Hour Task Force. The New Recommendations on Duty Hours from the ACGME Task Force. N Engl J Med. 2010 Jun 23.

[9] National Labor Relations Board. Boston medical center corporation and house officers' association/committee of interns and residents, petitioner, Case 1-RC-20574. November 26, 1999.

[10] Levine AC, Adusumilli J, Landrigan CP. Effects of Reducing or Eliminating Resident Work Shifts over 16 Hours: A Systematic Review. Sleep 2010; 33: 1043-53.

[11] Lockley SW, Cronin JW, Evans EE, Cade BE, Lee CJ, Landrigan CP, Rothschild JM, Katz JT, Lilly CM, Stone PH, Aeschbach D, Czeisler CA; Harvard Work Hours, Health and Safety Group. Effect of reducing interns' weekly work hours on sleep and attentional failures. N Engl J Med. 2004 Oct 28;351(18):1829-37.

[12] Szklo-Coxe M. Are residents' extended shifts associated with adverse events? PLoS Med. 2006 Dec;3(12):e497.

[13] Institute of Medicine. Resident duty hours: enhancing sleep, supervision, and safety (2009). P. 270. Accessed on October 8, 2011. http://books.nap.edu/openbook.php?record_id=12508&page=270

[14] Public Citizen. Petition to Reduce Medical Resident Work Hours. September 2, 2010. P. 21-29. Accessed on October 17, 2011. http://www.citizen.org/documents/1917.pdf.

[15] We accessed the OSHA General Duty Clause search engine on September 30, 2011, and, using multiple search terms, could not find any inspections that resulted in a citation for violating medical resident work-hour limits. Accessible at: http://www.osha.gov/pls/imis/generalsearch.html.

[16] See Public Citizen's petition to OSHA for a heat standard, September 1, 2011. The petition documents 112 inspections conducted under the General Duty Clause that resulted in at least one citation for unsafe heat practices. In many of these instances, the inspector cited and recommended to the employer the ACGIH guidelines on safe heat practices. Accessible at http://www.citizen.org/documents/Petition-for-a-heat-standard-090111.pdf.

[17] Center for Progressive Reform. Workers at Risk: Regulatory Dysfunction at OSHA. Accessed on October 6, 2011. http://www.progressivereform.org/articles/OSHA_1003.pdf.

[18] OSHA. Integrated Management Information System (IMIS) database. A search was conducted on October 18, 2011, of hospital inspections conducted by year (2008-11). The Standard Industrial Classification (SIC) code, 8062, was used. It refers to all hospitals classified as "Services-General Medical & Surgical Hospitals, NEC." Accessible at http://www.osha.gov/pls/imis/industry.html.