

## FEDERAL REGULATION OF HOSPITAL RESIDENT WORK HOURS: ENFORCEMENT WITH REAL TEETH

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In recent years, there has been an increase in the public's awareness of medical errors committed by hospital interns and residents who have been acutely and chronically sleep-deprived as a result of extremely long work hours.<sup>1</sup> This awareness has resulted in increased public concern regarding patient safety in teaching hospitals across the United States, as well as increased concerns regarding the safety and education of hospital residents themselves.

To address these concerns, the Accreditation Council for Graduate Medical Education (ACGME) appointed the Work Group on Resident Duty Hours and the Learning Environment in September 2001 to establish guidelines that "emphasize the responsibilities of programs, sponsoring institutions, and the accrediting body relating to safe patient care and an appropriate learning environment for residents."<sup>2</sup> While the ACGME Work Group deliberated on and finalized these guidelines, bills were introduced in both chambers of the United States Congress that would have established federal statutory restrictions on resident work hours.<sup>3</sup> At the same time, the Occupational Safety and Health Administration (OSHA) of the United States Department of Labor considered a petition submitted by the

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1. *E.g.*, Timothy B. McCall, Editorial, *No Turning Back: A Blueprint for Residency Reform*, 261 JAMA 909, 909 (1989). In this Comment, the terms "hospital residents" and "residents" refer to physicians in a clinical medical education or training program after graduating from medical school; the terms "hospital interns" and "interns" refer to physicians in their first year of a clinical medical education or training program after graduating from medical school (i.e., first-year hospital residents).

2. ACCREDITATION COUNCIL FOR GRADUATE MED. EDUC. (ACGME), REPORT OF THE ACGME WORK GROUP ON RESIDENT DUTY HOURS I (2002), <http://www.acgme.org/DutyHours/wkgroupreport611.pdf> [hereinafter ACGME REPORT]. The ACGME is responsible for accrediting all medical residency programs in the United States.

3. Patient and Physician Safety and Protection Act of 2002, S. 2614, 107th Cong. (2002); Patient and Physician Safety and Protection Act of 2001, H.R. 3236, 107th Cong. (2001).

consumer and health advocacy group Public Citizen requesting that OSHA promulgate federal regulations restricting resident work hours.<sup>4</sup>

The ACGME's efforts to establish its own resident work hour guidelines were largely intended to head off any attempts at federal regulation over resident work hours.<sup>5</sup> Although the ACGME ultimately succeeded in this endeavor, questions remain as to whether the federal government should regulate resident work hours despite the existence of the ACGME guidelines. This Comment develops an argument that answers this question in the affirmative. Part I presents a general background on the issue of restricting hospital resident work hours in the United States, including the attitudes of the medical establishment, medical educators, and hospital residents toward the issue. Some of the published scientific research on the effects of long work hours and sleep deprivation among residents is also reviewed. Part II reviews the history behind the resident work hour regulations promulgated in New York State in 1989, including the details of the incident that inspired these regulations (i.e., the Libby Zion case). The impact of these regulations on the medical community, political community and general public in New York State, and nationwide are also considered. Part III reviews the immediate legacy of the Libby Zion case, including compliance issues with the New York State regulations that have arisen since their promulgation. Part IV examines recent proposals for federal regulation of resident work hours. Part V examines the ACGME accreditation standards implemented in July 2003 and the reaction of the medical and graduate medical education communities to this attempt at self-regulation. Part VI reviews the findings of various studies on compliance with and attitudes toward the ACGME and New York State resident work hour restrictions in recent years. Part VII advances the argument that the federal government should regulate resident work hours rather than the states or the graduate medical education community because the federal government is better suited to implementing and enforcing such regulations successfully. Some suggestions for future federal legislation are also presented in this part. The conclusion gives some consideration to the likelihood of federal regulation of resident work hours in the near future.

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4. Petition from Sidney M. Wolfe, Dir., Public Citizen's Health Research Group, et al. to R. David Layne, Acting Ass. Sec'y for Occupational Safety & Health, U.S. Dep't of Labor (Apr. 30, 2001), available at <http://www.citizen.org/publications/release.cfm?ID=6771> [hereinafter Public Citizen Petition].

5. See *infra* notes 281, 283-84 and accompanying text.

## I. BACKGROUND

*A. Attitudes Toward Restrictions on Hospital Resident Work Hours*

The excessive work hours typical of residency programs have long been accepted within the medical and graduate medical education communities in the United States on the basis of two main justifying arguments: 1) long hours are essential for the continuity and thus quality of care provided to the patient; and 2) long hours are necessary for the quality of education provided to hospital residents.<sup>6</sup> According to Dr. Joseph Jack Fins, formerly of New York Hospital, long hours permit the “traditional physician-patient relationship founded on a fiduciary obligation . . . [in which] one physician cannot always be replaced by another [as a result of the] therapeutic relationship . . . [and the] trust that developed when responsibility for care [was] first assumed.”<sup>7</sup> In its 1989 position paper on resident work hours, the American College of Physicians (ACP) claimed that continuity of care represents the ultimate educational experience during residency:

The hallmark of physicians’ responsibility to their patients is continuity: Failure to provide for continuous care represents abandonment, which is morally unacceptable, professionally unethical, and legally proscribed. In contrast to reading and lectures, which serve well for teaching medical facts and logic, continued contact with patients over extended periods of time provides the primary opportunity for modeling the taking of responsibility.

In learning to take continuing responsibility for their patients, physicians have much in common with parents. All understand and applaud the dedication of parents who stay up all night with dependent, needy offspring. By the same token, it is unrealistic to expect residents to absorb the full meaning of responsibility for medically fragile or unstable patients who depend on them for care if their working hours are fixed according to rigid, arbitrary schedules.<sup>8</sup>

Similarly, Dr. Robert M. Glickman has commented that “[w]e do not practice medicine according to rigid, hourly shifts, so we should not teach our residents in that framework.”<sup>9</sup>

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6. See *infra* notes 7-11 and accompanying text.

7. Joseph Jack Fins, *Professional Responsibility: A Perspective on the Bell Commission Reforms*, 67 BULL. N.Y. ACAD. MED. 359, 362 (1991).

8. American College of Physicians, *Working Conditions and Supervision for Residents in Internal Medicine Programs: Recommendations*, 110 ANNALS INTERNAL MED. 657, 660 (1989) [hereinafter ACP Recommendations].

9. Robert M. Glickman, *House-Staff Training—The Need for Careful Reform*, 318 NEW ENG. J. MED. 780, 781 (1988).

Another argument that the medical and graduate medical education communities and even some residents offer to explain how long work hours benefit the quality of medical education provided to residents is that such work hours allow a physician-in-training to constantly follow the progress of an illness as well as the patient's recovery.<sup>10</sup> Such "hands-on" experience, they argue, is essential for the development of the resident's medical knowledge base and technical skills.<sup>11</sup>

Not all residents and members of the medical and graduate medical education communities, however, have accepted these justifications for long work hours. Some have claimed that residency is really a "rite of passage that tests residents' worthiness[,]"<sup>12</sup> whereby:

[T]he novice is expected to earn his group membership [into the elite society of physicians] by being able to tolerate specific forms of suffering, as is often the case with initiation rites. He is spurred to success by his superiors and models who convey the message, "I did it; therefore, you must do it too."<sup>13</sup>

In support of this claim, Richard C. Friedman et al. paraphrased a typical comment of sleep-deprived interns who expressed feeling "ashamed that [they] get tired and can't live up to the tradition of the iron men."<sup>14</sup> Others, such as Norman Cousins of the Program in Medicine, Law, and Human Values at the University of California at Los Angeles School of Medicine, have disparaged long work hours in residency as "disguised hazing at best and systematic desensitization at worst."<sup>15</sup> Referring to residency as a "human meat grinder," Cousins has remarked: "The custom of overworking interns has long since outlived its usefulness. It doesn't

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10. *E.g.*, ACP Recommendations, *supra* note 8, at 660 ("[P]hysicians learn techniques that help them to live with uncertainty and make good decisions under uncertain conditions" (citing M. C. Weinstein & Harvey V. Fineberg, *Clinical Decision Analysis* PP (W.B. Saunders, 1980)); Renée C. Fox, *Training for Uncertainty*, in *THE STUDENT-PHYSICIAN: INTRODUCTORY STUDIES IN THE SOCIOLOGY OF MEDICAL EDUCATION* 207, 218 (Robert K. Merton et al. eds., Harvard University Press 2d prtg. 1969); Alan J. Moskowitz et al., *Dealing with Uncertainty, Risks, and Tradeoffs in Clinical Decisions: A Cognitive Science Approach*, 108 *ANNALS INTERNAL MED.* 435 (1988); David A. Asch & Ruth M. Parker, *The Libby Zion Case: One Step Forward or Two Steps Backward?*, 318 *NEW ENG. J. MED.* 771, 774 (1988) ("[O]thers claim that the long hours are essential to proper training – that an understanding of the evolution of many acute diseases can be gained only through the observation of affected patients over time."); Amy Lynn Bloch, *The Post-Bell Commission Residency: Sleep vs. Care*, 261 *JAMA* 3243, 3243 (1989) ("Lost to the process is the input from those physicians who have done the most thinking about the patient's illness, as well as the learning that comes from being there, hands on, as events take their course.").

11. *See* Asch & Parker, *supra* note 10, at 774; *see also* Bloch, *supra* note 10, at 3243.

12. Asch & Parker, *supra* note 10, at 774.

13. Richard C. Friedman et al., *Psychological Problems Associated with Sleep Deprivation in Interns*, 48 *J. MED. EDUC.* 436, 440 (1973) [hereinafter Friedman 1973].

14. *Id.* at 438.

15. Norman Cousins, *Internship: Preparation or Hazing?*, 245 *JAMA* 377, 377 (1981).

lead to the making of better physicians. It is inconsistent with the public interest. It is not really worthy of the tradition of medicine.”<sup>16</sup>

Some residents have taken more direct action to effect change. In March 1975, to demand an eighty-hour work week and a fifteen-hour limit on consecutive work hours, residents in several New York City hospitals went on strike. The strike received extensive coverage in the press, as did the demands of the striking residents.<sup>17</sup> Calling the strike and subsequent collective bargaining negotiation process a “war,” then-president Richard A. Knutson, M.D., of the Committee of Interns and Residents (CIR) told the *New York Times* that the residents “did not go on strike just to hold a college demonstration[,]” and that even leaders of the American Medical Association (AMA) had expressed agreement with the union’s contention that “overly long hours are a threat to quality of care.”<sup>18</sup> With additional pressure from the CIR,<sup>19</sup> the hospitals eventually agreed to reduce the on-call frequency for the residents from every other night to every third night.<sup>20</sup> Although the strikers did not win their initial demands for specific work hour limits, the publicity that the strike received heightened the public’s awareness of the exhausting conditions under which residents traditionally worked, as well as the potential risks to patients associated with these conditions.

### B. Scientific Studies on Sleep-Deprived Hospital Residents

Over the years, many scientific studies on the effects of long work hours and sleep deprivation on hospital residents have been published in medical and scientific journals. The findings and conclusions of many of these studies appear to validate many of the concerns the public has regarding the effects of sleep-deprived residents on patient and resident safety.

#### 1. Cognitive Performance and Psychological Effects

C.H.M. Jacques et al. examined the effects of various amounts of reported sleep on the cognitive performance of 353 family practice residents from various

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16. *Id.*

17. Peter Kihss, *Pact Ends Doctor Strike; Staffs Return to Hospitals*, N.Y. TIMES, Mar. 21, 1975, at 1 [hereinafter *Pact Ends*]; Peter Kihss, *2 Sides in Hospital Strike Become Bitter in 3d Day*, N.Y. TIMES, Mar. 20, 1975, at 44 [hereinafter *2 Sides*]; Emanuel Perlmutter, *Internes Affirm Deadline for Hospital Strike Today*, N.Y. TIMES, Mar. 17, 1975, at 1.

18. *2 Sides*, *supra* note 17, at 44.

19. CIR is now the largest medical housestaff union in the United States, representing more than 12,000 hospital residents in California, Florida, Massachusetts, New Jersey, New York, the District of Columbia, and Puerto Rico. Committee of Interns and Residents, *Who We Are*, <http://www.cirseiu.org/ourlocal/> (last visited Mar. 11, 2006).

20. Asch & Parker, *supra* note 10, at 774; *Pact Ends*, *supra* note 17, at 44; CIR, *supra* note 19. “On-call” is the term for residents who are on duty for an extended period of time, including overnight hours.

post graduate years (PGYs) in 21 residency programs throughout the Commonwealth of Pennsylvania who took the American Board of Family Practice In-Training Examination in November 1988.<sup>21</sup> Test scores were used to evaluate cognitive performance among the residents.<sup>22</sup> Students in higher PGYs scored significantly higher than students in lower PGYs.<sup>23</sup> Moreover, losing the equivalent of one night of sleep “result[ed] in a change in test score[s] approximately equivalent to the change that occurs between the first and third year of residency training.”<sup>24</sup> However, the investigators also concluded from the results that “prolonged testing [of routine tasks] over several hours may be necessary to detect the subtle but significant differences in cognitive performance that are present with relatively mild degrees of sleep loss.”<sup>25</sup>

One of the most detailed studies on the psychological effects of sleep deprivation arising from long work hours among interns was conducted by Drs. Richard C. Friedman, J. Thomas Bigger, and Donald S. Kornfeld of the Columbia University College of Physicians and Surgeons (CPS) in New York City.<sup>26</sup> Between December 1969 and June 1970, Friedman et al. studied fourteen medical interns at Presbyterian Hospital at the Columbia-Presbyterian Medical Center, a teaching affiliate of the CPS.<sup>27</sup> None of the interns studied had a history of psychiatric treatment, and none had ever complained of psychopathological symptoms when rested.<sup>28</sup>

Although the normal work schedule for these interns required an on-call frequency of every other night, the interns examined in this study routinely chose to work two consecutive nights so that they could have every other weekend off-duty.<sup>29</sup> Therefore, the on-call shifts for these interns sometimes lasted up to sixty hours, during which the interns stayed awake for most of the time.<sup>30</sup> All interns were asked to complete a testing barrage at their convenience twice, once in a rested state and once in a sleep-deprived state.<sup>31</sup> Interns who were considered rested slept an average of seven hours during the thirty-two hours prior to testing,

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21. C.H.M. Jacques et al., *The Effects of Sleep Loss on Cognitive Performance of Resident Physicians*, 30 J. FAM. PRAC. 223, 224 (1990).

22. *See id.*

23. *See id.* at 225.

24. *Id.* at 227.

25. *Id.* at 223.

26. Richard C. Friedman et al., *The Intern and Sleep Loss*, 285 NEW ENG. J. MED. 201 (1971) [hereinafter Friedman 1971]; Friedman 1973, *supra* note 13, at 436-37.

27. Friedman 1971, *supra* note 26, at 201.

28. Friedman 1973, *supra* note 13, at 436-37.

29. *Id.* at 437.

30. *Id.*

31. Friedman 1971, *supra* note 26, at 201.

whereas interns who were considered sleep-deprived slept an average of 1.8 hours during the same duration.<sup>32</sup> Each intern served as his or her own control.<sup>33</sup>

There were four components to the testing barrage.<sup>34</sup> One of these components involved an electrocardiographic arrhythmia-detection test, a sustained-attention task to assess medical performance.<sup>35</sup> The other components were aimed at assessing psychological parameters, including the psychophysiologic states and the subjectively perceived moods of the interns.<sup>36</sup> Finally, each intern finished the testing barrage with a five to ten minute interview with the investigators during which any topic of the intern's choosing could be discussed. Most interns chose to discuss their "feelings at the moment and their attitudes both about their working schedule and its effect on their clinical performance."<sup>37</sup>

Intern responses to the psychological portions of the testing barrage indicated significantly less surgency (i.e., "feeling carefree, lively, talkative"), vigor, elation, egotism, and social affection and significantly more fatigue and sadness when sleep-deprived than when rested.<sup>38</sup> Moreover, the test results suggested that sleep-deprived interns exhibited significantly more psychophysiologic abnormalities overall than rested interns, and that sleep-deprived interns experienced higher degrees of physiologic, perceptual, and cognitive abnormalities.<sup>39</sup>

To summarize the comments derived from the interviews with sleep-deprived interns, the investigators grouped the comments of the sleep deprived interns into seven "symptoms" that were not reflected in comments from rested interns: difficulty thinking, depression, irritability, "referential feelings with extreme sensitivity to criticism," "depersonalization and derealization," "inappropriate affect usually associated with black humor," and "recent memory deficit."<sup>40</sup> As an example of a comment reflecting "difficulties thinking," the investigators paraphrased interns as saying:

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. Writing in charts is important to me. I write for attendings,

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32. *Id.* at 202.

33. *Id.* at 201.

34. *Id.*; Friedman 1973, *supra* note 13, at 437.

35. Friedman 1971, *supra* note 26, at 201-02.

36. *Id.* at 201; Friedman 1973, *supra* note 13, at 437.

