## Patient Characteristics and Patterns of Drug Use for Sleep Complaints in the United States: Analysis of National Ambulatory Medical Survey Data, 1997–2002

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#### **ABSTRACT**

Objectives: The aims of this work were to characterize ambulatory patients in the United States presenting with primary or secondary insomnia complaints and resultant diagnoses, and to describe the characteristics of patients treated with medications commonly used for sleep complaints.

Methods: Data from the National Ambulatory Medical Care Survey for the years 1997 through 2002 were analyzed. Data were stratified by patient characteristics, physician specialty, resulting diagnosis, and medications prescribed or provided. The unit of analysis was the individual patient visit; statistical comparisons were made using the  $\chi^2$  test for categorical variables and the Rao-Scott design-adjusted  $\chi^2$  test for comparisons of patient age groups.  $P \leq 0.05$  was the criterion for statistical significance. Cells containing <30 observations were not included in the statistical analysis.

Results: The data included 147,945 patient visit records; rates of physician response to the survey ranged from 62.9% in 1999 to 70.4% in 2002. Based on this sample, it was projected that 30 million office visits involved insomnia complaints over the 6-year period from 1997 to 2002 throughout the United States. With a total of 4.9 billion physician visits projected for that time period, 0.6% of visits were insomnia related. Women were 1.5 times more likely to have insomnia-related visits (P < 0.001). Overall, the greatest proportion of insomnia patients of both sexes was between the ages of 18 and 64 years (P < 0.001). Sleep difficulties were most frequently attributed to organic disorders, depression and/or anxiety, and primary insomnia (55.8%, 27.3%, and 9.8%, respectively; P <0.001). The most frequently prescribed or recommended medications were zaleplon/zolpidem and trazodone (28.5% and 32.0%, respectively; P < 0.001). Zaleplonand zolpidem were most frequently used for patients with organic diagnoses and those aged  $\le 65$  years (33.2% and 29.8%; P < 0.001).

Conclusions: Demographics of patients with insomnia and their diagnoses from 1999 to 2002 remained stable, but the use of medications changed predictably as newer agents became available. (*Clin Ther.* 2006;28:1044–1053) Copyright © 2006 Excerpta Medica, Inc.

Key words: sleep, hypnotic, primary care, triazolam, flurazepam hydrochloride, temazepam, zaleplon, zolpidem, trazodone, diphenhydramine.

#### **INTRODUCTION**

Insomnia—defined as difficulty initiating or maintaining sleep, or nonrestorative sleep associated with functional impairment the next day—is an underrecognized problem with significant public health consequences. In the United States, as many as 36% of adults and 32% of adolescents report some difficulty falling asleep, maintaining sleep, or achieving restorative sleep. 1-3 Between 9% and 15% of adults report daytime consequences of insomnia. 4 Moreover, for an estimated 10% of the adult population and 17% of adolescents, sleep difficulties are chronic. 5

Daytime repercussions of poor sleep include fatigue, sleepiness, impaired functioning, and impaired ability to concentrate, as well as depression, anxiety, and other mood changes.<sup>6</sup> These consequences, in turn, are associated with large health care expenditures, decreased work productivity, injuries, accidents, and a perceived decrease in quality of life.<sup>7-9</sup>

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Despite the impact of insomnia on quality of life, studies have found that only a fraction of patients with probable insomnia discussed their sleep difficulties with a physician.<sup>10,11</sup> One third of patients reporting the most severe sleep loss do not consider their problems to be serious.<sup>12</sup>

As more is learned about the physiology of sleep, the understanding that it is essential to good health has deepened. <sup>13</sup> Insomnia has long been accepted as a symptom of underlying organic or psychiatric disease. <sup>14</sup> More recently, sleep loss has been identified as a risk factor for cardiovascular events, diabetes, and obesity, all of which are becoming more prevalent in the United States. <sup>15–18</sup> In addition, insomnia that cannot be attributed to medical, psychological, or environmental factors is estimated to occur in 12% to 15% of patients with chronic insomnia. <sup>19</sup> This primary insomnia is thought to be a pathological state of hyperarousal characterized by prolonged sleep latencies on the Multiple Sleep Latency Test. <sup>13</sup>

