

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

RESMED CORP.

Petitioner,

v.

CLEVELAND MEDICAL DEVICES, INC.

Patent Owner.

Case IPR2023-00565
U.S. Patent No. 10,076,269

**DECLARATION OF DR. SUSHEEL PATIL
IN SUPPORT OF PATENT OWNER'S RESPONSE**

I. INTRODUCTION

I, Susheel Patil, declare as follows:

1. I have been asked by Plaintiff Cleveland Medical Devices Inc. (“Plaintiff” or “CleveMed”) to submit this declaration in the matter referenced above. I have reviewed the ‘269 Patent, its prosecution history, the *inter partes* review petition that Defendant ResMed Inc. (“Defendant” or “ResMed”) submitted regarding U.S. Patent No. 10,076,269 (“the ‘269 Patent”), the decision to institute by the Patent Trial and Appeal Board (“PTAB”), and the art cited in those documents. I am familiar with the technology at issue and what was known in the art at the time of the earliest priority date for the ‘269 Patent which is November 4, 2005.

II. EXPERIENCE AND QUALIFICATIONS

2. I hold a Ph.D. in Clinical Investigation from John Hopkins Bloomberg School of Public Health, Baltimore, Maryland, an M.D. from Jefferson Medical College, Philadelphia, Pennsylvania, and a B.S. in General Science from Pennsylvania State University State College, Pennsylvania. I completed internal medicine residency training and an additional year as chief medical resident at University Hospitals/Case Western Reserve University and a pulmonary and critical care fellowship at Johns Hopkins University, during which I completed sleep medicine training. I have been on faculty at Johns Hopkins, where I was the

Clinical Director of Sleep Medicine. I have approximately 18 years of professional medical experience in academia and the sleep medicine industry.

3. I am currently the System Director of Sleep Medicine at University Hospitals in Cleveland, Ohio, and a Clinical Associate Professor of Medicine at Case Western Reserve University. I am board certified in pulmonary, critical care, and sleep medicine. I am responsible for the delivery of sleep medicine related clinical and testing services throughout the entire UH health system, which includes seeing and evaluating patients, interpretation of diagnostic sleep testing, evaluating the efficacy of treatments for sleep disorders, and continual evaluation and implementation of new technologies to improve the sleep health of our patient population.

4. I have been active in numerous committees and leadership roles in the Sleep and Respiratory Neurobiology Assembly and Board of Directors for the American Thoracic Society, the American Academy of Sleep Medicine, and the American College of the Chest Physicians. At national committees for the Food and Drug Administration (FDA) I have provided expertise for FDA guidance in evaluating new digital technologies for diagnosing sleep disordered breathing. I have organized or spoken in numerous scientific symposia at the international meetings related to sleep medicine and participated in the development of important clinical guidelines in the sleep medicine field.

5. I have authored more than 30 publications and given invited lectures throughout the US in the area of sleep disordered breathing including sleep disordered diagnostics, management, and treatment. I have also been active in sleep medicine related public policy at the state level as the past-president of the Maryland Sleep Society.

6. In addition, I have extensive training and experience in clinical research including the conduct of observational studies and clinical trials. I have longstanding research interests in the pathogenesis of obstructive sleep apnea, HIV and sleep disorders, aspects of portable monitoring for sleep testing, clinical trials in sleep apnea therapeutics, and the role of hospital-based sleep testing. My past experiences have provided me with the knowledge base to evaluate the technology presented in this litigation.

7. Based on my background and experience of over 20 years in the field of sleep disordered breathing diagnosis and treatment and development of diagnostic and therapeutic technologies in the sleep and breathing field, I am familiar with many of the technologies used for the diagnosis and treatment of sleep disordered breathing, including in-lab and at home PAP treatments. Having practiced sleep and respiratory medicine over the past 20 years, I also understand the terminology used in the '269 Patent. In formulating my opinions, I have relied upon my knowledge, education, training, skill, and experience in the relevant art.

8. Additional details of my education, work experience, and research are summarized in my curriculum vitae (“CV”) attached as Appendix A to this Declaration.

9. My time is being billed at a rate of \$450 per hour, plus any direct expenses incurred. My compensation is based solely on the amount of time that I devote to activity related to this case and is in no way affected by any opinions that I render. I receive no other compensation from work on this action. My compensation is not dependent on the outcome of the case.

III. MEDICAL TERMINOLOGY

10. I am familiar with all of the medical terminology concerning the treatment and diagnosis of sleep disorders used in the ‘269 Patent and the art cited by ResMed in this case, which requires experience with medical devices in the field. For example, sleep disordered breathing, generally referred to as “sleep apnea,” is a chronic sleep disorder that is defined as a cessation (apneas) or reduction (hypopneas) in breathing during sleep that results in sleep fragmentation and/or low levels of oxygen during sleep. Individuals are characterized as having sleep apnea if they have at least 5 events per hour of sleep.

11. Sleep apnea causes patients to temporarily lose their breath during sleep, leading to choking or waking up gasping for air. Patients with sleep apnea can experience breathing pauses over 100 times each night. Many patients are

unaware of the breathing issues when sleeping and only become aware when a bedpartner reports the concern to them. Sleep apnea negatively affects how patients are able to sleep at night with chronic sleep loss, resulting in excessive daytime sleepiness and reduced sleep-related quality of life including but not limited to nonrestorative sleep, insomnia, nighttime urinary urgency, morning headaches. Sleep loss from sleep apnea can result in impairments in memory, concentration, social functioning, and workplace productivity. Ex. 2023, pg. 4, 17. This sleep loss not only negatively impacts the patient's quality of life but also has major medical and social costs estimated to be at least \$150 billion dollars per year. See, e.g., the '269 Patent, 1:27-39.

12. Traditionally, the identification of apneas and hypopneas requires several sensors including an airflow sensor (e.g. pneumotachograph, nasal pressure, and/or thermistor), electroencephalogram (EEG), and oximetry signal. Ex. 2029, Troester MM, Quan SE, Berry RB, et al, The AASM Manual for the Scoring of Sleep and Associated Events: Rules, Terminology and Technical Specifications, Version 3 (<https://aasm.org/clinical-resources/scoring-manual/>); Ex. 2023, pg. 5. It is generally accepted that an apnea is identified as almost the complete cessation of airflow. It is also generally accepted that a hypopnea is present when there is a reduction in airflow by $\geq 30\%$ in association with either a fall in oxygen saturation by at least 3 or 4% OR in association with an arousal from

sleep. An arousal from non-rapid eye movement (NREM) sleep is defined as an abrupt shift in electroencephalogram (EEG) signals to > 16 Hz for at least 3 seconds, with at least 10 seconds of preceding sleep. An arousal from rapid eye movement (REM) sleep has a similar definition but also requires a concurrent increasing in chin electromyogram (EMG) activity of at least 1 second. Additional sleep apnea event types have more subsequently been described, which include respiratory effort related arousals (RERAs). RERAs are breathing events defined by a duration of at least 10 seconds and characterized by increasing respiratory effort or inspiratory flattening based on a nasal pressure or positive airway pressure (PAP) signal of airflow, which leads to an arousal from sleep, and the event would not otherwise meet the definition of an apnea or hypopnea.

13. A person is characterized as having sleep apnea if they have at least 5 events (apneas, hypopneas, or RERAs) per hour of sleep, also known as the apnea-hypopnea index (AHI), respiratory disturbance index (RDI), or respiratory event index (REI). The AHI is the sum of all apneas and hypopneas divided by total sleep time (in hours). The RDI is the sum of all apneas, hypopneas, and RERAs divided by total sleep time (in hours). The REI is the total number of respiratory events divided by the monitoring time (in hours). The AHI, RDI, and REI are measures of the severity of sleep apnea in a person. The term, REI, is considered a surrogate of the AHI and is used in the context of measuring sleep apnea severity

based on home sleep apnea test devices or PAP devices that do not measure sleep time. Ex. 2029, Troester MM, Quan SE, Berry RB, et al, The AASM Manual for the Scoring of Sleep and Associated Events: Rules, Terminology and Technical Specifications, Version 3 (<https://aasm.org/clinical-resources/scoring-manual/>). A person has mild sleep apnea if their AHI/RDI/REI is between 5 and 15 events/h, moderate sleep apnea if their AHI/RDI/REI is between 15-30 events/h, and severe sleep apnea if their AHI/RDI/REI is greater than 30 events/h. A person has a “syndrome” of sleep apnea if they undergo a sleep study demonstrating an AHI/RDI/REI of at least 5 events/h AND have symptoms of sleep disruption, such as excessive daytime sleepiness. See Ex. 2028 at 1230-1235.

14. A person can have predominantly obstructive sleep apnea (“OSA”), central sleep apnea (“CSA”), or a combination of both. Sleep apnea events appear in three forms: obstructive, central, or mixed (a combination of both within the same event). Obstructive events are characterized by recurrent closing or narrowing of the airway due to physical obstruction from excessive relaxation of throat muscles and/or by the tongue or palate, which reduces the space for air to pass through, despite persistent breathing efforts by the affected person. Central events are characterized by recurrent episodes of brief breathing pauses or reductions in breathing due to a corresponding absence or reduction of breathing effort generated from the brain centers that control breathing. Mixed events are

breathing pauses characterized initially by an absence of breathing effort, followed by a return of breathing effort before the breathing pause ends.

15. Positive airway pressure (PAP) devices such as continuous PAP (CPAP) or auto-adjusting PAP (APAP) are typically used to treat sleep apnea, particularly OSA. These PAP devices transmit a positive pressure to effectively prevent narrowing of the airway and concomitant drops in oxygen level and arousals from sleep. CPAP delivers a constant pressure throughout the night to user. In contrast, APAP devices are more advanced and have mathematical algorithms to analyze the airflow signal for the presence of apneas, hypopneas, RERAs, snoring, or normal breathing. Based on an APAP device detection of respiratory events, an APAP device can automatically respond in real-time to reduce the severity of or prevent these individual events.