37. Friedman 1973, *supra* note 13, at 437.

38. Friedman 1971, *supra* note 26, at 201-02.

39. *Id.*

40. Friedman 1973, *supra* note 13, at 437-38.

residents, and students. It gets me scared when this happens because it means that I am losing control of my ability to think.<sup>41</sup>

Interns who felt depressed were paraphrased as saying that they had let a deceased patient down because “I was not successful treating him.”<sup>42</sup> Comments reflecting irritability among interns were paraphrased as saying:

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 can only think of one thing at a time. I can’t react to complexity. I give bad care to my patients, unfortunately. When I’m tired, I don’t give a Goddamn.<sup>43</sup>

Depersonalization and derealization were exemplified through paraphrased comments such as, “I feel as if I’m not really all there. I am discontinuous. My writing is discontinuous. I feel discontinuous.”<sup>44</sup> Memory deficits were reflected through the paraphrased comment that, “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.”<sup>45</sup>

Recently, researchers at the Harvard Medical School studied the effects of reducing intern work hours on sleepiness and attentional failures among interns.<sup>46</sup> Twenty interns at the Brigham and Women’s Hospital in Boston, Massachusetts were studied while working in coronary and intensive care units.<sup>47</sup> Each intern was studied while working in a traditional rotation schedule that included extended work shifts and an intervention schedule designed to limit work hours to sixteen or fewer consecutive hours.<sup>48</sup> Daily sleep logs, ambulatory polysomnography technology, and work logs were all used to study the interns while they worked.<sup>49</sup> The researchers concluded from their analysis of the data that eliminating extended on-call work shifts for interns in intensive care units “significantly increased sleep and decreased attentional failures during night work hours.”<sup>50</sup>

## 2. Medical Performance

Friedman et al. also conducted one of the first studies to examine the effects of sleep deprivation on the performance of interns on a task involving a skill

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41. *Id.*

42. *Id.* at 438.

43. *Id.*

44. *Id.*

45. *Id.*

46. Steven W. Lockley et al., *Effect of Reducing Interns’ Weekly Work Hours on Sleep and Attentional Failures*, 351 NEW ENG. J. MED. 1829, 1830 (2004).

47. *Id.* at 1830.

48. *Id.*

49. *Id.* at 1831.

50. *Id.* at 1829.



relevant to the practice of medicine.<sup>51</sup> Using the same group of fourteen interns at Presbyterian Hospital that had been used in their assessment of psychological effects of sleep deprivation arising from long work hours, the investigators examined the performance of these interns on a twenty-minute electrocardiographic arrhythmia-detection task when they were rested and sleep-deprived.<sup>52</sup> Monetary awards for the best testing performance (i.e., the fewest errors committed) were used as an incentive for the interns to perform well on the test.<sup>53</sup> It was found that the ability of interns to recognize arrhythmias on the electrocardiographic task was significantly impaired when they were sleep-deprived compared to when they were rested.<sup>54</sup> Moreover, three interns needed more time to complete the task, indicating impairment of concentration because the task required sustained attention on the part of the interns.<sup>55</sup> From these results, the investigators concluded that work schedules that induce sleep deprivation may “impair efficiency of performance.”<sup>56</sup>

Not all sleep deprivation studies involving skills relevant to the practice of medicine have yielded evidence that long work hours and sleep deprivation adversely affect the medical performance of residents. One study that surgeons and other physicians often cite in their defense of the residency system is that of Winslow Engel et al., who studied the effect of on-call schedules on the clinical performance and emotional state of seven medical interns.<sup>57</sup> Actors trained to pose as patients seeking medical consultation for common medical ailments were used to assess clinical performance, and questionnaires on subject fatigue and depression were used to assess emotional state.<sup>58</sup> The clinical performance of interns during post-call (i.e., after a twenty-four-hour on-call period) was not significantly different from their performance after a period of “rest” (i.e., no on-call duty).<sup>59</sup> From these results, Engel et al. concluded that “the major discernible effect of being on call was a reduction of the interns’ feelings of well-being.”<sup>60</sup> However, the investigators recognized that their results did not “imply that call has no effect on the quality of physicians’ work” and that “[a]cute mood changes may be partly responsible for the impairment of clinical abilities after call reported by

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51. Friedman 1971, *supra* note 26, at 201.

52. *Id.* at 201-02.

53. *Id.* at 201.

54. *Id.* at 202.

55. *Id.*

56. *Id.* at 203.

57. Winslow Engel et al., *Clinical Performance of Interns After Being on Call*, 80 S. MED. J. 761 (1987).

58. *Id.* at 761-62.

59. *Id.* at 762-63.

60. *Id.* at 763.

physicians themselves in surveys and anecdotally.”<sup>61</sup> Moreover, the investigators warned that the effect of on-call schedules on “mood and on the performance of sustained, repetitive tasks is more readily demonstrated and possibly of greater magnitude than the effect on the complex decisions made in clinical medicine.”<sup>62</sup>

In another study to determine the effects of sleep deprivation resulting from extended hours on the medical performance of residents, Timothy F. Deaconson et al. examined the performance of surgical residents working on-call every other night on a psychometric testing battery administered daily from 6:00-8:00 a.m. over the course of eighteen to nineteen days.<sup>63</sup> These tests were designed to measure the types of cognitive and motor skills deemed necessary for the effective practice of surgery: cognition, discernment, visual and auditory vigilance, and rapid eye-hand coordination.<sup>64</sup>

Sleep deprivation, which was defined to be “the lack of four hours of continuous sleep during the preceding 24 hours,” resulting from the on-call schedule did not have any significant effect on the overall cognitive and motor performance of the residents.<sup>65</sup> Making the assumption that performance on the psychometric tests accurately predicted performance in the operating room, the investigators concluded:

[T]he repetitive episodes of sleep deprivation associated with an every-other-night on-call schedule do not impair the performance of residents on psychometric tests and, by implication, performance in the provision of patient care. . . . Criticism of traditional hospital on-call schedules should be based on objective data. The evidence available to date does not support arbitrary recommendations to limit working hours of residents. Our data also do not support an assumption that sleep deprivation due to being on call adversely affects the capacity of residents to exhibit the cognitive and motor functions needed to provide appropriate patient care.<sup>66</sup>

After the publication of this study, however, other physicians drew alternate conclusions from the data set that contradicted those of the investigators.<sup>67</sup> One

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61. *Id.*

62. *Id.*

63. Timothy F. Deaconson et al., *Sleep Deprivation and Resident Performance*, 260 JAMA 1721, 1721 (1988).

64. *Id.* at 1722.

65. *Id.* at 1723.

66. *Id.* at 1727.

67. See e.g., Timothy B. McCall, Letter, *Sleep Deprivation and Performance of Residents*, 261 JAMA 859, 859 (1989) (arguing that “the [Deaconson et al.] study’s design is so flawed that their results and conclusions must be questioned”; that “[a] far more likely explanation of the data is that residents on call every other night are equally impaired before and after a night on call”; and that “[b]y failing to include a truly rested control group, such as age-matched nonphysicians, the study reached a probably mistaken conclusion.”).

study involving surgical residents attempted to shed light on the question of whether sleep deprivation in surgical residents contributed to postoperative complications.<sup>68</sup> Those residents who had operated on the day following a twenty-four-hour on-call shift were considered subject to sleep deprivation.<sup>69</sup> After retrospectively reviewing data from over 6,000 surgical cases including 351 identified postoperative complications, the investigators concluded that there was no significant difference between the frequency of complication when the resident was sleep-deprived and the frequency of complication when the resident was not sleep-deprived.<sup>70</sup>

Matthew Weinger et al. examined the effects of fatigue and sleep deprivation on the clinical performance of anesthesiology residents during routine surgical cases.<sup>71</sup> Arguing that the skills anesthesiologists possess to assure patient safety (e.g., “vigilance, short-term memory, resource allocation, and task prioritization”) are especially sensitive to the effects of fatigue and sleep deprivation, the investigators hypothesized that “fatigue would significantly tax the cognitive resources of these physicians and this would be manifested as altered task patterns and increased workload.”<sup>72</sup>

Two sets of experiments were conducted.<sup>73</sup> In one experiment, the performance of eight anesthesia residents in an actual operating room (OR) case was evaluated twice; once in a fatigued state during the night and once in a non-fatigued state during the day.<sup>74</sup> The OR cases selected for the nocturnal and daytime evaluations of each resident were similar in nature (e.g., complexity, skills required) and lasted between one and six hours.<sup>75</sup> Every ten to fifteen minutes, a trained observer in the OR rated the resident’s workload using a fifteen-point visual analog scale (VAS) on a computer. The resident also rated his or her workload using the same VAS.<sup>76</sup> As a further, albeit indirect measure of workload, the response latency of the residents to an alarm light stimulus given at random

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68. Daniel F. Haynes et al., *Are Postoperative Complications Related to Resident Sleep Deprivation?*, 88 S. MED. J. 283 (1995).

69. *Id.* at 284.

70. *Id.* at 287-89.

71. Matthew B. Weinger et al., *Evaluation of the Effects of Fatigue and Sleepiness on Clinical Performance in On-call Anesthesia Residents During Actual Nighttime Cases and in Simulated Cases* (Nov. 8-10, 1998), in NAT’L PATIENT SAFETY FOUND., ENHANCING PATIENT SAFETY AND REDUCING ERRORS IN HEALTH CARE: 1998 CONFERENCE PROCEEDINGS 306-10 (1998).

72. *Id.* at 306.

73. *Id.*

74. *Id.*

75. *Id.*

76. *Id.* at 306-07.

intervals every ten to fifteen minutes was monitored.<sup>77</sup> During the procedure, the observer also monitored the resident's activities using "custom software."<sup>78</sup>

All data was collected from the time the patient entered the OR until the patient left the room.<sup>79</sup> Subjective resident mood was assessed before and after each case using a ten-point mood VAS.<sup>80</sup> On average, nocturnal cases began at 2:14 a.m., after the resident had been awake for 18.3 hours, and lasted 180 minutes. Day-time cases began at 10:32 a.m., after the resident had been awake for 5.1 hours, and lasted 156 minutes.<sup>81</sup>

Residents reported being more "tired," "drowsy," and negatively disposed during nocturnal cases than during morning ones.<sup>82</sup> During nocturnal cases, residents spent significantly less time on manual tasks than during day-time cases, although their workload ratings were higher at night than during the day according to both the observers and the residents.<sup>83</sup> Nocturnal and day-time response latencies to light stimuli were not significantly different.<sup>84</sup> These results suggest that "fatigued physicians require additional cognitive resources to perform routine clinical tasks leading to increased workload, load shedding, and reduced 'spare capacity' to deal with potential crises[.]" or alternatively, that "fatigued clinicians may conserve their efforts, doing just what is necessary and no more."<sup>85</sup> Although the nocturnal cases were probably performed when the resident was sleep-deprived as well as fatigued, it was also possible that the day-time cases were performed while the resident still suffered from chronic sleep debt since the experimental design did not control the amount of acute and chronic sleep debt among the residents.<sup>86</sup> As a result, conclusions drawn from these results pertaining to the effects of fatigue on medical performance were more valid than conclusions pertaining to the effects of sleep deprivation on medical performance.

The other experiment that Weinger et al. conducted was designed to control acute and chronic sleep debt among the resident subjects, thus allowing for an examination of the effects of sleep deprivation on the performance of anesthesiology residents.<sup>87</sup> Twelve residents were evaluated while performing simulated anesthetics for two comparable four-hour laparoscopic surgical procedures on actors posing as patients, once after being awake for at least twenty-

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77. *Id.* at 307.

78. *Id.* at 306.

79. *Id.* at 307.

80. *Id.*

81. *Id.*

82. *Id.*

83. *Id.*

84. *Id.*

85. *Id.* at 308.

86. *Id.*

87. *See id.*

five hours (fatigued condition) and once after averaging two extra hours of sleep than normal for four consecutive nights (“satiated” condition).<sup>88</sup> Each resident was videotaped, and observers used these recordings to evaluate the activities and workloads of the residents.<sup>89</sup>

Although fatigue did not significantly affect task duration and workload, fatigued residents were observed to fall asleep more often than satiated residents.<sup>90</sup> Moreover, according to the investigators:

[These observations] may be explained by invariability in individual susceptibility and subjects’ responses to fatigue both in terms of patient care and non-patient care activities. In fact, in both the real and simulated environments, subjects employed a variety of sleepiness “defense strategies,” including conversation and busy work, to mitigate the effects of fatigue. Some subjects appeared to use these strategies more effectively than others and when successful, their use may have reduced any differences which otherwise might have been observed.<sup>91</sup>

Another explanation offered was that the “monotonous and routine nature of the cases studied in the simulator failed to stress subjects sufficiently to demonstrate the known cognitive effects of sleep deprivation,” and thus the effects of fatigue and sleep deprivation may “be most important during non-routine cognitively demanding situations.”<sup>92</sup>

Recently, researchers at the Harvard Medical School studied the effects of reducing intern work hours on the frequency of serious medical errors committed by the interns.<sup>93</sup> Studying interns at the Brigham and Women’s Hospital working in intensive care units,<sup>94</sup> the researchers found that interns made substantially more serious medical errors when they worked frequent shifts of twenty-four hours or more than when they worked shorter shifts<sup>95</sup> and concluded that eliminating extended work shifts and reducing the number of hours interns work per week can reduce serious medical errors in the intensive care unit.<sup>96</sup>

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88. *Id.* at 307-08.

89. *Id.* at 308.

90. *Id.*

91. *Id.*

92. *Id.* at 309.

93. Christopher P. Landrigan et al., *Effect of Reducing Interns’ Work Hours on Serious Medical Errors in Intensive Care Units*, 351 NEW ENG. J. MED. 1838, 1838-39 (2004).

94. *Id.* at 1839.

95. *Id.* at 1843-44.

96. *Id.* at 1847.

## II. THE LIBBY ZION CASE

In recent years, several high-profile incidents have exacerbated the public's perception of the dangers arising from patient care in the hands of overworked and sleep-deprived residents. Of these incidents, perhaps the most publicized was the case of Libby Zion.

### *A. Facts of the Case*

According to the report of the grand jury convened after the death of Libby Zion<sup>97</sup> and Asch and Parker's letter to the March 24, 1988, issue of the *New England Journal of Medicine*,<sup>98</sup> the case of Libby Zion progressed as follows.

Libby Zion, an eighteen year old female from New York, contracted a severe fever and earache (otalgia) a few days after getting a tooth extracted in late February 1984.<sup>99</sup> Despite treatment from her primary physician with erythromycin, an antibiotic, and chlorpheniramine (Chlortrimeton), an antihistamine, the fever persisted for several days and was accompanied by chills, muscle pains (myalgias), and joint pains (arthralgias).<sup>100</sup> When Libby's fever reached 105.8°F on March 4th, her father followed the advice of his physician and sent her to the emergency room at the New York Hospital in New York City.<sup>101</sup>

Upon arriving at the emergency room at 11:30 that night, Libby was examined by a junior (second-year) resident working on-call who was able to consult with an attending physician over the phone.<sup>102</sup> While obtaining Libby's medical history from Libby and her parents, the resident learned about the events summarized above.<sup>103</sup> In addition, the resident learned that since January 1984, Libby had been taking phenelzine (Nardil) three times daily as part of a prescribed psychiatric treatment for stress.<sup>104</sup> Libby admitted to frequent marijuana use but denied other illicit drug use.<sup>105</sup> She also denied using erythromycin and phenelzine that day because she felt "too ill" to do so.<sup>106</sup>

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97. Report of the Fourth Grand Jury for the April / May Term of 1986 Concerning the Care and Treatment of a Patient and the Supervision of Interns and Junior Residents at a Hospital in New York County 2 [hereinafter Grand Jury Report] (on file with author); Order Accepting Grand Jury Report as a Public Record (N.Y. Sup. Ct. Dec. 31, 1986) (on file with author).

98. Asch & Parker, *supra* note 10, at 771-75.

99. *Id.* at 771.

100. *Id.* at 771-72.

101. *Id.* at 772.

102. *Id.*

103. *Id.*; see *supra* notes 99-102 and accompanying text.

104. Asch & Parker, *supra* note 10, at 771.

105. *Id.* at 772.

106. *Id.*

After consulting with the attending physician (who was also the referring physician) over the phone three times during the examination, the resident had admitted Libby to the medical service at 2:00 a.m. on March 5th and put her under the care of another junior resident and an intern.<sup>107</sup> Both residents were on-call and had already been working for eighteen hours at the time of admission.<sup>108</sup> After being admitted to the medical service, Libby was given acetaminophen (Tylenol) and examined separately by the on-call intern and junior resident. In their respective admission notes, both residents indicated that Libby had been using phenelzine and “tentatively” diagnosed her with some form of “viral syndrome.”<sup>109</sup>

Over the course of the night, Libby’s condition gradually deteriorated.<sup>110</sup> At around 3:30 a.m., Libby was given an intramuscular dose of meperidine (Demerol) to control her agitation and shivering.<sup>111</sup> Because Libby’s restlessness only worsened after the meperidine injection, the intern first, at around 4:15 a.m., ordered Libby to be physically restrained and then at 4:30 a.m. ordered her to be given a dose of haloperidol (Haldol).<sup>112</sup> After a calm period from 4:30-6:00 a.m., Libby became restless again as her fever surged to at least 105.8°F.<sup>113</sup> At 6:30 a.m., Libby went into respiratory arrest.<sup>114</sup> Although a medical emergency team attempted to resuscitate her for forty-five minutes, the attempts were unsuccessful, and Libby Zion was officially pronounced dead at 7:45 a.m.<sup>115</sup>

According to the medical examiner’s report of March 6, 1984, the preliminary cause of Libby Zion’s death was bilateral bronchopneumonia.<sup>116</sup> Furthermore, Libby was reported to have had “hyperpyrexia (high fever) and sudden collapse shortly following injection of meperidine and haloperidol while in restraint for toxic agitation.”<sup>117</sup> Trace amounts of cocaine were also found in Libby’s nostrils as well as in pre-mortem serum samples, although the medical examiner ruled that these findings were only “presumptive” evidence of cocaine use rather than conclusive “to a reasonable degree of scientific certainty.”<sup>118</sup>

Suspecting that “inadequate care in the hands of overworked and undersupervised medical house officers” had contributed to his daughter’s death,

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107. *Id.*

108. *Id.*

109. *Id.*

110. *Id.*

111. *Id.*

112. *Id.*

113. *Id.*

114. *Id.*

115. *Id.*; see also Grand Jury Report, *supra* note 97, at 25.