Altogether, this growing body of evidence serves to emphasize the importance of identifying and treating insomnia effectively. Primary care providers, including doctors, nurses, and physician assistants, are uniquely positioned to educate patients about the importance of sleep and to identify and treat those with sleep difficulties. The aims of this work were to characterize ambulatory patients in the United States presenting with primary or secondary insomnia complaints and resultant diagnoses, and to describe the characteristics of patients treated with medications commonly used for sleep complaints using data from the National Ambulatory Medical Care Survey (NAMCS) collected over a 6-year period (1997-2002). Patient demographics, physician diagnoses, and prescribing patterns for commonly used sleep medications were evaluated for office visits involving primary or secondary insomnia complaints.

# MATERIAL AND METHODS Data Collection

The NAMCS is an annual survey of ambulatory practices in the United States, conducted by the Division of Health Care Statistics, the National Center for Health Statistics, and the Centers for Disease Control and Prevention. The survey yields data on individual outpatient office visits weighted to reflect national estimates describing the utilization of ambulatory medical care services in the United States. Participating physicians are primarily engaged in direct patient care, and include

those who are office based or practice at freestanding clinics. Visits to federally employed physicians; to specialists in anesthesiology, pathology, or radiology; or to hospital outpatient clinics are excluded from the survey.

Participating physicians were randomly assigned to 1 of 52 weeks and asked to record information on patients' visits using a systematic random sample of patient visits. In addition to sex, race or ethnicity, and source of payment for the visit, physicians documented patients' complaints and symptoms, diagnoses, and medications mentioned. NAMCS data for the years 1997 through 2002 were included in the analysis.

#### Patient Data

Patients were identified with insomnia (National Center for Health Statistics code 1135.120) as their primary complaint or as 1 of up to 3 reasons for a physician visit. Patients who presented with complaints of insomnia were diagnosed using the International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM).14 Insomnia diagnoses included ICD-9-CM codes 307.41 (transient disorder of initiating or maintaining sleep), 307.42 (persistent disorder of initiating or maintaining sleep), 780.49 (other short-sleeper subjective insomnia complaint), 780.51 (insomnia with sleep apnea), and 780.52 (other insomnia not otherwise specified). Similarly, patients who were diagnosed with depression and anxiety or other mental disorders had corresponding ICD-9-CM codes (Table I). All other diagnoses for patients who presented with a complaint of insomnia were included in the organic disease category.

## Physician Specialties

American Medical Association designations were used to define physician specialty into the following 4 categories: family practice or general practice, general internal medicine, internal medicine subspecialties (ie, pediatrics, surgery, obstetrics and gynecology, cardiology, dermatology, urology, neurology, ophthalmology, otolaryngology, and other specialties), and psychiatry. These categories were chosen to mirror previous research on sleep complaints using NAMCS data.<sup>21</sup>

## Medications Prescribed or Provided

Physicians were asked to list the drugs (prescription or over the counter) they prescribed or recommended to the patient at each visit.

Table I. Insomnia-related diagnostic codes from the International Classification of Diseases, Ninth Revision, Clinical Modification.<sup>14</sup>

Diagnosis	Codes
Sleep	307.41, 307.42, 780.49, 780.51, 780.52
Depression and anxiety	296.0-296.8, 300.4, 309.0-309.1, 311, 296.7, 300.0-300.2, 309.8
Other mental disorders	295.1-295.9, 296.9, 298.9-299.8, 300.1-300.9, 301, 304, 305.0-305.9, 308, 309-310, 312-314, 315, 319, 648, 780.5-780.7

Several studies have classified the most commonly used drug treatments for insomnia.<sup>21–25</sup> Therefore, the analyses were restricted to drugs most commonly used to treat sleep complaints.

