September 2, 2010

Honorable David Michaels, PhD, MPH
Assistant Secretary for Occupational Safety and Health
U.S. Department of Labor
Occupational Safety and Health Administration
200 Constitution Avenue, N.W.
Washington, D.C. 20210
(202) 693-2000

Dear Dr. Michaels,

Public Citizen, a consumer and health advocacy group with 150,000 members and supporters; the Committee of Interns and Residents/SEIU Healthcare (CIR/SEIU), a housestaff union, part of SEIU, representing over 13,000 resident physicians; the American Medical Student Association (AMSA), a national organization representing over 33,000 physicians-in-training; Bertrand Bell, M.D., Professor of Medicine at Albert Einstein College of Medicine and author of New York State Health Code 405 restricting resident physician work hours; Charles A. Czeisler, Ph.D., M.D., Baldino Professor of Sleep Medicine, Harvard Medical School; and Christopher P. Landrigan, M.D., M.P.H., Assistant Professor of Pediatrics and Medicine, Harvard Medical School, hereby petition the Occupational Safety and Health Administration (OSHA) to implement the following key regulations for the work hours of resident physicians and subspecialty resident physicians, (i.e., medical and surgical fellows), building from the recommendations made by the Institute of Medicine in its 2009 Report, *Resident Duty Hours: Enhancing Sleep, Supervision, and Safety:*

(1) A limit of 80 hours of work in each and every week, without averaging;
(2) A limit of 16 consecutive hours worked in one shift for *all* resident physicians and subspecialty resident physicians;
(3) At least one 24-hour period of time off work per week and one 48-hour period of time off work per month for a total of five days off work per month, without averaging;
(4) In-hospital on-call frequency no more than once every three nights, no averaging;
(5) A minimum of at least 10 hours off work after a day shift, and a minimum of 12 hours off after a night shift;
(6) A maximum of four consecutive night shifts with a minimum of 48 hours off after a sequence of three or four night shifts.

These recommendations are necessary for protecting the safety of resident physicians and subspecialty resident physicians. Their implementation would also have the secondary benefit of resulting in a safer, better standard of care for patients nationwide.

The petitioners request the Assistant Secretary for Occupational Safety and Health to exercise his authority under section 3(8) of the Occupational Safety and Health Act,[1] on the grounds that work hours in excess of the requested limits are physically and mentally harmful to resident physicians and subspecialty resident physicians, and that a federal work-hour standard is necessary to provide them with safe employment. Research has connected the typical resident work schedule to harm in four specific areas: motor vehicle accidents, mental health, pregnancy, and percutaneous injuries (such as needlestick injuries).

Resident physicians in the U.S. work among the highest number of hours in the professional world. Working these extreme hours for years at a time, predictably, has ill effects on personal health and safety. Multiple studies in the medical literature demonstrate that sleep-deprived and overworked resident physicians are at increased risk of being involved in motor vehicle collisions, suffering from depressed mood and depression, giving birth to growth-retarded and/or premature infants, and getting more percutaneous injuries. The signers of this petition believe that these are grave health outcomes and that any system allowing its workers to be subjected to such direct threats to well being is seriously flawed. For OSHA not to regulate resident physician work hours is to abdicate its responsibility to protect the health of those who care for the nation's sick and dying.

In order to fulfill OSHA's mission "to send every worker home whole and healthy every day,"[2] you must act now to address the dangers that extreme work hours pose for resident physicians and subspecialty resident physicians. Whereas previous appeals to limit resident physicians' work hours have focused on the well-documented risks patients face due to tired physicians, this petition concentrates on the often-overlooked health risks faced by the resident physicians who endure those long hours. As grounds for the work-hour standards requested above, we utilize a review of the medical literature to (1) characterize current working conditions in residency programs in the U.S., and to (2) provide evidence of the physical and mental harm that comes to resident physicians as a result of their long work hours. Next, we (3) review various responses to the problem of excessive work hours, including how other industrialized countries have acted to protect their resident physicians through mandated work-hour limits, and how our own federal government already protects workers and the public through hours-of-service regulations in a variety of transportation and other industries. Finally, we examine (4) the relevance of resident physician work-hours reduction to patient protection, (5) arguments against the reduction of resident physician work hours, and (6) the appropriate role of OSHA in regulating resident physician work hours.

To be absolutely clear, we are only asking OSHA to regulate and enforce resident physician work hours, a responsibility that is clearly within the agency's jurisdiction. We are not asking the administration to assume oversight of resident physician education and supervision functions. We believe the Accreditation Council for Graduate Medical Education (ACGME), the professional medical organization that currently oversees all resident physician training, should retain that function.

PART 1: RESIDENT PHYSICIANS WORK EXCESSIVE HOURS

A. THE RESIDENT PHYSICIAN WORK SCHEDULE

Depending on the type of residency, physicians-in-training can work anywhere from 60 to 100 or more hours a week, sometimes without a day off for two weeks or more. Specifics come from a nationwide prospective cohort study of US first-year resident physicians (interns) conducted by Landrigan *et al.*, which evaluated hours worked in 2002-2003 and 2003-2004.[3] Four thousand and fifteen interns participated in the study, providing 29,477 monthly reports of their work and sleep hours. Even after implementation of the ACGME's Common Duty Hour Standards in 2003,

- The average work week was 66.6 hours (95% confidence interval [CI] 66.3-66.9);
- The mean length of an extended shift was 29.9 hours (95% CI, 29.8-30);
- 29% of all work weeks were more than 80 hours in duration, 12.1% were 90 or more, and 3.9% were 100 hours or more;
- 83.6% of all interns reported hours of work in violation of the professional self-regulations that were established and are being monitored by the ACGME. This number far exceeds the rates of violations reported by resident physicians and residency programs to the ACGME, indicating both that widespread under-reporting exists, and that the ACGME's enforcement has been ineffective.

B. RESIDENT PHYSICIAN STRESS AND DISSATISFACTION WITH EXCESSIVE WORK HOURS

Resident physicians must deal with multiple stresses of patient care, patient death, the need for constant learning, the task of teaching medical students, the requirements of attending physicians and senior resident physicians, and the necessities of family and personal life — all while being subjected to the chronic sleep-deprivation and exhaustion caused by their excessive work schedules. In a study conducted by Schwartz *et al.*, 377 resident physicians answered a survey in which they were asked to rate the most stressful factors in their residency. Among choices such as "high mortality among patients" and "large patient load,"

resident physicians rated “lack of sufficient sleep” and “frequent overnight call” as the top two most negative factors of residency.[4] Small has written of a “house officer stress syndrome” caused in large part by sleep-deprivation and excessive work load, in which physicians-in-training may suffer from (1) episodic cognitive impairment, (2) chronic low-grade anger with outbursts, (3) pervasive cynicism, (4) family discord, (5) depression, (6) suicidal ideation and suicide, and (7) substance abuse.[5]

A number of studies have sought to identify resident physicians’ own perceptions of their training. Although they are not objective measures, resident physician opinions offer some insight into the problem. Daugherty *et al*. found that resident physicians had only a moderate level of satisfaction with their learning and work experience.[6] When satisfaction with specific aspects of the internship year was reported on a scale from 1 to 7 (least to most), it was found that resident physicians were most satisfied with what they learned (4.8) and their relationships within the hospital (4.8). They were least satisfied with friend and family relationships outside the hospital (3.9), and with personnel support services (3.6). Nearly 20% of respondents rated their internship experience as less than satisfactory.

In a Letter to the Editor of the *Journal of the American Medical Association* (JAMA), Dr. Murad Alam of the College of Physicians and Surgeons at Columbia University wrote:

> While many types of work require precision (e.g., computer programming) or concentration (e.g., air traffic control), medical internship is unique in requiring both from workers in a chronic state of fatigue. Living in the hospital for protracted durations prevents residents from obtaining respite from their job-related frustrations. The intrusiveness of being on-call barely allows for even a few minutes of privacy. For days at a time all personal activities are continually subordinated to the mantra of patient care. On-call responsibilities make residents exhausted, lonely, and unable to meet their own needs … [7]

In a survey completed by 108 male and female resident physicians, more than 40% of those who defined themselves as being in a committed relationship believed that they had “major problems” with their spouse or partner. Seventy-two percent of them believed that these problems were due to residency, and 61% of them reported that their spouse or partner agreed with this assessment.[8] Multiple regression analysis revealed that 50% of the variance in relationship stress could be accounted for by the following ten variables: high number of hours spent in the hospital, year of training, lack of moderate athletic activity, sleep deprivation, lack of family and social contact, inability to do daily errands, indebtedness, large amount of time spent doing housework, high number of spouse’s working hours, and fewer awake hours at home (model $F = 3.05$; $df = 14; 42$; $p < 0.002$). A paper describing a support group for the wives of resident

physicians found that they had prevailing feelings of anger, depression, frustration, and impotence in coping with their husbands' residency period.[9]

PART 2: EVIDENCE OF HARM TO RESIDENT PHYSICIANS

In our review of harms to resident physicians, we limited ourselves to studies that included resident physicians (and not physicians in general) as the study population, and only studies that used work hours or hours of sleep as the predictor variable, treating specific effects on health as the outcome variables. Application of these selection criteria resulted in elimination of some of the literature on resident physician harm; however, for four specific health hazards — motor vehicle crashes, mood alterations and depression, obstetric complications, and percutaneous injuries (e.g. needle sticks) — studies did match our selection criteria. For each hazard, we present background information, describe relevant studies, and summarize key findings.