16. I have reviewed the declaration, CV, and deposition testimony of Dr. Sharony, and it does not appear that he has experience in the medical device field or sleep medicine. Moreover, he uses terms in the medical field that have particular meaning that he overgeneralizes. For example, Dr. Sharony notes that hypopnea events “can be detected by measuring breathing volume and blood oxygen saturation” (p17). He further notes, “Nevertheless, no matter what threshold is used, there is a need to measure the blood oxygen level to count hypopnea events” (p18). A medical professional would know that these are

overgeneralizations. While some hypopnea events can be detected with measures of breathing volume and blood oxygen saturation together, other hypopnea events require measures of sleep to detect arousals and would be missed, resulting in underestimations of the true burden of hypopneas. Dr. Sharony also notes that a “POSITA would have known that AHI, like hypopnea, can be determined by measuring both breathing volume and blood oxygen saturation.” (p19). Again, this is an oversimplification. Since hypopneas are counted within the measure of the AHI, a POSITA would know that measures of arousals from sleep are needed for accurate determination of an AHI.

IV. STATE OF THE ART

17. It is important to understand the state of the art in the November 2005 timeframe. In 2005, CPAP devices were already known and were much more prevalent in the clinical setting than APAP devices. APAP devices were very expensive in the United States and utilized more commonly in either during attended sleep studies or in the research settings at this time. Ex. 2024, pgs. 8-9.

18. CPAP delivered a constant level of air pressure throughout the night. A healthcare professional or an equipment provider using a prescription would set the device’s pressure settings based on the results of a sleep study (polysomnography). CPAP did not offer significant data tracking capabilities, and the data that was reported mainly concerned measures of CPAP usage (e.g. hours

of CPAP use per day). Measures of the residual severity of sleep apnea were not commonly reported in 2005, if at all. In addition, masks in 2005 were bulkier and less customizable which lead to discomfort and mask leaks, which could lead to suboptimal delivery of the prescribed therapeutic pressure and result in inadequate treatment of a person's sleep apnea. Since mask leaks were a problem in the industry, it was common practice to measure pressure at the mask delivered to a pressure sensor via a small tube to better maintain a fixed pressure which would treat a person's sleep apnea condition. Finally, there was no opportunity for real-time feedback based on physiological data assessed by a CPAP device, as any data that was obtained required that a person with sleep apnea bring their device in to their healthcare professional or equipment provider office for a manual analysis on-device or generation and review of a report.

19. At the time of the invention, ResMed and Philips Respironics were the two primary CPAP manufacturers, with Fisher & Paykel commanding a small market share. Despite being one of the largest manufacturers of CPAP equipment in the relevant timeframe, ResMed does not identify any art that has all elements of the claims of the '269 Patent.

20. As a clinician practicing in 2005, I can confirm what the lack of relevant prior art suggests: At the time of the invention, there were no integrated systems or methods of treatment using pulse oximeter or other physiological

signals used with sleep testing aside from measures of airflow and pressure, which analyzed a subject's sleeping disorder or symptoms and adjusted the treatment device based, on these additional signals on the market. Furthermore, arousal detection in the clinical setting was based on EEG signals. Ex. 2023, pg. 5. Arousals or wakefulness detection-based algorithms were neither studied nor available in PAP devices until at least 2009 or later. Ex. 2023, pgs. 1-2.

21. The '269 Patent, however, identified symptoms related to arousal that should be used as part of the hypopnea diagnosis. For example, the '269 Patent describes the use of "at least two EEG electrodes" for measuring the subject's brain wave signals, respirations, electro-physiological signals, and the like. '269 Patent, Col. 3:9-15, 4:5-25, 6:10-16. It also identifies utilizing sensors for diagnosing a subject's sleeping disorder and/or symptoms, including g a subject's electro-physiological signals, such as EEG, EKG, EMG, EOG. See e.g., '269 Patent, Col. 5:31-39.

22. It is also important to note that medical devices, including CPAP devices, require FDA approval in order to be sold in the United States. Accordingly, once a device has cleared the FDA approval process, a manufacturer would not want to introduce major changes to the device's design because this would require submission of the modifications to a 510(k) application for FDA review and approval. Ex. 2026. This process is very time consuming and costly.

V. OPINIONS

A. FDA Approval Requirements Undermines Dr. Sharony's Conclusory Opinion that it Would be Obvious to Modify an Existing Device as Proposed

23. The Federal Food, Drug, and Cosmetic Act (FDCA) defines a medical “device” as follows:

(1) The term “device” (except when used in paragraph (n) of this section and in sections 331(i), 343(f), 352(c), and 362(c) of this title) means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is—

(A) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them,

(B) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or

(C) intended to affect the structure or any function of the body of man or other animals, and

which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes. The term “device” does not include software functions excluded pursuant to section 360j(o) of this title.

21 U.S.C. § 321(h).

24. Some high-risk devices require premarket approval before they can be legally marketed. FDCA Section 515. Examples of high-risk devices include implantable pacemakers, neurostimulators, long-term ventilators. For medium-risk

devices, like CPAP devices, a product may be cleared using the relatively fast and inexpensive 510(k) process, but only if the new device is “substantially equivalent” to an already cleared device. Ex. 2027. Accordingly, medical device manufacturers are not motivated to consider substantial changes to an existing design absent a very compelling reason to make the modification.

25. I have reviewed Dr. Sharony’s opinion that there would be motivation for modifying Genger’s CPAP as the system claim requires it: “[p]roviding the airflow sensor *within* Genger’s CPAP device puts the airflow data where Genger wants it, and avoids the need to transmit airflow data from an external sensor or change external sensor batteries”). However, this explanation does not overcome the fundamental technical problem with accurately measuring pressure with the proposed modification discussed above. Dr. Sharony’s statement does not acknowledge the unexplained and unrecognized modifications necessary to implement Dr. Sharony’s allegedly obvious design change, which could trigger the need for a costly, time-consuming FDA process.

B. Dr. Sharony’s Opinions Regarding Stahmann are not Medically Accurate

26. I have reviewed Dr. Sharony’s testimony that Stahmann’s disclosure of providing drug therapy to treat disordered breathing would have motivated a POSITA to “adjust drug therapy... based on the detected sleep events and/or what

Stahmann calls ‘characteristics’ of such events like AHI” and find his opinion factually and medically inaccurate. Ex. 1004, ¶ 123.

27. In one embodiment, Stahmann discloses that when “central apnea is detected, small amounts of carbon dioxide may be applied to the patient's air supply (e.g., via a positive airway pressure device) to mitigate the carbon dioxide instability that is leading to central apnea.” Stahmann at 311: 21-27. As the Examiner recognized during prosecution of the '269 Patent, this disclosure did not satisfy the requirement of adjusting the level of CO₂ based on “the level of severity of the subject's sleep disorder.” Ex. 1002 at 283. This is because the level of severity of a patient’s sleep disorder symptoms is based on the detection of a certain number of sleep disordered breathing events over a period of time. For example, a single apnea event over the course of an entire night’s sleep could represent a very low level of severity, potentially resulting in a downward adjustment of the pharmaceutical agent. '269 Patent at 22:9-12 (“Various embodiments of the present invention include a device for physically or chemically treating a subject’s sleeping disorder, which can be adjusted using the output of the level of severity of the subject's sleeping disorder.”); *id.* 22:30-34 (“With the present invention it is envisioned that modifications can be made to a subject's treatment regiment as the severity or level or the subject's symptoms increase or

decrease better regulating the therapeutic treatment of the subject's sleeping disorder.”).

28. Stahmann discloses adjusting breathing therapy based on AHI (Ex. 1010 at 232) and adjusting a drug therapy based on the patient’s cardiopulmonary status (Ex. 1010 at 302). A medical professional would understand that treatments for different conditions are not interchangeable, so there is no medical basis undergirding Dr. Sharony’s attempt to suggest an “obvious” treatment for a sleep disorder based on the level of severity of the patient’s sleep disorder symptoms from the disclosure of providing drug therapy to a patient suffering from a cardiopulmonary disorder.

29. My conclusion that Dr. Sharony’s opinions on this issue are not adequately informed by education and experience is confirmed based on his misapplication of Edgar’s teachings to the question of obviousness. Edgar neither discloses adjusting a pharmaceutical agent based on the level of severity of the patient’s symptoms nor using a pharmaceutical agent in conjunction with a CPAP to treat a patient’s sleep disorder or its symptoms.

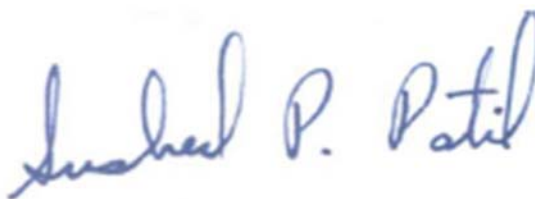
30. By way of background, masks in 2005 were bulkier and not always well fitted, which led to discomfort and mask leaks. Edgar, which is from that timeframe, discloses a method for administering doxepin, a sleep-promoting medication, to discourage the patient from intentionally or unintentionally

removing their mask during CPAP treatment. Ex. 1011 ¶ 0007; *id.* at ¶¶ 0032-0033 (administering doxepin analogs to encourage sleep). This intervention allows the patient to fall asleep faster, increases maximum sleep, and makes it less likely that the patient will remove the CPAP mask during treatment. *Id.* at ¶ 0406-0408.

31. A medical professional would understand that Edgar primarily addresses a different problem than the one solved by the claimed invention—namely, that patients would often remove the CPAP device while sleeping due to discomfort. As Edgar teaches, doxepin could be administered to improve the likelihood that the patient kept the mask on all night. See Edgar at Paragraphs 0406-0408. In this case, the treatment for the patient’s sleep disorder or symptoms was the positive pressure provided by the CPAP, not the doxepin.

I declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true, and that these statements were made with knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code.

Executed on the 29th day of July, 2024 in Cleveland, OH.



Susheel Pandit Patil, MD, PhD

APPENDIX A

Case Western Reserve University School of Medicine
Curriculum Vitae – Susheel P. Patil, M.D., Ph.D.

