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Sleep Deprived Physicians Considering Modafinil: Using a Controlled Substance for Cognitive Enhancement Gambles with Differential Drug Responses and Violates Ethical and Legal Duties Against Physician Impairment

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SLEEP DEPRIVED PHYSICIANS CONSIDERING MODAFINIL:

USING A CONTROLLED SUBSTANCE FOR COGNITIVE ENHANCEMENT GAMBLES WITH DIFFERENTIAL DRUG RESPONSES AND VIOLATES ETHICAL AND LEGAL DUTIES AGAINST PHYSICIAN IMPAIRMENT

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I. INTRODUCTION

In several employment sectors, the human need for sleep has been cast as an impediment to maximizing one's contribution to the professional field and a barrier that should be minimized or overcome. To achieve optimal productivity and push employees to perform for extended hours, the military advocates the use of psychopharmacological cognitive enhancement drugs (PCEDs) to enhance soldiers' vigilance and attention to detail on extended missions. Section II will describe the military's approach to cognitive enhancement and how scholars and physicians have suggested that physicians should adopt the military's rationale for using PCEDs to enhance mental acuity and alertness despite extreme physiological and cognitive exhaustion. Section III will address the endorsement for physician use of stimulant drugs such as modafinil as a solution to physician fatigue, specifically during the period of medical residency when physicians face long hours, overnight shifts, and demanding schedules. This section will also address how medical culture's unwavering imposition of this rigorous schedule and imposed sleep deprivation has neurological, cognitive, and physiological consequences on the physician, the physician's ability to practice medicine, and the quality of patient care. Section IV will explore why modafinil constitutes an unpredictable and problematic drug for physicians interacting with patients by providing an overview of the drug profile, how it is regulated by the FDA and the Controlled Substances Act, and a summary of research relating to the drug's intended and unexpected

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effects on subjects. Lastly, Section V will discuss how using modafinil during a shift violates the physician's ethical and legal duties to refrain from practicing medicine under the influence of non-medical drugs and how practicing while impaired can expose the physician to professional sanction or tort liability.

II. APPROACHING THE HUMAN NEED FOR SLEEP AS A PROFESSIONAL IMPEDIMENT

Using modafinil to improve concentration, alertness, or forgo sleep is classified as an enhancement because it constitutes "an intervention designed to improve human form or functioning beyond what is necessary to sustain or restore good health."[1] Rather than treating an existing illness or condition, using a drug for performance enhancement or sleep avoidance (PESA) constitutes an amplification or extension of human limits. The pressure to forgo sleep while maintaining productivity has been discussed as it relates specifically to two sectors of society: the military and the medical profession.[2] This section will discuss why and in what circumstances the military sanctions the use of stimulants including modafinil and how some physicians and scholars may use this logic as a means to permit or promote physician use of modafinil.

A. Learning From The Military: Fatigue As Commodity

Few sectors of society openly endorse the use of stimulants for PESA purposes. The military is one arena that directly promotes the use of stimulants (and sedatives) for use in combat or in circumstances of "operational necessity."[3] Operational necessity is defined as sustained or continuous operations when the mission consists of twenty four hours or longer to reach a common goal, where the soldier will encounter conflict with circadian rhythm patterns, and experience symptoms of sleep deprivation that interfere with the ability to perform on the mission.[4] Sleep

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1. Reinoud de Jongh et al., *Botox for the Brain: Enhancement of Cognition, Mood and Pro-Social Behavior and Blunting of Unwanted Memories*, 32 NEUROSCIENCE & BEHAVIORAL REVIEWS 760, 761 (2008).

2. Veikko Launis, *Cosmetic Neurology: Sliding Down the Slippery Slope?* 19 CAMBRIDGE QUARTERLY OF HEALTHCARE ETHICS317 (2010) (quoting Chatterjee on the obligation to extend one's self in social and work environments).

3. JIM FRASER, PERFORMANCE MAINTENANCE DURING CONTINUOUS FLIGHT OPERATIONS, at 26, *available at* http://www.public.navy.mil/navsafeen/Documents/aviation/operations/Performance Maintenance.ppt.; *see generally* Catherine Annas & George Annas, *Enhancing the Fighting Force: Medical Research on American Soldiers*, 25 J.OF CONTEMP. HEALTH L. & POL'Y 283 (2009).

4. FRASER, *supra* note 3, at 5.

deprivation increases the reaction time a soldier needs to respond to stimuli, diminishes memory, reduces attention, and can affect mood.[5] These normal responses to sleep deprivation interfere with the performance goal for members of the military to sustain "optimal job productivity with no or absolutely minimal adverse impact on safety, health, and general well-being.[6] Accordingly, the military classifies fatigue as a commodity to be managed.[7] Counter-fatigue training declares that all commanding officers and squadrons should adopt this philosophy by utilizing a combination of stimulants and sedatives to achieve the optimal productivity performance with minimal adverse impact on safety, health and well-being.[8]

By promulgating a goal for soldier performance that views the human need for sleep as an impediment to job performance, the military creates a problematic paradigm shift of what it means to sustain versus enhance productivity and the expected abilities required to do one's job. Counter-fatigue training specifically defines that providing a combination of timed stimulants and sedatives constitutes performance *maintenance*, not performance *enhancement*.[9] Including extending and prolonging human capabilities within the definition of maintenance is significant because it shifts the perception of physiological and cognitive normalcy. Within this framework, a soldier would take a stimulant to prevent the fatigue from impairing the soldier's physiological and cognitive state. This paradigm sets forth the proposition that soldiers should be able to perform continuously for as long as necessary to achieve the goals of the mission and that this does not constitute an enhancement.[10]

However, this definition strategically excludes the reality that a soldier's physiological and cognitive state are inherently tied to the satisfaction of biological requirements such as water, food, and sleep. When the normal curve of human capacity decreases after a certain number of hours awake, interceding with this level of capability necessarily constitutes an enhancement because it increases what the soldier would otherwise be able to do.[11] Re-defining this paradigm is

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5. *Id.* at slide 11.

6. WARFIGHTER ENDURANCE MANAGEMENT DURING CONTINUOUS FLIGHT AND GROUND OPERATIONS: AN AIR FORCE COUNTER FATIGUE GUIDE at 4, *available at* http://www.scribd.com/doc/1512815/US-Air-Force-WarfighterEnduranceManagement (hereinafter "Counter Fatigue Guide).

7. FRASER, *supra* note 3, at 19.

8. *See id.* COUNTER FATIGUE GUIDE, supra note 6, at 4.

9. FRASER, *supra* note 3, at 26.

10. Annas & Annas, *supra* note 3, at 287.

11. FRASER, *supra* note 3, at 12.

problematic and significant because it views baseline human capabilities as a shortcoming and sleep as a barrier to a particular level of expected and "necessary" performance.

B. Attention To Detail And Sustained Vigilance: The Military To Civilian Transition

This drive to enhance baseline performance when it begins to naturally decline can be an attractive proposition to individuals in other professions in the civilian sector where fatigue also serves as a barrier to mental acuity and alertness. As in the military, many other individuals encounter career demands that are not constrained by a clock or the individual's biological needs for sleep.[12] Several scholars have suggested that the use of psychopharmacological cognitive enhancement drugs (PCEDs) in the professional setting should not only be tolerated, but also encouraged for professionals such as air-traffic controllers, surgeons, and nurses who may work long shifts.[13] An article in the *Times* out of the UK proclaimed that everyone from judges, to cabinet ministers, to police, who may have trouble staying awake could all present a more alert and intelligent face to the world if they took modafinil.[14]

When an advisory panel for the FDA considered (and later rejected) endorsing expanded product usage, an FDA official echoed this sentiment, stating that it was "not completely obvious" that healthy people using modafinil to stay alert would constitute a "bad thing" because sleepy people can endanger others.[15] Although the FDA declined to officially expand acceptable uses for modafinil as a method to generally promote wakefulness, this concept of using the drug to enhance performance has been discussed as a possible solution to overcome mental and physical fatigue arising from long and demanding professional schedules.