## Statistical Analysis

The NAMCS survey uses a multistage probability design that involves probability samples of primary sampling units (PSUs), physician practices within PSUs, and patient visits within practices. The firststage sample is made up of geographic segments composed of counties, groups of counties or towns, and townships within the 50 states and the District of Columbia. The second stage involves a probability sample of practicing physicians selected from files maintained by the American Medical Association and the American Osteopathic Association. The final stage is the selection of patient visits within the annual practices of sampled physicians. An estimation procedure (which includes imputation) to adjust for the nonresponse of the physicians, and weights based on each stage of the sample, were used to produce unbiased national estimates. This procedure uses the Taylor expansion method to obtain a linear approximation for the estimator and then uses the variance estimate for this approximation to estimate sampling errors of estimators based on the strata of the complex sample design (SAS Proc Survey, SAS Institute Inc., Cary, North Carolina).26,27

The National Center of Health Statistics considers a relative SE ≤30% to be reliable; estimates are considered unreliable if there are <30 observations, regardless of the relative SE. The unit of analysis was

the individual patient visit; statistical comparisons were made using the  $\chi^2$  test for categorical variables and the Rao-Scott design-adjusted  $\chi^2$  test for comparisons of patient age groups.  $P \le 0.05$  was the criterion for statistical significance. All analyses were conducted using SAS software, release 9.12 (SAS Institute Inc.). Cells containing <30 observations were not included in the statistical analysis.

#### RESULTS

## Prevalence of Insomnia Complaints

Between 1997 and 2002, NAMCS collected data on 147,945 patient visit records, with response rates ranging from 62.9% in 1999 to 70.4% in 2002. During the period from 1997 to 2002, 2027 patient visits for primary or secondary complaints of insomnia were reported by physicians. This figure was used to estimate that 30 million patient visits over the 6-year period, or 5 million visits annually, related to insomnia would have occurred across the United States. With a total of 4.9 billion physician visits projected for the years 1997 and 2002 nationwide, 0.6% of visits were insomnia related. Family/general practice and general internal medicine physicians accounted for 53.4% of insomnia-related visits (Figure 1). Another 26.5% of insomnia-related visits were to internal medicine subspecialists, pediatricians, surgeons, and other specialists; the remaining 19.3% of visits were made to psychiatrists' offices.

## Patient Demographics

Patient demographics were different for individuals making office visits for primary or secondary insomnia complaints than for those making office visits for other reasons (Table II; Figure 2). Overall, women were 1.5 times more likely to make insomniarelated visits than men (P < 0.001). However, visits by male children (ie, aged <18 years) were more common than those by female children (P < 0.001). According to the results of the Rao-Scott  $\chi^2$  test, the distribution of visits for insomnia complaints by age was statistically significant from the distribution for noninsomnia-related visits for both sexes (P < 0.001). The percentage of visits by individuals aged ≥65 years comprised 24.5% of visits by either sex, regardless of the presence of insomnia complaints (P <0.001). Based on the Rao-Scott  $\chi^2$  test, distribution by race was also statistically significant for both sexes (P < 0.001).

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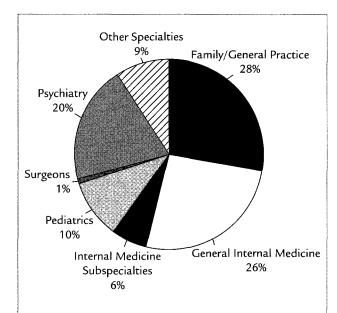


Figure 1. Physician specialties among patient visits for primary or secondary complaints of insomnia between 1997 and 2002, based on data from the National Ambulatory Medical Care Survey.