Susheel P. Patil, M.D., Ph.D.
November 27th, 2023

PERSONAL INFORMATION

Name: Patil, Susheel Pandit
Credentials: MD, PhD

Institution: Department of Medicine
Division of Pulmonary, Critical Care & Sleep Medicine
University Hospitals of Cleveland
Bolwell Building, Room 6125
11100 Euclid Avenue
Cleveland, OH 44106
Telephone: (216) 844-1867
Fax: (216) 844-2187
E-mail: susheel.patil@uhhospitals.org

Current Appointments:

2021– present	Clinical Associate Professor of Medicine Department of Medicine Case Western Reserve University
2021 – present	UH System Director of Sleep Medicine University Hospitals of Cleveland
2021 – present	Section Chief, Sleep Medicine Department of Medicine Division of Pulmonary, Critical Care, & Sleep Medicine University Hospitals of Cleveland

EDUCATION AND TRAINING (in chronological order):

Education

<u>Year</u>	<u>Institution</u>	<u>Discipline</u>
Bachelor of Science 06/1991 – 06/1993	Pennsylvania State University State College, Pennsylvania	General Science

Medical Degree 06/1993 – 06/1995	Jefferson Medical College Philadelphia, Pennsylvania	Medicine
Doctor of Philosophy 07/2000 – 07/2007	Johns Hopkins Bloomberg School of Public Health Graduate Training Program in Clinical Investigation Baltimore, Maryland	Clinical Investigation

PhD Thesis

The Contribution of Neuromechanical Mechanisms to the Pathogenesis of Upper Airway Obstruction During Sleep (2007)

Committee Members: Jonathan Samet, MD, MS (Advisor); Alan R. Schwartz, MD; Clarke Tankersley, PhD; Naresh Punjabi, MD, PhD; Frederick Brancati, MD, MHS; Philip L. Smith, MD

Post-Graduate Training

<u>Year</u>	<u>Institution</u>	<u>Discipline</u>
06/1995 – 07/1996	Department of Medicine University Hospitals of Cleveland Case Western Reserve University Cleveland, Ohio	Internship, Internal Medicine
07/1996 – 07/1998	Department of Medicine University Hospitals of Cleveland Case Western Reserve University Cleveland, Ohio	Residency, Internal Medicine
07/1998 – 06/1999	Department of Medicine University Hospitals of Cleveland Case Western Reserve University Cleveland, Ohio <i>Research Mentoring: Regis McFadden, asthma</i>	Chief Residency, Internal Medicine
06/1999 – 07/2004	Division of Pulmonary and Critical Care Medicine Department of Medicine The Johns Hopkins University School of Medicine Baltimore, MD <i>Research Mentoring: Alan R. Schwartz/Flip Smith, OSA pathogenesis</i>	Fellowship, Pulmonary, Critical Care and Sleep Medicine

ACADEMIC APPOINTMENTS

<u>Dates</u>	<u>Institutions</u>	<u>Position</u>
9/1/2021 - present	University Hospitals of Cleveland/ Case Western Reserve University Department of Medicine Division of Pulmonary, Critical Care, & Sleep Medicine	Clinical Associate Professor of Medicine
9/1/2021 – present	Senior Attending Physician University Hospitals of Cleveland Department of Medicine Division of Pulmonary, Critical Care, & Sleep Medicine	
4/1/2008 – 8/31/2021	Johns Hopkins School of Medicine Department of Medicine Division of Pulmonary & Critical Care Medicine Baltimore, MD	Assistant Professor of Medicine
7/1/2004 – 3/31/2008	Johns Hopkins School of Medicine Department of Medicine Division of Pulmonary & Critical Care Medicine Baltimore, MD	Instructor
7/1/1998 – 6/30/1999	Department of Medicine University Hospitals of Cleveland Case Western Reserve University Cleveland, Ohio	Senior Clinical Instructor

PROFESSIONAL APPOINTMENTS

09/2021 – present	System Director, Sleep Medicine University Hospitals of Cleveland
09/2021 – present	Section Chief, Sleep Medicine Department of Medicine Division of Pulmonary, Critical Care, & Sleep Medicine University Hospitals of Cleveland
2019 – 2021	Medical Director, Johns Hopkins Bayview Sleep Disorders Laboratory

07/2014 – 07/2017	Physician Lead, JHM Integrated Sleep Medicine Baltimore, MD
2013 – 2017	Medical Director, Johns Hopkins Hospital Sleep Disorders Laboratory
08/2010 – 08/2021	Clinical Director, The Johns Hopkins Sleep Medicine Program Division of Pulmonary and Critical Care Medicine

Staff Physician Appointments

05/2021 – 08/2021	Sibley Memorial Hospital Temporary appointment	Staff Physician
01/2021 – 08/2021	Kennedy Krieger Institute Provisional appointment for 6 months	Staff Physician
10/2004 – 08/2021	Johns Hopkins Hospital Baltimore, Maryland	Staff physician
10/2004 – 08/2021	Johns Hopkins Bayview Medical Center Baltimore, Maryland	Staff physician
02/1999 – 06/1999	Louis Stokes Cleveland VA Medical Center Cleveland, Ohio	Staff physician
06/1998 – 06/1999	University Hospitals of Cleveland Cleveland, Ohio	Staff physician

CERTIFICATION AND LICENSURE

Certification (Exams, Boards, other specialty certification):

Boards, other specialty certification:

1993	USMLE (#4-032-250-5), Step 1 (June 1993)
1994	USMLE (#4-032-250-5), Step 2 (August 1994)
1996	USMLE (#4-032-250-5), Step 3 (December 1996)
1999	Diplomate in Internal Medicine (August 1999) The American Board of Internal Medicine (lapsed in 2009)

2003	Diplomate, American Board of Sleep Medicine
2004	Diplomate in Pulmonary Disease (November 2004) The American Board of Internal Medicine Renewed: November 2014
2005	Diplomate in Critical Care Medicine (November 2005) The American Board of Internal Medicine Renewed: November 2015
2007	Diplomate in Sleep Medicine (November 2007) The American Board of Internal Medicine Renewed: November 2017
<u>Licensure:</u>	
1997 – 2000	Ohio - #35-07-3617 (10/10/1997 – 4/1/2000)
2000 – present	Maryland #D0058637 (5/1/2002 – present)
2021 – present	District of Columbia #MD048941 (3/17/21 – 12/31/22)
2021 – present	Florida Telehealth License #TPME1726 (6/1/21 – present)

MEMBERSHIP IN PROFESSIONAL SOCIETIES

Memberships

1996 – 2001	Associate Member American College of Physicians/ American Society of Internal Medicine
2000 – present	Member, American College of Chest Physicians
2000 – present	Member, American Thoracic Society Fellow, American Thoracic Society (ATSF)
2001 – present	Fellow, American Academy of Sleep Medicine (FAASM)
2002 – 2007	Member, American Federation of Medical Research
2008 – present	Member, Sleep Research Society

PROFESSIONAL SERVICES

Editorial Board Membership

2008, 2010, 2012, 2021	Contributor, Self-Education and Evaluation of Knowledge (SEEK) in Sleep Medicine, Editions 1-3, and 5
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American College of Chest Physicians

2009 – 2011	Co-Editor, Sleep Fragments Product of the Sleep and Respiratory Neurobiology Assembly of the American Thoracic Society
2015 – 2019	Editorial Board, CHEST
2019 – present	Associate Editor, CHEST (Sleep Medicine section)

Manuscript Reviewer

2005 – 2014	Peer reviewer for International Journal of Obesity and Related Metabolic Disorders
2006 – 2021	Peer reviewer for Journal of Applied Physiology
2008 – 2019	Peer reviewer for European Respiratory Journal and CHEST

Study Sections/Grant Review Committees

2010	Working Group Consultant for the NIH Sleep Disorders Research Advisory Board in preparation of the 5-year strategic plan for the National Center for Sleep Disorders Research
2013	Member, 2013 Humanitarian Projects Grant Review Committee American Sleep Medicine Foundation
2014	Ad-Hoc Reviewer, Special Emphasis Panel Ancillary Studies in Clinical Trials (HL-14-004) August 22 nd , 2014
2017	Ad-Hoc Reviewer, Special Emphasis Panel Sleep Health and Circadian Biology in HIV-Related Comorbidities (HL-18-005) December 5, 2017
2015 - 2018	Review Committee for Career Development Awards American Academy of Sleep Medicine Foundation
2015 2017, 2018	Review Committee for Focused Projects Awards for Junior Investigators American Academy of Sleep Medicine Foundation

2020	Committee Member Clinical Fellowship Rescue Funding Award Review Committee American Academy of Sleep Medicine Foundation
2021	Ad-Hoc Reviewer, Department of Veteran Affairs VA Office of Research and Development Rehabilitation Research and Small Projects in Rehabilitation Research (SPiRE) (I21) April 22, 2021

Advisory Group
NA

COMMITTEE SERVICE

International

2005	Scientific Program Committee Respiratory Neurobiology & Sleep Assembly 2006 American Thoracic Society International Conference
2006	Scientific Program Committee Respiratory Neurobiology & Sleep Assembly 2007 American Thoracic Society International Conference
2008	Scientific Program Committee Respiratory Neurobiology & Sleep Assembly 2008 American Thoracic Society International Conference
2008-2009	Nominating Committee Sleep and Respiratory Neurobiology Assembly American Thoracic Society
2009 - 2011	Sleep and Respiratory Neurobiology Assembly Website Co-Director American Thoracic Society
2009 – 2019, 2021 – 2022	Sleep and Respiratory Neurobiology Assembly Executive Committee Committee Member American Thoracic Society
2011 - 2013	Chair-Elect and Chair