A. MOTOR VEHICLE CRASHES

The news is peppered with stories of resident physician involvement in car crashes, or near crashes, while driving from the hospital. In January 1999, a resident physician named Valentin Barbulescu had just finished a long shift in the cardiac care unit and was driving off to take an important certification exam. Dr. Barbulescu was killed in a one-car crash in rural Pennsylvania, an accident his colleagues reported was due in part to fatigue.[10]

An emergency medicine resident physician wrote a letter in 1998 to the editor of the *Annals of Emergency Medicine*, describing how he woke up at the wheel just in time to stand on the brakes and skid 73 feet before hitting the back of a 10-ton truck going 5 miles per hour. He was on his way home from the second of two 12-hour night shifts. The resident physician suffered 10 fractures and the failure of his new marriage as a result of the accident.[11]

In 1990, a New York City resident physician fell asleep at the wheel of his car after a sleepless 36-hour shift at New York City Hospital, and awoke to find his car stopped on FDR Drive, with traffic driving around him.[12] A resident physician from the surgery program at Johns Hopkins, Dr. Moriarity, relates:

> I think outside the hospital, you know, most residents fall asleep at the wheel driving home from work. Almost every resident I know in that program [surgery] has fallen asleep at the wheel driving home from work. And many of them have been in car accidents. Inside the hospital, they fall asleep at the operating table…[13]

An informal survey published in JAMA in 1988 found that six out of seven surgical resident physicians had fallen asleep at the wheel while driving to and

from work, and three had been involved in car accidents.[14] One doctor commented, “Falling asleep at the wheel post-call is virtually *universal*. I have not found anyone who has not had this problem.”[15]

In the published scientific literature, there is strong evidence that resident physician work hours are associated with an increased risk of motor vehicle crashes, especially after working more than 24 continuous hours. In a *New England Journal of Medicine* study, published in 2005, the Harvard Work Hours, Health, and Safety Group collected monthly data from 2,737 interns across the U.S. to investigate the relationship between hours worked, motor vehicle crashes, near-misses, and incidents involving involuntary sleeping.[16] In a within-subjects analysis, the investigators found that the risk of a motor vehicle crash was increased significantly following a work shift of 24 hours or greater, compared with the risk of a crash following non-extended shifts (OR 2.3; 95% CI, 1.6-3.3). They also found a significantly increased risk of a near-miss accident (OR 5.9; 95% CI, 5.4-6.3) after a shift lasting more than 24 hours. Moreover, a dose-response relationship was identified in a second prospective analysis using the same dataset, providing strong evidence of a causal connection between extended shifts and the risk of motor vehicle crashes. For each additional 24-hour shift worked in a month, the probability of any motor vehicle crash increased by 9%, and the probability of a post-extended shift crash increased by 16%, in an additive fashion. Thus, for resident physicians on a “q3” (every third night) schedule, a schedule in which resident physicians work 10 extended duration ($\geq$ 24-hour) shifts per month (a common schedule, and one that is sanctioned by the ACGME under both the existing 2003 ACGME regulations, and under the proposed 2011 ACGME regulations), the risk of a crash after an extended duration work shift was increased 160% (i.e., 16% per shift x 10 shifts).

Researchers from Johns Hopkins Hospital examined how sleep deprivation affects driving in pediatric resident physicians, and used pediatric faculty as the control group. Questionnaires were administered to 70 pediatric resident physicians who were on call every fourth night, and to 85 faculty members who were rarely disturbed at night. The response rate was 87%. Resident physicians averaged 2.7 (SD 0.9) hours of sleep while on-call vs. 7.2 (SD 0.8) hours of sleep when not on-call ($p < 0.001$). Faculty slept 6.5 +/- 0.8 hours at night. Twelve-point-five percent of pediatric faculty had fallen asleep while at the wheel at a stop light over the preceding three years, compared to 44% of resident physicians ($p < 0.001$). Forty-nine percent of resident physicians reported falling asleep at the wheel (not necessarily at a stop light), and 90% of these events occurred after the resident physicians had worked an extended duration ($\geq$ 24-hour) shift. The authors reported, “One [resident physician] wrote that she routinely used her emergency brakes when stopped at a light because of her sleepiness post-call.” The report concluded, “We have demonstrated that [resident physicians] have an increased incidence of falling asleep at the wheel when driving home post-call, and this probably has resulted in increased … motor vehicle accidents.”[17]

Yet more evidence comes from an abstract published in *Anesthesiology*, in which investigators surveyed 74 anesthesiology resident physicians at the Hospital of the University of Pennsylvania. Resident physicians were asked to report traffic accidents, near-miss accidents, or traffic violations that occurred during their residency and which they attributed to fatigue. Information on traffic conditions, time of day, call frequency, and hours of sleep on-call prior to the crash was obtained. Seventy-eight percent (58) of the resident physicians responded. Crashes during residency were reported by 17% of the resident physicians, with all crashes occurring between 8 a.m. and 9 a.m. (driving home post-call) in "moderate" to "no" traffic. "Near misses" or narrowly avoided crashes were reported by 72% of resident physicians, with one-third of this group having had five or more. Most resident physicians (85%) indicated that they were specifically concerned for their safety because of fatigue while driving home post-call.

Wendt has referred to chronically sleep-deprived resident physicians as "misguided missiles."[18] This is not an exaggeration; resident physicians are truly impaired drivers. A prospective two-session within-subject study of 34 volunteer pediatric resident physicians (out of 115, or 30%) in JAMA compared sleepy resident physicians to intoxicated resident physicians.[19] Investigators examined the neurobehavioral performance of resident physicians at the end of a heavy-call month and compared it with the neurobehavioral performance of resident physicians after a light-call month. The light-call condition was equivalent to a clinic month with few overnight calls, if any. The heavy-call condition was similar to a traditional schedule of call every fourth or fifth night. The study found a decrement in post-call performance of the heavy-call group similar to that of a resident physician on a light-call month with a blood alcohol concentration of .04-.05 g. %, in the areas of sustained attention, vigilance, and simulated driving tasks. Reaction times were 7% slower ($p < .001$), commission of errors was 40% higher ($p < .001$), and speed variability was 71% greater ($p < .001$) in heavy-call resident physicians compared to light-call resident physicians.

Indeed, multiple studies establish that motor vehicle crashes are an occupational hazard for a significantly high number of resident physicians under their current working conditions. It is common sense that excessive work schedules contribute to resident physician fatigue and increase the risk of serious motor vehicle crashes. Moreover, resident physicians unfit to drive due to fatigue and sleep deprivation represent a threat to other drivers on the road. In 1998, a first year Anesthesia resident physician at Rush Presbyterian Medical Center in Chicago was driving home after an extended-duration work shift of 36 hours and rear-ended a car driven by Heather Brewster, a young graduate student whose severe head injuries changed her life forever.[20] The Brewster family sued Rush for scheduling the young resident physician to work such dangerously long shifts, but the hospital argued that it was the intern's decision to drive home, so the liability belonged solely to her. The state's highest court agreed. It is clear that

OSHA would be acting in the interest of both resident physician health and public health by reducing work hours for resident physicians.

B. MENTAL HEALTH

Negative Effects of Work Hours on Mood and Affect

Mood is defined as the prevailing subjective emotional state (such as happy, sad, euphoric, irritable, or agitated) of a subject, and affect is defined as how the subject's mood is expressed. Depressed mood in particular is characterized by general hopelessness, passivity, lifelessness, dysphoria, demoralization, and pessimism. Subjects can be irritable, emotionally unstable, and argumentative; some can be agitated and anxious, while others are quietly apathetic and vegetative.[21]

In 1973, a case study of 14 interns at Columbia Presbyterian Hospital was published to examine work hour effects on mood.[22] Although the hours worked then were longer than the hours worked now (resident physicians were on-call every other night, and often worked 60-hour shifts), the study is still relevant today because it shows how mood is negatively affected by lack of sleep. The following are comments taken directly from study subjects, all of whom experienced mood alterations:

> *Difficulty Concentrating.* "When I'm tired, even though my mind is active, I can't concentrate. I can't put things together in my mind so I don't even try. If a patient is really sick, I can pull myself together but I can't write down what I've done in the chart. What I write is a reflection of a fragmented thought process…. It gets me scared when this happens because it means that I am losing control of my ability to think."
>
> *Depressed Mood.* "My home life suffers and I miss my wife greatly. I feel ashamed that I get tired and can't live up to the tradition of the 'iron men.'"
>
> *Irritability.* "As I lose sleep, I get more explosive and more irritable. I snap at nurses and make them cry. I pick on the nursing staff rather than my wife or my patients. I'm ashamed of it in a way."
>
> "If you're on two nights in a row, you want to do as little as possible. You give bad care. I am irritated all the time then … I give bad care to my patients, unfortunately. When I'm tired I don't give a Goddamn."
>
> *Inappropriate Affect ("Black" Humor).* "I laugh at things that aren't really funny. I'm giggly when I'm tired. For instance last night a patient came in comatose. Another intern asked the patient: 'Do

> you have any parakeets at home?' I found this enormously funny and I laughed and laughed … Things don't seem so funny to me when I am rested. Another example of my sense of humor when I am fatigued would be: An intern gets a patient with congestive heart failure and pulmonary edema. He makes a wise comment like, 'Give her some vitamins and send her home.' That makes me crack up. I would not find such a remark funny when I am rested."
>
> *Memory Deficit.* "I would forget what I just said so my next sentence would make no sense. I also stop sentences midway a lot because I forgot what I wanted to say."

Other studies confirm these mood effects using objective measures. At Columbia University, investigators used the Nowlis and Green Mood Adjective Check List (MACL) to compare 14 interns when rested and fatigued. The MACL consisted of 33 adjectives describing 11 mood factors: aggression, anxiety, surgency (feeling carefree, lively, talkative), elation, concentration, fatigue, social affection, sadness, skepticism, egotism, and vigor. In the 32 hours before testing, rested interns slept a mean of 7.0 hours and fatigued interns slept a mean of 1.8 hours ($p < 0.001$). Tired resident physicians reported worse scores than rested resident physicians, with tired resident physicians having statistically lower scores in positive mood factors (surgency, vigor, elation, egotism, and social affection) and significantly higher scores in negative mood factors (fatigue and sadness).[23]

Another study randomly assigned 30 first-year internal medicine resident physicians to sleep-deprived (n = 16) and non-sleep-deprived (n = 14) groups, and followed them from the fifth to the ninth month of their internship year at the Medical College of Virginia Hospitals. The two groups had a similar age, sex ratio, and racial composition. Resident physicians in both groups were tested with the Multiple Affect Adjective Check List (MAACL) from 2 p.m. to 3 p.m. after being on-call or after having been off work. Sleep-deprived resident physicians (mean 2.7 hours sleep) reported greater mood disturbance than non-sleep-deprived resident physicians (mean 7.9 hours of sleep) in the different categories of the MAACL ($p < 0.05$).[24]

Researchers at Case Western Reserve University compared 34 pediatric resident physicians before and after a night of call with 27 resident physicians who were not on-call either day.[25] The different groups were tested using the Profile of Mood State scale (POMS), a 65-item adjective-rating measure that assesses mood state on a five-point scale. A total score is provided, as well as subscales for tension-anxiety, depression-dejection, anger-hostility, vigor-activity, fatigue-inertia, and confusion-bewilderment (higher score = worse mood state). The on-call group of resident physicians showed increased total negative mood state scores (pre-call: 54; post-call: 74), while the group not scheduled to work extended duration ($\geq$ 24-hour) work shifts on any of the days demonstrated improving total mood scores (Day 1: 60; Day 2: 49). The scores for all six subscales of the POMS also demonstrated increased negative mood for the on-

call group post-call, while the off-call group demonstrated improved mood on the second day.