Indeed, numerous publications connect the professional demands of select military operations to physician residents and surgeons (hereinafter "physicians" or "residents") who may experience fatigue as a barrier to mental acuity and alertness during sustained continuous work.[16] Scholars

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12. Simon Williams et al., *Waking Up To Sleepiness: Modafinil, the Media, and the Pharmaceuticalisation of Everyday/Night Life*, 30 SOC. HEALTH & ILLNESS 839, 845 (2008).

13. Barbara Sahakian & Sharon Morein-Zamir, *Professor's Little Helper*, 450 NATURE 1157, 1158 (2007).

14. Williams et al., *supra* note 12, at 847.

15. Andrew Pollack & Alicia Ault. *Advisory Panel Endorses More Uses for Stimulant*, N.Y. TIMES, Sept. 26, 2003.

16. *See* Anjan Chatterjee, *Cosmetic Neurology: the Controversy Over Enhancing Movement, Mentation, and Mood*, 63 NEUROLOGY 968, 972 (2004); Steven Rose & Timothy Curry, *In reply to: Fatigue*

have recently suggested that some proponents of psychopharmacological enhancement will use similar rationale to justify expanded usage of PCEDs such as modafinil into challenging professions within the civilian sector.[17] Similar to soldiers in the military, physicians also work in an unpredictable (albeit vastly different) setting that requires attention to detail and sustained vigilance for an extended period of time.[18] Continuity of care for a particular patient, extended surgery, or long shift hours all mean that the physician must be awake and functionally adept for physical care such as handling a scalpel or performing complex cognitive processing such as accurately diagnosing a mystery condition and appropriately treating a patient. As in the military, an error in judgment such as incorrectly diagnosing an emergency illness or a slip of the hand during surgery can mean the difference between life and death for a patient.

Recent literature boldly posits that physicians should not merely be permitted to use PCEDs, but also affirmatively endorses that physicians should use stimulants to enhance their physiological and cognitive processing as it begins to decline as they become more fatigued.[19] In the March 2010 edition of Mayo Clinic Proceedings, Drs. Rose and Curry declared that resident physicians have an ethical duty to reduce error during periods of fatigue.[20] Problematically, they argued this means ingesting a stimulant for performance enhancement and sleep avoidance during a shift when a resident physician is experiencing fatigue as the *more ethical choice* than forgoing the stimulant.[21] Similarly, Webb and colleagues have also raised the issue of physician sleep deprivation, and they characterize the problem of physician fatigue as a "state of impairment" that poses a danger to patients and contributes to medical errors. [22] However, Webb and colleagues channel this issue into wondering why physicians are permitted to care for patients when they are sleep deprived, when simply telling physicians to use PCEDs would

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Countermeasures, and Performance Enhancement in Resident Physicians, 85 MAYO CLINIC PROC. 300, 301-302 (2010); Annas & Annas, *supra* note 3, at 292-300.

17. *See* Chatterjee, *supra* 16; A Ravelingien & A. Sandberg, *Sleep Better Than Medicine? Ethical Issues Related to "Wake Enhancement,"* 34 J. OF MED. ETHICS 1,4 (2008).

18. *See* COUNTER FATIGUE GUIDE, *supra* note 6, at 7 (discussing how military work entails unpredictable settings, attention to detail and vigilance).

19. Rose & Curry, *supra* note 16; *see* Jadon Webb et al., *Contemplating Cognitive Enhancement in Medical Students and Residents*, 53 PERS. IN BIOLOGY & MED. 200 (2010).

20. Rose & Curry, *supra* note 16.

21. *Id.*

22. Webb et al., *supra* note 19, at 207.

minimize the "problem."[23]

This characterization reiterates the demands placed on physicians that simply cannot be achieved within the confines of human biological needs of restoration and sleep. Rather than focusing on the problem as physicians' inability to maintain professional performance during long shifts or without proper rest, we should shift the scrutiny to the problem of the physician schedule, specifically during the period of medical residency to better understand the demands placed on physicians.[24]

III. MEDICAL CULTURE'S HOSTILITY TOWARD SLEEP: TO WHAT COST?

A. Medical Culture And Physician Schedule Demands

Long shifts, overnight on call periods, and demanding schedules have been described as a necessary component of learning during physician residency.[25] In 2003, the Accreditation Council for Graduate Medical Education (ACGME) set forth standards and limits on resident duty hours and in 2010 it convened a task force to revise the standards.[26] The Task Force on Quality Care and Professionalism promulgated its new requirements in 2010, and the Common Program Requirements will be effective July 1, 2011. According to the Common Program Requirements, residents should not be scheduled for more than eighty hours per week as averaged over a period of four weeks, continuous on site duty may not exceed twenty-four hours (limited to sixteen hours for first year residents), and residents should be provided a ten hour rest period between duty hours.[27]

Despite these limits, the actual hours residents work may be significantly higher for three reasons. First, individual programs may apply for a ten percent increase in weekly duty hour limit, which could increase the weekly limit to eighty eight hours.[28] Second, the on site limit

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23. *Id.*

24. *See* Jennifer Whetsell, *Changing the Law, Changing the Culture: Rethinking the "Sleepy Resident" Problem*, 12 ANN. HEALTH L. 23 (2003) (discussing components of medical residency programs.)

25. Eleanor Stoller et al., *Strategies Resident Physicians Use to Manage Sleep Loss and Fatigue,* 10 MED. EDUC. ONLINE 1, 1 (2005).

26. Accreditation Council for Graduate Medical Education, *ACGME Duty Hours*, (2002), *at*: http://www.acgme.org/acWebsite/dutyHours/dh_index.asp.

27. Accreditation Council for Graduate Medical Education, *Common Program Requirements*, (2007), *at*: http://www.acgme.org/acWebsite/dutyHours/dh_ComProgrRequirmentsDutyHours0707.pdf. (herein after "Program Requirements").

28. *Id.*

only refers to accepting new patients within that timeframe.[29] After the on site limit, the standards provide for up to an additional six hours for transfer of care and education activities.[30] Lastly, the new standards clarified that residents should be provided ten hours between periods of duty, but only eight hours is actually required.[31]

Factoring in these additional guidelines, residents may still be working well over one hundred hours a week. If the institution adopts a schedule to maximize hours on duty, the amount of total hours residents work per shift could range upwards from twenty to thirty hours for first year residents and other residents, respectively.

This length of shifts means that residents may be required to skip sleeping altogether at the time in the circadian rhythm when the body should be sleeping.[32] Both the length of schedule and the potential to maximize duty hours means that residents may be required to report for a shift and rest at vastly a different time at each subsequent shift. Varying time on site and periods available for rest means residents are forced to sleep at different hours of the twenty four hour day depending on when a shift begins and ends. This scheduling conflicts with the human biological circadian clock, which requires a full seven days to reset and adjust to a new schedule.[33]

Even if residents had time adjust to a different sleep wake pattern, many residents may still not function well during the night periods based on internal cues of circadian rhythm, which anticipate periods of activity and rest even in the absence of lightness and darkness.[34] During the times when the body anticipates sleep but is on site working a shift, the resident may experience drowsiness, fatigue, and the inability to perform activities without falling asleep.[35]

Furthermore, if a program provides residents eight hours between periods of duty, this still does not allow for sufficient time for the resident to *sleep* eight hours after factoring in other activities such as traveling to and from work, finding time to eat, exercise, engage in social time with family or friends, or perform any other life activity. Sleeping less than