## Primary Diagnosis for Insomnia-Related Complaints

Analysis of primary diagnoses for insomnia-related complaints suggested differences by physician specialty (Table III). Organic disorders were predominant for all physicians except psychiatrists (P < 0.001). The proportion of organic-disorder diagnoses ranged from 57.6% of visits to family/general practice physicians to 86.8% of visits to internal medicine subspecialists. Finally, 0.9% of visits to psychiatrists for insomnia complaints resulted in an organic diagnosis. Overall, insomnia was the primary diagnosis for only 9.8% of insomnia-related visits. It was the primary diagnosis for 18.0% of insomnia-related visits to family/general practitioners, 11.5% of visits to general internal medicine offices, and 5.5% of visits to other internal medicine specialists. Insomnia was the primary diagnosis in only 1.9% of visits to psychiatrists. In contrast, psychiatrists diagnosed depression, anxiety, or both at 78.8% of insomnia-related visits.

Sex differences in primary diagnoses also were observed. For all physician specialties, more visits by females than males resulted in a primary diagnosis of insomnia (P < 0.001). A primary diagnosis of depression, anxiety, or both was significantly more common for visits by women than men, as well as for individuals aged 18 to 64 years of either sex (P < 0.001).

Table II.	Distribution	of all patien	ıt visits betweeı	า 1997	and 2002,	by demog	raphic ch	aracteristic.*

	Male	Visits	Female Visits		
Characteristic	Sleep Complaints	Other Complaints	Sleep Complaints	Other Complaints	
Sample, no. of visits	344	84,134	540	62,927	
National projection, no. of visits	10,945,556	1,965,769,519	19,495,308	2,891,462,355	
Age group, % of visits†					
<18 y	18.3	25.3	11.2	16.0	
18-44 y	25.8	23.7	32.8	33.3	
45-64 y	28.0	26.1	31.2	26.0	
≥65 y	27.9	24.9	24.8	24.7	
Race, % of visits‡					
White	86.0	86.6	85.3	86.1	
Nonwhite	14.0	13.4	14.7	13.9	

<sup>\*</sup>Data are national projections calculated based on the sample from the National Ambulatory Medical Care Survey (147,945 visits).

<sup>‡</sup>Data were insufficient and excluded from the analysis.

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<sup>†</sup> Age distribution difference was statistically significant for females (P < 0.003) but not for males (P = 0.077) (Rao-Scott  $\chi^2$  test).

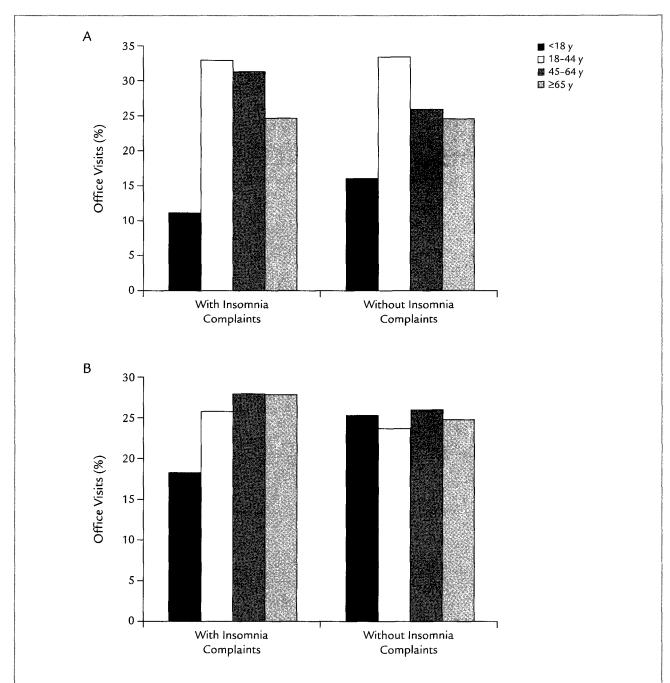


Figure 2. Office visits, by patient age, with or without insomnia complaints, based on data from the National Ambulatory Medical Care Survey for 1997 through 2002. (A) Females. (B) Males.

