

Up all night: The medicalization of sleeplessness

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## **ABSTRACT**

**MAIREAD EASTIN MOLONEY: Up all night: The medicalization of sleeplessness.**  
(Under the direction of Victor Marshall)

Sleeplessness – a universal experience with a variety of causes – may be increasingly diagnosed and treated as the medical condition insomnia, or “medicalized.” This research provides quantitative and qualitative evidence of the medicalization of insomnia at the level of patient-physician interaction. I analyze 14 years (1993-2006) of data from the National Ambulatory Medical Care Survey, a nationally representative dataset of physician office visits. I describe trends over time for: complaint of sleeplessness, diagnosis of insomnia and prescription of sedative hypnotics (select benzodiazepines, Trazodone and non-benzodiazepine sedative hypnotics [NBSHs]). Independent variables are age, gender, race and insurance status. To measure change over time, I conduct linear regressions using weighted visits, calculate slope estimates and report P-values. I also carry out semi-structured qualitative interviews with patients (N=27) prescribed a sedative hypnotic, and their physicians (N=8).

Between 1993 and 2006 complaint of sleeplessness increased 30% (3.3 million to 4.7 million); diagnosis increased 6-fold (869,000 to 5.2 million) and prescriptions for all sedative hypnotics increased. Most notable was the 23-fold increase in NBSHs (550,000 to 12.8 million). Slope change and differences in proportion were positive and significant for insomnia diagnoses, NBSHs and Trazodone. Female gender was significantly associated with

prescriptions of Trazodone. Patients 55+ were significantly more likely to receive a prescription for a benzodiazepine or a NBSH.

Physicians were cognizant and critical of medicalization. They conceptualized insomnia as a symptom, part of the aging process, or a reaction to stress – not a disease. Despite stated bias, respondents prescribed sleep aids at least some of the time. Compliance was influenced by time constraints, consumerism, and pre-existing prescriptions. Patients entered their office with medical knowledge from non-medical sources including the Internet, social networks and direct to consumer advertising.

Patients said that insomnia was a symptom of stress, anxiety or comorbid illness. Fear of addiction to sleep aids was common. Factors mediating their physician interaction were time constraints, pre-existing prescriptions and consumerism.

These data elucidate both the increased medicalization of sleeplessness and micro and macro fueling factors. Even when not formally re-defined as insomnia, sleeplessness is increasingly treated with medical solutions.

To Kevin

## ACKNOWLEDGEMENTS

In 2002, I had several concrete notions about graduate school: 1) my admission was almost certainly some sort of clerical error; 2) I would finish in four years if it killed me; and 3) I had to tackle the challenges of higher education all by myself.

I never did figure out if the first was true, but I'm pretty sure it's too late now. As for my time resolution, seriously attempting to complete the program in four years would have killed me. Most importantly, if #3 were true, I would never have completed the PhD program. Or maintained the barest modicum of sanity during the seven-year process. I am able to type these words from the safety of a post-doctoral fellowship because I had the best help – and lots of it – from some of the brightest and most generous spirits on the planet.

A great deal of credit is due to Victor Marshall. Victor chaired both my masters and dissertation committees, as well as one of my comps. He was my advisor, mentor, employer, and occasional life counselor. He never, ever gave up on me and he always had my back.

Many well-meaning people asked me in hushed tones if my dissertation committee was making my life a nightmare of revisions and non-stop work. I had to be honest: My committee was fantastic. I feel privileged to have worked with Barbara Entwisle, Gail Henderson, Bob Konrad and Peggy Thoits. They are not only brilliant and insightful, I honestly felt that they were rooting for me every step of the way.

Graduate school is an excellent producer of anxiety, and no topic struck the fear in me quite like statistics. Even though I did straightforward analyses for this dissertation, none of

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I also want to thank Michael Roettger and Gerald Lackey for getting me started with the NAMCS dataset. Importing fourteen years of data is no party, but they both used their smarts and good humor to help me through the importing and cleaning processes.

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## **CHAPTER 1**

### **OVERVIEW OF THE MEDICALIZATION OF SLEEPLESSNESS**

#### **Introduction**

The goals of this dissertation are: 1) to document and provide quantitative and qualitative evidence that sleeplessness, a universal experience with a variety of causes, is being re-conceptualized and increasingly diagnosed as the medical condition insomnia; and 2) to argue that key aspects of the medicalization process cannot be adequately understood without greater scrutiny of the doctor-patient interaction and the forces that influence its outcomes.

Medicalization is the process by which a formerly non-medical issue comes to be described, accepted or treated as a medical problem (Conrad and Schneider 1992; Zola 1986; Williams 2005). Medicalization theory has offered insight into the social construction of a number of disorders, but sleep and sleep disorders are relatively new fields of study for both the biological and social sciences (Williams 2005; IOM 2006). Traditional medicalization analysis offers insight into the social construction of illness primarily at the conceptual and institutional levels; these levels describe the ways in which concepts of illness are conceived, described and legitimized (Conrad and Schneider 1992; Conrad 2007).

I argue that these traditional analyses ignore a key component of the medicalization process – the interaction between patient and physician. I suggest that multiple mechanisms may be influencing the outcome of the patient physician interaction and providing



momentum to the medicalization of sleeplessness: a) the pharmaceutical industry as a key stakeholder in the disorder of insomnia and “educator” of both patients and physicians and b) an increased propensity for patients to act as consumers. In order to investigate the medicalization of sleeplessness, I use a mixed methods approach that is both descriptive and exploratory.

First, in order to address the research question, **Is there evidence of the medicalization of sleeplessness at the level of doctor-patient interaction?**, I conduct secondary analysis of the National Ambulatory Medical Care Survey [NAMCS], a nationally representative data set of physician office visits. My analyses focus on the outcomes of these office visits and measurable trends related to complaint, diagnosis, and treatment, that may be indicative of medicalization. These results provide a partial answer to the research question, as well as a framework for my qualitative analyses.

I also conducted interviews with both patients who sought medical attention for symptoms of insomnia and the physicians who treated them. The qualitative data address the aforementioned research question and offer greater insight into the manifestation of meso-level theoretical constructs within the patient-physician interaction.

This research contributes to the literature by expanding the limited sociological literature on the medicalization of illness at the interactional level and incorporating the example of insomnia. The intention of this research is not to determine whether the insomnia “epidemic” represents the increased prevalence of a “real” disease. Rather, I am interested in examining the social forces that may be fueling the perceived epidemic and how they may manifest in the interaction between doctor and patient in the form of increased patient complaint, diagnoses and prescriptions of sedative hypnotics.

In the following pages, I offer background information regarding sleeplessness including reported rates, risks and comorbidities, describe the social and economic costs of insomnia, and offer alternative explanations for an increase in sleeplessness. In Chapter 2, I discuss how medicalization theory informs my research, note my hypotheses and provide a brief overview of my methods. In Chapter 3, I provide detailed methodology, findings and a brief discussion about my quantitative analyses. Chapter 4 provides detailed qualitative methodology, as well as findings from physician interviews. In Chapter 5, I present data from patient interviews. Finally, in Chapter 6, I provide discussion linking together the quantitative and qualitative data. In addition, implications and future research opportunities are noted.

### **Background and Significance**

Sleep is a socially meaningful activity (Williams 2005; Hislop and Arber 2003; Kroll-Smith and Gunter 2005).<sup>1</sup> We routinely discuss our sleep, or lack thereof, with friends, partners and colleagues. The occasional inability to sleep, or sleeplessness, is part of the universal human experience and has been recorded by authors both ancient and modern, including the Roman poet Horace, William Shakespeare and Franz Kafka (Goldberg and Kaufman 1990; Bains 2006). Ancient Egyptians “record a lament for three living hells, one of which is ‘to be in bed and sleep not’” (Goldberg and Kaufman 1990: 8). Sleeping aids, in the forms of potions, herbs and rituals have been used for thousands of years, with varying degrees of success (Goldberg and Kaufman 1990; Williams 2005). Despite the endurance and prevalence of the experience of sleeplessness, recent publications in both the lay and

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<sup>1</sup> Simon Williams, whom I cite frequently throughout this proposal, has written perhaps the current definitive work on the sociology of sleep. Included in his book is a thorough and riveting discussion on the social history of sleep, which I will not attempt to reproduce here.

medical literatures have proclaimed sleeplessness an “epidemic” and insomnia is being labeled an “unmet public health problem” (Namen et al. 2002; Hamilton 2006; IOM 2006).

### *Rates of sleeplessness*

Have we truly become a nation of insomniacs? When defined as the inability to fall or stay asleep, insomnia is estimated to affect millions of individuals (IOM 2006; Baines 2006). However, due to vast differences in definitional criteria and reporting methods, it is debatable *exactly* how many adults are affected. Insomnia symptoms are variably reported as affecting ten to fifty percent of the US population (Goldberg and Kaufman 1990; IOM 2006). Most sources report that approximately 85 million to 100 million US adults experience at least occasional insomnia (IOM 2006; Nelson 2007). Approximately thirty million people, or 10% of the US population, are thought to suffer from chronic insomnia – a more persistent form of sleeplessness that is often linked to poor health outcomes (IOM 2006; Bains 2006; Nelson 2007).

Recent national surveys, such as the NSF Gallup poll (see Bains 2006), confirm an increase in reported symptoms of insomnia among the general public. Diagnoses of insomnia in a clinical context also appear to be on the rise. Data from the National Ambulatory Medical Care Survey [NAMCS], a nationally representative data set of physician office visits, indicates that office visits resulting in a diagnosis of insomnia increased fourfold between 1990 and 1998, from about 800,000 per year to 2.7 million<sup>2</sup> (Namen et al. 2002). There is evidence that patients presenting with sleeplessness as a reason for office visit are increasingly likely to receive a diagnosis of insomnia; previously, patients with the same

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<sup>2</sup> My 1998 estimates differ slightly, but not substantially, from those of Namen et al., due to differences in the scope of diagnostic codes used.

complaint were more likely to receive a diagnosis of depression or anxiety (Skaer et al. 1999).

### *Risk and comorbidity*

Insomnia appears to be most prevalent in women and older adults (IOM 2006; Bains 2006). African American and Asian individuals are less likely than whites to report insomnia or trouble sleeping (Pearson et al. 2006). Insomnia is more likely to occur in individuals of low socio-economic status [SES]; these individuals report greater subjective impairments such as excessive daytime sleepiness than their higher SES peers (Gellis et al. 2005). Other risk factors include mental illness, family history of insomnia, stressful lifestyle, and participation in shift work (Edinger and Means 2005).

Insomnia is highly comorbid with a number of physical and mental conditions. A recent national survey found that, of individuals who reported insomnia or trouble sleeping, only 4.1% *did not have* a co-occurring mental or physical health condition (Pearson et al. 2006). Physical and neurological conditions that are commonly comorbid with insomnia include obesity, congestive heart failure, hypertension, chronic pain syndromes, chronic renal failure, Parkinsonism, epilepsy and multiple sclerosis (Bains 2006; Pearson et al. 2006).

It is estimated that at least 40% of persons with insomnia suffer from mental illness (Ford and Kamerow 1989). Insomnia is often seen in conjunction with depression, anxiety disorders and even substance abuse (IOM 2006; Zee and Turek 2006). However, direction of causation is difficult to pinpoint. For instance, a study by Ford and Kamerow (1989) found that individuals suffering from persistent insomnia were more likely to *develop* major depression at a later date. While insomnia is considered a risk factor for disorders including

depression, anxiety and substance abuse, it may also be the result, or a symptom, of these disorders.

### *The social and economic costs of sleeplessness*

Related to the medicalization process is the concept of ‘healthicization’ or ‘surveillance medicine’ (Armstrong 1995; Conrad 2007; Seale et al. 2007). Healthicization promotes the idea that responsible citizens are morally obligated to take charge of their own health outcomes, both for the good of themselves and the good of the public (Seale et al. 2007). The social and legal consequences for not taking responsibility for one’s sleep habits are increasingly punitive. Excessive daytime sleepiness (EDS) has emerged as a medical diagnosis and is thought to affect approximately 10% of the population (Rosenthal 2005). In a relatively short period of time EDS has evolved from “a virtually unknown medical condition” to a “known public health risk” (Rosenthal 2005; 485).<sup>3</sup>

The most common cause of EDS is insufficient sleep, although it may be caused by, among other things, sedating medications or shift work (Rosenthal 2005). The consequences of EDS include “drowsy driving”; a behavior increasingly viewed as deviant and subject to social control. In many states, legislation has been passed to combat and penalize drowsy driving (NCSL 2007). “Driving while fatigued” is labeled a crime and, in cases of vehicle accidents with proof of driver fatigue, harsher penalties are enacted (NCSL 2007). In New York, legislation was recommended that would require medical examinations and mandatory sleep apnea testing for persons holding a commercial driver’s license (NCSL 2007). In the documentary *Wide Awake*, by insomniac Alan Berliner, a physician notes that scientists are

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<sup>3</sup> As Conrad astutely observes of EDS, “if this is a ‘disorder,’ it has a reasonably high prevalence among college students attending early or late classes!” (Conrad 2007: 12).

working to develop a “sleep-a-lyzer” to better detect the level of sleep deprivation in a reckless driver (2007).

Where once insomnia might have been seen as nothing more than an inconvenience, it is increasingly portrayed as a threat to both individual well-being and society at large. In addition to the aforementioned daytime sleepiness and drowsy driving, negative outcomes of insomnia are thought to include: decreased physical and mental health, reduced quality of life, decreased productivity, difficulty with memory, decreased work performance, increased absenteeism, and increased use of health care services (Bains 2006). Disasters of enormous proportion, including the Exxon *Valdez* oil spill and the Challenger space shuttle explosion, are currently thought to be the results of errors made by sleep-starved workers (Williams 2005). Economic costs of insomnia include substances used to treat sleeplessness, increased use of health care services, increase in workplace accidents and increased morbidity. For more detailed listing of the direct costs of insomnia, please see Table 1.

**Table 1: The Direct Costs of Insomnia in the United States for 1995.  
(Reproduced directly from IOM 2006: 159)**

	Cost (millions \$)
<b>Substances used for insomnia</b>	
Prescription Medications	809.92
Nonprescription medications	325.80
Alcohol	780.39
Melatonin	50.00
<b>Total cost of substances</b>	<b>1,966.11</b>
Health care services for insomnia	
Outpatient physician visits	660.00
Psychologist visits	122.40
Social working visits	75.30
Sleep specialist visits	18.20
Mental health organization	153.00
In-patient hospital care	30.80
Nursing home care	10,900.00
<b>Total</b>	<b>11,960.70</b>
<b>Total direct costs</b>	<b>13,926.11</b>

SOURCE: Walsh, JK, Engelhardt CL. 1999. The direct economic costs of insomnia in the United States for 1995. *Sleep* 22 (suppl 2):S386-S393.

#### *Current explanations*

Despite a measurable increase in the reported rates of insomnia symptoms and insomnia diagnoses, I believe that we should exercise caution in assuming that these indicators are tantamount to an increase in clinically significant insomnia at the population level. Arguably, a shift in the conceptualization of sleeplessness has taken place – from a symptom of a disorder to a disorder in and of itself - and while we may only speculate as to cause, the social and economic consequences of this trend make it worthy of further

investigation. In this section I outline three possible explanations for the sleeplessness “epidemic.”<sup>4</sup>

Changing cultural norms may be one factor fueling the sleeplessness epidemic (Mooallem 2007; Zee and Turek 2006). Technology allows us to participate in a global economy and a “24-hour workday.” In some workplace cultures, visible fatigue, whether from non-stop international travel or 18-hour workdays, is a badge of honor and proof of commitment to one’s company (Mooallem 2007). In addition, the ‘sandwich generation’ – adults who have both children living at home and parents who require substantial assistance – is expected to perform dual-duty caregiving and breadwinning roles, resulting in less sleep and poor health outcomes (Meltzer and Mindell 2006). Finally, an apparent cultural imperative to engage in excess – whether in work or play – has given rise to a new American motto: “You can sleep when you’re dead.”<sup>5</sup>

Dr. Thomas Roth, director of the Sleep Disorder and Research Center at Henry Ford Hospital in Detroit, “is cynical about the nation’s discussion on sleep” and describes public interest as “fashionable” (Hamilton 2006). Sleep has been dubbed “the new bottled water” and the cultural imperative to achieve the elusive 8 hours per night has begotten a multi-billion dollar industry (Singer 2007). A variety of consumer products including special pillows, mattresses, aromatherapies, lotions and soothing CDs are marketed to aid in the achievement of the ‘ideal’ eight hours of sleep per night (Williams 2005; Seale et al. 2007). Americans spend \$4.5 billion annually on prescription and non-prescription sleep medications combined. Nap centers, spa-like businesses where customers are allowed to

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<sup>4</sup> Hereafter, I will use the word “epidemic” sans quotation marks. This acknowledges that an insomnia epidemic – whether socially or biologically based – is in fact occurring.

<sup>5</sup> The exact origin of the phrase is unclear, but it is commonly associated with an infamous memo sent by Amazon.com management to its employees in a customer-service call center (Leibovich 1999).



comfortably recline in a dimly lit room for 20-40 minutes, are gaining in popularity (Hamilton 2006; Singer 2007). These centers are particularly popular in urban hubs of business; in New York City a twenty-minute nap can cost \$15 (Singer 2007).

Along with changing cultural norms, shifting US demographics may be playing a role in the insomnia epidemic. The US ‘Baby Boom’ generation, typically thought of as individuals born between the years 1946-1964, is now entering late-middle and older age. The need for sleep appears to decrease with age (Grigg-Damberger 2006). There is debate about whether this decrease in sleep time is ‘natural’ for older adults or the result of an increased likelihood of chronic illness or discomfort (Grigg-Damberger 2006; Zee and Turek 2006).

Regardless, men typically begin to experience decreased sleep time in their forties and women in their fifties; this reduction in sleep is typically caused or compounded by an increase in the number of times an individual wakes up during the night (Grigg-Damberger 2006). Many of the factors associated with sleeplessness – female gender, chronic illness and low SES – are more frequently found in older populations (Zee and Turek 2006). As noted by Barsky and Boros (1995), the ‘Boomer’ generation is also known for its decreasing tolerance for any ills or discomforts, resulting in increased visits to the doctor and demand for new and better drug treatments.

While cultural trends and an aging population are two possible factors fueling the insomnia epidemic, a recent essay in the New York Times, written by doctors, argues that the real epidemic is not in experiences such as insomnia, which they describe as “everyday,” but in the epidemic of diagnoses that translate normal human experience into illness or disorder (Welch et al. 2007). Highlighted in their critique are the following factors: a) the

medicalization of everyday life compounded by a decreased tolerance for discomfort, b) our country's large but poorly directed investment in health care, and c) the drive to discover diseases early, resulting in "pre" diagnoses like pre-hypertension, pre-diabetes and even pre-cancer. The end result is that more than 50% of the population receives a diagnosis of disease. This begs the question, "If more than half of us are sick, what does it mean to be normal?" (Welch et al. 2007).

Diagnoses confer a variety of both positive and negative connotations and consequences. Having a recognized disease provides benefits including personal validation, relief from guilt or anxiety, a social network and medical support (Ziporyn 1992). Some individuals desire the legitimacy afforded by medicalized disorders and may form support groups or grassroots organizations in an effort to leverage power and demand this recognition and its subsequent benefits (Barker 2008; Ziporyn 1992). Chronic Fatigue Syndrome (CFS) is an example of a disorder that lacks a biomedical blueprint at this time, but individuals (mostly women as they are the most common sufferers of CFS) have organized to fight for a medical definition and official diagnostic recognition (Richman and Leonard 2001).

From the sociological perspective, expansion and proliferation of diagnoses, including insomnia, appear to be on the rise. As I have summarized, changing cultural norms, an aging population or the medicalization process may each be fueling the insomnia epidemic. To some degree, all three factors are likely contributors. The focus of this dissertation, however, will be on the process of medicalization.

## **CHAPTER 2**

### **THEORY OF MEDICALIZATION AND HYPOTHESES**

In the following section I will outline the types of medicalization, levels of the medicalization process, and some of the forces that fuel it. I will focus on the pharmaceutical industry and increased consumerism, two factors that I believe are fueling the medicalization of insomnia at the level of physician-patient interaction. Finally, I will note the challenges of measuring medicalization.

#### **Types of medicalization**

Two major categories of ‘ills,’ expanding beyond biological or organic disease, are encompassed by medicalization: ‘deviant’ behavior and formerly ‘natural’ biological processes. Examples of deviance that have been partially or fully medicalized include: Attention Deficit Hyperactivity Disorder [ADHD], alcoholism, spousal abuse, child abuse, and social anxiety (Conrad and Schneider 1992; Lane 2007). Examples of natural processes that have become partially or fully medicalized include: pregnancy, pre-menstrual syndrome [PMS], fertility, overweight, aging, erectile dysfunction and (female *and* male) menopause (Armstrong 2003; Jutel 2006; Groopman 2002; Lock 1993; Rosenfeld and Faircloth 2006).

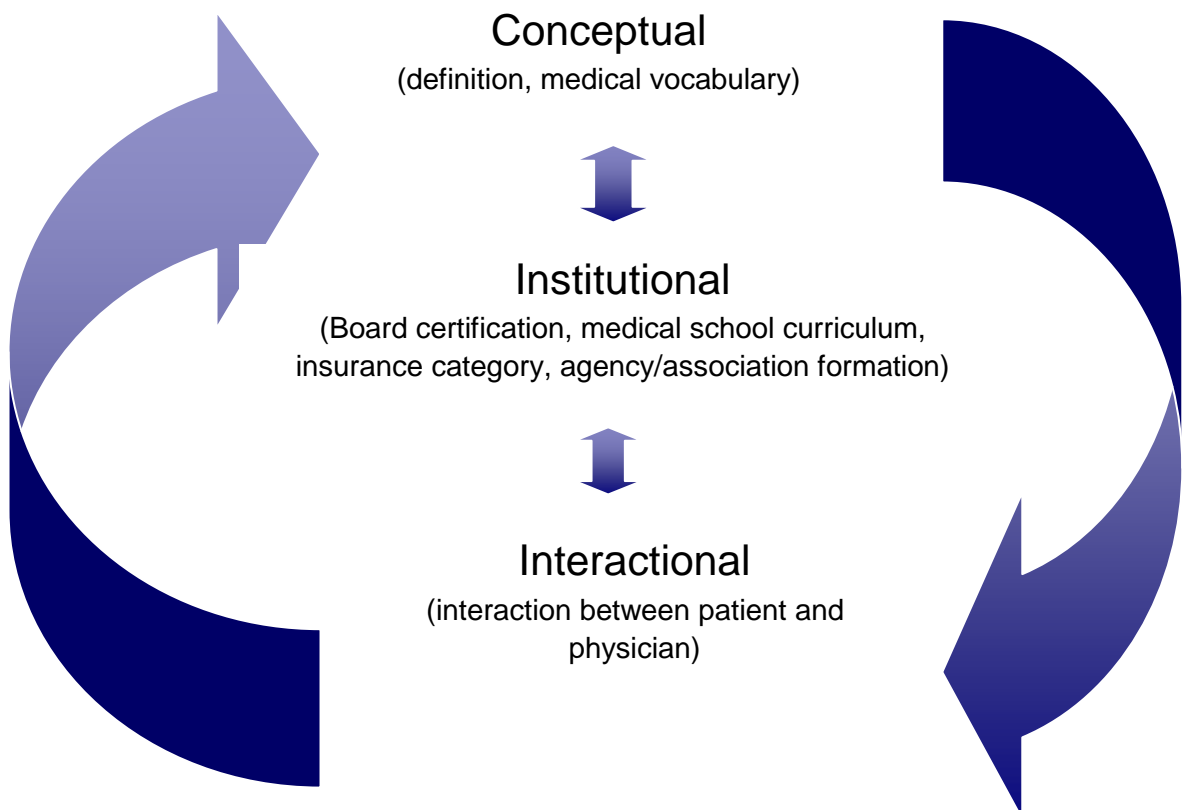
Categories of deviance and biological processes are not mutually exclusive. Sleeplessness is a salient example of a disorder that contains both of these elements. Sleep is a biological process, but as noted previously, excessive daytime sleepiness (EDS), a

consequence or symptom of insomnia, is increasingly considered a deviant behavior with punitive consequences, particularly in the context of “driving while fatigued” (NCSL 2007).

### **Levels of medicalization**

The process of medicalization occurs at three levels: institutional (codification and bureaucratization) conceptual (construction and use of medical vocabulary) and interactional (typically conceptualized as patient-physician but may include other individual level interactions). These levels are loosely viewed as hierarchical, particularly in earlier conceptualizations of medicalization, but are in fact iterative and influence one another. For a visual representation of this process, please see Figure 1.

**Figure 1: Levels of the Medicalization Process**



Traditional analyses of the medicalization process rely on evidence at the conceptual or institutional levels. According to Conrad and Potter (2000), the conceptual level is the “key” to the medicalization process. By definition, they assert, medicalization implies expansion of medical boundaries; one means of boundary expansion is altering parameters of diagnoses (Conrad and Potter 2000). Conceptual expansion of a previously defined disorder means that formerly excluded populations may be diagnosed and treated (Conrad and Potter 2000; Barker 2008). From the viewpoint of patients this may be a desirable outcome, as medical diagnoses offer legitimacy and affirmation of the illness experience (Barker 2008; Kroll-Smith and Floyd 1997). For drug companies, this outcome ensures a greater number of prescriptions may be written for a larger population of ‘sick’ individuals.

For instance, Attention Deficit Hyperactivity Disorder [ADHD] was initially conceptualized as a diagnosis of hyperactivity and inattention in children (Conrad and Potter 2000). Symptoms of ADHD were exhibited primarily in school settings and most children were expected to “outgrow” these symptoms by the time they reached adolescence (Conrad and Potter 2000). However, beginning in the 1980’s, a movement to recognize “adult hyperactives” was fueled by the “medicalization of underperformance” and increased availability of disability rights (Conrad and Potter 2000). Symptomatology expanded from the classroom to the workplace and even into the realm of interpersonal relationships. Thousands of adults, in turn, proclaimed via a deluge of medical and lay press that they “recognized” themselves in the descriptions of adult sufferers of ADHD. This conceptual expansion enabled thousands of previously undiagnosed adults and adolescents to receive a diagnosis of ADHD and to be treated accordingly, most often with prescription stimulants such as Ritalin (Conrad and Potter 2000).

Disease conceptions that are medicalized at the institutional level are typically guaranteed access to and influence on large sections of the population. Organizations may not only manage illnesses, but also create and promote them as well. The ‘disease’ of alcoholism serves as an example of this latter phenomenon. Medical professionals, though “not hapless bystanders...were not the leading crusaders” in the medicalization of alcoholism (Conrad and Schneider 1992: 73). The Yale Research Center of Alcohol Studies and the self-help group Alcoholics Anonymous were actively involved in influencing modern conceptions of excessive alcohol use (Conrad and Schneider 1992). These organizations were in large part responsible for re-casting chronic drunkenness as a disease instead of a sin or moral failing. In addition, E.M. Jellinek, early director of the Yale center, created the phase progression model of alcoholism and cemented the idea of alcoholism as a progressive, diagnosable, treatable disease (Conrad and Schneider 1992).

There is some evidence that insomnia has been medicalized at the conceptual and institutional levels. Conceptually speaking, one may point to the expansion of insomnia definitions, their increased number and the striking disparity<sup>6</sup> amongst them as evidence of medicalization. In 2004 the ICD-9-CM (International Classification of Diseases) Coordination and Maintenance Committee Meeting proposed expansion of the diagnostic categories for the following sleep disorders: insomnia, hypersomnia and sleep apnea. Their stated justification read: “Sleep medicine is a new but growing medical subspecialty” (2004: 29). Regarding insomnia, the committee proposed multiple new codes and subcategories to the existing ICD-9 codes. By their admission, these additions were intended to better align their diagnostic categories with the American Academy of Sleep Medicine’s manual “The

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<sup>6</sup> A disparity in definitions is potentially indicative of the medicalization process in that it indicates a lack of certainty of the ‘disease’ parameters or symptoms, while conversely ‘making it’ medical by use of a set medical definition.

International Classification of Sleep Disorders.” They promised, “In future revision, additional modifications will be proposed for other sleep disorders.” Though the proposed additions related to insomnia diagnoses are too extensive to list here, I include them in Appendix 1.

As previously noted, disparity amongst and between insomnia criteria makes for wildly divergent estimates of prevalence in epidemiological studies. This fact is not lost on clinicians and researchers and several have called for the construction and use of uniform criteria (Lichstein et al. 2003; Ohayon et al. 1997). In an effort to produce cohesive criteria, Lichstein and colleagues “reviewed two decades of psychology clinical trials...to determine common practice with regard to frequency, severity and duration [of insomnia]” and constructed quantitative criteria (2003: 427). Competing diagnostic methods lacking uniformity of criteria may serve to over-diagnose borderline populations and/or populations who would not meet different definitional criteria. While the quantification of insomnia symptoms may be useful in eliminating or reducing disparity in prevalence rates, it assumes a neutrality and objectivity that belies the qualitative context inherent in patient-physician interactions – a dimension I further explore in my research. Further exploration of the conceptualization of insomnia including the history of diagnoses construction and the current state of disparity, while beyond the scope of this study, would be a worthwhile topic for future research.

The institutionalization of sleep and sleep disorders is both relatively recent and, it seems, increasingly popular. One example of the institutionalization of insomnia, or more accurately its consequences, is evident in the aforementioned criminalization of “driving

while fatigued” (see page 6) (NCSL 2007). As noted by Conrad and Schneider (1992) the criminalization of deviance cannot occur without the specific sanction of the state.

Another indicator is the establishment of a myriad of organizations dedicated to raising education and awareness of sleep disorders. The National Sleep Foundation (NSF), a self-proclaimed “independent non-profit” organization that seeks donations (including the nonprofit staple: “Donate your old vehicle”) on its website, recently sponsored Drowsy Driving Prevention week November 5-11, 2007 ([www.sleepfoundation.org](http://www.sleepfoundation.org)). In addition, the NSF website offers a multitude of sleep “facts,” resources to facilitate sleep “at all ages,” a convenient online “sleep shop” and ways to get involved in “sleep advocacy.” The motto of the NSF is “Waking America to the Importance of Sleep” and their oft-cited 2005 sleep survey revealed that less than half of Americans report getting a good night’s sleep on a nightly, or near-nightly basis (NSF 2005). Interestingly, a recent New York Times article revealed that the NSF is “largely financed by the pharmaceutical industry” (Mooallem 2007).

The institutionalization of sleep disorders in the realm of medical education and specialization is relatively recent. In 1978, its inaugural year, the American Sleep Disorders Association (now the American Academy of Sleep Medicine [AASM]) created an examination committee for clinical polysomnography (an overnight test in a sleep laboratory that records physiological signs) and 21 candidates passed the exam (IOM 2006). The number of candidates completing the certification process grew exponentially and in 2005, approximately 32,000 candidates became “diplomats” of the AASM (IOM 2006). However, for many years AASM certification was not formally recognized by the American Board of Medical Specialties (ABMS). Responding to growing demand, the ABMS reconsidered its position. In 2007 the ABMS allowed physicians to become board certified in Sleep



Medicine. Although sleep medicine encompasses multiple sleep disorders, insomnia is by far the most commonly diagnosed and treated sleep disorder in the U.S. (IOM 2006; Bains 2006).

While institutional stakeholders and medical vocabulary may be powerful instigators and indicators of change, respectively, these phenomena may not seem highly relevant to individuals engaged in the illness experience. After all, it is within the physician office visit that patients share their perceived health issues and, in turn, physicians offer medical diagnoses and treatments. It is within this interaction that life problems are transformed into medical problems by the power of medical authority and thus, the outcomes of these interactions, taken together, have a major impact on the medicalization process. Put bluntly, if insomnia diagnoses are not being made and sedative hypnotics are not being prescribed then how can we assert that the process of medicalization is in fact occurring?

Although I have noted examples suggestive of the medicalization of insomnia at the conceptual and institutional levels, little sociological work has been done that examines individual experiences of sleeplessness. One exception is the work of Hislop and Arber (2003). Hislop and Arber (2003) examined the coping strategies of a small sample of women dealing with sleep problems. They concluded that the ‘personalized strategies’ used by their participants, (e.g., relocating to another room for sleep, taking warm baths or drinking warm milk) were evidence of the *demedicalization* of sleep disorders. However, as pointed out by others (see Williams 2005; Conrad 2007; Lowenberg and Davis 1994), the use of personal or holistic strategies to manage a problem is not necessarily evidence in favor of demedicalization. Nevertheless, I believe that Hislop and Arber offer a significant

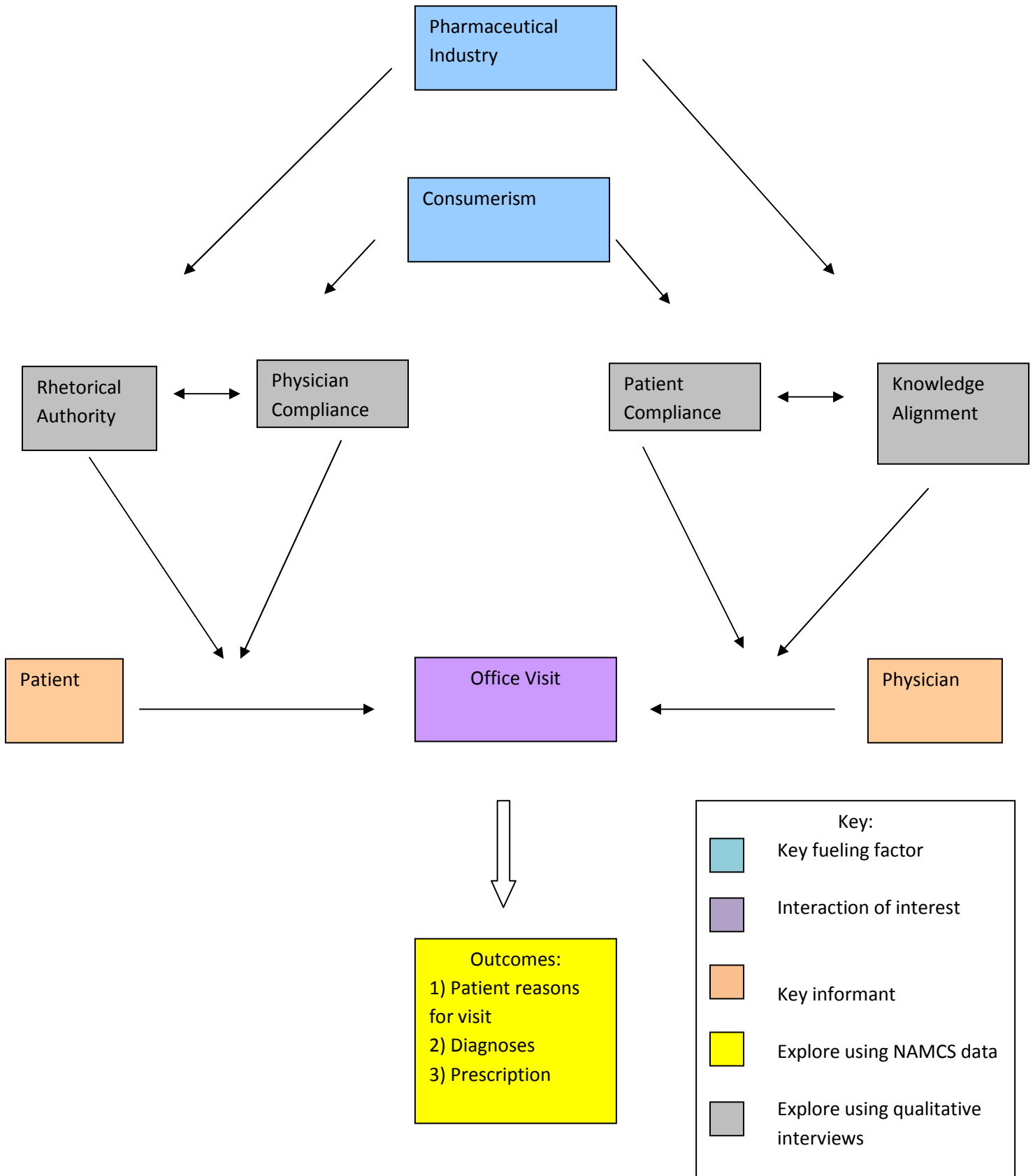
contribution to the literature by providing insight into the medicalization of sleep disorders at the individual level.

### **Forces of medicalization**

The forces that drive the medicalization process vary over time. Medicalization theory evolved from claims that medical professionals engaged in appropriating social ills as medical problems and claimed expertise in both diagnosis and treatment of these ills (Zola 1986; Conrad and Schneider 1992). In the previous century, the authority of the medical profession, medical and scientific discoveries, and increased specialization in the medical profession were highlighted as among the foremost factors fueling medicalization (Conrad 2005). In recent years, biotechnology (e.g. pharmaceuticals and genetics), patients acting as consumers, and ‘managed care’ have all been hypothesized as key agents of medicalization (Conrad and Leiter 2004).

I assert that, in the case of sleeplessness, two of these factors, the pharmaceutical industry and increasing consumerism among patients, are working symbiotically to further the medicalization process at the individual level. Considered contextually, these factors both instigate and are the result of shifting power dynamics between patients and physicians. In the following paragraphs I provide further detail on the pharmaceutical industry and consumerism, as well as introduce meso-level theoretical constructs that result from these macro level forces and potentially moderate the patient-physician interaction. For a visual representation of my conceptual model, please see Figure 2.

**Figure 2: Conceptual Model**



## *Pharmaceutical Industry*

The pharmaceutical industry is a key institutional stakeholder in the treatment of disease and disorder (Angell 2004; Elliott 2003; Rothman and Rothman 2003; Conrad 2005; Lane 2007). Many contend that drug companies do not merely sell drugs; they sell the disorders that create a need for their drug (Elliott 2003; Conrad 2005; Angell 2004; Lane 2007). Pharmaceutical companies counter that they are doing a public service by raising awareness of under-diagnosed and under-treated illnesses (Gellad and Lyles 2007; Kessler and Levy 2007). Regardless of the true motive of the pharmaceutical industry, education for the public or profit for their shareholders, it is undeniable that the pharmaceutical industry possesses powerful and influential marketing tools that have altered patient-physician interaction.

I argue that the pharmaceutical industry primarily targets consumers through direct to consumer (DTC) advertising and arms them with “rhetorical authority,” a form of medical knowledge gleaned from non-medical sources. Physicians also are targeted by sales visits, drug samples and/or gifts and continuing medical education (CME) courses are often sponsored and created by pharmaceutical companies. As sleep disorders are a minimal component of medical school curricula, these pharmaceutically sponsored forms of knowledge fill gaps in expertise and create “knowledge alignment” with the pharmaceutical companies. These factors, I suggest, may be moderating the patient-physician interaction.

### *Targeting patients*

According to Conrad (2005:6) a successful pharmaceutical marketing campaign convinces the consumer that his/her perceived disorder is both “common and abnormal, thus

needing treatment.” The primary mechanism that pharmaceutical companies use to convince consumers that they “need” a particular drug is direct-to-consumer (DTC) advertising. Pharmaceutical companies posit that DTC advertisements are “educational tools” that empower patients, arming them with valuable knowledge (Kessler and Levy 2007). Most advertisements, however, combine facts and rationale with emotional appeal (Frosch et al. 2007). Medication is seen as a socially sanctioned method of regaining control over a disorganized or unpleasant component of one’s life. Making changes to one’s lifestyle or other treatment options are rarely mentioned, if ever (Frosch et al. 2007).

Some would argue that pharmaceutical companies are merely tapping into our current obsession with a “culture of enhancement” (Elliot 2003; Rothman and Rothman 2003). American culture appears to grow increasingly intolerant of even mild symptoms or benign problems (Barsky and Boros 1995). Non-life threatening conditions have become the focus of increased medical specialization (Elliot 2003; Barsky and Boros 1995). As a result, there is a great deal of money to be made from treating consumers and their rapidly multiplying ills (Barsky and Boros 1995; Nelson 2007).

DTC advertisements urge consumers to “ask their doctor if [drug name here] is right for you.” Often patients are encouraged to visit the drug’s website where potential patients can play “games” or take quizzes that “test their knowledge” about a certain disorder. Both DTC advertisements and drug websites are designed to arm the patient with medical information from a non-medical source, a type of information Kroll-Smith has dubbed *rhetorical authority* (2003). Laypersons are encouraged to absorb the carefully delimited knowledge offered by the pharmaceutical company and use their rhetorical authority as a leveraging tool within the patient-physician encounter.

Websites for insomnia drugs are no exception. When I began this research in 2007 I visited both the Ambien and Lunesta websites. On the Lunesta website, I was encouraged to play a game, testing my knowledge of insomnia (Lunesta.com 2007). On the Ambien website I discovered a ‘helpful’ list of questions you can print and take to your doctor to aid him or her in making the correct diagnosis (of insomnia) (Ambien website 2007). At the end of the questionnaire, a 7-day free trial of Ambien CR was offered, as the patent for regular Ambien expired in that year.

Revisiting this website in 2009, I was immediately re-directed to ambiencr.com. In just two years Sanofi-Aventis has done an impressive job of marketing to adults of all demographics, while emphasizing the vast superiority of Ambien CR to ‘regular’ or generic Ambien. The main graphic on the home page depicts five adults (appearing to be an Asian woman, an African American man, a Caucasian women, a Latino woman and an older Caucasian man) standing, smiling, on an enormous rotating Ambien CR tablet. The tagline seems to promise more than just a good night’s sleep. It reads “Want to get more out of life? See how Ambien CR may help.” The testimonials offered by the fake patients<sup>7</sup> were fascinating and promised to restore one’s good humor, adventurous spirit, as well as one’s ability to be a good hostess, a “go-getter” at work, and a pancake-maker at home.

Lunesta has followed suit with a much expanded website including a “dream kit” offering helpful resources such as: “special savings,” a “doctor discussion guide”, a sleep calculator, an updated version of the 2007 game determining your lack of sleep, a sleep diary, sleep tips and a place to “share your story.” These tools not only offer rhetorical authority that can be leveraged in an office visit, but enable patients to self-identify as having a

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<sup>7</sup> Sadly, this attractive and diverse group were “not actual patients” nor were their fascinating testimonials authentic (“The Good-humored man is back”, “Mr. Fix-It”, “How I conquered the morning”, “How I faced reality” and “The Hostess with the Most-ess”).

problem that is both common and abnormal (Conrad 2005). Self-diagnosis and deciding upon a preferred treatment may occur long before the office visit (Barker 2008).

Pharmaceutical companies are committed to encouraging the use of sleep aids in particular because they are incredibly profitable (Saul 2007). In the first nine months of 2006, \$362 million was spent on advertisements for “the most popular sleeping pills, marketing the idea that interrupted sleep or the lack of instantaneous sleep are alarming conditions that require intervention” (Singer 2007). A pharmaceutical industry journal article proclaims: “Pharma’s ultimate customers are overweight and can’t sleep” (Kelly 2006: 86). Between 2001 and 2005, sales for prescription insomnia drugs have more than doubled, growing from \$1.1 billion to \$2.8 billion (Nelson 2007). The market is expected to double again by the year 2010, with sales projected to reach the \$5 billion mark (Nelson 2007).

The introduction of Ambien in 1992 heralded the entry of a new, ostensibly more effective family of sedatives. Ambien was the first of a new class of hypnotics, the non-benzodiazepine hypnotics, also commonly called the “z” drugs (due to the fact that their non-brand names contain the letter “z”). This newer generation of sleep drugs, which in addition to Ambien include Lunesta, Sonata and Rozeram<sup>8</sup> are thought to lack the negative side effects and risks of dependence present in the former hypnotic class of choice, the benzodiazepines.

Recently, however, the “z” drugs have come under criticism for two major shortcomings: a) lack of effectiveness and b) disturbing side effects exhibited by some patients. Recent data indicate that, while more effective than placebo, the newer generation sleep drugs, on average, reduce the amount of time it takes to fall asleep by 12.8 minutes and

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<sup>8</sup> Rozeram is technically not a “z” drug as it has a different mechanism of action and is promoted as strictly non-habit forming. However, I include it here as it is often discussed alongside the “z” drugs.

extend sleep time by 11.4 minutes (Saul 2007). Despite this minor-seeming benefit they are “wildly popular” with consumers (Saul 2007). This popularity has not been tempered by recent reports of bizarre side effects. In 2007, the FDA mandated the makers of Lunesta, Ambien and 11 other sleep medications to issue warnings about a host of reported risks including sleep-driving, sleep-eating, sleep-walking and making purchase while “asleep” (Saul 2007). One woman reported painting the front door of her house while “asleep” on Ambien (Saul 2007).

Despite the considerable increase in prescriptions written and profits accrued, the pharmaceutical industry (as well as many health professionals) claim that insomnia remains under-diagnosed and under-treated (Baines 2006; Nelson 2007). This “under-diagnosis” creates a market with “vast potential” (Nelson 2007:64). “Through educational efforts, *marketers can help increase [insomnia] diagnosis rates – and scripts*” (Nelson 2007:64, emphasis my own). It is unclear what exactly comprises these “educational efforts.” What is clear is that these companies do not merely market drugs, they market the ideas that justify the drugs and use targeted information to arm patients with rhetorical authority.