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29. *Id.*
30. *Id.*
31. *Id.*
32. FRASER, *supra* note 3, at 13.
33. *Id.* at 8; *see also* Robert Bird & Niki Mirtorabi, *Shiftwork and the Law*, 27 BERKELEY J. EMP. & LAB. L. 383, 389-390 (2006) (discussing how the circadian rhythm affects sleep and wake times and how adjusting the circadian rhythm disrupts the ability to sleep and the quality of sleep).
34. Bird & Mirtorabi, *supra* note 33, at 389.
35. *Id.* at 390.

eight hours has a marked effect on vigilance, and continually sleeping less than eight hours means that the residents' alertness and performance will deteriorate further over time.[36] Lastly, disrupting time available for sleep and scheduling sleep without regard for circadian rhythm patterns means that if the physician can and does fall asleep during the rest period, this sleep may be brief, fitful, and insufficiently restorative.[37]

The length of shift, rotation in shift times, and lack of rest between shifts means residents may have neither sufficient time to sleep and the time permitted may not correspond to biologically set periods that the resident needs sleep or can fall and stay asleep. In sum, the Common Program Requirements fail to sufficiently address how to accommodate residents' biological need for sleep. [38]

Some physicians and educators demonstrate striking resistance to reforming resident work hours, arising from medical culture's focus on service, sacrifice, and indoctrination.[39] Medical culture instills a belief that long hours are necessary to teach residents the rigors of the profession, instill a sense of selflessness, and encourage commitment to patient care.[40] Residents who voice concerns relating to the demanding schedule or register their need for more sleep may be dismissed as weak or whining without meritorious reason.[41] Physician residents may believe sleep loss constitutes an honored feature of residency training that they can overcome once they complete the residency program.[42]

Despite these potentially obscene schedules, some physicians who train residents insist these hours are a necessary component of medical training. [43] These physicians maintain that residents must learn how to function effectively despite fatigue, or that sleep deprivation constitutes a rite of passage to the medical profession.[44] Still other physicians refute that sleep deprivation even constitutes a problem and assert no studies show a connection between resident fatigue and medical errors.[45] Despite

36. Fraser, *supra* note 3, at 12, 15.

37. Bird & Mirtorabi, *supra* note 33, at 390.

38. *See* Whetsell, *supra* note 24, at 30 (some critics refer to residents' schedule as similar to working in a sweatshop).

39. David Villar Patton et al., *Legal Consideration of Sleep Deprivation Among Resident Physicians*, 34 JOURNAL OF HEALTH LAW 377, [12] (2001).

40. *Id.*

41. Merit Buckley, *Imposing Liability in the United States Medical Residency Program: Exhaustion, Errors, and Economic Dependence*, 12 DEPAUL J. HEALTH CARE L. 305, 315 (2009); Whetsell, *supra* note 24, at 46.

42. Stoller et al., *supra* note 25, at 9.

43. Whetsell, *supra* note 24, at 45-46.

44. *Id.*

45. Buckley, *supra* note 41.

these denials, research confirms that residents schedules do not allow for sufficient sleep, which negatively impacts both the physician and the patients under the care of the physician.[46]

B. Sleep Loss And Effect On The Physician

Sleep loss has enormous consequences for the physician's neurological, cognitive, and physiological state. To understand how to frame this problem, it is imperative to reiterate that these ill health effects do not arise from an independent existing condition or disease, but that they are a direct manifestation of restricting sleep. Since the introduction of shift work sleep disorder (SWSD), the line between what constitutes a disease and what constitutes a normal human response to external restrictive conditions has become increasingly blurred.[47] For physicians, experiencing cognitive and physiological fatigue becomes characterized according to medical culture- that physicians experience ill health effects from individual pathology, of not being "tough enough" to handle a rigorous schedule rather than acknowledging that the schedule itself directly contributes to ill health effects. As one commentator noted, this framework turns into trying to treat the human need for sleep.[48]

Pathologizing the human need for sleep ignores that sleep is a biological necessity that neither can, nor should, be "cured."[49] Sleep loss produces negative and cumulative effects on in the individual over time, resulting in a sleep debt.[50] Lack of sleep affects physicians across multiple dimensions, in both personal and professional settings.[51] Forgoing sleep for a night produces neurological and physiological effects similar to intoxication, degrading mental and motor skill performance.[52] In the professional arena, physicians who are sleep deprived have decreased cognitive ability and a negative impact on professionalism, task

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46. *See generally* Whetsell, *supra* note 24; Buckley, *supra* note 41; Patton et al., *supra* note 39.

47. Webb et al., *supra* note 19, at 205 (discussing FDA approval of modafinil for SWSD). A full discussion of medicalization and whether SWSD should constitute a condition is outside the scope of this article.

48. Anahad O'Connor, *Wakefulness Finds a Powerful Ally*. N.Y. TIMES. June 29, 2004.

49. Buckley, *supra* note, at 315 (discussing sleep as a biological necessity); *see* generally Ravelingien & Sandberg, *Sleep better than medicine? Ethical issues related to "Wake Enhancement,"* 34 J. MED ETHICS 9 (2008), (discussing how sleep and downtime creates balance in society.)

50. Stoller et al., *supra* note 25, at 2.

51. Sleep deprivation also interferes with physicians' personal relationships and poses safety concerns such as the inability to drive home from a shift when a physician is overly exhausted. *See* Stoller, *supra* note 25, at 1; Eric Olson et al., Sleep Deprivation, Physician Performance, and Patient Safety, 136 CHEST 1389, 1394 (2009).

52. Counter Fatigue Guide, *supra* note 6, at 3.

performance, and mood.[53] More specifically, studies show that continual sleep deprivation correlates with a profound decrease in ability to navigate motor and cognitive tasks, such as manual dexterity, reaction time, and recall tasks.[54] Sleep deprived residents report mood disturbances such as more sadness, more anxiety, less egotism, and less social affection and more psychophysiologic abnormalities than rested residents.[55] Importantly, these disturbances in mood also produced difficulty thinking and confusion, which directly affects residents' ability to perform various functions of the job from translating knowledge into practice and integrating knowledge, to effectively diagnosing and communicating with the patient.[56] Additionally, sleep deprivation results in an undesirable and unprofessional attitude toward colleagues and patients, which undermines the trust and care of the physician patient interaction.[57]

Sleep also serves as an important regenerative and protective mechanism to the neurological and physiological systems. During REM sleep the brain allows neuroreceptors to rest and themselves.[58] Withholding REM's restorative functions could adversely affect cognition and mood.[59] Non-REM sleep also serves an important function of sustaining a period of low metabolic demand on the brain and allows the brain's energy stores to replenish.[60] Eliminating periods of non-REM sleep interferes with the brain's plasticity and ability to support cognitive tasks.[61] Research also shows individuals who are chronically sleep deprived are at risk for further health problems such as increased risk of morbidity and mortality, hypertension, and compromised immune systems.[62] As science currently stands, no drug or other intervention can produce the same restorative functions as sleep to the body's neurological and physiological systems.

The negative effects of sleep deprivation are imperative to consider given the amount of residents who are sleep deprived. A study conducted by Stoller and colleagues to assess resident sleep patterns and impact of these patterns found high levels of sleep loss and fatigue among

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53. Stoller et al., *supra* note 25, at 1.
54. Patton et al., *supra* note 39, at 6.
55. *Id* at 5.
56. *Id.*
57. *Id.*at 7.
58. Walter Glannon, *Pyschopharmacological Enhancement,* 1 NEUROETHICS 45, 47 (2008).
59. *Id.*
60. *Id.*
61. *Id.*
62. *Id.*

residents.[63] While fifteen percent scored in the "mild sleepiness" range, eighty four percent of residents scored in a range where clinical intervention is typically indicated.[64] Not surprisingly, only one percent of residents scored in a desirable range.[65] This level of sleep deprivation among an overwhelming majority of resident physicians means they are experiencing the corresponding negative neurological and physiological effects of forgoing adequate sleep.[66]

C. Sleep Deprivation And Patient Safety

This overwhelming majority of resident physicians who experience sleep loss not only encounter personal health issues, but the effects of their sleep deprivation impacts patient care and safety.[67] As discussed above, sleep is necessary to replenish the brain to learn new information and skills. [68] Residency is designed to teach physicians complex and multi-faceted skills that they did not learn during the medical school program, which requires residents to be engaged and able to process and retain new information.[69] Learning new and specialized tasks is dependent on sleep to integrate this knowledge and subsequently recall these skills.[70] Thus, sleep deprived residents are less able to integrate the knowledge they are learning during their shifts and may be less likely to remember this information when interacting with future patients.