## Sleep Medications Prescribed or Provided

Table IV reports the characteristics of subjects with or without a sleep complaint who were prescribed or recommended a medication commonly used to treat sleep disorders. Comparisons of distributions using the Rao-Scott  $\chi^2$  test indicated significant differences in the use of sleep medications stratified by physician

specialty, patient sex, age, and primary diagnosis. Primary care physicians prescribed or provided the newer hypnotics (zaleplon or zolpidem) more often (29.0%) than other commonly used sleep medications, including temazepam (11.3%), trazodone (25.7%), or diphenhydramine (28.7%) (P < 0.004). Zaleplon or zolpidem was commonly prescribed or

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Table III. Distribution of primary diagnoses associated with insomnia complaints, among patient visits for primary or secondary complaints of insomnia between 1997 and 2002, by physician specialty and patient characteristic.\*

	Diagnostic Category					
Variable	Depression/ Anxiety	Other Mental Disorders	Sleep Complaints	Organic Disorders		
Sample, no. of visits (n = 803)	283	84	68	368		
National projection, no. of visits (n = 27,272,894)	7,446,414	1,922,659	2,674,630	15,229,191		
Primary diagnosis, % of visits (n = 27,272,894)	27.3	7.0	9.8	55.8		
Specialty, % of visits†  Family/general practice (n = 7,737,268)  General internal medicine (n = 6,762,436)  Medical subspecialties (n = 7,168,885)  Psychiatry (n = 5,604,305)  Sex, % of visits§  Female (n = 17,798,934)  Male (n = 9,473,960)	19.5 <sup>‡</sup> 20.9 <sup>‡</sup> 1.4 <sup>‡</sup> 78.8 30.0 22.3	4.9 <sup>‡</sup> 1.1 <sup>‡</sup> 6.2 <sup>‡</sup> 18.3 5.8 9.5	18.0 11.5‡ 5.5‡ 1.9‡ 9.9 9.6	57.6 66.5 86.8 0.9‡ 54.4 58.7		
Age group, % of visits <18 y (n = 3,711,119) 18-44 y (n = 8,471,857) 45-64 y (n = 8,400,147) 65-74 y (n = 6,689,771)	8.1 <sup>‡</sup> 37.0 32.8 18.8	1.4 <sup>‡</sup> 9.5 8.6 5.2 <sup>‡</sup>	0.7 <sup>‡</sup> 11.4 13.5 8.2 <sup>‡</sup>	89.8 42.1 45.1 67.8		

<sup>\*</sup>Data are national projections calculated based on the sample from the National Ambulatory Medical Care Survey (803 visits).

provided for organic disorders (33.2%; P < 0.001). Across all physician types, these agents were used during visits by patients who were aged  $\geq 65$  years. Trazodone was used more often overall (32.0% vs 28.5% for newer hypnotics) and specifically with patients who had a primary diagnosis of depression, anxiety, or both (52.8%) (P < 0.001).

## **DISCUSSION**

The number of projected visits for primary or secondary insomnia complaints in the United States was 30 million visits over a 6-year period (1997–2002), or 5 million visits annually, based on data from the NAMCS for that period. This projection is considerably higher than the 3.3 million annual visits estimated using NAMCS data for 1989 and 1990.<sup>21</sup> The reason for this increase is not clear, although increased public awareness of conditions such as sleep apnea,

combined with direct-to-consumer advertising of sleep medications, may have contributed to greater patient interest in seeking help.

The present analysis of data from NAMCS indicates that the majority of individuals with a sleep complaint sought care from primary care physicians. An estimated 63.9% of visits for primary or secondary complaints of insomnia were to family/general practice physicians, general internal medicine physicians, or pediatricians. Psychiatrist visits accounted for 19.3% of insomnia-related visits, 97.1% of which resulted in primary diagnoses of depression/anxiety or other mental disorders.