### *Targeting physicians*

Physicians may be increasingly relegated to the role of “gatekeeper” to technologies and pharmaceuticals, but they are still the individuals in control of the prescription pad, and pharmaceutical companies are keenly aware of this (Conrad 2005; Angell 2004; Lane 2007). While pharmaceutical companies spend billions of dollars to target patients, they spend even more money advertising to physicians (Angell 2004; IMS Health online 2007). In 2001, \$6.4



billion dollars were spent trying to promote drugs to physicians. In contrast, the DTC budget that year for consumers was \$2.6 billion (IMS Health online 2007).

The key mechanisms used by pharmaceutical companies to target physicians are: “detailing” by drug representatives, providing samples of complimentary drugs to be dispensed to patients and sponsoring education through continuing medical education (CME) courses (Angell 2004). Another mechanism, advertising in medical journals, comprises less than 1% of the pharmaceutical industry’s marketing budget and thus is worthy of only a brief mention (Angell 2004). However, it has been suggested that since many medical journals are financially dependent on drug advertisements, it is possible that they are influenced in their choices of which articles to publish (Angell 2004).

In 2001, 88,000 drug sales representatives visited doctor’s offices and nearly \$11 billion in “free samples” were dispensed (Angell 2004). In addition to free samples, drug representatives commonly provide free gifts, free meals and other niceties to doctors and their office staff. As Angell (2004) makes the case, these gifts and samples are hardly “free.” They are intended to create and maintain a customer base for their latest drugs and the billions of dollars spent on gifts and samples must be recouped in the cost of the drug. In fact, while doctors may protest that they are not influenced by the “3 F’s” drug representatives are trained to proffer – “food, flattery and friendship” – it is human nature to engage in reciprocity and physicians’ prescribing patterns often reflect this (Angell 2004).

As new competitors have entered the insomnia market, drug representatives have targeted physicians with increased dispensation of drug samples (Nelson 2007). According to Impact Rx, Takeda, the company that makes Rozerem, allowed doctors to provide four out of

ten treatments to their patients at no charge. Comparatively, the market leaders Ambien CR and Lunesta provided free product for only two out of ten patients (Nelson 2007).

Targeting physicians in the marketing of sleep drugs may be particularly effective because, until quite recently, physicians were offered very little training on sleep disorders in their medical school curriculum. According to one estimate, physicians in Great Britain received a cumulative total of 5 minutes of medical school education devoted to sleep disorders (Williams 2005). In the United States, 2007 was the first year that a physician could receive board certification as a sleep specialist (NSF 2007). As a result, physicians may believe that their clinical knowledge of sleep disorders is sub-par. In a recent survey, physicians were asked to rate their knowledge of sleep disorders; the majority ranked their knowledge as “fair” (60%) or “poor” (30%). Only 10% of physicians surveyed rated their knowledge of sleep disorders as “good” (Papp et al. 2002).

An effective way for drug companies to exploit this “gap” between education and practice is by sponsoring and influencing CMEs. CMEs allow pharmaceutical companies to tailor the information received by doctors about particular disorders, and particular drug treatments are often prominently featured (Angell 2004). Since physicians are required to regularly attend continuing education courses throughout their career, the CME’s meet a mutual need for doctors and drug companies (Angell 2004). I suggest that the combination of inveiglements – incentives, samples and CMEs - promote a *knowledge alignment* wherein doctor’s knowledge and skill gaps are filled by drug and disorder information presented by drug companies.

### *Patient as Consumer*

Patients wield increased power as they “consume” medical services and enter the doctor -patient relationship with the ability to self-diagnose and request a specific treatment (Conrad and Leiter 2004; Conrad 2005; Barker 2008). Even the pharmaceutical industry is recognizing the increased power of the patient (Kelly 2006). A pharmaceutical journal article proclaims “Consumers play a larger decision making role in their healthcare than ever before and they’re looking for ways to lead better lives” (Nelson 2007; 66). The idea of “better lives” is facilitated, in part, by the aforementioned burgeoning culture of enhancement.

No longer content with feeling or looking “normal,” expectations among the lay public have reached an all-time high as innovations in medical techniques and knowledge provide seemingly limitless opportunity for self-improvement (Rothman and Rothman 2003). Patients expect their state of health to be “better than well” and all it takes to achieve this state is the almighty dollar (Elliot 2003; Rothman and Rothman 2003; Greenhalgh and Wessely 2004). Consumer demand for cosmetic surgery, including breast enlargement, human growth hormone (HGH) therapy, and treatment for sexual “dysfunction” has increased exponentially (Rothman and Rothman 2003; Elliot, Conrad 2007; Wienke 2005; Rosenfeld and Faircloth 2006).

It is no wonder then, that sleep has in many ways become just another commodity. Jessie Gruman, president of the non-profit Center for the Advancement of Health is quoted as saying “Now when people can’t sleep for a couple of nights, they think they are part of a national sleep epidemic and there should be something to fix it. You can buy sexual arousal, a new shape for your face, a skinnier silhouette, so why shouldn’t you be able to buy sleep?” (Singer 2007). I contend that this increased consumerism is in part a by-product of increased

rhetorical knowledge among patients and is facilitated by greater amounts of *physician compliance*.

### *Physician compliance*

Physician compliance is “the expectation that physicians will accept patient expertise” regarding patient definition of the experience (i.e., diagnosis) and patient definition of the solution (i.e., treatment) (Freidson 1988; Barker 2008). As Barker demonstrates in a study of an online support group for Fibromyalgia syndrome (FMS) (2008) this type of encouragement was a prevalent theme among members. Members posting about negative physician experiences wherein their concerns were dismissed, their diagnosis not validated or their specific drug requests not prescribed, received sympathy from other online members and admonitions to search for a physician who would meet their requests. Patients seek physician compliance in an effort to have their illness experiences legitimized and treated. In the process, these patient-consumers are inadvertently reifying and expanding the boundaries of medical authority.

Barker’s research, while fascinating, provides insight into only one side of the interactional dyad. What incentive, if any, would a physician have to accept patient expertise? According to some physicians, when patients offer expertise derived from DTC advertising, it is an “intrusion” in the patient-physician interaction (Stange 2007). Valuable time is taken away from an already brief encounter and the extraneous knowledge and self-diagnosis may in fact obscure the underlying “true” issues that prompted the office visit (Stange 2007).

Why then, would some physicians be receptive when faced with a patient who demands their compliance in diagnosis and or treatment? Perhaps because, in some cases, it makes their jobs easier; physicians are faced with numerous barriers to doing their jobs properly. Outpatient visits average approximately 10 minutes of face-to-face time and physicians are expected to “prioritize, personalize, and integrate care for an average of 3 to 4 problems” (Stange 2007; 2). Given this plethora of constraints and barriers to an ideal office visit, some physicians may view a patient’s specific demands as a time and energy saving asset, rather than a nuisance.

In addition, physicians have long sought the goal of patient compliance, wherein patients adhere to their prescribed treatment regimen. Some medical sociologists have criticized the goal of patient compliance as a means of social control (Zola 1986). However, some physicians may view a patient’s request for a specific drug treatment as evidence that they will comply with the treatment regimen if they receive that particular drug.

*In sum...*

Unlike disorders that are recognized as being recently medicalized (e.g. chronic fatigue syndrome, multiple chemical sensitivity), sleeplessness is a condition that has existed and been recognized as part of the human condition for thousands of years (Goldeberg and Kaufman 1990). As previously noted, it is universally experienced (Bains 2006). Why then might rates of insomnia be increasing so rapidly?

As evidenced by Barker (2008) and others, the office visit can be used as a vehicle for constructing and expanding the boundaries of medical authority while simultaneously offering legitimacy to the patient’s perceived problems (see also Kroll-Smith and Floyd

1997). The patient and physician both bring knowledge to this interaction that is influenced and shaped, to some degree, by the pharmaceutical industry. The pharmaceutical industry uses a variety of advertising and “educational” strategies to imbue patients with rhetorical authority and to increase knowledge alignment among physicians. Rhetorical authority may reify consumerist tendencies among patients and prompt them to demand physician compliance. In turn, physicians may be more receptive to pharmaceutically induced rhetorical authority as it aligns with their own pharmaceutical-industry-influenced knowledge base. Some physicians may see offering acquiescence as a means of increasing patient compliance and increasing the efficiency of their interaction.

While it is evident that the outcomes of the patient-physician interaction are critical to the medicalization process, these processes are not well understood (Conrad and Schneider 1992; Barker 2008). Using the example of sleeplessness, I explore and describe the medicalization process at the interactional level. The following sections provide an overview of my research.

### **Measuring Medicalization**

How do we know when medicalization occurs at the interactional level? What does this part of the medicalization process look like? These are profound questions and they have not been sufficiently explored. There is debate about the amount of medicalization that occurs at the doctor-patient level, but “research on the medicalization of perceptions and practices in everyday medical practice could be illuminating” (Conrad and Schneider 1992: 82). While many have written about the medicalization process, few have attempted to measure it – on any level (Conrad 2007). Currently, there is no universally accepted,

quantitative or qualitative method for the measurement or tracking of the medicalization process (Conrad 2007). Typically medical sociologists describe the medicalization process using a combination of qualitative and quantitative methods. Commonly used methods include: tracking diagnosis conceptualization and/or expansion; measuring growth/dissipation of a diagnosis in a population; analyzing direct to consumer advertising and preferred method of treatment; measuring mentions within the lay press, assessing changes in medical literature or internet hits over a period of time; and/or noting the creation, number and type of institutional stakeholders. It is noteworthy that many of these measures are situated at the macro level and intended to describe trends at that level. Since the focus of this research is at the micro, or individual level, a mixture of qualitative and quantitative methods are used to explore and describe the medicalization of insomnia at the interactional level.

Specifically, using data from the National Ambulatory Medical Care Survey (NAMCS), a nationally representative dataset of physician office visits, I describe trends in patient reasons for office visit, diagnoses made and prescriptions written. Using qualitative interviews I ask the key players – patients and physicians – to provide their perspective and insights regarding observed trends. Using a semi-structured interview format that hones in on the factors that may influence the patient-physician interaction (including, but not limited to, advertising on the part of pharmaceutical companies and consumerism) and describing the outcomes of these interactions (e.g., patient complaint, physician diagnosis and treatment plan) via a nationally representative data set of office visits, I offer much-needed insight into the medicalization of sleeplessness at the interactional level.

## Hypotheses

I argue that the pharmaceutical industry is a key institutional stakeholder in promoting sleeplessness as a treatable medical disorder. Its “educational” and advertising efforts are targeted at the level of individuals – both patients and physicians. While it is difficult to directly measure the effects of Direct to Consumer (DTC) advertising on patients and drug representative interaction with physicians, I believe that successful influence of the pharmaceutical companies on doctors and patients, in tandem with an increased likelihood for patients to act as consumers, results in measurable trends. My guiding hypotheses are:

**Over a fourteen year period (1993-2006) I expect to find that the following office visit outcomes will increase significantly over time:**

**H1: The estimated mean number of office visits with a complaint of sleeplessness (insomnia).**

**H2: The estimated mean number of office visits that result in a diagnosis of insomnia.**

**H3: The estimated mean number of office visits that result in a prescription of a sedative hypnotic.<sup>9</sup> (This will not necessarily be dependent on a diagnosis of insomnia.)**

These hypotheses represent different levels of medicalization. As previously noted, complaints of sleeplessness have been recorded since ancient times and therefore complaint alone is not necessarily an indicator of medicalization, although it may be a precursor to an office visit. The labeling of the complaint as the medical condition insomnia is indicative of medicalization at the conceptual level. Still, a diagnosis may or may not result in a prescription. In terms of measurement, I argue that the prescription of a sedative hypnotic –

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<sup>9</sup> In this dissertation, “sedative hypnotic” will refer to a combination of the following drugs: the five benzodiazepines approved for use in insomnia, the non-benzodiazepine sedative hypnotics and the anti-depressant Trazodone.



with or without an accompanying diagnosis – is the most compelling evidence of the medicalization process.

In some cases, the medicalization of a particular disorder (e.g. gastric bypass and obesity, hormone replacement therapy and menopause) appears to be linked to the development and promotion of related medical or pharmaceutical treatments (Rothman and Rothman 2003; Conrad 2007). I believe the development and promotion of non-benzodiazepine hypnotics, introduced to the US market in 1993, has been concomitant with increased diagnosis of insomnia in individuals presenting with insomnia as a reason for physician visit (Skaer et al. 1999), as well as increased prescriptions. Unlike benzodiazepines, which are commonly prescribed for anxiety as well as sleeplessness, *non-benzodiazepine sedative hypnotics* are primarily indicated<sup>10</sup> to alleviate sleeplessness and thus I run a separate analysis for non-benzodiazepine hypnotics.

**H4: Over a fourteen year period (1993-2006) there will be a significant increase in the mean number of prescriptions for a non-benzodiazepine hypnotic. (This will not necessarily be dependent on a diagnosis of insomnia.)**

Because DTC advertisements and websites for insomnia feature actors who represent non-traditional sufferers of insomnia (e.g. men, younger persons, minorities), I expected that:

**H5: Over a 14 year period (1993-2006) the estimated proportion of individuals from “non-traditional” populations (those who are male, non-white, and/or younger) who receive a diagnosis of insomnia and/or a prescription for a sedative hypnotic will increase significantly.**

I use the NAMCS dataset to test these hypotheses.

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<sup>10</sup> Recently, zolpidem has been used off-label for the treatment of restless leg syndrome (RLS), but it is not indicated for RLS, nor is it necessarily effective.

While NAMCS data provide evidence of increased insomnia-related outcomes, these descriptive statistics do not provide insight into the dynamics of the patient-physician interaction; rather, they describe only the outcome of the office visit. In order to provide an interpretative context for these data, I conducted a series of interviews with both patients and physicians. These exploratory and semi-structured interviews offer insight into the patient-physician interaction surrounding sleeplessness. I also explore the concepts of rhetorical authority, physician compliance, patient compliance and knowledge alignment and how they may be moderating the patient-physician interaction.

### **Overview of Methods**

I conducted secondary analysis of the National Ambulatory Medical Care Survey [NAMCS], a nationally representative data set of physician office visits. I believe that NAMCS is an ideal data set to track the results of interactions between patient and physician. NAMCS provides data on “patient’s complaint(s), symptom(s) or other reason(s) for this visit (in patient’s own words)” and “[n]o similar data for visits to office-based physicians are available anywhere” (NAMCS 1996: 45). In order to maintain consistency of prescription and diagnostic codes I analyze 14 consecutive years of NAMCS data, beginning in 1993. I identify the following trends over time: insomnia as a patient reason for visit, physician diagnosis of insomnia and sedative hypnotics prescribed or continued. I report my findings on both the aforementioned dependent variables as well as the following independent variables: sex, age, race and insurance status.

In addition, I conduct semi-structured interviews with 27 patients and the 8 physicians who treated them for sleeplessness at a large Southeastern medical center. Patients

had received a prescription within the 6 months prior to being contacted for an interview and were asked to describe their insomnia experiences, treatments tried, and interactions with physicians. Physicians were asked to describe their experiences diagnosing and treating patients who complained of sleeplessness.

Detailed methodology for both qualitative and quantitative analyses is presented in the subsequent findings chapters. The use of both qualitative and quantitative methods provides triangulation and aids in the description and development of this understudied issue. As this research is largely exploratory in nature, the data analyses are complementary; overlapping and allow different facets to emerge, much like “peeling the layers of an onion” (Creswell 1994: 175). This research is a first step in a larger body of research. At the conclusion of this dissertation, I provide a section on ‘next steps.’

## CHAPTER 3

### A QUANTITATIVE PERSPECTIVE ON THE MEDICALIZATION OF SLEEPLESSNESS

This research examines the problem of sleeplessness, its transformation into the medical diagnosis of insomnia and focuses on the interaction between patient and physician. This interaction results in, arguably, the most tangible indicators of medicalization – increases in diagnoses and drug prescriptions.

The goal of this dissertation is to answer the question: Is there evidence of the medicalization of sleeplessness at the level of doctor-patient interaction? The objective of this chapter is to measure and describe insomnia-related trends over time that might be indicative of the medicalization process. In addition, I expect these analyses to suggest further steps in my research agenda<sup>11</sup>, as well as provide a macro-level context for patient and physician interview data. I use the following hypotheses to guide my analyses.

**Over a fourteen year period (1993-2006) I expect to find the following office visit outcomes will increase significantly over time:**

**H1: The estimated mean number of office visits with a complaint of sleeplessness (insomnia).**

**H2: The estimated mean number of office visits that result in a diagnosis of insomnia.**

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<sup>11</sup> To be explored in my post-doctoral work.

**H3: The estimated mean number of office visits that result in a prescription of a sedative hypnotic<sup>12</sup> (This will not necessarily be dependent on a diagnosis of insomnia).**

**H4: The estimated mean number of office visits that result in a prescription of a *non-benzodiazepine* sedative hypnotic (This will not necessarily be dependent on a diagnosis of insomnia).**

**In this same time period:**

**H5: The estimated proportion of individuals from “non-traditional” populations (those who are male, non-white, and/or younger) who receive a diagnosis of insomnia and/or a prescription for a sedative hypnotic will increase significantly.**

## **Methods**

### *Study Design*

I use the National Ambulatory Medical Care Survey [NAMCS], a population based, nationally representative survey of office-based physician visits in the US, to track insomnia-related trends over time. NAMCS is a national probability sample designed and managed by the National Center for Health Statistics (NCHS) of the US Centers for Disease Control and Prevention. Data collection has been conducted annually since 1989. NAMCS provides information from office-based physician visits comprised of both private-pay and public sector patients. Names are provided by the American Medical Association and the American Osteopath Association. Physicians who are hospital-based, federally employed, primarily engaged in teaching or research, or those who specialize in radiology, pathology and anesthesiology are excluded from the sample.

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<sup>12</sup> In this dissertation, “sedative hypnotic” will refer to a combination of the following drugs: the five benzodiazepines approved for use in insomnia, the non-benzodiazepine sedative hypnotics and the anti-depressant Trazodone.

A probability sample is drawn from counties, groups of counties, county equivalents, townships or towns. Next, a probability sample is drawn from the geographic unit sample and practicing physicians are identified. Approximately 3000 physicians, per year, are randomly chosen. Physician offices chosen through this method are randomly assigned a one-week period during which the physician or office staff must record each patient visit. For some larger practices, this is not feasible and a sample as low as 20% may be collected over the one-week data collection period.

Information is collected on patient demographics, services provided, diagnoses made and treatments prescribed. The National Center for Health Statistics considers cell sizes less than 30 to be unreliable. The basic sampling unit is the office visit. Data are weighted to reflect annual visit rates. Additional detail related to the three-stage probability sampling procedure, sampling variation and estimation procedures are described in depth on the NAMCS website, available at: (<http://www.cdc.gov/nchs/about/major/ahcd/ahcd1.htm>).

I use data from the time period 1993-2006. This 14-year period reflects consistency in the ICD-9 codes used for diagnosis of insomnia and several years before and after the FDA Modernization Act of 1997.<sup>13</sup> Ambien (zolpidem), the first of a new generation of sleep aids, was FDA approved in 1993 and entered the NAMCS database the following year.

My analytic sample included a mean of 27,896 observations (office visits) per year (low: 20,760; high 36,875). These cases were weighted to represent between 681,457,491 and 963,617,399 annual office visits in the US.

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<sup>13</sup> The FDA Modernization Act of 1997 greatly increased the scope and frequency of direct-to-consumer advertising by pharmaceutical companies.

## *Variables*

My dependent variables are: a) complaint of insomnia as reason for office visit b) diagnosis of insomnia and c) the prescription of sedative hypnotics.

*Reason for visit.* NAMCS allows physicians to list up to three reasons for office visit. Complaint of insomnia as reason for office visit includes complaints of “sleeplessness,” “can’t sleep,” and “trouble falling asleep.” NAMCS uses the National Center for Health Statistics [NCHS] code 1135.1.

*Visit-associated diagnoses.* Physicians provide up to three diagnoses per office visit. Diagnoses are classified using the International Classification of Diseases. For the years encompassed by this study, the ninth version was used (ICD-9). I analyzed the following ICD-9 diagnosis codes related to insomnia: 780.52 (Insomnia, unspecified); 780.50 (Sleep disturbance, unspecified); 307.47 (Other dysfunctions of sleep stages or arousal from sleep); 780.59 (Other sleep disturbances); 307.42 (idiopathic); 307.40 (Nonorganic sleep disorder, unspecified); 307.48 (Repetitive intrusions of sleep); 780.5 (Sleep disturbances); 780.56 (Dysfunctions associated with sleep stages or arousal from sleep); 780.55 (Disruptions of 24-hour sleep-wake cycle); 307.41 (Transient); 307.49 (Subjective complaint); 327.00 (Organic); 327.09 (Organic, other).<sup>14</sup>

*Drug classes.* The NCHS uses therapeutic classes based on the National Drug Codes (NDC). In 1993 and 1994, NAMCS allowed up to five medications to be listed. From 1995-2002, this number increased to six. From 2003 to 2006, a total of 8 medications could be listed.<sup>15</sup> Drug codes may be found at <http://www2.cdc.gov/drugs/>.

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<sup>14</sup> The use of these codes for insomnia in analyzing NAMCS have precedent in the literature (see Balkrishan, Rasu and Rajagopalan 2005).

<sup>15</sup> I recognize the potential interpretive problem this presents, and address it later in the chapter.

Based on preliminary interviews with physicians and the insomnia literature, I chose to analyze the following drugs from these classes: benzodiazepines, non-benzodiazepines and one drug from the class of anti-depressants. While many benzodiazepines are used to treat insomnia, they are also commonly used for the treatment of anxiety. I limit my sample to the five benzodiazepines that are specifically indicated for insomnia in the US: Triazolam, Temazepam, Estazolam, Flurazepam and Quazepam (Rasu, Shenolikar, Nahata et al. 2005).

The FDA approved Ambien and subsequent non-benzodiazepine sedative hypnotics [NBSHs] for the “short term treatment of insomnia” (Physician’s Desk Reference 2006: 2868). Prior to 2005, the only NBSH in the NAMCS dataset was Ambien (zolpidem). In 2005, the following drugs were added: Lunesta (eszopiclone), Sonata (zaleplon) and Rozerem (ramelteon).<sup>16</sup>

Although insomnia and depression are highly comorbid, anti-depressants are not typically indicated for the treatment of insomnia symptoms (IOM 2006). However, after consulting with both primary care physicians and sleep specialists, I chose to include an anti-depressant in my analysis – Trazodone. Trazodone is a tetracyclic antidepressant, initially manufactured under the brand name Desyrel<sup>17</sup> and approved for use by the FDA in 1982. While Trazodone is primarily indicated for depression, a popular off-label use is the treatment of insomnia (Walsh et al. 1998). Trazodone is the first-line insomnia treatment of choice for many physicians due to its low cost, non-addictive nature, and lack of common or serious side effects (Walsh et al. 1998; also, personal communication Head of Psychiatry at UNC 2008).

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<sup>16</sup> Rozerem has a different mechanism of action than the so-called “z” drugs (e.g. zopiclone, zolpidem, eszopiclone and zaleplon) and is promoted as non-habit forming. However, I include it here as it is often discussed alongside the “z” drugs.

<sup>17</sup> Trazodone is no longer manufactured under the brand name and is now only available as a generic.



For a list of all drugs used in this analysis and their NDC codes, please see Table 2.

**Table 2. Medications by brand name, generic name and medication code.**

<b>Brand Name</b>	<b>Generic Name</b>	<b>NAMCS Medication Code</b>
<i>Benzodiazepines</i>		
Prosom	Estazolam	92080 52068 92123
Dalmane	Flurazepam	08390 52350 12810
Doral	Quazepam	92022 55028 10257 92148
Restoril	Temazepam	26453 55668 30756
Halcion	Triazolam	13999 93419 96068 55928
<i>Non-benzodiazepine</i>		
Ambien	Zolpidem	93347 94035 57048
Sonata	Zaleplon	00039 70115
Lunesta	Esczopiclone	05033 70988
Rozerem	Ramelteon	05244 71023
<i>Anti-depressant</i>		
Trazodone (formerly Desyrel)	Trazodone	31997 55903 40520

### *Independent variables*

Independent variables of interest are: sex (male and female), age (55+ and <54), race (Black, White, Hispanic, Asian, Other) and insurance status (private, government, self-pay/other). Race categories mirrored the provided NAMCS categories. Insurance variables were collapsed into three categories and will be discussed in further detail in the section on “insurance status.” Age categories were divided at age 55, because it is well-established that insomnia is common in both men and women age 55 or older (Grigg-Damberger 2006; Ohayon 1997; Roth and Roehrs 2003).

### *Limitations*

Although I feel it is the best currently available data set with which to do these analyses, the NAMCS data are limited in several respects. The NAMCS survey was not designed to capture or measure the medicalization process. NAMCS data include only individuals who have both the motivation and means to make it to a physician’s office. This selection effect may under-represent lower-income groups who mainly use emergency services as their primary means of accessing health services. In addition, the patient is not the unit of analysis; the unit of analysis is the office visit.

Finally, the increasing number of drugs that physicians are allowed to list over time potentially complicates interpretation of my findings. How will I know if my drugs of interest are increasingly prescribed, or just more likely to be listed in the additional spaces? This is a serious limitation of the dataset as it relates to my research purposes, and I will address it at the end of the findings section.

### *Analytic method*

Data were imported using SAS software, version 9.0 (SAS Institute, Cary, NC). Program codes were created in SAS and then converted into SAS export files. These files were then converted into Stata files. All analyses were conducted using Stata version 10.0 (StataCorp, College Station, TX). I used the `svy`<sup>18</sup> command, which controls for the complex sample design of the NAMCS data. In addition, weighting (`svyset`) was required to appropriately link the sample to the population. SAS and Stata codes to correctly weight the sample were provided in the NAMCS documentation.

I computed descriptive statistics for all study variables. To examine changes in these insomnia related outcomes, I calculated the means for each dependent and independent variable. These means were multiplied by the estimated subpopulation to produce an estimated number of office visits; 95% confidence intervals (CIs) around these means were also calculated. To test the differences between certain means, I ran regressions of: insomnia as reason for office visit, insomnia diagnosis, and prescription of sedative hypnotics on various time periods. The first comparisons were across the entire period, comparing the means in 1993 to the means in 2006. Then, I divided the 14 year period into three analytic “regimes” and repeated the mean comparisons with first and last years from each regime. Similar comparisons of means for sex, race and age groups were computed by regime. In addition, linear trend statistics were calculated for the dependent variables in each regime and the overall time period.

Regimes were created in order to: a) capture trends in the data that might be related to social or institutional ‘fault lines’ (noted below) b) provide aggregate estimates of the

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<sup>18</sup> Prior to survey estimation commands the “`svyset`” command was used to specify the variables for sample weight, primary sampling unit and stratification variables.

relatively small number of minority patients with insomnia-related outcomes and c) describe trends in greater analytic detail than would be available from calculations of the overall period.

Regime 1: 1993-1997 begins one year prior to the introduction of Ambien to the NAMCS dataset and ends the year the FDA Modernization Act was passed, capturing a 5 year time period in which a) NBSHs were introduced to the market and b) mass-scale direct to consumer advertising [DTCA] was not yet used.

Regime 2: 1998-2001 begins the year after the passage of the FDA Modernization Act and ends the year in which 9/11 occurred. This time period captures the first four years of DTCA and ends at the year of a great national tragedy. Other research has shown that 9/11 was correlated with mood and sleep disorders and the uptake of negative coping behaviors such as drinking and use of drugs (Galea et al. 2002; MacGeorge et al. 2007; DiMaggio, Galea and Li 2009). Although stress effects may have been temporary (Knudsen et al. 2005), an uptake in sedative hypnotics is certainly plausible and worth exploring.

Regime 3: 2002-2006 begins the year following 9/11 and ends with 2006 – the most recently available year of data available from NAMCS when this research began. In addition to capturing 5 years post-9/11, DTCA expenses were higher in Regime 3, compared to Regime 2, as seen in Table 15 (in Chapter 6, page 183).

### *Overview of Findings*

In the following pages I will present, in text and in figures, the yearly mean estimates for each of my dependent variables (insomnia as reason for office visit; insomnia diagnoses; prescriptions of benzodiazepines; prescriptions of Trazodone; and prescriptions of non-

benzodiazepine sedative hypnotics (NBSHs)) along with 95% confidence intervals (CIs). I will then provide a brief summary of comparative drug trends, in text and in figures.

Next, I will present analysis of dependent variables by regime and overall time period. I use first and final year regression tests to determine significance of change over time. In addition, I provide linear trend statistics for overall periods and regimes. I then conduct significance tests by regimes using independent and dependent variables.

Finally, I attempt to address one of the major limitations of the data - variation in the number of drug codes allowed - and end with a brief discussion. More in-depth discussion of these, and the qualitative findings, is in Chapter 6.

## Findings

An average of 27,896 physician office visits were recorded each year in NAMCS (low 20,760: high 36,875). As seen in Table 3, visits were weighted to represent between 681,457,491 and 963,617,399 annual office visits in the US.

**Table 3. Yearly observations and weighted estimates for office visits in NAMCS, 1993-2006.**

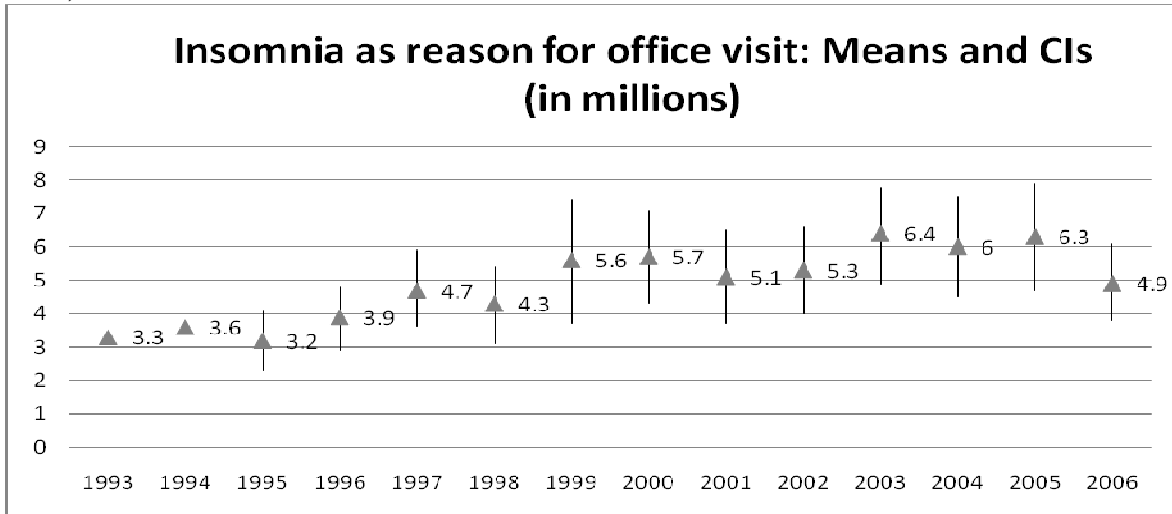
Year	Observations	Weighted Estimates
1993	35,978	717,191,408
1994	33,598	681,457,491
1995	36,875	697,082,010
1996	29,805	734,493,096
1997	24,715	787,371,906
1998	23,339	829,280,407
1999	20,760	756,733,854
2000	27,369	823,541,999
2001	24,281	880,486,669
2002	28,738	889,980,491
2003	25,288	906,022,756
2004	25,286	910,857,160
2005	25,665	963,617,399
2006	29,392	901,954,225

Insomnia as reason for office visit increased over the 14 year study period, but at a relatively slower rate when compared to insomnia diagnosis; both of these outcomes were outpaced by prescriptions for sleep aids, particularly NBSHs.

In 1993, insomnia was the reason for office visit in approximately 3.3 million cases (95% CI: 2.4, 4.1million), as shown in Figure 3. By 1997, the mean number increased to 4.7 million (95% CI: 3.0, 5.9million). After peaking in 2003 with approximately 6.4 million (95% CI: 4.9, 7.8 million) visits, the number decreased in 2006 to 4.9 million (95% CI: 3.8,

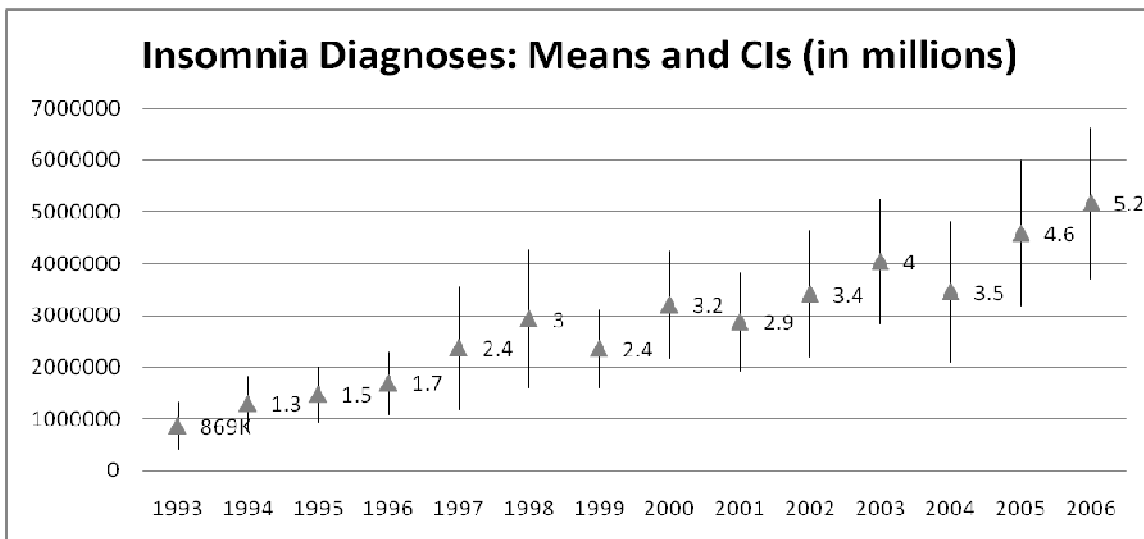
6.1 million). Comparing 1993 and 2006 there was about a 30% increase in complaint of insomnia as reason for office visit.

**Figure 3: Means and confidence intervals of insomnia as reason for office visit (1993-2006).**



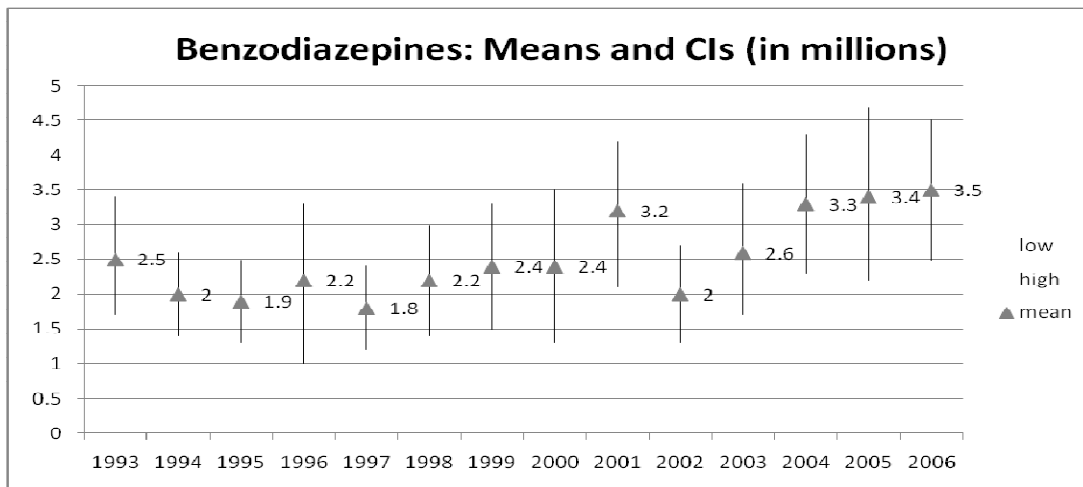
During the same period, office visits resulting in a diagnoses of insomnia increased nearly six-fold, from an estimated mean of 869,164 (95% CI: 417,000; 1.3 million) in 1993 to 5.2 million (95% CI: 3.7; 6.6 million) in 2006.

**Figure 4. Means and confidence intervals of insomnia diagnoses (1993-2006).**



Prescriptions for all sedative hypnotics increased over time. Office visits resulting in a prescription for a benzodiazepine increased by 39% when comparing 1993 to 2006 estimates. As seen in Figure 5, an estimated 2.5 million (95% CI: 1.7; 3.4 million) prescriptions were recorded in 1993. In 2006, benzodiazepines peaked with an estimated 3.5 million office visits resulting in a prescription (95% CI: 2.5; 4.5 million).

**Figure 5: Means and confidence intervals of benzodiazepine prescriptions (1993-2006).**



As demonstrated by Figure 6, office visits resulting in a prescription of Trazodone nearly doubled when comparing 1993 and 2006 rates, going from an estimated 2.8 million (95% CI: 2.1; 3.5 million) to 5.8 million (95% CI: 4.6; 6.9 million). Prescriptions peaked in 2005 with an estimated mean of 7.4 million (5.5; 9.3 million).



**Figure 6. Means and confidence intervals of Trazodone (1993-2006)**

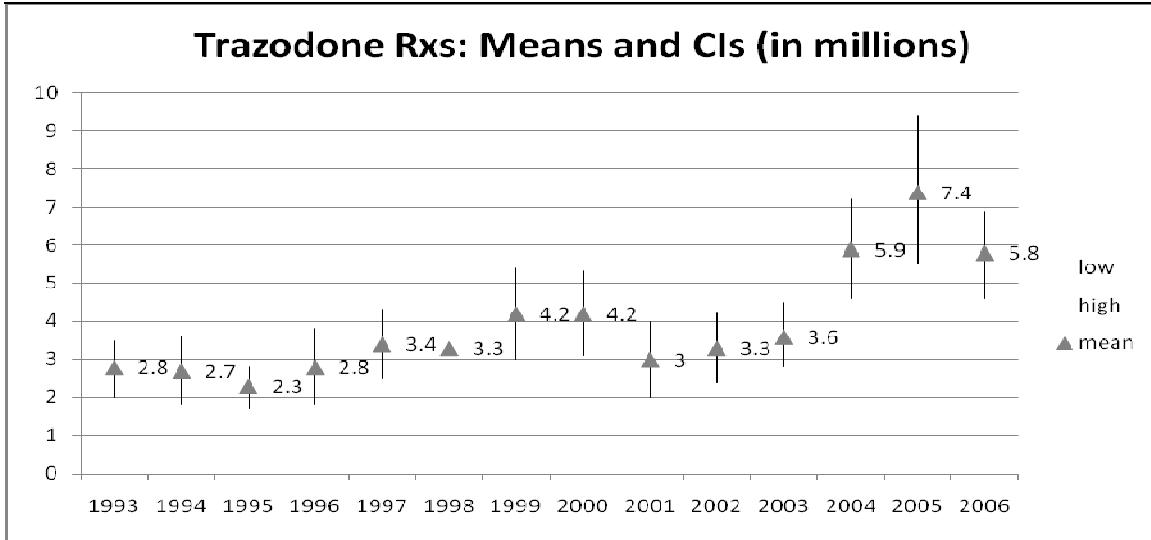
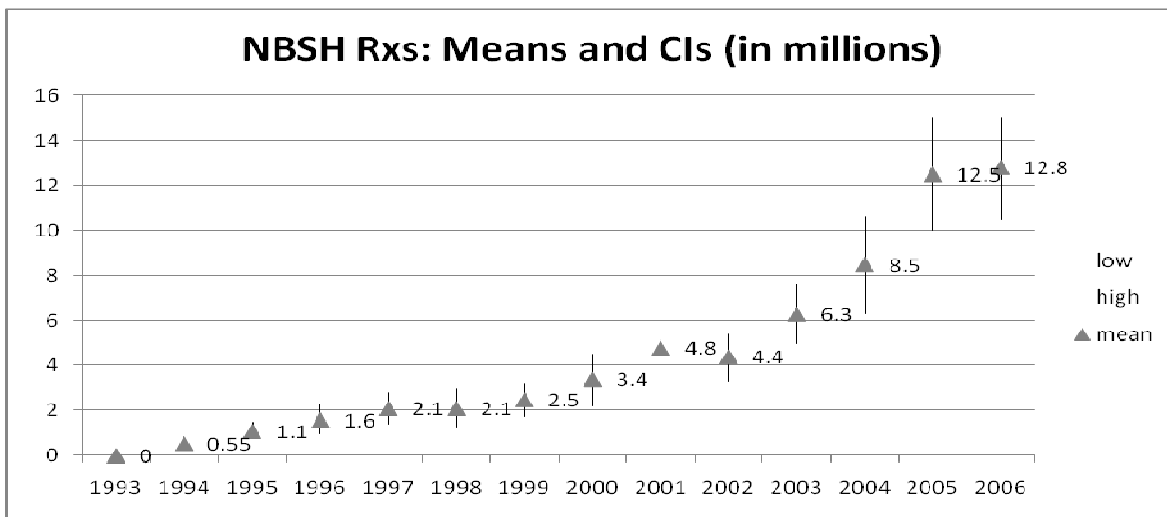


Figure 7 shows that office visits resulting in a prescription for a NBSH increased about 2000%, or 23-fold, when comparing 1994 to 2006. In 1994, Ambien garnered an estimated 550,345 (95% CI: 315,038; 785,584) prescriptions. Rates increased steadily, and by 2004, an estimated average of 8.5 million (95% CI: 6.3; 10.6 million) prescriptions were recorded. Lunesta, Sonata and Rozerem were added to the NAMCS survey in 2005. In 2006, nearly 12.8 million (95% CI: 10.5; 15 million) prescriptions were written for all NBSHs.

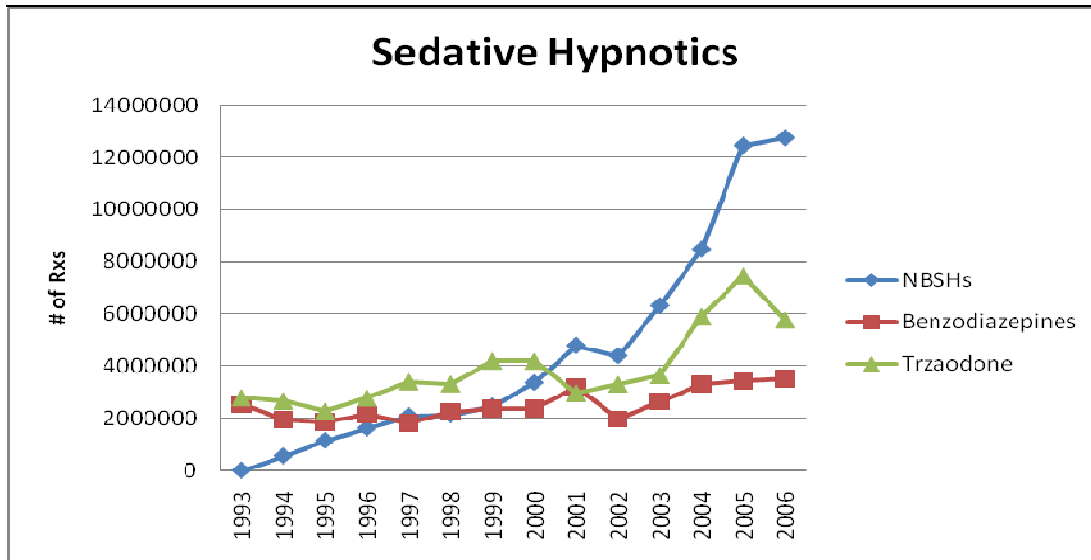
**Figure 7. Means and confidence intervals of NBSH prescriptions (1993-2006).**



*Summary of dependent variable trends*

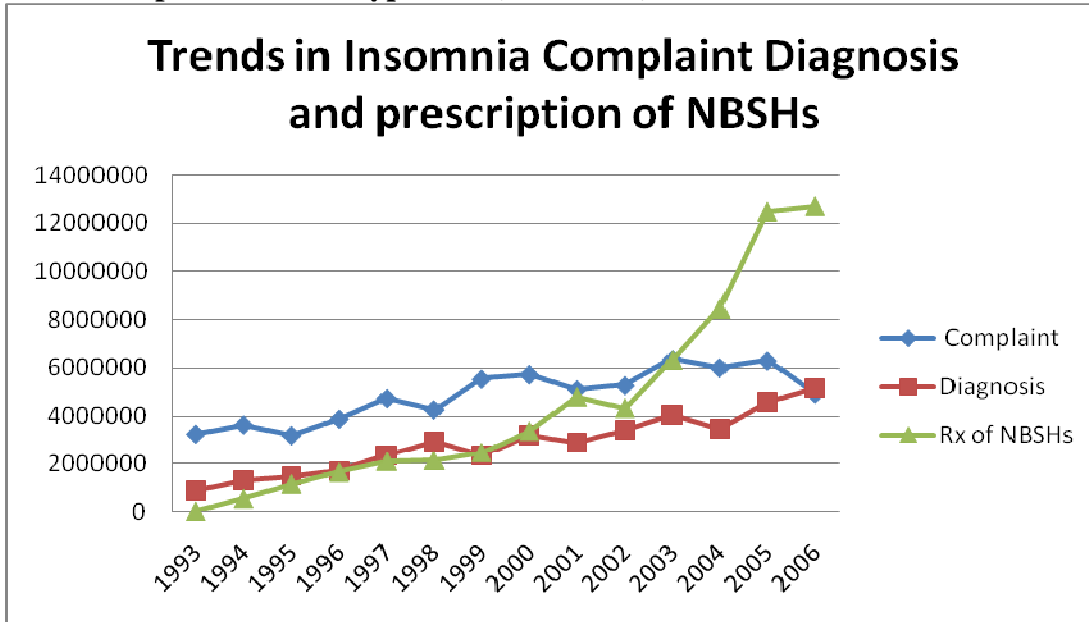
As seen in Figure 8, over the same 14 year period, visits resulting in a prescription for benzodiazepines, NBSHs and Trazodone have had somewhat different trend lines. When compared to NBSHs and Trazodone, prescriptions of benzodiazepines have remained relatively stable over time. Trazodone, prescribed at a roughly similar rate to benzodiazepines in 1993, increased at a higher rate than benzodiazepines. Comparing rates from 1993 to 2006, we see that prescriptions of Trazodone have approximately doubled. The most striking trend line in Figure 8 is that of the NBSHs. Since their introduction in 1994, prescriptions of NBSHs have increased about 23-fold and have far outpaced those for either benzodiazepines or Trazodone.