	Scientific Program Committee for the Sleep and Respiratory Neurobiology Assembly American Thoracic Society
2013 – 2022	Sleep and Respiratory Neurobiology Assembly Planning Committee Committee Member American Thoracic Society
2013 - 2014	Member, Scientific Program Committee Respiratory Neurobiology & Sleep Assembly 2014 American Thoracic Society International Conference
2013 - 2017	Chair-Elect and Chair Sleep and Respiratory Neurobiology Assembly American Thoracic Society
2015 – 2017	Board of Directors American Thoracic Society
2017 - 2019	Member, Task Force – Obesity Hypoventilation Syndrome: Evidence-Based Guidelines for Evaluation and Management American Thoracic Society
2020 - present	Committee Member International Classification of Sleep Disorders, 3 rd edition (ICSD-3) Revision Task Force American Academy of Sleep Medicine
2021	Writing Group Chair Multi-Society Chair, Response to Agency of Healthcare Related Quality Draft Report on “Continuous Positive Airway Pressure Treatment for Obstructive Sleep Apnea American Academy of Sleep Medicine Representative <i>Comment: I was asked to chair an international, multi-society response to the above report which has potential negative implications for the care of patients with obstructive sleep apnea.</i> https://j2vjt3dnbra3ps7ll1clb4q2-wpengine.netdna-ssl.com/wp-content/uploads/2021/04/ahrq-cpap-sleep-apnea-report-comment-letter.pdf
2021 – 2023	Chair, Sleep and Respiratory Neurobiology Assembly Advocacy Committee American Thoracic Society

National

2006 – 2013	National Sleep Awareness Roundtable American Thoracic Society Representative
2006 – 2009	Steering Committee, Vice Chair Sleep-Related Breathing Disorders Section American Academy of Sleep Medicine
2007 - 2009	Committee Member Task Force for the Clinical Guideline on the Evaluation and Management of Adult Obstructive Sleep Apnea American Academy of Sleep Medicine
2009 – 2012	Steering Committee Member Sleep-Related Breathing Disorders Section American Academy of Sleep Medicine
2012 – 2013	Member, Research Committee American Academy of Sleep Medicine Committee Member
2012 – 2018	American Board of Internal Medicine (ABIM) Sleep Medicine Test-Writing Committee Committee Member
2013-2015	Committee Member, Pulmonary Fellows Education Committee Meeting Development of Problem Based Learning Modules American Thoracic Society
2013-2015	Committee Member, Pulmonary Fellows Education Committee Meeting Development of Problem Based Learning Modules American Thoracic Society
2014	Committee Member, Sleep Tracing Maintenance of Certification Module American Thoracic Society
2013 - 2017	Member, Task Force – Impact of Mild Obstructive Sleep Apnea in Adults American Thoracic Society

2013 – 2019	Chair, Positive Airway Pressure Guideline Task Force American Academy of Sleep Medicine
2015 – 2017	Committee Member, Sleep and Transportation Safety Awareness Task Force American Academy of Sleep Medicine
2016 – 2017	Mentor, American Thoracic Society Mentoring Program
2016 – 2018	Committee Member, Sleep Fellowship Models Exploratory Committee American Academy of Sleep Medicine
2016 – 2019	Committee Member, Payor Policy Review Committee American Academy of Sleep Medicine
2018	Participant, Food and Drug Administration (FDA) - Public Workshop - Study Design Considerations for Devices Including Digital Health Technologies for Sleep Disordered Breathing in Adults – “Current Definitions of SDB” April 16, 2018 <i>Comments: Provided expertise on current approaches to defining sleep disordered breathing as part of a large panel of experts giving the FDA guidance as they consider how to evaluate new digital technologies for diagnosing sleep disordered breathing</i> (https://www.fda.gov/medical-devices/workshops-conferences-medical-devices/public-workshop-study-design-considerations-devices-including-digital-health-technologies-sleep#documents)
2019	Participant, Network of Experts Food and Drug Administration (FDA) Center for Devices and Radiological Health American College of Chest Physicians Representative March 1 st , 2019 <i>Comments: Asked to provide expertise regarding the assessment of effectiveness outcomes of sleep disordered breathing devices; specifically, the type of validation studies that might be appropriate to evaluate these new technologies, success criteria, and clinically meaningful differences, as well as risks and benefits of these tools</i>
2019 – 2021	Novitas Solutions Medicare Contract Advisory Committee AASM representative <i>Comment: Provide expertise on pulmonary and sleep-related matters to the organization that administers one of the local</i>

coverage determinations for the Center for Medicare and Medicaid Services

- 2019 Subject Matter Expert on Hypoglossal Nerve Stimulation policy to the Novitas Solutions Medicare Contract Advisory Committee June 13, 2019
Comment: I reviewed the literature regarding HGNS and served as a subject matter expert to the Medicare CAC in developing the policy on HGNS that will be effective for all Medicare patients
- 2020 Optimal NIV Medicare Access Proposal and Technical Expert Panel.
Co-Chair, Section on Bilevel Transition from CPAP- When Therapeutic Benefit Was Not Achieved
October 3rd, 2020
Comment: This Technical Expert Panel was convened for Medicare to review and recommend changes to the National Coverage Determination for Respiratory Assist Devices.
- 2021 - present Task Force Member
Clinical Practice Guideline, Diagnosis and Management of SDB in Inpatient Settings
American Academy of Sleep Medicine
- 2022 - present American Board of Internal Medicine (ABIM) Pulmonary Disease Approval Committee
Committee Member
- 2023 – present Board of Directors
American Academy of Sleep Medicine
- 2023 Chair, Writing Group
Multi-Society Commentary on Agency for Healthcare Research And Quality (AHRQ) Report on Treatment of OSA with CPAP – Response from the AASM, SRS, CHEST, and ATS

Regional

- 2010 – 2020 Board Member
Maryland Sleep Society
- 2010 – present Polysomnography Professional Standards Committee Member
Maryland Board of Physicians
- 2014 – 2017 Chair, Polysomnography Professional Standards Committee

Maryland Board of Physicians

2017 – 2019

President, Maryland Sleep Society

Hospital Affiliate

1997 - 1998

Co-Chair
Association of Residents and Fellows
University Hospitals of Cleveland

1997 - 1998

Resident member
Graduate Medical Education Council
University Hospitals of Cleveland

2005 - 2006

Committee member, Lung Research Conference
Pulmonary and Critical Care Division
Johns Hopkins University

2008 – 2013

Clinical Operations Committee
Pulmonary and Critical Care Division
Johns Hopkins University

Educational Committees

NA

HONORS & AWARDS

1984

Eagle Scout

1992

Commendation for Community Service
“Bridging the Gaps”
Presented by the Mayor of Philadelphia

2002

Henry Christian Award
Presented by the American Federation of Medical Research

2002

Trainee Research Merit Award
Associated Professional Sleep Society
June 2002

2003

Henry Christian Award
Presented by the American Federation of Medical Research

2003

Clinical Research 2003 Outstanding Junior

Investigator Award
Presented by Clinical Research 2003 Conference
Baltimore, MD

2004 Young Investigator Honorable Mention Award
Presented by the American Academy of Sleep Medicine
June 2004

EDUCATIONAL ACTIVITIES

Teaching:

1998 – 1999	Morning Report Department of Medicine University Hospitals of Cleveland Case Western Reserve University Cleveland, Ohio
1998 – 1999	Morbidity and Mortality Conferences Department of Medicine University Hospitals of Cleveland Case Western Reserve University Cleveland, Ohio
1998 – 1999	Morbidity and Mortality Conferences Department of Medicine Louis Stokes Cleveland VA Medical Center Cleveland, Ohio
2005	Clinical Skills Course, 3 rd quarter Instructor Johns Hopkins School of Medicine Baltimore, Maryland
2008 – 2016	Sleep Medicine Fellowship Associate Program Director Johns Hopkins University
2016 – 2021	Sleep Medicine Fellowship Program Director Johns Hopkins University

RESEARCH ACTIVITIES

Inventions, Patents, Copyrights: N/A

SYSTEM INNOVATION AND QUALITY IMPROVEMENT ACTIVITIES

NA

ORGANIZATIONAL ACTIVITIES

Institutional Administrative Appointments:

2010 – present	Clinical Director, The Johns Hopkins Sleep Medicine Program Division of Pulmonary and Critical Care Medicine
2013 – 2017	Medical Director, Johns Hopkins Hospital Sleep Disorders Center
2013 – 2017	Physician Lead, Johns Hopkins Medicine, Integrated Sleep Medicine Program
2019 – 2021	Medical Director, Johns Hopkins Bayview Sleep Disorders Center

Conference Organizer/Session Chair

2006	“Obesity in Clinical Practice” Co-chair (Clinical Topics in Pulmonary Medicine) American Thoracic Society International Conference San Diego, CA May 22 nd , 2006
2006	“Sleep, Breathing, and Metabolic Function” Co-Chair (Scientific Symposia) American Thoracic Society International Conference San Diego, CA May 24 th , 2006
2007	“Non-pulmonary Sleep Medicine for the Pulmonary Physician” Co-Chair (Post-graduate Course) American Thoracic Society International Conference San Francisco, CA May 19 th , 2007

- 2007 “The Clinical Significance of REM-related Obstructive Sleep Apnea – An Epiphenomena or A Real Disease?”
Co-chair (Symposium)
Associated Professional Sleep Societies
Minneapolis, MN
June 11, 2007
- 2008 “Quantitative Analysis of Sleep – Exploring Complementary Paradigms to Visual Based Scoring”
Chair (Symposium)
Associated Professional Sleep Societies
Baltimore, MD
June 9th, 2008
- 2009 “Comprehensive Update In Sleep Medicine” (2 day course)
Co-Chair (Post-graduate Course)
American Thoracic Society International Conference
San Diego, CA
May 15-16th, 2009
- 2011 “Obesity: Clinical Implications for the Clinical Practice of the Pulmonary, Critical Care, and Sleep Physician”
Co-Chair, Scientific Symposia
American Thoracic Society International Conference
Denver, CO
May 16th, 2011
- 2013 “Measures of Sleep Disordered Breathing – Severity and Health-Related Outcomes”
Co-Chair (Post-graduate Course)
Course Faculty with Hands-On Session
American Thoracic Society International Conference
Philadelphia, PA
May 18th, 2013
- 2013 “Controversies in sleep apnea pathophysiology: An expert debate”
Co-Chair (Scientific Symposia)
American Thoracic Society International Conference
Philadelphia, PA
May 20th, 2013
- 2015 “For Success Choose the Best: New Tools for Identifying Sleep Disordered Breathing”
Co-Chair, Poster Discussion Session
American Thoracic Society International Conference 2015