Numerous studies have examined the impact of physician fatigue on patient care, finding increased errors and other negative effects on the physician patient interaction.[71] In one study, eighty one percent of residents admitted that sleep has negatively affected their patient care in some manner.[72] In another study, when medical errors were compiled, forty one percent of physicians attributed the error to exhaustion.[73] The

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63. Stoller et al., *supra* note 25, at 3.

64. *Id.*

65. *Id.*

66. Many scholars have compared resident physician schedules to other professions such as pilots and truck drivers where federal regulation places limits on working hours as a measure for public safety. *See* Patton et al., *supra* note 39, at 7.

67. Olson et al., *supra* note 51, at 1391.

68. Bhavin Sheth et al., Practice Makes Imperfect: Restorative Effects of Sleep on Motor Learning. 3 PLoS ONE e3190 (2008); Glannon, *supra* note 62, at 47.

69. Whetsell *supra* note 24, at 25-28.

70. Sheth et al., *supra* note 68, at e3120.

71. *See* Whetsell, *supra* note 24, at 31; Buckley, *supra* note 41, at 315; Patton et al., *supra* note 49, at 7; Olson et al., *supra* note 51, at 1391.

72. Buckley, *supra* note 41, at 315.

73. *Id.*

California Board of Medical Quality Assurance conducted a study that showed in seventy five percent of cases, physicians reported knowledge of a negative impact on patient care arising from long work shifts.[74] Even if physicians do not commit an error, they may not be providing optimal care for patients if they fail to notice patient symptoms or issues they would have seen had they been more rested.[75] Other residents have reported such extreme exhaustion that they literally fall asleep onto their patients during their shift. [76] Thus, sleep deprivation has a direct and striking correlation to suboptimal physician patient interactions or medical error.

Compounding these startling admissions is emerging evidence relating to physician self-assessment of professional abilities despite sleep deprivation. Despite this level of error related to fatigue, Stoller and colleagues found some residents believe they develop a tolerance for sleep deprivation or that they can still perform their duties if they only "fight" sleep hard enough.[77] This overconfidence in ability despite sleep deprivation is unsupported by any evidence, and the statistics above suggest the contrary- that sleep deprivation endangers both the physician and the patient especially if the physician cannot accurately gauge her own limitations of practice arising from fatigue.[78]

IV. WHY MODAFINIL IS NOT A SOLUTION TO PHYSICIAN FATIGUE

Both scholars and physicians have suggested that residents should use the stimulant modafinil as a solution to overcome fatigue and prevent medical error.[79] However, suggesting or advocating that physicians use modafinil to forgo sleep and mitigate the effects of sleep deprivation from impairing the physician's physiological and cognitive state ignores the importance of sleep rather than a substitute and fails to consider the legal and ethical appropriateness of prescribing federally regulated stimulant drug for enhancement. To address why physicians using stimulants such as modafinil is neither a safe nor appropriate answer to the problem of physician fatigue, this section will describe modafinil, how it is federally regulated, and provide studies showing the drug's intended and unintended effects. This section will explain why individual physicians, employers, or

74. Whetsell, *supra* note 24, at 31.
75. *Id.*.
76. *Id.*
77. Stoller et al., *supra* note 25, at 8.
78. *Id.*
79. Rose & Curry, *supra* note 16, at 301-302; Webb et al., *supra* note 19.

physician associations should not adopt a practice of using modafinil for PESA based on the high potential for deleterious effects to the physician and patients.

A. Modafinil's Drug Profile

The FDA approved modafinil to improve wakefulness in adult patients with excessive sleepiness associated with sleep apnea, shift work sleep disorder, and narcolepsy.[80] The FDA has not approved modafinil for additional indications and specifically declined to expand approval to treat fatigue , so physicians prescribing modafinil to patients for other conditions occurs off-label. The exact mechanism of how modafinil works is unclear, but is believed to work selectively through the sleep/wake centers of the brain to activate the cerebral cortex, which is essential for wakefulness.[81] Studies have shown modafinil serves as a countermeasure for sleep loss and sustains continued wakefulness improve attention, alertness, spatial planning, and visual pattern recognition memory.[82]

Clinical trials show modafinil carries risk of producing both minor side effects such as headaches, nausea, and nervousness, as well as serious side effects such as rashes including Stevens-Johnson syndrome or a host of psychiatric symptoms such as mania, delusions, hallucinations, aggression, and suicidal ideation.[83] Other studies show negative side effects related to mood and behavior, including experiences of aggression and irritability.[84]

However, modafinil is not indicated for use by healthy individuals and the manufacturer, Cephalon, has specifically addressed patients using modafinil for PESA purposes.[85] In 2003, an article in the Residency Program Director's Alert suggested modafinil may provide a solution to

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80. Provigil package labeling, FOOD AND DRUG ADMINISTRATION, *available at*: http://www.accessdata.fda.gov/drugsatfda_docs/label/2007/020717s020s013s018lbl.pdf.

81. Media Fact Sheet: Provigil, Cephalon, *available at*: http://www.cephalon.com/fileadmin/media/downloads/PROVIGIL_Fact_Sheet.pdf; de Jongh et al., supra note 4, at 762.

82. de Jongh et al., *supra* note 1 , at 763.

83. Provigilpackage labeling. , FOOD AND DRUG ADMINISTRATION, 12-15 (Aug. 17,2007), *available at*: http://www.accessdata.fda.gov/drugsatfda_docs/label/2007/020717s020s013s018lbl.pdf.

84. *See* Douglas Kim, *Modafinil: The Journey to Promoting Vigilance and its Consideration by the Military in Sustaining Alertness*, HARV. L. SCHOOL LEGAL ELECTRONIC DOCUMENT ARCHIVE, *available at*: http://leda.law.harvard.edu/leda/data/826/Kim_07.html.

85. *Provigil package labeling*, FOOD AND DRUG ADMINISTRATION, 11-12 (Aug. 17, 2007), *available at*: http://www.accessdata.fda.gov/drugsatfda_docs/label/2007/020717s020s013s018lbl.pdf; Cephalon Response to JAMA Article, *The Effects of Modafinil on Dopamine and Dopamine Transporters in the Male Human Brain*, CELPHALON (Mar. 2009), *available at*: http://www.cephalon.com/media/jama-article-the-effects-of-modafinil-on-dopamine.html.

address resident physician's long and irregular schedules.[86] Responses from residency program directors poured in, and one director asserted, "There is no role for modafinil use by resident physicians. It is unethical and irresponsible for physicians to use a stimulant drug while performing duties related to patient care."[87] A Cephalon representative responded by deferring to FDA approved indications, stating that modafinil is a Schedule IV prescription drug and not intended for use in helping residents work longer hours, nor is the drug intended to help healthy people forgo sleep."[88] Despite this statement, in 2006 and in 2007 Cephalon attempted to broaden the market for modafinil by disseminating advertising material expanding the drug's use indication by directing physicians to consider modafinil when patients present with complaints of tiredness, decreased activity, or lack of energy.[89] Whether intentional or not, this statement implicitly suggested physicians should prescribe modafinil to generally boost wakefulness, which may be construed to encompass physicians prescribing modafinil to other physicians who present with fatigue because of too many hours on duty.