**Figure 8. Trends in Sedative Hypnotic prescriptions over time (1993-2006).**



As seen in Figure 9, insomnia as reason for office visit has typically been higher than insomnia diagnosis. However, in 2006, the trend lines for complaint and diagnosis seem to converge.

**Figure 9. Trends over time in Insomnia Complaint, Diagnosis and prescription of Non-benzodiazepines sedative hypnotics (1993-2006).**



As seen in Figure 9, office visits resulting in a prescription for a NBSH have, over time, far outpaced complaint and diagnosis of insomnia.

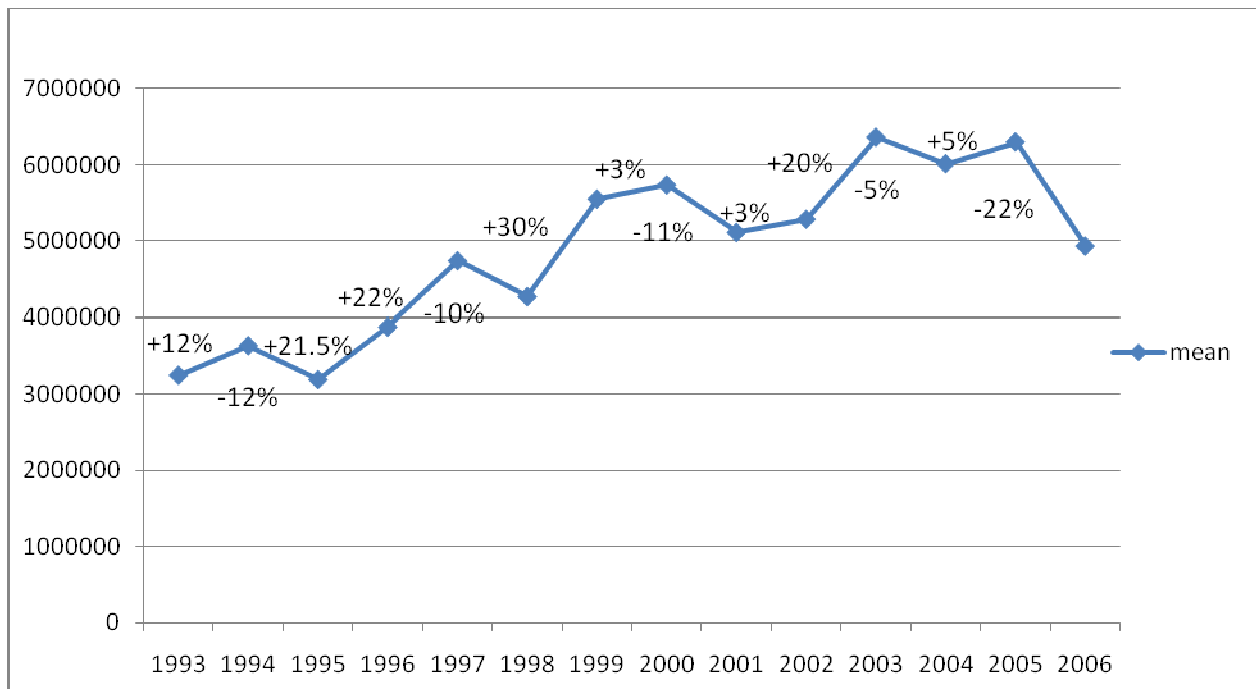
*Analysis of Dependent Variables by Regime*

I conducted significance tests comparing mean levels of the dependent variables in regimes. Linear regressions were conducted between the first year (1993) and the final year (2006) of analysis using weighted visits, as well as for the first and last years of regimes. In addition, slope estimates were calculated for the overall period and regimes. P values, mean proportion of visits at the beginning and end of each period, differences between proportions, slopes and a graph of the percent change by year are reported below.

*Significance tests for complaint of insomnia*

The estimated mean number of complaints of insomnia, and percent change over time, are graphed in Figure 10. As a reason for office visit, complaint of insomnia did not significantly change between the beginning and end of each regime and none of the regime slopes were significant either, as seen in Table 4. The slope for the entire period from 1993 to 2006 is positive and statistically significant, however, this should be interpreted with caution because the sample consists of only 14 observations. When assessing the slope of the overall line, and the three regimes, I find similar trends for the first and second regimes. The slopes for Regimes 1 and 2 are positive and not very different from each other and the overall trend. However, Regime 3 is very different and has a negative slope, indicating a downward trend in number of insomnia complaints.

**Figure 10. Insomnia as reason for office visit, percent change over time (1993-2006).**



**Table 4. Overall and Regime-based proportion differences and slopes for complaint of insomnia as reason for office visit.**

<i>Period</i>	<i>Proportion</i>	<i>Difference</i>	<i>P-value (difference)</i>	<i>Slope</i>	<i>P-value (slope)</i>
Overall: 1993-2006	0.0045 v. 0.0055	0.0010	0.307	218,398	0.000**
Regime 1: 1993- 1997	0.0045 v. 0.0060	0.0015	0.127	321,819	0.094
Regime 2: 1998-2001	0.0051 v. 0.0058	0.0007	0.522	271,437	0.464
Regime 3: 2002-2006	0.0059 v. 0.0055	-0.0004	0.620	-76,501	0.760

\* **P<0.05**      \*\***P<0.01**

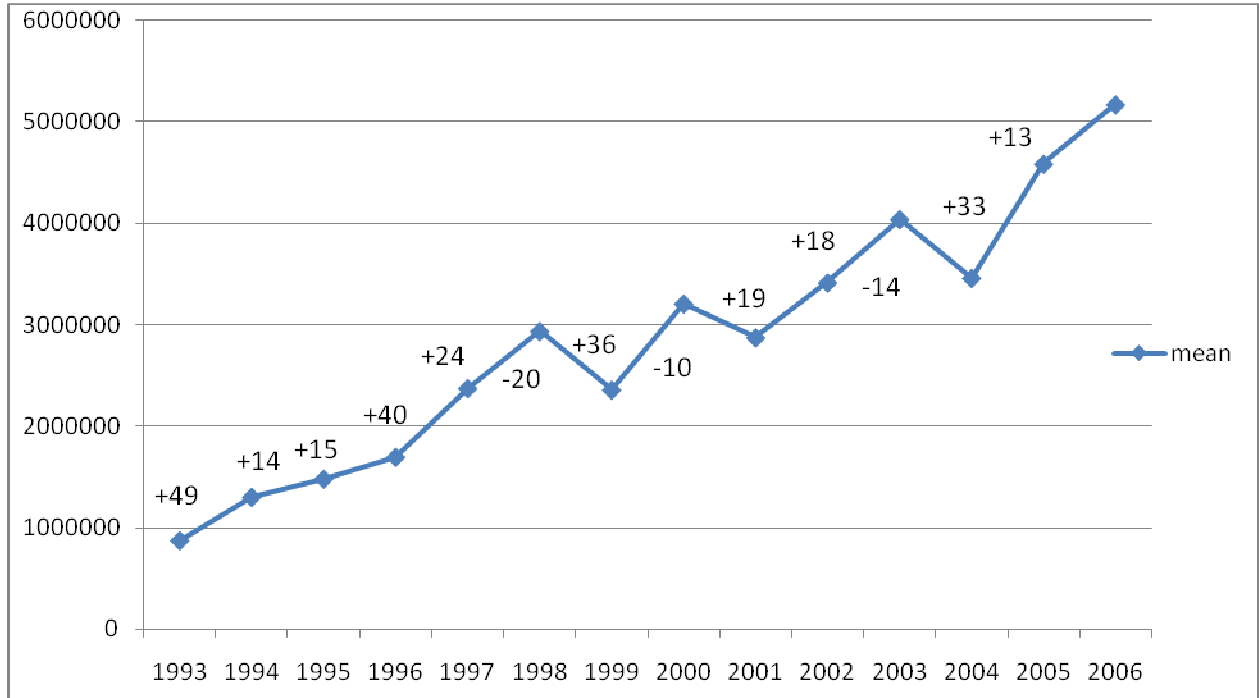
Had I only assessed the overall time period, it would appear that the slope trend is significantly positive. Breaking the time period into three regimes allows me to gauge some of the subtleties present in the data trends, particularly the downward slope in Regime 3.

*Significance tests for insomnia diagnosis*

The estimated mean number of insomnia diagnoses, and percent change over time, are graphed in Figure 11. When comparing 1993 to 2006 there was a statistically significant increase in the proportion of insomnia diagnoses (at the 0.000 level), as seen in Table 5. However, when breaking this down by regimes, only Regime 1 (1993-1997) showed significant increase (at the 0.05 level). There was no significant change in Regimes 2 and 3. The slopes mirror these results.

Again, breaking the trend into three regimes gives a more nuanced picture of change over time, compared to looking at the entire period.

**Figure 11. Insomnia diagnoses, percent change over time (1993-2006).**



**Table 5. Overall and Regime-based proportion differences and slopes for insomnia diagnoses.**

<i>Period</i>	<i>Proportion</i>	<i>Difference</i>	<i>P-value (difference)</i>	<i>Slope</i>	<i>P-value (slope)</i>
Overall: 1993-2006	0.0012 v. 0.0057	0.0045	0.000**	290,571	0.000**
Regime 1: 1993- 1997	0.0012 v. 0.0030	0.0018	0.032*	339,772	0.006**
Regime 2: 1998-2001	0.0035 v. 0.0033	-0.0002	0.772	66,254	0.759
Regime 3: 2002-2006	0.0038 v. 0.0057	0.0019	0.084	406,324	0.066

\* **P<0.05**      \*\***P<0.01**

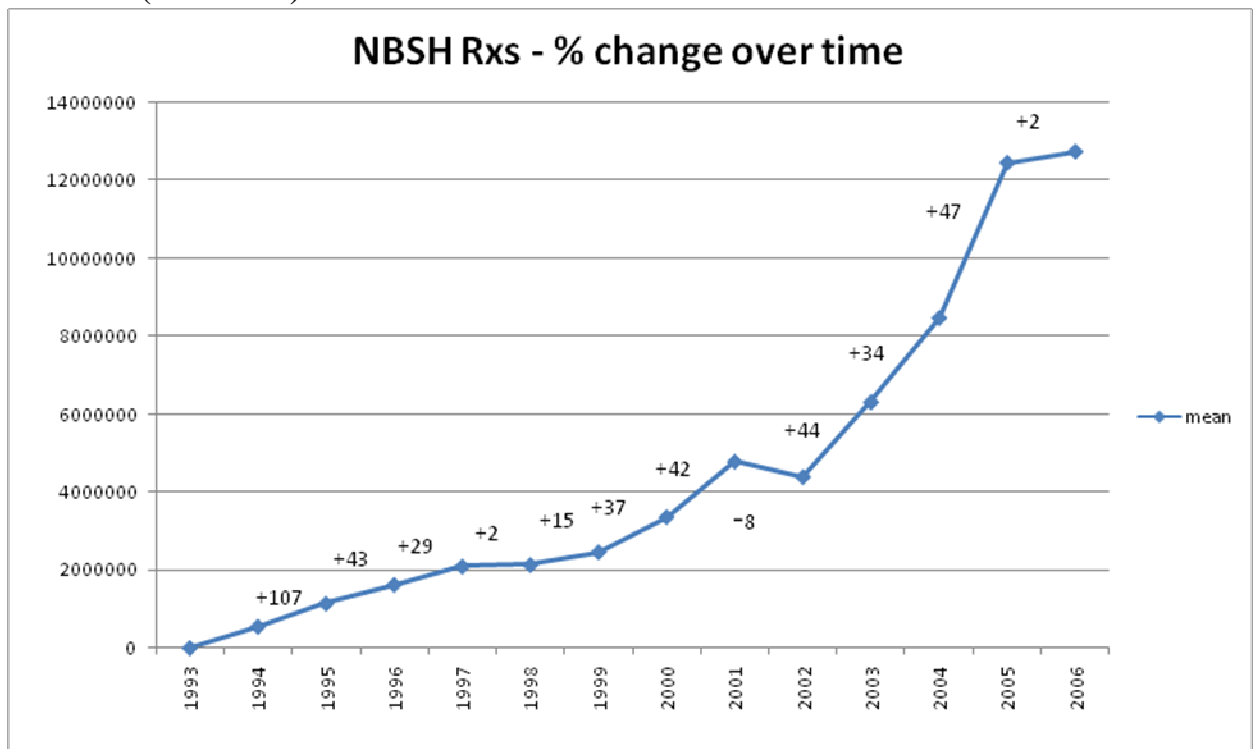
*Significance tests for non-benzodiazepines*

The increase in office visits resulting in a prescription for a non-benzodiazepine sedative hypnotic was statistically significant in all of the regimes tested, as well as for the

overall period, as seen in Table 6. These tests did not include 1993, as NBSHs were not introduced into the NAMCS dataset until 1994.

The Regimes indicate the increasing rate of growth in number of NBSHs prescribed, whereas looking at the whole time period slope implies a constant rate of change across the entire period. Thus, a single line is not a good representation of the curvilinear trend of this variable over time. The overall trend for annual estimated means, and percent change over time is seen in Figure 12.

**Figure 12: Prescriptions for Non-benzodiazepine sedative hypnotics, percent change over time (1993-2006)**



**Table 6. Overall and Regime-based proportion differences and slopes for prescription of NBSHs.**

<i>Period</i>	<i>Proportion</i>	<i>Difference</i>	<i>P-value (difference)</i>	<i>Slope</i>	<i>P-value (slope)</i>
Overall: 1994-2006	0.0008 v. 0.0141	0.0133	0.000**	914,766	0.000**
Regime 1: 1994- 1997	0.0008 v. 0.0027	0.0019	0.000**	511,319	0.002**
Regime 2: 1998-2001	0.0026 v. 0.0054	0.0028	0.001**	886,543	0.036*
Regime 3: 2002-2006	0.0049 v. 0.0141	0.0092	0.000 **	2,286,887	0.004*

\* **P<0.05**      \*\***P<0.01**

*Significance tests for benzodiazepines*

The estimated mean number of office visits resulting in benzodiazepine prescriptions, and percent change over time, are graphed in Figure 13. As seen in Table 7, the prescription of benzodiazepines does not appear to change significantly between 1993 and 2006.

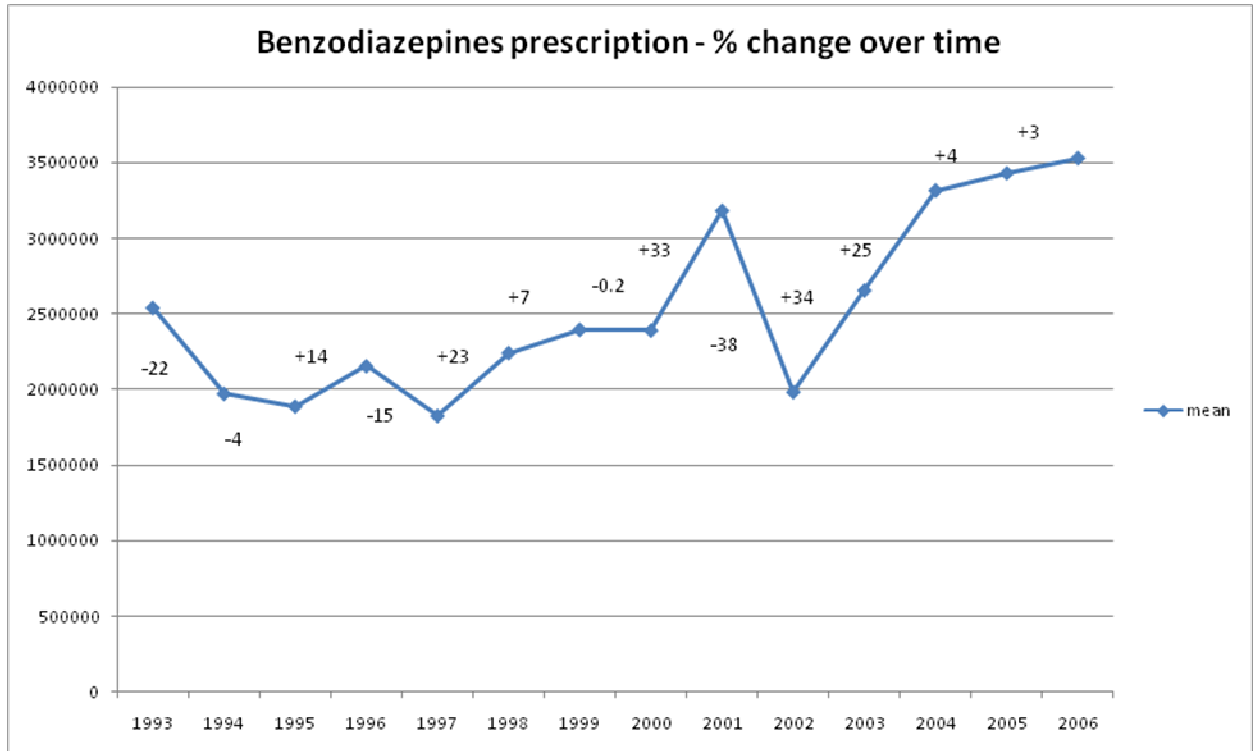
However, there is a statistically significant increase when comparing 2002 to 2006. The P-value was not significant for other Regimes.

Regimes 1 and 2 show no significant change in slope, however, the last Regime shows a significant increase. Looking at the overall slope, there is a significant increase in the number of benzodiazepines prescribed over this time period.

Once more, breaking the 14 year period into smaller blocks of time allows for greater detail of trends to emerge.



**Figure 13. Prescriptions for benzodiazepines, percent change over time (1993-2006).**



**Table 7. Overall and Regime-based proportion differences and slopes for prescription of benzodiazepines.**

<i>Period</i>	<i>Proportion</i>	<i>Difference</i>	<i>P-value (difference)</i>	<i>Slope</i>	<i>P-value (slope)</i>
Overall: 1993-2006	0.0035 v. 0.0039	0.0004	0.652	107,575	0.002**
Regime 1: 1993- 1997	0.0035 v. 0.0023	-0.0012	0.074	-124,690	0.201
Regime 2: 1998-2001	0.0027 v. 0.0036	0.0009	0.245	282,106	0.146
Regime 3: 2002-2006	0.0022 v. 0.0039	0.0017	0.014*	387289.2	0.020*

\* P<0.05

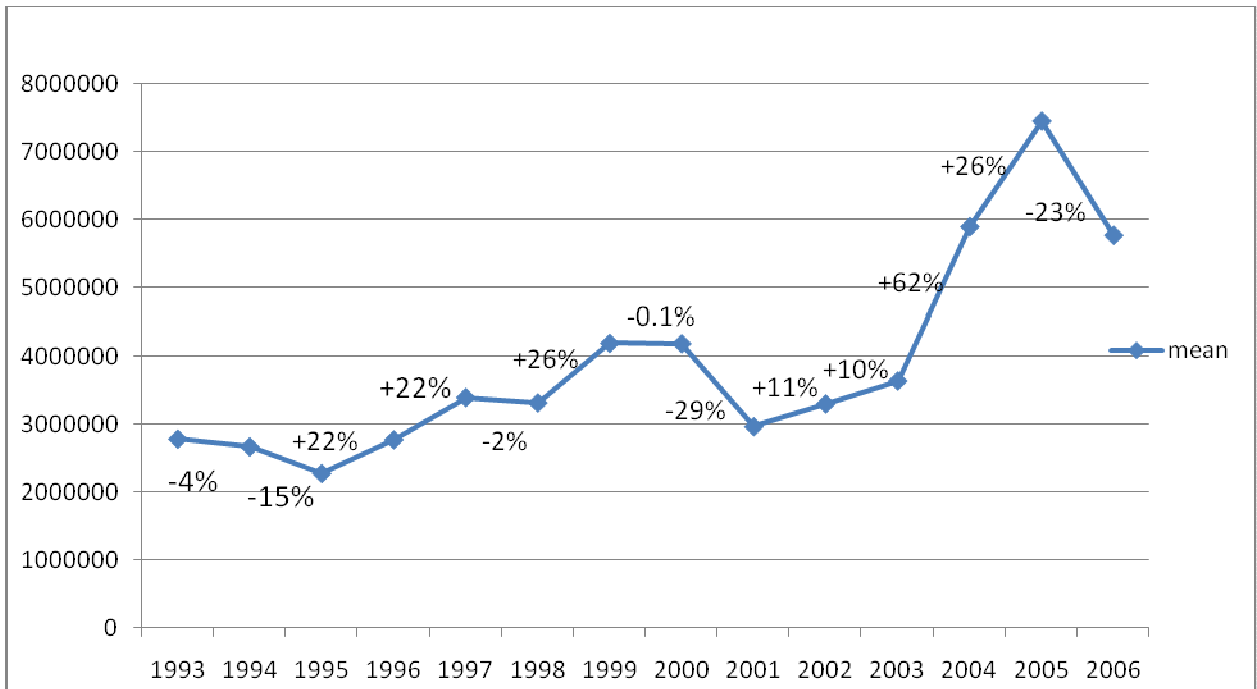
\*\*P<0.01

*Significance tests for Trazodone*

As seen in Table 8, when comparing 1993 to 2006, there is a positive, significant change in the number of Trazodone prescriptions recorded in NAMCS. However, when calculating by regime, only Regime 3 (2002 v. 2006) is significant. Similarly, when calculating the slopes, the overall period has a significant positive change over time. However, due to the positive and negative changes in the final two years of Regime 3 more or less cancelling one another out, the slope does not appear to change significantly (as seen in Figure 14), despite the fact that the number of office visits resulting in prescriptions does change quite a bit.

Once more, the division of the overall period into 3 Regimes, offers a level of analytic detail that would have been obscured by calculation of just the overall period.

**Figure 14. Prescriptions for Trazodone, percent change over time (1993-2006).**



**Table 8. Overall and Regime-based proportion differences and slopes for prescription of Trazodone.**

<i>Period</i>	<i>Proportion</i>	<i>Difference</i>	<i>P-value</i>	<i>Slope</i>	<i>P-value (slope)</i>
Overall: 1993-2006	0.0039 v. 0.0064	0.0025	0.003**	282,036	0.001**
Regime 1: 1993- 1997	0.0039 v. 0.0043	.0004	0.589	132,743	0.366
Regime 2: 1998-2001	0.0039 v. 0.0034	-0.0005	0.459	-105,625	0.781
Regime 3: 2002-2006	0.0037 v. 0.0064	0.0027	0.002**	872,874	0.103

\* **P<0.05**      \*\***P<0.01**

*Significance Tests by Regime, using independent and dependent variables*

Estimated means were calculated and multiplied by the subpopulation in order to produce an estimated number of cases, by age group, sex, race and insurance status for the varying regimes. Regression tests were conducted to detect statistical significance. I report results by dependent variable and regime. For unweighted descriptive statistics of the study population by regime please see Table 9. Weighted totals for independent and dependent variables by regime are available in Table 10, Panels A through E, at the end of this chapter.

**Table 9. Descriptive statistics of the study population by regime (unweighted numbers).**

<b>All Visits</b>	<b>Regime 1 1993- 1997</b>	<b>Proportion</b>	<b>Regime 2 1998- 2001</b>	<b>Proportion</b>	<b>Regime 3 2002- 2006</b>	<b>Proportion</b>
<b>Total (%)</b>	160,971 (42%)		95,749 (24%)		134,369 (34%)	
<b>Age</b>						
<55	100,517	.62	57,675	.60	79,533	.59
55+	60,454	.38	38,074	.40	54,836	.41
<b>Sex</b>						
Female	93,909	.58	54,646	.57	76,779	.57
Male	67,062	.42	41,103	.43	57,590	.43
<b>Race</b>						
White	130,581	.81	77,190	.81	104,030	.77
Black	13,171	.08	8,204	.09	12,020	.09
Hispanic	11,760	.07	6,826	.07	12,978	.10
Asian	4,913	.03	3,038	.03	3,937	.03
Other	546	<.01	491	<.01	1,404	.01
<b>Insurance status<sup>19</sup></b>						
Private	107,473	.67	56,172	.59	76,503	.57
Government	51,229	.32	28,687	.30	45,394	.34
Other	27,969	.17	13,415	.14	18,440	.14

*Age and Regimes*

I divide the regime populations into two age categories, age 55+, and those 54 and below. These categories were created because adults typically begin to experience sleep issues by their 6<sup>th</sup> decade of life (Grigg-Damberger 2006; Ohayon 1997; Roth and Roehrs 2003) and this age division is sometimes used in clinical trials for sleep drugs (Siversten et al. 2006). In addition, the use of sedative hypnotics in older adults is increasingly under scrutiny as their use in this age group may lead to injurious falls (Siversten et al. 2006). In

<sup>19</sup> Insurance categories will add to more than the total, due to individuals having both public and private insurance

each regime, about 40% of the office visits were with patients over age 54. See Table 10 (page 75) Panel A for further detail.

Insomnia as reason for office visit increased for both age groups over time. Only in Regime 3 was the difference between the proportions of complaint of insomnia, by age group, statistically significant. Age was a significant predictor of an insomnia diagnosis only in Regime 1. These are interesting findings because they do not parallel the current literature on insomnia in older adults. This may be due, in part to the fact that other analyses use the age groups of 65+ and below 65. Although I feel my decision to use the 55+ and under 55 categories was supported by prevalence of insomnia and concerns over sedative use in this age group (Siversten et al. 2006; Grigg-Damberger 2006; Ohayon 1997; Roth and Roehrs 2003), I plan to use the 65+ distinction in future analyses.

Prescriptions for benzodiazepines increased over time, when comparing Regime 3 to the previous regimes. In each of the three time periods, individuals 55+ received a significantly higher proportion of the prescriptions, when compared to younger patients.

In addition to seeing a large increase in the overall prescriptions for NBSHs over time, I found that a significantly higher proportion of patients aged 55+ received a prescription in each regime.

Although prescriptions of Trazodone increased over time, age was not significantly associated with it in any of the regimes. The proportion of office visits with younger and older adults receiving a prescription for Trazodone was quite similar in each regime.

### *Sex and Regimes*

NAMCS accurately reflects the fact that women are more likely to utilize health services than men in both younger and older adult populations (Green and Pope 1999; Kaye Crittendon and Charland 2008). In each of the three regimes, roughly 40% of the patients were males.

Estimated means were calculated by transforming sex into a dummy variable. Estimated means were multiplied by the subpopulation in order to get an estimated number of cases, by sex, for the varying regimes.

Insomnia complaints for both sexes increased over time, but significant differences were not consistent. In Regime 1, the proportion of men who had a complaint of insomnia was significantly higher than the proportion of women. The opposite was true in Regime 2, and there was no significant difference in Regime 3.

In all of the regimes, office visits with female patients were more likely to result in diagnoses for insomnia than those with male patients, but for these data, sex is not a significant factor in predicting insomnia diagnosis. Again, this is an interesting finding as it contradicts much of the current literature on insomnia.

Sex of patient was not predictive of any prescription drug other than trazodone – women were more likely to receive it in all regimes. Women were also significantly more likely to receive a prescription for a NBSH, but only in the third regime.

### *Race and Regimes*

NAMCS is limited by non-self-report of race. The physician, or staff member, who fills out the NAMCS forms supplies patient race. Population estimates for “other race”

(individuals whose race was not entered as Black, White, or Asian and whose ethnicity was not Hispanic) were calculated in order to ensure that the means added correctly to the total regime population mean. However, due to the very small Ns of “other race” and the high standard error (making estimates unreliable), I will not be reporting results for that particular variable.

In Regime 2, Asians were significantly more likely to have an office visit with a complaint of insomnia than Caucasians or Blacks. Caucasians were significantly more likely than African Americans to have an office visit as a result of insomnia complaint in Regime 3. No other differences among races were significant.

In Regime 2 similar proportions of office visits for African Americans and Caucasians resulted in a diagnosis of insomnia – both proportions were significantly higher when compared to Hispanic office visits. No significant differences were found in other regimes.

Only in Regime 2 was there a statistically significant difference between races in comparing prescriptions of benzodiazepines – Caucasians having a higher proportion of office visits resulting in a prescription for a benzodiazepine when compared to African American office visits.

In every regime, Caucasians not only received the highest number of prescriptions for NBSHs but had significantly higher proportions of prescriptions compared to African-Americans and Hispanics in Regime 1, Hispanics in Regime 2, and African Americans in Regime 3.

In all three regimes, Caucasian office visits were significantly more likely to result in a prescription for Trazodone than the office visits of Asians. In Regimes 2 and 3, the

proportion of Caucasian office visits resulting in a prescription for Trazodone was also significantly higher than the proportion of Hispanic office visits resulting in the same prescription. In Regime 2, African American office visits were also significantly more likely to result in a prescription for Trazodone than Hispanic office visits.

Among these inconsistent trends, it appears that Caucasians office visits are more likely to receive a prescription for a sedative hypnotic than the office visits of minorities. Some literature suggests that minorities are less likely to complain of insomnia, and would thus be less likely to receive a prescription (Pearson et al. 2006).<sup>20</sup>

### *Insurance Status*

Insurance variables in NAMCS changed quite a bit over the years. In 1993 and 1994, they were dummy variables that included a category for HMO. In 1995 a categorical option was introduced into the survey. The categories included “PPO,” “Insured, fee for service,” “HMO/Other prepaid,” “Self-pay,” “No charge,” “Other,” and “Unspecified but insurance checked.” There were also dummy variables from the previous years that included Medicare, Medicaid, and Worker’s Compensation. In 1997, the categorical values changed yet again and most of the dummy variables were done away with. The “paytype” categories (private insurance, Medicare, Medicaid, worker’s comp, self-pay, no charge, other, unknown and blank) remained relatively stable over time until 2005 when dummy variables for the same categories were added back in. Combining the categories, trying to maintain a semblance of continuity and coding them in SAS was tedious, but I created four categories – private insurance, government insurance, self-pay and other. However, when running crosstabs for the independent and dependent variables by regime, I discovered that the cell sizes for self-

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<sup>20</sup> This may, in part, be due to a correlation between low-SES and race and the dispensing of free samples.



pay and other were at times less than 30.<sup>21</sup> To correct this, I combined the two categories, creating “self-pay/other.” It is worth noting that office staff could code more than one insurance type for the patient, so numbers add up to more than 100%. This coding scheme is not ideal, but given the intricacies and lack of continuity in the NAMCS data, I feel it is the best option at this time.

Insurance status in relation to complaint of insomnia was only statistically significant in Regime 2 when a higher proportion of office visits were paid for with government insurance, compared to both private and self-pay/other. In Regime 1, a higher proportion of office visits resulting in an insomnia diagnosis were paid for by government insurance, compared to private. In terms of drugs prescribed, government insurance was often more significantly associated with the prescription of a sedative hypnotic at an office visit, when compared to either private or self-pay/other. This was true in all regimes for the benzodiazepines and Trazodone; in Regimes 1 and 3 it was also true for the NBSHs.

## **Discussion**

In the final section of this chapter, I summarize my findings and discuss whether my original hypotheses were supported. I also address one of the major limitations of this dataset – the inconsistency of drug mentions over time in NAMCS. Finally, I discuss next steps for future analyses. In-depth discussion, linking both my quantitative and qualitative findings, is in Chapter 6.

### *Summary*

Analyzing NAMCS data over a 14 year period, I found a striking difference in rates of insomnia complaint and diagnosis when compared to sleep aids prescribed. Prescriptions

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<sup>21</sup> NAMCS documentation states that cell sizes <30 offer unreliable estimates, and should not be used.

for all sedative hypnotics have increased over time, some quite significantly. In particular, the 23-fold increase in the prescription of NBSHs has far outpaced the prescription of other sedative hypnotics, as well as the complaint and diagnosis of insomnia. Given that NBSHs are exclusively indicated for the treatment of sleeplessness, the disparity between the prescription treatment and the complaint and diagnosis for which these drugs are meant to be used is remarkable and worthy of further exploration. I argue that medicalization theory may help explain the considerable disparity between complaint of insomnia, diagnosis of insomnia and the prescription of NBSHs.

Another interesting finding was the eventual convergence of the trend lines for insomnia complaint and diagnosis. Research has noted that, formerly, complaints of insomnia were more likely to result in a diagnosis for a mental illness (Skaer et al. 1999). While we can assume that not every complaint of insomnia results in a diagnosis, and that many insomnia diagnoses arise from an office visit scheduled for a different complaint, these trend lines suggest that insomnia complaint may increasingly lead to an insomnia diagnosis. Alternately, insomnia may be increasingly likely to be brought up by the patient or physician in the context of an office visit where insomnia was not initially a complaint. The latter scenario would be more in line with the medicalization hypothesis.

I am unsure why the number of office visits with an insomnia complaint would go down in the final year by 22%. However, diagnoses and most drug prescriptions for insomnia continue to increase. This disparity between complaint, diagnosis and treatment may offer further evidence of medicalization and will be discussed further in the conclusion chapter. I look forward to seeing if this trend continues when the NAMCS 2007 data set is released.

Analysis of Regimes offered nuanced detail of trends over time for both dependent and independent variables. In Regime 3, office visits for those aged 55 or over were significantly more likely to be the result of a complaint of insomnia when compared to those who were younger. Office visits resulting in a diagnosis were significantly associated with older age only in Regime 1. A significantly higher proportion of benzodiazepines were prescribed to office visits for those 55+ in each regime, compared to office visits for younger patients.

Significant differences between male and female office visits were not consistently observed for insomnia complaint or diagnoses. Sex of patient was not significantly predictive of a prescription treatment other than trazodone; office visits for females were more likely to result in a trazodone prescription in all regimes.

In terms of insomnia complaint, some significant differences in proportion of office visit by race were observed, but they were not consistent across regimes; similarly, there were no consistent, significant differences for race and diagnosis. Though trends were also inconsistent for treatment, it does appear that office visits by Caucasians were more likely to receive a prescription for a sedative hypnotic when compared to other groups. Reasons for this could include likelihood of complaint and likelihood of receiving a free sample instead of a prescription.

In relation to complaint and diagnosis of insomnia, government insurance was significantly and positively related (compared to other forms of insurance) in Regime 2 and 1, respectively. Government insurance was also positively and significantly associated with the prescription of a benzodiazepine and Trazodone in all regimes; in Regimes 1 and 3, this relationship was also true.

### *Initial Hypotheses*

I began this research with five hypotheses, which I restate and address here.

**Over a fourteen year period (1993-2006) I expect to find the following office visit outcomes will increase significantly over time:**

**H1: The estimated mean number of office visits with a complaint of sleeplessness (insomnia).**

I cannot entirely reject the null hypothesis for H1. When comparing the proportions of office visits in 1993 to those in 2006 that were the result of a complaint of insomnia, the difference is small (0.0010) and the P-value insignificant. However, when evaluating the slope of the line over time, it appears that the slope trend is significantly positive ( $P < 0.000^{**}$ ).

**H2: The estimated mean number of office visits that result in a diagnosis of insomnia.**

The p-values for both the comparisons of office visit proportion (1993 v. 2006) as well as the slope of the trend line indicate significant, positive change over time. Thus, I reject the null hypothesis for H2.

**H3: The estimated mean number of office visits that result in a prescription of a sedative hypnotic. (This will not necessarily be dependent on a diagnosis of insomnia.)**

When looking at the slopes for each of the sedative hypnotics measures (benzodiazepines, Trazodone and NBSHs), each shows a significant and positive increase over time. In addition, measuring the difference in proportion over time indicates significant, positive change for both Trazodone and the NBSHs, but not for the benzodiazepines. Due to the inconsistency in the measures of change over time for the benzodiazepines, I cannot fully

reject the null hypothesis, but would argue that, when taken as a whole, the sedative hypnotics have seen significant and positive change between 1993 and 2006.

**H4: The estimated mean number of office visits that result in a prescription of a *non-benzodiazepine* sedative hypnotic. (This will not necessarily be dependent on a diagnosis of insomnia.)**

Given the 23-fold increase in the number of office visits that resulted in a prescription of a NBSH, as well as the significant and positive p-values for both proportional difference and slope over time, I can unequivocally reject the null hypothesis in the case of H4.

One potential explanation for the rise in the prescription of these sedative hypnotics is increased spending on direct to consumer advertising [DTCA]. As this is relevant to not only my quantitative, but qualitative findings, I will broach this subject in the general discussion in Chapter 6, and present, in text and figures, evidence from prior research estimating DTCA expenses for sleep drugs.

**In this same time period:**

**H5: The estimated proportion of individuals from “non-traditional” populations (those who are male, non-white, and/or younger) who receive a diagnosis of insomnia and/or a prescription for a sedative hypnotic will increase significantly.**

Due to the small numbers available for each year for my independent variables, I was unable to use individual year data from NAMCS to create estimates of 1993 v. 2006 proportions, nor did I calculate slope statistics (N would be equal to 3, and each of the points would represent either 4 or 5 years of data). Instead, I looked for significant differences among the aggregate data created for the Regime calculations. In looking at results from the regime tests, I concede that I cannot reject the null hypothesis for H5.

With the exception of Trazodone - women were significantly more likely than men to be prescribed Trazodone in all of the regimes tested - there were no consistent differences among the sexes. When comparing age groups, there were consistent trends only in the prescription of benzodiazepines and NBSHs. In each Regime, office visits for patients who were 55 or older were significantly more likely to result in a prescription for one of those drugs, compared to office visits for patients under age 55. While racial differences were inconsistent across dependent variables and regimes, Caucasians office visits were usually *more* likely to result in a diagnosis or a drug, if there was a significant difference at all.

*A notable limitation*

Overall, my most significant and striking finding is the increase in number of office visits that result in the prescription of a sedative hypnotic. However, one of the major limitations of this dataset is the inconsistency in number of drugs physicians were allowed to record, over the years. As previously mentioned, in 1993 and 1994, NAMCS allowed up to five medications to be listed. This number increased to 6 from 1995 to 2002, and then again to 8 in the final 4 years of data. This is a serious, potential confounder to my findings. While I argue that a 23-fold increase in any drug is significant and denotes an actual increase in drug prescribing, I also wish to address the potential problem of “listing bias,” or the likelihood that sleep drugs are more likely to be listed as space for more drug listings become available.

As seen in the unweighted counts of the number of medications prescribed in Table 11, the mode for each year is “0.”

**Table 11. Number of Medications prescribed, unweighted counts (1993-2006).**

	<b>1993</b>	<b>1994</b>	<b>1995</b>	<b>1996</b>	<b>1997</b>	<b>1998</b>	<b>1999</b>
0	14,180	13,103	15,057	12,379	9,713	8,996	7,573
1	10,527	10,126	10,110	8,054	7,117	6,369	5,745
2	5,483	5,158	5,717	4,848	3,792	3,609	3,348
3	2,718	2,489	2,828	2,130	1,857	1,996	1,787
4	1,435	1,233	1,407	1,060	921	990	904
5	1,635	1,489	710	549	550	547	558
6	0	0	1,046	785	765	832	845
7	0	0	0	0	0	0	0
8	0	0	0	0	0	0	0
<i>TOTAL</i>	35,978	33,598	36,875	29,805	24,715	23,339	20,760

	<b>2000</b>	<b>2001</b>	<b>2002</b>	<b>2003</b>	<b>2004</b>	<b>2005</b>	<b>2006</b>	<b>TOTAL all years</b>
0	10,765	10,236	11,023	9,061	10,180	8,431	8,585	149282
1	7,573	6,204	7,461	6,588	6,248	6,326	6,826	105274
2	3,996	3,391	4,421	3,844	3,421	3,743	4,544	59315
3	2,128	1,732	2,270	2,033	1,909	2,258	2,714	30849
4	1,087	935	1,189	1,192	1,020	1,366	1,821	16560
5	667	517	735	757	658	965	1,307	11644
6	1,153	1,266	1,639	573	477	722	966	11069
7	0	0	0	345	388	598	762	2093
8	0	0	0	895	985	1,256	1,867	5003
<i>TOTAL</i>	27,369	24,281	28,738	25,288	25,286	25,665	29,392	391,089

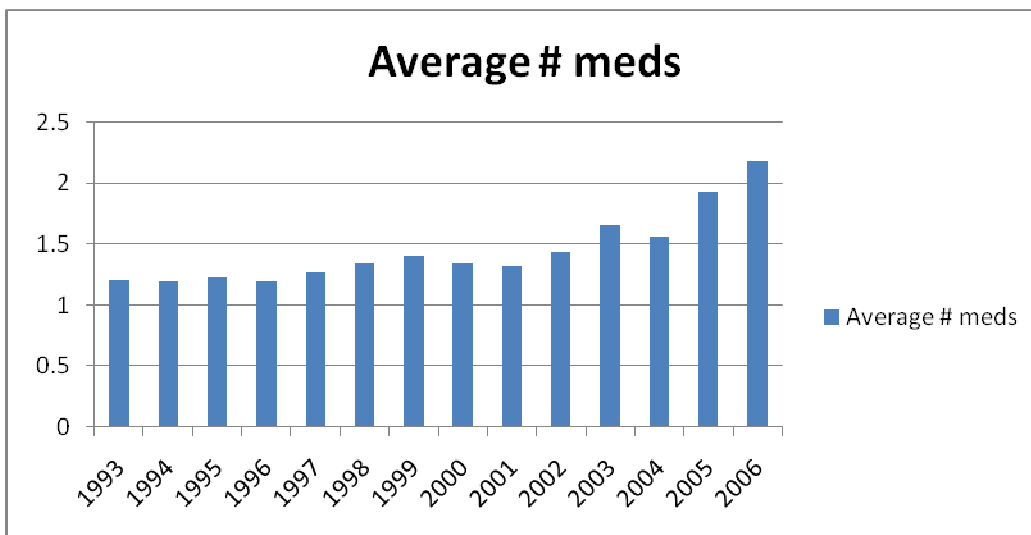
As seen in Table 12, the mean number of drugs actually listed as a percent of the allowable listed never exceeded 27%. In addition, the mean number of drugs increased by only 1 drug on average over a 14 year period of time, even though the allowable drug listings went up by 3.

**Table 12. Average number of prescriptions per office visit, by year (1993-2006).**

Year	Total observations	Mean	Std. Dev	Max allowed	Mean # of drugs as percent of allowable listed (mean/max*100)
1993	35,978	1.21	1.37	5	24%
1994	33,598	1.20	1.36	5	24%
1995	36,875	1.23	1.48	6	21%
1996	29,805	1.20	1.45	6	20%
1997	24,715	1.27	1.50	6	21%
1998	23,339	1.34	1.55	6	22%
1999	20,760	1.41	1.59	6	24%
2000	27,369	1.34	1.59	6	22%
2001	24,281	1.32	1.65	6	22%
2002	28,738	1.44	1.69	6	24%
2003	25,288	1.66	2.02	8	21%
2004	25,286	1.57	2.06	8	20%
2005	25,665	1.93	2.23	8	24%
2006	29,392	2.18	2.36	8	27%

In ‘transition years’ (1994-1995; 2002-2003) there is no substantive change, and over time, the upward trend appears to be a primarily smooth, slow-growing curve.

**Figure 15. Average number of medications in NAMCS (1993-2006).**





I argue that, while the increase in allowable categories may have had some impact on the significant increase in sedative hypnotics over this time period, it cannot fully explain the increase and does not negate or substantially diminish my findings.

In sum, in this chapter I have systematically described, in text and in figures, trends over time in complaint, diagnosis and treatment of insomnia. I discovered some interesting disparities in insomnia-related outcomes, particularly when comparing the prescription of NBSHs to the complaint and diagnosis of insomnia. Analyses of independent variables were also conducted. Further discussion of these, and the qualitative results, is available in Chapter 6.