Studies thus consistently show that resident physicians experience negative, unhealthy alterations in mood as a result of their long work shifts. These effects last longer than just the post-call day. In one study that demonstrated this, 52 volunteer medicine resident physicians (out of a possible 148, or 35%) were followed each of three days post call (on a 1-in-4 schedule) and were assessed on mood (POMS) and sleepiness scales (ESS).[26] Sixty percent (31) of these volunteers returned usable data. The results showed that actigraphy recorded total sleep time (TST) on-call was 3.8 +/- 2.4 hours. Recovery sleep after call was inadequate to stabilize mood. In fact, the effects of call lasted well into the off-call days, with tension, depression, and anxiety leveling on the first post-call day, and vigor, fatigue, and confusion leveling after the second post-call day. Put another way, the investigators said, “Call affects [resident physicians’] mood[s] for much of the time when off call and potentially their personal and professional interactions during this period as well”.

Depression

Distinct from depressed mood is depression, a clinical term requiring that at least five of nine defined criteria are met for a period of at least two weeks. One of the five signs must include either depressed mood or anhedonia (loss of interest/pleasure in life), and the other four can include appetite disturbance with weight change, sleep disturbance, psychomotor disturbance, fatigue or loss of energy, feelings of worthlessness or guilt, diminished ability to concentrate, and recurrent thoughts of death/suicidal ideation.[27] High rates of depressed mood place resident physicians in a higher risk group for developing clinical depression. Indeed, as many as 30% of resident physicians experience depression at one time during their residencies.[28] Female physicians have been shown to be especially vulnerable.[29]

In research utilizing the Center for Epidemiological Studies-Depression (CES-D) scale, a predictor of depression, investigators surveyed 68 medical house officers at Rhode Island Hospital. [30] They administered the test on a monthly basis for a year, with a response rate of 83%. Twenty-one percent of respondents reported “depressed” scores, defined as a CES-D score equal to or greater than 16 (on a scale of 0 to 60). When classified by year, 29% of first-year resident physicians, 22% of second-year resident physicians, and 10% of third-year resident physicians reported depressed scores ($p < 0.0001$). (Resident physician work schedules typically improve as residency progresses.) When responses were examined by rotation (the specialty in which a resident physician is currently working), depressed responses were most frequently received during those rotations that routinely required over 80 hours of work per week. Twenty-five percent of resident physicians reported depressed responses while on ward rotations, and 32% while on intensive care unit rotations, both of which can require 100 hours of work per week. The author concluded, “The increased

frequency of depressive symptoms on ward and intensive care rotations may be, in large part, caused by long working hours and sleep deprivation."

In a study at two hospitals in St. Louis, investigators interviewed 53 interns at the end of their first year of training.[31] Based on established criteria for clinical depression, 16 (30%) had an episode of depression during their internship, of which 13 were definite depressions and 3 were probable depressions. The depressed and non-depressed groups were very similar in terms of age, sex, marital status, and type of internship. Medical, social, and childhood histories were not significantly different either. Eleven of the 16 interns became depressed within the first few months of their training. Four of the 16 had suicidal ideation, three had a suicidal plan, and six experienced marital problems for the first time. One subject who had made a suicidal plan thought of five or six ways to kill himself so that his wife could collect insurance. Six depressed interns had feelings of hopelessness, two had fear of losing their minds, and three called their spouses while on night call, crying and saying they couldn't go on. Of the 11 whose depression began in the first two months, seven were working more than 100 hours per week. Of the five who became depressed later in their internship, three were working more than 100 hours per week at the time of the onset of their depression.

A larger study showed similar results. A volunteer cohort of 740 (58% of 1,271 invited), interns was assessed for depressive symptoms before commencing residency, over the course of the first year, using the nine-item Patient Health Questionnaire (PHQ-9) depression score.[32] On this test, scores can range anywhere from 0 to 27, with higher numbers indicating more severe depression. The percentage of participants who met criteria for depression increased from 3.9% before internship to 25.7% during internship ($p < 0.001$). (The raw score increased from 2.4 prior to internship to a mean of 6.4 during internship.) Most of the subjects who met criteria were moderately depressed. Factors associated with depression during internship were perceived medical errors, stressful life events, and increased work hours ($p < 0.001$).

Moreover, depression is problematic not only for resident physicians themselves, but for their patients. In a three-center study of the relationship between medical error and depression, Fahrenkopf *et al.* found that 74% of all resident physicians met criteria for occupational burnout (Maslach Burnout Inventory) and 20% of all resident physicians scored positive for depression using a validated screening instrument (Harvard Department of Psychiatry Screening Tool). Virtually none of the resident physicians had been diagnosed with depression prior to beginning residency. Of great concern is that doctor depression has a profound impact on the care of patients: depressed resident physicians made six times as many medication errors in the care of their patients than did their non-depressed colleagues.[33]

In sum, while it is certainly possible that the difficult nature of medical work in residency contributes to the development of depression, it is supported by evidence that excessive work hours are also a major factor. Fatigue and sleep deprivation caused by excessive work hours contribute to depressed moods in resident physicians, placing them in a high-risk group for developing clinical depression, and in turn increasing their risk for suicidal ideation and suicide. Even more alarming, studies suggest that the development of major depression is linked to a higher risk of future depressive episodes.[34] We may thus be predisposing resident physicians to mental illness. Experts have agreed, "This combination of stress and fatigue may lead to severe psychologic repercussions, which may first appear as disappointment, loss of idealism, and isolation, and then progress to feelings of helplessness, impaired performance, and outright depression."[35] The authors of another study concluded, "In view of the special vulnerability of medical trainees to occupational stress, all efforts are warranted to reduce sleep deprivation in the medical profession."[36] It is reasonable to expect that reducing work schedules to allow for more sleep should reduce both the incidence of depressed mood and the likelihood of developing depression.

C. OBSTETRIC COMPLICATIONS

A growing number of women are entering the medical profession, and almost 50% of married, female resident physicians will become pregnant during their residency.[37] Moderate increases in work schedule more than 40 hours are not consistently associated with adverse pregnancy outcomes.[38] However, excessive levels of work are associated with obstetric complications.

In the best-designed investigation, Klebanoff *et al.* sent questionnaires to 5,096 female physicians who had graduated from medical school in 1985 and to a random sample of 5,000 of the 12,306 male physicians who graduated the same year.[39] Eighty-seven percent (4,412) of the female resident physicians and 85% (4,236) of the wives of male resident physicians responded to the questionnaire, which included questions on outcome of each pregnancy and number of hours worked. Resident physician women reported working twice as many hours per week during their pregnancies as did the wives of the male resident physicians. Between the two groups overall, investigators found no statistically significant differences in the proportion of pregnancies that ended in miscarriage, ectopic gestation, stillbirths, preterm delivery, or intrauterine growth retardation. However, three important findings were identified. First, premature labor requiring bed rest or hospitalization was nearly twice as common among the female resident physicians as among the male resident physicians' wives (11.3% vs. 6.0%, $p < 0.001$). Second, preeclampsia or eclampsia was also twice as common among the resident physician women as the resident physician men's wives (8.8% vs. 3.5%, $p < 0.001$). Third, for those resident physicians working 100 or more hours per week during the 3rd trimester, there was more than twice the risk of preterm delivery compared to those working fewer than 100 hours (10.3% vs.

4.8%, p = 0.04). Premature labor, preeclampsia/eclampsia, and preterm delivery (in women resident physicians working over 100 hours), were thus found to be significant problems for the pregnant resident physicians.

Another study validated these findings on pre-term labor and preeclampsia. An anonymous, cross-sectional survey of 4,674 Obstetrics and Gynecology resident physicians was conducted to assess pregnancy-related outcomes. The survey was administered before an in-service training exam and was returned with a 95.5% response rate. When factoring out surveys with errors, 4,357 remained for analysis. Female resident physicians were compared to their male resident physicians' spouses. Of those who reported, roughly 70% of female resident physicians worked more than 80 hours per week during their pregnancy. Total hours worked by the comparison group (male resident physicians' spouses/partners) were not recorded, but researchers did find that only 68.5% of male resident physicians had a spouse that worked. Investigators found that female resident physicians had a statistically significant higher risk of preterm labor (RR = 2.4, p = 0.03) and preeclampsia (RR = 5.7, p = 0.01), as well as another negative health outcome, fetal growth restriction (birth weight below the 10^{th} percentile for gestational age, p = 0.002) when compared to the spouses of their male counterparts.[40]

In another study, intrauterine growth restriction was found to also be a negative health effect of working excessive resident physician hours. Investigators surveyed 1,025 female board-certified obstetricians about their pregnancies before, during, and after residency.[41] The response rate was 49%. The mean number of hours worked during residency was 78.9, compared to 36.4 before residency and 46.5 after residency. A critical finding was that infants delivered during residency were more likely to be born with intrauterine growth restriction compared to those delivered before or after residency (rates of 1.2%, 8.2%, and 1.0%, before, during, and after residency). Worse, the average birthweight of firstborn infants delivered during residency was found to be significantly lower than the birthweight of firstborn infants delivered before residency (3,146 g., SD 696 vs. 3525 g., SD 455, respectively; p < 0.001). Although mean birthweights were low in infants delivered after residency (3,263 g., SD 556; p < 0.005), they were still higher than birthweights of infants born during residency. The low birthweight rates (defined as any birthweight below 2500 g.) were 3.7%, 11.6%, and 2.6% before, during, and after residency, respectively.

Researchers have additionally hypothesized that the long hours of residency may cause more pregnancies to fail. Using the same data set, Klebanoff *et al.* also compared early-pregnancy complication rates in female resident physicians with those among partners of male resident physicians.[42] The life-table probability of spontaneous abortion was 14.8% for female resident physicians and 12.6% for the partners of male resident physicians (RR = 1.18, 95% CI 0.96-1.45), a difference that was concerning, but that did not reach statistical significance.