B. Federal Regulation of Modafinil Under the Controlled Substances Act

Under federal regulations set forth in the Controlled Substances Act, modafinil is classified as a Schedule IV controlled substance, which means it carries a potential for abuse, the drug has an accepted medical use, and abuse of the drug may lead to physical or psychological dependence.[90] 21 USC§ 829(c) dictates that a practitioner may only dispense Schedule IV substances to a patient by a valid prescription.[91] Section § 1364.04 sets forth a two prong requirement that for a prescription to be valid, a practitioner must issue it (1) for a legitimate medical purpose (2) in the course of professional practice.[92] I have argued elsewhere that the strict requirements set forth in the Controlled Substances Act limits physicians'

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86. Kelli Westcott, *Modafinil, Sleep Deprivation, and Cognitive Functioning in Military and Medical Settings*, 170 MILITARY MED. 333, 335 (2005).

87. *Id.*

88. *Id.*.

89. *Id.*

90. *Provigil package labeling*, FOOD AND DRUG ADMINISTRATION, 29 (Aug. 17, 2007), *available at* http://www.accessdata.fda.gov/drugsatfda_docs/label/2007/020717s020s013s018lbl.pdf; 21 USC §812 (b)(4).

91. 21 USC §829(c).

92. 21 USC §829. The statute does provide an exception where a practitioner other than a pharmacist may directly dispense the drug in a circumstance such as where the practitioner provides the patient a sample size drug during the office visit.

discretion to legally prescribe a controlled substance such as modafinil for PESA purposes. That is, "prescribing modafinil for PESA constitutes neither a legitimate medical purpose nor is prescribing PCEDs within the defined course of professional practice for physicians."[93]

Modafinil's regulatory classification means that the legality of prescribing controlled substances such as modafinil for enhancement purposes is far from established or accepted and cannot be assumed.[94] If a physician chooses to expand the confines of practice and prescribe modafinil to another physician, the prescribing physician gambles with potentially facing sanction by the state medical licensing board or even criminal penalty.[95] Controlled substance regulation recognizes the potential that prescription drug use/abuse has on both the individual arising from dependency as well as the potential for public harm to society.[96] Growing literature on studies examining the effects of modafinil further illuminates the reason for strictly regulated prescribing modafinil and adhering to stringent criteria for a valid prescription.[97]

C. Effects of Using Modafinil

In 2010, Repantis and colleagues published a comprehensive review of the effects of using modafinil that examined the following outcomes: mood, wakefulness, motivation, attention, concentration, memory, learning and executive functions.[98] Several studies in the review showed that modafinil improved motivation, enhanced performance for particular tasks, and improved memory on particular tasks.[99] In addition to these desirable effects, some studies demonstrated subjects experienced a sense

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93. *See* Katherine Drabiak-Syed, *Reining In The Pharmacological Enhancement Train: We Should Remain Vigilant About Regulatory Standards For Prescribing Controlled Substances*, under review for publication.

94. The Ethics, Law, and Humanities Committee of the American Academy of Neurology assumes prescribing of drugs for neuroenhancement is legally permissible, but does not explain its conclusion. Additionally, the Committee states that the medical principles for prescribing medications for treatment are the same as for enhancement, but this ignores the goals and guidelines within the purpose of medicine. *See* Dan Larriviere et al., *Responding to Requests From Adult Patients for Neuroenhancements: Guidance of the Law, Ethics, and Humanities Committee*, 73 NEUROLOGY 1406, 1408-1410 (2009).

95. *See* Drabiak-Syed, *supra* note 93 (discussing sanction by state medical board or criminal violation of the Controlled Substances Act for prescribing modafinil for PESA).

96. Panelists Normal Miller et al., Controlled Substance Laws; Are They Meeting the Health Needs of the Public?, 7 MICH. ST. J. MED. & LAW 81, 82 (2003).

97. *See* Drabiak-Syed, *supra* note 93 (discussing elements required for a valid prescription of a controlled substance).

98. Dimitris Repantis et al., *Modafinil And Methylphenidate For Neuroenhancement In Health Individuals: A Systematic Review*, 62 PHARMACOLOGICAL RESEARCH 187 (2010).

99. *See id.* Sustaining performance over time constitutes an enhancement as the subject becomes fatigued because the subject's performance would decrease absent any drug intervention.

of elation, or a high feeling, even to the point of being "overalert."[100] Other studies in the Repantis and colleagues review demonstrated negative effects on subjects. Some subjects felt increased anxiety or aggression and in one particular study, subjects reported experiencing both elation as well as anxiety.[101]Repantis and colleagues also found studies that demonstrated pertinent negative effects, such as decreasing subjects' amount and accuracy of speech and communication.[102] These studies show some subjects may experience the intended drug effects of feeling vigilant and increasing cognitive functioning, some may not, and some may experience the intended effect along with undesirable and even counterintuitive effects such as anxiety or inability to communicate.

In addition to research on how modafinil affects rested, healthy individuals, Repantis and colleagues separately reviewed studies that specifically tested modafinil on sleep deprived subjects. This additional research echoed some of the results above, but established several pertinent differences for how sleep deprived individuals respond to modafinil. Although some studies showed modafinil decreased fatigue and enhanced attention or memory, other studies showed that modafinil reduced subjective fatigue, but had no effect on attention or memory, which declined over time according to the subject's level of fatigue. These studies also showed that modafinil's efficacy can be tied to the time of day subjects are participating in the study and that modafinil may be less effective at night.[103] Other studies demonstrated modafinil was only effective with a particular dose, or that its efficacy lasted only a short time.[104] Repantis and colleagues surmised that for some subjects, modafinil may have cognitive enhancing effects for the first dose after a period of moderate sleep deprivation.[105] However, as the subject becomes more and more fatigued either from acute or chronic sleep deprivation, the modafinil will work to sustain the subject's sense of vigilance, but it will no longer produce the cognitive enhancing effects.[106]

Compiling multiple studies and finding studies that tested the drug on sleep deprived subjects shows both unexpected results and how the drug's effects change depending on the subject's level of fatigue, which are central to considering how the drug would potentially affect physicians. If

100. Repantis et al., *supra* note 98.
101. *Id.*
102. *Id.*
103. *Id.*
104. *Id.*
105. *Id.* at 204.
106. *Id.*

a physician takes modafinil as a measure to ward off future fatigue, she may experience an emotional high, become anxious, or experience communication difficulties that could interfere with her ability to assess the patient's needs, interact with the patient to communicate a course of action, and relay this information to the care team. If a physician takes modafinil once he is fatigued, he may find it promotes his sense of being alert, but he cannot remember information from a particular rotation to accurately place this patient's symptoms or physically fumbles when attempting to suture a wound. More problematically, the fatigued physician may not recognize the decreasing efficacy of the drug on his physiological and cognitive abilities and fail to see his own impairment.

D. Differential drug responses and unpredictable effects on physicians

These results as a whole showed that modafinil can enhance or improve motivation, performance, or memory, but these effects may only apply to particular individuals, only pertain to particular tasks, or the drug may not produce this effect at all in individuals who are sleep deprived. In other words, sleep deprived residents who take modafinil may experience a sense of vigilance or decreased fatigue, but their cognitive functioning may still decline as they become more and more sleep deprived. If the physician expects an increase in cognitive functioning and does not experience this result, the physician may attempt to remedy the result by escalating the dose, which could produce a different set of negative effects and side effects altogether.[107] Notably, the studies also show modafinil can produce unintended effects such as anxiety, aggression, or decreased ability to communicate, each of which undermine how a resident would approach and interact with patients and other physicians.