**Table 10. (Panels A-E) Bivariate Relationships between dependent variables and independent variables (weighted numbers).**

<b>A. Insomnia as reason for office visit</b>						
	<b>Regime 1 (1993-1997)</b>		<b>Regime 2 (1998-2001)</b>		<b>Regime 3 (2002-2006)</b>	
	<i>N</i> <i>(millions)</i>	<i>Proportion</i>	<i>N</i> <i>(millions)</i>	<i>Proportion</i>	<i>N</i> <i>(millions)</i>	<i>Proportion</i>
<b>Total</b>	18.7		20.7			28.9
<b>Age</b>						
<55	12.1	0.0051	13.0	0.0063	19.2	0.0069*
55+	6.6	0.0052	7.6	0.0063	9.7	0.0055
<b>Sex</b>						
Female	10.2	0.0047	13.8	0.0071**	16.3	0.0060
Male	7.3	0.0059*	6.9	0.0051	12.6	0.0067
<b>Race</b>						
White	14.2	0.0050	15.9	0.0061	22.9	0.0066*B
Black	1.7	0.0051	1.8	0.0060	1.8	0.0044
Hispanic	2.1	0.0072	1.7	0.0061	2.8	0.0059
Asian	0.7	0.0058	1.3	0.0118*W, B	1.1	0.0072
All other	0.01	0.0015	0.02	0.0013	0.2	0.0057
<b>Insurance</b>						
Private	11.6	0.0048	11.6	0.0057	17.0	0.0063
Govt.	7.6	0.0067**O, P	6.8	0.0072	9.5	0.0064
Other	3.2	0.0051	3.2	0.0075	3.6	0.0064

<b>B. Insomnia Diagnoses</b>						
	<i>Regime 1 (1993-1997)</i>		<i>Regime 2 (1998-2001)</i>		<i>Regime 3 (2002-2006)</i>	
	<i>N</i> <i>(millions)</i>	<i>Proportion</i>	<i>N</i> <i>(millions)</i>	<i>Proportion</i>	<i>N</i> <i>(millions)</i>	<i>Proportion</i>
<b>TOTAL</b>	7.7		11.4		20.7	
<b>Age</b>						
<54	4.4	0.0019	6.4	0.0031	13.4	0.0041
55+	3.3	0.0026*	5	0.0041	7.3	0.0048
<b>Sex</b>						
Female	5.0	0.0023	7.5	0.0038	12.3	0.0046
Male	2.7	0.0019	3.8	0.0029	8.4	0.0045
<b>Race</b>						
White	5.6	0.0019	9.2	0.0036* H	15.9	0.0046
Black	1.2	0.0037	1.1	0.0039* H	1.2	0.0029
Hispanic	0.6	0.0019	0.4	0.0015	2.1	0.0044
Asian	0.4	0.0031	0.6	0.0050	1.0	0.0066
All other	0	0	0.06	0.0032	0.3	0.0087
<b>Insurance</b>						
Private	5	0.0021	7.1	0.0035	12.8	0.0047
Govt.	3.2	0.0028*P	3.7	0.0040	5.9	0.0040
Other	1.3	0.0021	1.0	0.0024	2.7	0.0048

<b>C. Office visit resulting in a prescription of a Benzodiazepine</b>						
	<b>Regime 1 (1993-1997)</b>		<b>Regime 2 (1998-2001)</b>		<b>Regime 3 (2002-2006)</b>	
	<i>N</i> <i>(millions)</i>	<i>Proportion</i>	<i>N</i> <i>(millions)</i>	<i>Proportion</i>	<i>N</i> <i>(millions)</i>	<i>Proportion</i>
<b>Total</b>	10.4		10.2		14.9	
<b>Age</b>						
<55	4.1	0.0017	4.7	0.0022	6.6	0.0024
55+	6.2	0.0050**	5.5	0.0046**	8.3	0.0047**
<b>Sex</b>						
Female	6.4	0.0030	5.9	0.0030	8.8	0.0033
Male	3.9	0.0027	4.3	0.0032	6.0	0.0032
<b>Race</b>						
White	7.3	0.0027	8.5	0.0033** B	11.1	0.0032
Black	1.0	0.0031	0.4	0.0012	1.3	0.0031
Hispanic	1.3	0.0045	0.8	0.0031	1.7	0.0036
Asian	0.2	0.0018	0.3	0.0027	0.3	0.0019
All other	0.009	0.0008	0.05	0.0028	0.2	0.0043
<b>Insurance</b>						
Private	5.2	0.0022	4.5	0.0022 *O	7.2	0.0027
Govt.	6.1	0.0054 **O,P	4.5	0.0048**P	7.3	0.0049**O, P
Other	1.8	.0029**P	1.5	0.0036	1.9	0.0034

<b>D. Office visit resulting in a prescription of a Non-benzodiazepine sedative hypnotic</b>						
	<b>Regime 1 (1993-1997)</b>		<b>Regime 2 (1998-2001)</b>		<b>Regime 3 (2002-2006)</b>	
	<i>N</i> <i>(millions)</i>	<i>Proportion</i>	<i>N</i> <i>(millions)</i>	<i>Proportion</i>	<i>N</i> <i>(millions)</i>	<i>Proportion</i>
<b>Total</b>	5.4		12.8		44.4	
<b>Age</b>						
<55	2.8	0.0012	6.6	0.0032	21.9	0.0078
55+	2.6**	0.0021**	6.2	0.0051**	22.4	0.0126**
<b>Sex</b>						
Female	3.6	0.0017	8.1	0.0041	30.0	0.0110**
Male	1.8	0.0013	4.7	0.0035	14.4	0.0080
<b>Race</b>						
White	4.7	0.0016*B, **H	10.7	0.0041**H	35.5	0.0103**B
Black	0.3	0.0008	1.0	0.0033	2.9	0.0069
Hispanic	0.3	0.0009	0.5	0.0017	4.2	0.0089
Asian	0.2	0.0013	0.5	0.0047	1.2	0.0077
All other	0	0	0.02	0.0013	0.4	0.0099
<b>Insurance</b>						
Private	3.3	0.0014	7.4	0.0037	25.9	0.0096
Govt.	2.4	0.0021*O, P	4.3	0.0046	16.8	0.0113**O, P
Other	0.8	0.0013	1.2	0.0030	5.2	0.0092

<b>E. Office visit resulting in a prescription of Trazodone</b>						
	<b>Regime 1 (1993-1997)</b>		<b>Regime 2 (1998-2001)</b>		<b>Regime 3 (2002-2006)</b>	
	<i>N</i> <i>(millions)</i>	<i>Proportion</i>	<i>N</i> <i>(millions)</i>	<i>Proportion</i>	<i>N</i> <i>(millions)</i>	<i>Proportion</i>
<b>Total</b>	13.9		14.7		26.0	
<b>Age</b>						
<55	8.9	0.0038	9.0	0.0043	15.0	0.0054
55+	5.0	0.0040	5.7	0.0047	11.0	0.0062
<b>Sex</b>						
Female	10.0	0.0046**	9.7	0.0050*	17.3	0.0064**
Male	3.9	0.0027	5.0	0.0037	8.7	0.0046
<b>Race</b>						
White	11.6	0.0040**A	13.0	0.0050**B , H	21.2	0.0061**A *H
Black	0.961	0.0030	1.0	0.0032**H	1.9	0.0046
Hispanic	1.0	0.0035	0.3	0.0011	1.9	0.0040
Asian	0.2	0.0018	0.4	0.0033	0.4	0.0026
All other	0.07	0.0062	0.05	0.0031	0.5	0.0128
<b>Insurance</b>						
Private	8.7	0.0036	7.5	0.0037	14.2	0.0053
Govt.	5.4	0.0048**O ,P	5.2	0.0056*P	9.6	0.0065*P
Other	2.5	0.0041	2.3	0.0056 *P	3.6	0.0063

Note: Individual totals may not add to expected total, due to rounding.

Note: Insurance categories will equal >100%, as more than one insurance category could be checked, per office visit.

\* P-value < 0.05

\*\*P-value < 0.01

A=significant and positive, compared to Asian

B= significant and positive, compared to Black

H= significant and positive, compared to Hispanic

P=significant and positive, compared to Private

G=significant and positive compared to Government

O=significant and positive, compared to Other

## **CHAPTER 4**

### **PHYSICIAN PERSPECTIVES ON SLEEPLESSNESS**

The objective of this and the following chapter is to provide insight into the patient-physician interaction surrounding sleeplessness by providing qualitative analysis of interviews with both patients treated for sleeplessness and their physicians. The current chapter provides detailed methodology, qualitative findings and a brief discussion of my physician interviews. I focus on the evidence of the medicalization of sleeplessness and the factors present in the patient-physician dyad that may be fueling the medicalization process.

#### **Methods**

##### *Sample*

My sample consisted of physicians practicing in an Internal Medicine Clinic (IMC) affiliated with a large Southeastern University. In addition to their clinic responsibilities they also, to varying degrees, engage in research, teaching and mentoring of interns and residents.

##### *Recruitment*

An email was sent by the head of the Internal Medicine Clinic to all 24 of the clinic physicians describing the project and asking doctors to contact me if they had any interest in participation. See Appendix 2 for a copy of the email. All recruitment materials and physician interview questions were approved by the UNC Institutional Review Board (Study

#: 08-0593, IRB approval received 6/6/08). In addition to gaining UNC-IRB approval, this project was approved by the IMC in-house research committee.

### *Interviews*

Interviews lasted approximately 30 to 60 minutes and were semi-structured in nature. Interviews were carried out in a private office space or conference room within the hospital and were recorded with consent.

I asked participating physicians to fill out a short demographic form that included questions about their race, age and years in practice. In addition, I asked them to estimate the frequency with which they heard insomnia complaints, whether complaint of insomnia was typically primary or secondary (to another complaint) and if they thought patient complaint of insomnia has increased, decreased, or stayed about the same during their time in practice.

I used an IRB-approved interview protocol to guide the conversation and provide continuity across interviews. However, physicians often brought up topics of interest that were not covered in the interview guide. Insights that seemed interesting or relevant were discussed further and often informed the topical structure of subsequent interviews. As a “thank you” for the physician’s valuable time, a small donation was made to the Clinic’s Education Fund.

Please see Appendix 3 for a copy of the physician interview questions.

### *Coding and Analysis*

Data were transcribed from the interview recordings. All transcripts were given an in-depth initial read-through. Next, I performed a “first pass” coding on three of the transcripts.



I chose an early interview, an interview performed mid-way through the process, and the final interview. These transcripts reflected the evolution of conversations and relevant themes that emerged over time and allowed me to construct a comprehensive “first pass” code list.

First pass codes were then added to a list of “housekeeping codes.” Housekeeping codes represented themes that were expected to emerge, based on the theoretical framework of medicalization and some of my key interview questions. Housekeeping codes included: medicalization, age, gender, race, SES, insomnia context, insomnia definition, physician compliance, rhetorical authority, physician education and training, practice type, and role of drug company.

Many of the housekeeping codes became “Free nodes” in NVivo. Free nodes in NVivo are “stand alone” codes. NVivo also contains a coding or “node” system referred to as tree nodes. Tree nodes are helpful because they allow for multiple, related codes, or “families,” to cluster together. For instance, rhetorical authority, originally a free-standing concept was turned into a tree node when I realized I wanted to make distinctions between the origins of rhetorical authority (e.g. internet vs. friends and family).

Other emerging codes were created as tree nodes. One example is the concept of attitude. During the coding process it became evident that attitude toward diagnosis and treatments was a critical part of this qualitative analysis. In addition, the contrast between patient and physician attitudes seemed important to the medicalization process. Separate, but related, tree nodes were created to capture these attitudes.

Using the first-pass code list, I read and coded all of the transcripts. During the coding process, a few new themes emerged and codes were consequently revised, deleted, added or expanded. A final code list is available in Appendix 4.

During the coding process, I wrote memos about emergent themes, and themes I thought might be conceptually connected; illustrative quotes were added. A memo example is available in an appendix. [Please see Appendix 5]

After using the revised code list to do a second coding pass on all of the transcripts, I uploaded the transcripts into NVivo and coded them a final time. In this coding pass, I was working from hard copies that had been coded using the “final” code list, but it was also another opportunity to assess codes and their use within an interview.

Using NVivo, I was able to print coding reports of particular nodes, as well as visually assess the way selected portions of text were double-coded or triple-coded, and so on. Co-occurring codes were common and codes that frequently appeared together offered insight and a framework for my analyses.

### *Limitations*

There are several limitations to my design. As previously noted, I was not able to carry out direct observation of office visits centered on a complaint of insomnia or resulting in the prescription of a sedative hypnotic. In asking patients and physicians to talk about their past encounters, I introduce an element of recall bias.

I must also allow that the day-to-day practice of the physicians differs significantly from the office-based physicians surveyed in NAMCS. IMC physicians interviewed carry out research and/or teach in addition to their clinic responsibilities. These additional responsibilities could theoretically heighten their investment in the medicalization process.

Another distinction of this clinic is that residents and interns have far more limited interaction with drug representatives than most of their peers. A few years prior to this study,

the Chairman of the Department of Medicine decided to no longer allow the infamous “drug lunches” (lavish, free lunches provided by representatives from pharmaceutical companies) that have been a hallmark (and, at times, highlight) of being a practicing physician. To that end, this IMC is spending an extra \$40,000 per year to provide lunches (personal communication Drs. C. and M<sup>22</sup>, November 2007). While this impacts my ability to assess one of the fueling factors in my conceptual model – the influence of the drug companies on physician compliance - it did not impact the physicians’ ability to express their opinion of the relationship between drug companies and patient and physician attitudes toward prescription sleep aids.

Finally, the small size and narrow demographic profile of this convenience sample preclude it from being generalizable to a larger population.

### **Findings**

Twenty-four physicians received the clinic director’s email; eight agreed to participate in this study. Two of the physicians were women,<sup>23</sup> and all were Caucasian. They ranged in age from 32 to 63 and their years in practice reflected this range (1 to 38 years, mean = 14). On average, they saw 36 patients a week, but the range was broad (8-80). The mean number of patients seen in a month was 144. For further demographic detail, please see Table 13.

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<sup>22</sup> For purposes of confidentiality, I cannot identify these physicians by name.

<sup>23</sup> Due to the small number of female participants, in cases where a gendered pronoun is used I will use the masculine. This is intended to provide an extra measure of confidentiality.

**Table 13. Physician Descriptives.**

	Mean or %, range
Age	45 (32, 63)
Male	75% 25%
Caucasian	100%
Years in Practice	14 (1, 38)
Years in this clinic	11 (1, 33)
Patients seen in a week	36 (8, 80)
Patients seen in a month	144
Patients who complain of insomnia in a month	12 (2, 40)
Patients complain: In context of other problems As a primary complaint	100% 0%
(Over time) Patient complaints have Increased Decreased Stayed about the same	50% 0 50%

Physicians in this sample reported that an average of 12 patients per month complained to them of insomnia (range= 2 to 40). When asked if patients complained of insomnia in the context of another problem or if it was a primary complaint, all eight said that it was presented in the context of another problem. The sample was evenly split on whether patient complaint of insomnia has increased or stayed about the same during their time in practice. No-one reported that it had decreased.

**Is there evidence of the medicalization of sleeplessness? If so, what forces might be fueling the process?**

To best answer these questions, I focus on three components of the physician interviews: their language, attitude and reported behavior. Specifically, I highlight the language that they use to discuss medicalization, their attitudes toward insomnia diagnosis and treatment and their prescribing behaviors.

I expand upon and give examples of the meso-level theoretical constructs that may be moderating the patient-physician interaction: consumerist attitudes, rhetorical authority, physician compliance, patient compliance and knowledge alignment. I address the concepts of patient compliance and knowledge alignment on a very limited level, as physicians have little knowledge of patient's behavior once they exit the office visit, and the physicians in this sample have restricted or no contact with pharmaceutical representatives.

#### *Language of medicalization*

Physicians in this sample used sociological language, discussed facets of the medicalization process and were able to offer another example of a medicalized disorder.

To varying degrees, all of the physicians in this sample appeared cognizant of the medicalization process, and a few even used sociological language when discussing it. One physician used the term “disease mongering,”<sup>24</sup> another discussed “case findingness.” Two physicians asked me if I had read the work of Norman Hadler (a physician who writes on the expansion of disease categories and the over-use of medications in American society). A couple of physicians used the specific term “medicalize” and other examples of medicalization were discussed.

*Yeah...I think we tend to medicalize insomnia to a large degree....I think the majority of cases of insomnia are due to stressors in life and normal variance and I think they*

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<sup>24</sup> (see Moynihan, Heath and Henry 2002)

*are usually not psychiatric diagnoses but I think to gain the diagnosis of insomnia it ought to be that. (Doc 4)*

*I think sometimes these direct to consumer commercials or advertising makes people think they have a problem when they don't. And then medicalizes it and makes them want medicine when they don't necessarily need it. (Doc 2)*

Another physician discussed the medicalization process in terms of awareness and its relationship to “case-findingness.”

*You know, there are lots of ways to raise the awareness and case-findingness out there. And then all of a sudden you get, just like with any condition. If you start doing more case-finding you start calling things that we used to call normal, disease. Right? And so, all of a sudden you're treating people who are on the more mild spectrum. And you're kind of left in this quandary well what's disease and what's not? What should be treated and what shouldn't? (Doc 3)*

When asked if he thought there was an epidemic of sleeplessness, one physician described, eloquently and at length, the process of disease “creation” using the examples of high blood pressure and post-traumatic stress disorder. He also employs the term “disease mongering.”

*I would say it's two things, it's ascertainment bias and also disease mongering. Where we search. And we can create. Well, disease mongering is the most cynical way to put it. But there are a lot of conditions that we do not define statistically. Diseases, that we define them epidemiologically. For example, a 50 year old man with a blood pressure systolic of 145 has statistically a normal blood pressure. Statistically well within the 95% of the normal people. But we've decided that since strokes and heart attacks go up in the population starting at about 140 that we're going to define 145 as abnormal. So it depends on whether or not you want to make your disease criteria-based or normative-based. And so if you change the definition of an illness then you will ascertain more cases. So it's not just an ascertainment bias which is a measurement phenomenon it would also be, and more sophisticated epidemiologists will have the term for me, for this. But when you can create a disease, you can define a disease into existence, if you relax the criteria or you make them broad enough so that you'll encompass a lot more people. And that's been done all the time. I mean, for example in the psychiatric literature there's some controversial examples about how post-traumatic stress disorder, it used to be considered that you had to have some terrible experience like being on the Bataan death march or being raped or something like that. Some extraordinary experience, negative experience is the trigger. But now that's been relaxed. And so obviously the number of people who will have the disease is greater. Or who will be diagnosed with it. It also does serve*

*commercial interests though to expand the diagnosis of a disease if there is a treatment. (Doc 5)*

Two physicians departed from the topic of insomnia to parallel it with another, arguably medicalized, disorder – toenail fungus.

*Seeing commercials about insomnia makes people more inclined to think of it as a disease process. I mean it's the same thing as the toenails, you know? I mean those fungal nails. Fungal nails did not necessarily. I mean some people came in and complained about their fungal nails but now a lot of people come in and complain about fungal nails 'cause it's all over the TV. And they say, well I think I have fungal nails and I need a prescription for this. And there's a bit of that with respect to insomnia, that being bombarded with it makes people start thinking about their sleep pattern more and it's not always clear that is what has generated the visit or the inquiry, but I think it is bound to, to some extent. And then, and so that's the one half of it, is just making people start thinking about, Oh, do I have a sleep problem. Maybe I should talk to my doctor about it. And the other one is then, a specific pill that they could request when they came in. (Doc 7)*

*And think about, I remember when Lunesta was all over and it's like the butterfly waking up all happy. You know, they will come in, Oh, I want to try that one. And it kind of made me giggle because I was like, well 'cause you watched it last night with the butterfly waking up...I mean, I'm trying to think of another, you're doing this in terms of insomnia but like toe fungus is another one that they were really pushing. I mean, I have people who are really ill, dialysis and diabetes and they want their toe fungus and they want the pill for that. And that's just, I don't know what would make them think of that unless they've, you know, why would they ask me for a pill for their toe fungus unless they saw an advertisement? And that would be certainly never something that I would ever bring up. So it does affect, I mean it affects what you end up [doing], it affects the agenda you have with them. (Doc 2)*

Although none of the physicians were enthusiastic about the medicalization of sleeplessness, a couple of physicians pointed out that the complaint of insomnia could aid in the discovery of a mood disorder.

*The only other positive might be if people are really talking about their insomnia and it does cover a mood disturbance you may actually get a little more, you know, insight into their mood that you might not. You know, sometimes men are less, they don't want to talk about depression as much, so they might talk about their insomnia. It gets you to be able to open the door and talk more about mood disturbance. And I guess that's probably the case for a few of my patients. So that might be a positive of it, I don't know. (Doc 2)*

In sum, several of the physicians in this sample used targeted terminology – including “medicalize”, “disease mongering” and “case-findingness” - to describe the medicalization process. They seemed keenly aware of factors that aided in the medicalization process, such as the expansion of a disease category and the influence of advertisements (discussed later in more detail), and were able to relate the medicalization of sleeplessness to other medicalized disorders such as toe fungus.

#### *Attitudes toward diagnosis*

By definition, a medicalized disorder is a symptom or set of symptoms formerly considered a “normal” biological or behavioral process (Conrad 2007). Physicians in this sample were reluctant to categorize insomnia as a disease process. Insomnia was typically described as either a) a symptom of another disease process (typically a mood disorder) or b) a normative process – particularly when viewed in the context of aging.

#### *Insomnia as symptom*

The following quote highlights physician views on insomnia as a symptom.

*Well, to me insomnia is to mood as fever is to pneumonia. It's not a disease, it's a symptom. So I don't treat insomnia. You know, it's very rare that I find someone who has insomnia for which it's not related to a mood disorder. Depression or something like that. And I do not use benzodiazepines or sleep tablets or things like that because I feel that it would be like treating pneumonia with an aspirin to remove the fever. So typically I'm looking for a mood disorder, anxiety disorder, panic disorder, or some other reason which is underlying the sleep disorder. That may be even something as simple as chronic pain. It may be something that has to do with other things keeping them awake. Maybe they're having reflux at night. There are lots of different reasons. But I don't view insomnia typically as a disease. (Doc 1)*



*There are rarely patients who have, you know, you screen them for everything and all they have is trouble sleeping and have insomnia but everything else is fine. I mean I think you can almost always find something else to address. But...the portrayals are that this person is a beautifully healthy person who just can't sleep and now they take this drug and they're happy. (Doc 2)*

One of the physicians who used the term “medicalize” (began on page 86) continued the quote to address what he felt were the root causes of insomnia.

*It is getting ahead of myself, for the majority of patients I see I feel like are normal life variance of that and there is relatively few cases that I see where I would say this is a medical diagnosis of insomnia. (Doc 4)*

In the following quote, Physician 5 goes beyond the symptom versus disease distinction by emphasizing the clinical impact. Further he states, “we are being led to believe” certain things about insomnia, which, in his judgment are inaccuracies.

*In most people insomnia is a symptom, it's like sneezing. In my, that's my judgment, not my opinion. You have to understand the clinical impact. If everyone stopped their Ambien for a week in this country, it wouldn't even register on a public health level. If everyone stopped their insulin or aspirin for a week, who needed to be on those medicines, it would register as a big public health problem. Or, let's say a month. It would register as a huge public health problem. But we're being led to believe that the clinical impact of this is as important, is on par with things like being on insulin for diabetes or aspirin if you have heart disease, or certain blood pressure medicines if you have heart failure. Certainly if you have someone with advanced heart failure and you told them to stop their after-load reducing medicines, which is a fancy term for kind of a blood pressure medicine that takes stress off the heart. There wouldn't be enough, and you told them to do it for two weeks, there wouldn't be enough hospital beds in the country to accommodate all those people. (Doc 5)*

Later, he notes:

*You know, we have made some important advances in sleep disturbances like obstructive sleep apnea. We know, but that's, I don't think that's what we're talking about. We're talking about this generic symptom which is basically a subjective symptom which does not involve any measurable disturbance in the physiology. You know, like a sleep study you can actually see some bad things happening. (Doc 5)*

### *Insomnia as normative process*

Some doctors commented that the larger problem may be in patient expectations about what constitutes “normal” sleep and how this may or may not relate to their daytime function.

*So insomnia is a great example because probably just about everyone has had a sleepless night. And a whole lot of people may have a few of those together. And is that pathological that needs treatment or not? And that's a values question of how bad that is to that individual and how, what the relative risks and benefits of the medication are, if you're going to use medication. (Doc 3)*

Physician 6 talked specifically about changing patients “norms” regarding sleep.

*There's a whole thing about what should be the expectation about sleep and how we make the expectation you're supposed to sleep 8 hours in this perfectly blissful state and that that's not [what we're] really evolutionarily programmed to do. I was reading this thing in the New York Times magazine or maybe it was in the New Yorker about really people have this thing where they're supposed to wake up at 3 in the morning and be kind of semi-alert for an hour and then go back to sleep and that was well recognized and considered to be normal. And then we kind of said, no, no, no you're supposed to have your suspended animation state for 8 hours. And that may be too high of a bar.... So I try to talk about well, so you're not sleeping well, so what does that mean. If it just means that you're not getting 8 hours sleep and you think that's the norm then we're not likely to intervene. You just try to then change your norm. (Doc 6)*

Physician 2 clarified that daytime function was a key indicator in whether and how he chose to treat sleeplessness.

*Sometimes another, I didn't say this earlier, but another question I ask patients now is, how do you function during the day? Many people may not sleep well, you know, or may not sleep straight through for 8 hours, but they are getting, accomplishing everything they need to do. They have energy, they're fine, they're not sleepy during the day. So does that person really have a sleep problem? Right? I mean if you're functioning the next day, probably not. So that's where I struggle a little bit. (Doc 2)*

Related to the idea of sleep “norms” is the issue of aging. As noted in the background section, many believe that reduced sleep time may be a normal part of the aging process.

*“I’ve come to think that it’s really rare for some, for people over 40 to sleep through the night....Yeah, more and more I try to normalize fractured sleep. And maybe that’s from my, just from my own experience and from talking to so many patients. And that’s another way I divert this and don’t prescribe. It’s getting up, you know, waking up once or twice a night. Sometimes staying awake for an hour seems really normal by the time you get to a certain age. And not something to be treated with a pill. And so then it’s a matter of resetting expectations. That, ok, well you don’t need as much sleep. You don’t need to spend as much time in bed.” (Doc 7)*

*And we know for example that the elderly tend to have more sleep fragmentation. And they may not stay sleep as long, and that may be physiologic. Although I’m not an expert in this. You know, we tend to think of that sleep fragmentation or sleeping for shorter periods as being a common phenomenon in the elderly. Although they do catch up in the day by taking naps and such. Yeah, but those are, that’s how I would conceptualize it. (Doc 5)*

Another physician alluded to the fact that older patients are more likely to have multiple comorbidities.

*The other context is in older folks who are not doing well, who are tired, who just don’t seem to feel well. And it’s a combination of a number of symptoms. They haven’t been eating well, or you know don’t have much energy, not much enthusiasm. They’re tired, they don’t feel well, they don’t sleep well. They can’t stay asleep they wake up early, can’t go back to sleep. They have racing thoughts through their heads at night when they’re trying to lie down. So there are many contexts which it would come up in, but it’s not usually, not ever just a single isolated event. I rarely, I don’t think I can recall very many people ever coming in and saying you know, I’m perfectly fine, everything is great, I just can’t sleep. (Doc 1)*

None of the physicians in this sample stated that they thought insomnia was a biologically-based disease process. It was either considered a symptom of another disease process – typically a mood disorder - or described as a normative, if unpleasant, part of life for most people, especially as we age.

### *Attitudes toward Insomnia Treatment*

An integral part of the medicalization process is the use of prescription drugs to treat a disorder. Physicians are still considered the gatekeepers to the prescription pad (Conrad 2007) and it seems logical that their expressed attitudes toward sleep aids may have some impact on their prescribing practices. Physicians in this sample discussed both behavioral and prescription treatments. Prescription treatments mirrored the categories analyzed in the NAMCS dataset: Trazodone, non-benzodiazepine sedative hypnotics (NBSHs) and benzodiazepines.

The physicians in this sample emphasized that they try to utilize behavioral techniques or “sleep hygiene” prior to, or in lieu of getting out the prescription pad. The following quotes are representative of their attitudes towards different sleep therapies.

#### *Non-prescription sleep treatments*

The concept of sleep hygiene arose in the first interview I conducted and was a topic of discussion – to varying degrees – in all of the physician interviews. The practice of sleep hygiene offers guidelines on health practices (diet, exercise, substance use) and environmental factors (light, temperature, noise control) (IOM 2006). Discussion of sleep hygiene was both a diagnostic technique and a suggested treatment for sleeplessness.

*The first thing we'll do is we'll try to figure out how much coffee they're drinking or how much soda they're drinking or, what they're eating before they go to bed, what they do before they go to bed. You know, do they relax, have they just been doing a whole lot of work. I mean, there are a lot of reasons that people can increase or decrease their levels of stress. And those are the more common things. Sometimes I tell them, ok just have a warm glass of milk and sit down and relax. So sleep hygiene is critical. And many times people, you'll find, are doing things you just couldn't imagine doing before sleep. [Like] maybe having a couple of cups of coffee at 3 or 4 in the afternoon. Not realizing the caffeine has a long half-life and will keep them awake at night. (Doc 1)*

When asked if he ever talked to his patients about lifestyle or behavioral changes, this physician told me:

*I do, and that is where I will start. I will tend to talk to them about regular bedtimes, regular awakenings, not watching television in their bed, trying to use their bed mostly just for sleep, caffeine intake, reducing caffeine intake, alcohol intake, any other drugs they may be using around bedtime. And that is always where I start and try to see if that will help someone before medication. (Doc 4)*

Physician 6 talked about sleep hygiene and its use as a first line treatment before prescription therapy.

*For the people who don't have obvious depression then the next thing is to ask them about sleep hygiene. So, then I'll usually start with ok, so tell me about your sleeping. .... When you get to the people that are like, I just wake up and I'm awake and I can't get back to sleep, then you do a little bit of probing about caffeine and what have they tried previously. And usually my first intervention is a sleep hygiene recommendation, so no caffeine at all if possible or at least after noon. And then I focus on, try an exercise intervention, so getting exercise, aerobic exercise during the day not close to bedtime. As a way of helping people to relax and go to sleep, I usually do that first. And then if that's not effective then we talk about pharmacologic therapy if it's bothering them enough that they want to do something. (Doc 6)*

### *Prescription sleep treatments*

Despite their stated preferences for the use of non-pharmaceutical solutions, for a variety of reasons (discussed in more detail in the section on “prescribing behaviors”) most of the physicians in this sample routinely wrote prescriptions for sleep aids. The three types of sleep aids they mentioned were (in order of physician preference) Trazodone, NBSHs and benzodiazepines.

#### *Trazodone*

Trazodone was the first-line prescription of choice for many of these physicians. Most preferred it because of its non-addictive properties.

*But I also tend to use Trazodone a fair bit, not necessarily for its anti-depressive actions but as a sleep agent. So if they really want a pharmacologic therapy and*

*aren't fixated on one I typically will suggest Trazodone at 50 mgs to start with and then 100 and I'll go up to 200. And a fair number of people have gotten good success with that. But some people it doesn't work, so I won't say that it's always effective. (Doc 6)*

Physician 5, while acknowledging it is not habit-forming, opined that Trazodone was primarily effective in patients also being treated for depression.

*There's another class of medicine that's used for sleep aid and depression. That's called Trazodone. Now, Trazodone has never been shown to really help with insomnia outside of treating people, if you are treating them concomitantly with other medicines for depression. I tend not to believe it. And in order to minimize the amount of polypharmacy I just don't use Trazodone. But it is not known to cause physical or psychological dependence. It's not a controlled substance. (Doc 5)*

The only negative side effect mentioned for Trazodone was the possibility of hangover.

*If someone for example, let's say we're treating them for depression and their sleep hasn't quite gotten as better as I would like, I'll often add Trazodone which is an antidepressant, which is very effective. The only problem is it gives them a hangover in the morning. So, to some extent you're limited in how well you can use it, you know. (Doc 1)*

#### *NBSHs*

The non-benzodiazepine sedative hypnotics are by far the most oft-prescribed sleep aids, both at a national level and in this practice.

*Mostly I prescribe zolpidem in either 5 or 10 milligrams. And very occasionally temezepam. And I guess rarely triazolam....Occasionally patients will come in and they've seen advertisements for Lunesta and think that, well that might have some advantage for them. (Doc 7)*

NBSHs are preferred to the older generation sleep aids because they are typically thought to have fewer negative side effects or addictive potential. (Although, in a later quote, this physician questions whether there is good clinical evidence to support some of these ideas).

*You know, for example the sleep aids are controlled substances. You know, I think it's a relatively minor transgression to keep prescribing them, compared to let's say benzodiazepines chronically or opioids chronically for pain, other controlled substances. Where I can have objective evidence that if I'm prescribing them inappropriately, these other controlled substances, that I'm doing this person harm.*

*They're no longer as productive as they used to be. They're exhibiting certain kind of, we call them drug-seeking behaviors. In all honesty I don't see, I won't see that degree of misbehavior as I would maybe with certain narcotics, certain opioids, pain relievers. Another reason I'm willing to put up with it, with what I consider is suboptimal prescribing on my part. (Doc 5)*

When asked why Ambien was his prescription sleep aid of choice, this physician told me:

*It's just what I've gotten used to prescribing. If someone came to me and said that they wanted to try Sonata I would be happy to prescribe it for them. But I think it's generally true about physicians that we kind of figure out the medicines that we're most comfortable with within a given class. And I haven't found, I'm not aware of any other medications that have been proven to be far superior to Ambien. (Doc 3)*

### *Benzodiazepines*

Benzodiazepines, an older generation of sleep aids, are still commonly used. These physicians noted that benzodiazepines can be quite useful in situations where sleeplessness is fueled by anxiety.

*Certainly sedative hypnotics and benzodiazepines, they certainly have a role in lots of different areas, but I do not routinely prescribe them for sleep unless, and there again, the caveat here is that I just saw a woman yesterday actually who is a 78-year-old woman, very nice older lady with diabetes and her daughter-in-law is dying of ovarian cancer so she is under a lot of stress right now and that is understandable. She is having trouble falling asleep so I gave her a prescription for clonazepam, a very small dosage, like 0.125 mg, I think, very small; but again talked to her about how that would be used for, we would use this over a few weeks. So that is an example of that but, overall I do not prescribe benzodiazepines for sleep unless it is an acute cause like that....Zolpidem or Ambien, that will be the one that I will prescribe if I decide to initiate therapy by myself. (Doc 4)*

However these physicians were cautious in their prescribing practices because of the known potential for addiction.

*Benzodiazepines which are sometimes used for sleep but also a lot for anxiety, I tend to not use a lot of those. So maybe it's more for these controlled medications or schedule 2 medication that I feel like I try not to prescribe. So there may be certain classes that I'm more averse to prescribe. (Doc 3)*

### *Prescribing behaviors*

Nationally representative data (described in Chapter 3) indicate that, particularly in relation to NBSHs, physicians are increasingly likely to prescribe a sleep aid. What forces influence this critical office visit outcome? I posit that the forces of consumerism, physician compliance, rhetorical authority, knowledge alignment and the influence of insurance companies directly influence the outcome of a hypnotic prescription. These interviews offer valuable insight into these elements and how they may present in physician office visits.

Physicians noted the presence of consumerist attitudes among patients, as patients request specific drugs and bring pharmaceutically-sponsored coupons into the office visit.

Physician compliance seems to be motivated by various factors, including the aforementioned consumerist attitudes. The influences discussed most frequently in these interviews include the presence of time constraints; a “soft” bias toward sleep aids that rarely precluded the writing of a prescription; the propensity for patients to enter the encounter with pre-existing prescriptions; and, to some degree, the physician motivation to achieve patient compliance.

According to these physicians, rhetorical authority [RA] is commonly seen in their office visit interactions and patients acquire their medical information from a variety of non-medical sources. DTCA, or direct-to-consumer-advertising is a catch-all phrase for various forms of media that advertise directly to patients, and was mentioned by most of the physicians. More specific sources of RA, the internet and social networks, were also mentioned.

I touch on the concept of knowledge alignment. Although my original conceptual model included the influence of pharmaceutical companies on physicians, this particular



sample, as previously noted, does not see drug reps. Despite this fact, some of the physicians expressed their opinions on the pharmaceutical industry, and I have included their quotes.

Finally, I briefly note an unexpected finding - the influence of the insurance companies on physician prescribing behaviors.

### *Consumerism among patients*

Patients increasingly act like the physician office visit is one more service industry, to the extent that they engage in doctor-shopping and other consumerist behaviors.

Consumerism was evidenced by the use of coupons for prescription drugs, patient instigation of a diagnosis or prescription, and awareness of “doctor-shopping” (the practice of finding a physician who will give you your desired prescription).

Two of the physicians mentioned that patients had entered the office visit with coupons for a free trial of a specific sleep drug.

*At some point he said he wanted to try, it was pretty early on, he wanted to try Ambien. In fact, he brought in a coupon, said, you know I can get these free with this coupon. I'd just like to try it and see if it helps because sometimes I have trouble sleeping. And you know, so I thought sure you know you've got a coupon you want to try sometimes, that's fine. (Doc 3)*

Physician 1 noted quizzes in addition to coupons.

*KI: Oh yeah, I see coupons. But it's not new to Ambien I mean they do it for Viagra for all those things, you know.... And somebody will say I took the Pfizer quiz and I need the medicine*

*I: And how do you respond?*

*KI: I just simply tell them. I say, well, think about it for a moment, if I were your car salesman I could give you a quiz to make you want to buy my car. (Doc 1)*

Physician 3 also noted how patients are more likely to bring up the issues of sleep, and in his estimation, they “bring it up all the time.”

*Um, patients in my experience patients almost always bring it up. I don't ask about it as a general routine thing. It's such a, it's so common to have occasional insomnia, that, I just have never found it useful to ask about it. But people bring it up all the time....Most have seen commercials or talked to friends that take medicine for the insomnia and have an impression that medicine would help them. (Doc 3)*

When I asked Physician 1 to give me an example of an instance where he had refused to prescribe a requested medication, his answer hinted at the concept of “doctor-shopping.”

*KI: Oh well I've had people, matter of fact, who stopped coming.*

*I: What do you think their next course of action is?*

*KI: They'll find a doctor who will give it to them. And that's not too hard. (Doc 1)*

Physician 5 also referred to the healthcare system as a “marketplace.”

*So this is why direct to consumer advertising is insidious because patients hear one thing from the TV and then their friends and then the physician's put into a position of contradicting a belief that the patient has already established. And it's not a therapeutic situation for a generalist physician who's expected to kind of monitor a variety of problems. You know the rheumatologist for this person can always decide that this sleeping aid, and appropriately, is not what they have to deal with. “Go ask your primary care doctor.” So that's what makes it difficult for primary care. Because I know the patients, it's a marketplace, a lot of them could go out and find a doctor and also get samples. (Doc 5)*

He also gave a specific example of a patient who had “doctor-shopped.”

*But you know, interestingly, people will get what they want. So I have a patient who's very loyal to me because I diagnosed her with a very unusual disease, well not so much an unusual disease but a serious disease at a young age. And she comes to me and she's on Lunesta and something else, so I know she's seeing another doctor. And I never prescribe Lunesta but I know she's seeing another doctor who's prescribing this. And it probably started out of the sample cabinet, but I don't refill it for her. (Doc 5)*

### *Physician compliance*

The following paragraphs outline some potential contributions to physician compliance : time constraints, “soft bias”, pre-existing prescriptions, and patient compliance.

### *Time constraints*

One physician mentioned the issue of sleep three times during the interview. It initially came up about midway through the interview.

*Are you spending more time talking about their insomnia than you could be talking about, because you only have 20 minutes with them, than their preventive medicine or other things that might be more of an impact on their health. But it does. (Doc 2)*

Once the recorder was turned off, this physician became somewhat more relaxed and candid and the issue of time was re-introduced. With his permission, I restarted the recorder:

*Sometimes if a patient has a lot of complaints and other health problems and they mention their insomnia and they're interested in a medication sometimes it's easier to write the prescription than it is to take a lot of time talking about behavioral modification. I always do try to talk about it, but sometimes there are just I think there are days that you write it, without. And you, well, you readdress it, but you do write it without much more discussion than that. (And a moment later)  
And sometimes you feel bad for people who are just trying to be informed about their health and then their sources are getting them more and more confused. And then it's for us, confusing because it's taking us time we could be taking care of our patients with what we have perceived as being, not meaningful but really will help them. So, cardiovascular prevention, or cancer prevention, but we're spending all this time talking about sleep. And that's, to them what they're focused on. But really what I'm focused on is your blood pressure is really high or this other issue, so it can be hard. (Doc 2)*

Physicians also spoke of conflicts that may occur during time negotiation.

*And you know, we negotiate....and it's an unspoken negotiation at times and even negotiation itself the very act sometimes involves conflict and resolving conflict as you go. And first of all, there's not necessarily time to resolve all these little conflicts or these latent conflicts. And second of all you have to balance that kind of negotiation against the really important business, the really important business of the clinic visit. (Doc 5)*

Physician 8 echoed these sentiments.

*And also, I mean I think the other thing that would be interesting to explore is what are the other competing issues that are in the visit. So, if this is all I was dealing with then I might in certain people take more time than otherwise I might not if I'm also dealing with their diabetes, their hypertension and all their social issues that may be impeding their ability to take care of themselves. (Doc 8)*

Related to time is *when* during the office visit the complaint of insomnia arises.

*It's never the center of the visit and most likely it's at the tail end, when you've already finished evaluating things. In your mind you're done with the visit and ready to go on to see the next patient and you know, maybe the last thing you do is the paperwork and write prescriptions and they say "And will you refill my Ambien?" And you so sort of, you know, maybe you've forgotten they're on it. But now are not prepared to address it in any detail. And you sort of assume "I guess I've already been through this before because I've prescribed it before." And so you say "Oh yeah, what dose are you taking? And how many nights a week do you use it?" (Doc 7)*

### *"Soft bias"*

In this section I discuss what I have termed "soft bias"<sup>25</sup> against sleep aids. In cases where they did not feel it posed a danger to the patient's health or was counter-indicated by some other condition or medication interaction, the majority of physicians in this sample were comfortable with, if not enthusiastic about, prescribing sedative hypnotics for sleep. However, these physicians also noted the habit-forming nature of most sleep aids, as well as the negative side effects they are likely to engender in older populations.

Only two physicians indicated that they routinely refused to prescribe sleep aids. One physician discussed his preference not to use sedatives for sleeplessness, instead urging patients to try sleep hygiene practices, but called it a "soft bias" against medication.

*Oftentimes people will say they're doing all of those things. Or they'll say, yeah, I have a TV in my room but that's not what's keeping me awake. So, I talk about [sleep hygiene] every time because I have this bias against prescribing a lot of the sleep medicine. But on the flip side of that, it's a very soft bias. The flip side of that bias is that I know for some people it really makes their lives better and so I don't mind prescribing it that much. But I have this, I don't know if it has to do with my values or my own biases in life but I feel like I need to try and get them to manage their sleep without medications. And you know, I'll tell them you can get hooked on these medications and things like that. And a lot of patients actually when you start talking about it they'll say, yeah I'd rather not try medicine yet. Let me see if I can do ok. And then a lot of patients just want something for the hard nights. (Doc 3)*

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<sup>25</sup> Derived from Physician 3's quote.

Another viewpoint expressed is that while these drugs may not be particularly helpful, they are not particularly harmful either.

*But I do, people will often bring up sleep problems and we'll talk about it, and I'll make recommendations for behavioral changes and lifestyle changes and I won't offer the medication even though I can sense that they might like on. And if they don't push me on it then we'll just say you know, let's see how this goes and we'll reevaluate next month when you come in and we'll see if this takes care of it. If they push back and they say I really want a medicine for this then I'll let them try a medicine. I don't feel like I have to engage in that sort of, I don't know, it feels very parental to me and it's not something that's going to hurt them, then I'm ok....And at the end of the day it's really a values question because some of these things are not that helpful. They cost money. And is it, you know are they, is it really bad for patients to take an Ambien every night? It may not be the end of the world. Might cost our healthcare system a lot of money and that may be bad if we thought about things that way, but we don't think about things that way in our country. (Doc 3)*

Near the end of the interview, Physician 5 mentioned some rare but bizarre side effects of prescription sleep aids.

*Someone told me a funny story recently about of friend of theirs who was, you know it was like a doctor who ended up taking some Ambien. Next thing you know he was out in the road naked or something like that. [laughs] No seriously. Fortunately the people who picked him up realized that he was probably completely psychologically deranged at that time. And you know I've seen like a Baptist minister try to take off a nurse's clothes in the hospital once when he was given a dose of Ambien. He became disinhibited. It was really. But I've seen that with the Benzodiazepines, people have these paradoxical reactions to sedative hypnotics. And you certainly see that with alcohol. There are some people who are meek and mild and you give them a few drinks and the next thing you know, they're a raging bull. So, you know, and the alcohol works on a similar set of receptors in the brain. (Doc 5)*

In addition, he discussed their potential for addiction.

*And they've [NBSHs] never even been shown to be safer, cause less dependence than the benzodiazepines. You know there's a lot. The Benzodiazepines were certainly overused for a while. Not mainly for insomnia but for anxiety and other psychiatric disorders. They certainly can cause physiologic and psychologic dependence, the latter which we call addiction. But you would be hard pressed to find a clinical trial that compares the addictive potential of the new drugs, Lunesta, Sonata, Ambien to the Benzodiazepines. Its been suggested that they're less addictive and it's perplexing to me that some of the commercials can say that they're not habit forming, when indeed they're scheduled, they're controlled substances. You have to have a special license to prescribe them. A DEA license. And certainly we see clinically that people*

*become psychologically and physically dependent on them. And I don't think there's any proof that they're less apt to cause that. It's been suggested, but there's not a clinical trial that I know of, that shows it. (Doc 5)*

In fact, when other physicians mentioned concern about sleep aids, their most common issue was the issue of dependence.