In summary, these results point to increased risks for preterm labor requiring serious hospitalization, preeclampsia or eclampsia, and preterm delivery in female resident physicians. Other studies suggest that the children of resident physicians can also suffer from decreased birthweights and intrauterine growth restriction. The author of one study agreed that available research includes "sufficient findings to suggest that heavy exertion and fatigue may cause premature deliveries, decreased birthweights, and other complications in pregnant residents."[43] In a review of the literature on pregnancy complications of resident physicians, another author concluded, "[T]he greatest factor leading to poor pregnancy outcomes among physicians seems to be time spent working, particularly during late pregnancy."[44] The signers of this petition believe that even modest work-hour limitations would significantly reduce these adverse outcomes.

D. PERCUTANEOUS INJURIES

In addition to the other health problems resident physicians face from working excessive hours, they suffer a greater rate of percutaneous injuries, such as needlesticks or cuts from medical equipment. These injuries are dangerous because they can transfer infectious diseases like Hepatitis C or HIV from an infected patient via blood. A prospective within-subjects cohort study of 2,737 interns, using a web-based survey, showed a substantially increased risk of percutaneous injury (PI) during day shifts after overnight call (extended work) compared to day shifts without a preceding overnight call (non-extended work), OR 1.61 (95% CI, 1.46-1.78).[45] The mean duration of resident physicians' work preceding those injuries occurring after an extended work shift was 29.1 consecutive hours. Fatigue was identified by resident physicians themselves as a leading cause of these injuries. Resident physicians who worked overnight calls were much more likely to say fatigue was involved (44%) than their counterparts who only worked a regular shift (18%) ($p = 0.02$). In sum, the authors concluded, "The association of these injuries with extended work duration is likely due to the adverse cognitive effects of the sleep deprivation associated with such extended work".

General surgery and the surgical sub-specialties (e.g. Orthopedics, Neurosurgery, and Urology) are universally recognized for requiring trainees to work longer hours than any other medical specialties and having the longest training — five years or more. The operating room setting is particularly dangerous because of the numerous sharp instruments necessary to perform invasive procedures and surgical resident physicians — because they are learning new technical skills — are particularly susceptible to injury.[46] An Annals of Surgery study from 2005 found that 20 to 38% of all procedures in one urban academic teaching hospital involved exposure to HIV, HBV or HCV.[47] A study published in 2007 in the *New England Journal of Medicine* reported on a survey of 582 surgery resident physicians (83% response rate) at 17 medical centers. The survey found that by their final year of training, 99% of resident physicians

suffered a needlestick injury. For 53% of those surgical resident physicians, the injury had involved a high-risk patient. Lack of time was the most common reason given for the cause of the injury (57%), followed by fatigue (15%).[48]

PART 3: EXISTING HOURS LIMITATIONS FOR RESIDENT PHYSICIANS AND NON-RESIDENT PHYSICIANS

A. CURRENT WORK STANDARDS

The U.S. has responded to the problem of excessive resident physician work hours in ways that have so far proven inadequate. It was only in 1981 that the governing body with authority over all U.S. residencies, the Accreditation Council for Graduate Medical Education (ACGME), began to require that resident physicians have any time to rest at all.[49] In 1984, an 18-year-old woman named Libby Zion died in a teaching hospital in New York City. Her father alleged the death was due to poor care given by tired, overworked, and badly supervised resident physicians. In response, a grand jury recommended residency improvements, and in 1987, the Bell Commission (named after Bertrand Bell, M.D., who is also a signatory to this petition) was formed, suggesting specific limits on resident physician work hours. Finally, in 1989, the New York legislature passed section 405 of the New York State Health Code, which charged the New York State Health Department with enforcing an 80-hour maximum work week. ACGME then followed with work-hour restrictions on some specialties, but it wasn't until 2003 that ACGME issued universal rules. These changes included:

- An 80-hour work week averaged over four weeks, including in-house call;
- A maximum onsite work shift of 24 hours with up to six additional hours of educational or patient transfer-related activities, which has been universally interpreted as a 30-hour shift;
- Call no more frequently than one night in every three, averaged over four weeks;
- One day in seven off without educational or clinical duties, averaged over four weeks.

The ACGME promised to revisit the 2003 rules in five years.[50] In 2008, the Institute of Medicine issued a report, "Resident Duty Hours: Enhancing Sleep, Supervision, and Safety". The IOM report was the product of an exhaustive 12-month review by a panel of experts charged with examining the existing system of medical training and the evidence regarding fatigue, resident physicians, and patient safety. The Institute concluded that it is unsafe for resident physicians to work for more than 16 hours without sleep:

> The Committee believes there is enough evidence from studies of resident physicians and additional scientific literature on human performance and the need for sleep to recommend changes to resident training and duty hours

aimed at promoting safer working conditions for residents and patients by reducing resident fatigue. [51]

The Committee made far-reaching recommendations for change in the training of resident physicians. Key recommendations are summarized below:

- No change to the 80-hour work week, averaged over four weeks;
- A maximum shift length of 16 hours. If a training program wanted to continue with a 30 hour shift, it must provide a mandatory five-hour protected sleep period between 10 p.m. and 8 a.m., with no new patients admitted after 16 hours;
- Maximum in-hospital call frequency every three nights (not averaged over four weeks)
- At least one 24-hour period off per week (no averaging) and at least of one 48-hour period off per month;
- Night work must not exceed four consecutive nights and must be followed by a minimum of 48 continuous hours off, if three or four shifts are worked;
- There must be 10 hours off after a regular work shift, 12 hours off after night work, and 14 hours off after an extended duration ($\geq$ 24-hour) work shift (and the physician must not return before 6 a.m. the next day).

On July 8, 2010, the ACGME issued new recommendations of its own, the majority of which do not heed the Institute of Medicine's recommendations:

- No change to the 80-hour work week, averaged four weeks;
- Maximum duration of work shifts for interns (first-year resident physicians) that do not exceed 16 hours;
- Intermediate- and senior-level resident physicians (second year resident physicians and higher) can still be scheduled for 28-hour shifts (24-hour shifts with an additional four hour period to provide for education and patient transfer responsibilities);
- Maximum in-hospital call frequency of every third night, no averaging;
- One day off per week, averaged over four weeks;
- Weekly work-hour exceptions of up to 88 hours per week;
- Resident physicians must not be scheduled more than six consecutive nights of night work;
- Resident physicians must have eight hours off between work shifts, with some exceptions.

In sum, the ACGME proposed new rules fall far short of the improvements recommended by the IOM and those necessary to protect patients and resident physicians from harm. The 80-hour workweek requirement should not be averaged over 4 weeks, as ACGME suggests. This would continue to allow programs to regularly work resident physicians more than 80 hours in a given week but still average 80 hours per week over four weeks. The proposed standards would permit interns to work up to 20 consecutive 16-hour shifts,

which could occur, for example, during a three-week ICU rotation. Harm to resident physicians and errors that adversely affect patient safety result from fatigue, and working 90 or 100 hours in a single week provides inadequate time for recovery sleep. Such a work schedule could lead to a level of impairment associated with sleep deprivation that would far exceed that induced by working 30 consecutive hours. This could thereby result in a greater degradation of resident physician safety and patient safety than what results from current practice.

The recommendation that intern (first-year resident physician) shifts be capped at 16 hours is a positive development, but it should apply to all resident physicians. There is no biological rationale to support the notion that interns suddenly become able to withstand the proven deleterious effects of extended shifts upon completing their internships. That most of the studies showing the risks of fatigue were conducted amongst interns[52] does not mean upper-level resident physicians do not suffer fatigue from sleep deprivation too. Extensive data from the laboratory and a growing body of literature from clinical settings indicates that resident physicians' performance deteriorates in the same manner as interns working extended shifts. Resident physicians are at increased risk of motor vehicle crashes after working for 24 hours.[53] Their risks of making medical errors are elevated both when conducting simulated procedures,[54 55 56] and more importantly, when providing care in clinical settings. [57]Even with interns' work hours held constant, elimination of upper-level resident physicians' 24-hour shifts is associated with a decrease in medical errors and patient mortality.[58 59] After studying this issue for more than a year, the IOM of the National Academies — a multi-disciplinary body of experts from across fields — concluded that it was unsafe for any resident physician to work for more than 16 consecutive hours without sleep.[60] If OSHA allows the ACGME to go forward with its proposal to authorize 28-hour shifts for the more than 80,000 U.S. resident physicians beyond their first years of residency training, in wanton disregard of the advice of the IOM and in defiance of the well-founded concerns of the American public,[61] OSHA will be responsible for knowingly endangering both the resident physicians and their patients. There are no data to show that individuals can 'learn' to do without sleep or that experience can overcome the detrimental effects of 24 to 28 hours of continuous wakefulness, whereas there are hundreds of laboratory reports showing sleepiness-dependent decrements in performance in adults of the same age as resident physicians. Choosing to apply a 16-hour maximum shift duration limit to interns alone, and justifying the decision by stating that data are only available on interns, is too myopic an application of the science regarding work hours and safety. It is untenable to argue that one day after graduating from internship, a resident physician loses her/his susceptibility to the health and occupational hazards associated with working for 24 to 28 hours straight when a day earlier, according to the same regulations, it was unsafe for the resident physician to do so. Furthermore, scheduling resident physicians to work for 24 to 28 consecutive hours exposes a subset of resident physicians who, for medical or biological reasons, are most vulnerable to the effects of sleep

loss. This is an unacceptable risk.[62] As the government entity whose core responsibility is to promote the health and safety of American workers, OSHA has the responsibility to promulgate regulations that will protect the health and safety of resident physicians. ACGME has chosen not to follow this course that the IOM recommended, therefore it is the responsibility of OSHA to step in and provide regulations that will protect these workers.