The differences in how subjects responded to modafinil and whether they exhibited the intended effects are also significant. Repantis and colleagues review showed modafinil works in varying degrees. Different individuals may experience its effects in a vastly different manner, and it may only be effective for particular tasks or situations. Different individuals may be more susceptible to experiencing negative effects of the drug either in addition to, or instead, of experiencing the intended effects.[108] Some research also suggests a vastly different individual

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107. Kim, *supra* note 84, at 22.

108. Alain Buguet, *Modafinil- Medical Considerations for Use in Sustained Operations*, 74 AVIATION,

reaction based on dosage as well as individual reaction to a particular dosage.[109] In one study, subjects who took higher doses of modafinil experienced jitteriness, shaking, headaches, and hallucinations.[110] As pharmacist Danielle Turner noted, the effects of modafinil are neither homogenized nor predictable.[111] These differences are central to considering the accuracy to which we can predict how individuals will react to taking modafinil, whether physicians would in fact experience the noted "positive" effects of the drug, or whether physicians would encounter negative outcomes relating to affect, mood, or physiological side effects.

Accordingly, some physicians who take the drug with the expectation of increasing cognitive functioning during periods of fatigue may find that the fatigue dissipates so they no longer fall asleep literally on their patients, but they do not have the ability to process the patient's symptoms and consider the appropriate course of action because their mind cannot focus. Furthermore, different individual responses to the drug can produce significant negative effects that would undermine the physician's ability to perform duties required for optimal interaction between the physician and the patient as well as the physician and the hospital staff. The physician taking modafinil could become aggressive toward the patient, undermining trust in the physician-patient relationship or become unyielding toward other hospital staff, straining employee relations. In another scenario, if the physician experiences impaired communication or anxiety, this may also lessen the physician's ability to form a positive relationship with the patient and understand all relevant symptoms or concerns may decrease and the physician may be unable to effectively relate this information to the rest of the care team. Studies cannot fully capture distinct individual response to the drug, especially when a physician uses the drug when he is experiencing real fatigue and is attempting to interact with a real patient or perform meticulous tasks such as assisting in a surgery. Furthermore, the controlled conditions of these studies cannot adequately predict how the drug would affect real sleep deprived physicians navigating the real demands of challenging patient cases.[112]

SPACE, AND ENVTL. MED. 659, 662 (2003).

109. *Id.*

110. *Id.* at 661.

111. Danielle Turner, *Cognitive Enhancement in the Pharmacy*, 280 THE PHARMACEUTICAL J. 691, 692 (2008).

112. Kim, *supra* note 84, at 21, 23, 27 (discussing operational applicability); Eric Racine & Cynthia Forlini, *Expectations Regarding Cognitive Enhancement Create Substantial Challenges*, 35 J. OF MED. ETHICS 469 at 469 (2009) (discussing how published studies do not account for the complexity and diversity of activities in thinking and learning.)

E. Unintended Problematic Effects of Modafinil Use

1. Overconfidence

Numerous studies found an unintended but significant effect on subjects' self-monitoring and self-assessment.[113] These studies demonstrated subjects misjudged their level of impairment arising from fatigue and ability to perform various study tasks, and that subjects were overconfident in projecting their own abilities.[114] Within two hours of ingesting modafinil, subjects rated their ability to perform various cognitive tasks as higher than their actual ability performing study tasks.[115] One study noted this becomes problematic because if the subject taking the drug experiences the subjective effects differently than the overt performance, then this increases the potential for human error.[116] This finding becomes even more troubling when taken together with Stoller and colleagues observation that some physicians believe they adapt to less sleep and retain the same cognitive abilities.[117] In practice, this could mean that a group of physicians forgo taking modafinil because they believe despite their fatigue, their cognitive abilities are intact. The second group who uses modafinil over a period of time builds more and more sleep debt and believes that the drug increases their cognitive abilities, when in fact their minds become more and more exhausted and they are objectively unable to perform at the level at which they believe they are performing.

If a physician takes modafinil with the expectation of increasing cognitive ability during a period of sleep deprivation on a long shift, then the physician may believe he is able to think through all possible diagnoses for the new patient or that he is able to perform a complex surgery, when in fact his cognitive ability and physiological abilities have decreased dramatically from his state of fatigue. This poses numerous problems beyond the obvious of the physician providing inefficient and possibly dangerous care, but it also raises the concern of self-assessment and external assessment of the physician's care by the rest of the care team.

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113. Buguet, *supra* note 108, at 662; Kim, *supra* note 84, at 19; Repantis et al., *supra* note 98, at 204.
114. Kim, *supra* note 84, at 19.
115. Buguet, *supra* note 108, at 662.
116. Kim, *supra* note 84, at 19.
117. Stoller et al., *supra* note 25, at 2.

2. Potential for Abuse and Dependence

Initial research and Cephalon's marketing material claimed that modafinil carried a "superb safety profile" and functioned differently than existing stimulants because it did not affect dopamine in the brain or pose risk of addiction.[118] However, post-market surveillance revealed modafinil does implicate dopamine by blocking dopamine transporters in the brain, which increases the amount dopamine in the brain.[119] This means despite original assertions relating to the drug's safety profile, individuals using the drug do in fact face the potential for drug dependency and addiction.[120] Repantis and colleagues' review also found that in several studies subjects reported experiencing the "good drug" effects of a stimulant drug, marked by a feeling of elation or "high" in some subjects or at certain dosages.[121] The federal regulatory classification of modafinil as a Schedule IV controlled substance explicitly recognizes that modafinil poses risk of abuse and addiction to individuals using the drug. [122] Modafinil's potential to induce addiction is also significant as it means physiological or psychological dependency on the drug may undermine the individual's autonomous decision-making capacity to weigh the risks and benefits related to continued use of modafinil.[123]

The potential for abuse or dependence has serious implications for physicians who may use the drug because they think they cannot work a long shift without modafinil and become psychologically dependent on using it. Even if a physician experiences the intended effects of increased vigilance and cognitive abilities during the first few uses of the drug, the physician may attempt to forgo sleep for long periods of time or sustain a schedule with only a few hours of sleep and eventually the drug's potential for cognitive enhancement will likely decrease. The physician then may continue taking the drug believing this to be the only way to work the required shifts, or begin taking higher doses to compensate to the diminishing effects. Alternatively, and more troubling, the physician may continue taking a steady dose of modafinil but she may not be able to

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118. Westcott, *supra* note 86, at 334.

119. Nora Volkow, et al., *Effects of Modafinil on Dopamine and Dopamine Transporters in the Male Human Brain*, 301 J. OF THE AM. MED. ASS'N. 1148 (2009).

120. *Id.*; Heidi Ledford, *Cognitive Enhancement Drug May Also Cause Addition*, NATURE NEWS, *available at*: http://www.nature.com/news/2009/090317/full/news.2009.170.html.

121. Repantis et al., *supra* note 98, at 194-201.

122. Provigil package labeling, FOOD AND DRUG ADMINISTRATION, *available at* http://www.accessdata.fda.gov/drugsatfda_docs/label/2007/020717s020s013s018lbl.pdf; 21 USC§ 812 (b)(4) (2006).

123. Larriviere et al., *supra* note 94, at 1410.

accurately assess a growing decline in her professional skills if she subjectively feels alert. That is, a physician may continue to use modafinil based on perceived need or as a mechanism to feel alert on each shift and the normal response of fatigue to inform the physician that his body and brain need rest becomes muted. This scenario raises cause for concern because the physician is still sleep deprived, the physician's fatigue is negatively affecting patient care and the physician's interaction with the rest of the care team, but now the physician's does not recognize that these potential problems are arising from sleep deprivation and continued use of modafinil.