*I struggle a lot with the medicines. You know, I think that um, you know, I worry that patients will rely on them and that their sleep cycles will become disrupted. So I um, I try to focus on the behavioral. (Doc 2)*

*Well, I think Ambien is certainly habit-forming. Um, the others probably too. I don't know with the dependency. I'm not sure you could say they're addicting, to take it once a day a short acting, you know, you don't crave it. They're habit forming because, and I think you get a rebound. Maybe just from my own experience, taking them for jetlag for a few days and then leaving it off and staying up a lot. And um, and I think. So um, I think again there's sort of, there is a bit of a dependency. (Doc 7)*

Ironically, this physician also mentioned that a pre-existing dependence may in fact lead him to just refill the prescription.

*And then I may, you know, if somebody's using [Ambien] every night I may try to address that. Or if they're, actually if they're using it every night I feel like it's already a lost cause. If they're using it three or four nights a week I may say, you know that's sounding like you're really getting dependent upon it and maybe we ought to try to cut back a little bit. And you know, give them quantities to reflect that. Maybe some effort to cut back. If they say they're taking it every night, and I do have some patients that are doing that and I think have probably just gotten there by gradually over the years, then I just am likely to have given up on it, and I say OK, here it is. With refills. (Doc 7)*

Another concern about sleep aids, even those that are sold over the counter, is their use in older populations.

*I mean you kind of get into when somebody gets frail and elderly you begin to worry that they're going to fall on the way to the bathroom in the middle of the night. But or that maybe when they start having their mild cognitive impairment that they're having some drug effect left over the next day that is impairing their cognitive function....The harms are more in the frail elderly. (Doc 7)*

*Like elderly folks, you really shouldn't prescribe antihistamines because they can have delirium and things like that. So there are some side effects, but Benadryl generally is pretty innocuous. I don't think it's really hurting anyone but I guess I've just been taught in my years of education that it wasn't a great sleeping medication. (Doc 3)*

#### *Pre-existing prescription*

Two of the eight physicians denied prescribing sedative hypnotics to their patients with sleep problems. There was one exception to their refusal stance, borne out by both their own admission and the hospital database-generated records from the prior 6 months. These physicians allowed that they would continue a prescription for sedative hypnotic that had been originally prescribed by another physician, even if they would not necessarily prescribe it themselves.

*Yeah, I've had a couple of older folks who come in who were living over at some of the higher-rent, you know, assisted living, who had been taking medicines for years. The doctor's given them Ambien or Lorazepam for years so they think since maybe their spouse died and they were a little excited, just kept on it. And I say to them, you know, well I'm not going to, I really don't think you should take it. We'll give you a schedule for tapering a dose down to remove it. And most of them when they do it feel better, but it impairs their memory, it does a lot of things. I just don't see any reason for them to be on it. (Doc 1)*

One physician noted that a certain set of older female patients were quite interested in maintaining their prescription for Valium and would request it specifically.

*It's much more likely to be benzos that they've been on forever. So in our practice there's older women who've been on valium for 100 million years. And it's like (shrugs) yes, you can have your valium. They're not escalating but they were put on it as mother's little helper and they've been on it. And so unfortunately they're going to continue that. And I've had people especially ask for that. Valium. I want my valium. 70 year old women. 80 year old women....I'll say, don't we want to start something longer acting like this clonazepman. NO! I want my valium! [Laughs] (Doc 8)*

This physician admitted he was willing to prescribe outside of his comfort zone, in order to continue a patient's prescription from a previous physician.

*And um, with Ambien at least, which is the one that I prescribe. I haven't gotten used to prescribing Sonata or any of the others, I don't even know if they're still out. [laughs] and I don't prescribe benzos for sleep, unless someone comes to me and they've been taking it for 20 years, and then I'll just continue prescribing it. (Doc 3)*

### *Patient Compliance*

While all of the doctors in this sample said they discussed sleep hygiene with their patients, they were cognizant that some patients “just want the medicine.”

*Every time this comes up I give them the sleep hygiene talk. And I get these looks back at me like I just want a medicine. Is kind of how I feel at least, maybe they're not thinking that way, but. (Doc 3)*

Some physicians indicated that offering a treatment based on patient request was one way to gain compliance. In response to the question “How much influence on your ultimate decision does patient request play?” one physician answered:

*A lot. Since there's not, since I don't feel like there's a whole lot of difference between them. And if they have an idea what's going to be beneficial, then there doesn't seem to be any advantage to contradicting them and saying, well why don't you take this instead. It sort of sets me up for failure. Like for them to say, oh, well I tried this that you suggested and it didn't work. [laughs] so, since I don't have a whole lot invested in which one they use then I might, then there's no point in being contradictory about it. (Doc 7)*

When asked if he ever designed a treatment plan, based on how well he thought a patient would comply with it, one candid physician said, “Yeah, that's a hard question. I mean I think we probably always do, but we wouldn't admit that we do. Yeah.” (Doc 8)

One physician talked about physician compliance could extend well beyond the sleep drug. In certain cases, he felt that allowing a sleep drug enabled him to keep the patient



compliant with the more serious health issues he was dealing with. This quote is quite layered and also encompasses themes such as: role of insurance company, doctor shopping, and DTCA.

*I have a patient who is a PhD researcher, semi-retired here in his 8<sup>th</sup> decade of life. Who is absolutely insistent that these make his quality of life so much better. He takes them every night. We've had some struggles about prior authorization. I've had to set some limits because he assumes that I'm going to fill out all this paperwork. And I've told him that I don't fill out the paperwork, my staff will and they'll do it when they get around to it. But I do not call 800 numbers as a physician to get prior authorization for sleeping meds. And I think we've come to some equilibrium. And he can always find another doctor if he doesn't like the way I approach his sleeping medicine issue. But for something that's not, as I see, a compelling public health [issue]. And he came to me on these medicines, so this was not a conversation that I initiated. So it's very hard to take someone off that. Especially when they have several other needs like diabetes and high blood pressure and that you need to keep that person in your clinic because you realize that you can give them. You know, you're negotiating with them, so I think that's a relatively small price to pay to keep them, to let this person stay on a medicine that he takes every night. Which I know he doesn't, he shouldn't probably be taking every night because it's probably no longer effective. But at the same time I'm balancing that against the fact that I realize that there's quite a bit of good that I can do, and that this clinic can do in making sure that his diabetes and hypertension are well-controlled. So it's kind of like the real politique of medicine. You're going to ignore a few, ignore a few, put up with a few sub-optimal practices because you know that the impact on the other ones can so outweigh that. And that's what I'm often dealing with in my very complex population is that I'm not making an issue of it and of course this works very much to the advantage of industry. They realize if physicians feel committed to their patients and I can't, conflict is definitely counter-therapeutic in clinical medicine. So this is why direct to consumer advertising is insidious because patients hear one thing from the TV and then their friends and then the physician's put into a position of contradicting a belief that the patient has already established. (Doc 5)*

### *Rhetorical authority*

As noted in the background section, the concept of rhetorical authority describes the phenomena wherein patients seek and receive medical knowledge from non-medical sources (Kroll-Smith 2003). These sources vary, but physicians in this sample noted several, including direct-to-consumer advertising (DTCA), social networks and the internet).

## *Direct-To-Consumer Advertising (DTCA)*

By far, the most commonly discussed source of rhetorical authority was that of DTCA.

*Whereas it's possible that in the past it was something that, well, yeah I had some sleepless nights but I'm not going to bring that up, that's not going to be the major issue that I discuss with my doctor. But all of a sudden this is something that we can treat with medications that are appealing. So, I don't know exactly, I suspect DTCA has some effect but it may not be directly through, you know, telling the patient, the patient coming in and asking me. It may be that we've just raised the awareness and comfort level with talking about it across society and DTCA is one factor in increasing that awareness....So I don't know, that's kind of how I think about it. I can't, I'm not willing to lay all the blame on DTC but I'm sure it plays a role. (Doc 3)*

Some of the physicians in this sample had fairly negative feelings toward DTCA and the effect it had on the patient's knowledge and/or the patient-physician interaction. This physician describes his negative feelings, as well as noting the propensity to self-diagnose.

*I: Would you say that it's common for patients to come in and request a specific drug for sleep?*

*KI: Ask for a specific one? [Yeah] Yeah, I mean I think people will come for what they've seen on TV or in the magazines and say Oh, I want Ambien CR instead of Ambien. You know and they'll ask, what do you think of that? So yes, people very often specifically ask for medications by name.*

*I: And what do you think of that?*

*KI: I struggle with that. I think it's terrible. I actually really hate it. I think that, you know, if the patient has a particular idea of what they want before they see you, it can be hard. It can be hard to make sure you're doing the right thing for them and, and if that's they're expectation is that they're going to leave with that medicine. You know, are they relying on what your expertise is? And are they going to be unhappy unless they get this medicine. And sometimes they'll come in with cards that they've ripped out from the magazines that say get your 10 day free trial of this one. So, you know, I struggle with it. But sometimes if they're, you know, I will, I'll say fine, this is the way I approach it and I try to go through it with them. But if this is what you're very interested in, ok, I'll write you for it....It makes me sort of laugh in some senses. It's like, they come in with the treatment, you know, without even going through the diagnostic process. (Doc 2)*

Physician 4 talked extensively about rhetorical authority, and its pros and cons.

*The way our medical system is established and they way it works is you know we live in a capitalist system so the pharmaceutical company is there to make a profit,*

*understandably, so what they do is they will do direct marketing. What they want to do and I guess you can understand this from a business-end perspective is that they want to sell their product to people so they will put that, sort of make that very known to someone so they will go in and ask physicians about that so, that is across all different medications I think that that happens. (Doc 4)*

When asked how he felt about these outside sources of information, he clarified his stance.

*So first of all I think that is a good thing and the way I have been trained is to have a lot of that push and pull and that is again, so my philosophy in medicine is that is what I like to do with patients, I like to talk with patients. So, I like people to be informed and I welcome people reading on the outside. I think that is a great thing. The medical system we are in right now is not such that it is practical to have the all-knowing and it was never even a reality, you know, the all-knowing physician being a paternalistic, for lack of a better word, person guiding the patient. So what we have now is a lot more interaction and push and pull. Now the problem I have there is I think that push and pull, or a lot of that information is not the best. So when the drug companies give that information I think people are skewed in lots of different directions. So you know the challenge with that is finding a clear source of information for patients to use to advocate for themselves and you have pharmaceutical companies who are, they have some hopes to advocate for a patient but they are trying to make a profit also, so that is clear. It is sort of a double edged sword, you know. (Doc 4)*

Other doctors took issue with the tactics of drug companies.

*I try to be very clear with my patients that they um, that there's no evidence that any one of them are better than the other. And that obviously the advertising can't suggest that. It doesn't, it's illegal for them to state that one sleep aid works better than the other. You'll never see that. And in fact, the classic example is the one you see for pain medicines. "Nothing works better than Advil." That's how it's phrased. But it's absolutely illegal the company will get fined if the company says Advil works better than Aleve. But nothing works better is an interesting semantic subterfuge.....well nothing else works better because they're all equally....But they can't say their products are any better than the older ones. They can't even say, interesting, although they say they're not habit-forming. I don't even think they're allowed to, they're not allowed to say they're less habit forming than older sleep medicines. But to the non-sophisticated public, or less sophisticated about the laws and regulation regarding detailing of drugs, don't recognize that distinction. That semantic distinction. You know, you can't get away with submitting a peer reviewed paper by initiating a comparison and not completing it. And if you had a high school English teacher who was paying attention, they would take 3 points off your essay because you did not complete your comparison. But that's marketing. So they can't say that they're better, and they can't say that they're safer, explicitly. But it's strongly implied in the presentations of their ads. (Doc 5)*

## *Social Networks*

Other sources of RA include friends or family.

*Or it's something their friends took. And, I even had a patient one day who started talking a little bit about sleep. And we had a very candid discussion about it. And you know, she was wanting to get something for travel. Which I'm fine with. You know, people are traveling. But she said, you know I went on a weekend away with, I think she's about 60 this woman, with a bunch of my female friends and every single one of them was on Ambien. And she laughed at that. She actually thought it was, you know. Do all of us really have all these problems and need to be on this medicine? So, I think they also hear what they're friends are taking and so it kind of explodes the number of people who are taking these medications. And it's hard to argue. It's often hard to argue with patients. You know, if they perceive that they have a problem with sleep, it's sometimes hard to talk them into that, after talking and taking the history and seeing that they're able to accomplish the things during the day, it's still hard to make them believe that they don't have a problem with it. (Doc 2)*

One physician discussed the interplay between commercials and social networks.

*I suspect that direct to consumer advertising probably makes the conversation about that much more common. So a lot of my patients aren't coming in saying that they saw a commercial. Although, I guess everyone's seen a commercial by now, because these medicines are always advertised. But a lot of them have talked to their friends how have been on medication. And so, you kind of, you know, it's like the diffusion of innovation curve, I don't know if you're familiar with that, or if you've read the tipping point. This notion that as soon as something becomes prevalent in society it spreads really fast like a wildfire. So if you start doing direct to consumer advertising and you get a few more people on these medications and you get people starting to talk about it. Somebody mentions at a cocktail party oh yeah, I take Ambien. (Doc 3)*

## *Internet*

Although he specifically cites the dangers of the internet, this physician makes it clear that it is not so much the vehicle, but the message that is troubling.

*I: Do you think that you've seen any effects of direct to consumer advertising in terms of the way that patients talk to you about specific drugs?*

*KI: Yeah. Not so much sleep, sleep pills. I think because there's so much already out about sleep pills, but and I would say, not so much television. Although I think it does have an effect and the drug companies control it, but the Internet is your biggest enemy. There's so much garbage on the Internet. Ah, that's where we find our biggest enemy.*

*I: Tell me more about that.*

*KI: Well, someone will look up and say gee, you know, I have this, I have this disease and I need this medicine for it because somebody said so on the Internet.... And so, the point here is that the capacity to distinguish between good and bad information, whether it be on the television or on the Internet just isn't reachable by most folks. They don't know how to evaluate critically. So, ah and they almost always will begin with the following "What your doctor doesn't know..." is the introduction. "What your doctor hasn't told you..." or "What your doctor is keeping from you..." to make it seem like, you know, if you're not espousing, because you've got some sort of secret vendetta against their product. (Doc 1)*

One physician mentioned another sleep disorder that he has had patients self-diagnose with, based on internet information.

*A few people have been on the internet for restless leg. Like, this has got to be what I have. Because I've read on the internet and this is my diagnosis and I've got to be on something for it. (Doc 8)*

It is worth noting that one physician actually encouraged the use of the internet to promote sleep hygiene.

*I used to go through the whole rigmarole about sleep hygiene and now it's convenient, particularly if my patient has internet access, I write down "sleep hygiene" and say Google this and you're going to find a whole bunch of information about behaviors that can help you overcome insomnia. (Doc 7)*

### *Knowledge Alignment*

As previously noted, the fact that this particular group of physicians does not currently have regular interaction with drug company representatives, making this sample less than ideal in terms of ascertaining the influence of the drug companies on the knowledge about sleep disorders. However, this lack of regular interaction did not preclude them from having thoughts on the matter.

*I certainly get patients coming in lobbying for a particular medicine.... you know, they've gotten samples of it. Our clinic, you know, samples, we can just end that part of the discussion now. We don't keep samples in our clinics so. But you know, having*

*samples available to physicians is a powerful tool in the hands of the pharmaceutical companies to popularize a new product. I don't know what the literature is on detailing physicians in terms of whether it improves patient care, or physician education. The pharmacy companies would argue that it does. I do know the literature because I'm an educator of residents that there's not a single study ever that shows that pharmaceutical influence on resident physicians improves how care is delivered. They almost all show that it promotes bad decision making. That the literature on detailing residents, taking them to dinner and giving them pens, that they're more likely to make non-guideline based, non-evidence based decisions when treating physicians. There may be a separate, parallel literature looking at physicians already out of residency and practice. So there's no reason to believe that this will have a beneficial effect on physician practice. And from at least the resident physician literature, there's every reason to believe that this kind of promotion to patients and physicians by the commercial interests alone will have a negative impact. (Doc 5)*

One physician compared the motives of sleep aid makers to those of the cigarette companies.

*Yes, I mean it's, does it concern me, yeah. Well it's sort of a commercial thing isn't it? I mean, it's all about making money. And I think, that the drug companies, it's like the cigarette companies have de-emphasized that these drugs are habit forming. But there's not near enough information about that out there so that people understand that that's the case. I mean it's so self-serving to be able to market something that's habit-forming isn't it. (Doc 7)*

Physician 1 had been in the department for many years and had seen drugs reps come and go.

He emphatically told me the following:

*My policy has been from Day 1, I do not see drug reps. I don't talk to them. I don't take any of their pills, I don't take pens, I don't take anything. And some years ago when I was assistant chair of the department what we did is we got rid of all the lunches that they supplied for the house staff. Because I felt that it was not ethical. For many reasons. And then for a while after I left they started having them back. But now I think the policy is not having them. But, I just simply think that it's not a good way to get information. Information is biased, it can be. And I don't think it's a good way to, to show young people about the best way to get information. I have never talked to drug reps. Never. (Doc 1)*

#### *Influence of insurance companies*

An unexpected addition to my set of theorized influences was that of insurance companies. Recently, insurance companies have limited the amount of sleep aids that can be

prescribed in a month. This increased bureaucracy was viewed in both negative and positive ways.

*No, you know the principle issue that we have to confront is what insurances will pay for. So, I mean that's where it gets to be problematic because getting multiple forms to fill out and send back in. A lot of times patients don't want to have another patient encounter in order to get their prescription refilled. We don't make people come in to get refills. So that's work being done for free in time that I'm supposed to be doing something else. So every time you get 2 or 3 forms for the prior authorization, for this and that, that becomes the onerous part. So trying to avoid that is kind of important. (Doc 6)*

One physician saw the limitations enacted by the insurance companies as potentially helpful to the physician.

*You know I think I generally when it comes to prescriptions I really try to have exhausted is there anything else underlying like sleep apnea or a problem. Are you really following behavior modification and then, I'll try the medications for sleep. And generally if I'm the first person to meet, you know, to discuss this with a patient I will try to say, OK, something like Ambien, I don't want you to take it every night. But if you kind of need it for two or three nights and then go back to not taking it. So try to use it kind of re-set. The idea is like re-setting. And actually the insurance companies are helping us with that because they're not covering, they're not all covering patients for every night taking Ambien. They're only giving them 15 a month or something like that. So, I wouldn't say, helping, but they're trying to limit it. (Doc2)*

Another physician emphatically felt that getting involved in prior authorization for sleep aids was a waste of his time.

*I've had them come in and ask for Ambien CR and I frankly just tell them. I mean, if they have insurance, yeah I'll write you the Rx but if your insurance company balks, I'm not going to fill out the extra paperwork, I mean that's, just so you can this drug. And interestingly I'm not tormented with too much extra paperwork for the sleep aids. Because I think in this case the insurers have drawn a line. They don't really even want to pay for them at all in general. They either pay for them or they don't and I don't get too involved in having to do what are called prior authorizations for sleep aids. (Doc 5)*

He even gave a specific example of refusing to do the extra paperwork for a patient, and the patient's reaction.

*I had a patient who was already on Ambien and he wanted Lunesta and I said I don't think it's going to work any better. And I think at one point I did prescribe it, but then his insurer came back and wanted all this proof that he'd failed other trials and I said bluntly, I don't have the time to do this. And it's not a good use of my time and I'm not going to do it. And he wasn't happy about it. But I let him know. (Doc 5)*

In sum, physicians in this sample offered insight into the medicalization process through the language they used to discuss medicalization, their attitudes toward insomnia diagnosis and treatment and their prescribing behaviors. A confluence of factors including consumerism, physician compliance, rhetorical authority, knowledge alignment and the influence of insurance companies seem to be contributing to the medicalization of insomnia via the patient-physician interaction.

I end this section with the following lengthy, but interesting, physician quote. I ask the reader to consider two things: a) Does this quote reflect a reality that some of us are all too familiar with? and b) Is this patient using Ambien to treat a sleep disorder, or something else?

*But you know, because I'm like this myself, I know that when he lies down to go to sleep his mind is spinning on 3 different grants he has to write and it's hard to shut one's mind off. And he's gotten in this cycle, I think, where he's not able to separate himself from his work very well and it's interfering with his sleep. And we've talked about that and you know, should he cut back, how should he deal with this. And kind of when push came to shove when he takes the Ambien he does fine. He sleeps well. He wakes up refreshed. He's able to be productive at work and he can do all the things he likes to do, so he'd like to stay on the Ambien. And you know, I'd offered [psychological] therapy to him, I recall and he really wasn't interested in pursuing that....I actually have a few professors [laughs] that are kind of in that category. And it's interesting because I, I think in those cases I sort of relate because I have had times when I've been really busy and I've woken up early with work on my mind.....I guess I feel like I sense what they're describing as going on in their mind and why they have trouble turning things off. But I've found that they, I'm thinking of another professor in my mind right now whose also really kind of high-powered successful person who would rather keep going at his pace than trying to slow down and maybe have a little more work like that. Now this is my hypothesis that they're driving themselves too hard and they can't turn off because they're working right up*



*until the time when they hop into bed and they're working as soon as they wake up.*  
(Doc 3)

## **Discussion**

In the following section, I provide an overview of my findings. More in-depth discussion, linking these findings to the patient interviews and the quantitative findings, is available in Chapter 6.

In order to gain insight into the patient-physician interaction surrounding sleeplessness and explore the forces that might be fueling the medicalization process, I conducted in-person, semi-structured interviews with 8 physicians who practice in an Internal Medicine Clinic. Focusing on the language they use to describe medicalization, their attitudes toward insomnia and their reported prescribing behaviors, I gained insight into several factors that influence the patient-physician interaction. These factors include consumerism among patients, physician compliance, rhetorical authority, knowledge alignment, and to some degree, the influence of insurance and drug companies. Evidence from these interviews seems to indicate that the medicalization of insomnia is occurring.

Physicians in this sample seemed keenly aware of the medicalization process and used sociological language - including the terms “medicalize,” “disease mongering” and “case-findingness” to describe it. Use of such ‘sociological’ language begs the question – do these physicians think about medicalization in the same way that Conrad and others have conceptualized it? I argue that their understanding of the concept is very sociological. Physicians in this sample not only use sociological terminology, but are also able to describe parts of the medicalization process (e.g. expansion of disease criteria), link it conceptually to fueling factors (e.g. DTCA), and give other examples (e.g. toenail fungus). While their

proximity to and employment in an academic research center may facilitate this awareness, their academic insight is not necessarily a limitation of the study. However, it does lend itself to a follow-up study with physicians in the community. I suspect that non-academic physicians may not use precisely the same language, but they may have similar conceptions of the process and its prevalence.

My respondents typically characterized insomnia as a normal process, often related to aging, or the symptom of another disorder, typically a mood disorder. They noted that individual or cultural norms seemed to be influencing their patients' perceptions of sleep, their ideas of what was abnormal and thus treatable. Regardless of the root of the problem, however, these physicians indicated that their patients were not shy about asking for something to help them sleep.

Physicians in this sample had mixed feelings about insomnia treatments. Despite the arsenal of sleep drugs at their disposal, every doctor I interviewed broached the topic of sleep hygiene; most asserted that it was their first line, or preferred, treatment. It is important to note that there are no consistent definitions of sleep hygiene and even these physicians, who all mentioned some sort of behavioral or lifestyle intervention were not necessarily consistent across the board. Nevertheless, I was told that some patients were not open to the idea of sleep hygiene or they just 'wanted the medicine.'

Trazodone was the preferred prescription treatment for most of these physicians, as it has few side effects and does not cause dependence. Benzodiazepines, despite their potential for addiction, were used by many of these doctors, particularly for older patients who had been on them for many years and were not escalating in their use of the drug. However, as seen in the NAMCS data, the most popular sleep drugs nationally and in this practice are the

newer-generation non-benzodiazepine sedative hypnotics. They are also, not coincidentally, the most heavily advertised, as will be explored in Chapter 6.

Physicians admitted that their prescribing behaviors were influenced by a plethora of factors, including consumerism among patients. My respondents reported that patients asked for drugs by name and sometimes brought in pharmaceutical-company-produced coupons. While shifts in the patient physician relationship have eroded physician power, and rhetorical authority ensures that they are no longer the sole holders of an esoteric body of knowledge, physicians are still seen as the gatekeepers to prescription medications. However they are, to some degree, at the whim of the patient consumer, and they are not naïve to this fact. Some of these doctors showed great candor and admitted that patient preference did influence their prescribing choices, and that it could be used as a means of gaining patient compliance.

The physicians I spoke with seemed cognizant that if patients were not given what they wanted they could, and would, take their business elsewhere. My respondents did not seem overly bothered by this, it was noted with little more than a shrug or a laugh – but given the intense commitment and dedication that each and every one of these physicians demonstrated towards their patients and practice, I do wonder if further probing would have revealed more frustration or dissatisfaction with this facet of consumerism.

One interesting phenomenon I noted: all of the physicians in this sample had at least some degree of bias against the prescription sleep medications – ranging from flat-out refusal to prescribe them to patients not already taking them, to fears about dependence, to biases against their cost or lack of effectiveness. Most exhibited an attitude that one doctor called a “soft bias” – essentially, a mixture of concern about dependence or side effects, mitigated by mostly positive or neutral experience with the drugs leading them to conclude that they are

‘doing no harm.’ Regardless of their self-proclaimed ‘soft’ or ‘hard’ biases, every physician in this sample prescribed these medications, even if only in restricted quantities or in exceptional situations. This lack of parallel between attitude and behavior intrigued me and prompted me to recognize my vast over-simplification<sup>26</sup> of the concept of physician compliance.

As evidenced by these practitioners, physician compliance is not merely the expectation or action of physicians accepting patient expertise regarding diagnosis or treatment (Freidson 1988), but a complex decision making process where physicians must, in a matter of minutes or even seconds, weigh a myriad of pros and cons and emerge with the best decision possible for an individual patient.

In this study many things, including time constraints, influenced physician compliance. While these doctors may actually be able to spend more time with patients than the national average of 10 minutes (Stange 2007), they nevertheless discussed their limited time and how it affected their ability to listen to patients, prioritize health issues, and make decisions about withholding or prescribing medications.

Another influence on physician compliance was the existence of a pre-existing prescription. Physicians in this sample indicated repeatedly that, even though they engage in primary care, their patients often come in with prescriptions written by other doctors, with the expectation of renewal or refill. Even the two physicians who stated that they did not prescribe sleeping pills, did not necessarily refuse patients in the case of a pre-existing prescription. This apparently common scenario raises another issue - continuity of care. In

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<sup>26</sup> In fairness, the bureaucratic pressures, psychological nuances and biological possibilities a physician must navigate in any given patient interaction are well beyond the scope of most of our experience and thus my lay understanding of physician compliance, even with these insights, is bound to be somewhat naïve.

sharp contrast to the ‘Golden Age of Doctoring’, patients, particularly older patients, may see multiple physicians concurrently. Doctors may or may not be aware of what these other physicians are prescribing – and this fragmentation of care could be potentially dangerous.

According to these physicians, patients commonly exhibited medical knowledge from non-medical sources. Rhetorical authority came from many sources including social networks and the Internet, but most commonly these physicians mentioned the influence of DTCA. These physicians noted a relationship between DTCA and patient request. While some had moderate feelings about it (“I’m not willing to lay all the blame on direct to consumer advertising, but I’m sure it plays a role”) others were more vehement in their feelings (“I think it’s terrible. I actually really hate it”). One physician made a connection between DTCA and the social networks that influenced their patients (“So if you start doing direct to consumer advertising and you get a few more people on these medications and you get people starting to talk about it. Somebody mentions it at a cocktail party. ‘Oh yeah, I take Ambien’.”). Although physicians in this sample do not have direct contact with drug company representatives, that did not dissuade them from having opinions on the drug companies and their means of pushing their products. One participant compared the motives of sleep aid makers to those of tobacco companies (“I mean it’s so self-serving to be able to market something that’s habit-forming, isn’t it?”).

An unexpected finding was the influence of insurance companies. Increasingly, it seems, insurance companies are limiting the number of sleep aids that can be prescribed in a month. Perhaps it is the increasing awareness that, though promoted otherwise, these drugs can be quite habit forming and are in fact controlled substances. It may also be related to the 2007 FDA warnings about the strange side effects that, though uncommon, can be quite

serious – or at the very least, embarrassing (as seen in the anecdote about the dis-inhibited Baptist Minister). One physician intimated that the drug companies might be, in fact, “helping” them by limiting the amount of drugs that patients can receive.

In sum, multiple factors emerged that influence the patient-physician interaction surrounding insomnia including: consumerist attitudes on the part of the patient, predispositions to physician compliance, the prevalence of rhetorical authority, and the unexpected influence of the insurance companies in limiting sleep aids. Data from these interviews seems to indicate that physicians are aware of the medicalization of insomnia, and that it is in fact occurring through a confluence of factors – many of which seem outside of their control. The next chapter will explore insights from the patient interviews, and in Chapter 6, I will compare and contrast patient and physician attitudes toward insomnia and its treatments.

## **CHAPTER 5**

### **PATIENT PERSPECTIVES ON SLEEPLESSNESS**

The objective of this chapter is to provide insight into the patient-physician interaction surrounding insomnia by exploring the patient perspective. In the following pages, I provide detailed methodology, qualitative findings from 27 patient interviews and a brief discussion. I focus on patient's experience with insomnia, interactions with physicians, patient attitude toward insomnia treatment and sources of medical information from non-medical sources.

#### **Methods**

##### *Sample*

##### *Recruitment*

I consulted the head physician in the Internal Medicine Clinic (IMC) to compile a list of prescription sleep drugs commonly used in the clinic. In order to collect a sample of patient participants, a list of National Drug Codes (NDCs) of these sedative hypnotics were submitted to the clinic database group on June 19, 2008. A query was run and I received a list of IMC patients who had been seen in the clinic and prescribed one or more of the following drugs within the previous 6 months: Ambien, (generic zolpidem), Ambien CR, trazadone,

triazolam, temazepam, Lunesta, Rozerem, or Sonata. In addition to patient names, I was given their address, telephone number and prescribing physician.<sup>27</sup>

Physician participants were asked, prior to the initial interview, if they would be willing to help identify appropriate patient subjects. Physicians were given the query-generated list of patients for whom they had prescribed a sedative hypnotic within the last 6 months and asked to rule out patients who had been prescribed a sedative hypnotic for less than a four week period of time, patients who were prescribed a sedative hypnotic for travel purposes only, and patients who were not fluent in English.<sup>28</sup>

Once identified, potential patient participants received a lead letter signed by their IMC primary care physician explaining the nature of my research project. The lead letter requested the patient's permission to be contacted by a researcher (Mairead Eastin Moloney). Enclosed in the letter was a postage-paid, 'opt-out' postcard. Subjects were informed that they could either return the postcard in the mail if they do not wish to be contacted *or* simply refuse to participate when contacted by the interviewer via telephone. If I did not receive an opt-out postcard from a patient, I called them using an IRB-approved phone script and asked if they would like to participate in a research project on insomnia. Subjects were assured that their participation, or lack thereof, in no way affected their access to care at the IMC or its affiliated hospital. For examples of the follow-up letter to physicians, IRB-approved lead letter to patients, opt-out postcard and phone script, please see Appendices 6-9.

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<sup>27</sup> This method did not capture patients who had received a paper prescription, nor those whose prescriptions had been called in to a pharmacy.

<sup>28</sup> This criterion was necessary, due to my lack of fluency in a language other than English.



## *Interviews*

Patients were asked to participate in a face-to-face interview that would be conducted in a private office; patients unwilling or unable to conduct face-to-face interviews were given the option of participating in a phone interview. Interviews were semi-structured and lasted approximately 25 to 75 minutes. Patients were asked to sign an IRB-approved consent form. Both phone and in-person interviews, with the express consent of the participant, were taped and transcribed. Patients were asked to describe their experience of sleeplessness, their interaction(s) with physicians<sup>29</sup> regarding their sleeplessness, other (non-medical) sources of information they may have consulted about their sleeplessness and any treatments they may have tried. Patients also filled out (in-person interviews), or responded to a short list of demographic questions, available in Appendix 10. Strict measures were taken to protect confidentiality. Patients received a \$25 gift card to Target department store for their participation.<sup>30</sup> A copy of the IRB-approved interview questions is available in Appendix 11.

## *Coding and Analysis*

The procedures for coding and analyses of the patient interviews were identical to those of the physician interviews. Please refer to pages 81-83. The code list, however, was somewhat different, and a copy is available in Appendix 12.

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<sup>29</sup> Due to the small number of female physicians, in cases where a gendered pronoun is used by the patient, I have changed it to the masculine. This is intended to provide an extra measure of confidentiality.

<sup>30</sup> Two patients requested that the \$25 instead be donated to the charity of their choice. These requests were honored.

### *Limitations*

These patients were sampled on the basis of a prescription for a sedative hypnotic. While useful in identifying patients who had seen their doctor with, and been treated for, a complaint of sleeplessness, it excludes patients who had successfully tried other methods of managing their sleeplessness.

In addition, although I asked physicians to eliminate patient interview candidates based on the limited criteria noted above, it is possible (though unlikely, given their exclusion of very few patients) that physicians selected only patients from the list whom they thought would discuss their interactions in a positive light.

The use of the IMC-affiliated hospital database to generate patient names and prescriptions for sedative hypnotics does not accurately represent all prescriptions written for sedative hypnotics in the IMC during the time period of interest. By using the database I potentially exclude paper prescriptions written, and those called in to a local pharmacy. Nevertheless, it was the most systematic option of data collection available and avoided creating extra work for the physicians, as well as the bias that would have resulted from asking physicians to 'nominate' patients for interview.

Patients in this study, having received a lead letter from their primary care physician, may have feared that their interview responses would be reported back to their physician. Participants were assured that this was not the case, however, it is a valid possibility that the study's connection to their physician altered their level of candor.

Patients in this sample were asked if they thought they were influenced by direct-to-consumer advertising. A follow-up question was "Do you think others might be influenced?" This may seem 'leading', but in fact has a related precedent in the literature. Studies have

been done in which health care professionals are asked if they think they are influenced by drug representatives and detailing. Most say no, but believe their colleagues are much more likely to be influenced. (For a recent example, see Wiley-Blackwell 2009.)

Like the physician sample, the total number of participants interviewed is small, and patient level of education was higher than one would expect from a random sample. Thus, these results are not necessarily generalizable to other patient populations.

### **Findings**

Of the 53 patients I contacted, 27 agreed to participate in this study. The majority of patients preferred to be interviewed over the phone; I conducted six in-person interviews. Ten of the participants were male. Three participants were African American; two refused to identify their race, and the remainder were Caucasian. Ages ranged from 31 to 78 and the average age was 50. This was an extremely well-educated sample. Ten participants had some form of advanced degrees (advanced degrees included: MA/MS, JD, RN, PhD, MD, PharmD). Eight held bachelor's degrees and 6 had either some college, or an associate's or technical degree. Two participants had high school diplomas and one participant had some high school education. Eighteen participants had private insurance. Ten had Medicare, and none had Medicaid. Five participants said they had no insurance and three of them mentioned that they received "charity care" at the IMC. For further detail of patient demographics, please see Table 14.

**Table 14. Patient Demographics (N=27)**

<b># of patients</b>	<b>Patient Number</b>	<b>DOB</b>	<b>Sex</b>	<b>Education</b>	<b>Race</b>	<b>Private Insurance</b>	<b>Medicare</b>	<b>Medicaid</b>
1	1	1940	M	BA/BS	Caucasian	Y	Y	N
2	2	1938	M	JD	Caucasian	Y	Y	N
3	3	1960	F	some college	Caucasian	Y	N	N
4	4	1961	F	MA/MS	Caucasian	N	Y	N
5	6	1947	F	AA/tech	Caucasian	Y	N	N
6	9	1957	M	PhD/MD	Caucasian	Y	N	N
7	12	1951	M	BA/BS	Caucasian	Y	N	N
8	14	1976	M	BA/BS	Caucasian	Y	N	N
9	16	1946	F	some college	Caucasian	N	N	N
10	17	1956	F	some HS	African American	N	N	N
11	19	1926	F	RN	Caucasian	Y	Y	N
12	21	1957	F	some college	African American	N	Y	N
13	22	1954	M	MA/MS	Caucasian	Y	N	N
14	23	1941	F	PhD/MD	Caucasian	Y	Y	N
15	25	1946	M	HS	African American	N	N	N
16	26	1925	M	PhD/MD	Caucasian	Y	Y	N
17	28	1955	F	some college	Caucasian	N	N	N
18	30	1956	M	AA/tech	Caucasian	Y	N	N
19	31	1978	F	BA/BS	NA	N	N	N
20	33	1940	F	HS	Caucasian	N	Y	N
21	34	1953	F	BA/BS	Caucasian	Y	N	N
22	37	1962	F	BA/BS	Caucasian	Y	N	N
23	38	1947	F	BA/BS	Caucasian	Y	N	N
24	39	1944	M	MA/MS	Caucasian	Y	N	N
25	42	1955	F	PharmD	Caucasian	Y	N	N
26	43	1931	F	Some grad	NA	N	Y	N

				school				
27	46	1937	F	MA/MS	Caucasian	Y	Y	N

**Is there evidence of the medicalization of sleeplessness? If so, what forces might be**

**fueling the process?** To best answer these questions, I focus on the individual experience of insomnia, the interaction with the physician, patient attitudes toward insomnia treatments and sources of knowledge. Some of the themes that arose in these discussions paralleled themes from the physician interviews, including consumerism, physician compliance, time constraints of physicians, pre-existing prescriptions, rhetorical authority and the influence of insurance companies. Patient participants were unaware that I was doing a dissertation on medicalization and lacked the meta-awareness of the process possessed by physicians. Thus, explicit discussion of medicalization is limited. Unique to this chapter is the individual’s perspective of the causes and impacts of insomnia. An unexpected finding was the amount of unprompted discussion about fears of sleep drug dependence.

*The individual experience of insomnia*

Individuals spoke candidly about their experiences with insomnia. Symptoms typically entailed difficulty falling asleep and/or difficulty staying asleep. Most did not report early morning awakening. All reported experiencing insomnia symptoms for at least two years. One patient reported battling insomnia for the past 20 years and a couple of patients said that they had had trouble sleeping for as long as they “could remember.”

*KI: But I do have a lot of difficulty sleeping. I, going to sleep initially is not the big problem for me. But staying asleep through the night is. I usually wake up after 3, 4 hours. Use the bathroom and then I have a LOT of difficulty getting back to sleep, way too often. Sometimes I read. And that gets my mind off whatever it is I’m focused on that was causing concern for me. You know that’s the kind of thing that I, I think I dwell on at night and can forget about during the day. So reading, whatever I’m interested in reading, sometimes helps, sometimes I read in bed. Sometimes I go out*

*to the living room and read on the couch. But I am often awake for a couple of hours during the night. And um, that's the story of my difficulty with sleeping.*

*MM: Ok. So about how long have you been having these issues with your sleep.*

*KI: I was thinking about that this morning because I figured that would be one of your questions.[laughing] I think about 20 years. (PT 46, emphasis, their own)*

This patient's 'normal' bedtime is currently when most are waking up for the day.

*KI: I have trouble falling asleep.*

*MM: Ok. Once you get to sleep you're able to stay asleep?*

*KI: Sometimes I am. Sometimes I'm not.*

*MM: Ok, and what's your regular bedtime.*

*KI: Right now, it's 6, 7 o'clock in the morning. (PT 31)*

This patient told her physician:

*Well, I said to him, you know, I just cannot keep going on. I'm so tired, I wake up at night. I can't keep functioning because I'm absolutely exhausted. And I just have to, you know you've got to give me something so that I can sleep and stay asleep. I mean sometimes it's not a problem going to sleep. It's the waking up where I just cannot get back to sleep. (PT 3)*

A couple of patients told me that they dreaded trying to sleep at night.

*I told my daughter about 3 weeks ago I said, you know I dread to see bedtime come. Because it's twisting, turning. I wake up some mornings 'til my neck literally sore and hurting from twisting and turning. I get up; I sometimes get up three times a night. I come in here sit in a chair. Or go back, think I can lay back down. And I did the same thing last night. I got back up at 2 o'clock and come in here and read a little while and thought if I get out of the bedroom and do it, you know, I might get sleepy and could go back, go back to sleep. But it didn't work. I was still awake at daylight this morning. And I don't have anything on my mind, that, that's what bothers me. That I, that it could keep me awake. And, I, I just, I don't know what it is. (PT 33)*

Although an extreme example, this woman was simultaneously exhausted from lack of sleep and yet terrified of sleep.

*But you know what the deep sleep is what I'm afraid of. If I fall in a deep sleep when I wake up my body is traumatized. Like something's happened in my sleep. I don't know. Deep sleep. As long as I can be asleep and I can hear stuff going on around me then I'm fine. But if I go into a deep sleep, when I wake up it's like, you know. Awful. Like I went somewhere that I didn't want to be. (PT 12)*

While patients communicated the discomforts of insomnia, when asked directly, few reported significant daytime impairments. This patient noted that it didn't seem to have any ill effects.

*KI: It's mostly thinking about things that have happened. Well, actually I'm not even thinking half the time. I'm just lying there with my eyes wide open not really thinking about anything and just can't simply go to sleep. I keep saying 'this is stupid, go to sleep lady.'*

*MM: Tell me how, tell me a little bit about how not sleeping affects you during the daytime.*

*KI: It actually doesn't seem to affect me at all. (PT 19)*

The most commonly reported impairments were fatigue and irritability. For instance, Patient 21 told me, "If I haven't slept for a couple of days I'm irritable. Extremely tired and fatigued." Another patient noted a feeling of depression, in addition to fatigue.

*Just a general feeling of tiredness. Feeling like I haven't been to bed. [PAUSE] some general vague feelings of just, depression, you know, feeling like I'm just dragging through the day. And nothing to look forward to in the evening! [Like] a good night's sleep, you know. (PT6)*

Patients, rarely, if ever, discussed their insomnia as a medical diagnosis. When asked, patients either denied receiving a formal insomnia diagnosis or talked about their diagnoses of mood disorders; a few mentioned that they had diagnoses of obstructive sleep apnea [OSA]. Some patients "normalized" their insomnia – similar to the way that physicians did in the previous chapter – by linking it to aging or hormonal changes.

One patient, out of the 27, seemed to accept and even embrace her unusual sleep pattern. She had learned to 'manage' it by re-arranging her schedule.

*It has always been difficult for me to get up in the morning. It's just, you know, kind of a painful experience to get up in the morning. And um, I'm, I had a roommate in college who JUMPED out of bed and [happy noises] started the day and I thought ahhh. [Sighs] how can she do that? And then, but as the day goes....And as the day goes along I wake up more and more and I hardly ever take a nap because it takes me so long to get to sleep. And then finally by evening I'm wide awake and ah! [happy noise] You know everything is bright and I get my work done and then it gets to be midnight and then one, and two and everybody else is in bed, and I, and I can't go to*

*sleep. And this is, I have been this way as long as I can remember. But I would try all sorts of different things. And I tried over the counter sleep things and, and I just. And the thing I found was that if I could get a job where I didn't have to be at work in the morning, and I could go to work at noon and work until midnight, I was great, you know I was fine. And so that's essentially what I've done, most of my life. Except that I had a boss who insisted on having meetings at 9:30 at the morning. And I, I would get to those meetings not having slept because my experience is that the earlier I know I'm going to have to get up the harder it is to go to sleep. (PT 23)*

When asked what she thought the cause of her sleeplessness was, she answered:

*Well my guess is that some people are born night owls and some people are born larks and I'm definitely not a lark. Being a night owl, I'm, I feel like I'm always fighting. When I do go to bed, I'm not sleepy. I'm maybe sleepier earlier in the day but by the time it's time to go to bed, I'm not sleepy. And so I'm fighting that, my body clock. And then if I know that I have to do something particular the next day I start to worry about how I'm going to do it if I don't have enough sleep and that makes it worse. And I think that's the [laughing] the core of the problem. (PT 23)*

Another, more common attitude of normalization was connecting one's sleep issue to the aging process.

*But the sleeping is a problem. But it could be related to getting older. Who knows? I don't know. But anyhow. It bothers you when you can't go to sleep at night. So I don't know what to do or how to fix it. (PT 33)*

In conjunction with age, some women mentioned menopause or hormonal changes as probable causes. Said one patient, "So I have trouble falling asleep....And I've been experiencing that for about. It seemed to have started when I hit peri-menopause. So geeze, probably 5, 6 years now at least" (PT 42). Another woman told me:

*I have had problems with sleep for a really long time. And I could never tell if it was because I'm getting older, you know, I'm getting closer to menopause. And I couldn't, I didn't know if that was what it was, or if it's heredity, because my mom has terrible problems with sleep too. So I've had problems for probably the last 5, 6 years. (PT3)*

Some of the male patients mentioned having an enlarged prostate that had them up several times a night to urinate.