116. Asch & Parker, *supra* note 10, at 772.

117. Medical Examiner’s Report, *quoted in* Grand Jury Report, *supra* note 97, at 26; see also Asch & Parker, *supra* note 10, at 772.

118. Grand Jury Report, *supra* note 97, at 28-29.

former prosecutor and *New York Times* commentator Sidney Zion convinced the District Attorney of New York County, Robert Morgenthau, to open a grand jury investigation into the death of Libby Zion.<sup>119</sup>

*B. Findings of the Grand Jury Investigation*

As a result of “insufficient evidence, especially regarding the cause of death,” the grand jury did not find any of the individual physicians involved in the case criminally responsible for the death of Libby Zion, and no criminal indictments were returned against New York Hospital or its medical staff.<sup>120</sup> Instead, the grand jury effectively indicted the hospital’s residency system,<sup>121</sup> which was similar to that existing in most American teaching hospitals at the time. In its final report, the grand jury criticized the residency system for permitting resident fatigue resulting from long work hours and lack of supervision in the emergency room, both of which the grand jury contended might have contributed to the “unnecessary” death of Libby Zion.<sup>122</sup>

To prevent such emergency room tragedies from occurring again in the future, the grand jury included five recommendations in its report. The first of these was that: “The State Department of Health should promulgate regulations that mandate all level one [highest ranking] hospitals to staff their emergency rooms with physicians who have completed at least three years of post-graduate training and who are specifically trained to evaluate and care for patients on an emergency basis.”<sup>123</sup>

This recommendation was made in response to the finding that an “undersupervised and inexperienced” junior resident had examined Libby Zion upon her arrival in the emergency room, rather than an attending physician.<sup>124</sup> Such practices were legal since state laws at the time neither required experienced physicians to staff emergency rooms nor established a prerequisite level of experience for a physician to work in an emergency room.

Second, the grand jury recommended that:

The State Department of Health should promulgate regulations to insure [*sic*] that interns and junior residents in level one hospitals are supervised contemporaneously and in-person by attending physicians or those members of the house staff who have completed at least a three year post-graduate residency program. These regulations should

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119. Asch & Parker, *supra* note 10, at 771.

120. Grand Jury Report, *supra* note 97, at 2.

121. Asch & Parker, *supra* note 10, at 772.

122. *Id.* at 29-39; *see also* Asch & Parker, *supra* note 10, at 772-73.

123. Grand Jury Report, *supra* note 97, at 39.

124. *Id.*



narrowly define the circumstances which interns may practice medicine without direct supervision.<sup>125</sup>

This recommendation was made in response to the finding that upon being admitted to the medical service, Libby Zion had been put under the direct care of a junior resident and an intern, both of whom were not supervised in-person by an attending physician.<sup>126</sup> Although state laws and regulations at the time permitted interns and other unlicensed residents to offer patient care services if they were placed under the “supervision” of a licensed physician, no state law or regulation explicitly defined “supervision” and what it should entail.<sup>127</sup>

The third recommendation of the grand jury addressed the fact that the intern had ordered Libby Zion to be physically restrained without first re-examining her in-person: “Legislation should be enacted to prescribe when a patient in a medical hospital may be physically restrained and to standardize the care and attention necessary for a patient in restraints.”<sup>128</sup> Fourth, to address the fact that both the junior resident and intern who cared for Libby Zion overnight had already been working for about eighteen hours when she was admitted to the medical service, the grand jury recommended that, “The State Department of Health should promulgate regulations to limit consecutive working hours for interns and junior residents in teaching hospitals.”<sup>129</sup> Finally, the grand jury recommended that, “The State Department of Health should conduct a study to determine the feasibility of requiring level one hospitals to implement a computerized system to check for contraindicated combinations of drugs.”<sup>130</sup> This recommendation was in response to the fact that Libby Zion had been given meperidine, even though the residents caring for her were aware of her recent treatment with phenelzine, which is known to contraindicate meperidine.<sup>131</sup> Moreover, the grand jury investigation revealed that, unbeknownst to the intern and residents who had examined her when she arrived at the hospital and emergency room, Libby had been taking two other drugs in the days prior to her death that were contraindicated to phenelzine: oxycodone (Percodan), which her dentist had prescribed after her tooth extraction, and chlorpheniramine, which Libby’s primary physician had initially prescribed for her fever.<sup>132</sup>

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125. *Id.* at 44.

126. *Id.*

127. *See id.* at 45-47.

128. *Id.* at 49.

129. *Id.* at 53.

130. *Id.* at 54.

131. Asch & Parker, *supra* note 10, at 773.

132. Grand Jury Report, *supra* note 97, at 34-35.

### C. *Aftermath of the Libby Zion Case*

The Libby Zion case received much attention from the press,<sup>133</sup> raising public concerns regarding the effects of fatigue and lack of supervision on the quality of patient care in teaching hospitals across the United States. Criticism also came from local political figures. For example, Andrew Stein, President of the New York City Council and consumer advocate for health care in New York City, published a study by the city health department that implicated medical mistakes as a significant contributor to the occurrence of deaths in hospitals all over the city.<sup>134</sup>

Legal action taken by the family of Libby Zion also helped to publicize this case and the issue of sleepy interns and patient safety. Sidney Zion sued New York Hospital and four physicians for medical malpractice resulting in the wrongful death of his daughter.<sup>135</sup> In February 1995, a New York jury found three of the four defendant physicians negligent and awarded damages to Libby Zion's family.<sup>136</sup> The jury, however, cleared New York Hospital of any wrongdoing.<sup>137</sup>

#### 1. *The Bell Commission*

In response to these developments and concerns, the Commissioner of the New York State Department of Health (NYSDOH), Dr. David Axlerod, asked nine distinguished New York physicians to sit on the newly-formed New York State Department of Health Ad Hoc Committee on Emergency Services, under the chairmanship of Bertrand M. Bell, M.D.<sup>138</sup> The members of this committee, which came to be known as the "Bell Commission," were asked to review the grand jury report stemming from the Libby Zion case and to discuss its ramifications.<sup>139</sup>

After reviewing the grand jury report, the Bell Commission endorsed the five recommendations of the grand jury and proposed several complementary

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133. See e.g., David Margolick, *New York Hospital And 4 Doctors Are Sued In Death of Patient*, N.Y. TIMES, Aug. 27, 1985, at B18; Ronald Sullivan, *Grand Jury Assails Hospital in '84 Death of 18-Year-Old*, N.Y. TIMES, Jan. 13, 1987, at B3; Ronald Sullivan, *Hospital Admits Fault in Patient's Death*, N.Y. TIMES, Mar. 24, 1987, at B3.

134. Asch & Parker, *supra* note 10, at 773.

135. *Zion v. New York Hosp.*, 590 N.Y.S.2d 188 (N.Y. App. Div. 1992). For details on the verdict and post-verdict proceedings, see COURT TV LIBRARY, *ZION V. NEW YORK HOSPITAL (2/95)* (1999), <http://www.courtTV.com/archive/casefiles/verdicts/zion.html> [hereinafter COURT TV LIBRARY].

136. COURT TV LIBRARY.

137. *Id.* The jury also found Libby Zion 50% responsible for her own death for her failure to inform the treating physicians that she had used cocaine and other prescription drugs. However, in post-trial proceedings, the judge threw out the contributory negligence portion of the verdict and ultimately fixed damages at \$375,000 against the three physicians who had been found liable at trial. *See id.*

138. Letter from Bertrand Bell, M.D., Chairman of N.Y. State Dep't of Health Ad Hoc Comm. on Emergency Servs., to Dr. David Axelrod, Comm'r, N.Y. State Dep't of Health (June 2, 1987) (on file with NYSDOH and author) [hereinafter NYSDOH Letter]; Asch & Parker, *supra* note 10, at 773.

139. NYSDOH Letter, *supra* note 138, at 1.

recommendations in a letter to Dr. Axelrod dated June 2, 1987.<sup>140</sup> Among these complementary recommendations were specific guidelines for the regulation of resident work hours and the improved supervision of interns and junior residents. The Commission's proposed restrictions on resident work hours included: 1) a limit of twelve consecutive hours for work shifts involving direct patient care in Emergency Medical Services with more than 15,000 visits per year, with at least eight hours off between work shifts; 2) a limit of sixteen consecutive hours for work shifts involving direct patient care in services other than Emergency Medical Services, with at least eight hours off between work shifts; and 3) restrictions on "moonlighting" work by prohibiting "an individual person who has worked the maximum consecutive hours in one hospital" from working "in a different hospital in a consecutive fashion."<sup>141</sup>

With regard to resident supervision, the Bell Commission stated that hospitals should make available "appropriate contemporaneous and in-person supervision of resident and intern physicians by attending physicians or appropriately credentialed supervisory physicians [twenty-four hours a day, seven days a week]."<sup>142</sup> Furthermore, the Commission emphasized the necessity of specifying the supervisory responsibility of senior medical staff, declaring:

[P]atient care in the teaching hospital is conducted by a team of physicians and nurses with the attending physician ultimately responsible. In the process of making more explicit the levels of supervision required of residents, the specific roles and responsibilities of the personal attending physic[i]an and of nurses in teaching hospitals should be considered.<sup>143</sup>

Recognizing that the concerns and grievances that the medical and graduate medical education communities might have regarding the Grand Jury's recommendations, the Bell Commission heard testimony for two days in August 1987 on the issue of resident work hours from experts and other informed representatives from the medical profession and the graduate medical education community.<sup>144</sup> Among the parties that sent representatives to testify on their behalf were the ACGME, the ACP, the American College of Surgeons, the AMA, the Association of American Medical Colleges (AAMC), the Association of Program Directors in Internal Medicine, the CIR, the Greater New York Hospital Association, and the Health and Hospitals Corporation.<sup>145</sup> According to Asch and Parker, much of the testimony focused on "potential problems of implementation,

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140. *Id.* at 1-6.

141. *Id.* at 3.

142. *Id.*

143. *Id.* at 3.

144. Asch & Parker, *supra* note 10, at 773.

145. *Id.*

including effects on graduate medical education, hospital staffing, malpractice litigation, and health care financing.”<sup>146</sup>

After further deliberations, the Bell Commission submitted its final report to the NYSDOH on October 7, 1987.<sup>147</sup> In the report’s introduction, the Commission justified its deliberations in claiming that its motivation was “focused on improving the quality of medical care of patients in a hospital emergency department and in the in-hospital environment.”<sup>148</sup> As a result of this focus, the Commission concentrated its deliberations on: 1) “the responsibility of the hospital to assure that mature and skilled supervision of residents is provided by attending physicians for all patients at all times[;]” and 2) “changes in the working conditions of residents which would enhance their capacity to deliver critically important medical service and also increase the value of the educational experience.”<sup>149</sup>

Seventeen specific recommendations were presented to the NYSDOH in the Bell Commission’s report, including modified versions of those presented in the Commission’s letter to Dr. Axelrod.<sup>150</sup> With regard to resident work hours, these modifications included: 1) exclusion of the eight hour duty-free intershift period from the recommended restrictions on emergency room resident work hours; and 2) changing the restrictions on non-emergency room resident work hours so that the consecutive hour limit was increased from sixteen to twenty-four consecutive hours for a total of eighty hours a week averaged over a four-week period, while leaving out any mention of duty-free intershift periods.<sup>151</sup> The Commission adopted its previously proposed restrictions on moonlighting in its final report.<sup>152</sup>

## 2. Reaction to the Bell Commission Reforms

### a. Promulgation of the Bell Regulations in New York

After their issuance, the Bell Commission recommendations received extensive political support throughout New York State. As a result of political and public pressure, in addition to its own public hearings and consultations with

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146. *Id.* at 773.

147. NEW YORK STATE DEP’T OF HEALTH AD HOC COMM. ON EMERGENCY SERVS., REPORT OF THE NEW YORK STATE AD HOC ADVISORY COMMITTEE ON EMERGENCY SERVICES: SUPERVISION AND RESIDENTS’ WORKING CONDITIONS (1987) (on file with NYSDOH and author) [hereinafter NYSDOH REPORT].

148. *Id.* at 1.

149. *Id.* at 1-2.

150. *Id.* at 2-8; *cf.* NYSDOH Letter, *supra* note 138.

151. NYSDOH REPORT, *supra* note 147, at 6; *cf.* NYSDOH Letter, *supra* note 138, at 4.

152. NYSDOH REPORT, *supra* note 147, at 6.

national and state leaders in medical education,<sup>153</sup> the NYSDOH promulgated regulations adopting the Commission's recommended reforms.<sup>154</sup> These regulations, which went into effect on July 1, 1989, and are codified as section 405.4 of Title 10 of the New York Codes, Rules and Regulations (NYCRR),<sup>155</sup> include modifications of the Bell Commission recommendations such as: 1) a blanket restriction of twenty-four consecutive work hours for all residents in New York State;<sup>156</sup> 2) re-introducing the eight-hour buffer between working shifts;<sup>157</sup> and 3) conditional flexibility in the work hour restrictions to accommodate the realities of hospital health care service, provided that the resident does not become overworked and overly fatigued as a result of the extended hour limits.<sup>158</sup> Moreover, the regulations require residency programs to "tak[e] disciplinary action or other corrective measures against any individual providing service in violation of the physicians' work hour limits set forth in [the regulation]."<sup>159</sup> If a program fails to take such corrective measures for violations of the work hour limits, the regulations imply that residents in the program may not provide patient care services.<sup>160</sup> Officially, enforcement of these regulations has been through NYSDOH citations and fines where violations have been uncovered by the state agency.<sup>161</sup>

*b. Reactions within the Medical and Graduate Medical Education Communities*

There have been mixed reactions to the New York State regulations from within the medical and graduate medical education communities. Steven C. Reiner's comments summarized the central points of the debate that arose in the wake of the Bell Commission Reforms:

Were one to draw a curve plotting resident hours against resident fund of knowledge (or performance on board scores, or any other quality judgment), it would surely result in a normal distribution. Residents forced to work long and laborious hours would be victims of a

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153. Peter Slocum, Letter, *The New Health Code Regulations Concerning Postgraduate Medical Education in New York State*, 90 N.Y. ST. J. MED. 39, 40 (1990); Asch & Parker, *supra* note 10, at 773.

154. See N.Y. COMP. CODES R. & REGS. tit. 10, § 405.4 (2004).

155. *Id.*

156. *Id.* § 405.4(b)(6)(ii)(b).

157. *Id.* § 405.4(b)(6)(iv).

158. *Id.* §§ 405.4(b)(6)(i) & (b)(6)(ii)(c)-(d).

159. *Id.* § 405.4(f)(3)(vi).

160. *Id.* § 405.4(f) ("Patient care services may be provided by physicians in post graduate training programs accredited by [ACGME] . . . or an equivalent accrediting agency approved by the New York State Education Department, only if the following conditions are met," where one of the conditions is taking corrective measures for violations of the resident work hour limits).

161. Jennifer F. Whetsell, *Changing the Law, Changing the Culture: Rethinking the "Sleepy Resident" Problem*, 12 ANNALS HEALTH L. 23, 54 (2003).

deteriorating educational process. Falling short of a minimum number of clinical conferences and didactic experiences would probably result in a poorer educational process. By a similar line of reasoning, the American College of Physicians concludes that responsibility of residents for an excessively large number of patients obviously carries certain risks, including inattention to important medical detail and difficulty in devoting the requisite time to the various elements of humane care. Responsibility for too few patients provides inadequate learning opportunities and is poor for morale. Its recommendation would include training programs that provide appropriate relief for resident teams during and after excessively demanding nights on call, and specific guidelines for acceptable numbers of patients admitted per resident during continuous duty hours.<sup>162</sup>

Reiner also reported on the results of a telephone survey he conducted of ten directors of residency programs in family medicine, internal medicine, and general surgery in New York State.<sup>163</sup> These results indicated that although most of the directors agreed that the changes mandated by 10 NYCRR §405.4 would have a neutral or “somewhat positive” effect on the “usual and customary cognitive skills” of residents as a result of increased time for rest, the majority of directors believed that the new regulations would have a significant negative effect on the development of resident psychomotor skills, the availability of residents to perform outpatient services, and continuity of care.<sup>164</sup> Directors in family medicine believed that the new regulations would conflict with the continuity of care requirements that the American Board of Family Practice mandated for residents.<sup>165</sup>

The ACP, reflecting the opinions of many senior physicians and medical educators, challenged the validity of several assumptions underlying 10 NYCRR §405.4 and proposed seven recommendations that effectively established guidelines for regulations on resident working conditions and supervision in internal medicine programs.<sup>166</sup> One of these recommendations specifically addressed work hours:

Resident duty hours must be kept within reasonable specific bounds. However, consecutive hours residents spend with their sick patients must not be rigidly limited to an extent that produces undesirable consequences for patient care and resident education.