Denver, CO
May 20th, 2015

- 2016 “Bench to Bedside: Translational Science in Sleep Disordered Breathing”
Co-Chair, Poster Discussion Session
American Thoracic Society International Conference 2016
San Francisco, CA
May 18th, 2016
- 2016 “The Best of Everything: Hot Topics in Sleep Medicine”
Co-Chair, Mini-Symposia
American Thoracic Society International Conference 2016
San Francisco
May 18th, 2016
- 2017 “Management of Sleep Disordered Breathing”
Lead Discussion Facilitator, Thematic Poster Session
American Thoracic Society International Conference 2017
Washington D.C.
May 23rd, 2017
- 2018 “Diagnosis and Treatment of Sleep Disordered Breathing”
Lead Discussion Facilitator, Thematic Poster Session
American Thoracic Society International Conference 2018
San Diego, CA
May 21st, 2018
- 2021 Panel Discussion on Long-term Outcomes Research in OSA
Session Chair
SLEEP 2021 – Virtual Conference
June 13th, 2021
- 2022 Critical Decisions and Steps Before the Next Big Trial of CPAP
Session Co-Chair
American Thoracic Society International Conference 2022
San Francisco, CA
May 15th, 2022

- | | |
|------|--|
| 2023 | <p>Risky Business: Predicting Consequences of OSA
 Session Moderator
 American Thoracic Society International Conference 2023
 Washington DC
 May 2023</p> |
| 2023 | <p>Time to Rethink CPAP Therapy: A Review of the AHRQ Report and Future Directions
 Session Speaker
 SLEEP 2023
 Indianapolis, IN
 June 7, 2023</p> |
| 2023 | <p>Big Data in Sleep Apnea, New Approaches to Address Research Questions and Improve the Patient Experience
 Session Moderator
 SLEEP 2023
 Indianapolis, IN
 June 7, 2023</p> |

Invited Talks, Panels:

1. “Neuromechanical Control of Upper Airway Obstruction During Sleep”. April 5th, 2004, Pulmonary, Critical Care, and Sleep Medicine Grand Rounds. Wayne State University.
2. “Neuromechanical Control of Upper Airway Obstruction During Sleep”. April 19th, 2004, Division of Pulmonary and Critical Care. Invited Speaker. Oregon Health Sciences University.
3. “Neuromechanical Control of Upper Airway Obstruction During Sleep”. April 23rd, 2004, Division of Pulmonary and Critical Care. Invited Speaker. MetroHealth Hospitals.
4. “Contribution of Neuromechanical Properties to Upper Airway Collapse”. November 15th, 2004, Division of Sleep Medicine. Invited Speaker. Brigham and Women’s Hospital.
5. “The Obesity Epidemic: A Pulmonologist’s Perspective”. Session: “Obesity in Clinical Practice”. American Thoracic Society 2007 International Conference. May 22nd, 2006. San Diego, CA
6. “Upper Airway Control in Sleep Apnea”. New Horizons in Sleep III. June 9th, 2006. University of Maryland. Invited Speaker. Baltimore, MD.
7. “The Basis of Clinical CPAP Titration”. Meet the Professor Symposia. Association of Professional Sleep Societies 2006 International Conference. June 19th, 2006. Salt Lake City, UT
8. “Sleep Disordered Breathing: Parsing the Upper Airway and Ventilatory Phenotypes”. Session: Beyond the Apnea-Hypopnea Index: New Approaches for Quantifying Sleep Related Breathing

Disturbances. Association of Professional Sleep Societies 2006 International Conference. June 20th, 2006. Salt Lake City, UT.

9. “Central and Obstructive Sleep Apnea: Clinical Characteristics And Therapeutic Interventions”. Oral Presentations Chair. Association of Professional Sleep Societies 2006 International Conference. June 19th, 2006. Salt Lake City, UT.
10. “Pathophysiology of Adult Sleep Disordered Breathing” Session: 5th Pulmonary Fellows in Sleep Training Conference. CHEST 2006 International Conference. October 21st, 2006. Salt Lake City, UT.
11. “Transitioning From Fellowship to Junior Faculty in a Sleep Medicine Career” Session: 5th Pulmonary Fellows in Sleep Training Conference. CHEST 2006 International Conference. October 21st, 2006. Salt Lake City, UT.
12. “Management of the Patient Using Continuous Positive Airway Pressure After the Sleep Study” Session: Sleep Medicine for the Sleep-Challenged Chest Physician. CHEST 2006 International Conference. October 21st, 2006. Salt Lake City, UT.
13. “Obstructive sleep apnea – Parsing the Upper Airway”. February 23rd, 2007, Pulmonary and Critical Care Medicine Grand Rounds. University Hospitals of Cleveland, Cleveland, OH
14. “Obstructive sleep apnea – Parsing the Upper Airway During Sleep”. November 30th, 2007, Scripps Clinic Sleep Center Conference, Scripps Clinic, La Jolla, CA.
15. “Pulmonary and Cardiovascular Physiology during Sleep”. National Sleep Medicine Course 2008. August 8th – 10th, 2008. Chicago, IL.
16. “Pathogenesis and Outcomes Related to Sleep Apnea”. National Sleep Medicine Course 2008. August 8th – 10th, 2008. Chicago, IL.
17. “Technical aspects of sleep testing”. American College of Chest Physicians Sleep Medicine Board Review. Aug 22nd, 2008. Orlando, FL.
18. “Excessive daytime sleepiness: medicolegal aspects”. American College of Chest Physicians Sleep Medicine Board Review. Aug 24th, 2008. Orlando, FL.
19. “Polysomnography: Technical Aspects and Artifacts”. Session: Comprehensive Update in Sleep Medicine (Post-graduate Course) American Thoracic Society 2009 International Conference. May 15th, 2009. San Diego, CA.
20. “Obesity-Related Mechanisms in the Pathogenesis of Upper Airway Collapsibility”. Featured Speaker for Session. American Thoracic Society 2009 International Conference. May 20th, 2009. San Diego, CA.

21. "The Influence of Weight Loss on Respiratory and Upper Airway Physiology". Session: Burgers, Bedtime and Breathing: Why Ventilation Fails in the Sleeping Obese Patient. American Thoracic Society 2009 International Conference. May 20th, 2009. San Diego, CA.
22. "Recent Advances in Sleep and Breathing". Session: SLEEP 2009 Year in Review (Post-graduate Course). Association of Professional Sleep Societies 2006 International Conference. June 19th, 2006. Seattle, WA.
23. "Technical aspects of sleep testing". American College of Chest Physicians Sleep Medicine Board Review. Aug 21st, 2009. Phoenix, AZ.
24. "Excessive daytime sleepiness: medicolegal aspects". American College of Chest Physicians Sleep Medicine Board Review. Aug 22nd, 2009. Phoenix, AZ.
25. "Polysomnography and Practice Parameters Trivia Session". American College of Chest Physicians Sleep Medicine Board Review. Aug 22nd, 2009. Phoenix, AZ.
26. "Effects of Surgical Weight Loss on Obstructive Sleep Apnea". Invited Speaker – 1st Annual Virginia Academy of Sleep Medicine Meeting. October 9th, 2009. Charlottesville, VA.
27. "What Every Clinical Should Know About Polysomnography". Invited Speaker – 45th Respiratory Care Journal Conference – Sleep Disorders: Diagnosis and Treatment. December 10th, 2009. San Antonio, TX.
28. "Overview of Sleep Disordered Breathing – Statement of the Problem" as part of the "Respiratory Neurobiology – What is the Latest?" postgraduate course. American Thoracic Society 2010 International Conference May 15th, 2010. New Orleans, LA.
29. "Bariatric Surgery and OSA – A Weighty Matter". Invited Speaker – 1st Annual Maryland Sleep Society Meeting. May 22, 2010. Baltimore, MD.
30. "Excessive Sleepiness – Medicolegal Aspects and Countermeasures" as part of the "Best Practices in Sleep Medicine" postgraduate course. Association of Professional Sleep Societies International Conference. June 5th, 2010. San Antonio, TX.
31. "Technical aspects of sleep testing". American College of Chest Physicians Sleep Medicine Board Review. Aug 27th, 2010. Orlando, FL.
32. "Excessive daytime sleepiness: medicolegal aspects". American College of Chest Physicians Sleep Medicine Board Review. Aug 28th, 2010. Orlando, FL.
33. "Polysomnography and Practice Parameters Trivia Session". American College of Chest Physicians Sleep Medicine Board Review. Aug 28th, 2010. Orlando, FL.
34. "Upper Airway Collapse and the Utility of Pcrit". 2011 American Thoracic Society State of the Art Course in Sleep Medicine. March 5th, 2011. San Diego, CA.