The demographics of those seeking help for sleeping difficulties has not changed appreciably since the publication of an earlier analysis of NAMCS data.<sup>21</sup> Adults aged 45 to 65 years accounted for the largest proportion of patient visits for insomnia. Visits for

<sup>†</sup>Physician specialty was excluded from statistical analysis due to insufficient observations.

<sup>&</sup>lt;sup>‡</sup>Sample size was too small to include in statistical analysis.

<sup>§</sup>Sex difference was statistically significant (Rao-Scott  $\chi^2$  test: P < 0.001).

Distribution of visits of patients who received recommendations or prescriptions for sleep medications (regardless of diagnosis or sleep Diphenhydramine complaint) between 1997 and 2002, by demographic characteristic. Values are percentages of office visits unless otherwise specified.\* 14,045,837 22.2 370 28.7 19.5 29.7 22.9 20.9 20.0 22.8 19.4 25.4 28.1 1 20,265,002 Trazodone 32.0 740 25.7 26.4 24.6 54.0 32.9 30.3 36.8 34.5 24.0 52.8 43.9 23.5 18,057,691 Zolpidem/ Zaleplon 28.5 29.0 34.6 28.0 22.5 28.7 28.3 31.9 557 22.7 29.8 25.2 33.2 Temazepam 7,046,438 226 10.8 15.2 10.5 12.3 6.5 9.2 18.3 11.6 11.1 7.3 9.1 Triazolam/Flurazepam Hydrochloride 3,846,388 134 6.1 4.9 6.9 5.0 8.2 5.8 7.9 7.5 6.3 Internal medicine subspecialties (n = 15,730,672) Vational projection, no. of visits (n = 63,261,356) General internal medicine (n = 14,339,353) Family/general practice (n = 18,791,198) Other mental disorders (n = 2,898,249) Depression/anxiety (n = 2,898,249) Overall, % of visits (n = 63,261,356) Organic disorders (n = 25,839,578) Sample, no. of visits (n = 2027) Psychiatry (n = 14,400,133) Primary diagnosis, % of visits§ 18-44 y (n = 18,936,241)Insomnia (n = 1,961,856) 45-64 y (n = 25,312,999) Female (n = 41,529,756) Male (n = 21,731,601) ≥65 (n = 19,012,116) Age group, % of visits‡ Specialty, % of visits Sex, % of visits† Fable IV. Variable

<sup>\*</sup>Data are national projections calculated based on the sample from the National Ambulatory Medical Care Survey (2027 visits)

<sup>&</sup>lt;sup>†</sup>Sex difference was statistically significant (Rao-Scott  $\chi^2$  test: P = 0.008).

<sup>&</sup>lt;sup>‡</sup>Age difference was statistically significant (Rao-Scott  $\chi^2$  test:  $P \le 0.001$ ).

Primary diagnosis and physician specialty had too few observations and were excluded from the analysis.

sleep disorders were somewhat more likely to be for women, particularly women aged 18 to 44 years (P < 0.001). However, more pediatric visits for sleeping problems were for boys in the present analyses; this observation was also noted in the earlier publication.<sup>21</sup>

Individuals who were aged ≥65 years did not comprise a greater percentage of office visits for insomnia complaints or for other reasons than persons in the other 3 age groups. In the present analysis, older patients accounted for 24.8% of office visits regardless of the reason for the visit. However, in 2000, this age group constituted 12.4% of the overall population.<sup>28</sup> Thus, more visits per person were made by older people than by individuals in other age groups. Because chronic illness is likely to increase with age, it is not surprising that organic disease was the most frequently reported diagnosis for insomnia in this age group.<sup>29</sup>