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162. Steven C. Reiner, *The Impact of the New Code Regulations on Postgraduate Medical Education in New York State*, 89 N.Y. ST. J. MED. 457, 460-61 (1989).

163. *Id.* at 460.

164. *Id.*

165. *Id.*

166. ACP Recommendations, *supra* note 8, at 657-63.

Residents must not disengage themselves from care of their patients until proper management and continuity of care are assured.<sup>167</sup>

Physicians from teaching hospitals in New York<sup>168</sup> and Massachusetts<sup>169</sup> expressed concerns that the twenty-four-consecutive-hour regulations in 10 NYCRR §405.4 would result in an increase in transfers of patients as resident physicians came and went with the clock, resulting in a greater risk of miscommunication that could result in fatal errors.<sup>170</sup>

In February 1989, five months before the date of implementation of the regulations in 10 NYCRR §405.4, Douglas et al. analyzed an experimental sixteen-hour schedule that the Department of Medicine at the New York Hospital-Cornell Medical Center imposed on about half of the residents in its general medical service.<sup>171</sup> The schedule was designed to meet the requirements of 10 NYCRR §405.4. It was found that interns working the sixteen-hour schedule were “uncomfortable with their inability, due to time constraints, to finish their notes and follow through on patient work-ups during their shifts” and felt that the “multiple turnovers allowed more room for error and affected the continuity, and possibly the quality, of patient care.”<sup>172</sup>

One psychiatry intern publicized her complaints about this sixteen-hour schedule in a letter to the *Journal of the American Medical Association*:

The joy of climbing into my own bed on a call night has been immense. The feeling that I am losing out on an essential part of my training is disturbing.

I am suffering under this new system, as are the patients. When, at 11 PM, I sign off of a case that is just beginning to reveal itself and then do not show up until 7 o'clock the next morning, something essential is lost forever. In those 8 hours, the treatments have often had their most important effects and the patient has either “turned the corner” or “started to crump.” Lost to the process is the input from those physicians who have done the most thinking about the patient’s illness, as well as the learning that comes from being there, hands on, as events take their course.

These scheduling changes, intended to enhance the quality of patient care, in fact distance the intern from the patient. Shortly after a patient

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167. *Id.* at 660.

168. R. Gordon Douglas, Jr. et al., *Bell Commission Requirements: Doctors or Factory Workers?*, 101 TRANSACTIONS AM. CLINICAL & CLIMATOLOGICAL ASS'N 91 (1989); Fins, *supra* note 7, at 360; Glickman, *supra* note 9, at 781.

169. Edwin P. Maynard, *State Residency Regulation: A View from Out of State*, 67 BULL. N.Y. ACAD. MED. 355, 357 (1991).

170. *See e.g.*, Douglas et al., *supra* note 168, at 92-97.

171. *Id.* at 94.

172. *Id.*

has disclosed his or her problems to the primary physician, that physician leaves the hospital. Moreover, the changing of shifts at 11 PM multiplies the number of times a physician signs over a case and increases the opportunities for miscommunication. Clichés like “continuity of care” gain real meaning here.

Under the trial schedule, there is no effective way to pass the baton. The one intern aware of the nighttime developments completes a 24-hour shift as the rest of the team arrives for 7 AM rounds. Traditionally, the intern has joined the team for morning rounds and worked through the next 12 hours. Under the Bell Commission’s rules, the intern cannot join in rounds without violating the “24-hour rule.” The new team is deprived of the intern’s knowledge of the patients, and the intern is deprived of the learning experience gained in rounds.<sup>173</sup>

Especially vocal in their opposition to residency reform were the old guards in surgical training. In his written opinion on sleep deprivation and resident call schedules, Dr. Robert E. Condon of the Department of Surgery at the Medical College of Wisconsin in Milwaukee claimed that:

A new resident must learn that one can work all night; he or she may hate it but can function and function effectively. Whether the resident physician hates it or not does not really matter. Physicians’ view of this issue is much less important than patients’ right to receive care.<sup>174</sup>

With regard to the regulations on resident work hours implemented in New York State in the wake of the Libby Zion case and the Bell Commission recommendations, Condon reflected the opinions of many old-guard surgeons when he referred to the restrictions as “arbitrary” and expressed his concern that “[t]he 80-hour limitation interferes with important principles of patient care, both the primacy of a patient’s call on a physician and a patient’s right to expect continuity in care.”<sup>175</sup>

To support their argument that such restrictions were in fact arbitrary, the old-guard surgeons cited various studies that provided evidence in support of the contention that sleep deprivation arising from extended work hours among surgical<sup>176</sup> and medical residents<sup>177</sup> had no effect on the neurobehavior and medical performance of these residents. Once the arbitrariness of the restrictions was established, the surgeons then warned that reduced resident work hours would be detrimental to both the quality of care that the surgical residents offered to

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173. Bloch, *supra* note 10, at 3243-44.

174. Robert E. Condon, *Sleep Deprivation and Resident Call Schedules*, 46 CURRENT SURGERY 361, 364 (1989).

175. *Id.*

176. *E.g.*, Deaconson et al., *supra* note 63, at 1721.

177. *E.g.*, Engel et al., *supra* note 57 at 761.



patients<sup>178</sup> and the quality of postgraduate medical training offered to the surgical residents.<sup>179</sup> Reiner also provided evidence that some residents believed the same way as the old-guard surgeons, citing “informal discussions” with residents who “voiced the opinion that ‘shift work’ and mandatory time off leaves them uneasy about maintaining continuity of patient care and uninterrupted clinical experience at important moments.”<sup>180</sup>

Responding to these concerns, Commissioner Axelrod agreed to allow the addition of three hours to the on-call period for the purpose of transferring information between residents under the conditions that these additional hours be used only twice a week and that they be included in the eighty-hour per work week limit.<sup>181</sup> Moreover, the final regulations allowed the Commissioner of Health to approve “alternative schedule limits of up to fifteen hours for attending physicians in a hospital emergency service” that receives more than 15,000 unscheduled visits per year, provided that the alternative schedule “contributes to the hospital’s ability to meet its community’s need for quality emergency services,” that patient volume during the extended period is “substantially less than for other hours of the day,” and that “adequate rest time is provided between assignments and during each week to prevent fatigue.”<sup>182</sup> Moreover, the final regulations carve out an exception for on-call surgical residents working at night,<sup>183</sup> excluding such on-call night duty from the twenty-four-hour consecutive limit and the eighty-hour weekly limit provided that: 1) the “hospital can document that during such night shifts [surgical residents] are generally resting and that interruptions for patient care are infrequent and limited to patients for whom the [surgical resident] has continuing responsibility”; 2) such on-call night duty is scheduled no more than every third night; 3) continuous assignments including on-call night duty is followed by a non-working period of at least sixteen hours; and 4) policies and procedures are developed and implemented to “immediately relieve a postgraduate trainee from a continuing assignment when fatigue due to an unusually active ‘on call’ period is observed.”<sup>184</sup> The regulations also allow departments that do not have a high volume of acutely ill patients and that have infrequent nocturnal on-call shifts to

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178. See Timothy F. Deaconson et al., Letter in Reply, *Sleep Deprivation and Performance of Residents*, 261 JAMA 863, 863 (1989) (responding to comments on the study reported in Deaconson et al., *supra* note 63) (“Patients expect their physician to respond whenever they are in need and, further, to continue to provide care throughout their illness. Patients also expect physicians to deliver care that meets accepted standards. Does loss of sleep in fulfillment of the first expectation impair fulfillment of the second?”).

179. Richard L. Cohen, Letter, *Sleep Deprivation and Performance of Residents*, 261 JAMA 862, 863 (1989).

180. Reiner, *supra* note 162, at 459.

181. Douglas et al., *supra* note 168, at 96.

182. N.Y. COMP. CODES R. & REGS. tit. 10, §§ 405.4(b)(6)(i)(a)-(c) (2004).

183. *Id.* § (b)(6)(ii)(d).

184. *Id.* § (b)(6)(ii)(d)(1)-(4).

“develop and document scheduling arrangements other than those set forth” in the regulations.<sup>185</sup>

Shortly after the promulgation of 10 NYCRR §405.4, the Hospital Association of New York State filed a lawsuit against NYSDOH challenging the new regulations.<sup>186</sup> However, the Supreme Court of New York for Albany County upheld the regulations.<sup>187</sup> Rejecting plaintiff’s claims that the work-hour limitations were “arbitrary” and tantamount to an “abuse of discretion,” the court held that NYSDOH had the authority to promulgate regulations restricting resident work hours in order to promote quality medical care in New York State.<sup>188</sup>

Despite such intense resistance to the regulations from some segments of the medical and graduate medical education communities, many other members of the medical and graduate medical education communities reacted positively to the Bell Commission Reforms. In fact, most physicians and groups within these communities agreed that a re-evaluation of current practices in graduate medical education regarding resident work conditions and supervision would be beneficial to the future of the profession.<sup>189</sup>

In critiquing Reiner’s 1989 article in the *New York State Journal of Medicine*,<sup>190</sup> NYSDOH Director of Public Affairs Peter Slocum attacked many of the positions of the medical and graduate medical education communities regarding the detrimental effects of 10 NYCRR §405.4 on the quality of medical care that residents offered and the quality of medical education offered to residents.<sup>191</sup> Slocum argued that Reiner and other old-guard physicians used “outdated” evidence to support the contention that the new regulations would negatively affect the quality of resident education and cited the ACGME, the Residency Review Committee for Internal Medicine, and the Pediatric Residency Review Committee as parties within the graduate medical education community that supported the implementation of a shorter work week for residents.<sup>192</sup> With regard to the negative effects of the regulations on continuity of care, Slocum called the issue “a red herring”:

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185. *Id.* § (b)(6)(ii)(c). In particular, the regulations specifically identify departments in anesthesiology, family practice, and medical, surgical, obstetrical, and pediatric services as examples of services with “a high volume of acutely ill patients” that may not develop scheduling arrangements other than those set forth in the regulations. *Id.*

186. *Hosp. Ass’n of N.Y. St. v. Axelrod*, 546 N.Y.S.2d 531 (N.Y. Sup. Ct. 1989), *aff’d* 565 N.Y.S.2d 243 (N.Y. App. Div. 1990).

187. *Id.* at 533.

188. *Id.*

189. See ACP Recommendations, *supra* note 8, at 657; ASS’N OF AMER. MED. COLLEGES, *Resident Supervision and Hours*, 63 J. MED. EDUC. 421 (1988).

190. See Reiner, *supra* note 162.

191. Slocum, *supra* note 153, at 39-40.

192. *Id.*

Unless a resident is to be on call 24 hours every day, continuity of patient care will necessarily be interrupted at some point. Nevertheless . . . the commissioner of health has introduced flexibility into the regulations which allows time for the orderly transfer of information from those residents going off duty to those coming on. Also, it was always recognized that a resident in the midst of caring for a critically ill patient, such as one experiencing diabetic ketoacidosis, or in the middle of an operation, would be expected to continue the care of the patient as indicated.<sup>193</sup>

Many residents also responded positively to the reforms.<sup>194</sup> In an editorial published in the February 10, 1989 issue of the *Journal of the American Medical Association*, Dr. Timothy B. McCall wrote:

The single most important stress reduction measure is a reduction in working hours. It is long shifts and long workweeks that lead to sleep deprivation. It is the lack of free time, caused by long hours, that devastates residents' personal lives. The New York guidelines offer a reasonable starting point. Eighty hours per week—the equivalent of two full-time jobs—is enough! The mandated day off per week should also help. After implementation, the regulations can be fine-tuned. . . .

Marathon shifts and constantly changing day/night schedules disrupt diurnal rhythms and exacerbate chronic sleep loss. New York's proposed shift-length requirements seem reasonable.<sup>195</sup>

McCall also noted that it was "ironic" that the old guards in surgical and obstetrics and gynecology (Ob/Gyn) education would oppose residency reform as strongly as they did since "surgical and obstetric trainees probably endure more prolonged sleep loss than any other residents, and the malpractice risk in these specialties is already astronomical."<sup>196</sup>

It was during this time (i.e., the late 1980s) that the ACGME began to regulate resident work hours.<sup>197</sup> In particular, the ACGME required all residency

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193. *Id.* at 40.

194. See e.g., Joseph Conigliaro et al., *Internal Medicine Housestaff and Attending Physician Perceptions of the Impact of the New York State Section 405 Regulations on Working Conditions and Supervision of Residents in Two Training Programs*, 8 J. GEN. INTERNAL MED. 502, 505 (1993).

195. McCall, *supra* note 1, at 909 (footnotes omitted).

196. *Id.*; see also Timothy B. McCall, *The Impact of Long Working Hours on Resident Physicians*, 318 NEW ENG. J. MED. 775, 778 (1988) ("Considering the legal climate, however, it may be even more expensive to maintain long working hours. In light of the New York experience, malpractice lawyers will now scrutinize any mishap in patient care involving residents. If it is argued successfully that regulations similar to those proposed in New York might have prevented the mishap, teaching hospitals could be held liable. Many additional salaries could be paid with the settlement of one large malpractice claim.").

197. ACGME, STATEMENT OF JUSTIFICATION/IMPACT FOR THE FINAL APPROVAL OF COMMON STANDARDS RELATED TO RESIDENT DUTY HOURS (Sept. 2002), available at <http://www.acgme.org/DutyHours/impactStatement.pdf> [hereinafter ACGME JUSTIFICATION]; see also

programs in all specialties in the United States to adopt specific work hour requirements, including limits on on-call shifts to every third night and allowances for each resident to have at least one day off from work each week.<sup>198</sup>

### III. GROWING PUBLIC CONCERNS: THE LEGACY OF THE LIBBY ZION CASE

In the aftermath of the Libby Zion case, it had been widely believed that the Bell Commission Reforms would have significant ramifications for the residency systems in hospitals across the United States.<sup>199</sup> Legislatures in several states considered legislation aimed at regulating resident duty hours.<sup>200</sup> However, none of these states adopted such regulations; as of October 2005, New York was the only state to have codified restrictions on resident work hours into law.<sup>201</sup> This has largely been the result of resistance from the medical and graduate medical education communities.<sup>202</sup> Reiner, in response to Slocum's critique of his earlier article,<sup>203</sup> illustrates the type of powerful rhetoric that has been used to derail legislation at the state level:

Although this debate continues, the fact is it has proven impossible to demonstrate that an otherwise healthy, energetic, and vigorous house staff member, motivated to learn and perform, will deteriorate as a result of 24 or 36 hours of continuous duty. Since I assume that a major motivation on the part of the New York State Department of Health in implementing these regulations was to improve quality of care, it would behoove it to prove that quality of care does indeed deteriorate after 24 hours prior to implementing its rigid regulations. . . .

The thrust of my article was to emphasize that those who should be deciding residents' work hours, residents' work rules, the presence or absence of resident impairment, and the residents' stress load should indeed be the medical educators. Most of the rest of the nation seems to be headed in this direction, and only New York State (and perhaps Massachusetts) has decided to imprison the medical education process in rigid rules . . . .

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Diane Scarponi, *Group threatens to revoke Yale surgical accreditation*, ASSOCIATED PRESS (May 6, 2002), and Liz Kowalczyk, *Heart Surgeons Suffer Long Hours, Less Pay*, BOSTON GLOBE (June 30, 2002), at A1.

198. See ACGME JUSTIFICATION, *supra* note 197.

199. Maynard, *supra* note 169, at 355.

200. See e.g., Whetsell, *supra* note 161, at 55 n.173; Jacques et al., *supra* note 21, at 223; Reiner, *supra* note 162, at 458 & n.12; see also Amer. Med. Stud. Assoc., *The Resident Work Hour Issue: State Efforts*, <http://www.amsa.org/rwh/efforts.cfm> (last visited Mar. 1, 2006).

201. Whetsell, *supra* note 161, at 55 n.173.

202. See *id.*; Lindsay Evans, *Commentary, Regulatory and Legislative Attempts at Limiting Medical Resident Work Hours*, 23 J. LEGAL MED. 251, 255-56 (2002).

203. See Reiner, *supra* note 162, at 457.

[Assuming that the NYSDOH fails] to demonstrate an improvement in overall quality of house staff care [as a result of the 10 NYCRR §405.4 regulations], this expensive experiment should be terminated. Control of the medical education process should be wrested from the hands of the health bureaucrats and returned to the deans, program directors, and house staff representatives at the local level.<sup>204</sup>

Nevertheless, public and political pressure proved potent enough to overcome some of this rhetoric from the medical and graduate medical education communities. Some medical specialties voluntarily began placing restrictions on the work hours of young physicians in their residency programs, while others continued to have no enforced restrictions whatsoever.<sup>205</sup> Among the latter, residency programs in surgery were notorious for having the longest duty hours. According to some reports, residents in surgical programs routinely worked at least 100 hours a week,<sup>206</sup> with some residents working over 120 hours a week, depending on the particular program.<sup>207</sup> Residency programs in Ob/Gyn and family medicine had similar hours.<sup>208</sup> Work shifts lasting 36 hours and work hours totaling over 100 hours per week were common for residents in many other specialties as well.<sup>209</sup>

#### A. Compliance with 10 NYCRR § 405.4

Nine years after the enactment of 10 NYCRR § 405.4, the NYSDOH conducted a survey of 391 residents in twelve teaching hospitals in New York State to assess hospital compliance with the state regulations.<sup>210</sup> The survey results, which were released to the press on May 18, 1998, were drawn from the

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204. Stephen C. Reiner, Response Letter, *The new health code regulations concerning postgraduate medical education in New York State*, 90 N.Y. ST. J. MED. 40, 40-41 (1990).