We also strongly urge that OSHA require a minimum of 10 hours off work between shifts and a minimum of 12 hours off work after a night shift and 48 hours off after a sequence of three- to four-night shifts, as recommended by the IOM. Given the need for commuting and basic activities of daily living, resident physicians provided with only eight hours of time off per night will typically obtain six or fewer hours of sleep, a duration that is suboptimal in its own right, and one that is extremely concerning in a setting in which resident physicians are experiencing recurrent acute sleep deprivation due to ongoing 24+ hour shifts. Given that resident physicians often arrive well before their scheduled shifts to update themselves on their patients and often need to stay longer than their scheduled hours to continue to care for their patients, resident physicians may well have less than four hours of time for sleep on many occasions if the scheduled interval between shifts is only eight hours. With the expectation that resident physicians will be so conscientious, an interval of 10 hours between scheduled shifts is critical; otherwise, resident physicians are placed in the untenable position of having to choose between their work-hour regulations and their patients' needs. Moreover, at least 12 hours off duty should be required after working the night shift, as recommended by the IOM, given the need to get sufficient recovery sleep after each shift. Even when healthy young adults the age of resident physicians are in a completely dark and quiet environment, when sleep time is scheduled during the circadian daytime, healthy individuals lie awake in bed 20 to 25% of the time due to prominent circadian variations in sleep propensity.[63] Environmental factors such as noise and light further reduce sleep during the daytime.[64] Therefore, more time off after night shifts is required in order for resident physicians to obtain adequate sleep during the daytime, as recognized by the IOM.[65] This was the basis of the IOM recommendation that a minimum of 12 hours off duty be required after night shifts. While 10 hours between shifts is not perfect from a biological perspective, eight hours is certainly inadequate. Insufficient time off between extended shifts very quickly leads to critical vulnerabilities in performance, as chronic sleep deprivation builds, compounding the decrements seen with acute sleep deprivation alone.[66]

Further, resident physicians need one day off per week, but ACGME suggests that days off be averaged over four weeks. Working 12 or 24 days straight can increase fatigue to dangerously high levels. Moreover, working six consecutive night shifts, each of which can be up to 16 hours in duration, can result in the buildup of dangerous levels of cumulative fatigue. The IOM proposed a much safer limit of four consecutive night shifts. The IOM recommended a maximum of four consecutive night shifts given the robust literature from other occupational

settings that performance deteriorates with multiple consecutive night shifts. After three to four consecutive nights of work, error and accident rates increase significantly across occupations[67] due to the direct effects of circadian misalignment, and its indirect adverse effects on daytime sleep.[68] With only eight hours off duty between consecutive 16-hour night shifts, resident physicians will only likely sleep four to five hours in the day between shifts. When multiplied over several days, resident physicians will very quickly develop chronic sleep deprivation and reach unsafe levels of sleepiness.[69] [70] There is no reason to believe that this would not hold true for resident physicians. We are very concerned that allowing resident physicians to work six consecutive 16-hour night shifts per week (96 hours/week) for three weeks in a row, which the proposed regulations would allow given the proposed averaging of the 80-hour work week across four weeks, could very well be even more hazardous than the 2003 ACGME regulations. For the ACGME to disregard these risks, after having had the benefit of the comprehensive evidence review conducted by the IOM, represents an enormous missed opportunity to improve both resident physician health and safety and patient care.

B. COMPLIANCE

One of the critical reasons for OSHA to assume regulatory control of U.S. residencies is that ACGME is not up to the job. In fact, ACGME has admitted as much — **they acknowledge reports suggesting that the "2003 limits did not increase residents' hours of sleep or reduce fatigue … [and] failed to show that the duty-hour limits had a positive effect on the quality and safety of inpatient care"**.[71] By definition, since the rules were intended to accomplish this, the problem is with enforcement. This is a challenging task for several reasons: The ACGME's monitoring and compliance is based on resident physicians reporting violations in their own programs — but the ACGME does not provide whistleblower protection. Reporting violations hurts the resident physician because a program could be put on probation or lose its accreditation.

In addition, the ACGME cites the "frequency and intensity" of work-hour surveillance required "given the nearly 9,000 accredited programs" as a reason for why its monitoring of hours violations is difficult. Although the ACGME has proposed to monitor the new rules with an annual site visit and compliance report to each "sponsoring institution," it is unclear how ACGME will accomplish this given the vast number of programs to monitor and its past failures.

Consider two studies that document poor compliance with the ACGME's 2003 rules. In one study, a confidential, prospective cohort of 4,015 U.S. interns, investigators found that 83.6% of interns reported violations of the ACGME's 2003 standards during one or more months.[72] Sixty-seven-point-four percent reported working shifts of 30 hours or more. Forty-three percent reported working more than an average of 80 hours per week, even allowing for the ACGME's practice of permitting averaging of work hours across a four-week period.

In the other study, researchers conducted an intensive prospective cohort study of 220 U.S. pediatric resident physicians to assess changes between the pre- and post-2003 work-hour limits.[73] The results showed no change in resident physicians' frequency of call, in total hours worked, or in total sleep hours. Rates of MVAs, occupational exposures, and depression did not change either.

OSHA must not allow these violations to occur any longer, and given ACGME's track record and lack of accountability as a private-sector organization, it cannot be counted on to make improvements on its own.

C. OTHER COUNTRIES' RESPONSES TO EXCESSIVE RESIDENT WORK HOURS

While the U.S. has been largely ineffective in seriously addressing the long-work-hour problem, other industrialized countries have taken active and successful steps to regulate resident physician work hours. Indeed, most of the industrialized world already regulates resident physician work hours. Over the past 15 years, legislation, directives, decrees, and collective agreements that limit average weekly hours worked by `resident physicians have been instituted (see Table 2).[74, 75, 76]

Nations that have limited resident physician work hours have done so by designing new approaches to residency programs that emphasize both efficiency and learning. These are implemented by changing shift schedule policies (such as implementing a night float call system, in which rested resident physicians take over the night shift), redefining resident physician duties to include fewer menial tasks, hiring additional ancillary staff, and transferring more workload to faculty physicians. Because they made it a priority, other countries have demonstrated that it is indeed possible for hospitals to schedule reasonable work weeks for their resident physicians.

In the European Union (E.U.), resident physician work hours are regulated through the European Working Time Directive (EWTD).[77] Established in 1993, it was initiated to "promote health and safety at work, given the clear evidence that people who work long hours run higher risks of illness and accidents." At first, the directive included physicians but not resident physicians. That changed in 2000, and the new rule required all health systems in the E.U. to limit resident physicians to working no more than 48 hours per week, by 2009. Some countries had to transition to the limit, like the United Kingdom (U.K.), while others, like Denmark, were already there. Under these rules, resident physicians also get a minimum of one day off per week.

In the Asia-Pacific region, New Zealand has enforced a maximum work week of 72 hours for resident physicians since 1985.[78] It limits one shift to no more than 16 hours, including call. Resident physicians are also not permitted to work more than 12 days without a 48-hour period of rest.

Enforcement of work hours varies across countries.[79] In the U.K., employers under the National Health Service (NHS) have this responsibility, with compliance monitoring done by the NHS executive and the British Medical Association. In Germany, the government agency responsible for enforcement is the same one responsible for all employee hours, the trade supervisory board. The New Zealand Residents Doctors' Association negotiates contracts for their members, and enforces these provisions. Because of Australia's voluntary compliance system, there is no enforcement entity. In Canada, enforcement varies according to province.

Table 1 Work-Hour Regulations in Selected Countries[80]

	How Hours are Regulated	Maximum Hours Averaged per Week	Maximum Consecutive Hours per Shift	Minimum Rest Hours Between Shifts
Denmark	Legislation and Collective Agreements	37	13-16	11
El Salvador[81]	NA	Often >120	36	NA
European Union	European Commission and Collective Agreements	48	13	11
New Zealand	Collective Agreements	72	16	8
United Kingdom	European Working Time Directive	48	13	11

In sum, much of the industrialized world has acted to restrict resident physician work hours because of concerns about worker health and patient safety. In many cases, these initiatives have come about through partnerships with state and federal governments. This is in stark contrast to how work-hour changes are made in the United States. There is no government partnership — there is only the ACGME, which is a private, professional entity that is not accountable to the public. The restrictions put in place by these other countries go far beyond what is being considered in the United States. The EU has limited work hours to 48 hours per week and consecutive work hours to 13. New Zealand has similarly limited shifts to 16 consecutive hours since 1985.

D. U.S. Work-Hour Regulations in Other Industries

The federal government has long recognized the importance of government regulation of work hours in the transportation and other industries. Under the jurisdiction of the Department of Transportation (DOT) and its daughter organizations, work-hour limits and rest-period requirements for the highway, aviation, railroad, and maritime industries have been established. The Federal Aviation Administration (FAA) does not allow airline pilots to fly more than 34 hours per week or eight hours in a single day. The Federal Motor Carrier Safety

Administration (FMCSA) limits drivers in commercial industries (trucking, bus drivers, etc.) to no more than 11 hours of driving after 10 consecutive hours off duty for property carrying drivers, and 10 hours of driving after eight consecutive hours off duty for passenger carrying drivers.[82] The Federal Railroad Administration (FRA) and the U.S. Coast Guard (USCG) have likewise put work-hour regulations in place for operators in the railroad and maritime industries. These work-hour requirements have been instrumental in maximizing worker and public safety for many years.

In recent years it has become increasingly clear that fatigue plays a major role in transportation safety. A large volume of research designed to further delineate the relationship between fatigue/sleep deprivation and performance/safety has been completed, and more studies are currently underway. Following accident studies conducted in the 1980s, the National Transportation Safety Board (NTSB), the federal agency responsible for investigating significant accidents in transportation, issued a set of recommendations to the DOT in 1989: to investigate fatigue and its relation to safety, to educate transportation industry workers on work and its relation to health, and to revise current hours-of-service regulations to maximize the safety of its workers and the people they serve. The result has been a collaborative effort among organizations within the DOT to "modify the appropriate Codes of Federal Regulations to establish scientifically based hours-of-service regulations that set limits on hours of service, provide predictable work and rest schedules, and consider circadian rhythms and human sleep and rest requirements."[83]

As a result of major accident investigations, special investigations, and safety studies that identified operator fatigue as a factor, the NTSB has issued more than 70 fatigue-related safety recommendations to the DOT since their 1989 recommendation. For the fiscal years 1990 through 1998, the DOT spent more than $30 million on fatigue research.[84] OSHA has, to our knowledge, conducted no research on resident physician fatigue, even though work hours of resident physicians greatly exceed the regulated work hours in these other industries.