35. "Sleep, Fatigue, and Work Performance: The Rationale Behind Resident Duty Hours". Medical Grand Rounds. Johns Hopkins Hospital. March 18th, 2011.
36. "Sleep Disordered Breathing". 56th Annual Philip A. Tumulty Topics in Clinical Medicine. May 4th, 2011. Baltimore, MD
37. "Commercial Motor Vehicle Drivers: Waking Up to Sleep Apnea". 2nd Annual Maryland Sleep Society Meeting. May 20th, 2011. Baltimore, MD
38. "Sleep Disordered Breathing". 2011 Mid-Atlantic Current Clinical Issues in Primary Care Conference (Prim-Med). August 4th, 2011. Baltimore, MD
39. Technical aspects of sleep testing". American College of Chest Physicians Sleep Medicine Board Review. Aug 26th, 2011. San Antonio, TX.
40. "Excessive daytime sleepiness: medicolegal aspects". American College of Chest Physicians Sleep Medicine Board Review. Aug 27th, 2011. San Antonio, TX.
41. "Polysomnography and Practice Parameters Trivia Session". American College of Chest Physicians Sleep Medicine Board Review. Aug 27th, 2011. San Antonio, TX.
42. "The Best of the ATS Fragments Workshop". 2011 American Thoracic Society State of the Art Course in Sleep Medicine. March 5th, 2011. San Diego, CA.
43. "Bariatric Surgery and Sleep Apnea – A Hefty Matter". Invited Speaker at Jefferson Medical College. March 23rd, 2012. Philadelphia, PA.
44. "Sleep and Sleep Disorders" GE HealthAhead Program webinar presentation. April 19th, 2012 (online).
45. "Obstructive Sleep Apnea and Driving Safety". 2012 American Thoracic Society Fellows Track Symposium at the 2012 American Thoracic Society International Conference. May 18th, 2012. San Francisco, CA.
46. "Management of Sleep Disordered Breathing: Special Populations and Modalities: Novel Therapies for Obstructive Sleep Apnea". 26th Annual Meeting of the Associated Professional Sleep Societies. June 9th, 2012, Boston, MA.
47. "Pre-operative Evaluation of OSA: When Can Home Sleep Testing Replace In-lab Testing?" 2012 Society of Anesthesia and Sleep Medicine Annual Meeting. October 11th, 2012, Washington, D.C.
48. "Obstructive Sleep Apnea and Weight Loss: Why Does OSA Get Better? Implications for Sleep Apnea Pathogenesis". Sleep Medicine Grand Rounds. University of Pittsburgh School of Medicine. December 6th, 2012. Pittsburgh, PA.

49. “Effects of Sleep Apnea and Sleep Loss on Driving Performance”. 22nd Annual Meeting of the American Academy of Dental Sleep Medicine. June 1st, 2013. Baltimore, MD.
50. “Limitations of Portable Monitoring”. Panel Discussion: Portable Monitoring for Sleep Apnea. CHEST 2013. October 29th, 2013. Chicago, IL.
51. “Update in Sleep Medicine: Novel Therapies for OSA”. Johns Hopkins: Update and Board Review Pearls in Pulmonary and Critical Care Medicine”. August 7th, 2013: Cambridge, MD
52. “Sleep Disordered Breathing and Cardiovascular Disease – An Update”. Johns Hopkins Hospital Cardiology Grand Rounds. January 22nd, 2014: Baltimore, MD.
53. “Old, New, and Novel Treatments for Obstructive Sleep Apnea: It’s Not all CPAP”. Saint Agnes Hospital: Medical Grand Rounds. January 23rd, 2014: Baltimore, MD.
54. “Old, New, and Novel Treatments for Obstructive Sleep Apnea: It’s Not all CPAP”. Boston University: Medical Grand Rounds. February 13th, 2014: Boston, MA.
55. “How to Manage Non-Adherence: Strategies and Multidisciplinary Alternatives to CPAP”. American Academy of Sleep Medicine Winter Course: Emerging Clinical and Business Trends in Sleep Medicine. February 21st, 2014: Phoenix, AZ.
56. “Pro: Is Complex Sleep Apnea Fact or Fiction – A Pro-Con Debate”. American Academy of Sleep Medicine Winter Course: Emerging Clinical and Business Trends in Sleep Medicine. February 21st, 2014: Phoenix, AZ.
57. ““Old, New, and Novel Treatments for Obstructive Sleep Apnea: It’s Not all CPAP”. Johns Hopkins Bayview Medical Center: Medical Grand Rounds. March 25th, 2014: Baltimore, MD.
58. “Upper Airway and Respiratory Control During Sleep and Non-Pulmonary Sleep Disorders”. Facilitator- Thematic Poster Session. American Thoracic Society International Conference 2014. May 20, 2014: San Diego, CA.
59. “Consumer Directed Technology for the Management of Sleep Disorders and Advances in Non-PAP Treatments for OSA”. PG Course: Gizmos and Gadgets: Using Technology to Enhance the Care of Patients with Sleep Disorders. SLEEP 2014. June 1st, 2014: Minneapolis, MN.
60. “Anesthesia in the Sleep Apnea Patient: What Should the Clinician Know?”. Virginia Academy of Sleep Medicine Annual Conference. November 14th, 2014: Richmond, VA.
61. “What to Do With All That Download Data”. American Academy of Sleep Medicine Sleep Medicine Trends 2015. February 21st, 2015: Scottsdale, AZ.
62. “Con: OSA Should Not Be Treated First”. American Academy of Sleep Medicine Sleep Medicine Trends 2015. February 21st, 2015: Scottsdale, AZ.

63. “Con: A Full Face Mask Should Be Used as a First Line Interface for OSA”. Maryland Sleep Society Annual Meeting. April 25th, 2015: Baltimore, MD
64. “What A Respiratory Care Practitioner Needs to Know About Sleep Medicine”. Johns Hopkins Bayview Medical Center Annual Respiratory Conference. May 8th, 2015: Baltimore, MD
65. “Adaptive Servoventilation in Heart Failure”. 8th Annual Virginia Academy of Sleep Medicine Conference. November 13th, 2015: Richmond, VA.
66. “Novel Therapies for Obstructive Sleep Apnea”. PG Course: Management of Sleep Disordered Breathing: Special Populations and Technologies. SLEEP 2015. June 7th, 2015: Seattle, WA
67. “What a Busy Internist Should Know About Sleep Apnea”. Annual Scientific Meeting of the Maryland Chapter of the American College of Physicians. January 29th-30th, 2016: Ellicott City, MD.
68. “Severity Markers of OSA – Assessing AHI, RDI, and ODI”. American Academy of Sleep Medicine Sleep Medicine Trends 2016. February 14, 2016: Phoenix, AZ.
69. “Home Sweet Home: Does Home Sleep Apnea Testing Replace Traditional Testing?”. Medical Grand Rounds. Johns Hopkins Hospital. April 8th, 2016.
70. “Obstructive Sleep Apnea and Weight Loss: a Hefty Matter”. Pulmonary and Critical Care Grand Rounds. University of Pittsburgh Medical Center. April 22nd, 2016.
71. “Adaptive Servoventilation in Heart Failure: Time to Rethink Our Approach?”. Johns Hopkins Bayview Medical Center Annual Respiratory Conference. May 6th, 2016: Baltimore, MD
72. “The Monitored Self and Sleep”. PG Course: Trends in Sleep Medicine. SLEEP 2016. June 11th, 2016: Denver, CO
73. “Bedtime Stories”. A Women’s Journey; Johns Hopkins Medicine 2016 Annual Meeting. November 5th, 2016: Baltimore, MD.
74. “Clinical Practice Guidelines: Diagnostic Testing for OSA and PAP Therapy”. American Academy of Sleep Medicine Sleep Medicine Trends 2017. February 18, 2017: Phoenix, AZ.
75. “Hands On Session: Understanding Advanced PAP Devices”. American Academy of Sleep Medicine Sleep Medicine Trends 2017. February 18, 2017: Phoenix, AZ.
76. “Sleep Testing: Who, What, Where, When, Why, and How?”. 62nd Annual Tumulty Topics in Clinical Medicine”. May 11th, 2017: Johns Hopkins University, Baltimore, MD.
77. “Pathogenesis of Obstructive Sleep Apnea in Obesity”. Session: Interactions Between Fat and Flow. American Thoracic Society 2017 International Conference. May 24th, 2017. Washington D.C.

78. “Con: Sleep Labs are Obsolete for the Perioperative Assessment of Sleep Disordered Breathing”. Society of Anesthesia and Sleep Medicine: 7th Annual Meeting. October 19-20th, 2017: Boston, MA.
79. “Full Face vs. Nasal Masks in the Treatment of OSA: Equal Efficacy?”. 8th Annual Virginia Academy of Sleep Medicine Conference. November 4th, 2017: Richmond, VA.
80. “Current Definitions for Sleep Disordered Breathing”. Speaker and Panel Member. Public Workshop - Study Design Considerations for Devices Including Digital Health Technologies for Sleep Disordered Breathing in Adults, April 16, 2018.
81. Faculty. Lecture on: “OSA with chronic pain on methadone & mixed OSA/CSA”. Hands-on Faculty. Advanced PAP Therapy: Treatment of Sleep Disordered Breathing – Beyond OSA. PG Course. American Thoracic Society International Conference 2018. May 18th, 2018: San Diego, CA.
82. “Sleep Disorders and the Opioid Crisis”. PG Course: Trends in Sleep Medicine. SLEEP 2018. June 2nd, 2018: Baltimore, MD.
83. “Update on CPAP”. Post-graduate course: OSA Diagnosis and Management. World Sleep Congress, September 22nd, 2019: Vancouver, Canada
84. “2019 PAP Guidelines for OSA: What is New?”. Sleep Medicine Trends 2022. February 22, 2020. Tampa Bay, FL.
85. “Obstructive Sleep Apnea – Approaching to Treatment Using a Physiologic Paradigm”. John Jones Lectureship, West Virginia University Department of Medicine Grand Rounds. February 28th, 2020, Morgantown, WV.
86. “Sleep Disordered Breathing in HIV Patients”. Noon Conference. West Virginia University, Division of Pulmonary, Critical Care, and Sleep Medicine. February 28th, 2020, Morgantown, WV.
87. “PAP Therapy for OSA: Clinical Practice Guidelines Update. Meet the Professor. SLEEP 2019. June 11th, 2019. San Antonio, TX.
88. “Obesity Hypoventilation Syndrome and Non-invasive Ventilation: Executing the Guideline – Proposed Quality Metrics for Long-term NIV in OHS”. CHEST 2020 Annual Meeting. October 20, 2020. Virtual due to COVID.
89. “The Home NIV Expert Panel Report to Medicare: OSA, OHS, and CSA – Bi-level PAP for Patients Intolerant of CPAP”. CHEST 2020 Annual Meeting. October 5, 2021: New Orleans, LA.
90. “How Does Sleep Affect Cardiometabolic Health”. American Association of Clinical Endocrinology (AACE) Cardiometabolic Conference. October 1, 2022: San Antonio, TX.