205. Anne Barnard & Liz Kowalczyk, *Medical Resident Workload Curbed*, BOSTON GLOBE, June 13, 2002, at A1.

206. See Anne Barnard, *Surgery Residents' Long Hours Draw Warning for Yale*, BOSTON GLOBE, (May 20, 2002), at A1 [hereinafter *Surgery Residents' Long Hours*] and Anne Barnard, *Hospitals Mull Impact of 80-Hour Limit for Residents*, BOSTON GLOBE, June 15, 2002, at B1 [hereinafter *Hospitals Mull Impact*].

207. *Surgery Residents' Long Hours*, supra note 206; Lawrence K. Altman & Denise Grady, *Hospital Accrator will Strictly Limit Hours of Residents*, N.Y. TIMES, June 13, 2002, at A1.

208. Altman & Grady, supra note 207; *Hospitals Mull Impact*, supra note 206; Vicki Seltzer et al., *Resident Scheduling: Night Float Programs*, 77 OBSTET. & GYN. 940, 942 (1991).

209. See Ceci Connolly, *Shorter Hours Mandated for Young Doctors: Grueling Schedules' Effects on Residents, Patients Cited*, WASH. POST, June 13, 2002, at A1.

210. Bertrand M. Bell, *How the New York State Regulatory Environment has Failed to Reduce Errors in Health Care*, in NAT'L PATIENT SAFETY FOUND., ENHANCING PATIENT SAFETY AND REDUCING ERRORS IN HEALTH CARE 298-301 (1998); see also Press Release, N.Y. State Dep't of Health, NYS Hospital Fined for Violating Resident Work Hours (June 18, 1998), available at <http://www.health.state.ny.us/press/releases/1998/workhrs.htm>.

findings of unannounced inspections of the hospitals in March 1998.<sup>211</sup> All twelve of the hospitals surveyed were reported to violate 10 NYCRR §405.4: 37% of the residents surveyed worked more than eighty-five hours per week, and 20% of the residents surveyed worked more than ninety-five hours per week, while 28% of the residents surveyed worked fewer than seventy-five hours per week.<sup>212</sup> Ninety-four percent of residents in New York City hospitals were reported to work more than eighty-five hours per week.<sup>213</sup> Among the surgical residents surveyed in New York City teaching hospitals, seventy-seven worked more than ninety-five hours per week; among the surgical residents surveyed in upstate New York hospitals, 32% in upstate New York worked more than ninety-five hours per week.<sup>214</sup> Thirty-eight percent of non-surgical residents were reported to work shifts longer than twenty-four hours.<sup>215</sup> Some residents at one New York City hospital reportedly worked 126 hours in one week.<sup>216</sup> Although none of the residents surveyed made mistakes that jeopardized patients during the inspections and improvements in resident supervision were noted,<sup>217</sup> the survey revealed that New York State regulations were inadequate since hospitals, according to then-NYSDOH Commissioner Barbara A. DeBuono, M.D., MPH, made hardly any attempts to reduce residents' hours.<sup>218</sup> The NYSDOH was "very, very disturbed" by these results.<sup>219</sup>

The non-compliance of the New York hospitals became a topic of discussion in one of the sessions of a conference held at the Annenberg Center for Health Sciences at Eisenhower in Rancho Mirage, California in November 1998. The conference examined ways to enhance patient safety and to reduce errors in the American health care system.<sup>220</sup> Various organizations involved in health care and the health sciences participated in the conference, which included a session on "the impact of fatigue and sleep deprivation on [patient] safety."<sup>221</sup> At the session, Bertrand M. Bell attributed the non-compliance of the New York hospitals to "cultural" factors and "educational imperatives too ingrained" within the medical and graduate medical education communities "to be changed by mere force of

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211. Bell, *supra* note 210, at 298.

212. *Id.*

213. *Id.*

214. *Id.*

215. Randy Kennedy, *Residents' Hours Termed Excessive in Hospital Study*, N.Y. TIMES, May 19, 1998, at A1.

216. *Id.*

217. *Id.*

218. *Id.*

219. *Id.*

220. See NAT'L PATIENT SAFETY FOUND., ENHANCING PATIENT SAFETY AND REDUCING ERRORS IN HEALTH CARE: 1998 CONFERENCE PROCEEDINGS (Nov. 8-10, 1998).

221. See Bell, *supra* note 210, at 297-310.

law.”<sup>222</sup> Chief among these factors is an educational philosophy that “is based on the tacit acceptance of errors, even the most egregious errors, as an inevitable part of the training experience” and “does not encourage its students to ask when they are uncertain or don’t know.”<sup>223</sup> To remedy this problem, Bell suggested that medical specialty boards should take the lead in forcing changes within the culture of graduate medical education and promoting residency reform by “setting benchmarks for adverse events in hospitals [and thus] begin[ning] the reform of a most significant, but undiscussed, cause of medical error in hospitalized patients—poorly supervised, sleep deprived, chronically fatigued house staff.”<sup>224</sup> Bell also suggested that the press could play a role in “reminding hospitals” to obey legally mandated restrictions on resident work hours and conditions.<sup>225</sup>

At the same session, anesthesiologist David M. Gaba, M.D., of the Veterans Affairs Palo Alto Health Care System in Palo Alto, California, addressed the issue of the scarcity of stories pertaining to patient deaths resulting from fatigue-induced errors.<sup>226</sup> Although recognizing that “a catastrophic outcome does not occur frequently even when a clinician falls asleep for minutes,” there is still “a strong tendency when errors are made to blame the individual for an ‘isolated’ and individual lapse, rather than to indict the latent errors in the system that might have generated the lapse.”<sup>227</sup> Nevertheless, Gaba asserted that since “every other industry in which continuous operations with high hazard are required has recognized and is dealing with the potential for fatigue-induced errors and injuries in the workplace,” the preponderance of excessive work hours among physicians represents a “profound aberrance.”<sup>228</sup> For this reason, Gaba referred to physician work hours as “the sore thumb of organizational safety in tertiary health care.”<sup>229</sup>

### B. Negative Publicity

In 2000, ABC News aired a documentary series entitled *Hopkins 24/7* which reported on the real-life human dramas that continuously unfold at the Johns Hopkins Hospital in Baltimore, Maryland.<sup>230</sup> Over the course of three months, a team of journalists and cameramen from ABC News were allowed to follow the

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222. *Id.* at 299.

223. *Id.*

224. *Id.* at 301.

225. *Id.*

226. David M. Gaba, *Physician Work Hours: The ‘Sore Thumb’ of Organizational Safety in Tertiary Health Care*, in NAT’L PATIENT SAFETY FOUND., ENHANCING PATIENT SAFETY AND REDUCING ERRORS IN HEALTH CARE: 1998 CONFERENCE PROCEEDINGS 302-05 (Nov. 8-10 1998).

227. *Id.* at 303.

228. *Id.* at 305.

229. *Id.* at 301.

230. *Hopkins 24/7: Throughout Day and Night at Johns Hopkins* (ABC television broadcast Sept. 28, 2000) (available at <http://www.lexisnexis.com> through ABC News Transcripts).

medical staff while they worked, as well as to solicit comments from them.<sup>231</sup> During one episode, third-year surgical resident Rita Moriarity, M.D., stated that:

I think the worst part of training as a surgical resident is, no question, the hours. You routinely work 110 to 130 hours a week, and I probably don't have to tell you that there are 168 hours in a week. So that leaves 38 to 48 hours in a week to commute, to get your entire week's worth of sleep, to see your spouse, eat, clean your house, pay your bills, do everything else, and it's nearly impossible to do that.<sup>232</sup>

The documentary also reported that some surgical residents at the hospital worked on-call shifts as long as sixty consecutive hours. As she approached her sixtieth hour on-call during the filming of the documentary, Moriarity decided to quit her residency:

Yeah, I need to leave . . . . Obviously, part of the reason we all go to medical school is to take care of people, but after being awake for 56 hours or more, all you really care about, I think, or at least all I really cared about was me. And so I—I just decided I wasn't willing to live that way.<sup>233</sup>

Several U.S. newspapers have reported on the stresses and extreme working conditions of residency training. The Health Section of the *Washington Post* printed several articles pertaining to these topics on March 27, 2001. One article reported that some anesthesiologists have admitted to falling asleep while monitoring unconscious patients, and surgeons have stated that "it is not unusual to see residents fall asleep in the operating room, sometime while holding scalpels or other instruments."<sup>234</sup> The same article quoted a resident saying, "You actually start wishing patients would die so you could get some sleep."<sup>235</sup> Another article reported on the "Day (and a Half) in the Life of an Intern."<sup>236</sup> An editorial accompanying these articles commented:

What this brilliant physician-to-be is learning in her residency is how not to live. The personal habits she's acquiring on the job are all bad. She is being trained not to do all the things that physicians are supposed to tell their patients to do: Eat healthfully, exercise regularly, make time for relationships, don't work too hard, don't stress out and make yourself sick. . . .<sup>237</sup>

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231. *Id.*

232. *Id.* at 3.

233. *Id.* at 3, 18.

234. Sandra G. Boodman, *Low Experience, High Expectations*, WASH. POST, Mar. 27, 2001, at H1.

235. *Id.*

236. Sandra G. Boodman, *A Day (and a Half) in the Life of an Intern*, WASH. POST, Mar. 27, 2001, at HE16.

237. Abigail Trafford, *Second Opinion*, WASH. POST, Mar. 27, 2001, at T05.



The *Seattle Times* reported on a survey at the University of Washington that revealed “high levels of burnout” among residents in internal medicine, resulting in what many residents claimed to be “suboptimal” patient care.<sup>238</sup> In a report on cardiac surgeons, the *Boston Globe* reported that many surgical residents were avoiding cardiothoracic surgery because of its “culture of grueling hours and now its declining pay,” resulting in a decreasing quality pool of cardiac surgeons over time.<sup>239</sup>

C. “Big Stick” Challenges to the Residency System before the  
2003 ACGME Guidelines

Several challenges to the hospital residency system in the United States were mounted even before the 2003 ACGME accreditation standards went into effect. In May 2002, the ACGME reportedly threatened to revoke the accreditation of the general surgical residency program at Yale-New Haven Hospital, one of the teaching hospitals of the Yale School of Medicine, if it did not take steps to improve the working conditions of its residents.<sup>240</sup> In its confidential report issued to the hospital in March 2002, the ACGME cited weekly work hours that averaged over 100 hours per week and an on-call shift frequency of every other night among residents in the program.<sup>241</sup> Moreover, the Senior Vice President of Medical Affairs and Chief of Staff of the hospital, Dr. Peter N. Herbert, admitted later on National Public Radio that on several rotations in the hospital’s general surgical program, residents did not have one day off each week as required at the time by the ACGME for all specialties.<sup>242</sup>

Then on May 7, 2002, a group of three hospital residents filed a class-action lawsuit in the United States District Court for the District of Columbia against several national medical organizations and hospitals across the United States for “conspiring [to keep resident] wages low and work hours and shifts unreasonably long” through their use of the National Resident Matching Program (NRMP).<sup>243</sup> According to the plaintiffs’ complaint: “[The] defendants contract, combine, and

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238. Warren King, *Medical Residents Report High Levels of Burnout: UW Survey Reveals Possible Lapses in Care*, SEATTLE TIMES, Mar. 5, 2002, at B1.

239. Liz Kowalczyk, *Heart Surgeons Suffer Long Hours, Less Pay*, BOSTON GLOBE, June 30, 2002, at A1.

240. *Surgery Residents’ Long Hours*, *supra* note 206.

241. *Id.*

242. Interview by John Ydstie with Peter Herbert, Senior Vice President of Medical Affairs and Chief of Staff, Yale-New Haven Hospital, *All Things Considered* (Nat’l Pub. Radio, May 21, 2002) (LexisNexis through National Public Radio); *see also* Barnard & Kowalczyk, *supra* note 205, at A1.

243. Complaint at ¶ 23, *Jung v. Ass’n of Am. Med. Colls.*, No. 1: 02CV00873PLF (D.D.C., May 7, 2002), available at <http://www.aamc.org/newsroom/jungcomplaint/jung-nrmp.pdf>. The NRMP was established in 1952 and was assigning over 80% of the available hospital internship positions in the United States to graduating medical students every March by the year 2000. *Id.* ¶¶ 71, 84.

conspire to restrain competition in the recruitment, hiring, employment and compensation of resident physicians by regularly exchanging among themselves competitively sensitive information on resident compensation and other terms of employment.”<sup>244</sup>

The plaintiffs further alleged that since the NRMP assigns one “single, specific and mandatory” internship position to each graduating medical student,<sup>245</sup> this “unlawful information exchange” constitutes a conspiracy among the defendants for the “purpose and effect of depressing, standardizing and stabilizing compensation and other terms of employment”<sup>246</sup> and thus eliminates the possibility for residents to negotiate terms of employment such as wages and work hours. The plaintiffs argued that market-style “competition for resident services” among the hospital employers is eliminated since the NRMP system allows the employers to “obtain resident physicians without . . . a bidding war [over compensation].”<sup>247</sup> Furthermore, the plaintiffs alleged that as a result of this “lack of competition,” hospital employers are allowed to impose dangerously long work hours on their resident physicians, “exploit[ing them by] routinely requiring 60 to 100 hours of work per week, or more, often including 36-hour and 48-hour shifts.”<sup>248</sup>

#### IV. PROPOSED FEDERAL REGULATION OF RESIDENT WORK HOURS

Stories such as those featured in *Hopkins 24/7* and other media sources provided the impetus for a petition submitted to OSHA on April 30, 2001, by Public Citizen’s Health Research Group (HRG); CIR; the American Medical Student Association; Bertrand M. Bell, M.D., Professor of Medicine at Albert Einstein College of Medicine and former chairman of the Bell Commission; and Klingman P. Strohl, M.D., Professor of Medicine and Director of the Center for Sleep Disorders Research at Case Western Reserve University.<sup>249</sup> The petition requested that OSHA promulgate regulations restricting resident work hours<sup>250</sup> and recommended the adoption of specific resident work hour restrictions similar to those in 10 NYCRR §405.4 and recommended by various groups involved in residency reform.<sup>251</sup> Among the restrictions requested in the petition were: 1) an

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244. *Id.* ¶ 73.

245. *Id.* ¶ 83.

246. *Id.* ¶¶ 73, 83.

247. *Id.* ¶¶ 92, 84.

248. *Id.* ¶ 96. The United States District Court for the District of Columbia ultimately granted judgment on the pleadings in favor of the defendants. *Jung v. Ass’n of Am. Med. Colls.*, 339 F.Supp.2d 26 (D. D.C. 2004), *motion to amend denied by* 226 F.R.D. 7 (D. D.C. 2005).

249. Public Citizen Petition, *supra* note 4.

250. *Id.*

251. *Id.* at pt. 7.

eighty-hour work week; 2) a limit of twenty-four consecutive hours for resident on-call shifts; 3) an on-call frequency of every third night averaged over a period of two weeks; 4) at least one full day off duty every seven days averaged over a period of two weeks; 5) a period of at least ten hours between work shifts; and 6) a limit of twelve consecutive hours on duty for “emergency medicine residents working in hospitals receiving more than 15,000 unscheduled patient visits per year.”<sup>252</sup> In arguing for these restrictions, the petition explicitly contrasted the sixty-hour on-call shifts reported in *Hopkins 24/7* to “the 128 hours *off* from work that most Americans enjoy.”<sup>253</sup>

Several months later, bills aimed at imposing federal statutory restrictions on resident work hours were introduced in both chambers of the United States Congress: in the House of Representatives, Rep. John Conyers Jr. (Democrat, Michigan) introduced the “Patient and Physician Safety and Protection Act of 2001” on November 6, 2001 (PPSPA 2001); in the Senate, Sen. Jon S. Corzine (Democrat, New Jersey) introduced the “Patient and Physician Safety and Protection Act of 2002” on June 12, 2002 (PPSPA 2002).<sup>254</sup> Both bills were intended to “amend title XVIII of the Social Security Act to reduce the work hours and increase the supervision of resident-physicians to ensure the safety of patients and resident-physicians themselves.”<sup>255</sup> The specific regulations and resident work hour restrictions proposed in these bills were essentially identical to those proposed in the Public Citizen petition<sup>256</sup> and the accreditation standards that the ACGME proposed at around the same time,<sup>257</sup> although the Congressional bills also included a limit of twelve consecutive hours on duty in emergency departments<sup>258</sup> and one full weekend off each month.<sup>259</sup> To justify these statutory work hour restrictions, Congress cited neglect on the part of the medical community in “adequately address[ing] the issue of excessive resident-physician work hours[,]”<sup>260</sup> as well as precedents in federal regulation of work hours in other industries “when the safety of employees or the public is at risk.”<sup>261</sup>

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252. *Id.*

253. *Id.* at pt. 1 & n.5.