The Federal Motor Carrier Safety Administration

The National Highway Traffic Safety Administration (NHTSA) estimates that each year, drowsy drivers may be responsible for as many as 103,000 crashes, [85] which result in more than 1,500 fatalities and 71,000 injuries.[86] In the interest of highway safety, the Motor Carrier Act of 1935 resulted in hours-of-service regulations for commercial drivers, based on the rationale that "it is obvious that a man cannot work efficiently or be a safe driver if he does not have an opportunity for approximately 8 hours of sleep in 24."[87]

Table 2. Selected Hours-of-Service Regulations in the Department of Transportation.[88]

Occupation	Limits
U.S. Interstate Truck and Bus Drivers : 1938; 1962; 2003; 2005; 2008	<11 driving hours within a 14-hour interval <14 consecutive hours from start to end of work >8 consecutive rest hours <60 work hours per 7 days; <70 work hours per 8 days >34 consecutive hours off between work weeks
U.S. Airplane Pilots (1-2 pilot airplanes): 1950s	<8 daily flight hours <16 daily work hours >8-12 hours rest required (since 1985) <34 hours flight time per week
U.S. Railroad Operators: 1907, modified 1969 & 1976 & 1988	<12 work hours per day >8-10 hours rest required per day

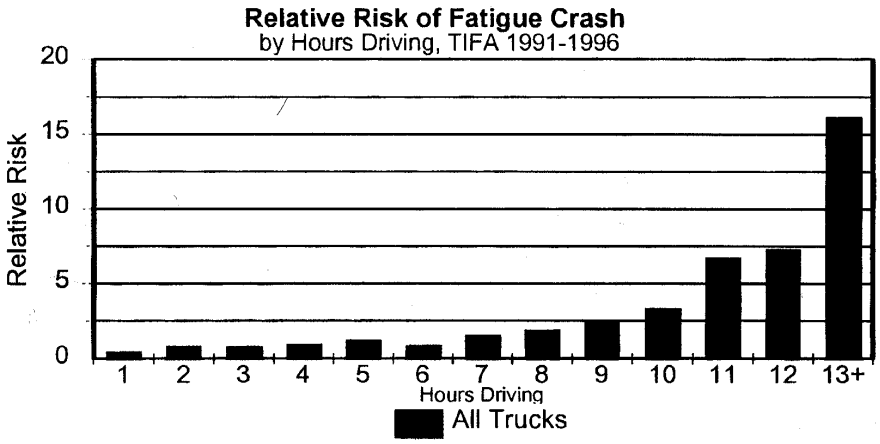
Research conducted since that time confirms this claim, and has identified the link between sleepiness and crashes, accidents, and errors previously attributed to fatigue and inattention. According to the FMCSA, there is evidence that "many crashes occur as a result of commercial motor vehicle (CMV) driver error, that driver error is often the result of inattention, that inattention can often be the result of fatigue, that the fatigue which causes inattention is often related to sleep deprivation, and that sleep deprivation is often related to working conditions of drivers."[89] In 1985, the American Automobile Association (AAA) Foundation for Traffic Safety in "A Report on the Determination and Evaluation of the Role of Fatigue in Heavy Truck Accidents" examined 250 accident reports of heavy-truck accidents in six Western states.[90] The study concluded that fatigue was the probable or primary cause of 41% of those heavy truck accidents. The NTSB's

1990 study of 182 heavy truck accidents that were fatal to the driver showed that 31% of the accidents in this sample involved fatigue. Fatigue, drugs that are taken to counteract the symptoms of fatigue, drugs that aggravate fatigue, and the interaction of fatigue and drugs were found to be major factors in accident causation.[91]

Another set of studies examined fatigue in terms of the role of continuous service time in causing accidents. In the 1970s, the Federal Highway Administration (FHWA) conducted a study on truck and bus drivers which found that by the maximum-allowed 10 hours of driving time, driver performance deteriorated, driver alertness diminished, rest breaks became less effective, and accident probability increased.[92] Many studies have corroborated the finding that increased service time leads to increased accident risk. A review of a series of truck driver fatigue research studies from the late 1970s to the early 1990s found that time on task appears to have a limited effect on accidents for regular daily work periods less than 11 hours, but may have a more profound impact if the work periods are more than 12 hours.[93] In a survey of 1,000 heavy-goods vehicle drivers undertaken in 1982-1983, the accident risk rate after 11 hours of work was nearly double (1.82 times baseline) that for work periods shorter than 11 hours.[94] Saccomanno *et al*. found higher overall accident risk associated with 9.5 continuous hours of service or longer compared to baseline.[95] A case-control study including truck crashes in Washington state from June 1984 through July 1986 matched to a comparison sample with similar roadway, time of day, and day of week characteristics, found higher relative risks associated with more than eight hours of driving.[96]

According to a chart published by the FMCSA in the May 2, 2000, Federal Register, a driver runs 16 times the risk of having a fatal accident during the 13th hour of driving than during the first. (See Figure 1.) A study by Lin *et al*. also described a rising risk curve: the first 4 hours of driving had the lowest accident risk, followed by increases in risk of 50% or more up until the end of the seventh hour, 80% until the eighth hour, and 130% until the ninth hour.[97] In a mini-review by Folkard, it was determined that the safest work-shift duration for commercial drivers is six to nine hours.[98] In terms of weekly service time, a 1996 study by Bowen found that based on a total of 173,110 reported hours of driving time, “it seems that after 80 hours on duty [in an eight-day period], the accident rate rises precipitously.”[99]

Figure 1.



Additional research has identified factors other than continuous driving time as causes of fatigue-related accidents. A 1995 study of 107 accidents (62 of which were fatigue-related) found that the three most important factors that affected fatigue-related accidents were duration of sleep in the last sleep period, the total hours of sleep during the 24 hours prior to the accident, and the presence of split sleep periods. The truck drivers in fatigue-related accidents in this sample had an average of 5.5 hours of sleep in the sleep period prior to the accident, as compared to eight hours for drivers in the non fatigue-related accidents. Many of the truck drivers involved in fatigue-related accidents did not recognize that they were in need of sleep and believed that they were rested when they were not — about 80% rated the quality of their last sleep before the accident as good or excellent. The study concluded that driving at night with a sleep deficit is far more critical in predicting fatigue-related accidents than simply nighttime driving. Moreover, sleep accumulated in short time blocks (split sleep) was found to impede recovery of performance.[100] The sleep characteristics of subjects in this study — decreased sleep in the last sleep period, decreased total hours of sleep in the last 24 hours, and split sleep periods — are all shared by resident physicians under their present working conditions.

Of the different modes of transportation, most data on the relationship between fatigue and safety are available for highway transportation. In the highway transportation industry, research has confirmed the common-sense notion of restricting hours of service, as excessive work schedules have been shown to cause injuries and cost lives. The evidence thus far has been so convincing that driver fatigue was voted the number one safety concern of the FHWA 1995 Truck and Bus Safety Summit, a meeting of over 200 drivers, motor carrier representatives, government officials, and safety advocates.[101]

The Federal Aviation Administration

Aviation work-hour limits were addressed in the Civil Aeronautics Act of 1938 and the Federal Aviation Act of 1958. Depending on the type of domestic flight, pilots may fly no more than 34 hours per week. On domestic flights, the limit is generally eight hours of flying per 24-hour period.[102]

The FAA reports that 21% of the accidents citing errors in the Aviation Safety Reporting System (ASRS) were related to general issues of fatigue.[103] As an example, pilot fatigue is believed to have contributed to the crash of American Airlines Flight 1420, which skidded off the runway of Little Rock (Arkansas) International Airport on June 2, 1999, killing the pilot and 10 others. The accident occurred after the crew had worked more than 13 hours.[104]

In a study entitled, "A Review of Flightcrew-Involved, Major Accidents of the U.S. Air Carriers, 1978 Through 1990," the NTSB sought to learn more about flight crew performance by evaluating characteristics of the operating environment, crew members, and errors made in major accidents. [105] It found that crews comprising captains and first officers who had been awake longer than the median number of hours of others in their crew position made more errors overall, with significantly more procedural and tactical decision errors.

In 1995, the NTSB examined operator fatigue in its safety studies on flight crew errors, commuter airlines, and aviation safety in Alaska. Under Part 135.261 of the Title 14 Code of Federal Regulations, Alaska is permitted longer flight service hours than the rest of the states, due to its remoteness from the 48 contiguous states. The Board concluded that "the consecutive, long duty days currently permitted [in Alaska] … for commuter airline and air taxi flight crews can contribute to fatigue and are a detriment to safety."[106]

The Federal Railroad Administration

The Railroad Hours of Service Act was first enacted in 1907, substantially revised in 1969, and amended in 1976 and 1988. In an oral statement at a September 16, 1998 Senate Safety Hearing, Administrator Joline Molitoris of the Federal Railroad Administration (FRA) commented:

> Fatigue and the railroad industry have been synonymous for over a hundred years. In some industries, this might be only a quality of life issue. In railroading, it is a life and death safety issue. About one-third of train accidents and many employee injuries and deaths are caused by human factors. We know fatigue underlies many of them. Hundreds of communications from employees and their families eloquently testify to the devastating effects of fatigue…. all employees, contract and management, must be able to work within policies that *assure* them, their companies and the communities they serve, that they are alert and able to operate safely.[107]

As with the airline industry, freight and passenger rail operations are conducted 24 hours a day, subjecting employees to extensive night work, irregular work schedules, and extended work periods with few or no days off. Fatigue has been thought to be a significant contributing factor to major train accidents in past years. For example, on November 7, 1990, two freight trains collided in Corona, California. The NTSB investigation concluded that "the engineer of train 818 failed to stop his train on the Corona siding at the stop signal because he was asleep or in a microsleep brought about by chronic and acute fatigue … a result of the irregularity and unpredictability of his work schedule."[108] Another widely publicized example of a fatigue-caused crash was the June 5, 1995 collision of two New York City Transit subway trains on the Williamsburg Bridge in Brooklyn. One person was killed and 69 treated for injuries, with total damages exceeding $2.3 million. The train operator failed to take action to stop his train because he was asleep.[109]

The U.S. Coast Guard

Work-hour regulations for the maritime industry date back to 1908. In 1997, work-hour regulations from the Standards for Training, Certification, and Watch-keeping of the International Maritime Organization (IMO) also became effective.