*MM: Hmm. OK. So when you say sleep issue, is it trouble falling asleep, staying asleep, do you wake up multiple times?*



*KI: It's waking up. And part of that is probably a growing and large prostate and taking Hytrin for that to relax that muscle. Because I get up, on a good night twice in the evening to urinate and it could be 4 or 5 times if I'm concerned about, you know if I'm just worrying about something. (PT2)*

*Even now I, I, usually don't get to sleep until 1:30, 2 o'clock. And that's when and I'm still on Xanax. Aand ah, melatonin, take that too. [Sighs] So, I just, just and then also I have a BPH prostate. So, since I've had that which has been five or six years I guess since it started. I have frequent urination at night a lot. (PT 39)*

This particular quote underscores how framing it in this normative fashion means they are not 'sick' and could be described as 'anti-medicalization.'

*I know that increasing age and menopause does bring on insomnia and it's just, I just look on it as part of the aging process. Because so many people that I know that are in my age group has those same, they have the same issues. So I said, well, you know, we can't all be sick! [LAUGHS] So it's pretty much how I look at it. (PT6)*

Patients in this sample had a myriad of health issues ranging from cancer to fibromyalgia, heart disease to mood disorders. The most commonly disclosed comorbidity was mood disorder. Several patients told me that they had received a diagnosis of depression. Anxiety or stress were issues for many and in fact, when asked to a) describe their insomnia experience or b) estimate the cause of their insomnia, most patients in this sample cited anxiety or stress.

*A lot of times I just feel like my mind is racing. And I can't quiet that down and I can't, you know, make it blank so that I won't think anything. A lot of times songs are running through my head and I'll never be able to get that song out of my head. It'll just keep me up and keep me up. (PT3)*

This patient attributed his sleeplessness to both his chronic health condition and worrying.

*Well, I guess first of all, I'm a known worrier so. I have great problems falling asleep. And up until I was diagnosed with COPD back in the fall I thought it was a panic disorder....But prior to the COPD and all that, as I said I was a chronic worrier and I always worried about my youngest son and his children and everything so. It's just chronic. (PT 1)*

Another patient's sleep pattern was disturbed by obsessive thoughts.

*I don't sleep very good at night unless I do take something. It's hard for me to fall asleep because I think about the whole day. I can't just fall asleep. It takes me hours to fall asleep. Because I will have to think about every minute of that day. Up until the time that I got ready to lay down. And ah, it just goes on and on and on and on. And so that's why, that's my sleep pattern. And then when I wake up I'm tired because I didn't get enough sleep. I didn't go to sleep you know early because I went to bed early but I didn't go to sleep and then I wake up every hour. (PT 12)*

Several of the patients told me that they had very stressful jobs, or jobs they disliked. When asked if she could name one or two primary causes for her issues with sleep, one patient shot back: "I can tell one right off the bat. I hate my job" (PT 34).

This patient noted a confluence of factors: his age, "worrier" personality and his stressful job.

*I think it's a function, in part, of age. I think it's also a function of my own personality. Of being a basic worrier about whatever....I'm different than most people and probably worry more. And have enough responsibility. I'm running a program here that doesn't get the support I think it should and so I'm always kind of tilting with it. (PT2)*

Others had very stressful life situations that seemed to have sparked their sleeplessness. This patient in her early sixties had multiple stressors and care-giving responsibilities that she directly linked to her issues with sleep.

*MM: What do you think the cause might be with your sleep issues. Would you say maybe it comes from a life circumstance, or maybe...*

*KI: [interrupts] Now I have a lot of stress in my life. My husband he's, he has kidney failure. And I help look after my parents, they're in their 80's. You know I go clean for them once a week. And you know I'm busy helping everybody else a lot.*

*MM: So it sounds like you're a caregiver to multiple family members.*

*KI: Right. I am. And then I watch my grandchildren in the afternoons when they come home from school. So. I you know, I have a busy life which is good and I'm thankful for, but um. I don't have a lot of time for myself. (PT16)*

For some patients, it went beyond stress or worrying. One patient, when asked what she thought caused her issues with sleep replied: "I think early, um, a childhood trauma." (PT 21)

Other patients had experienced deaths in the family that coincided with the onset of their sleep problems. Said one patient “Really kind of started having my [sleep] problem after, seems like after my husband passed away” (PT 33). And another told me “The catalyst of getting an actual prescription for sleeping started 8 years ago with the death of my grandson” (PT 6).

It seems that some may have always been predisposed to anxiety and this was exacerbated by stressful events.

*KI: Anxiety. Anxiety. That will do it. My husband worries about nothing. And his head hits the pillow and he rarely gets, wakes up at all during the night. He sleeps until the alarm goes off in the morning. I just, I just tend to worry about whatever. And um, so yeah, I think it's anxiety.*

*MM: Ok. And is that anxiety something that you've experienced just in the last 20 years or has it been something you experienced longer.*

*KI: I think it's my nature to, to focus on things in my life and decide that I can worry about them and I need to worry about them. I think it's just part of my personality. (PT 43)*

Later, when discussing her treatments for sleeplessness (Ambien and Valium) she mentioned, “Now I use valium much more freely. Perhaps five years ago my husband at that time was ill, was dying, it was a terribly tense time” (PT 43).

In sum, patients in this sample typically had trouble falling or staying asleep at night. Some woke up several times per night. Like their doctors, these patients related many of their sleep problems to the aging process. Most of the sample had comorbidities in the form of a physical or mental illness.

Many of the patients in this sample described themselves as “worriers” and discussed the inability to “turn off” their brains when lying in bed. Others disclosed traumas or intensely stressful times that had triggered their bouts with sleeplessness. A few individuals had multiple care-giving roles and many in this sample had diagnoses of mood disorders.

These insights prompt the following questions – is their sleeplessness a symptom of mood disorder? A personality trait? A normal reaction to stress? What is really being treated here?

### *Interactions with physicians*

Most patients in this sample reported positive interactions with their IMC physicians about sleeplessness. A few patients described interactions with physicians outside the IMC. Factors that seemed to shape these interactions and their outcomes included time constraints, consumerism, pre-existing prescriptions and physician attitudes toward treatment. I will address each in turn, in the following pages. Though the perspective is different, it is noteworthy that these were also factors mentioned in physician interviews.

### *Time constraints*

Echoing the previously interviewed physicians, patients in this sample discussed the impact of the physician's limited time on their interaction. This patient, who may have had special insight because her daughter was a physician, noted both the constraint of time and its relationship to managed care.

*But then there's so many things that a doctor needs to remember to ask about in their[visit]. You've got 15 minutes and you have to diagnose, figure out, what, you know who this person is, what's wrong with them. Get the diagnosis. Get their prescriptions written and write up your paper work. And you've got 15 minutes to do it! And then you've got the next person. And I don't think that's fair. And I don't think it's right. And I don't think any of us are going to get all of our needs taken care of. How's the doctor going to have time to ask about sleep when, when those are the circumstances? [Incredulous laughter] We've got to do something about our health care system. It's, it really, really needs to ah, get some work done on it. And I don't know who came up with the idea this middle, this middle layer of the [system]. You know that you have to call and get permission before you can have the doctor. [Oh, managed care] Of managed care yes. The managed care system seems to me that that's just taking money that could be, being funneled into actual care. Instead of the managed part. [Laughing] (PT 23)*

Patient 9 was in a unique position to discuss challenges to today's physician, as he was one.

In addition, his perspective echoes that of some of the IMC physicians.

*[Sighs] Well, number one as doctors, as physicians have less time to spend with their patients and there's a you know growing physician shortage and there's a growing aging population. My guess is the tendency is, the simple thing to do is just give the patient a pill, you know and not to delve into the you know, the why about, why the patient's not sleeping. But just to, like I said, you have a limited amount of time to deal with each of these issues. So if the patient complains that they're having trouble sleeping, first thing that most doctors would do, especially if it's a first time complaint would be, simply get their prescription pad out, write a prescription. And as a patient made a, mentioned a drug by name, that would be even easier because usually you wouldn't argue with the patient you would just write them a prescription....you know we're expected to crank the patients through, to see patients every 15 minutes and fill our schedules up. And so the doctors are under more pressure to see more patients and generate more revenue so you don't have the time to sit and explore some of these issues. (PT9)*

When I asked her if her doctor had ever talked to her about sleep hygiene, this patient noted time constraints and how she had ultimately sought information from other sources.

*Well, actually, I have read a lot about it. I don't think any physician has actually taken the time to tell me that. They don't usually have time to sit and tell me much of that sort of thing. However, I've done a fair amount of reading about it. And I've read all those things and I try and practice those things. (PT 43)*

This patient recognized the challenges doctors face, but asserted that her doctor would be willing to take time for her.

*I think that Dr. X would be very willing to take the time. I think the time is the primary issue for physicians who are you know, practicing medicine. Um, but I think if I let him know that this was a concern of mine, it affects my, you know my living and therefore eventually my health, he would take the time to discuss it with me, share his knowledge, become more knowledgeable if he felt he didn't have knowledge at hand, it was appropriate for me. So yeah, I think that he, I think he's a very unusual physician. But I think yes, he would, he would take time and do whatever he could do to um, help me. (PT 46)*

In sum, some of the patients in this sample recognized the time constraints that doctors operated under and how it could influence their interactions about sleep. The physician-patient of the sample echoed sentiments seen in the previous chapter; specifically, that the limitations of time might make a physician more likely to just “simply get their prescription pad out, write the prescription.”

### *Consumerism*

Even though physicians are still technically in charge of the prescription pad, several of the participants in this study admitted to me that their first experience with a particular sleep drug (typically Ambien) was by trying someone else's. In a way, this is almost like hyper-consumerism – the determined ‘customer’ bypasses the normal route for prescriptions, heading first to a source where they are essentially guaranteed to get what they want. This could also be viewed as a way to ‘try before you buy.’

*At first [my doctor] prescribed valium and I think I took a half a valium but that was just Whoa, my gosh. That just made me feel too crappy the next day. And um, so I took that for, aaah I don't know. Like I said, it's not like I do it every single night. But when I took that I took it for maybe 6 months to a year, maybe once a week a so, and like I said, I just felt really, really crappy. So, um, my mom. [Laughs] My mom you know, whose got sleep problems too, had Ambien. So she gave me some Ambien and I tried Ambien and oh my gosh, greatest drug ever invented.... It worked for her and so I talked to her about this and I said, you know, you gave me a lot of great things, but you also gave me your insomnia. And, you know, so I knew she was taking Ambien. And she said, well let me give you one of these. (PT3)*

This patient was candid and unapologetic about using his wife's Ambien.

*MM: When did you begin taking Ambien?*

*KI: I really began taking my wife's prescription because I don't use it very often. I usually take about a quarter of a 10 mg. And, or half. So, what she got took care of my needs, because I don't use it very often. You know, I'm using it more now because I would much rather develop some dependency on Ambien than lose sleep at this point. But, perspectives change when you get a little older, post-heart attack, which I had back in '98. So you see the world a little differently.*

*MM: Right, right. So you started occasionally using your wife's and then um, at what point did you ask your previous physician for a prescription? Do you recall?*

*KI: A couple of years ago, I don't remember. (PT2)*

Another patient who admitting trying someone else's prescription told me:

*Well, initially yes. Because when he first prescribed the Ambien to me, because my wife takes Ambien as well. And um. [PAUSE] She talked about how good it, you know how it relaxed her and helped her to sleep and so I thought I'd give it a try and it does seem to help considerably....so yes, I have taken my wife's Ambien before and that's what prompted me to ask Dr. X for it as well. (PT 30)*

I correctly assumed that most patients would not admit to doctor shopping, even if they had engaged in it. One patient did tell me that she had considered it when seeking to continue a benzodiazepine prescription from another physician.

*KI: Um. Well, when I started working down at NAME I switched my doctors down there. And I'll be honest with you, that was the main concern of mine that I would get, I would not have switched doctors if I felt like I could not get the sleeping medication. And you know, he keeps a close check on it. And I do not abuse it or use more of it than I should. So he has continued to prescribe it for me.*

*MM: Ok, and so, what you were saying a second ago is that that is a major concern for you.*

*KI: Uh-huh*

*MM: and that in fact if he was not willing to prescribe that, that you would, you would then want to find someone who would, is that correct?*

*KI: Probably so, yes, in all honesty.(PT 28)*

This patient spoke of an interaction he had had with an IMC-affiliated psychiatrist.

*But I went to the psychiatrist that was in the same office for medications. And at some point I had been getting prescriptions from him for a couple of years at least he said he had read this article that Xanax you know could be really addictive and he um, he um, wanted to stop giving me the medication. And not give me anything else. And I was ah, and I said what am I supposed to do. And he said you know, try ah, herbs. Try going to bed earlier, whatever, you know, and it, and ah, none of that worked. I mean I really, it's a problem. And at that point I was still working so um, that was the only time I had an issue with this doctor. And I ended up going to, eventually going to a different psychiatrist. (PT 39)*

The following quote not only exemplifies consumerism but touches on how the insurance companies and the Internet moderate the patient-physician relationship.

*MM: Apparently some insurance companies have said you can only have 15 pills a month. Is that something you've run into?*

*KI: You know, I have not, but Dr. X mentioned that to me at the last visit where I asked for some Ambien...I got the generic and I have not had a problem with that but it wouldn't surprise me, which I think is really kind of unfortunate, but it wouldn't surprise me. I think, I think if that were the case I would probably go to Canada and buy the generic.*

*MM: Well that's a bonus of you traveling internationally a lot.*

*KI: No, no, no. You can do that over. You can do that actually over the internet to Canada. Drugs.com, which is pretty reputable so I don't feel too bad about that. [Laughing] (PT 42)*

Consumerist attitudes were evident among some of the patients. Some engaged in hyper-consumerist behavior by seeking sleep drugs from a friend or family member, allowing them to try the drug before buying it. A handful of patients also alluded to doctor shopping. However, many of these patients entered their office visits with pre-existing prescriptions.

#### *Pre-existing prescriptions*

Just as in the physician interviews, I found there were several reasons why docs tended to comply with patient request. A familiar one is the presence of pre-existing prescription. These interactions were apparently cut and dry and not particularly memorable. When pressed, most patients could not recall the 'exact' conversation.

*MM: And if you can recall the interaction where you first left your doctor's office with a prescription for Ambien, I'd be interested in hearing about how that interaction went. Who brought up the sleeplessness? Was it you, or was it your doctor. And how you decided upon a course of treatment together.*

*KI: You know, I think it, I can't, I cannot remember all that much. I know though that a couple of years ago I was in a time in my job where it was very, very, very high stress. And I really couldn't sleep a lot at all. And I was working all, probably 10 to 12 hours a day, 7 days a week. And it was high enough stress where I said you know, I've got to be able to sleep at night and I walked in and I asked for a couple of months of Ambien and it was from the nurse at work. Or the PA at work. And, and so she gave me some. Because I knew it was going to be pretty much short term where it was pretty impactful. So and then because it was, it works pretty well actually and so now*



*when I. And I've asked my, my regular physician [at the IMC], I've asked him, you know and he's given me a few months here. You know like a month's supply with the one or two refills and I just have some on hand. (PT 42)*

This patient got quite defensive when asked about his interaction with an IMC doctor about sleep (an assumption I had made based on his recent prescription).

*You know, your assumption that he's treated me for sleep is incorrect. The only thing, I've seen him one time for a physical. Because the internist I had for many years, NAME retired at [the] IMC. And I asked my good friend and former neighbor NAME for someone he would recommend. And that's how I got Dr. X. And I had my first and only physical, annual physical with him last February. And I wanted a um, a um, Ambien prescription renewed. And that's about the extent of my conversation with him about anything related to sleep. So, he gave me a prescription. (PT2)*

The following quote exemplifies how most patients recalled their interactions with doctors in instances where they were had a pre-existing prescription for a sleep aid.

*MM: Ok. And so, um, if you can remember how it came up with Dr. X, did you present it as hey I've tried this before, I need it again or.*

*KI: Yes, basically that was all. I just told him I was having problems sleeping and you know, that was all. I didn't go into any detail or anything. I mean he had known I had been on the ah. In fact, I don't even know. At the beginning when he first become my doctor I might have been on the paxil and Buspar, I don't remember. But I had lost my, I had lost a job.*

*MM: Oh.*

*KI: I remember he prescribed, what did he prescribe Klonipin for me which I never took. But, I don't know if I, like I said, it's hard for me to remember but I might have been on those other medications and he would ask me about sleep and I would say I have trouble sleeping so. I don't know. I just can't remember the exact conversation.*

*MM: Sure. Do you recall if you felt like he was receptive or not to your, to your needs.*

*KI: Yeah, he was receptive, definitely. (PT 34)*

To summarize, many of the patients in this sample had prescriptions for sleep aids written by physicians other than their IMC doctor. It was not uncommon for them to seek a renewed or refilled prescription from their IMC doctors and it seems that most complied without much hesitation. Patients did not often recall these simple interactions in great detail.

### *Physicians' attitude toward treatment*

Patients confirmed that IMC physicians routinely suggested lifestyle/behavioral changes or touted the tenets of sleep hygiene; patient response to these suggestions was more indicative of their own attitudes toward treatment than that of their physicians. Thus, discussion of sleep hygiene practices are reported in the section “patient attitudes toward treatment.” In the end, however, all of these patients received a prescription for a sleep aid. In this section, I focus on physicians’ attitudes toward prescription medications.

When patients discussed interactions related to acquiring a prescription treatment, different prescribing ‘personalities’ emerged. Doctors were described as alternately ‘cautious’ or ‘free-wheeling.’

#### *The cautious prescriber*

Most of the patients in this sample indicated that their physicians were ‘middle of the road’ in terms of prescribing practices. There was a tendency to use words like “cautious,” “conservative” and “careful.”

*He was more cautious. He wasn't like, Uh-huh, take this here and you go to sleep. You know. He explained some things. 'I can prescribe, but it would be best not to, but, I can prescribe something to help you sleep.' But, you know he didn't want nothing for me to get addicted to now. (PT 25)*

*I would be more than willing to try different medications that ah, might be helpful. The doctors tend to not want to make changes very frequently though. So they have been probably more conservative than I would like. (PT22)*

*I think Dr. X is careful. Yeah, he's not sitting there going 'Ooooh, yeah, here, just take this.' And he's not, he's not saying 'no, I never prescribe these.' (PT 42)*

*I don't feel that there was reluctance [sic], but they also wanted to follow [up] and make sure. You know. I mean I felt that it wasn't like an open prescription pad, you know, that they wanted to know if it was helping and that sort of thing. (PT 38)*

*Yes, initially it was Ambien and then the zolpidem. Ah, and he's very ah, conservative. And he asked me a LOT of questions. I could tell that, you know, he was concerned about giving it to me, and he would make sure which day I needed it. (PT 30 – emphasis his)*

An attitude of resistance led one patient to question the physician's knowledge of sleep aids. He said "I don't know whether his hesitancy to prescribe anything is due to he doesn't know that much about it or either his hesitancy is about what sleeping aids help people sleep" (PT 33). However, others seemed to appreciate the physician's point of view, even as they felt frustrated with their options.

*Yeah, and I think that's when he give me the Trazodone. And he talked with me in-depth about it, you know, and he, he just don't like to prescribe something that. He told me though, he said I have a hesitance about prescribing anything to my patients that, like sleeping pills and things. And I think well, you know, I understand where's he's coming from too and I don't want to get hooked on anything. But do I do this [not sleep] forever? You know what I'm saying? (PT 33)*

#### *The free-wheeling prescriber*

This was an uncommon characterization. However, in these characterizations it is the physician who is eager, or at least extremely open, to prescribing the drug.

*MM: How do you feel like the physicians that you've encountered, what is sort of their openness to prescribing medications for your sleep issues.*

*KI: I think very open. I'd say like a 9 [out of 10]. I mean, even Dr. X who wants to put me on something else he's like "Ambien's great!". ...I mean all the feedback I've gotten. I feel like I could go in there, a stranger off the street, and they'd just write up a medication. So, I feel like that. They just use it as like a tool for them to not have to deal with it. Like 'Oh, I'll just prescribe them Ambien because it's working and we haven't heard anything.' You know? Instead of you know, doing other measures,*

*psychotherapy. You know what I mean? When it comes to the sleep I think that they're just very open to it. And even my wife...she's like, they're like what do you want to be on? Is there anything that you've heard of that you want to be on? I think her doctor asked her that. You know. So, and Dr. X [previous physician] was like that too. He was like do you see any other[drugs]? Because I joked about all these sleep drugs. I'm like gosh, everywhere I go I see sleep commercials in newspaper and in print and media. It's like this whole country is sleepless! And he's like yeah, if there's anything else you want to try just bring it in. You know he was just really like kind of like freewheeling, you know. (PT14)*

This individual was suspect of not only physicians, but the FDA.

*Physicians are really [sighs] apparently quite interested in um, prescribing medication that may or may not be [safe] because they are, they have been approached by a drug company....I wouldn't hazard a guess on that one, but certainly it seems kind of obvious to me since they always. Since many of them and I'm not including my own physician here necessarily but, um, many of them have copious samples of recent, brand new drug medications, you know, drug things. And um, I think the system in this country is completely screwed up. ...And one of the things that's going on in the world is corruption of the Food and Drug Administration. (PT 43)*

I asked the following patient how willing her physician was to prescribing sleep medication.

*MM: Uh-huh. And how open, if you could again think of a scale of 1 to 10, how open to prescribing sleep medication did you feel like Dr. X was.*

*KI: A 10. (PT 34)*

In sum, most physicians in this sample seemed cautious or conservative in their approach to the prescription of sleep aids. This attitude toward sedative hypnotics verifies what physicians told me in their interviews. However, patients indicated that a few doctors were more liberal in their prescription policies.

#### *Patient attitude toward insomnia treatments*

Patients in this sample preferred prescription medication to sleep hygiene practices, although a handful did report strange side effects from Ambien. A surprising finding was the

number of patients who discussed fears of becoming dependent on sleep aids, particularly as I did not raise this topic in the interviews.

Patients confirmed that their physicians had spoken to them about sleep hygiene or making changes in their lifestyle and behaviors. However, few found these suggestions helpful in practice.

*Well, some nights it's very hard. I'll lie in bed and I'll be sleepy when I go to bed, but when I lie down I can't go to sleep. So I lay there about 30 minutes and I try to do what all I read in these books and little pamphlets that tell you to get up and stay up a little bit and then come back to sleep. Well some nights I do that 3 times or 4 [laughs] and some nights I'm up 1 o'clock, 2 o'clock or 3 o'clock in the morning before I ever get situated enough to fall asleep. And maybe once in a while I'll get up and take a hot bath, because that's supposed to relax you. I try to do the things that I've been told that might help. And it might [help] some but I, I'll fall asleep and then I'll wake back up. I just you know, hadn't had a, don't have a good night's rest and I'll wake up as tired as if I'd just gone to bed. (PT 16)*

One patient was frustrated with his inability to get a prescription for daily use and complained of being “lectured” on sleep practices he found “impractical.”

*Also know that, that at least my doctors have been unwilling to give people just a prescription for daily use....I think that they need to be more aggressive with their approach. And they need to put a greater sense of reality into treating their patients. You know having; you know having a doctor tell me that um, I should get more sleep or allow myself more time to sleep is sometimes not practical. To tell a, you know, to tell someone not to do something, which they know is not normal is not a practical approach. So, you know, a lot of, remember I told you about all the lectures. A lot of, a lot of the content of those lectures ok, is great from you know, being in the ivory tower and being academic about it....Taking or helping the patient with an action that can be actually implemented and yield a result is probably a better approach to take. And I've found that a lot of the things that I've heard out of this experience have been a little too impractical in nature. (PT 22)*

Similarly, this patient found the suggestions impractical.

*And like I said my doctors never brushed it off at all. But I think, I don't know that some of them realized how it really affects your whole being. You know. I mean, just are not sleeping then, most of the night. Just laying there. And they'd say get up and go read a book or something. Well, that's hard to do. I mean, I feel like that would disturb my husband if I get up. Although he's told me it never would, if I wanted to*

*get up. But, that didn't help me either. To go get up and do something and then I'd lay back down and I'm actually more wide awake after I've done that. (PT 38)*

This patient found neither behavioral suggestions, over the counter remedies, nor a Trazodone prescription helpful.

*KI: That's what I don't understand why I can't get to sleep. Why, and I, like I've said I've drank milk. Dr. X told me to drink some more milk. I said I don't. Take warm milk.....And but anyhow I'm just, I'm just not sleeping. I have took the Tylenol PM and stuff like that. Well that makes my legs cramp, seems like. Dr. X has gave me a, I forgot the name of it, it was kind of like ah, take it at night but it was kind of like an antidepressant too, I think, or something to that effect. And it didn't help.*

*MM: Was that Trazodone. Do you remember?*

*KI: I think it was. Yes, that's what it was. That's the name, yep. So, um, but nothing I'm doing seems to be helping. I mean I just stay awake all night long. (PT 33)*

It was clear, however, that in certain instances patients were actually incorporating 'bad' behaviors into their sleep-inducing attempts. For instance, the artificial light and stimulation from television and/or a computer monitor are to be avoided at least an hour prior to bedtime (IOM 2006).

*And I lie there and I keep, try not to be thinking about things but unfortunately, they keep, things keep rolling around in my head. And I just can lie there 2 and 3 hours without falling asleep. And then sometimes I try not to do that. I've read that 20 minutes is all you should do [in the bed]. But I still try longer than that because we share a king size bed which doesn't bother my husband too much. But if I'm gone from there too long he worries about whether something's happened. Anyway I usually give up and go upstairs to a room that's away from everybody else and I can play stupid games on the computer like solitaire and FreeCell and things. And anything to be monotonous enough to put me asleep. And after I do that for an hour or two I usually go down and go right to sleep. (PT 19)*

This patient may have realized in describing his home versus vacation sleep routines, that one appeared to be much more conducive to sleep.

*And, at home, what I generally do is, my wife goes to sleep about 11, 11:30, sometimes midnight. And if I'm not tired, which is often the case, then I'll go in the living room and mess with the computer or watch TV until I'm tired. Which is like 1:30 or 2. But when we're together like in a hotel room I guess I can't do that. And so*

*I just, I just lay in bed 'til I go to sleep and I seem to get to sleep without staying awake. (PT 39)*

On the whole, patients in this sample reported that their prescription sleep aids were generally effective, although a few reported that every night use diminished or eradicated the effectiveness. Although side effects were uncommon, a couple of patients did report sleep walking and possible sleep-eating. This particular patient had had several episodes of sleep-activity.

*Ah, it ah, like I said [the Ambien is] not always real effective. Sometimes it just knocks me right out and other times you know. And of course one of the side effects of it is that I do things. I occasionally will do things that I have no memory of. My son called me one night and we talked on the phone for 30 minutes. And the next day he said mom have you made a decision about what we talked about last night. And I said, WHAT?? [LAUGHS] I had no idea that I had carried on a perfectly lucid conversation with him in the [night]. You know. I had no idea. I got up one night and ate a piece of pizza out of the refrigerator. I had no memory of doing that. My twin sister was visiting with me and ah, I had one of my granddaughters, she was a baby at the time. And she said, NAME started crying and you got up and you came down the hall and you picked her up and you, and you come out of the bedroom with her. And you staggered back down the hall. That's another thing, it makes you walk like you're drunk. She said you staggered back down to the hall to your bed and put her in the bed with you. And [LAUGHING] I had no, absolutely no idea how that child got in bed with me the next morning. But my sister was there to witness it so she could tell me. So that is one side effect about it that I don't like. (PT 6)*

Despite physician discussions related to the habit-forming nature of these drugs, an unexpected finding in these data is the frequency with which patients mentioned the topic of addiction or dependence. One candid patient said:

*So I do...use Ambien. Not every night but quite a bit. Well, gee. If I could take it every night and I felt like I wouldn't become dependent on it, I would. (PT 42)*

Many in this sample expressed a reluctance to take sleeping pills, or even pills in general.

*And I tried it, you know, a lot of people that they have pills to get up by, pills to go to sleep by and I myself wanted to not be that person. Occasional, which is not bad, I don't think. Occasionally when you really can't go to sleep or you need a good*

*night's rest, I may take a pill. But overall I try to stay away from them, but I do have them in case I do, you know. It's a great help that a-way. (PT 25)*

Another patient went so far as to deem regular medicine taking not “normal,” saying “I don’t want to really use any medicine if I can help it because I don’t want to get used to doing things like that. I don’t think that’s a normal thing for people” (PT 19). Even the physician in the sample expressed concerns about the habit-forming nature of Ambien.

*I've been reluctant to use [Ambien] on a regular basis. You know, even though I'm a physician, and even though truthfully that proba-, that may be less habit forming than Tylenol PM, I don't know. But I'm still reluctant to use the prescription sleep medication because I don't want to get, get addicted. But yet, my perception is that since Tylenol PM is not, is over the counter, I'll use that with you know, I'm more comfortable using that. (PT9)*

Another patient was very stressed about getting dependent on Ambien.

*I told [my doctor] I didn't want to take it every night. I had took it a lot to begin with so I got rested and then I told him I said it was helping but I hate to take it every day. Because I didn't want to get addicted to it. So now what I do, he lets me keep some but I don't take it over a couple times a week. And then I've cut back to one. I want, even if I have to stay up until 1 o'clock in the morning I've tried not to take but one because I don't want to make myself totally depend on something like that. (PT 16)*

She later elaborated on her fear.

*I tell you I've had drug addiction in my husband's family and it's made me. I guess I'm. They sent me to a psychologist one time because I wouldn't take my medicine. [laughs]....I feel sometimes I feel like I don't want all that medicine in me, to take all that medicine. When you've seen what it would do to people it's sort of scary. And I just want to make sure that I don't ever over-use anything. (PT 16)*

This patient makes an interesting point about his prescription drug use.

*And ah, you know, the issues of addiction um, you know, I've been on Xanax for most of the last 16 years....I don't feel like I have the need to take more, you know. But it really helps me get to sleep. You know, if that's an addiction, I'm addicted. But I mean I've been on antidepressants for that time and, I guess I'm addicted to that to. Or not. (PT 39)*



In sum, most patients allowed that they had tried some variation of sleep hygiene practice but, for the most part, they found it to be ineffective or impractical. In these discussions, however, it became clear that some patients were engaging in poor sleep hygiene as part of their bedtime routine.

In terms of prescription drug use, most patients found their sedative hypnotics to be helpful, particularly if they were prescribed Ambien or zolpidem. However, a few patients reported that these drugs lost effect when used on a routine basis and a very small number of patients reported strange side effects including sleep-walking and sleep-eating. As I did not ask about issues of addiction, it was particularly striking to me that many of these patients initiated discussions about their fears of dependence.

#### *Sources of rhetorical authority*

Patients in this sample discussed multiple sources of rhetorical authority, although some patients did tell me that their only information they had gotten about sleep was from their physicians. Like the physician sample, direct to consumer advertising [DTCA] was the most commonly mentioned source of rhetorical authority. Other sources mentioned were social networks and print media.

#### *DTCA*

All of the patients in this sample were aware of DTCA for sleep aids but most viewed them (and other drug ads) negatively. Only a few patients admitted that the ads might have influenced their interactions with physicians. The most common response from participants was that they were not influenced by DTCA, but that other people probably were.

This patient openly admitted that his knowledge of Ambien came from an ad and that that was his prompt to ask his doctor about it.

*My, my knowledge of Ambien came from the commercial and I did ask the doctor about that and you know, and he thought that, sure, it might be good to switch from the Xanax and see how this worked. (PT 39)*

One patient admitting to seeing and requesting not one, but two drugs from advertisements. She had tried the drug Lyrica after seeing it advertised. Unfortunately, it did not provide her any relief from fibromyalgia.

*MM: Ok. Ok. Any other, any other times when you can think of. You mentioned the Ambien CR; I know that's being really, ah, it's advertised a lot on TV.  
KI: Yeah, that's where I saw that. And my doctor, I asked him if the CR would be any different. And I don't really think they knew how it would affect me differently, or if it would. So we tried that, but that, I just couldn't function the next day. I was so groggy. Still. So, I went back to the plain Ambien. (PT 37)*

These patients, though they said they were not influenced by DTCA, did think that drug companies were effective in getting people to think about their products.

*I think, and not just sleep aid medicine. I think all medicine that is advertised on the TV for all the different things, like being able to go to the bathroom, or stuff with your eyes. I think it cues people to say, well hey, maybe that would work for me. (PT 30)*

*MM: Yeah. So I'm curious if people feel like seeing those advertisements on television influence them to ask their doctor for a specific name brand. What do you think?  
KI: I think it does. I think people just notice that, hey, these commercials are on and I'm still awake. Maybe I should talk to my doctor about this. It leads them to ask for a specific medication. (PT 31)*

In the following quote, the patient made a distinction between the ads for the sleep drugs and other types of drugs.

*KI: No, and I see advertised all the time Ambien CR or something, which is the sustained release or something. But it hasn't made me want to try it. As a matter of fact a lot of the ads just turn me off.  
MM: What is it about them?  
KI: I guess I don't like commercials. And they're ongoing. I mean you can't watch the*

*evening news or anything now, or a ballgame or anything else without being bombarded left and right with Viagra and Cialis and everything else. And this is during prime time. And I think there's a time and place for everything. And I think the pharmaceutical companies, although my daughter-in-law is with one of them, are just [PAUSE] spending a fortune on advertising and the price of medication keeps going up and I think that's part of it. I don't think it's all research and development. I mean, that may be their development, by advertising, but...Spireva and the Advair commercials are, they're toned down. And they're realistic and they don't bother me. As a matter of fact they're encouraging to know that they are helping people. I just think more and more ads are going to the drug companies and I just don't like it, because I think that's part of the cost. And they're not going to convince me to use any of them. So. Maybe some people it would, but it just doesn't turn me on. (PT1)*

Another interesting perspective emerged from the physician-patient.

*You know it's interesting my brother in law is a pharmacist and he was, we were chatting and he was telling me that the ah, the butter-, the Lunesta butter fly is, has been extremely popular and very recognizable. And um, it's interesting. Now I've never asked for Lunesta, but ah, I can specially remember their ads on TV. And so, I would imagine that that does have an influence on patients asking their doctors for sleep aid prescriptions. And they you know they advertise Ambien quite a bit as well. The ads now you know focus on Ambien CR, which is you know a controlled release and I can picture the ad on TV where they have, ah, you know it has two different types. There's a white part of the pill and a yellow part of the pill and it looks like spark, you know they show the pill coming together with little sparkly ingredients and things. And I don't know if other people pay that close attention, but I can picture the sleep aid ads from TV....The good news/bad news is these medicines do help. The only thing is I think sometime the direct-to-consumer-advertising might increase the dependency on some of these drugs. But I don't know that for a fact. It just seems like it's going to make more patients request sleep aids. (PT9)*

This patient felt like ads were being 'pushed down his throat' and doctors seemed in on the game.

*I think with all the new medications out there that they've just been so free to kind of um, promote and kind of want to fill. It seems they just want to fill a prescription for these sleep medications. Like I said, I feel like it's just like a new tool that they have, now. And, you know I see a lot of the advertising and all of the, you know like going into all the doctor's offices now it just seems like it's everywhere. It's like, you know, they're just really pushing. It seems like that whole part of the pharmaceutical whatever, industry just pushing that down your throat. Like basically everybody needs to be on sleep medication. And I think that the doctors are kind of in a sense like, I don't know if their, what their incentive is, but they're just really eager to push it. (PT14)*

The following quotes exemplify what most patients told me – that they were not influenced by DTCA . But ,when asked if they thought others were influenced by DTCA, they invariably said yes.

*KI: I view those advertisements as purely a way for the pharmaceutical companies to get more revenue for the medications. I have listened to my doctors and their warnings about becoming dependent on these medications. And you know basically weighing the different information I've chosen to take a conservative approach to dealing with these medications. So you know the advertising has very little influence on my approach.*

*MM: So your approach has been to really take a conservative approach to these medications and to view the advertisements as a revenue making endeavor on the part of the drug companies. If you had to guess would you say that they are largely influential on other people however?*

*KI: Yes. I believe that they are very influential on a lot of people. (PT 22)*

Though lengthy, the following exchanges exemplify the attitude that ads may be effective on other people, but not the speaker.

*MM: So the knowledge that you've gained through you know internet, TV shows, what have you. Do you feel like that information influenced your interactions with your physicians at all?*

*KI: No, I actually I don't. Uh-huh.*

*MM: OK, how about advertisements for prescription drugs. Do you ever find yourself asking your doctor about drugs for, that you've seen advertisements for?*

*KI: You know I never, I never do I. For sleep or for anything.*

*MM: For anything.*

*KI: Aaah, not too much because I'm not. The, the, no, no. Uh-huh. No.*

*MM: Ok.*

*KI: No. Even, even the Ambien I didn't. That came about through my colleagues from work, so that wasn't....it wasn't something I saw on TV and said oh I must have. It was, oh really this works really well for traveling to the UK. Yeah.*

*MM: Right, right. Ok, just in doing this research I've become extremely aware of the amount of advertisements for sleep aids that are on television.*

*KI: yes.*

*MM: and particularly in the evening obviously. [Yep] But so I was curious if you thought that those ads might have influence on other people.*

*KI: Oh yes I, I am sure they do. I'm sure they do. (PT 42)*

Another example goes further.

*MM: And some people see those and they, they in turn do ask their doctors for specific brand names of medications. Is that something that you've ever done?*

*KI: No, I don't believe in it.*

*MM: More generally though in terms of the advertisements for sleep aids do you think that even though they're not something that might influence you, do you think they might play a role in other people asking for prescription medications.*

*KI: Oh yes, I definitely think that kind of advertising has influenced people.*

*MM: Why do you think that they might be convincing for other people.*

*KI: Because [pause] I hate to say it, but if you look at the voting population.*

*[Laughing] You will discover that most people are completely gullible, quite uneducated and just parrot what they hear. (PT 43)*

A different patient thought that advertisements could be potentially positive for the patient-physician interaction.

*MM: And one place I'm curious if people get their information is from the drug advertisements that are on television or in magazines for sleep aids. Have you, have you noticed those advertisements.*

*KI: I haven't been aware of noticing but I, I certainly flip through magazines, see ads for prescriptions and I know I saw Ambien advertised. So that may, that may be something that has encouraged me to feel like that would be helpful.*

*MM: OK, ah, so you think that in fact might influence you in thinking it's helpful.*

*KI: Yeah.*

*MM: In general, there are so many advertisements, direct to consumer advertisements for so many pharmaceuticals these days.*

*KI: Yes.*

*MM: Are there other advertisements that you may have seen that you've then actually taken action and gone to your doctor and said, you know, I saw this ad for so and so and I'd like to try that.*

*KI: Um, no, I don't think so.*

*MM: No. Ok. Do you think that advertisements might encourage people who maybe hadn't thought about their sleep issues to, to go and talk to their doctor about sleep aids. I mean this is obviously a hypothetical.*

*KI: Yes. I would think so. You know. Just knowing that are other people out there who have enough difficulty so that they would discuss it with their doctor would make one feel like, you know, he's not going to feel like I'm really strange or unusual if I. Yeah, I think that that probably would have a freeing effect. (PT 46)*

DTCA was the most commonly discussed form of rhetorical authority. Many patients seemed to view it negatively and only a few admitted to being influenced by it. However, patients invariably believed that they were less vulnerable to these messages, compared to others.

### *Other sources of rhetorical authority*

While DTCA was by far the most discussed source of rhetorical authority, some patients mentioned friends and family as sources of knowledge. One patient said that in addition to the internet, she had sought information from friends with sleep issues.

*KI: Yeah, and friends. I guess I've had a couple of friends who struggled with sleep too. And just talking to them and hearing what they did and what they do. And that sort of thing.*

*MM: Are their issues with sleep similar to yours, different from yours, or. In other words, do they have sleep apnea or are they struggling with.*

*KI: No, Uh-huh. One of them ended up having restless leg syndrome. But I think she's doing better now. But she was one of. And one is a new friend that I have, that does have sleep apnea. Which is kind of interesting. Because we didn't realize it and we started talking one day and, but you know, I think it's good to have a support group. (PT 38)*

Patient 14 gained information about sleeping pills from family and friends.

*MM: What were some of the other sources that you felt like you gained knowledge about sleep and sleep treatments from? Like people talk about Internet, TV, book, magazines, newspapers, friends or family. Which of those sources, if any?*

*KI: Oh, I mean I would definitely say just interactions between my family and friends. I mean it's just like. You know in the last 10 years like you know, I'm very open with medications that I'm on and everything and they've just been like, Oh you take Ambien too, you take Ambien too. So um, you know I think it's not like this taboo that you're like you know. It's like you're on a sleeping pill. You know. Versus like you're on like lithium or something. (PT 14)*

Part of the ease of these conversations, he thought, was due to the fact that Ambien didn't carry some of the negative stereotypes, or stigma, associated with other drugs.

*It's like, I mean I feel that with my like colleagues and then people, I'm a manager and I openly talk about people that can't sleep I'm like you know you should go see a doctor and maybe get some help. I'm like, I'm on Ambien, but I'm also on other stuff that I don't tell them about. And people just say how wonderful these sleep medications are and they help them and yeah, so I don't think there's a stigma at all associated with it. (PT14)*

This quote is noteworthy because, even though it references an over the counter treatment, the patient said she had not considered sleep “a problem that a doctor might help me with.”

*Yeah, I've tried [over the counter medications]. I don't think I discussed that with a physician but a friend with whom I taught for a long time took Tylenol PM every night for years and years and years before she went to bed. And that was the only way she could sleep and it worked like a charm and she always did it. And she said NAME if you're having trouble sleeping try Tylenol PM. Well, I felt that it made me. It felt too strong to me. It felt like I. I felt in the morning like I was on knock-out drops. I didn't like that. But I didn't discuss with a doctor. I just asked my friend and used my friend's advice. Because it just seems like sleeping. I didn't really think of it in terms of a problem that a doctor might help me with. (PT 46)*

Print media and the Internet were mentioned with some frequency, and though most deemed the information not that helpful, this patient had found one 'trick' to be helpful.

*And then we read up on the internet about, you know all the tricks of the sleeping. You know, have a dark room, go to bed at the same time very night. [Laughing] Etc, etc, etc. none of which [helped]. But one, one of those tricks I have been using and it has helped a lot, and that is a sleep mask. (PT 23)*

This patient said she had gained information from many sources.

*MM: Other than the doctors at [the IMC], are there other sources that you've used to gain knowledge about sleep issues, such as the internet, watching TV, reading books or magazines or talking to friends and family?*

*KI: Oh, yeah. All.*

*MM: all of the above.*

*KI: Yeah. Newspaper, did you say that one too? Whenever something is on about sleep or insomnia I always read it or look it up or whatever, but at this point I always know everything they have to say. (PT 4)*

Another patient told me that she had sought information at a library.

*I was desperate so I did it, that's why I did. I went to the library. [Uh-huh] Because I was trying to do everything else I could before medication. (PT 21)*

In sum, people in this sample used a variety of sources of rhetorical authority.

Patients mentioned friends, family, the internet, TV, and print media as sources they had turned to in order to learn more about sleep.

### *The influence of insurance companies*

Like physicians, several patients noted that insurance had limited the amount of pills they could get in a month.

This patient went into great depth about how he perceived the role of the insurance company to influence the doctors. This quote provides an interesting parallel to the physician interviews as a couple of the doctors discussed how much they didn't like dealing with the insurance companies on certain issues and would warn their patients to that effect.

*I think that the doctors and assistants, medical assistants is, again too tied into what the insurance companies will allow versus pushing back on the insurance companies. I think that they just tend to be compliant with the insurance companies. I don't think they are willing or able to fight the insurance companies. Because I believe that it's just a battle that they're not willing to invest the time and effort in. Because it is such a big battle....I think our insurance system is very, very much financially driven and for certain things. You know for example if you have a catastrophic issue they're very, very good, ok. But when you have something like this where there is no direct correlation to a life and death situation or they don't see themselves in a liability or a legal implication immediately I think that they are going to take every step possible to minimize their expense versus you know solving the problem. (PT 22)*

This patient was prescribed Paxil for her obsessive-compulsive disorder.

*That other doctor that I was telling you about, the older fellow, one day he gave me, he upped the strength of the Paxil. Well Dr. X had already gave me, I take like 40 milligrams a day. But then my insurance company didn't want to pay for two pills. They wanted to pay for one. So then a lot of the times I was only taking one anyway. So they just, they cut it down. So he had to cut it down so that they would pay for it. (PT 12)*

Although the role of insurance arose more frequently in the physician interviews, a few patients in this sample mentioned that insurance played a role in their ability to receive certain medications.



## Discussion

In this discussion, I summarize my findings from the patient interviews. In Chapter 6, I create further linkages between these data and the previously discussed quantitative and qualitative findings.

To gain further insight into the patient-physicians interaction surrounding sleeplessness and explore evidence of the medicalization process, I interviewed 27 patients. All of the participants in this sample were patients of the IMC physicians I had previously interviewed. Patient interviews were semi-structured, lasted between 25 and 75 minutes and were conducted in-person or over the phone.

Interviews focused on patient's reported experience of insomnia, their interactions with physicians, attitudes toward insomnia treatment and sources of rhetorical authority. A few patients mentioned the role of insurance, but it was not nearly as prevalent a theme, compared to physician interviews. An unexpected theme was patient fears of dependence on sleep aids.