254. Patient and Physician Safety and Protection Act of 2001, H.R. 3236, 107th Cong. (2001) & Patient and Physician Safety and Protection Act of 2002, S. 2614, 107th Cong. (2002).

255. *Id.* (purpose paragraphs of the bills).

256. Public Citizen Petition, *supra* note 4, at pt. 7.

257. H.R. 3236, and S. 2614; *see also infra* notes 270-72 and accompanying text (discussing local and national concern over the effect of resident sleep-deprivation on quality of patient care).

258. H.R. 3236 § 3(a)(2) & S. 2614 § 3(a)(2) (adding new subparagraph (j)(1)(A)(ii)(III) to Section 1866 of the Social Security Act (42 U.S.C. § 1395cc)).

259. *Id.* § 3(a)(2) (both attempting to add subparagraph (j)(1)(A)(ii)(II) to Section 1866 of the Social Security Act (42 U.S.C. § 1395cc)).

260. H.R. 3236, § 2(6) & S. 2614, § 2(6).

261. H.R. 3236, § 2(6) & S. 2614, § 2(8).

Both PPSPA bills charged the Secretary of the United States Department of Health and Human Services (DHHS) with the responsibility of promulgating regulations “as may be necessary to ensure [that] quality of care is maintained during the transfer of direct patient care from one postgraduate trainee to another at the end of each such 24 hour period”<sup>262</sup> on duty, as well as in consideration of “cases of individual patient emergencies.”<sup>263</sup> However, the bills permitted the suspension of the statutory restrictions during “a state of emergency declared by the Secretary [of Health and Human Services (HHS)] that applies with respect to that hospital.”<sup>264</sup> The bills also included provisions pertaining to: mechanisms for handling complaints from residents regarding violations of these federal work hour restrictions;<sup>265</sup> whistleblower protections for hospital employees who “in good faith” report violations of the restrictions;<sup>266</sup> monitoring hospital compliance of the restrictions;<sup>267</sup> and enforcement of the restrictions through the imposition of civil monetary and administrative penalties, including exclusion from “Federal health care programs” such as Medicare and Medicaid, against violators of the restrictions.<sup>268</sup> Moreover, the bills allowed for the appropriation to the Secretary of HHS of “such amounts as may be required to provide for additional payments to hospitals for their reasonable additional, incremental costs incurred in order to comply with the requirements imposed by this Act (and the amendments made by this Act).”<sup>269</sup>

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262. H.R. 3236, § 3(a)(2) & S. 2614, § 3(a)(2) (both attempting to add subparagraph (j)(1)(B) to Section 1866 of the Social Security Act (42 U.S.C. § 1395cc)).

263. H.R. 3236, § 3(a)(2) & S. 2614, § 3(a)(2) (adding new subparagraph (j)(1)(B) to Section 1866 of the Social Security Act (42 U.S.C. § 1395cc)).

264. H.R. 3236, § 3(a)(2) & S. 2614, § 3(a)(2) (adding new subparagraph (j)(1)(C) to Section 1866 of the Social Security Act (42 U.S.C. § 1395cc)).

265. H.R. 3236, § 3(b)(2) & S. 2614, § 3(b)(2).

266. H.R. 3236, § 3(c) & S. 2614, § 3(c). As defined in the bill, an employee acts “in good faith” if he or she “reasonably believes” that the “information reported or disclosed is true” and that “a violation has or may occur.” *Id.* § 3(c)(2).

267. H.R. 3236, § 3(b)(4) & S. 2614, § 3(b)(4).

268. H.R. 3236, § 3(b)(3) & S. 2614, § 3(b)(3); *see also* Social Security Act (SSA), Pub. L. No. 89-97, § 1128A(a) (codified as amended at 42 U.S.C. § 1320a-7a(a) (West 2003 & Supp. 2005)) & § 1128B(f)(1) (codified as amended at 42 U.S.C. § 1320a-7b (West 2003 & Supp. 2005)), 79 Stat. 286 (1965) (defining “Federal health care program” as “any plan or program that provides health benefits, whether directly, through insurance, or otherwise, which is funded directly, in whole or in part, by the United States Government” or “any State health care program, as defined in [the Social Security Act]”).

269. H.R. 3236, § 4 & S. 2614, § 4.

## V. SELF-REGULATION BY THE GRADUATE MEDICAL EDUCATION COMMUNITY

A. *The 2003 ACGME Guidelines*

Negative coverage in the press and national media of sleepy doctors since the Libby Zion case in 1984 aroused concerns in the American public and the U.S. Government that sleep-deprived residents genuinely threatened patient and resident safety. The New York State regulations promulgated in 1989 were a manifestation of such concern at the state level, while the Public Citizen petition in 2001<sup>270</sup> and the Patient and Physician Safety and Protection Acts of 2001 and 2002<sup>271</sup> were manifestations of these concerns at the national level. As a result of these growing concerns and demands for state and federal regulation of resident work hours, the ACGME was compelled to appoint the Work Group on Resident Duty Hours and the Learning Environment in September 2001. Charged with the task of establishing guidelines to “emphasize the responsibilities of programs, sponsoring institutions, and the accrediting body relating to safe patient care and an appropriate learning environment for residents,” the ACGME Work Group deliberated for several months before issuing its recommendations in a report published on June 11, 2002.<sup>272</sup>

Among the ACGME Work Group’s recommendations were a proposed set of accreditation standards for residency programs nationwide that included specific restrictions on resident work hours, such as: 1) an average maximum limit of eighty work hours per week for residents over a four-week period; 2) a maximum limit of twenty-four consecutive hours for on-call duty; 3) an average maximum for on-call frequency of every third night over a four-week period; 4) an average of one day off from work each week over a four-week period; and 5) a minimum period of ten hours free from work in between duty periods.<sup>273</sup> Recognizing the educational and health care functions of residency programs, as well as the variations between individual programs, the ACGME Work Group also offered several recommendations permitting limited deviations from the hour restrictions. For example, individual programs would be permitted to request a maximum increase in the work hour limits to eighty-eight hours per week averaged over a four-week period if a “sound educational rationale” could be provided for the limit increase.<sup>274</sup> The twenty-four-hour limit on on-call duty could be extended by a maximum of six hours to allow for “inpatient and outpatient continuity, transfer of

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270. Public Citizen Petition, *supra* note 4.

271. Patient and Physician Safety and Protection Act of 2001, H.R. 3236, 107th Cong. (2001); Patient and Physician Safety and Protection Act of 2002, S. 2614, 107th Cong. (2002).

272. ACGME REPORT, *supra* note 2, at 1.

273. *Id.* at 3.

274. *Id.*

care, educational debriefing and formal didactic activities[.]”<sup>275</sup> although residents would not be allowed to assume responsibility for new patients after working for twenty-four consecutive hours.<sup>276</sup> Failure to comply with these standards could potentially result in loss of accreditation for a residency program.<sup>277</sup>

The ACGME guidelines also provided recommendations for enforcing and promoting compliance with its new accreditation standards on resident work hours.<sup>278</sup> These recommendations included: 1) intensifying information collection related to work hours; 2) dramatically shortening the review cycles for programs and institutions that violate the new accreditation standards on work hours; 3) invoking the ACGME procedure for Rapid Response to Alleged Egregious Accreditation Violations or Catastrophic Institutional Events where there is evidence of a serious violation of the new accreditation standards; 4) generally enhancing programs’ and institutions’ accountability for compliance; and 5) monitoring the ACGME’s compliance systems to foster consistent enforcement of the new accreditation standards through increased training of site visitors, concurrent review of information on duty hours by a dedicated ACGME Subcommittee on Resident Duty Hours, to be established in the coming months, and retrospective review of [a Residency Review Committee’s] practices by the Monitoring Committee.<sup>279</sup> The intent of these enforcement provisions was to make programs, institutions, and resident partners comply with the ACGME accreditation standards.<sup>280</sup>

In February 2003, the ACGME Board of Directors formally approved the accreditation standards proposed in the June 2002 report.<sup>281</sup> The guidelines went into effect on July 1, 2003.<sup>282</sup> As a result of this action by the ACGME, neither of the bills federalizing the regulation of resident work hours was ultimately passed.<sup>283</sup> Similarly, OSHA formally rejected the Public Citizen petition to have

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275. *Id.*

276. *Id.*

277. *Id.* at 6.

278. ACGME REPORT, *supra* note 2, at 6-8.

279. *Id.* at 6.

280. *Id.*

281. ACGME, INFORMATION RELATED TO THE ACGME’S EFFORT TO ADDRESS RESIDENT DUTY HOURS AND OTHER RELEVANT RESOURCE MATERIALS (June 2003), *available at* [http://www.acgme.org/acWebsite/dutyHours/dh\\_index.asp](http://www.acgme.org/acWebsite/dutyHours/dh_index.asp).

282. ACGME, ADVISING THE ACGME ON THE IMPLEMENTATION AND MONITORING OF THE DUTY HOUR STANDARDS: THE FIRST REPORT OF THE ACGME DUTY HOUR SUBCOMMITTEE (June 2003), *available at* [http://www.acgme.org/acWebsite/dutyHours/dh\\_subcomreport0603.pdf](http://www.acgme.org/acWebsite/dutyHours/dh_subcomreport0603.pdf).

283. *See* 147 CONG. REC. H7852 (daily ed. Nov. 6, 2001) (referring H.R. 3236 (PPSPA 2001) to the “[House] Committee on Energy and Commerce, and in addition to the [House] Committee on Ways and Means for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned.”); 148 CONG. REC. S5454 (daily ed. June 12, 2002) (referring S. 2614 (PPSPA 2002) to the Senate Committee on Finance). No

OSHA regulate resident work hours in October 2002.<sup>284</sup> In rejecting Public Citizen's request for such federal regulation, the Assistant Secretary for Occupational Safety and Health cited the then-pending ACGME action:

OSHA believes that the ACGME and other entities are well-suited to address work-duty restrictions of medical residents and fellows. These entities have extensive experience in patient health, employee health, and medical education and training. They are in a good position to address the issue in a manner that comports with the complexity of the various interests. Moreover, the ACGME has an effective and precisely-focused enforcement tool: it can revoke a residency program's accreditation. The ACGME also conducts regular site visits and follow-up monitoring of accredited residency programs, which provide the group with an effective vehicle for ensuring compliance with work-duty restrictions. . . .

Because the issues involved with medical resident hours go well beyond job safety and affect hospital patient safety, because other knowledgeable groups are taking action to work on this problem, and because OSHA's rulemaking resources are fully committed to working on a range of critical workplace health and safety issues, the Agency has decided to deny your petition. However, we are looking into various non-regulatory alternatives to inform the public about the potential safety and health effects of worker fatigue.<sup>285</sup>

*B. Reaction within the Medical and Graduate Medical Education Communities*

All of these events in 2002 evoked many differences of opinion among residents and members of the medical and graduate medical education communities. Those opposed to the new ACGME accreditation standards once again raised concerns about the possible detrimental effects of the hour restrictions on continuity and quality of patient care and medical education. Responding to the proposed ACGME accreditation standards, one professor of pediatrics reminisced about his own residency experience and remarked:

So do doctors in training today still have to work all night to learn how to heal? I wish I could say no in a reassuring way. But I can't. The middle of the night is still prime time for those who want to learn how to be a doctor. . . .

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substantive action of significance appears to have been taken on these bills since these committee referrals were reported in the *Congressional Record*.

284. Letter from John L. Henshaw, Assistant Secretary for Occupational Safety and Health, U.S. Dep't of Labor, to Sidney M. Wolfe, M.D., Director, Health Research Group, Public Citizen (Oct. 4, 2002), available at <http://www.citizen.org/documents/ACFC2B.pdf>.

285. *Id.* at 2-3.

As we re-evaluate how we train doctors, we need to remember that there are few better times for physicians to learn than at 3 o'clock in the morning. It is when most of us older docs are at slumber that physicians-in-training get to frame their own decisions and make an indelible difference in the lives of others. This is the only reliable way I know to transform a student into a doctor.<sup>286</sup>

Not surprisingly, chiefs of surgical residency programs and other established surgeons were once again especially vocal in their opposition to the ACGME's work hour restrictions. As had been the case in their opposition to the Bell Commission Reforms, these surgeons continued to cite old studies in the literature to support their arguments that the ACGME restrictions were arbitrary and that such restrictions would be detrimental to quality of surgical care and quality of surgical education.<sup>287</sup>

These protests, however, have not prevented well-established physician groups from endorsing the ACGME recommendations. At its 2002 meeting, the AMA House of Delegates (HOD) adopted a set of amended recommendations that the AMA Council on Medical Education (CME) proposed in a report it issued on resident working conditions.<sup>288</sup> These recommendations largely agreed with the proposed accreditation standards of the ACGME and the proposed restrictions in the Public Citizen petition.<sup>289</sup> In fact, the recommendation of the HOD with respect to the total length of the work week was even more liberal than those of the ACGME, providing that residents should not work more than 80 hours per week averaged over a two-week period rather than the four-week period that the ACGME had advocated.<sup>290</sup> Both the CME and the HOD also adopted the principle that "limits on total duty hours must not adversely impact resident physician participation in the organized educational activities of the residency program."<sup>291</sup> The HOD eventually adopted a modified set of recommendations from the CME, which included modified versions of all the demands of the Public Citizen petition, except for the addition of a recommendation that a twelve-hour limit be placed on work in "high intensity settings" such as the emergency department.<sup>292</sup> The HOD recommendations included: 1) a limit of twenty-four consecutive hours for resident

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286. Howard Markel, *Doctors Learn in the Long Night Hours*, N.Y. TIMES, June 19, 2002, at A23.

287. See *supra* notes 167-70 and accompanying text; see also Deaconson et al., *supra* note 63, at 1726-27; Haynes et al., *supra* note 68, at 287-88.

288. AM. MED. ASS'N COUNCIL ON MED. EDUC. (CME), REPORTS OF THE COUNCIL ON MEDICAL EDUCATION, RESIDENT PHYSICIAN WORKING CONDITIONS (CME REPORT 9-A-02) 351-56 (June 15-20, 2002), available at [http://www.ama-assn.org/ama/pub/category/print/7094.html#cme\\_9](http://www.ama-assn.org/ama/pub/category/print/7094.html#cme_9) [hereinafter CME REPORT].

289. See Public Citizen Petition, *supra* note 4, and accompanying text.

290. CME REPORT, *supra* note 289, at 355.

291. *Id.*

292. See *id.* at 352-53. But see Public Citizen Petition, *supra* note 4, at pt. 7 (not recommending the twelve-hour shift limit for Emergency Room physicians).



on-call shifts plus an extension of up to six hours for the purpose of “complet[ing] the transfer of care, patient follow-up, and education[,]” provided that the resident was not assigned any new patients during those six hours; 2) an on-call frequency of every third night averaged over a period of two weeks; 3) at least one full day off duty every seven days averaged over a period of two weeks; and 4) a period of at least ten hours between duty shifts.<sup>293</sup> In addition, the CME and HOD formally endorsed the new ACGME accreditation standards proposed in June 2002.<sup>294</sup>

## VI. COMPLIANCE WITH AND ATTITUDES TOWARD RECENT RESIDENT WORK HOUR RESTRICTIONS

### A. *The ACGME Accreditation Standards*

Since the implementation of the ACGME accreditation standards in July 2003, reaction and compliance within the graduate medical education community has been varied. The ACGME has reported that out of 2,027 programs that received full accreditation reviews between July 2003 and June 2004, 101 programs (5%) received one or more citations related to non-compliance of the accreditation standards on resident work hours, the majority of which involved violations of the eighty-hour weekly limit (fifty-two citations), the one-day-off-every-seven-days restriction (twenty-nine citations), and the twenty-four-plus-six-consecutive-hours restriction (twenty-seven citations) respectively.<sup>295</sup> Moreover, out of 25,176 residents surveyed in 1,489 residency programs, 834 residents (3.3% of the responding residents) in 370 programs (24.8% of the responding programs) reported working more than eighty hours per week during the previous four weeks.<sup>296</sup> The ACGME interpreted this result as “likely relat[ing] to factors associated with individual residents’ learning and practice performance, rather than program level non-compliance with the standards.”<sup>297</sup> However, the ACGME also reported that the survey “found a few programs where the majority of residents worked significantly beyond the duty hour limits.”<sup>298</sup>

Several independent studies on the effects of complying or attempting to comply with the ACGME accreditation standards have also been reported since

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293. CME REPORT, *supra* note 288, at 355-56.

294. *Id.* at 356.

295. ACGME, THE ACGME’S APPROACH TO LIMIT RESIDENT DUTY HOURS 12 MONTHS AFTER IMPLEMENTATION: A SUMMARY OF ACHIEVEMENTS 1-2 (2004), available at [http://www.acgme.org/acWebsite/dutyHours/dh\\_dutyhoursummary2003-04.pdf](http://www.acgme.org/acWebsite/dutyHours/dh_dutyhoursummary2003-04.pdf).

296. *Id.* at 1-2.

297. *Id.* at 2.