V. MODAFINIL (MIS)USE AND PHYSICIAN IMPAIRMENT DEFINED BY STATE LAW

The unpredictability of how physicians would react to modafinil along with the danger that using modafinil poses to physicians and patients means modafinil constitutes an ill-advised solution from a pragmatic perspective. In addition to these concerns, if a physician uses modafinil while on duty, this implicates a prohibition against practicing medicine while using or under the influence of non-medical drugs. This section will describe how a physician using modafinil during a shift violates the physician's ethical and legal duties governing the medical profession. Importantly, violation of these duties can result in professional sanction to the physician or expose the physician and hospital to medical malpractice liability.

A. Use, Misuse, Abuse, and Dependence

When a physician takes a prescription controlled substance for a non-medical reason for enhancement, this practice can range from occasional use to dependency and addiction. Unlike taking a prescription controlled substance for a legitimate medical purpose, federal regulatory agencies do not recognize a permissible "use" of stimulant drugs for enhancement purposes.[124]

If physicians use modafinil for PESA, this "use" can be considered misuse or abuse.[125] The Substance Abuse and Mental Health Services Administration (SAMHSA) defines the use of prescription drugs for a

124. *Prescription Medications: Misuse, Abuse, Dependence, and Addiction, Substance Abuse Treatment Advisory, Substance Abuse and Mental Health Services Administration, available at:* http://www.kap.samhsa.gov/products/manuals/advisory/pdfs/Prescription-Meds.pdf

125. *Id.*

non-medical reason as using the drug for the experience that the drug causes.[126] SAMHSA clarifies these non-medical reasons include using a drug to stay awake, increase focus, or increase attention.[127] According to these definitions, a physician who obtains a prescription and uses modafinil to forgo sleep during a long shift or to increase waning concentration is using modafinil for a non-medical reason. The National Institute on Drug Abuse (NIDA) equates non-medical use of prescription drug use, to prescription drug abuse.[128] This includes the use of modafinil for cognitive enhancement purposes. Thus, according to SAMSHA and NIDA's definitions, physician use of modafinil for PESA constitutes misuse and abuse of the drug. These definitions are significant because they reiterate that the military's erasure of removing the line between maintenance and enhancement cannot apply to how we classify civilian use of modafinil. This is especially salient in a closely regulated profession such as physicians.

Physician use of modafinil for PESA may also rise to the level of dependency and addiction. The Diagnostic and Statistical Manual IV defines substance dependence as a "maladaptive pattern of substance use leading to clinically significant impairment or distress" and sets forth a list of criteria that signify addiction.[129] Physicians may be especially prone to substance abuse as a means to alleviate the high stress of the profession and their ability to access a supply of drugs.[130] Even if physician use of modafinil for PESA does not rise to the level of dependency, SAMSHA's and NIDA's classifications that non-medical use of the drug for enhancement constitutes misuse or abuse is significant because it delineates how to approach a physician's ethical and legal duties of practicing medicine.

B. Physicians' Ethical Duty to Refrain From Substance Use/Abuse

Standards governing the practice of medicine recognize the link between physicians' level of well-being (or impairment) and the quality of

126. *Id.*

127. *Prescription Drug Abuse in the Workplace, Substance Abuse and Mental Health Services Administration*, 1 (Nov. 29, 2010), http://www.workplace.samhsa.gov/Workplaces/pdf/Prescription%20Drug%20Abuse%20Fact%20Sheet.pdf.

128. National Institute of Drug Abuse, Definition for Prescription Drug Abuse (Nov. 23, 2010), MedLine Plus, *available at*: http://www.nlm.nih.gov/medlineplus/prescriptiondrugabuse.html.

129. AMERICAN PSYCHIATRIC ASSOCIATION. DIAGNOSTIC AND STATISTICAL MANUAL IV OF MENTAL DISORDERS. (2000).

130. *Prescription Drug Abuse in the Workplace, Substance Abuse and Mental Health Services Administration*, 1 (Nov. 29, 2010) http://www.workplace.samhsa.gov/Workplaces/pdf/Prescription%20Drug%20Abuse%20Fact%20Sheet.pdf.

care a physician can provide to patients. As in other professions such as public carriers or police officers, physicians and patients fall into the legal category of a "special relationship" that implicates public health and safety.[131] These other "special relationship" professions set forth explicit limits on work hours and prohibit substance abuse during shifts in recognition that a person's performance of the occupation is particularly susceptible to decreased physiological and cognitive functioning arising from fatigue or substance abuse. [132] Furthermore, physicians must perform technical tasks using specialized skills and exercise professional judgment relating to diagnosis and treatment options, which constitutes what some scholars have classified as safety-sensitive work.[133] That is, patient care involves such a high risk of injury from even a momentary lapse of attention or judgment that professional guidelines governing the medical profession explicitly prohibit substance abuse during a shift.[134]

The American Medical Association's (AMA) Office of General Counsel recognizes the immense responsibility that physicians must uphold in caring for patients and the effect that physician substance abuse can have on the physician's ability to perform duties and deliver optimal care to the patient.[135] The Office of General Counsel has stated, "When physicians or other individuals who are employed to protect the health and safety of the public abuse drugs, the consequences are potentially life threatening. . .[W]hile there are no good data in the extent to which drug abuse by physicians results in substandard patient care, even a small risk cannot be tolerated. The harm to a patient from an impaired physician can be life threatening."[136] The AMA articulated this position in Opinion 8.15 regarding substance abuse, which unequivocally states that it is unethical for a physician to practice medicine while under the influence of a controlled substance, alcohol, or other chemical agents that impair the ability to practice medicine.[137]

Applying SAMSHA's and NIDA's definitions, a physician *using* modafinil for PESA during a shift equates to a physician *abusing* modafinil during a shift. As discussed in Section IV, a physician's use of

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131. Dana Devon, *Drug Testing of Health Care Workers: Toward a Coherent Hospital Policy*, 23 AM. J. L. AND MED. 399, 415 (1997).

132. *See* Patton et al., *supra* note 39, at 20.

133. Devon, *supra* note 130, at 407.

134. *Id.*

135. Devon, *supra* note 131, at 406.

136. *Id.* at 407.

137. American Medical Association, *Opinion 8.15 Substance Abuse* (Nov. 29, 2010), *available at*: http://www.ama-assn.org/ama/pub/physician-resources/medical-ethics/code-medical-ethics/opinion815.shtml.

modafinil for PESA during a shift poses a risk to the physician arising from numerous unintended effects and side effects that would unpredictably affect the physician's performance, judgment, and patient care abilities. Permitting or endorsing physician use of modafinil knowing these attendant risks to patients is incompatible with the AMA's stance and express prohibition against practicing medicine under the influence of a controlled substance. As the Council on Ethical and Judicial Affairs aptly noted, when a physician's health is compromised, so too is the patient's.[138]

C. Physicians Legal Duty to Refrain From Substance Use/Abuse

State legislatures recognize the link between physician impairment, the ability to effectively practice medicine, and the resulting effects on patient care. To monitor physicians' ability to practice medicine, state law sets forth two complementary statutory sections. First, state law contains specific prohibitions against practicing medicine while impaired or practicing while under the influence of drugs. Second, state statutes task the respective state medical boards with the duty of protecting patients, the obligation to investigate allegations of impaired physicians, and the authority to respond appropriately with treatment or professional sanction.[139] To understand how state law approaches a physician using modafinil, this subsection will describe how three different states define impairment and what actions these states may take to address an impaired physician.

1. Professional Misconduct and Physician Impairment

States statutes vary with respect to how each legislature defines professional misconduct arising from physician impairment or a decline in the ability to effectively practice medicine.[140]

New York defines professional misconduct as "practicing the profession while the ability to practice is impaired by alcohol, drugs, physical disability, or mental disability" or "being habitually drunk or being dependent on, or a habitual user of narcotics, barbiturates,

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138. *See* Physician Health and Wellness, *Report on the Council on Ethical and Judicial Affairs 5- I-03*, 2, *available at*: http://www.ama-assn.org/ama1/pub/upload/mm/code-medical-ethics/9031b.pdf (last visited Nov. 29, 2010).