Compared with other age groups, a larger proportion of patients aged 18 to 64 years who presented with insomnia complaints received a diagnosis of depression, anxiety, or both (P < 0.001). This finding is similar to the poll conducted by the National Sleep Foundation, which found that people of this age range tend to lose sleep, especially during the week.<sup>12</sup>

Also consistent with results of other studies that report sleeping problems occurring in 30% to 40% of the general public, <sup>10–12,30</sup> only a small percentage of patients discussed sleep problems with a physician. In the present analysis, physicians reported that only 0.6% of patients visiting their offices had a primary or secondary sleep complaint. Although this finding was similar to that obtained from the much smaller sample in the earlier NAMCS analysis, <sup>21</sup> the magnitude of this discrepancy is surprising.

According to a Gallup survey, 5% of patients with insomnia have visited a doctor specifically for help with the problem and 30% have reported discussing sleep problems with their doctor.¹¹0 In a recent study by Aikens and Rouse,¹¹¹ 700 consecutive patients aged ≥18 years who visited a nonurgent primary care clinic were surveyed about insomnia complaints. In that study, 52% of individuals with probable insomnia reported discussing their sleeping problems with a doctor.¹¹ The current analysis was based on a physician survey, whereas the work by Aikens and Rouse was based on a patient survey, a methodological difference that may contribute to a large discrepancy in results (0.6% vs 52.0%). Patients may believe they are discussing their sleeping difficulties with the doctor, but

are not successfully communicating their concerns. Physicians, on the other hand, may be more focused on other complaints or underlying conditions and not document the insomnia complaints on the survey. In either case, the difference in perceptions of reported insomnia complaints may confound accurate diagnosis and treatment.

Furthermore, with the approval of nonbenzodiazepine receptor agonists (ie, zolpidem in 1992 and zaleplon in 1999) for the short-term treatment of insomnia, and with the corresponding increase in direct-to-consumer advertising, it is not surprising that there has been an increase in use of these newer sedative hypnotics. Recent studies reviewing health care claims data have reported that a large proportion of patients receiving one of these newer medications did not have a diagnosis of insomnia.<sup>31,32</sup>

The current analysis has several notable limitations. First, the NAMCS database does not provide any information on whether prescriptions were dispensed or filled, which may result in an overestimation of the use of medication. Second, this work focused only on prescription and over-the-counter drugs commonly used to treat sleep complaints as defined in the literature. Herbal remedies and drugs less commonly used to treat sleep complaints were not assessed. Behavioral or other nonpharmacologic treatments for sleep disorders were not evaluated. Third, this work broadly classified physicians into 4 groups, which may result in classification bias limiting the generalizability of the results beyond the classifications used in this work. Fourth, the number of observations for some cells was too small to be included in statistical analysis. Finally, patient complaints were categorized from verbatim recordings of their stated complaints. This method may tend to underestimate some complaints, such as insomnia, which may have been raised in conversation.

### **CONCLUSIONS**

Demographics of patients with insomnia and their diagnoses from 1999 to 2002 remained stable, but the use of medications changed predictably as newer agents became available.

This analysis suggests a discrepancy between the estimated prevalence of sleep complaints reported in the literature and the level of patient-reported and physician-diagnosed sleep disorders as recorded by the NAMCS. It may be possible to reduce this gap by

increasing physician awareness of the costs and consequences of sleep disorders, both to the patient and society. Improved patient education regarding the importance of sleep, as well as the availability of non-pharmacologic and pharmacologic treatments for sleep disorders, may also help improve disease recognition and appropriate treatment. Further study is warranted to facilitate efficient identification and treatment of patients with sleep disorders.

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College of Clinical Pharmacy, April 2005, Myrtle Beach, SC; 10th Annual International Meeting of the International Society for Pharmacoeconomics and Outcomes Research, May 2005, Arlington, Va; and 19th Annual Meeting of the Association of Professional Sleep Societies, June 2005, Denver, Colo.

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