91. “Obesity Hypoventilation – What to do When CPAP Doesn’t Work: What is the role of inspiratory time extension for improving ventilation?” CHEST 2022 Annual Meeting. October 15, 2022: Nashville, TN.
92. “Time to Rethink CPAP Therapy: A Review of the AHRQ Report and Future Directions: CPAP Therapy for Cardiovascular Prevention – Still Worth Considering?” SLEEP 2023 Annual Meeting. June 7th, 2023. Indianapolis, IN.
93. “Moving toward Equitable Care for Sleep Apnea in the United States: Positive Airway Pressure Adherence Thresholds: An Official American Thoracic Society Policy Statement – An ATS Sleep and Respiratory Neurobiology Webinar. June 30th, 2023. Co-Moderator.
94. “ATS Clinical Practice Guidelines, Webinar Series: Strategies to Assess Effect of CPAP amongst Patients with Symptomatic OSA; A Workshop Report. ATS Sponsored Webinar November 14th, 2023. Discussant.
95. “Positive Airway Pressure and Sleep Disordered Breathing: Does the Interface Matter?” 2023 Jean S. Marx Memorial Education Forum. Cleveland, Ohio. November 16th, 2023.

RESEARCH/GRANT SUPPORT

FUNDING

Extramural Funding (current, pending, previous):

Current

Pending/Submitted

None.

Previous

Obesity and Upper Airway Reflex Control During Sleep

NRSA 1 F32 HL68418-01	2001 – 2002	9.6 CM
NIH/NHLBI		
PI: Patil		

Obesity and Upper Airway Reflex Control During Sleep

NRSA 1 F32 HL68418-02	Patil	2003 – 2004	9.6 CM
NIH/NHLBI			

Clinician Scientist Award

JHU School of Medicine	Patil	2005	9.6 CM
“Neuromodulation of Upper Airway Obstruction During Sleep”			

Clinical Research Feasibility Fund

Johns Hopkins Bayview Patil 2004-2006 1.2 CM
Medical Center GCRC
“Effects of Adiposity in Sleep Apnea”

1 K23 HL077137 (Patil) 6/1/05 – 6/10/10 9.0 CM
NIH/NHLBI
Total Directs Costs: \$748,750
“Neuromodulation of Upper Airway Obstruction During Sleep”
Role: Principal Investigator

Research Agreement (Schwartz) 01/5/09 – 12/31/10 1.2 CM
ResMed Corporation \$134,427
Sleep Apnea Treatment Device
The purpose of this project is the development and testing of novel treatment devices for sleep apnea.

R44 HL091687 (Lane) 07/01/08 - 06/30/11 1.2 CM
NIH – subcontract from Key Technologies \$27,381
Disposable Respiratory Flow Measurement Device

Mechanisms of Sleep Apnea in Severe Obesity

RO1HL050381 (PI: Schwartz) 07/01/09 – 7/31/13 1.2 CM
NIH/NHLBI Competing Continuation
Total Directs Costs: \$2,168,763
Role: Co-Investigator

Human and murine models will be probed to characterize the mechanisms of upper airway dysfunction during sleep in obesity. Dramatic surgical weight loss and specific nocturnal interventions will be implemented to elucidate specific physiologic, metabolic and inflammatory mechanisms causing upper airway dysfunction during sleep. Complementary murine experiments will be used to establish specific adipocytokines and metabolic pathways in the pathogenesis of upper airway obstruction during sleep.

Mechanisms and Effectiveness of Weight Loss Methods in Diabetes and Sleep Apnea

1R01DK089557-01
(PI: Clarke/Brancati) 7/1/2010 – 12/31/15 2.4 calendar
months
NIH/NIDDK/NHLBI RFA
Total Directs Costs: \$1,174,294 Direct Costs: \$386,410
Role: Co-Investigator

Conduct a phase 2 randomized clinical trial comparing the effects of gastric bypass surgeries vs. dietary weight loss on sleep apnea and glucose metabolism. Explore the differential mechanisms of the different weight loss strategies in improving diabetes and sleep apnea.

Center for Sleep-Related Symptom Science

1 P30 NR014131

(PI: Page/Smith)	9/26/12 – 6/30/16	0.0 CM
	First Year Direct Costs: \$479,999	

Role: Center Faculty

The grant creates a Center that will serve as a catalyst for investigators to develop the necessary expertise to undertake the measurement of sleep outcomes as well as a promoter of interdisciplinary collaboration and partnerships to enable sustainable growth in the conduct of sleep research.

Walgreen and JH Collaboration	09/01/16 -08/31/17	0.00 CM
(PI: Patil)	\$25,000	
Sleep apnea: yoU Getting Assessed Rapidly – a Pharmacy Led Use of a Screening device (SUGAR-PLUS)		

The goal of this proposal is to assess a pharmacy intervention to increase early recognition of OSA in patients with type 2 diabetes mellitus.

Examining the effects of exercise on vascular function in OSA		
R15HL133884	07/01/16 -06/30/20	0.6 CM
Towson Univ./NHLBI		
(PI: Dobrosielski)	Total Direct Cost: \$441, 527	
	Sub only: \$50,133	

The goal of this proposal is to examine the effects of exercise on endothelial function in those with untreated obstructive sleep apnea. Specifically, to understand if OSA attenuates the benefits of exercise on endothelial function.

Submitted but Not Funded

1U34HL105315-01 (PI: Patil/Punjabi)	9/1/2010	3.6 calendar months
NIH/NHLBI RFA		
Total Directs Costs: \$1,500,000	First Year Direct Costs: \$500,000	
Reducing Cardiovascular Risk in Sleep Apnea		

Conduct a phase 2 randomized clinical trial of the treatment of obstructive sleep apnea with CPAP over 1 year and its effects on reducing cardiovascular risk.

PA-13-313 (Bowler)	07/01/2016 – 08/31/19	0.60 CM
Towson Univ./NIH	\$12,281 Sub only	
Examining the vascular effects of exercise in obstructive sleep apnea		

The goal of this proposal are to examine the whether the effects of acute and chronic exercise are attenuated in individuals with untreated OSA compared to those without OSA.

R15HL133884 (Dobrosielski)	09/01/16 -08/31/17	0.48 CM
Towson Univ./NHLBI	\$9,979 Sub only	
Examining Cardiometabolic Risk in the Sleep AHEAD cohort		

The goal of this proposal is to examine in individuals with T2DM and OSA a) the effects of an intensive lifestyle intervention (ILI) on cardiometabolic biomarkers, b) whether greater reductions in OSA severity predict greater improvements in cardiometabolic biomarkers at 1 year and 4 years after the ILI intervention compared to a educational intervention.

R01DK112583 (Coughlin)

12/1/16 – 11/30/2021

0.60 CM

NIH

\$499,999

The role of sleep and eating behaviors in bariatric surgery outcomes

The goal of this proposal are to examine the extent to which eating behaviors, sleep, and sleep disorders predict 18-month bariatric surgery-related outcomes.

BIBLIOGRAPHY

Peer Reviewed Articles

Original Research

1. **Patil SP**, Krishnan JA, Lechtzin N, Diette GB. In-hospital mortality following an acute exacerbation of chronic obstructive pulmonary disease. Arch Int Med 2003;163 (10): 1180-1186 [PMID: 12767954].
2. Schneider H, **Patil SP**, Canisius S, Gladmon EA, Schwartz AR, O'Donnell CP, Smith PL, and Tankersley CG. Hypercapnic duty cycle is an intermediate physiologic phenotype of sleep disordered breathing linked to mouse chromosome 5. J Appl Physiol 2003; 95 (1) :11-19 [PMID: 1279409].
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7. de Souza-Batista CM, Yang RZ, Lee MJ, Glynn NM, Yu DZ, Pray J, Ndubizuza K, **Patil S**, Schwartz A, Kligmann M, Fried SK, Gong DW, Shulinder AR, Pollin TI, McLenithan JC. Omentin plasma levels and gene expression are decreased in obesity. *Diabetes* 2007; 56 (6):1655-1661 [PMID: 17329619].
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11. Liu A, Pichard L, Schneider H, **Patil SP**, Smith PL, Polotsky V, Schwartz AR. Upper airway neuromechanical control in an isolated murine upper airway model. *J Appl Physiol* 2008; 105 (4): 1237 – 1245 [PMID: 18653751].
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16. McGinley B, Halbower H, Schwartz AR, Smith PL, **Patil SP***, Schneider H. Effect of a high-flow open nasal cannula on obstructive sleep apnea in children. *Pediatrics* 2009 (1); 124:179-188 [PMID 19564298].*This paper was the first to demonstrate the effects of high nasal flow therapy for pediatric sleep apnea. My role involved study design and manuscript preparation.
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19. Brown TT, **Patil SP***, Jacobson LP, Margolick JB, Laffan AM, Godfrey R, Johnson J, Johnson L, Reynolds S, Schwartz AR, Smith PL. Anthropometry in the prediction of sleep disordered breathing in HIV-infected and –uninfected men. *Antivir Ther* 2010; 15 (4): 651-659 [PMID 20587858]. *This was the first publication from an important study looking at the relation between HIV status and sleep apnea; this study demonstrated traditional predictors of OSA were not useful in predicting OSA status in HIV+/HAART- patients, though viral load and measures of inflammation were. My role was in study design, clinical protocol implementation, data collection, data analysis, and manuscript preparation.
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active neuromuscular states during sleep. My role was in study design, data collection, data analysis, and manuscript preparation.