Patient interviews allowed me to put faces, voices and personal history to bear on the national level trend statistics discussed in Chapter 3. Patients' descriptions of their insomnia experience were consistently unpleasant. Individuals in this sample reported difficulty falling and/or staying asleep. Some woke up multiple times during the night. Commonly reported next-day impairments were fatigue and irritability; however, some reported little or no impairment.

Like physicians, some of the patients in this sample 'normalized' their insomnia experiences by placing them in either the context of their individual circadian rhythm (being a "night owl" versus a "lark") or in relation to the aging process. Women sometimes

associated the onset of their insomnia with mid-life hormonal changes and men mentioned prostate issues that woke them up multiple times a night to urinate, exacerbating their insomnia.

In general, this was a sample with high levels of physical and psychological comorbidities. Patients self-disclosed a variety of health issues including heart disease, obsessive-compulsive disorder, fibromyalgia, arthritis, obstructive sleep apnea and depression. Most striking was the amount of participants who, when asked to cite a probable cause for their sleeplessness or describe their sleeplessness, noted life stress and symptoms of anxiety. Patients talked about “racing thoughts,” being unable to turn off their minds, lying awake and ruminating about the day, etc. They also revealed hating their jobs or having very stressful jobs, surviving dying spouses or grandchildren, and taking on multiple care-giving roles. In short, despite the level of comorbidity, this group had plenty of life issues to lose sleep over.

When describing interactions with physicians, patients were generally positive. Like their doctors, they noted several factors that potentially mediate the office visit outcome. These factors include: time constraints, consumerism, pre-existing prescriptions and physician attitudes toward treatment. A couple of the patients seemed to have special insight into the issues of time that face physicians today. One of these patients was a physician and the other, a mother of a physician (neither of whom is affiliated with the clinic in question). They were not the only participants who discussed time; but they both discussed how the typical 15 minute visit was insufficient to address all health issues, and may lead to hasty decisions regarding the treatment of sleeplessness.

Consumerism among these patients was evident in mentions of trying other people's sleep medications before seeking a prescription, switching physicians if their drug choice was refused and buying drug on the internet. Trying the prescription of a friend or family member is not legal, but does provide a convenient and cost-free way of 'trying before you buy.' Admissions of doctor-shopping or buying drugs from alternate sources were uncommon, but I suspect this may be related to a previously addressed limitation of the study – patients may have feared that their physicians would have access to these interviews.

Many of the patients in this study had pre-existing prescriptions for sleep aids from other doctors. This parallels what physicians told me in their interviews. Pre-existing prescriptions are not only a motivator for physician compliance, but because the interactions were described as brief and straightforward, I did not receive detailed accounts of these interactions.

When describing the physician interaction surrounding prescription insomnia treatment, different prescribing 'personalities' emerged. By far, most patients used words like "cautious," "careful" and "conservative" to describe their physicians prescribing preferences. Interestingly, a small number of patients described their physicians as far more liberal with prescription medications; one went so far as to describe one of his physicians as "freewheeling." Another patient extrapolated from physicians being "interested" in prescribing certain drugs, to the corruption of the FDA.

Patients in this sample confirmed physician assertions that lifestyle and behavioral changes were high on their list of first-line insomnia treatments. A few patients had read about sleep hygiene practices on the Internet. Regardless of their source of information, patients typically found their efforts to engage in these practices ineffectual or impractical.

However, in describing their sleep routines a few patients revealed to me that they maintained such sleep-hygiene “don’ts” as watching television or being on the computer late at night or right before bed.

Generally, these patients were satisfied with their prescriptions sleep aids – particularly if they had a prescription for Ambien or its generic, zolpidem. However, some chronic users found that it lost effectiveness over time, and a couple of patients experienced side effects including sleep-walking and sleep-eating. Others experienced next-day hangovers from using Trazodone or over the counter medications.

Concerns about drug dependence or addiction were raised in physician interviews, but I did not expect it to be a common theme in the patient interviews. Nevertheless, the topic arose frequently and quite a few patients told me of their reluctance to depend on these drugs to get them to sleep. A couple of people opined that drug taking was unnatural or too prevalent in our society. In a more extreme example, one woman told me that she had been sent to see a psychiatrist for not taking her medications; her rationale was that she had seen drug addiction in her husband’s family. But as one patient points out “I’ve been on Xanax for most of the last 16 years....if that’s an addiction, I’m addicted. But, I mean I’ve been on antidepressants for that time and, I guess I’m addicted to that too. Or not” (PT 39).

Once more paralleling physician interviews, patients were most likely to discuss DTCA as compared to other forms of rhetorical authority. Drug advertisements – not just for sleep aids - were generally viewed negatively. When asked explicitly if *they* were influenced by DTCA, only a few patients admitted to seeing drug ads and subsequently asking their doctors for prescriptions. The rest asserted that they were immune, but that ads were probably

effective on others. One patient did note that they could be useful for making patients feel they were not “strange” or “unusual” and could be “freeing” in the doctor-patient interaction.

Other forms of rhetorical authority mentioned were social networks, the Internet, and print media. One patient noted that her friends with sleep issues had served as an informal “support group.” Another noted that she had not thought sleep was something one talked to a doctor about, but she had taken advice from a friend on an over-the-counter sleep medication. A different patient noted that there seemed to be a lack of “taboo” surrounding Ambien that made it more acceptable to talk about with family and friends, as opposed to certain psychiatric medications.

A small number of patients discussed the impact of the insurance companies on their access to, or cost of, prescriptions. One patient in particular seemed miffed that his doctors were not “willing to invest the time and effort in” battling insurance companies. Another patient described how her insurance company refused to pay for her prescribed dose of Paxil; the physician’s solution was to lower the dosage.

A major difference between these and the physician interviews was the lack of explicit discussion around the medicalization of sleeplessness. Unlike the physicians, patients were initially unaware that I was interested in exploring medicalization. Not surprisingly, patients lacked the meta-awareness about the process that was so striking in the physician interviews. A few patients made indirect references to medicalization. Several patients suggested that DTCA might make people believe they are sick or at least in need of a certain medication. One patient told me “I’m like, gosh, everywhere I go I see sleep commercials in newspaper and in print and media. It’s like this whole country is sleepless!” (PT 14). But some of the patient observations were more in line with de-medicalization, such as the woman who

proclaimed, when referring to all her friends who had sleep issues “We can’t all be sick!” And, as previously referenced, one patient said “I didn’t really think of [sleep] in terms of a problem that a doctor might help me with” (PT 46). Finally, perceptions of sleeping pills as unnatural or even dangerous may be antithetical to their popularity.

In sum, patients described their experiences with insomnia, interactions with physicians, attitudes toward insomnia treatment and sources of rhetorical authority. Multiple subjects, including consumerism, rhetorical authority, physician time constraints, pre-existing prescriptions, and the influence of insurance companies offered parallels and contrasts to physicians thoughts on the same topics. An unexpected finding was the number of patients who, unprompted, described their concerns about dependence on, or addiction to, sleep aids. Data from these interviews indicates that patients are aware of some of the fueling factors of the medicalization process, particularly DTCA, but do not necessarily place their individual experiences in the context of these larger forces. Further discussion of these, and related findings from previous chapters, is considered in Chapter 6.

## CHAPTER 6

### INTEGRATED DISCUSSION AND CONCLUSIONS

#### **Overview of Research Intent and Methodology**

The goals of this dissertation are to provide quantitative and qualitative evidence of the medicalization of sleeplessness at the level of patient-physician interaction and elucidate how gaining a greater understanding of the forces influencing this interaction and its outcomes are vital to understanding the medicalization process. Medicalization, as previously noted, is typically conceptualized as the way in which social problems or formerly normative biological processes are re-conceptualized as having a medical definition and a medical treatment (Conrad 2007).

In an effort to answer my research question, **“Is there evidence of the medicalization of sleeplessness at the level of doctor-patient interaction?”** I carried out a mixed methods research agenda that offered evidence at both the macro and micro levels.

I believe that the use of a mixed methodology was particularly apt for gaining insight into my research question. As noted by Creswell “the problems addressed by social and health science researchers are complex, and the use of either quantitative or qualitative approaches by themselves is inadequate to address the complexity” (2009: 203). In addition, this work is intended to appeal to an interdisciplinary audience who may have diverse methodological approaches (Creswell 2009).

Collectively these data indicate that the medicalization of sleeplessness is occurring at the level of patient-physician interaction. The quantitative data describe trends over time at the national level and highlight the disparities between complaint, diagnosis and treatment. The qualitative data help elucidate some of the forces that may be influencing these insomnia-related outcomes and fueling the medicalization process.

In this chapter, I briefly summarize my quantitative and qualitative findings; highlight indicators of medicalization at both the macro and micro level of analyses; propose specific forces that seem to be fueling the medicalization of sleeplessness; note the limitations of this research; suggest directions for future research; and propose public health implications of the medicalization of insomnia.

### **Brief summaries of findings**

#### *Quantitative Findings*

I analyzed 14 years of data from the National Ambulatory Care Survey (NAMCS), a nationally representative data set of physician office visits for the following insomnia-related outcomes: insomnia as reason for office visit, insomnia diagnoses, and the prescription of sedative hypnotics.

In 1993, insomnia was recorded as a reason for office visit in approximately 3.3 million cases. This number increased to about 4.7 million in 2006 – representing about a 30% increase from first to last year of the time period. Over this same time period, the number of office visits resulting in a diagnosis of insomnia increased about 6-fold, from 869,000 to 5.2 million. Office visits resulting in a prescription for a benzodiazepine increased by nearly 40% - from an estimated 2.5 million to 3.5 million. Prescriptions of Trazodone nearly doubled,



going from about 2.8 million in 1993 to 5.8 million in 2006. The largest increase, 23-fold, was for the non-benzodiazepine sedative hypnotics (NBSHs). Their first year in the NAMCS database (1994) about 550,000 prescriptions were written. This increased to 12.8 million in 2006.<sup>31</sup>

Looking at the overall period, the slope and differences in proportion were both positive and statistically significant for insomnia diagnoses, NBSHs, and Trazodone. Results were mixed for insomnia complaint and benzodiazepines. Only for the NBSHs were the slope and proportion differences consistently positive and significant in each regime; other regime outcomes were either not significant, or had a mixture of significant and non-significant results.

Analyzing my independent variables (race, sex, age and insurance status) there were few significant trends. Women were significantly more likely than men to be prescribed Trazodone in all of the regimes tested; there were no other consistent, statistically significant trends when looking at sex and dependent variables. In each regime, patients 55 and older were significantly more likely to receive a prescription for a benzodiazepine or a NBSH, compared to younger patients. While racial differences were inconsistent based on regime and dependent variable, when compared to African American, Asians and Hispanic office visits, Caucasians were significantly more likely to receive a diagnosis or drug, if there was a significant difference to report.

Of my hypotheses, only H2 (estimated mean number of office visits resulting in a diagnosis of insomnia will increase significantly between 1993 and 2006), and H4 (estimated mean number of office visits resulting in a prescription for a NBSH will increase

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<sup>31</sup> As you will recall, NAMCS is representative of only some outpatient clinics, and excludes: hospitals and hospital affiliated clinics, certain physician subspecialties and all inpatient facilities. For a more comprehensive estimate of insomnia scripts dispensed in certain years, please see Table 17 (page 200).

significantly between 1993 and 2006), were fully supported. However, H2 and H4 are the strongest indicators of the medicalization process and thus their significance should not be minimized.

Some of my hypotheses received partial support. In H1 (estimated mean number of office visits with a complaint of insomnia will increase significantly between 1993 and 2006) the difference in mean proportions from 1993 and 2006 was not significant, but the slope trend is significant and positive ( $P < 0.000^{**}$ ). For H3 (estimated mean number of office visits resulting in a prescription of a sedative hypnotic will increase significantly between 1993 and 2006) the slopes for each of the sedative hypnotics measures (Benzodiazepines, Trazodone and NBSHs) show significant and positive change over time. However, when comparing mean proportions, Trazodone and NBSHs remain significant; benzodiazepines are not. Due to the inconsistency in the measures of change over time for the benzodiazepines, I cannot fully reject the null hypothesis, but would argue that, when taken as a whole, the sedative hypnotics have seen significant and positive change between 1993 and 2006. For H5 (The estimated proportion of individuals from “non-traditional” populations [those who are male, non-white, and/or younger] who receive a diagnosis of insomnia and/or a prescription for a sedative hypnotic will increase significantly), the results were so inconsistent that I failed to disprove the null hypothesis.

### *Qualitative Findings*

#### *Physician interviews*

The 8 physicians in this sample seemed aware of the medicalization process and were able to discuss it using sociological terms such as “medicalize,” “disease mongering” and

“case-findingness.”<sup>32</sup> They were able to give examples of other medicalized disorders (e.g. toenail fungus), identify fueling factors (e.g. direct-to-consumer advertising [DTCA]) and describe parts of the medicalization process (e.g. expansion of diagnostic criteria). In addition, these physicians did not view or describe insomnia as an independent disease state. Instead, they characterized it as a symptom of another disorder (typically a mood disorder) or a normal, if unfortunate, part of the aging process, or a reaction to life’s stressors.

Perhaps because of this characterization, physicians preferred to treat sleeplessness with behavioral/lifestyles changes or “sleep hygiene” practices. Barring that, the doctors in this practice used Trazodone (preferred for its non-addictive nature) and benzodiazepines (particularly for people who had been using them for years); but the most requested and most prescribed drug was Ambien, or its generic, zolpidem. Every physician I interviewed expressed some degree of bias against these sleep medications, but most expressed a ‘soft’ bias – essentially the feeling that these drugs may not be ideal (typically embodied in concerns about dependence) but don’t seem to be generally harmful.

For physicians in this sample, compliance appeared to be motivated by a variety of factors, including: time constraints, consumerism among patients, a pre-existing prescription from another physician, and the hope of gaining patient compliance with other regimens. As evidenced by these interviews, physician compliance may go beyond accepting patient expertise and/or complying with a request for medication. These physicians must make complex decisions in short periods of time while hoping to emerge with the best possible decision for the patient’s health. Pre-existing prescription was possibly the strongest motivator for physician compliance. Even the two physicians who told me that they do not

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<sup>32</sup> These terms, though they have substantive overlap, do not have identical definitions. Ideally, ‘medicalization’ lacks judgmental connotations (see Williams et al. 2008). Nevertheless, they connote similar ideas and meanings.

prescribe sleep aids complied with requests for these drugs if the patient entered the interaction with a pre-existing prescription.

Physicians at the IMC reported that their patients entered the office visit with medical knowledge from non-medical sources ('rhetorical authority'). Sources included the Internet and social networks, but by far the most commonly mentioned was direct-to-consumer advertising (DTCA). One physician, citing Gladwell's The Tipping Point (2000), traced a conceptual path from DTCA to discussion among social networks to the social acceptability of sleep aids and patient request for a sleep aid.

As these physicians do not see drug representatives, I did not necessarily expect the topic to arise in our interviews; however, several in the sample expressed disdain for drug companies, drug representatives and their profit-making motives. An unexpected finding was the influence of insurance companies on the office visit. Some insurance companies have recently limited the amount of sleep aid pills prescribed in one month to 15. Physicians did not necessarily see this as a negative limitation, but were not happy about the extra paperwork required by patients who requested more than the 15 pill per month maximum.

#### *Patient interviews*

I had 27 interview participants; all were patients of the IMC physicians previously interviewed. Each patient had received a prescription for a sedative hypnotic within the six months prior to my IMC data query of June, 2008. A few patient interviews were conducted in person, but most took place over the phone. Unique to these interviews was the individual experience of, and perspective on, insomnia. I also focused on their interactions with

physicians, their attitudes toward prescription treatments and their sources of rhetorical authority.

Patient descriptions of insomnia included images of discomfort, unrest and anxiety. Like their physicians, patients did not seem to conceptualize insomnia as a disease state. When asked to speculate as to the cause of their sleeplessness, most said it was the product of stressful lives or anxious thoughts. Many of these patients discussed other health issues. Respondents disclosed, among other health conditions, heart disease, arthritis, fibromyalgia, depression and obsessive-compulsive disorder. Nevertheless, they most strongly associated stressful life issues with the onset or continued cause of their issues with sleep. These issues included demanding jobs, multiple care-giving roles and family deaths.

Despite their self-identified life or psychological struggles, all of the patients in this sample had sought a medical solution to their sleep problem in the form of a prescription drug. Most had tried other forms of self-treatment, including over the counter sedatives and melatonin, prior to seeking a prescription drug. Patients confirmed that their physicians discussed lifestyle and behavioral changes and/or the tenets of sleep hygiene prior to writing a prescription. Despite this information, some patients revealed that they routinely engaged in poor sleep hygiene practices (e.g. watching TV or playing on the computer late at night). Most rejected the “impractical” and “ineffective” behavioral solutions suggested by their physicians in favor of medication.

Patients noted several influential factors mediating their physician interaction. These often echoed physician-mentioned issues and included: time constraints, having a pre-existing prescription, consumerism and, to a lesser degree, the role of the insurance company. Patients who had special insight into physician time constraints tended to work in health care,

or have relatives in health care. Many of the patients in this sample entered the office visit with a pre-existing prescription from another physician. These participants were the least likely to recall details of their interaction with their IMC physician. Others did not have prior prescriptions, but had ‘sampled’ the prescription sleep aids of family or friends.

Paralleling physician statements were patient insights about rhetorical authority. Numerous sources of medical information were mentioned, including friends, family, print media and the Internet. However, DTCA was the most discussed form of rhetorical authority. Interestingly, patients in this sample were apt to say that, though aware of DTCA, it did not affect them. But when asked if they thought it influenced others, they invariably assumed that it did.

Unlike physicians, patients in this sample did not seem explicitly aware of the medicalization process. In fairness, I was not explicit about the medicalization-related portion of my research agenda and I did not use the term “medicalize” at any point in the patient interviews. However, patients were keenly aware of some fueling factors, particularly DTCA. Conversely, some patients exhibited attitudes that might be interpreted as ‘anti-medicalization.’

### **Macro indicators of the medicalization of sleeplessness**

In this section I highlight some of the macro indicators of the medicalization of insomnia as evidenced by NAMCS data. I use evidence from patient and physician interviews to speculate about some of the fueling factors behind these macro trends.

1. *There was a striking difference in the rates of insomnia complaint and diagnosis as compared to sleep aids prescribed.*

People have complained of insomnia for millennia (Sumners-Bremner 2008) and thus increased complaints of insomnia are not, in and of themselves, sufficient to argue the occurrence of medicalization. Increased diagnoses are more compelling indicators that medicalization is occurring (Conrad and Potter 2000). Most compelling, I argue, is the use of a medical treatment for a formerly ‘normal’ biological process or social issue. Thus, while only two of my initial hypotheses were fully supported by these analyses (H2 and H4), the significant, positive trends I found in both diagnosis and prescription treatment offer compelling evidence of the medicalization of sleeplessness at the national level.

However, while both outcomes were significant and positive, the two trends did not increase in tandem, nor did they exactly mirror the trend in insomnia complaint. To recap, between 1993 and 2006 insomnia complaints increased by about 30% (from 2.3 million to 4.7 million). Comparatively, diagnoses of insomnia increased about 6-fold (from 869,000 to 5.2 million) This increase was positive and significant over time on all statistical measures, as was the nearly 100% increase in Trazodone<sup>33</sup> prescriptions (2.8 million to 5.8 million).

Benzodiazepines also experienced increase a 40% increase in prescriptions over time (from 2.5 to 3.5 million), but statistical measures of change were not uniformly significant. Most striking was the positive and significant 23-fold increase in the number of office visits resulting in the prescription of a non-benzodiazepine sedative hypnotics [NBSH] (from 550,000 in 1994 to 12.8 million in 2006). The primary indication for NBSHs is the treatment

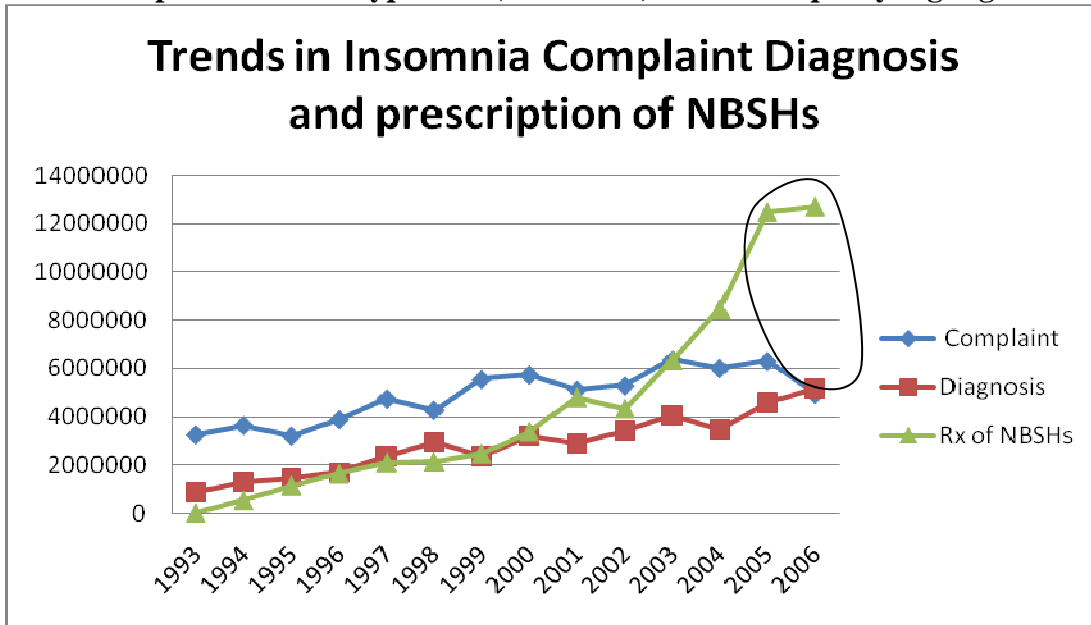
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<sup>33</sup> Although the primary indication for Trazodone is depression, it is not considered a very effective anti-depressant. The significant increase in its use is almost certainly indicative of its increased use as a sleep aid (personal communication, Head of UNC Psychiatry Department, 2008).

of short-term insomnia (Physician’s Desk Reference 2006: 2868), making the interpretation of these drug trends less ambiguous than for either Trazodone or the benzodiazepines.

While this 23-fold increase is striking, perhaps more interesting is the gap between insomnia complaints and diagnoses, compared to sleep aids prescribed. Please see the circled area in Figure 16 below for a visual representation of this gap.

**Figure 16. Trends over time in Insomnia Complaint, Diagnosis and prescription of Non-benzodiazepines sedative hypnotics (1993-2006) with discrepancy highlighted.**



In short, by 2006, there were 8.1 million more office visits resulting in a prescription for a NBSH than office visits with a complaint of insomnia. Similarly, there were 7.6 million more office visits resulting in a prescription for a NBSH than office visits resulting in a diagnosis of insomnia.

In an age of medical bureaucracy, the prescription of a medical treatment is not necessarily tied to a diagnosis (Thomas et al. 2006). In addition, the design of NAMCS may lend itself to producing a disparity between diagnoses and medications. For each office visit,



only 3 diagnoses, but between 5 and 8 medications may be listed.<sup>34</sup> If the participants in my sample are any indication, individuals who suffer from insomnia may have multiple, concurrent health issues. This listing bias could be one reason that complaint and diagnosis of insomnia lag well behind the prescription of sedative hypnotics.

Even with this limitation the large and growing disparity between diagnosis and prescription is still noteworthy and deserving of further exploration. I argue that this gap may be, in part, due to the increasing medicalization of sleeplessness. Motivated by DTCA and rhetorical authority, patients may be self-diagnosing at increasing rates and asking for specific sleep medications by name. Physicians in this sample indicated that this was fairly common in their patient population. Patients interviewed were not likely to admit to self-diagnosis, but some allowed that they had asked for a prescription by name (particularly if they came in with a pre-existing prescription or had tried someone else's.)

There may also be evidence that physicians are increasingly willing to treat patient's social problems with medical solutions. Physicians in this sample noted that insomnia in their patients only rarely had a biological origin. Nevertheless, they all prescribed sleep aids. As seen in patient and physician interviews, patient compliance is motivated by a number of factors. These potential fueling forces should be explored in greater detail.

## *2. The lines for complaint and diagnosis converge.*

Another outcome worth noting is the convergence of the trend lines for complaint and diagnosis of insomnia (see Figure 16 above). Regardless of the non-significant trend in complaint, diagnoses are increasing significantly over time, and thus the number of complaints and diagnoses appear to converge in 2006. Other research has indicated that past

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<sup>34</sup> Depending on the year in question.

complaints of sleeplessness were more likely to result in the diagnosis of a mental illness (Skaer et al. 1999). Trends in these data seem to indicate that a complaint of sleeplessness may be more likely to result in a diagnosis of insomnia. However, insights gleaned from patient and physician interviews lead me to suggest that a separate or complementary phenomenon might be occurring. Patients and/or physicians may be increasingly likely to bring up the topic of sleep in the context of an unrelated office visit.

According to my physician subjects, insomnia was almost never the primary reason for office visit, but patients were likely to raise the subject and/or ask for medication. This may be partially fueled by increased consumerism among patients. [See page 98 for example of physician quote]. Although physicians in this sample said it was more likely for the patient to bring up insomnia or request a sleep aid during the course of an office visit, a couple of patients felt that insomnia drugs were being pushed by physicians. [See page 148 for example of patient quote].

Whether by patient request or physician push, or both, the convergence in these trend lines indicates at least partial support for the medicalization hypothesis and in particular points to the possibility of increased consumerism among patients. While not likely in the physician population I interviewed, it is also possible that physicians are increasingly likely to “push” diagnoses or drugs.

It is worth noting that insomnia complaints appear to have decreased by 22% from 2005 to 2006. Only future releases of NAMCS data can help me determine if this dip is an anomaly or evidence of a trend. Regardless, the fact that diagnoses and drug prescriptions continue to increase in that same year may also be interpreted as further evidence of medicalization

3. *The process of medicalization does not seem to occur uniformly over time and is likely influenced by a variety of social forces and institutional factors.*

Breaking the 14-year time period into three distinct regimes offered insight into nuances of the data that would have been otherwise obscured. It would appear that, even of the statistically significant trends, the changes in my dependent variable outcomes did not happen uniformly over time. I will address statistically significant regime trends here (significant overall trends have been previously discussed).

For diagnosis of insomnia, only the first regime indicates significant, positive change. As I discuss later, it is possible that the introduction of the NBSH hypnotics is fueling the diagnosis of insomnia. A more significant increase occurred in the time period [1993-1997] when these drugs were introduced, compared to later regimes.

Prescription of NBSHs is the only dependent variable for which an increase in prescriptions in every regime was significant. However the steepest rate of increase appears to occur in Regime 3. This may be linked to increased DTCA spending between 2002 and 2006. (see Table 15 on page 183)

Prescriptions of benzodiazepines had positive, significant change in Regime 3 for both mean proportion differences and slope statistics. I speculate that perhaps there was an increase of benzodiazepine use in Regime 3 as a lingering after effect of September 11. More likely, the aging of the population may play a role as older age is significantly associated with the prescription of the less expensive benzodiazepines (Rasu et al. 2005).

Trazodone is interesting because there is a significant difference in the mean proportion differences only for Regime 3. The slope calculation for this regime was not significant because in 2006, Trazodone prescriptions decreased by about 23% from the

previous year, negating an otherwise positive and significant trend line. It is possible that, again 9/11 and/or the increase in DTCA spending and/or the aging of the population may be fueling this significant trend in Regime 3. One reason that the trend may have taken a downward turn in 2006 is because of the introduction of the newer NBSHs (Lunesta, Sonata, etc.) and the increased DTCA spending on the NBSHs in 2006.

In terms of independent variables, there were few consistent, noteworthy patterns in relation to dependent variables, but I will examine the significant trends more closely here.

In each regime, older persons are more likely than those under age 55 to receive a prescription for a benzodiazepine. This finding supports other research on sleep aids using NAMCS (see Rasu et al. 2005). Government insurance is also significantly associated with the prescription of a benzodiazepine in each regime (when compared to private or “other” insurance options). I hypothesize that this is likely due to the use of Medicare and Medicaid by older populations, confirming the findings of Rasu and colleagues (2005).

When considering Trazodone there are three significant trends. In terms of the likelihood of having an office visit result in a prescription of Trazodone: women are more likely than men, whites are more likely than minorities, and those with government insurance are more likely than those with private or other insurance. I believe these are related to the demographic trend of an aging population and the social fact that women exhibit more help-seeking behaviors than men in healthcare settings, are more likely to be depressed, and are more likely to use medication (Green and Pope 1999; Kaye, Crittendon and Charland 2008).<sup>35</sup>

Finally, older age and Caucasian race were significantly associated with an office visit resulting in the prescription of a NBSH. In two of the regimes, government insurance

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<sup>35</sup> Trazodone is commonly indicated for the treatment of insomnia with comorbid depression.

had a significant association to this outcome, compared to private or other insurance. Once more, I think that age and insurance are likely collinear.

I can only speculate as to the causes of significant versus non-significant change across regime, and it is beyond the scope of this work to determine all possible causes. However, it is possible that social, institutional or demographic forces such as the introduction of the NBSHs to the market, the passage of the FDA Modernization Act in 1997, its full implementation in 1999, the tragedy of 9/11, and the aging of the US population may all have played roles in speeding or slowing the medicalization process. These data suggest that the medicalization process has a variety of fueling factors that may evolve over time.

In sum, these quantitative data offer a picture of trends occurring between 1993 and 2006. These trends did not occur uniformly over time. This leads me to conclude that developing a measure for the medicalization of sleeplessness, and other medicalized disorders, may be quite useful in pinpointing these fueling factors. I will further discuss this concept later in the chapter.

Dividing the 14 year time period into 3 distinct regimes may have aided in the identification of potential fueling factors, and identification of changing rates of the medicalization process over time. Although I speculate about the factors that fuel these trends, these macro outcomes are the sum product of a multitude of individual office visits over time. In order to gain further insight into what occurs in these individual interactions, I have incorporated findings from the qualitative interviews to fill some of the interpretive gaps. I now focus on these qualitative data and some of the micro indicators of the medicalization of sleeplessness.

## **Micro indicators of the medicalization of sleeplessness**

### *Qualitative data from interviews*

Patient and physician perspectives added interpretive depth to the national level trend statistics presented in Chapter 3 and revisited in this chapter. In addition, conducting these separate patient and physician interviews allowed me to see points of agreement or dissent in accounts of the office visit. Overall, patient interviews confirmed physician accounts of the interaction and added additional insight into some of the forces that may be influencing office visit outcomes.

#### *1. Life problems are being treated with medical solutions.*

Physicians in this sample told me that they did not view insomnia as a primarily medical issue. Instead of categorizing insomnia as a disease process, these physicians typically described it as a) a normative process, particularly when viewed in the context of aging or b) a symptom of another disease or disorder, typically a mood disorder.

Similarly, patients ‘normalized’ their sleeplessness by relating to personality (“I’m a worrier”), aging (“It could be related to getting older.”), age-related hormonal changes (menopause or enlarged prostate), and stressful lives. None of these patients seemed to view their sleeplessness as a discreet disease state. In fact, when asked directly to assess the cause(s) of their insomnia, patient responses typically centered on accounts of stress or symptoms of anxiety. In fact, this sample had many reasons to be over-burdened. Patients disclosed past trauma, multiple care-giving roles, sick relatives, deaths in the family, demanding jobs and a myriad of physical and mental health issues. In sum, there was no

shortage of reasons that these people lay awake at night, or were awoken repeatedly by nothing more than their restless minds.

This begs the question, if both the patients and physicians in this sample independently demonstrated awareness that insomnia was most often caused by life issues, why then are physicians prescribing these drugs and why are patients requesting and consuming them? I argue that the findings of this study are indicative of social and cultural trends that have been explored in depth by other scholars (see Elliot 2003; Conrad 2007; Rosenfeld and Faircloth 2006; Groopman 2002; Rothman and Rothman 2003; Horwitz and Wakefield 2007; Lane 2007; Herzberg 2009). Life and life processes are increasingly thrust into the province of medical authority and treated with medical solutions (Conrad 2007). Sleeplessness may be just the latest in a long line of formerly ‘normal’ life experiences, that can now be ‘fixed’ with a pill.

*2. Consumerism, a fueling factor of the medicalization process, was abundantly present in this sample.*

Increasingly, patients challenge medical authority by seeking medical knowledge from non-medical sources (rhetorical authority) and view the physician’s office as one more venue for the buying and selling of goods (Kroll-Smith 2003; Conrad 2007). The trend of consumerism in medicine was well-documented in the 1983 book by Haug and Lavin, and appears to have only strengthened with time.

Physicians described a variety of consumerist behaviors exhibited by their patients. Asking for specific name brand sleep aids was fairly common. The use of coupons was less common but was mentioned by a few physicians. One physician referred to the healthcare

system as a “marketplace” and doctors in this sample seemed well aware that some patients, if not prescribed the drug of their choice would “find a doctor who will give it to them. And that’s not too hard” (Doc 1). Physicians didn’t seem too bothered by these attitudes and practices, but I was struck by the fact that this was an incredibly caring and conscientious group of physicians. I wondered if targeted probing would have revealed more candid responses.

Patients were less forthcoming about doctor shopping, although a couple of them made it clear that they were willing to switch physicians in order to get their preferred drugs. None of them mentioned coupons, but several did discuss trying the prescription sleep aid of a family member or friend before seeking a prescription from an MD. In exercising this ‘hyper-consumerist’ behavior of seeking sleep drugs from friends or family members, these individuals were able to bypass potential rejection and sample a drug before committing to its purchase. Again, I wonder if their conscious or unconscious desire to be seen as ‘good’ patients restricted them from expressing more consumerist attitudes and behaviors.

Despite my sense that further probing would have revealed even more consumerism in these office interactions, I found the concept to be alive and well in this sample. While shifts in the patient-physician relationship have eroded physician power, and rhetorical authority ensures that they are no longer the sole holders of an esoteric body of knowledge, physicians are still seen as the gatekeepers to prescription medications (Kroll-Smith 2003; Conrad 2007; Charles et al. 1999) except when patients can easily ‘sample’ pills of friends or family members. I suggest that the lack of stigma attached to the use of prescription sleep aids, as noted in both patient and physician interviews, makes consumerist attitudes and behaviors more socially acceptable. Drug companies are likely aware of this perception, and



as I discuss in a subsequent section, sleep drugs are some of the most heavily marketed drugs on the market.

3. *Sleeplessness appears to be only partially medicalized.*

As I described in Chapter 4 and reviewed in this chapter, physicians in this sample seemed intensely aware of medicalization and demonstrated this awareness through their use of sociological language (“medicalize,” “disease mongering,” etc.); ability to relate sleeplessness to other medicalized conditions (e.g. toenail fungus); knowledge of fueling factors (e.g. DTCA); and ability to identify key parts of the process (e.g. expansion of diagnoses).

In this instance, patient interviews were quite distinct from physicians’ interviews. Patients were initially unaware that I was interested in exploring medicalization and, not surprisingly, lacked the meta-awareness about the process that was so striking in the physician interviews. Some patients demonstrated knowledge of fueling factors, particularly DTCA, and a couple made connections to drug commercials for other medicalized disorders (e.g. erectile dysfunction, fibromyalgia) (see Rosenfeld and Faircloth 2006; Barker 2008). Similar to a physician in the sample, one patient was able to trace a conceptual path from DTCA to conversations among social networks to, ultimately, a request for a prescription. Other patients suggested that DTCA might make people believe they are sick or at least in need of a certain medication. One patient told me “I’m like, gosh, everywhere I go I see sleep commercials in newspaper and in print and media. It’s like this whole country is sleepless!” (PT 14).

However, some of the patient observations were more indicative of an anti-medicalization attitude toward sleeplessness. One woman proclaimed, when referring to all her friends who had sleep issues “We can’t all be sick!” Although she said this with a laugh, some would argue that it belies the messages that direct-to-consumer advertising promotes – that we are, in fact, all sick enough to need medication (Conrad 2007; Elliot 2003; Moynihan, Heath and Henry 2002). Another patient told me “I didn’t really think of [sleep] in terms of a problem that a doctor might help me with” (PT 46). In addition, these patients did not express unambiguously positive attitudes toward sleep aids or the taking of medication in general. Some opined that taking pills wasn’t “natural”; more commonly patients expressed fears or concerns about the potentially addictive nature of sleep drugs.

These findings suggest that the medicalization of sleeplessness is only partial. In order for it to be more advanced, I argue that perception of sleeplessness needs to be shifted away from a symptom, a reaction to stress, or a part of the natural aging process to one of a disease state. The notion that insomnia is a symptom rather than a disease, and that this conceptualization is actually constructed and reinforced by the British media was recently written about by Williams and colleagues (2008). However, it would not surprise me to see this conceptual shift occur over time, and particularly in the US where the drug companies hold tremendous authority over the promotion and pricing of sleep drugs.

Despite the lack of evidence in my small qualitative sample, conceptual change may already be occurring on other levels. An article entitled “Insomnia: Symptom or Diagnosis?” explicitly addresses the symptom versus diagnosis distinction and concludes that “viewing insomnia as a symptom or epiphenomenon of other disorders can be unfounded. This view may deprive patients of treatment, which might not only cure their insomnia, but may also

reduce symptoms associated with the assumed ‘primary’ disorder” (Harvey 2001: 1037).

Interestingly, this viewpoint is shared by many in the pharmaceutical industry (Nelson 2007; Koroneos 2007).

Finally, even if the conceptualization of and explanations for insomnia are not currently presented in a strictly medical context, what these data draw pointed attention to is the fact that –with or without a formal diagnosis - the availability of a ‘safe’ and convenient medical treatment and the insurance companies’ willingness to pay for this treatment (within their proscribed limits) provides alleviation from – and thus medicalizes - these life problems.

### **Forces that may be fueling the medicalization of sleeplessness**

For years the (pharmaceutically funded) National Sleep Foundation (NSF) has been sounding a warning that we are in the throes of an insomnia epidemic (Weiss 2008).

Recently, however, a University of Maryland study (2008) indicated that Americans may be getting enough sleep, after all. Although the National Sleep Foundation claims the average US adult sleeps only 7 hours or less, nightly, the University of Maryland study shows an increase in time slept, from about 8 hours a night a decade ago to 8.4 hours a night in 2005 (University of Maryland 2008; Lloyd 2008).

So what to believe? Unfortunately, these data cannot answer the question of whether the sleeplessness epidemic is real. But, the data reported in this dissertation do indicate significant shifts in the increased diagnosis and treatment of insomnia. The US may not have an epidemic of insomnia. But, to borrow a phrase, we may have an “epidemic of diagnoses” (Welch, Schwartz and Woloshin 2007) and, I would add, an epidemic of treatments.

In the previous pages I suggested macro and micro indicators from my analyses that support the medicalization hypotheses. In the following section I highlight some potential fueling forces of this process. I will now touch briefly on the changing patient-physician relationship and the possibility that the introduction of a newer, ‘safer’ treatment (NBSHs) has fueled increased awareness and treatment of insomnia. I then focus on the growth and influence of direct to consumer advertising (DTCA) and its relationship to the medicalization of insomnia.

*1. Changes in the patient physician relationship.*

In the ‘golden age of doctoring’ commonly thought of as the time period from about 1950 until the 80’s, physicians assumed the dominant role in the patient-physician dyad. ‘Paternalism’ was the prevalent approach to medical care and patients assumed deference to the specialized body of knowledge held by physicians (Freidson 1988; Charles, Gafni and Whelan 1999).

Since the introduction of managed care, the patient-physician interaction has been increasingly influenced by outside factors including time constraints, fragmentation of care and the authority of insurance companies. Two of these influences may be speeding the medicalization of sleeplessness, while the third, may actually be constraining it.

Both patients and physicians in this study noted multiple factors that influenced or constrained the office-visit interaction. These limitations – consumerism, desire for patient compliance, rhetorical authority, ‘soft’ bias, etc. - may be in fact fueling the medicalization process as they make it easier for a physician to write a prescription than refuse a patient’s request for a medication. A countervailing factor may be the power of the insurance company

to limit the number of sleep aids that may be prescribed in a month. However, physicians did not seem to mind the possibly ‘helpful’ limitations put in place by the insurance companies; although they did find the additional paperwork necessary to bypass these limitations an extra hassle that they tried to avoid.

## *2. Invention of a cure pushed the disease*

The medicalization of some disorders appears to be linked to the development and promotion of related medical or pharmaceutical treatments (e.g. gastric bypass and obesity, hormone replacement therapy and menopause) (Conrad 2007; Rothman and Rothman 2003). These data suggest that the development and promotion of non-benzodiazepine hypnotics, introduced to the US market in 1993, has been concomitant with increased diagnosis and treatment of insomnia. I assert that the introduction of the NBSHs in 1993 are paramount to the increases in people being diagnosed and/or treated for a sleep disorder.

Most physicians in this sample admitted to having only a ‘soft’ bias against the NBSHs, despite recent increased warnings about strange side effects (Saul 2007), evidence that they are only marginally effective in providing more sleep time and that they may be better amnesiacs than sleep aids (Saul 2007B)

The role of a new drug in creating or expanding a medicalized disorder is not new (Tone 2009; Herzberg 2009), so what makes Ambien so different from Milltown? The answer to this question may be the advent of legal, widespread, multi-media, multi-million dollar campaigns featuring creative and catchy ‘hooks.’ In short, the invention of the treatment may only take a disorder so far, it is up to the advertising executives to ensure the branding and success of the drug.

### 3. *The influence of DTCA*

While I posit that the pharmaceutical industry is a key fueling force of the medicalization of sleeplessness, I am unable to measure the impact directly using these data. Data on direct to consumer advertising spending are available, but as this was not the key focus of my dissertation and I lacked the funds to purchase independently collected data, I present here facts and figures that were published elsewhere. For an overview of prescription drug promotional spending, please see Table 15.

**Table 15: Prescription Drug Promotion and Research and Development, 1997-2005.**

<b>Year</b>	<b>Spending on DTC advertising</b>	<b>Spending on promotion to physicians</b>	<b>Retail value of samples</b>	<b>Research &amp; Development</b>
1997	\$1.1	\$3.9	\$6.0	\$15.5
1998	\$1.3	\$4.6	\$6.6	\$17.1
1999	\$1.8	\$4.8	\$7.2	\$18.5
2000	\$2.5	\$5.6	\$8.5	\$21.4
2001	\$2.7	\$5.9	\$10.5	\$23.5
2002	\$2.6	\$6.6	\$11.9	\$25.7
2003	\$3.3	\$7.4	\$13.5	\$27.1
2004	\$4.0	\$7.8	\$15.9	\$29.8
2005	\$4.2	\$7.2	not available	\$31.4
Average annual % increase	19.6	9.0	14.9	9.3
Total %increase, 1997-2005	296.4	86.0	162.4	103.3

**(Source: U.S. Government Accountability Office, [Prescription Drugs: Improvements Needed in FDA's Oversight of Direct-to-Consumer Advertising](#), GAO report Number GAO-07-54, December 14, 2006. (All figures in Billions) Reprinted from: [http://www.sourcewatch.org/index.php?title=Direct-to-consumer\\_advertising\\_in\\_the\\_United\\_States](http://www.sourcewatch.org/index.php?title=Direct-to-consumer_advertising_in_the_United_States)**

As seen in Table 15, the average annual percentage increase in DTC spending is about 20% from 1997 to 2005. This trend increased in 2006, and some estimates indicate that from 1997 to 2006, direct-to-consumer spending increased by 320%, from just over \$1 billion to \$4.5 billion (Kelly 2007). From 2000 to 2006, DTC growth increased more sharply, as drug companies shifted their dollars away from physician detailing in order to increase advertising dollars on TV and magazine campaigns (Kelly 2007). In the same six year period, the use of prescription sleep aids increased by more than 60%.

In 2006, makers of all sleeping pills combined spent more than \$600 million on advertising (Saul 2007). Of the top ten most advertised brands, Lunesta had the highest budget of any brand (\$300 million) (Kelly 2007). By comparison, about \$200 million was spent on the Ambien brand (West 2007). Trying to grab a share of the market, newcomer Rozerem spent about \$100 million in advertising (West 2007). Despite Lunesta's impressive advertising budget, Ambien and Ambien CR held onto the lion's share of the sleep aid market – accounting for 27.6 million out of 44 million sleep drug prescriptions written in the US. Restoril (temazepam) came in second place with 7.3 million prescriptions, and was followed by Lunesta at 5.8 million prescriptions (Saul 2007).

By comparison, in 2005, the makers of Lunesta spent about \$215 million, while Sanofi-Aventis, the makers of Ambien, spent approximately \$90 million in an effort to compete – nearly double what they spent in 2004 (Saul 2006; West 2007). In the past few years, several

of the NBSHs (notably Ambien and Lunesta) have appeared on Top 20 and Top 10 lists for highest DTCA budgets.

These large advertising budgets seem to have paid off. In 2006, sales for Lunesta and Ambien alone totaled more than \$3 billion (Saul 2007). In just the first quarter of 2007, the best selling NBSHs have earned the following: Ambien - \$653 million; Lunesta \$181 million; Rozerem \$28.1 million (Koroneos 2007). Moreover, figures from IMS Health statistics indicate that comparing 2001 to 2005, insomnia sales increased by over \$1.5 billion. Please see Table 16 below.