A 1996 U.S. Coast Guard (USCG) analysis of 279 incidents showed that fatigue contributed to 16% of critical vessel casualties and 33% of personal injuries. [110] Three factors were identified that could be combined to calculate a Fatigue Index score for casualty cases, which could then be used as a predictor for accidents: (1) the number of fatigue symptoms reported by the mariner, (2) the number of hours worked in the 24 hours prior to the casualty, and (3) the number of hours

slept in the 24 hours prior to the casualty. These findings parallel those found in commercial driving, demonstrating that the effects of limited sleep apply across different industries.

In a survey of 141 mariners from eight commercial ships (six tankers and two freighters), data on work and sleep patterns as well as other information pertinent to fatigue were collected.[111] The incidence of critical fatigue indicators such as severely restricted sleep durations per 24-hour period, very rapid sleep onset times, and critically low alertness levels suggested that fatigue is a regular occurrence in commercial vessels. The study concluded that sleep disruption, reduced time between watches, fragmented sleep, and long workdays are the principal contributors to the problem.

One of the most high-profile examples of fatigue-related accidents which has compelled the USCG to examine its hours-of-service regulations is the *Exxon Valdez* oil spill. Ranking among the worst environmental disasters to date, the spill resulted in untold death to wildlife, affected 1300 miles of shoreline, and cost $2.1 billion in clean-up efforts.[112] The three-man crew was held responsible for running the ship aground on Bligh Reef on March 24, 1989. The official NTSB Marine Accident Report states:

> The performance of the third mate was deficient, probably because of fatigue, when he assumed supervision of the navigation watch from the master about 2350 [almost midnight]. The third mate's failure to turn the vessel at the proper time and with sufficient rudder probably was the result of his excessive workload and fatigued condition, which caused him to lose awareness of the location of Bligh Reef. There were no rested deck officers on the *Exxon Valdez* available to stand the navigation watch when the vessel departed from the Alyeska Terminal.[113]

Relevance of Governmental Regulations in Other Industries to the Health-Care Industry

The justifications for hours-of-service regulations in the transportation industries share many parallels with those in medicine. At the DOT-sponsored Operator Fatigue Management Conference in August of 2000, representatives from all transportation modes agreed that "the incidence of fatigue is underestimated in virtually every transportation mode" and that "it is likely that fatigue is a bigger contributor to incidents, accidents, and fatalities than many realize."[114] The petitioners believe that this statement applies to resident physicians and their patients as well, for several reasons.

First, as discussed above, workers in the four transportation industries commonly experience long shifts, long weekly hours, irregular shifts, work cycles that do not operate on a 24-hour schedule, and accumulated loss of sleep (sleep debt).

Resident physicians experience similar, and in nearly all cases worse, work schedules. Second, research conducted in the different transportation modes has converged on common concepts concerning the roles of duration of continuous service, duration of sleep in the last sleep period, duration of wakefulness since prior sleep, duration of sleep in the last 24 hours, split sleep schedules, and sleep debt, and their relation to human performance and safety. Resident physicians are not exempt from the outcomes predicted by the principles of sleep-wake biology. Third, the efforts of the DOT and the NTSB exemplify the role of the federal government in creating regulations that protect workers and save lives. The commitment to sleep research, implementation of hours-of-service regulations, efforts to revise hours-of-service regulations according to scientific principles, and collaboration with industry and labor, all serve as models for OSHA to follow.

PART 4: THE SAME RULES TO PROTECT RESIDENT PHYSICIANS AND SUBSPECIALTY RESIDENT PHYSICIANS WILL ALSO PROTECT PATIENTS

More than just harming resident physicians, long work hours have been shown to have negative effects on patients by increasing chances for accidents and errors in the delivery of medical care. A significant body of literature supports the common-sense notion that it is unsafe to subject patients to sleep-deprived and exhausted physicians-in-training.

In a randomized controlled trial, interns were found to make 35.9% more serious medical errors while working a traditional schedule with 24+ hour shifts occurring every third night, as compared with a schedule that limited their shifts of 16 consecutive hours ($p < 0.001$).[115] In a separate nationwide cohort study of injuries to patients caused by medical management (adverse events), researchers found that interns working five or more 24+ hour shifts in a month reported 7.5 times as many fatigue-related errors that injured a patient, and four times as many fatigue-related errors that led to a patient's death than did those who did not work 24+ hour shifts.[116] Altogether, one in five interns reported making a fatigue-related error that injured a patient, and one in 20 reported making a fatal error due to fatigue. These data suggest that thousands of patients may die each year in the U.S. due to resident physicians' extreme work schedules.

Other studies have shown that well-rested resident physicians outperform their sleep-deprived peers on a wide range of tasks, including basic rote memory, language, and numeric skills;[117] retention of information and problem-solving skills;[118] tests of visual attention, short-term memory, and coding ability;[119] and tests of concentration.[120] The procedural skills of resident physicians have also been shown to suffer under conditions of sleep deprivation or restriction, with decreases in resident physicians' performance of electrocardiogram interpretation,[121] anesthesia monitoring,[122] intubation of mannequins,[123] and simulated laparascopic cholecystectomy.[124] A paper published in the journal

Nature found that staying awake for 24 hours impairs cognitive psychomotor performance to the same degree as having a 0.1% blood alcohol level, a value above many U.S. legal driving limits (0.04 g. %-0.08 g. %).[125]

One of the strongest arguments for reducing resident physician work hours is an ethical one: overwork interferes with the development of professional values and attitudes that are an essential part of being a physician.[126] Fatigue can cultivate anger, resentment, and bitterness — often directed at the patient — rather than kindness, compassion, or empathy. As was evident from many of the studies on negative mood and its relationship to long work hours, this attitude is promoted when meeting a patient's needs becomes incompatible with meeting a resident physician's own needs. The following entry from a resident physician's diary illustrates the types of feelings engendered by typical resident physician work schedules:

> 1AM and I'm ready to go to bed: one should never be ready to go to bed in the ICU [Intensive Care Unit] — you'll always be disappointed. Anyway, I'm on my way to the EW [Emergency Ward] … when there's a code [cardiac arrest]. Get up there and find [a resident physician] trying to intubate a lifetime asthmatic who is as blue as this ink. I keep thinking — he's blue enough to go to the ICU. I keep hoping he's going to be too blue to go anywhere. Probably a nice man with a loving wife and concerned children, but I don't want that SOB to make it because I've got one special who is going to keep me up 2 more hours. I don't need an intubated, blue, pneumothoraxed SOB coming to my unit… I don't want the asthmatic SOB to live if it means I don't sleep. I don't want the special to live if it means I don't sleep. I just want sleep.[127]

Although patient protection is not the principal focus of this petition, it is clear that in protecting resident physicians from long work hours, OSHA would also be protecting patients.

PART 5: ARGUMENTS AGAINST REDUCING WORK HOURS

The following arguments are often made against reducing housestaff hours: (1) continuity of patient care will be disrupted; (2) long hours are necessary in order to sufficiently train physicians; (3) training under conditions of fatigue and sleep deprivation prepares resident physicians to function should these conditions arise in future practice; and (4) long hours promote favorable character attributes in physicians, such as discipline, endurance, responsibility, self-reliance, confidence, collegiality, and humility. The signers of this petition believe that two important questions must be asked: What is the incremental gain on any of these measures of working a 24-hour shift versus a 16-hour shift, and what are the risks against which these incremental benefits are being weighed? The risks have been reviewed in this petition, and have been shown to be substantial to

both patients and physicians. On the other hand, there are no data supporting the claims of proponents of the current situation.

The continuity-of-care argument claims that (1) long continuous hours worked by an individual physician are necessary for the delivery of good care to his or her patients, and that (2) long, continuous hours are necessary for the physician to receive adequate training. First, it is inevitable that there will be breaks in the continuity of care for patients. Attending physicians, for example, are scheduled to go home after shifts much shorter than those worked by resident physicians. Resident physicians, on the other hand, have been traditionally expected to subordinate their needs to the "ideal" of spending as much time with their patients as possible. Studies increasingly demonstrate serious harm to resident physicians as a result of these long hours. But there is no evidence to support the contention that eliminating extended shifts leads to lower care quality. Quite the contrary, both the randomized controlled trials cited in the prior section, and a host of cohort studies, have demonstrated that eliminating 24-hour shifts improves the quality of care. In a systematic review of the literature, Levine *et al.* found that in seven out of 11 published studies, eliminating or reducing shifts of longer than 16 hours led to improvements in patient-care quality and safety;[128] in no studies did care quality deteriorate as a result of shortened hours. Decisions regarding how to schedule resident physicians — both with respect to patient care and resident physician well-being — must be based upon scientific evidence, not unsubstantiated arguments.

Second, resident physicians need not spend 30 continuous hours at a hospital in order to learn from their patients. Most diseases are seen a number of times in the course of multi-year residency programs, and resident physicians can also learn from the experience or reports of other resident physicians. With rational redesign of programs, it is possible to preserve or improve education despite reducing hours of work. In the Levine *et al.* systemic review, 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).[129]

The profession of medicine is a continuous learning process, with many opportunities for necessary skills to be obtained throughout a physician's career. With the rapidly changing nature of medicine, the ability to develop a well-balanced life with a well-established ability to continue to learn are at least as important as any experience to be gained between the 80th and 100th hour of a work week. Moreover, much of a resident physician's time is spent on non-educational activities. In a time-motion study of internal medicine resident physicians at two urban hospitals in New York City, Knickman found that 19% of internal medicine resident physicians' time was spent on activities that could be done by nurses, laboratory technicians, or other staff.[130] A meager 3.1% of their time was actually spent exclusively seeing patients. This raises the question of

why more ancillary staff is not hired to allow resident physicians added time for educational activities and to reduce work hours. Green has argued that the real reason is that it is economically more favorable for hospitals to use resident physicians as inexpensive labor to complete necessary tasks than to hire ancillary personnel who require higher salaries.[131] It has been calculated that substituting ancillary staff to provide services currently provided by resident physicians would cost hospitals approximately $58,000-$78,000 annually (in 1993 dollars) per resident physician, because resident physicians' salaries per hour actually worked are so low.[132] A more recent study put the annual labor costs of implementing the 2008 IOM recommendations at $1.6 billion (in 2006 dollars).[133]

The argument that, by training long hours, resident physicians will learn to function under the harsh conditions of real-world practice is false. Very few physicians work such long hours after residency. In fact, according to a very recent survey, the trend in the last decade has been "a steady decrease in hours worked per week … for all physicians".[134] U.S. physicians work an average of about 50 hours per week. In addition, on-call shifts occur less frequently. Being "on-call" for an attending physician is different than for a resident physician. While the resident physician must be physically present in the hospital, the attending physician usually has the luxury of taking call from the comfort of his or her own home. The attending physician must be available to come into the hospital if there were an emergency, but that rarely happens. In fact, the culture fostered in some residencies is one that discourages resident physicians from bothering the attending physician overnight. If the resident physician cannot handle a patient and has to ask for help from the attending physician, it is considered by some attending physicians and/or some resident physicians to be a sign of weakness.