298. *Id.*

July 2003. These studies have reported positive,<sup>299</sup> negative,<sup>300</sup> and mixed<sup>301</sup> results regarding compliance among surgical residency programs. One neurologist

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299. W. Todd Cockerham et al., *Resident Work Hours: Can We Meet the ACGME Requirements?*, 70 AM. SURG. 687 (2004) (reporting changes to the schedules of surgical residents that were compliant with the ACGME standards without compromising patient care or resident education); Michael J. Goldstein et al., *A 360 Degrees Evaluation of a Night-Float System for General Surgery: A Response to Mandated Work-Hours Reduction*, 61 CURR. SURG. 445 (2004) (reporting that the institution of a specialized night-float or continuity-care system for in-house coverage of “general surgical services in a large metropolitan university hospital had initial success in meeting the mandated changes in resident work hours, and that the continuity-care system reduced resident fatigue, improved quality of resident life, and improved patient care as judged by patients and nurse”); Michael W. Arnold et al., *Has implementation of the 80-hour work week made a career in surgery more appealing to medical students?*, 189 AM. J. SURG. 129 (2005) (concluding that the ACGME standards have had a “positive effect on our medical students’ perceptions of a surgeon’s lifestyle, and hopefully, increase[d] their interest in a surgical career.”).

300. David M. Jakubowicz et al., *Effects of a Twenty-Four Hour Call Period on Resident Performance During Simulated Endoscopic Sinus Surgery in an Accreditation Council for Graduate Medical Education–Compliant Training Program*, 115 LARYNGOSCOPE 143, 145 (2005) (reporting that among general surgical residents following current ACGME work hour mandates: there was no diminution in performance in an endoscopic sinus surgery simulator before and after a twenty-four-hour on-call period; there was a trend toward improved speed at the expense of accuracy; and repetition on the simulator in the postcall period can result in improved proficiency); Aaron A. Cohen-Gadol et al., *Resident Duty Hours Reform: Results of a National Survey of the Program Directors and Residents in Neurosurgery Training Programs*, 56 NEUROSURGERY 398 (2005) (reporting that on the basis of their early experience, the majority of the residents and program directors in neurosurgery think: that the ACGME duty hour guidelines have had an adverse effect on continuity of patient care and resident training; that the effects of these guidelines on neurosurgery programs should be carefully monitored, because more sophisticated solutions may be needed to address house staff fatigue; and that strategies to enhance the educational content of the residents’ work hours and to preserve continuity of patient care are necessary).

301. Chandrasekhar Bob Basu et al., *The Effect of the Accreditation Council for Graduate Medical Education Duty Hours Policy on Plastic Surgery Resident Education and Patient Care: An Outcomes Study*, 114 PLASTIC & RECONSTR. SURG. 1878 (2004) (reporting that plastic surgery residents in the Baylor College of Medicine Multi-Institutional Integrated Plastic Surgery Program perceived reduction of resident work hours through adherence to the ACGME guidelines to have beneficial effects on patient care and clinical/operative duties, academic duties, and resident quality of life, but that: these benefits may increase cross-coverage workloads; residents were concerned about faculty perception of their changes in postcall duties; contrary to previously published findings in the general surgery literature, the current results indicate that residents do not believe that this policy negatively affects continuity of patient care; adherence to this policy may improve patient care on multiple levels; the effect on the operative experience remains to be elucidated; and further large-scale and longitudinal research design and analysis is warranted to better assess the results of the ACGME resident work hours policy in plastic surgery resident education); Kathryn A. Mendoza & L.D. Britt, *Resident Operative Experience During the Transition to Work-Hour Reform*, 140 ARCH. SURG. 137-39, 142 (2005) (finding from a study of surgical residents that: 1) there were no significant differences in the operative volume of chief residents based on work-hour model, program setting, or graduating class; 2) there was no significant difference in chiefs’ operative volume between programs that experimented with work-hour reform and programs that did not experiment with work-hour reform in 2002-2003; 3) there was no relationship found between work hours and volume of operative cases; 4) there was an inverse relationship found between work hours and operative volume for residents in New York programs; and concluding that several correlates must be considered for effective assessment and evaluation of the impact of work-hour reform on surgical training and education.).

has even argued that complying with the ACGME accreditation standards creates potential conflicts with the professional ethics rules governing neurologists.<sup>302</sup> For example, the Code of Professional Conduct developed by the Ethics, Law & Humanities Committee of the American Academy of Neurology includes provisions pertaining to: 1) the fiduciary and contractual duties of neurologists to consider the interests of their patients first; 2) the resolution of conflicts of interest that may arise for neurologists in the best interest of their patients; and 3) the general obligation of neurologists to support the patient's medical interests when they are compromised by policies of the health care institution or agency.<sup>303</sup> The commentator argues that complying with the ACGME accreditation standards may at times conflict with these professional ethical obligations.<sup>304</sup>

### B. State Law

Recent studies on compliance with and attitudes toward 10 NYCRR §405.4 in New York State have also yielded mixed results. In 2002, NYSDOH reported that fifty-four of eighty-two teaching hospitals inspected since November 2001 had violated the state regulations.<sup>305</sup> Reporting preliminary results of annual audits through October 2002 that an independent organization contracted by the State of New York had conducted on the state's teaching hospitals to assess compliance with 10 NYCRR §405.4, one researcher found that seventy-five of 118 teaching hospitals (63.6%) audited were non-compliant with some component of the state regulations.<sup>306</sup> The most common citations for non-compliance were for working in excess of twenty-four consecutive hours (45%) and working in excess of eighty hours per week, averaged over four weeks (28%).<sup>307</sup>

In another statewide survey of general surgery residents in New York State conducted just before the implementation of the ACGME accreditation standards, most respondents reported general compliance with 10 NYCRR §405.4 in their surgical residency programs.<sup>308</sup> However, "a substantial portion" of the

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302. Dan Larriviere, *Duty Hours vs Professional Ethics: ACGME Rules Create Conflicts*, 63 NEUROLOGY E4, E5 (2004) (arguing that the ACGME has "created a system that creates conflicts for residents who wish to practice ethically when doing so would violate the hour requirements[.]" and that "[r]ather than create a system that forces residents to sacrifice the ethics of the profession for patient safety, the ACGME should promulgate rules or effectuate changes that promote both.").

303. *Id.* at E4.

304. *Id.* at E4-E5.

305. Press Release, New York State Dep't of Health, State Health Department Cites 54 Teaching Hospitals for Resident Working Hour Violations (June 26, 2002), available at [http://www.health.state.ny.us/press/releases/2002/resident\\_working\\_hours.htm](http://www.health.state.ny.us/press/releases/2002/resident_working_hours.htm).

306. T. Johnson, *Limitations on Residents' Working Hours at New York Teaching Hospitals: A Status Report*, 78 ACAD. MED. 3, 4 (2003).

307. *Id.* at 4.

308. Edward E. Whang et al., *Implementing Resident Work Hour Limitations: Lessons from the New York State Experience*, 237 ANNALS SURG. 449, 453 (2003).

respondents also reported that compliance with the state regulations had detrimental effects on their surgical training and quality and continuity of patient care.<sup>309</sup> The surveyors found that such negative attitudes were more prevalent among senior residents and residents at academic medical centers than among junior residents and residents at community hospitals.<sup>310</sup>

Some commentators have argued that negative attitudes towards the 10 NYCRR §405.4 have created “roadblocks” preventing the successful implementation of the state regulations.<sup>311</sup> Examples of such roadblocks may include “a long-standing tradition of ‘hazing’ first-year residents with long, unsupervised hours; medical community resistance to the notion of residents’ sleep deprivation and dislike of government interference; and a general fear within the medical community of increased medical malpractice liability and other indicia of ‘blame culture.’”<sup>312</sup>

Negative attitudes, in addition to the implementation of the ACGME accreditation standards, may also be contributing to the inability of other states to pass laws to regulate resident work hours.<sup>313</sup> Since July 2003, no state has passed such a law.<sup>314</sup>

#### VII. THE FEDERAL GOVERNMENT SHOULD REGULATE RESIDENT WORK HOURS BECAUSE IT IS WELL-SUITED FOR SUCH REGULATION

Given the public’s concern over the negative impact of sleep-deprived residents on patient and resident safety and the recent scientific evidence validating these concerns, regulating resident work hours is now much easier to justify than has been the case in the past. States and the graduate medical education community nationwide have already attempted to impose restrictions on resident hours. However, neither states nor the graduate medical education community are as well positioned or equipped as the federal government to effectively regulate resident work hours in the nation’s hospitals.<sup>315</sup> Although the New York State

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309. *Id.* at 453.

310. *Id.* at 451.

311. Whetsell, *supra* note 161, at 59-65.

312. *Id.*

313. *See e.g., id.* at 55 n.173 (“A small handful of other states—Massachusetts, California, Pennsylvania, and Hawaii—considered adopting legislation limiting residents’ hours in the late 1980s.” However, none of these bills were actually passed); *see also* Amer. Med. Stud. Assoc., *The Resident Work Hour Issue: State Efforts*, <http://www.amsa.org/rwh/efforts.cfm> (last visited Mar. 1, 2006).

314. *Id.*

315. Several commentators writing before and after the implementation of the ACGME guidelines have agreed with this general proposition. *See* Dori Page Antonetti, *A Dose of their Own Medicine: Why the Federal Government Must Ensure Healthy Working Conditions for Medical Residents and how Reform should be Accomplished*, 51 CATH. U. L. REV. 875, 909-915 (2002) (concluding that PPSPA 2001 and regulations by DHHS to regulate resident work hours should be enacted to protect doctors and

regulations and the ACGME accreditation standards represent attempts at state regulation and self-regulation “with teeth,” the federal government has the personnel and financial resources to bring about compliance and successful implementation of resident work-hour restrictions more effectively. As Senator Corzine remarked in his comments on the Senate floor when he introduced the PPSPA 2002:

Today, I am introducing legislation that not only recognizes the problem of excessive work hours, but also creates strong enforcement mechanisms. The bill also provides funding support to teaching hospitals to implement new work hour standards. Without enforcement and financial support, efforts to reduce work hours are not likely to be successful.<sup>316</sup>

Therefore, despite the existence of state regulations and the ACGME guidelines, the federal government should nevertheless pass laws and promulgate regulations restricting resident work hours in hospitals throughout the United States.

*A. There is a Strong National Public Interest in Regulating Resident Work Hours*

As examined in Part I(B) of this Comment, many scientific studies published since the 1970s suggest that long work hours and sleep deprivation among hospital residents pose significant risks to the safety of patients and residents.<sup>317</sup> Most recently, studies have indicated that long work hours and sleep deprivation among residents affect the frequency of attentional failures among residents and medical errors committed by residents in high-pressure work

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patients); Andrew W. Gefell, Note & Comment, *Dying to Sleep: Using Federal Legislation and Tort Law to Cure the Effects of Fatigue in Medical Residency Programs*, 11 J. L. & POL'Y 645, 648-49 (2003) (arguing that third-party tort liability offers “compelling benefits” as an alternative or supplement to “regulatory attempts to change residency working conditions[,]” but concluding that enforced public regulation of resident work hours such as PPSPA 2001 proposes “far less frightening costs and maintains the benefits of well-rested physicians.”); Whetsell, *supra* note 161, at 25 (proposing a “framework for a model the federal government should use to establish a system that not only changes the law [regulating resident work hours], but also the culture [of the medical profession].”); Robert Neil Wilkey, *Federal Whistleblower Protection: A Means to Enforcing Maximum-Hour Legislation for Medical Residents*, 30 WM. MITCHELL L. REV. 331, 335 (2003) (arguing that “providing whistleblower protection for medical residents is an effective means of enforcement – in particular, that such protection is relatively more effective than either civil fines or discretionary oversight by the ACGME[,]” and that “whistleblower protection can be a superior method of enforcement to ensure that any proposed maximum-hour legislation is effectively administered.”). *But see* Evans, *supra* note 202, at 264-67 (arguing and concluding that, in the interest of legislative and economic efficiency, federal regulation of resident work hours should not be enacted until the system already in place to control excessive resident work hours is improved).

316. 148 CONG. REC. S5456 (daily ed. June 12, 2002) (Sen. Corzine’s introductory remarks on S.2614 (PPSPA 2002)).

317. *See supra* notes 21-96 and accompanying text.

environments such as intensive care units.<sup>318</sup> Medical errors obviously have a significant impact on public health, which both the national public and federal government have a strong interest in protecting.

The federal government also derives its interest in regulating resident work hours from its financial involvement in the health care system. In the PPSPA 2001 and PPSPA 2002, Congress declared that the federal government, through its Medicare program, “pays approximately \$8 billion [\$8,000,000,000] per year solely to train resident-physicians in the United States, and as a result, has an interest in assuring the safety of patients treated by resident-physicians and the safety of resident-physicians themselves.”<sup>319</sup> With such large amounts of public money going into the health care system, the federal government clearly has an interest in not only how the money is spent, but also ensuring that the public money does not support a graduate medical education culture that has potentially harmful effects on public health. As Senator Corzine remarked in introducing the PPSPA 2002 to the Senate:

My legislation makes compliance with these work hour requirements a condition of Medicare participation. Each year, Congress provides \$8 billion to teaching hospitals to train new physicians. While Congress must continue to vigorously support adequate funding so that teaching hospitals are able to carryout this important public service, these hospitals must also make a commitment to ensuring safe work conditions for these physicians and providing the highest quality of care to the patients they treat.<sup>320</sup>

*B. Other Attempts at Regulating Hospital Resident Work Hours  
Have Been Ineffective*

*1. States have been Ineffective at Regulating Resident Work Hours*

As reviewed in sections III(A) and VI(B) of this Comment, various state efforts to regulate resident work hours have been unsuccessful.<sup>321</sup> Numerous state legislatures have failed to pass laws regulating resident work hours, largely as a result of opposition from medical professionals and graduate medical educators.<sup>322</sup> In New York State, where 10 NYCRR § 405.4 has been in effect since 1989,

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318. See Landrigan et al., *supra* note 93, at 842-47 and Lockley et al., *supra* note 46, at 1830.

319. H.R. 3236, § 2(1); S. 2614, § 2(1).

320. 148 CONG. REC. S5456 (daily ed. June 12, 2002) (Sen. Corzine’s introductory remarks on S.2614 (PPSPA 2002)).

321. See *supra* notes 210-29, 305-14 and accompanying text.

322. See *supra* notes 200-02 and accompanying text.

widespread non-compliance with the regulations and their ineffective enforcement have made implementation extremely difficult.<sup>323</sup>

Analysts have suggested many reasons to explain these difficulties in passing and implementing state regulations on resident work hours. Hospitals in New York have argued that the financial costs of hiring additional staff to comply with 10 NYCRR § 405.4 have been “prohibitively expensive.”<sup>324</sup> Although the New York State legislature has authorized “a significant amount of annual funding to comply with the regulations,” the NYSDOH has not required hospitals to make an accounting of how this money has been spent, and hospitals have not voluntarily offered such reports.<sup>325</sup> Some commentators have suggested that the hospitals “eagerly accept the money but use the funds on other things, and not for its intended purpose.”<sup>326</sup>

Lack of funding has also impacted the ability of New York State agencies to consistently enforce 10 NYCRR § 405.4.<sup>327</sup> Budget cuts at the state and local level have contributed to this lack of funding.<sup>328</sup> Reduced funding prevented the NYSDOH from regularly inspecting hospitals for compliance with 10 NYCRR § 405.4 during the 1990s. Given the decreased risk that violations of the regulations would be uncovered,<sup>329</sup> and given the relatively modest penalties for such violations,<sup>330</sup> it is not surprising that hospitals in New York have not been deterred from engaging in large-scale non-compliance with 10 NYCRR § 405.4.

Another suggested reason for the ineffectiveness of state regulations has been “conscientious objections” from physicians who have “vowed not to honor the regulations from the beginning, purportedly believing in their hearts that the changes would lead to detrimental effects on patients.”<sup>331</sup> Moreover, it has been argued that the New York regulations do not take into consideration the nature of the graduate medical education culture, which is characterized by “steep hierarchies in which junior staff do not question senior staff” and in which “physicians exercise a great deal of control over healthcare delivery and . . . simply do not want to be told what to do, particularly in the absence of what they deem [to

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323. See *supra* notes 210-29, 305-11 and accompanying text.

324. Whetsell, *supra* note 161, at 61.

325. *Id.*

326. *Id.*

327. *Id.* at 62.

328. *Id.*

329. *Id.*

330. *Id.* In 2000, the New York State legislature earmarked \$168 million of its \$2.9 billion health budget for enforcing 10 NYCRR § 405.4. The legislature also increased the maximum fine amount to \$50,000 for repeat violations of the regulations. *Id.* Although a significant increase from the previous penalty of \$2,000 per violation, *id.*, this increase does not have the same deterrent effect that suspension from Medicare or Medicaid would have under federal regulation.

331. *Id.* at 63.

be] solid empirical findings that contradict their healthcare philosophy.”<sup>332</sup> It has been argued that the graduate medical education community is reluctant to abide by state or federal regulations because it traditionally likes to set its own standards, and because government regulations put in place a “blame system” that creates an “overwhelming fear of malpractice liability” which makes hospitals “very defensive.”<sup>333</sup>

*2. Self-Regulation by the Graduate Medical Education Community may not be Adequate*

Although self-regulation by the graduate medical education community through the ACGME guidelines has had some initial success,<sup>334</sup> various factors may render such self-regulation inadequate. Given that the ACGME is part of the graduate medical education community, it is still vulnerable to the cultural influences and pressures of the community. Cultural pressure within the graduate medical education community to resist reform may hamper the effectiveness of implementing the ACGME guidelines, perhaps to a greater degree than has been the case in implementing 10 NYCRR §405.4. Senator Corzine’s introductory remarks on the PPSPA 2002 even hint at a possible influence that the graduate medical education culture had in the drafting and establishment of the ACGME accreditation standards:

While the medical community has been aware of [the problem of sleep-deprived residents] for many years, the issue has largely been pushed under the rug. Only recently has the medical community taken a more serious look at the problem . . . .