**Table 16. Insomnia Medications – Total U.S. Sales \$ in Thousands (000)**

Rank	Drug	2001	2002	2003	2004	2005
Class total		\$1,143,346	\$1,443,885	\$1,761,430	\$2,113,025	\$2,757,063
1	Ambien	\$986,000	\$1,273,624	\$1,574,643	\$1,899,648	\$2,139,192
2	Lunesta	***	***	***	***	\$321,794
3	Sonata	\$93,407	\$105,798	\$112,906	\$121,728	\$117,282
4	Ambien CR	***	***	***	***	\$72,951
5	Restoril	\$12,835	\$19,865	\$33,788	\$39,614	\$42,875

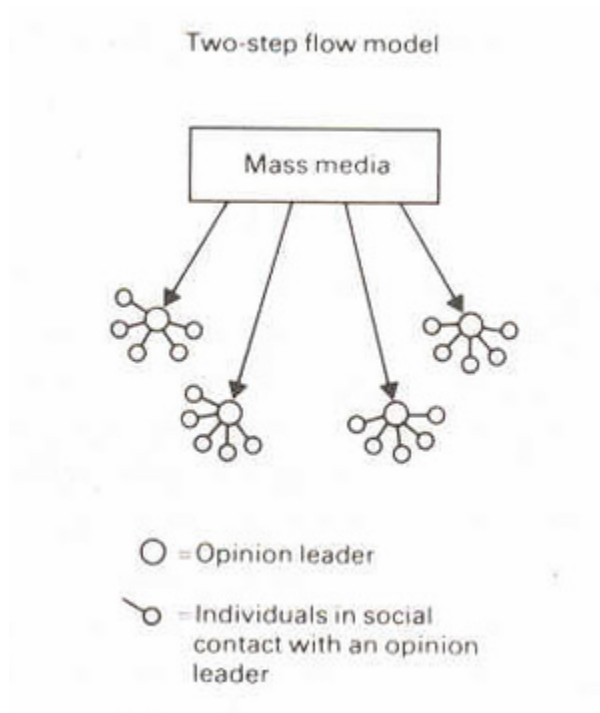
(Table reproduced from IMS Health, IMS National Sales Perspective, 2/2006)

It would be naïve to propose that DTCA is solely responsible for changes in consumer behavior. More likely, to be influential is the domino effect that DTCA may engender. As noted in patient and physician interviews, DTCA enables topics like sleeping pills to become part of the conversation at a cocktail party or by the water cooler, where it is then filters into common social exchange and is normalized among social groups. According to Katz and Lazarsfeld (1955), knowledge from DTCA is dispersed into the public and then when an “opinion leader” mentions the ad or the drug at a social gathering or at work, the



message flows to a broader, more receptive audience (Katz and Lazarsfeld 1955).<sup>36</sup> One or more of the audience members may seek a prescription of the drug from their physician and not realize that they have been influenced by DTCA. This may, in part, explain the responses of most of my patient sample who claim to not be influenced at all by DTCA. (A reproduction of the two-step flow model is available below in Figure 17.

**Figure 17. Katz and Lazarfeld Two-step flow model of communication.**



**Source: Katz and Lazarsfeld (1955)**

To clarify, it is not merely the availability of a drug treatment that has been critical to the medicalization of sleeplessness, but the influence and success of their marketing campaigns in spreading the three-fold message: a) you may have an undiagnosed issue with sleep b) there is a safe and effective treatment for your issue c) all you need do is talk to your doctor about getting Drug X.

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<sup>36</sup> Interestingly, the original study on 'opinion leaders' was carried out in a physician population.

## Conclusions

The findings of these analyses allow me to draw several inferences:

1) The medicalization of sleeplessness is being propelled by both the introduction *and* the marketing of a new medical treatment (the non-benzodiazepine sedative hypnotics).

Marketing campaigns encourage patients to ask their doctor if the advertised drug is “right” for them, creating a “medicalization-amplifying feedback loop” (Conrad 2007).

2) Although physicians still act as ‘gatekeepers’, patients wield increasing power in the patient-physician dynamic and physician compliance is influenced by a multitude of mitigating factors, including: time constraints, consumerist attitudes, increased fragmentation of care and the influence of rhetorical authority.

3) Measuring the rapid uptake of NBSHs provides one measure of the medicalization of sleeplessness – confirming the work of other social scientists and medical doctors who assert that life problems are increasingly likely to be treated with medical solutions.

### *Contributions to the literature*

This research offers contributions to multiple disciplines and interest areas: the sociology of sleep, medicalization theory, and health research.

### *Sociology of sleep*

The study of sleep and sleep disorders are relatively recent topics of interest. Sleep is also an increasingly vibrant area of sociological study (see Williams et al. 2008; Wolf-Meyer 2008; Williams 2005; Seale et al. 2007; Hislop and Arbor 2003; Kroll-Smith 2003 Meadows

2005). However, to the best of my knowledge, only Hislop and Arbor (2003) have researched the medicalization of sleeplessness at the individual level; their work, and their collaboration with Meadows, looked at the sleep practices of couples. No research that I'm aware of has investigated the medicalization of sleeplessness at the level of patient-physician interaction; nor has other sociological work measured sleep-related trends across time using a representative data set of physician office visits.

### *Medicalization theory*

A great deal of excellent work has been carried out in the area of medicalization theory (please see Chapter 2 for a detailed description of medicalization theory and its contributors). However, much of the research on medicalization has been historical, qualitative and descriptive in nature. In addition, prior medicalization research has focused on the ways in which illness is conceived, described and legitimized by pinpointing the social construction at the conceptual and institutional levels (Conrad and Schneider 1992; Conrad 2007). Notable exceptions, and good examples of the exploration of medicalization at the interactional level include work by Barker (2008), Kroll-Smith and Floyd (1997), and Hislop and Arbor (2003). However, in general, the interactional level of medicalization has largely been understudied and few have tried to pinpoint possible measures of medicalization.

This work also emphasizes the outcomes of the patient-physician interaction. While the factors and forces that lead an individual or group of individuals to enter the physician's office are important, I argue that if diagnoses are not being made and/or prescriptions are not being written then how can we conclusively assert that the process of medicalization is occurring? Some might point to the example of the newly recognized genetic disorders that

have been conceptualized and are recognized at an institutional level, but do not yet have medical treatments. Although a salient point, I would argue that researchers and pharmaceutical companies are racing to find medical treatments for these disorders and that they will not be fully medicalized until such treatments have been discovered and made available to the public.

In addition, I suggest that mixed-methods studies of medicalization are under-utilized. Had I pursued a strictly quantitative dissertation, I would have likely argued that the medicalization of sleeplessness is further along. However, insights gained from the physician and patient interviews allowed me to better understand the nuances of this phenomenon and determine that the medicalization of sleeplessness is still underway.

The work of Conrad is important and a foundation to this, and any good piece of medicalization research. However, I would challenge Conrad and Potter's (2000) assertion that the conceptual level is "key" to the medicalization process. I assert that if (or when) shifts in perception from symptom to diagnosis, or life problem to disease state occur, the most compelling evidence of increased medicalization will not be found in Diagnostic and Statistical Manuals, or even in broader definitions of insomnia in the International Classifications of Disease, but in the context and outcomes of the physician office visit. More specifically, it appears that the invention, introduction and uptake of a medical treatment provides a short-cut to the medicalization process.

The relationship between medical classification and medical treatment must also be further scrutinized. In the case of sleeplessness, despite patient and physician acknowledgment that insomnia is not necessarily a disease, but a symptom (this viewpoint also appears to be prominently portrayed in the UK media, see Williams et al. 2008), it is

possible that physicians are ‘diluting’ the power of certain medical diagnoses by using them as a) shorthand for unpleasant symptoms that are related to life circumstance and/or b) a necessary box to check in order to fulfill the requirements of an insurance form. If this is the case, then the use of a medical treatment might be a more ‘robust’ indicator that an issue has been ‘made medical.’

Further, the *sequencing* of the medicalization process could be a fruitful area of academic interest. While this particular example of a medicalized disorder seems to imply a pattern of Treatment – Diagnosis – Conceptualization, this does not seem to be the case for other disorders (e.g. genetic disorders). It might be interesting to discern if certain sequences lead to more rapid medicalization than others. In order to assess rate of medicalization, however, we will need to construct a testable scale (or other instrument) than can offer a reliable measurement of medicalization.

### *Measurement of Medicalization*

Few have attempted to measure medicalization, or even to define what that process might look like. In his 2007 Book, “The Medicalization of Society” Conrad takes this issue on directly. Interestingly, the examples he uses of the measurement of medicalization are centered on treatments (Hormone replacement therapy (HRT) for menopause, breast implants for small breasts, increasing prescriptions of psychotropic medications for adolescents with Attention Deficit Hyperactivity Disorder). Moreover, as he documents the rise and fall of HRT for menopause and breast implants, he concludes that despite their rise and fall “the medicalization itself – the defining of the problem in medical terms – did not change. What changed was the implementation of medicalized interventions” (2007: 126). However,

sleeplessness may better be viewed as a problem which is more defined by the medical intervention, than by being conceptualized as a medical problem. Evidence for this view is provided by the inconsistency in insomnia definitions.

One way I have tried to measure the medicalization of sleeplessness is by tracking trends over time in a nationally representative data set of physician office visits. While I do not assume this to be the only, or even the ideal measure, charting trends in insomnia-related outcomes at a national level does offer some insight into the growth of medicalization of sleeplessness over time. This type of measurement also allows me to infer factors that might have been more critical to the medicalization process – in this case the introduction and promotion of the newer, non-benzodiazepine sedative hypnotics [NBSHs].

### *Health Research*

Many of the findings of this research re-affirm or closely approximate those from other studies using the NAMCS dataset to look at insomnia-related outcomes (Namen et al. 2002; Skaer et al. 1999; Rasu et al. 2005; Balkrishnan et al. 2005 ). However, to the best of my knowledge, no other study in the health (or sociological) literature has looked at a time period of this length (14 years) or this particular time period (1993-2006); nor have they subdivided the time period into analytic regimes based on possible social and institutional ‘fault lines.’ My research contributes not only a longer span of time in which to analyze trends, but adds a sociological dimension. In addition, I emphasize the differences in the proportions of my dependent variable, rather than raw or weighted totals; thus taking into account certain established social trends (e.g., women are more likely to utilize health services and use prescription drugs).

## **Limitations and Future Research**

The limitations of these data are myriad and are detailed on pages 43, 83, and 123 of this manuscript; thus, I will not reproduce them here. However, I will re-address some of the major concerns and introduce some new insights on one limitation in particular (the setting of the Internal Medicine Clinic).

### *Quantitative*

NAMCS was neither intended nor designed to capture or measure the medicalization process. Although I feel it is the best currently available data set with which to do these analyses, the NAMCS data are limited in several respects. NAMCS captures only specific subsets of office-based physician visits. NAMCS does not capture the type of physicians or patients (based in an academic center) who participated in the qualitative portion of this research.

NAMCS data include only patients who have both the motivation and means to make it to a physician's office. This selection effect may under-represent lower-income groups who mainly use emergency services as their primary means of accessing health services. In addition, the patient is not the unit of analysis; the unit of analysis is the office visit. Thus, results are suggestive of, but not equivalent to, patient outcomes.

The increasing number of drugs that physicians are allowed to list over time potentially complicates interpretation of my findings (going from 5 to 8 over the 14 year period). This potential for "listing bias" is a serious, potential confounder to my findings. However, as descriptive statistics on pages 72-73 indicate, the mean number of reported

drugs increased by only 1 drug on average over a 14 year period of time, even though the allowable drug listings went up by 3. I argue that, while the increase in allowable categories may have had some impact on the significant increase in sedative hypnotics over this time period, it cannot fully explain the increase and does not negate or substantially diminish my findings, particularly the 23-fold increase in prescription of NBSHs over time.

Finally, due to the cross-sectional nature of the NAMCS data it is impossible for me to tell if the increase in uptake of sleep medications is via new patients or returning patients. It is possible, though not probable, that these data are capturing not only non-unique patients across years, but also within a year. This is, however, unlikely given that the data collection periods for physician offices are one week in duration, and thus less likely to capture repeat visitors. And while I do not think this potential issue negates the robust finding of the 23-fold increase in NBSHs, it might be more problematic for the less dramatic increases in benzodiazepines, or perhaps even Trazodone.

In order to address some of these concerns and further my research agenda, I intend to work with future releases of NAMCS data and propose the following analyses:

- a) generating proportion comparisons over time and slope trends for the dependent variables in office visits for those 65+ and those under 65. (In order to assess the usefulness of these different age distinctions compared to the 55+ and under 55 age categories originally used).
- b) a multivariate analysis that takes into account whether or not the regime interacts with the different demographics and whether demographic categories are interacting with one another (for instance race and insurance status, gender and age).
- c) uploading and analyzing the NAMCS 2007 data as soon as they are available.



### *Qualitative*

A previously noted limitation, the setting of the Internal Medicine Clinic (IMC), may in fact be considered a strength of my research design.<sup>37</sup> Although I had originally conceptualized multiple pathways through which the pharmaceutical companies are able to influence the patient-physician interaction, by choosing the setting of a university-affiliated Internal Medicine Clinic where physicians are not allowed to see drug company representatives, I have perhaps created a sort of ‘natural experiment.’ That is, if only one pathway is available for the drugs companies (DTCA as opposed to DTCA and physician detailing) I am in a sense controlling for the influence of physician detailing and providing a stronger analysis of consumerism. My findings suggest that one pathway alone may be more than adequate to influence the patient-physician interaction. It may also have heightened the awareness of the physicians in this sample to the power of DTCA.

This does, however, highlight another limitation. Although the physicians in this sample seem critical of, if not occasionally hostile to, the influence of ‘Big Pharma,’ they still prescribe these popular and heavily advertised sleep aids. It is possible that by invoking other constraints – time, pre-existing prescription, patient compliance, etc. – they are presenting themselves in a more favorable light.

Conversely, the vast majority of patients in this sample claimed to view DTCA in a negative light and discern its profit-making motives (although, apparently, the rest of us are not so insightful). Some patients seemed to go out of their way to assure me that they didn’t want to, and had no intention of, taking these drugs every night or becoming “hooked” on them. But again, the obvious irony is that every single one of these patients had a prescription

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<sup>37</sup> I would like to acknowledge Bob Konrad for his ability to see the potential strengths of this limitation.

for a sleep aid – the majority for the most popular and heavily advertised<sup>38</sup> sleep aid in the world – Ambien

I would argue that patients, and physicians, were not generally or consciously presenting their actions in a deceptive way; but I must acknowledge the possibility that they were unconsciously presenting themselves in the most positive light and that that is a limitation of this work.

### *Future Research*

A critical limitation of this work is the lack of a comparison group for my patients with insomnia. By design, all patient participants used, at least occasionally, a prescription sleep medication. While effective as a recruitment strategy, this exclusion negates the participation or input of patients who have effectively treated their insomnia with the following methods: cognitive behavioral therapy [CBT], sleep hygiene, or any number of complementary or alternative treatments. It also excludes patients who suffer from sleeplessness, but have been refused a prescription for a sleep medication. Future research should actively attempt to recruit individuals who did not meet the inclusion criteria of this study; their input could be invaluable in further exploring the medicalization of sleeplessness. In addition, the small sample size of this study makes it impossible to generalize these findings to larger or more diverse populations. A follow-up study with a larger and more varied sample would provide additional insights and enhance generalizability of findings.

As previously noted, the physicians in this sample were cognizant and critical of the medicalization process. This is likely due to the academic culture in which they practice.

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<sup>38</sup> Although in recent years Lunesta has spent more advertising dollars (Kelly 2007) the Ambien brand is still the most advertised, over time.

Replication of this research in other practice settings – e.g. community clinics or private practice where physicians interact with drug representatives – would, I predict, be far less likely to find physicians who share the attitudes and insights of my sample. Meso-level factors such as clinic culture and setting, presence of peer-influence, relationship with drug representatives, use of drug samples and time spent with patient are worthy of deeper consideration in future work.

Though this study was limited in its exploration of the physician-patient interaction surrounding sleeplessness, future research could focus on other means of capturing and analyzing this interaction. Direct observation of the patient and physician interaction would be ideal. Alternately, the use of videotaped patient complaint (using real or representative patients) or standardized case-study narratives could be used to elicit physician response.

This study has underscored the importance of examining the interactional level of medicalization. In addition, I suggest that the use of a mixed methodology aids not only in the identification of both macro and micro indicators of medicalization, but sheds light on the way in which these factors and forces interact and influence one another. Future work – whether exploring the medicalization of sleeplessness or some other medicalized issue - should consider the patient-physician interaction a rich source of data about the process of medicalization, the factors that influence it and the outcomes it produces.

My research also raises questions about the sequencing and measurement of medicalization. I propose the following research questions be explored: Does sequence of medicalization process differ by disorder? Is it related to rate of medicalization? How can medicalization be effectively and reliably measured?

Finally, I would suggest that the medicalization of insomnia is a topic of interest engaging to scholars in disciplines outside of sociology. Dialogue and collaboration with researchers in the fields of public health, medicine, anthropology, psychology, health services and economics (to name a few), could be enormously fruitful in providing insights into causes of sleeplessness, the medicalization process and the patient-physician interaction.

### **Implications for Public Health**

Despite multiple limitations, this research has important implications for public health. Physicians in this sample did not view insomnia as an epidemic or a public health problem. Most classified it as either a normative process or an uncomfortable part of the aging process. One physician went into some detail as to why he did not view insomnia as a public health issue [see quote on page 90].

While physicians did discuss the potential side effects and potential for addiction with the sleep drugs, they did not address the potential public health impacts of the medicalization of insomnia. As noted in the introductory chapters of this research, the FDA raised concerns about the safety and efficacy of the non-benzodiazepine hypnotics just a few years after they were introduced to the market (Wagner et al. 1998) and mandated additional warnings for the makers of Lunesta, Ambien and 11 other sleep medications in 2007.

Although only a small number of my non-representative sample reported odd side effects from taking Ambien, hosts of other patients across the country have reported bizarre behaviors including sleep-driving, sleep-eating, sleep-walking and making purchase while “asleep” (Saul 2007). Increasingly, Ambien is found in the bloodstream of impaired motorists (Barclay 2006).

Another risk, discussed in both my physician sample and in the literature (see Siversten et al. 2006) is the use of sedative hypnotics among older adults. This group is at greater risk from unnecessary falls, if they are in a sedated state. Given the demonstrated efficacy of cognitive behavioral therapy (CBT) in this population, falling injuries related to sleep drug sedation may be largely avoidable (Siversten et al. 2006).

Treating sleeplessness with sedative hypnotics may be unnecessarily costly to both our health care system and our public health. Other, non-drug based treatments have proven equally or more effective. A review of 48 clinical trials found that 70 to 80 percent of patients benefit from behavioral therapies for at least 6 months after completion of treatment (Morin 2005). Behavioral therapies are cost-effective and have no known side effects. The practice of sleep hygiene offers guidelines on health practices (diet, exercise, substance use) and environmental factors (light, temperature, noise control) and can benefit anyone who lives in a setting shaped by artificial light and 24-hour access to communications technology (IOM 2006).

Despite the fact that behavioral therapies and sleep hygiene practices have demonstrated efficacy, prescription sleep aids are still the treatment of choice for the vast majority of physicians who see patients with insomnia (Rybarczyk et al. 2005). Clinicians are not necessarily unwilling to utilize non-prescription treatments for sleeplessness, but most lack awareness of their efficacy and training in their implementation (IOM 2006). Patients, in turn, lack awareness of many of the health implications associated with sleeplessness and their “education” in sleep aids is more likely to come from a television advertisement starring a glowing moth than from a medical professional or trained educator.

Recently, the Institute of Medicine reviewed public education efforts made by the National Center on Sleep Disorders Research, Centers for Disease Control and Prevention and private foundations, and found the current investment in education and awareness campaigns to be “limited” (IOM 2006: 175). Preventive techniques such as reduction of occupational stress, job-sharing, flexible hours and the implementation of sleep hygiene into school curricula could all be important in reducing the public health burden of sleeplessness.

"Sleeplessness" may very well be a public health problem, but its medicalization as insomnia--a transformation into a diagnostic entity with a predominantly pharmacological solution--is also problematic. Such a process may entail unnecessary costs to the health care system and increase the risk of harming the population being diagnosed and treated, thus posing a related but distinct public health issue.

**Table 17. Insomnia Medications – Total U.S. Dispensed Scripts in Thousands (000)**

<b>Rank</b>	<b>Drug</b>	<b>2001</b>	<b>2002</b>	<b>2003</b>	<b>2004</b>	<b>2005</b>
Class total		\$29,183	\$32,548	\$35,211	\$38,103	\$43,126
1	Ambien	\$17,319	\$20,601	\$23,324	\$25,700	\$26,556
2	Temazepam	\$6,969	\$7,059	\$7,122	\$7,681	\$8,094
3	Lunesta	***	***	***	***	\$3,333
4	Sonata	\$1,791	\$1,886	\$1,775	\$1,652	\$1,452
5	Triazolam	\$1,277	\$1,269	\$1,274	\$1,313	\$1,322

(Table reproduced from IMS Health, IMS National Sales Perspective, 2/2006)

## **Appendix 1:**

### Additions to the ICD-9-CM

#### ICD-9-CM COORDINATION AND MAINTENANCE COMMITTEE MEETING

OCTOBER 7-8, 2004

Topic: Insomnia, hypersomnia and sleep apnea

Sleep medicine is a new but growing medical subspecialty. The American Academy of Sleep Medicine has published “The International Classification of Sleep Disorders” that contains diagnostic, severity, and duration criteria to aid clinical diagnosis and treatment of sleep disorders. The Academy has been working with NCHS staff to bring the ICD up to date with the current classification of sleep disorders.

Below are proposals to expand the ICD-9-CM in the areas of insomnia, hypersomnia and sleep apnea. In future revision, additional modifications will be proposed for others sleep disorders.

#### TABULAR MODIFICATIONS

291 Alcohol-induced mental disorders

291.8 Other specified alcohol-induced mental disorders

New code

291.82 Alcohol-induced sleep disorders

Alcohol-induced hypersomnia

Alcohol-induced insomnia

292 Drug-induced mental disorders

292.8 Other specified drug-induced mental disorders

New code



292.85 Drug-induced sleep disorders

Drug-induced hypersomnia

Drug-induced insomnia

307 Special symptoms or syndromes, not elsewhere classified

307.4 Specific disorders of sleep of non-organic origin

Add

Excludes: organic hypersomnia (349.40-349.49)

organic insomnia (349.30-349.39)

307.41 Transient disorder of initiating or maintaining sleep

Add

Adjustment insomnia

29

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ICD-9-CM COORDINATION AND MAINTENANCE COMMITTEE MEETING

OCTOBER 7-8, 2004

307.42 Persistent disorder of initiating or maintaining sleep

Add

Idiopathic insomnia

Add

Paradoxical insomnia

Add

Primary insomnia

Add

Psychophysiological insomnia

307.44 Persistent disorder of initiating or maintaining wakefulness

Add

Idiopathic hypersomnia with long sleep time

Add

Idiopathic hypersomnia without long sleep time

Add

Insufficient sleep syndrome

Primary hypersomnia

Add

Excludes: sleep deprivation (V69.4)

349 Other and unspecified disorders of the nervous system

New sub-

349.3 Organic disorders of initiating and maintaining sleep [Organic

category

insomnia]

Excludes: insomnia NOS (780.52)

insomnia not due to a substance or known physiological

condition (307.41-307.42)

insomnia with sleep apnea NOS (780.51)

New code

349.30 Organic insomnia, unspecified

New code

349.31 Insomnia due to non-mental health condition classified

elsewhere

Code first underlying condition

New code

349.32 Insomnia due to mental health condition

Code first mental health condition

Add

Excludes: alcohol-induced insomnia (291.82)

drug-induced insomnia (292.85)

New code

349.39 Other organic insomnia

New sub-

349.4 Organic disorder of excessive somnolence [Organic

category

hypersomnia]

Excludes: hypersomnia NOS (780.54)

hypersomnia not due to a substance or known physiological

condition (307.43-307.44)

hypersomnia with sleep apnea NOS (780.53)

30

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ICD-9-CM COORDINATION AND MAINTENANCE COMMITTEE MEETING

OCTOBER 7-8, 2004

New code

349.40 Organic hypersomnia, unspecified

New code

349.41 Recurrent hypersomnia

Klein-Levin syndrome

Menstrual related hypersomnia

New code

349.42 Hypersomnia due to non-mental health condition

classified elsewhere

Code first underlying condition

New code

349.43 Hypersomnia due to mental health condition

Code first mental health condition

Add

Excludes: alcohol-induced hypersomnia (291.82)

drug-induced hypersomnia (292.85)

New code

349.49 Other organic hypersomnia

New sub-

349.5 Organic sleep apnea

category

Excludes: Cheyne-Stokes breathing (786.04)

hypersomnia with sleep apnea NOS (780.53)

insomnia with sleep apnea NOS (780.51)

sleep apnea in newborn (770.81-770.82)

sleep apnea NOS (780.57)

New code

349.50 Organic sleep apnea, unspecified

New code

349.51 Primary central sleep apnea

New code

349.52 High-altitude periodic breathing

New code

349.53 Obstructive sleep apnea (adult) (pediatric)

New code

349.54 Idiopathic sleep-related non-obstructive alveolar

hypoventilation

Sleep related hypoxia

New code

349.55 Sleep-related hypoventilation/hypoxemia in conditions classifiable elsewhere

Code first underlying condition

New code

349.56 Central sleep apnea in conditions classified elsewhere

Code first underlying condition

New code

349.59 Other organic sleep apnea

31

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ICD-9-CM COORDINATION AND MAINTENANCE COMMITTEE MEETING

OCTOBER 7-8, 2004

780 General symptoms

780.5 Sleep disturbances

Add

Excludes: organic hypersomnia (349.40-349.49)

organic insomnia (349.30-349.39)

organic sleep apnea (349.50-349.59)

Revise

780.51 Insomnia with sleep apnea, unspecified

Revise

780.52 Other Insomnia, unspecified

Delete

Insomnia NOS

Revise

780.53 Hypersomnia with sleep apnea, unspecified

Revise

780.54 Other Hypersomnia, unspecified

Delete

Hypersomnia NOS

Revise

780.57 Other and unspecified sleep apnea

V69 Problems related to lifestyle

New code

V69.5 Behavioral insomnia of childhood

## **Appendix 2:**

### Email from Clinic Director to the IMC Physicians

Mairead Moloney, a doctoral candidate working with XX at the XX is studying the medicalization of insomnia. She would like to interview you about your experience with this phenomenon and, with your permission, interview several of your patients who have problems with insomnia. She has IRB approval for her project and plans to get started next week. She can meet with you in the clinic or in your office at a time that is convenient for you and she will not be approaching patients in the clinic. I think you will find her work interesting and I hope you will lend your support to her project.

XX



### Appendix 3:

#### Physician Interview Guide

*(all prompts are response-dependent and noted in italics)*

Hello Dr. X, thank you so much for taking the time to talk to me today. I'd like to ask you some questions about your interactions with patients who complain of insomnia.

To begin our interview will you please briefly describe the type of patients that you see in your practice *(in terms of age, SES, burden of disease, gender, insurance status)*?  
What is the average length of your office visits?

As you know, I'm trying to learn more about how patients and doctors interact on the topic of insomnia. As I understand it, insomnia is defined as the inability to fall asleep or stay asleep. Is this correct?

I'd like to get a general sense of how you evaluate and manage insomnia in your patients, but if you have any specific examples you could use to illustrate your points, that would be very helpful to me.

First, tell me how do you evaluate patients with insomnia? *(How do you medically evaluate whether you are looking at primary insomnia v. transient insomnia? Do you do a full physical? Who brings it up? How does it come up in the context of the office visit?)*

***Do you ever:***

Talk to your patients about making behavioral or lifestyle changes? *( Under what circumstances? If so, could you give me an example? Who initiated this conversation – you or the patient?)*

Talk to your patients about sleep hygiene (a more formal set of behavioral and lifestyle suggestions)? *(Under what circumstances? If so, could you give me an example? Who initiated this conversation – you or the patient?)*

Talk to your patients about over the counter medications for insomnia? *(Under what circumstances? If so, could you give me an example? Who initiated this conversation – you or the patient?)*

Talk to your patients about herbal or alternative treatments? *(Under what circumstances? If so, could you give me an example? Who initiated this conversation – you or the patient?)*

Refer patients with insomnia to a psychologist? *(Under what circumstances? Examples? What factors might lead you to this decision? Who initiated this conversation – you or the patient?)*

Refer patients to a sleep clinic? *(Under what circumstances? Examples? What factors might lead to this decision? Did you initiate this conversation or did the patient? Do you find sleep clinic evaluations to be helpful in these circumstances?)*

Design a treatment plan based on how well you think a patient will comply with it? *(Under what circumstances? Example?)*

### **General Treatment Questions**

I'd like to get your take now on the different kind of prescription medication options that are available for insomnia.

Do you have particular medications that you tend to prescribe for patients with insomnia?  
(*Why or why not?*)

How long do you typically prescribe these medications for? (*Why do you choose that time period? What if they ask for refills?*)

How common is it for patients to request a specific medication such as Ambien or Lunesta?  
(*How do you feel about this? Do you think that patients are influenced by advertisements for certain hypnotic drugs? Do they ever request older-generation hypnotics such as valium, to help them sleep?*)

Does the patient request for a specific drug influence what you choose to prescribe, or not prescribe?

Can you give me an example of a time when you did not choose to prescribe a hypnotic medication to a patient who had requested one? (*How did they react?*)

Now that we have talked about how you generally manage and treat insomnia. I was wondering if you could walk me through a couple of different, specific, anonymous examples of patients you have seen for insomnia.

### **First Example<sup>39</sup>**

First, I'd like to ask you to walk me through the most recent (OR, *a recent*) visit you had by a patient who complained of sleeplessness.

(*When was it? What were the patient's basic characteristics? How did the issue arise in the context of the office visit? Who brought it up? Was it the patient's main complaint or did they come to the visit because of another complaint? How did they present it/what language did they use to talk about it? What affect was the insomnia having on their life? How did you determine the origin of the issue? Any co-morbidities? Would you say this is a fairly typical insomnia case? Why or why not?*)

### **Diagnosis**

Did he or she identify their sleeplessness as being the result of a life circumstance (social issue), a mental issue, or a physical issue?

Do you think the patient's insomnia was the result of a life circumstance (social issue), a mental issue or a physical issue?

Did you offer the patient a diagnosis?

Had the patient already diagnosed him or herself?

Did the patient agree/disagree with your diagnosis?

### **Treatment**

---

<sup>39</sup> Physicians who agree to be interviewed will be notified in advance that I will be asking them for recent examples of patients they have seen who suffer from insomnia. This is expected to aid in physician recall during this interview.

What type of treatment did you decide upon? (*Did the patient have any input in this? Did the patient request a specific treatment/medication?*)

### **Second Example**

Can you give me an example of an interaction with a patient around this issue that didn't go well? ("not going well" could include issues of pt/phys disagreement, non-compliance, not getting better?, etc.)

### **Repeat Diagnosis and Treatment Questions**

#### *Education*

I've read that there is not a lot of training on sleep disorders, including insomnia, in medical school or residency. Do you agree with that?

How comfortable were you in diagnosing and treating insomnia when you first began practicing medicine? How about now?

What sources of information have you used to learn more about insomnia?

Do you think that the number of patients you have seen for insomnia over the years has increased, decreased, or stayed about the same?

Do you think there is a specific "type" of patient (general, stereotype) who complains of insomnia in terms of race, sex, SES, age?

Do you think that DTCA (direct to consumer advertising) has any influence on the treatment a patient will request? (*Do patients ever refer to specific advertisements?*)

Do you think that drug companies have any influence on the treatment choices physicians in your practice make?

This completes the interview portion of our time together today. Thank you! Is there anything else you would like to add?

## Appendix 4:

### Physician Interview code list

<b>Free Nodes</b>	<b>Tree Nodes</b>
Aging Issues	Addiction Issues
Consumerism	<b>Attitudes</b>
Doc Exper Sleeplessness	Attitude twd Dx (diagnosis)- Patient
Effects of Sleeplessness	Attitude twd Dx – Physician
Gender	Attitude twd Tx – Physician
Insomnia Context	Attitude twd Tx - Patient
Insomnia Definition	<b>Comorbidities</b>
Insomnia Trends	Comorbidities - Physical
Medicalization	Comorbidities – psych
Physician Compliance	Comorbidities – OSA
Physician Edu - Training	<b>Physician Information Sources</b>
Practice Type	Phys Info – CMEs
Primary Insomnia	Phys Info – Colleagues
Patient Type	Phys Info - Drug Reps
Patient visit - example	Phys Info - Experience - trial and error
Patient-Doc Interaction	Phys Info – Jrnls
Race	<b>Misc.</b>
Role of Drug Co.	PT stereotype
Role of US Hlthcare - insurance	<b>Rhetorical Authority</b>

SES	RA - DTC advert
Stigma	RA - friends and family
Symptom v. Disease	RA - Internet
Time	RA - magazines, books, news, tv
	<b>Referrals</b>
	Referral - Psych
	Referral - sleep clinic
	<b>Rx Related</b>
	Rx by Prev Doc
	Rx Name Brand Request
	Side effects-Effectiveness
	<b>Treatments</b>
	Sleep Hygeine
	Tx - Anti-Depressant
	Tx - Bnzo
	Tx - CAM
	Tx - NonBnzo
	Tx - OTC
	Tx - Trazadone

## Appendix 5:

### Memos from Coding process

February 22, 2009

Preliminary Findings

**1. Doctors in this sample are savvy about medicalization.** They bring it up in the interview and sometimes even use that term. This degree of self-awareness and sociological insight is likely due to the fact that they are trained and practice in a highly respected academically-oriented medical center. While this is an interesting finding, it must also be noted in my limitations section that these docs are not representative of the types of clinicians represented by the NAMCS survey. It is possible that docs in private practice would be less likely to discuss the medicalization process. While a limitation, I also think that this is a solid reason to do a follow up study with private practice docs.

Example quotes:

*I: Ok, so you mention psychiatric diagnosis, do you see insomnia as a psychiatric diagnosis or more physiological or could it be both?*

*A: Yeah, I think we tend to do that and I think we tend to medicalize insomnia to a large degree. I think it is not, I think the majority of cases of insomnia are due to stressors in life and normal variance and I think they are usually not psychiatric diagnoses but I think to gain the diagnosis of insomnia it ought to be that. It is getting ahead of myself, for the majority of patients I see I feel like are normal life variance of that and there is relatively few cases that I see where I would say this is a medical diagnosis of insomnia. If that make sense. (Doc 4)*

**2. Physician compliance is presented in a framework of limitations** – (too little) time; effort of negotiation; patients will go elsewhere is they don't give in; feeling they can do their pts a lot of good in other areas and giving in this one is no big deal as, so far, these drugs seem fairly benign.

Example quote:

*KI: yeah, so sometimes one thing I didn't mention was sometimes if a patient has a lot of complaints and other health problems and they mention their insomnia and they're interested in a medication sometimes it's easier to write the prescription than it is to take a lot of time talking about behavioral modification. I always do try to talk about it, but sometimes there are just I think there are days that you write it, without. And you, well, you readdress it, but you do write it without much more discussion than that. (Doc 2)*

## Appendix 6:

### Follow-up letter for Physicians Interviewed

Dear Dr. X,

Thank you again for our recent interview. As we discussed, I'd like to follow up with you on the patient interview piece of my project.

Enclosed are two documents. One is a list (generated by a request to the ISD) of your patients who have received sedative hypnotics in the last 6 months. The other is an IRB approved lead letter that I will ask you to sign before I send it to potential patient participants. Enclosed with the letter will be a postage-paid card they can drop in the mail if they do not wish to participate.

Please look this over when you have a chance and let me know if there are patients I should **\*rule out\*** as potential contacts. Please rule out patients who have:

- a) taken sedative hypnotics for less than a month OR
- b) been prescribed these drugs primarily for travel purposes OR
- c) have minimal English-speaking skills (unfortunately, I am not fluent in another language).

At your convenience, you may return the patient list to me with **\*non-eligible patients crossed out or deleted\***. Please let me know if you have any questions.

Best,

Mairad



## **Appendix 7:**

### Patient Lead Letter

*Sleeplessness in America Project*

DATE

PATIENT NAME

PATIENT ADDRESS

Dear PATIENT,

I am writing to ask you to consider participation in a research study about sleep problems here at the XXX Carolina's Internal Medicine Clinic. Mairead Eastin Moloney, a doctoral candidate at the University of North Carolina at Chapel Hill, is interested in learning more about why increasing numbers of people seem to be experiencing sleep problems in this country and how people talk to their doctors about these problems.

If you choose to participate, you will be called by Ms. Moloney. She will describe the study to you in more detail and ask you if you would be willing to participate in either an in-person or a phone survey. After you complete the interview you will be given a Target gift card worth \$25 to thank you for your time.

Your participation is completely voluntary and deciding not to participate in this study will not change your ability to get health care at XXX. This study has been reviewed and approved by the School of Medicine's Institutional Review Board on Research Involving Human Subjects. All information you give to Ms. Moloney will be kept completely confidential and will be used only for research purposes.

As a follow-up to this letter, Ms. Moloney will call you. If you do not want to participate in this study, you may return the postage-paid postcard, enclosed. Alternately, you may also tell Ms. Moloney when she calls that you are not interested in participating in the study. It is important that we learn more about sleep problems, including insomnia. Ms. Moloney's work hopes to promote better understanding of how patients experience and treat sleep problems and how they talk to their physicians about these problems. I hope that you will consider participating in this study.

Sincerely,

Dr. XXXXX, MD

**Appendix 8:**

Text of self-addressed, postage paid, opt-out postcard

**Sleeplessness in America Project**

Return this postcard only if you **DO NOT** want to be contacted for the Sleeplessness in  
America Project.

---

Please print name

## Appendix 9:

### Introductory phone script for insomnia patients

Hello, my name is Mairead and I'm calling to follow-up on the letter you received from Dr. X. I would like to ask you to be in a research study on people who have been treated for sleep issues including insomnia. As a doctoral student, I want to find out what people like you do about sleeplessness and the types of treatments that you try. Sleep issues seem to be a growing problem in our country and your participation in this research may help us better understand what people are dealing with, and how they are interacting with their physicians about these matters.

I'd like to ask you some questions about your health and your medical care related to your sleep problems. The interview would take about 30 minutes and may be completed in person. Your participation is voluntary. If you choose not to agree to an interview, it will not affect your ability to get health care at XXX. Anything you tell me will be kept completely confidential and will be used only for research purposes. Your doctor will not know if you choose to participate and your responses will never be shared with him or her. After you complete the interview, you will receive a \$25 gift card to Target to thank you for your time.

As part of this study I will collect your name, address and telephone number. However, if you choose to complete an interview, all this information and the information you give me about your health and health care will be stored *only* with an identification number, *not* with your name. Information that could identify you will be stored in a locked file cabinet in a

locked office until the research is completed. Any reports on the interviews carried out for this research will use pseudonyms (or fake names) only and will not contain identifying information of any kind.

If you have any questions about this study, or your rights as a human subject, you can call Dr. X at XXXXXXXX. Additionally you may contact my faculty advisor, Dr. Victor Marshall at 919-843-8067 or the UNC IRB at 919-966-3113. I also have their email addresses here if you would like to write those down as well (marshall@schr.unc.edu or IRB\_subjects@unc.edu).

Are you willing to participate in this study by participating in an interview?

*If yes:* Thank you. Would you like to schedule an in-person interview?

*If yes:* Would you prefer an in-person or phone interview?

*If no:* Thank you for your time. End call.

**Appendix 10:**

Patient Information Form

**Patient Information Form**

**Participant # \_\_\_\_\_**

**Year of Birth:** \_\_\_\_\_

**Sex:** M                      F

**Highest Level of Education Achieved:**

*(Please circle one)*

Less than high school

Some high school

High school diploma

Some college

AA or technical degree

BA or BS

Some graduate school

MA or MS

PhD or MD

How would you describe your race or ethnicity? \_\_\_\_\_

Do you have private insurance? Yes              No

Medicare?    Yes    No

Medicaid?    Yes    No

## Appendix 11:

### Patient Interview Questions

*(all prompts are response-dependent and noted in italics)*

I'm interested in learning more about how people experience sleep issues in America. Are you willing to talk with me today about your experiences with sleep issues? (If yes go to intro...) (If NO, Would you like to reschedule our interview or decline future participation? If DECLINE, Thank you so much for your time.)

#### *Intro*

I'd like to start out by asking you a few basic questions about your sleeplessness and then talk to you specifically about your interaction with Dr. X, and any other medical professionals you may have talked with about your sleep issues.

So, first, please tell me a little bit about your issues with sleep.<sup>40</sup>

*(How often do you experience it? How long have you been experiencing it? What did you do when you first began experiencing issues with your sleep? Have your issues with sleep changed over time or stayed pretty much the same?)*

Do you engage in shift work or other kinds of work that might make your sleep issues worse?

Has your sleep issues affected the rest of your life/work/daily routines? *(If so, how?)*

What do you think is the cause of your issue(s) with sleep?

Were there other health problems you thought were related to your sleep issues? *(Did you bring them up or did your doctor? OR Did your doctor agree/disagree?)*

Before seeing a doctor, how did you try to deal with your sleep issues?

What made you decide to talk to Dr. X. about your sleep issues?

#### **Interaction**

At this point, I would like you to describe for me, in as much detail as you care to provide, your office visit with Dr. X where the two of you discussed your sleeplessness. (prompts: *Who brought it up? How did you describe your sleep issues to the doctor? What was his/her reaction? (or) How receptive was the doctor to your concerns?)*

#### **Diagnosis**

Did he/she offer you a diagnosis?

Do you agree with that diagnosis?

Were there other health problems that your doctor thought might be related to your sleep issues? *(What do you think?)*

#### **Treatment**

---

<sup>40</sup> I will begin by using vague terms such as "sleeplessness" or "issues with sleep" and then transition into using whatever language they use when answering (e.g. if they talk about their insomnia, then that is the term I will adopt.)

How did you decide upon a treatment? (*Did your doctor suggest a course of action? Did you suggest a course of action?*)

Did you discuss any over the counter treatments?

How about any alternative or herbal treatments?

How about behavioral or lifestyle changes?

Did you and your doctor discuss the idea of you seeing another kind of professional about your sleep issues, like a psychologist or a sleep specialist?

If you receive a prescription for an Rx, did you get it filled? (*How long did you take the drug for? What was your experience like?*)

Have you had any more recent interactions with Dr. X about your sleep issue? (*If so, how did they go?*)

Have you had interactions with other physicians about your sleep issue? (if yes)

Was this before or after seeing Dr. X?

Please tell me about your best and worst interactions surrounding these encounters.

Some doctors are very knowledgeable about sleep issues whereas others are less so because sleep issues are a new topic of interest and they may not have much training in them. In your encounters, how knowledgeable did you find your doctors to be?

Some doctors are very open to prescribing medications for sleep issues, other doctors are more reluctant to do so. What types of physicians have you encountered?

Other than doctors, were there other sources that you used to gain knowledge about sleep issues, such as the internet, watching tv, reading books/magazines/newspapers, talking to friends and family?

Did you gain this knowledge before or after your encounters with doctors? (If so, what?)

Do you think this knowledge had any influence on your interaction with your doctor?

Do you think that, specifically, advertisements for prescription sleep drugs had any influence on your interaction with your doctor?

Thank you so much for talking to me today! Is there anything else you would like to add?



## Appendix 12:

### Patient Interview Code List

<b>Free Nodes</b>	<b>Tree Nodes</b>
Consumerism	<b>Attitudes</b>
Patient Experience of sleeplessness	Attitude twd Dx (diagnosis)- Patient
Patient Effects of Sleeplessness	Attitude twd Dx - Doc
Gender	Attitude twd Tx - Doc
Insomnia Context	Attitude twd Tx - Patient
Burden of insomnia	<b>Comorbidities</b>
Normalization of insomnia	Comorbidities - Physical
Medicalization	Comorbidities - psychological
Physician Compliance	Comorbidities - OSA
Satisfaction with Physician	<b>Insomnia Cause</b>
Addiction Issues	Anxiety/stress
Aging Issues	Trauma/tragedy
Time	Age-related
Symptom v. Disease	Gender-related
Patient-Doc Interaction	Other illness related
Race	Don't know
Role of Drug Co.	<b>Rhetorical Authority</b>
Role of US Hlthcare – insurance	Misc. or multiple
SES	RA - DTC advert
Stigma	RA - friends and family

	RA - Internet
	RA - magazines, books, news, tv (print media)
	<b>Referrals</b>
	Referral - Psych
	Referral - sleep clinic
	<b>Rx Related</b>
	Rx by Prev Doc
	Rx Name Brand Request
	Side effects-Effectiveness
	<b>Treatments</b>
	Sleep Hygeine
	Tx - Anti-Depressant
	Tx – Bnzo
	Tx – CAM
	Tx - NonBnzo
	Tx – OTC
	Tx – Trazadone
	Tx – home remedies

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