Moreover, it is important to recognize that in those cases when attending physicians do remain awake overnight, they have been found to cope with sleep deprivation no better than trainees, despite years of experience with it. In a retrospective study of surgical and obstetrical complications over a 10-year period, Rothschild *et al*. found that attending physicians obtaining less than a six-hour opportunity to sleep overnight had three times as many complications in the operating room as compared with those who had more than a six-hour opportunity to sleep.[135] The notion that resident physicians should experience sleep deprivation in their training to prepare them for those times in the future when they may experience it again thus appears misguided. Studies in medicine, other occupations, and the laboratory do not support the notion that one can learn to cope with sleep deprivation. Indeed, emerging studies strongly indicate that chronic sleep deprivation greatly magnifies the ill effects of acute sleep deprivation, leading to as much as a 10-fold worsening in the effects of acute sleep loss.[136]

In sum, whereas there is evidence that physical and mental harm comes to resident physicians and that performance decreases with sleep deprivation and

fatigue, there is no evidence to suggest that reducing work hours would decrease the quality of patient care, that 80 hours per week is insufficient to train resident physicians, or that resident physicians are better prepared for the future because they trained more than 80 hours per week. Moreover, there is positive evidence that medical errors decrease with reduced work schedules[137] and that resident physicians' performance and moods get better with rest,[138] both of which translate into better patient care. If policy is to be based on evidence and not opinion, the federal government is obligated to protect resident physicians and their patients by reducing resident physician work hours. It is quite clear that public opinion strongly supports reducing resident work hours.[139] In a telephone survey of 1,200 people using random digit telephone dialing, researchers found that 81% believed that reducing resident physician work hours would be very or somewhat effective in curtailing the problem of medical errors. Further, only 1% approved of shifts lasting more than 24 hours.

PART 6: OSHA HAS JURISDICTION OVER LIMITING RESIDENT PHYSICIAN WORK HOURS

In November of 1999 the National Labor Relations Board (NLRB) overturned the 1976 *Cedars-Sinai, St. Clare's Hospital* precedent that ruled that resident physicians are primarily students rather than employees, stating that this previous determination was "flawed in many respects," and that "ample evidence exists here to support our finding that interns, residents, and subspecialty resident physicians fall within the broad definition of 'employee.'"[140] The Board argued that resident physicians' "status as students is not mutually exclusive of a finding that they are employees."

The NLRB's rationale had four elements. First, resident physicians and subspecialty resident physicians (called "housestaff") were determined to work for an employer (the hospital) within the meaning of the Act. Second, housestaff are compensated for their services by the hospital, and the hospital withholds federal and state income taxes, as well as social security, from their salaries. Further, housestaff receive fringe benefits reflective of employee status, such as worker's compensation, paid vacations, and sick leave; parental and bereavement leave; and insurance coverage such as health, dental, life, and malpractice. Third, housestaff provide patient care for the hospital, the service that the hospital sells. Lastly, housestaff were also found to be unlike students in that they do not pay tuition or student fees.

The NLRB thus fundamentally changed the thinking applied to resident physicians, asserting that housestaff are no longer considered primarily students. "That they [housestaff] also obtain educational benefits from their employment does not detract from this fact. Members of all professions continue learning throughout their careers." The Board concluded that "house staff are employees … and … are therefore entitled to all the statutory rights and obligations that flow from our conclusion." The signers of this petition believe that these rights entitle

housestaff not only the freedom to organize for collective bargaining, but also to expect that OSHA will protect them as employees from unsafe labor practices, the way they would workers in other industries. The NLRB decision clearly brings regulation of resident physician work hours under OSHA's jurisdiction.

Moreover, whereas hours-of-service regulations put forth by the DOT, for example, have been made possible by the existence of industry-specific statutes, there are no such statutes for resident physician working conditions, and OSHA is therefore the only government organization within whose purview regulation of resident physician work hours falls. Furthermore, OSHA has previously established standards for the protection of health-care workers when it promulgated the Bloodborne Pathogens Standard[141] to protect health-care workers from needlestick injuries.

PART 7: REQUESTS

PETITIONERS' REQUESTS

Public Citizen, the Committee of Interns and Residents/SEIU Healthcare, the American Medical Student Association, Dr. Bertrand Bell, Dr. Charles Czeisler, Dr. Christopher Landrigan, and other petitioners request that the following hours-of-service regulations be applied to resident physicians in all residency and subspecialty fellowship programs:

(1) A limit of 80 hours of work in each and every week, without averaging;
(2) A limit of 16 consecutive hours worked in one shift for *all* resident physicians and subspecialty resident physicians;
(3) At least one 24-hour period of time off of work per week (no averaging) and one 48-hour period of time off of work per month (no averaging);
(4) In-hospital on-call frequency no more than once every three nights, no averaging;
(5) A minimum of at least 10 hours off work after a day shift, and a minimum of 12 hours off work after a night shift;
(6) A maximum of four consecutive night shifts with a minimum of 48 hours off after a sequence of three or four night shifts.

Work hours should be measured as time at the work-site; time asleep at the work-site should be counted as work hours. Time off work should be measured as time away from the hospital while not on-call. The regulations shall not be construed to require or permit a resident physician to abandon his or her patient in need of emergency or critical care. In an extreme situation proven by the hospital to be a patient-care emergency, and when that resident physician cannot be replaced by a rested resident physician, or his or her skills are not replaceable, the resident physician's or subspecialty resident physician's work that day may exceed the maximum 16-consecutive-hour shift or 80-hour per week limit in order to complete that patient's emergency care. This does not

mean that resident physicians may be scheduled to be present at a work-site in excess of the 16-hour-per-day or 80-hour-per-week limit, or that new patients may be assigned at or near the end of that time.

These requested rules differ from the 2011 ACGME proposal in several ways. First, whereas the most recent ACGME rules call for an 80-hour work week averaged over a four-week period, the signers of this petition are calling for an 80-hour work week that is not averaged. The signers believe that two 100-hour weeks and two 60-hour weeks are not consistent with minimizing harm to physicians and patients, and that exceptions to an 80-hour week should not be granted to any residency programs. The ACGME suggests exemptions allowing certain residencies to exceed 80 hours of work per week. As stated previously, we believe the same standard should apply to all specialties, as they are based on human biological limits, not particular specialty-based functions. We suspect that many surgical programs, long known for their vigorous opposition to work-hour restrictions, will want to seek work week exceptions. We therefore request an 80-hour limit of work per week be applied to all residency and subspecialty fellowship programs, across specialties. Second, the ACGME rules call for a maximum continuous shift time of 16 hours for interns, but they allow for intermediate and senior resident physicians to work up to 28 hours. The differential treatment makes no sense, since all resident physicians are at risk of harming themselves and patients. In the Levine *et al.* systematic review cited above, intermediate-level and higher resident physicians, as well as interns, were found to provide better care when shifts exceeding 16 hours were eliminated. Third, the ACGME proposal provides for one day off per week, averaged over four weeks. Again, working two continuous weeks, at such an intense pace, is not consistent with minimizing fatigue. Fourth, in-hospital on-call frequency should be no more than every third night without averaging, for all resident physicians. The ACGME proposal seems to suggest that this would only apply to intermediate and senior-level resident physicians, but not to interns. Even if resident physicians were working no more than 16-hour on-call shifts, there should not be any rule that allows them to work on-call more often than this, which would greatly increase the risk of excessive fatigue. Fifth, as recommended by the Institute of Medicine, resident physicians should get a minimum of 10 hours off work after a daytime work shift, and 12 hours off work after a night shift. This is necessary to allow for adequate sleep time that will prevent the build-up of sleep debt over time that results from chronic sleep restriction. The ACGME proposal requires only eight hours off work between shifts, which would lead to inadequate sleep on a regular basis, once commuting time and personal responsibilities are accounted for. Finally, the ACGME should follow the recommendations of the IOM and prohibit resident physicians from working more than four consecutive night shifts, and following three to four consecutive nights of work, a 48-hour period free of work should be provided to allow for recovery sleep and prevent the buildup of sleep debt. The current ACGME proposal allows for resident physicians to work six night shifts in a row, a number demonstrated to lead to an increased risk of accidents and errors.[142]

Enforcement

Furthermore, the signers of this petition request that strict enforcement accompany the regulations, as inadequate enforcement policies have been a source of failure in previous efforts to limit resident physician work hours:

(1) Resident physician and subspecialty resident physician schedules should be recorded and kept as public records by the hospitals, available for OSHA inspection;
(2) There must be an official and confidential procedure for whistleblowers to report violations to OSHA;
(3) Unannounced inspections should occur on a frequent basis;
(4) OSHA must establish enforcement mechanisms so that violations incur fines sufficient to deter those violations.

Conclusion

Evidence convincingly demonstrates that excessive work schedules risk resident physicians' lives and health, in terms of automobile safety, mental health, pregnancy complications, and percutaneous injuries. OSHA can readily adopt the standards requested in this petition, which are based on an expansion of those put forth by the ACGME. ACGME has failed to demonstrate that it can enforce tighter work-hour rules on its own.

After establishing the requested regulations, as a second, necessary step, OSHA should then proceed to investigate resident physician work hours more thoroughly to determine if even stricter standards are required. As elegantly defined in its enabling legislation,[143] the Occupational Safety and Health Act of 1970, OSHA's mission is to "assure so far as possible every working man and woman in the Nation safe and healthful working conditions."[144] The signers of this petition believe that OSHA should immediately establish the requested work-hour regulations for resident physicians and subspecialty resident physicians to fulfill this mission.

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