As a result of . . . increased public pressure on the medical community to address this quality of care and labor issue, the Accreditation Council for Graduate Medical Education, ACGME, announced today new work hour recommendations. This is an important first step. But while some of their recommendations are commendable, *they would still require residents to work in excess of 80 hours a week and 30-hour shifts*. I look forward to working with the Council to adapt strong standards that are not only recommendations, but are enforceable requirements that truly protect patients and residents.<sup>335</sup>

Moreover, with its limited financial and personnel resources, it is questionable whether the ACGME can adequately enforce its guidelines uniformly and effectively throughout the country. Finally, given the relatively harsh nature

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332. *Id.* at 63-64.

333. *Id.* at 64.

334. *See supra* notes 295-304 and accompanying text.

335. 148 CONG. REC. S5456 (daily ed. June 12, 2002) (Sen. Corzine’s introductory remarks on S.2614 (PPSPA 2002)) (emphasis added).



of revoking accreditation, the ACGME may be hesitant to inflict such a sanction on members of the graduate medical education community that violate its accreditation standards on resident work hours. As of May 2005, there have been no reported cases of hospitals losing accreditation for violating the ACGME accreditation standards.<sup>336</sup>

### *3. Enforcement of Resident Work Hour Restrictions Through Tort Law is Undesirable*

At least one commentator has suggested using state tort systems as a means to force hospitals to regulate resident work hours.<sup>337</sup> In particular, it has been proposed that hospitals be subject to third-party liability for harms caused by a fatigued resident, where the fatigue results from the resident's long work hours at the hospital.<sup>338</sup>

However, enforcement through the tort system has not been viewed favorably compared to other enforcement methods.<sup>339</sup> Imposing third-party liability on hospitals for harms caused by its fatigued residents could potentially reduce the quality of care in hospitals as the hospitals take steps to avoid liability, forcing the hospitals to "choose between providing comprehensive patient care services around the clock and sending residents home to ensure reasonable working hours."<sup>340</sup> Moreover, subjecting hospitals to "unpredictable tort judgments could disrupt necessary community services" such as emergency care, and could lead to such detrimental consequences as "increased medical costs, shrunken patient care services or even bankruptcy of health care institutions."<sup>341</sup> Therefore, enforcement

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336. The ACGME threatened to withdraw the accreditation of the internal medicine program at the John's Hopkins Hospital when violations of the ACGME guidelines were reported by a resident rotating through the program and the ACGME conducted a site visit shortly after the guidelines went into effect in July 2003. The threatened withdrawal was to take effect in July 2004. In September 2003, the hospital submitted to the ACGME documentation of general compliance with the accreditation standards. As a result, ACGME modified its earlier decision to withdraw accreditation and instead granted the program probationary accreditation. After a second site visit in October 2003, ACGME restored full accreditation status to the program. See Patrick Gilbert and Mary Ellen Miller, *Out of time*, HOPKINS MED (2004), available at <http://www.hopkinsmedicine.org/hmn/W04/top.cfm>; JOHNS HOPKINS MEDICINE, HOPKINS RESIDENCY PROGRAM REGAINS FULL ACCREDITATION, available at [http://www.hopkinsmedicine.org/Press\\_releases/2003/12\\_20\\_03.html](http://www.hopkinsmedicine.org/Press_releases/2003/12_20_03.html) (last visited Mar. 1, 2006); see also Troy Madsen, *A Whistleblower's Story* (Nov. 23, 2005), available at <http://www.amsa.org/tnp/whistleblower.cfm>.

337. Gefell, *supra* note 315, at 682-86.

338. *Id.* at 682. Under this theory, for example, if a motorist is struck by a resident driving home from a long work shift at the hospital, the hospital may be held liable to the motorist. *Id.*

339. *Id.* at 684-86.

340. *Id.* at 684-85 (footnotes omitted).

341. *Id.* at 684-86 (footnotes omitted).

of resident work hour regulations through tort law is neither effective nor desirable as a matter of public and legal policy.<sup>342</sup>

*C. The Federal Government has the Authority and Resources to Effectively Enforce Resident Work Hour Restrictions*

*1. Federal Spending Power*<sup>343</sup>

In the past, the federal government has regulated residency programs through its exercise of the spending power. For example, Congress imposed various requirements on residency programs receiving graduate medical education funding through Medicare in the Balanced Budget Act of 1997.<sup>344</sup> These requirements, which were in addition to the existing requirement that residency programs be accredited,<sup>345</sup> included restrictions on the number of Medicare-funded residents in each program and incentives for hospitals to further downsize their programs.<sup>346</sup> According to one commentator, “[h]ospitals responded to the regulations favorably by downsizing their residency programs, which furthered the government’s goal of reducing the number of specialists entering the medical profession.”<sup>347</sup>

Based on this successful implementation of a federal health care policy through the exercise of the federal spending power, Congress might be able to use the spending power as a means of effectively implementing and enforcing federal restrictions on resident work hours. In fact, the spending power is implicitly invoked in both PPSA bills as part of the legal justification for regulating resident

342. An appellate court in Illinois recently considered many of the issues presented in this section. See *Brewster v. Rush-Presbyterian-St. Luke’s Medical Center*, 836 N.E.2d 635 (Ill. App. Ct. 2005) (affirming decision of lower court that hospital was not liable for injuries resulting from a car accident caused by one of the hospital’s interns, where the intern was driving home from a thirty-six-hour shift at the hospital and fell asleep while driving).

343. U.S. CONST. art. I, §8, cl. 1. For more on the federal spending power, see *South Dakota v. Dole*, 483 U.S. 203 (1987) and *Buckley v. Valeo*, 424 U.S. 1, 90-92 (1976).

344. Balanced Budget Act of 1997, Pub. L. No. 105-33, 111 Stat. 251 (1997) (codified as amended in scattered sections of 42 U.S.C.); see also Antonetti, *supra* note 313, at 891.

345. Antonetti, *supra* note 315, at 891 (noting that “the federal government provides substantial financial support to graduate medical education” and that “[r]esidency programs are considered approved only if they are accredited” (footnotes omitted)); see also 42 U.S.C. § 1395ww(h)(5)(A) (“The term ‘approved medical residency training program’ means a residency or other postgraduate medical training program participation in which may be counted toward certification in a specialty or subspecialty and includes formal postgraduate training programs in geriatric medicine approved by the Secretary.”).

346. Balanced Budget Act of 1997, § 4623 (establishing a “[l]imitation on number of residents and rolling average FTE count”); *id.* at § 4626 (establishing “[i]ncentive payment under plans for voluntary reduction in number of residents”); Antonetti, *supra* note 315, at 891. These requirements were imposed “in light of the growing number of residency positions; the excess of medical specialists; the geographic mal-distribution of primary care physicians;” and to “make the physician workforce more responsive to the public’s health care needs.” *Id.* at 891 (footnotes omitted).

347. Antonetti, *supra* note 315, at 891 (footnote omitted).

work hours through federal law.<sup>348</sup> The mere threat of suspension from participation in Medicare and Medicaid for violating federal restrictions on resident work hours would be expected to significantly impact the way teaching hospitals treat these restrictions. Such a sanction is arguably harsher than the ACGME's sanction of revoking accreditation, and would have a definite deterrent effect on violators of federal resident work hour restrictions.<sup>349</sup>

*2. The Federal Government is Better able to Overcome the "Cultural" Pressure to Resist Regulation of Resident Work Hours than are State Governments and the ACGME*

Federal regulation and enforcement of resident work hour restrictions would have a number of advantages over state regulation and self-regulation by the graduate medical education community. With vastly greater financial and personnel resources than states and the ACGME, the federal government could enforce its restrictions on resident work hours more effectively than the states or the ACGME could enforce theirs. Although the medical and graduate medical education communities may resist federal regulation of resident work hours as much as they have resisted state regulation of the same, the federal government's vast enforcement resources should be sufficient to overwhelm such resistance.

Coming from outside the graduate medical education community, federal regulators would be better able to resist the cultural pressures that influence the ACGME and that state regulators have had difficulty overcoming. Furthermore, as an outsider to the graduate medical education community, federal regulators probably will not have the same hesitations as the ACGME to inflict harsh sanctions on violators of federal resident work hour restrictions. Any sanctions for violating federal restrictions on resident work hours would therefore give such federal restrictions "real teeth that bite" to a much greater extent than the ACGME guidelines and perhaps even 10 NYCRR §405.4.

*3. The Federal Government has Experience in Regulating Work Hours in Various Industries*

Another advantage that the federal government would have in regulating resident work hours would be its experience in regulating work hours in other

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348. See *supra* note 316 and accompanying text ("[Without] financial support, efforts to reduce work hours are not likely to be successful.").

349. As an alternative to such harsh sanctions as suspension of participation in Medicare and Medicaid, one commentator has argued that whistleblower protections offer an excellent means of enforcing public, governmental regulations of resident hours in that they give residents an "incentive to disclose working condition violations and encourage them to assume a regulatory or oversight role." Wilkey, *supra* note 315, at 346-54. Both PPSPA 2001 and PPSPA 2002 contain provisions establishing whistleblower protections. H.R. 3236 § 3(c); S. 2614, § 3(c).

industries. For example, Congress has mandated and authorized various federal agencies to regulate the work hours of, *inter alia*, commercial pilots,<sup>350</sup> commercial drivers,<sup>351</sup> railroad operators,<sup>352</sup> and maritime crews.<sup>353</sup> Given these existing examples of federal regulation of work hours in entire industries, it would not be overly difficult for DHHS or any other federal agency acting within its jurisdiction to follow the example of these federal agencies and promulgate regulations restricting resident work hours, should Congress authorize them to do so.

*D. Suggested Mechanisms for Federal Regulation of Resident Work Hours*

Federal regulation of resident work hours may take on a variety of forms. The two PPSPA bills attempted to regulate resident work hours through a combination of statutory work hour restrictions<sup>354</sup> and authorization for the Secretary of Health and Human Services to promulgate regulations<sup>355</sup> implementing these statutory restrictions. An alternative mechanism for regulating resident work hours at the federal level that Congress might want to consider in the future would be to leave it entirely up to DHHS to establish resident work hour restrictions through its administrative rulemaking process.

Should Congress decide to leave it entirely to DHHS to regulate resident work hours, Congress may want to consider passing legislation that authorizes the creation of an Advisory Committee on Resident Work Hours within the DHHS to assist the DHHS rulemakers in formulating and drafting regulations that restrict resident work hours.<sup>356</sup> This advisory committee would consider and submit recommendations to the Secretary of HHS and DHHS rulemakers on issues such as:

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350. 14 C.F.R. § 121.471 (2005).

351. 49 C.F.R. pt. 395 (2004).

352. *Id.* pt. 228 (2004).

353. 46 U.S.C. § 8104 (2004).

354. H.R. 3236, § 3(a)(2); S. 2614, § 3(a)(2) (adding new subparagraph (j)(1)(A) to Section 1866 of the Social Security Act (42 U.S.C. § 1395cc)).

355. *Id.* § 3(a)(2) (adding new subparagraphs (j)(1)(B) and (j)(1)(C)(2) to Section 1866 of the Social Security Act (42 U.S.C. § 1395cc)); *id.* at § 3(b)(1)-(2).

356. The author would like to acknowledge the following individuals for inspiring the policy and legislative suggestions that appear in this section: Christopher P. Landrigan, M.D., M.P.H., Director of the Sleep and Patient Safety Program at Brigham and Women's Hospital, Research Director of the Children's Hospital Boston Inpatient Pediatrics Service, and Assistant Professor of Pediatrics at Harvard Medical School; Shantha W. Rajaratnam, Ph.D., LL.B., Visiting Assistant Professor, Division of Sleep Medicine, Brigham and Women's Hospital, Harvard Medical School; Steven W. Lockley, Ph.D., Associate Neuroscientist in the Division of Sleep Medicine at Brigham and Women's Hospital and Lecturer in Medicine at Harvard Medical School; and Charles A. Czeisler, Ph.D., M.D., Chief of the Division of Sleep Medicine at Brigham and Women's Hospital, and Co-Director of the Division of Sleep Medicine and the Frank Baldino, Jr., Ph.D., Professor of Sleep Medicine at Harvard Medical School.

- 1) Specific consecutive and weekly work hour restrictions for hospital residents, including restrictions on moonlighting and exceptions for states of emergency or emergency situations declared by a health care facility.
- 2) Appropriate means of enforcing federal restrictions on resident work hours, including informing all medical students in clinical training, hospital residents, other health care professionals, and health care consumers of their right to report violations of federal resident work hour restrictions; whistleblower protections for health care providers who report violations of such federal restrictions; and required reporting by hospitals and other health care facilities to determine compliance with such federal restrictions.
- 3) Appropriate procedures for DHHS to receive and investigate reported violations of the federal resident work hour restrictions, including the filing of anonymous complaints and complaints by medical students in clinical training, hospital residents, other health care professionals, and health care consumers; and the identification or creation of a new position within DHHS with the responsibility of investigating reported violations of the federal restrictions.
- 4) Appropriate monetary and non-monetary penalties for violations of the federal resident work hour restrictions.
- 5) Appropriate monetary and non-monetary incentives to encourage hospitals and other health care facilities that provide clinical training to health care providers to develop fatigue management programs and work environments that minimize the effects of fatigue.
- 6) Appropriate means to educate and inform medical students, hospital residents, supervising physicians, medical staff, and other health care professionals on the effects of acute and chronic sleep deprivation on the health and safety of physicians, and on the quality of patient care provided by such physicians.
- 7) The use of fatigue countermeasures to mitigate the effects of long work hours and sleep deprivation among hospital residents, including naps before and during long work shifts, rest breaks, and legal stimulants such as caffeine and light therapy.
- 8) Requiring hospital residents and other health care providers who have been awake for a certain number of hours to inform patients under their care of this fact and of the potential safety impacts of their sleep deprivation and to obtain the informed consent of each of these patients to continue providing patient care for or to perform any medical or surgical procedure on these patients.
- 9) The estimated costs that hospitals may incur in order to comply with any statutory mandates passed by Congress or regulations issued by DHHS relating to resident work hours, including expenses required for hospitals to hire additional medical and support staff in order to comply

with any federal resident work hour restrictions, and the cost of educating medical students in clinical training, hospital residents, and other health care providers on the effects of sleep deprivation on medical performance and safety.

10) The need for DHHS and, if necessary, Congress to appropriate such amounts as may be required to provide for additional payments to hospitals for the additional estimated costs determined in issue (9).<sup>357</sup>

DHHS would use the recommendations submitted by the Advisory Committee as guidance for drafting and promulgating regulations pertaining to resident work hours in the United States. Once the recommendations have been submitted, the Advisory Committee would advise DHHS rulemakers on the actual drafting of the federal regulations, as well as advise DHHS in general on any issue relating to the regulation of resident work hours in the United States.

To ensure that a variety of interests and points of view are represented on the Advisory Committee, members of the Advisory Committee might include representatives of the following stakeholders: medical educators, including graduate medical education programs and medical schools; the medical profession; hospitals and other health care facilities that have residency programs; hospital residents; medical students; federal, state, and local governments, including state medical licensing boards; and health care consumers.<sup>358</sup> The Advisory Committee should also include among its members experts in sleep deprivation, including those who are practicing physicians; and experts in health care law, policy, or regulation, including those who are or have been regulators, lawmakers, or policymakers in health care. These members, who would not be considered representatives of particular stakeholders, would provide a credible academic and intellectual element to the Advisory Committee's discussions of the issues listed in this section. The Advisory Committee would also be permitted to invite other experts and consultants to attend and participate in its meetings, which would also be open to the public.<sup>359</sup>

#### CONCLUSION

Both PPSA bills provide the federal government with a solid legislative basis to authorize federal regulation of resident work hours in hospitals throughout

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357. The proposals for an Advisory Committee on Resident Work Hours, the issues to be considered by the Advisory Committee, and the membership of the Advisory Committee are all based in large part on suggestions made by the individuals named in note 356. See E-mail from Christopher P. Landrigan, M.D., M.P.H., Director of the Sleep and Patient Safety Program at Brigham and Women's Hospital, Research Director of the Children's Hospital Boston Inpatient Pediatrics Service, and Assistant Professor of Pediatrics at Harvard Medical School, to author (Aug. 23, 2005, 11:34:34 EDT) (on file with author).

358. See *supra* notes 356-57.

359. See *supra* notes 356-57.

the United States. The bills include provisions that take advantage of the federal regulatory and enforcement resources that can make federal regulation of resident work hours more effective than current regulation efforts by the states and the ACGME. However, although federal regulators may be able to overcome the resistance of the graduate medical education community to restrictions on resident work hours, such federal restrictions must first exist. Despite its weaknesses, the existence of self-regulation by the ACGME may make Congress reluctant to pass legislation to federally mandate restrictions on resident work hours. This is especially true given the current political environment in Washington, D.C., dominated by opponents of “Big Government” and regulation. Nevertheless, federal regulation of resident work hours should remain on the table for Congress to consider in the future, especially if the ACGME regulatory efforts prove to be as ineffective as New York’s efforts have been in this area.