139. *See* Phyllis Coleman & Ronald Shellow, *Restricting Medical Licenses Based on Illness is Wrong-Reporting Makes it Worse*, 9 J. L. & HEALTH 273, 281-282 (1994/1995).

140. The following state law discussion is only a small example of how some states define impairment.

amphetamines, hallucinogens, or other drugs having similar effects."[141] The first clause can be interpreted to mean that a physician using a controlled substance with the ability to change the physician's judgment, affect, and skills constitutes practicing while impaired. The second clause's non-inclusive listing means that modafinil would likely also fall into the category of these drugs because like the other listed drugs, modafinil is regulated as a controlled substance. Further, modafinil is classified within the subcategory of stimulant drugs along with amphetamines and would have similar intended enhancement effects. Using modafinil in a habitual manner refers to a range of use frequency, either from using every shift to turning to modafinil as the solution when the physician seeks to forgo sleep and obtain a cognitive functioning boost. By listing several examples of professional misconduct, the legislature unequivocally seeks to classify practicing medicine in a condition that would pose a danger to patients or undermine the physician's professional skills and judgment as professional misconduct.[142]

Similar to New York, Michigan's statute refers to the concept of impairment and the relationship of a physician's substance use. Michigan states that "impaired or impairment means the inability or immediate impending inability of a health professional to practice his or her health profession in a manner that conforms to the minimum standards of acceptable and prevailing practice for that health profession due the health professional's substance abuse, chemical dependency, or mental illness or the health professional's use of drugs or alcohol that does not constitute substance abuse or chemical dependency."[143] According to the plain meaning of the statute, one possible interpretation infers that a physician's use of modafinil equates to an inability to practice medicine in a manner that conforms to the prevailing practice because using stimulants for PESA during a shift is not the current prevailing practice. Even without this assumption, this definition recognizes that the mere use of a substance even if it does not rise to dependency can compromise the physician's professional ability to practice medicine. The standard of practice set forth by the AMA reiterates that physician use of substances during a shift imposes a potentially grave risk of harm to patients.[144] Accordingly, under New York's law mere use modafinil during a shift would constitute a state of impairment.

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141. N.Y. EDUC. LAW § 6509 (2010).
142. N.Y. EDUC. LAW § 6509 (2008).
143. MICH. COMP. LAWS § 333.16106(a) (2010).
144. *See* Devon, *supra* note, at 406-407.

On its face, Texas' law appears to set a higher bar for unprofessional conduct or physician impairment. Texas provides that a violation occurs when the physician "is unable to practice medicine with reasonable skill and safety to patients because of: . . . excessive use of drugs, narcotics, chemicals, or another substance."[145] Despite the qualification of "excessive use," which would seem to permit occasional of use substances such as modafinil during a shift, the statute contains an additional informative clause. A subsequent section states that a physician who "fails to practice medicine in an acceptable professional manner consistent with public health and welfare" commits a professional violation.[146] As discussed in Section IV, studies show modafinil affects individuals in varied ways, sometimes achieving the desired result of vigilance and cognitive enhancement, sometimes only sustaining vigilance without affecting cognition, and, problematically, in some instances undermining the user's ability to self-assess capabilities and performance.[147] These scientific results indicate that using modafinil constitutes using a substance that impairs judgment, professional capabilities, performance, and elevates the risk of medical mistake or injury to the public. Thus, like New York and Michigan, Texas would likely classify physicians using modafinil during a shift as a professional violation.

Although states may approach the issue with slightly varied terminology, these states demonstrate that legislatures recognize the effect that substance use during a shift has on a physician's professional capabilities, judgment, and skills. This decline in ability directly undermines a physician's ethical duties to protect the health and safety of the patient because it exposes patients to a risk of harm from error or oversight. Repantis and his colleagues' review showed that a physician who continues to take modafinil while sleep deprived and building more and more sleep debt may experience a sense of vigilance, but he may no longer receive the cognitive boost, and may not be cognizant of his diminishing cognitive function. The potential for decline in a physician's ability along with the significant possibility of overconfidence means using modafinil for PESA would likely impair the physician's ability to practice medicine.

2. Consequences of Professional Violation and Impairment

Once the state medical board receives allegations of a physician's

145. TEX. OCC. CODE ANN. § 164.051(4) (2010).
146. TEX. OCC. CODE ANN. § 164.051(6) (2010).
147. *See generally* Repantis et al., *supra* note 98.

alleged professional misconduct or impaired practice, the state medical board may take several courses of action outlined in a corresponding section of the respective state's statute. New York promulgates penalties for professional misconduct that range from the rehabilitative end of the spectrum such as mandated training or courses, to holding a hearing to suspend or revoke the physician's state license to practice medicine.[148] Michigan authorizes the state medical board to conduct an investigation into the allegations and refer to the appropriate committee to impose sanction on the alleged offending physician.[149] Finally, Texas generally authorizes the state medical board to take disciplinary action against the offending physician.[150] Each of these provisions demonstrate the legislatures' intent to sanction behavior and actions where physicians' judgment, capabilities, and performance is compromised and where potential harm to patients increases. Therefore, if a physician chooses to use modafinil during a shift, the physician will not only face personal health risks and expose his or her patient to additional risks, but may also face the possibility of sanction for committing a professional violation.

In addition to professional sanction, a physician who practices medicine while impaired or commits a professional violation may face varied claims under medical malpractice tort liability. For example, Michigan, specifically states that a physician who practices medicine while impaired violates a general duty of negligence or a failure to exercise due care.[151] Additionally, the hospital that employs the physician may face liability if it breaches its duty to provide quality medical care to its patients.[152] The potential for individual and corporate liability provides an additional incentive for the physician to not use modafinil and for the hospital to prohibit its use while on site.

VI. CONCLUSION

Physicians as a profession are already exposed to ill health effects arising from long, demanding schedules and sleep deprivation and exposing physicians and patients to additional risks by permitting or advocating that physicians simply use a stimulant drug is inappropriate and problematic. Although the military has creatively redefined the terms for permitting and endorsing stimulants such as modafinil as a means to

148. N.Y. EDUC. LAW § 6511 (2008).
149. MICH. COMP. LAWS § 333.16221 (2010).
150. TEX. OCC. CODE ANN. § 164.051 (2010).
151. See MICH. COMP. LAWS § 333.16221 (2010).
152. Devon, *supra* note 130, at 412-419.

achieve alertness during continuous performance, further research of the modafinil's effects demonstrate numerous pragmatic, ethical, and legal concerns of crossing the bridge into civilian use. Modafinil cannot biologically replace sleep and it does not fix the underlying problem that physician exhaustion creates for the physician's cognitive, neurological, and physiological health and its direct correlation to suboptimal patient care. The FDA has not approved modafinil as a means to generally increase wakefulness or counteract employer imposed sleep restriction. Federal regulations set forth in the Controlled Substances Act strictly control physician prescribing of this stimulant in recognition of its powerful effects and potential for abuse. Additionally, recent studies demonstrate both the unpredictability of modafinil's capability to produce its desired result once the user becomes sleep deprived and the troubling implications for the user to effectively evaluate performance and ability under the influence. These differential drug reactions and unintended side effects are fundamentally incompatible with the safety sensitive medical profession. Notably, federal agencies recognize that physicians' special relationship with patients means prohibiting the use of a substance that could elevate risk of injury to the patient. Furthermore, if physicians choose to circumvent these ethical duties of practicing medicine, physicians are still bound by a legal duty to refrain from substance use that impairs their ability to practice medicine during patient care and may face professional sanction or tort liability for noncompliance with state law for using modafinil.