24. Hoshino Y, Ayuse T, Kobayashi M, Kurata S, Kawai M, Schneider H, **Patil SP**, Schwartz AR, Kirkness JP, Oi K. The effects of hormonal status on upper airway patency in normal female subjects during propofol anesthesia. *J Clin Anesth* 2011 (7); 23:527-33 [PMID 22050795].
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29. Seif F, Patel SR, Walia HK, Rueschman M, Bhatt DL, Blumenthal RS, Quan SF, Gottlieb DJ, Lewis EF, **Patil SP**, Punjabi NM, Babineau DC, Redline S, Mehra R. Obstructive sleep apnea and diurnal nondipping hemodynamic indices in patients at increased cardiovascular risk. *J Hypertens.* 2014;32 (2):267-75 [PMID 24351803].
30. Brigham EP, **Patil SP**, Jacobson LP, Margolick JB, Godfrey R, Johnson J, Johnson-Hill LM, Reynolds S, Schwartz AR, Smith PL, Brown TT. Association between systemic inflammation and obstructive sleep apnea in men with or at risk for HIV infection. *Antivir Ther* 2014; 19 (8): 725-733. [PMID 24518040].
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[PMID 24991815]. *This was a seminal publication published from the MACS cohort; demonstrating that there is a high prevalence of sleep apnea in people living with HIV despite a normal BMI. Previous studies did not have control groups. My role was in study design, clinical protocol implementation, data collection, data analysis, and manuscript preparation.

34. Punjabi NM, Shifa N, Dorffner G, **Patil S**, Pien G, Aurora RN. Computer-Assisted Automated Scoring of Polysomnograms Using the Somnolyzer System. *Sleep*. 2015; 38 (10):1555-66 [PMID: 25902809].
35. Biselli P, Grossman PR, Kirkness JP, **Patil SP**, Smith PL, Schwartz AR, Schneider H. The effect of increased lung volume in chronic obstructive pulmonary disease on upper airway obstruction during sleep. *J Appl Physiol* (1985). 2015 Aug 1;119(3):266-71 [PMID:26048975].
36. Llanos OL, Galiatsatos P, Guzmán-Vélez E, **Patil SP**, Smith PL, Magnuson T, Schweitzer M, Steele K, Polotsky VY, Schwartz AR. Pharyngeal collapsibility during sleep is elevated in insulin-resistant females with morbid obesity. *Eur Respir J*. 2016; 47 (6):1718-1726 [PMID: 27103392].
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38. Sowho MO, **Patil S**, Schneider H, MacCarrick G, Kirkness JP, Wolfe LF, Sterni L, Cistulli PA, Neptune ER. Sleep disordered breathing in Marfan syndrome: Value of standard screening questionnaires. *Mol Genet Genomic Med*. 2019 Nov 10:e1039. doi: 10.1002/mgg3.1039 [PMID: 31707771].
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40. Dobrosielski DA, Kubitz K, Park H, **Patil SP**, Papendreu C. The effects of exercise training on vascular function among overweight adults with obstructive sleep apnea. *Translational Sports Medicine* 2021. <https://doi.org/10.1002/tsm2.254> [PMID: 24870569].
41. Kubitz KA, Park H, **Patil SP**, Papendreu C, Dobrosielski DA. The effects of an exercise intervention on executive function among overweight adults with obstructive sleep apnea. *Sleep and Biological Rhythms* 2022. <https://doi.org/10.1007/s41105-022-00433-1>. [PMID: 37143578].
42. Wickwire EM, Zhang X, Munson SH, Benjafield AV, Sullivan SS, Payombar M, **Patil SP**. The OSA patient journey: pathways for diagnosis and treatment among commercially insured individuals in the United States. *J Clin Sleep Med* 2023. doi: 10.5664/jcsm.10908. Online ahead of print [PMID: 37950451].
43. Abreu AR, Stefanovski D, **Patil SP**, Siddharthan T, Chediak A, Wallace DM, Punjabi NM. Neuromuscular Electrical Stimulation for Obstructive Sleep Apnea: Comparing Adherence to Active and Sham Therapy. *ERJ Open Research*; DOI: 10.1183/23120541.00474-2023.

Clinical Practice Guidelines/Consensus Statements

1. Epstein LJ, Kristo D, Strollo PJ, Friedman N, Malhotra A, **Patil SP**, Ramar K, Rogers R, Schwab RJ, Weaver EM, Weinstein MD. Clinical guideline for the evaluation, management, and long-term care of obstructive sleep apnea in adults: Adult Obstructive Sleep Apnea Task Force of the American Academy of Sleep Medicine. *J Clin Sleep Med* 2009; 5:263 – 276 [PMID: 19960649].
2. Chowdhuri S, Quan SF, Almeida F, Ayappa I, Batool-Anwar S, Budhiraja R, Cruse PE, Drager LF, Griss B, Marshall N, Patel SR, **Patil S***, Knight SL, Rowley JA, Slyman A; ATS Ad Hoc Committee on Mild Obstructive Sleep Apnea. An Official American Thoracic Society Research Statement: Impact of Mild Obstructive Sleep Apnea in Adults. *Am J Respir Crit Care Med*. 2016; 193 (9):e37-54. [PMID: 27128710]. *A meta-analysis and major respiratory society statement that demonstrated that treatment of mild OSA improves sleepiness and quality of life but not other outcome measures. My role was in study design, data abstraction, data synthesis, and manuscript preparation.
3. Gurubhagavatula I, Sullivan S, Meoli A, **Patil S**, Olson R, Berneking M, Watson NF. Management of OSA in commercial motor vehicle operators: Recommendations of the AASM Sleep and Transportation Safety Awareness Task Force. *J Clin Sleep Med* 2017 (5); 13: 745-758 [PMID 28356173].
4. **Patil SP***, Ayappa IA, Caples SM, Kimoff RJ, Patel SR, Harrod CG. Treatment of Adult Obstructive Sleep Apnea with Positive Airway Pressure: An American Academy of Sleep Medicine Clinical Practice Guideline. *J Clin Sleep Med*. 2019;15(2):335-343 [PMID: 30736887]. **I chaired the committee that developed and published this clinical practice guidelines on the use of PAP therapy for sleep apnea. This guideline has implications not only for sleep medicine physicians but also general clinicians caring for patients with sleep apnea. My role was in the oversight of the process; data abstraction; data synthesis; data evaluation; and manuscript preparation.*
5. **Patil SP***, Ayappa IA, Caples SM, Kimoff RJ, Patel SR, Harrod CG. Treatment of Adult Obstructive Sleep Apnea with Positive Airway Pressure: An American Academy of Sleep Medicine Systematic Review, Meta-Analysis, and GRADE Assessment. *J Clin Sleep Med*. 2019; 15(2):301-334 [PMID: 30736888]. **I chaired the committee that developed and published the meta-analysis on the effect of PAP therapy for sleep apnea. My role was in the oversight of the process; data abstraction; data synthesis; data evaluation; and manuscript preparation.*
6. Mokhlesi B, Masa JF, Brozek JL, Gurubhagavatula I, Murphy PB, Piper AJ, Tulaimat A, Afshar M, Balachandran JS, Dweik RA, Grunstein RR, Hart N, Kaw R, Lorenzi-Filho G, Pamidi S, Patel BK, **Patil SP***, Pépin JL, Soghier I, Tamae Kakazu M, Teodorescu M. Evaluation and Management of Obesity Hypoventilation Syndrome. An Official American Thoracic Society Clinical Practice Guideline. *AM J Resp Crit Care Med* 2019; 200: e6-e24 [PMID 31368798]. **This is the first society supported clinical practice guideline developed for the treatment of obesity hypoventilation syndrome. My role was in data abstraction and manuscript preparation.*

7. Wilson KC, Kaminsky DA, Michaud G, Sharma S, Nici L, Folz RJ, Barjaktarevic I, Bhakta NR, Cheng G, Chupp GL, Cole A, Dixon AE, Finigan JH, Graham B, Hallstrand TS, Haynes J, Hankinson J, MacIntyre N, Mandel J, McCarthy K, McCormack M, **Patil SP***, Rosenfeld M, Senitko M, Sethi S, Swenson ER, Stanojevic S, Teodorescu M, Weiner DJ, Wiener RS, Powell CA. Restoring Pulmonary and Sleep Services as the COVID-19 Pandemic Lessens. From an Association of Pulmonary, Critical Care, and Sleep Division Directors and American Thoracic Society-coordinated Task Force. *Ann Am Thorac Soc* 2020 Nov;17(11):1343-1351 [PMID: 32663071] **I was one of 3 individuals on this Task Force to conceive and write recommendations for how sleep centers should consider opening sleep testing and clinic services amidst the COVID-19 pandemic.*

8. Gay PC, Owens RL; **ONMAP Technical Expert Panel**. Executive Summary: Optimal NIV Medicare Access Promotion: A Technical Expert Panel Report From the American College of Chest Physicians, the American Association for Respiratory Care, the American Academy of Sleep Medicine, and the American Thoracic Society. *Chest*. 2021; 160:1808-1821 [PMID: 34339685] **I was a member of the Technical Expert Panel**

9. **Patil SP**, Collop NA, Chediak AD, Olson EJ, Vohra KP; **ONMAP Technical Expert Panel**. Optimal NIV Medicare Access Promotion: Patients With OSA: A Technical Expert Panel Report From the American College of Chest Physicians, the American Association for Respiratory Care, the American Academy of Sleep Medicine, and the American Thoracic Society. *Chest*. 2021;160:e409-e417 [PMID: 34339689] **I was a member of the Technical Expert Panel**

10. Mokhlesi B, Won CH, Make BJ, Selim BJ, Sunwoo BY; **ONMAP Technical Expert Panel**. Optimal NIV Medicare Access Promotion: Patients With Hypoventilation Syndromes: A Technical Expert Panel Report From the American College of Chest Physicians, the American Association for Respiratory Care, the American Academy of Sleep Medicine, and the American Thoracic Society. *Chest* 2021; 160:e377-e387 [PMID: 34339686]. **I was a member of the Technical Expert Panel**

11. Morgenthaler TI, Malhotra A, Berry RB, Johnson KG, Raphaelson M; **ONMAP Technical Expert Panel**. Optimal NIV Medicare Access Promotion: Patients With Central Sleep Apnea: A Technical Expert Panel Report From the American College of Chest Physicians, the American Association for Respiratory Care, the American Academy of Sleep Medicine, and the American Thoracic Society. *Chest* 2021; 160: e419-e425 [PMID: 34339687]. **I was a member of the Technical Expert Panel**

12. Wolfe LF, Benditt JO, Aboussouan L, Hess DR, Coleman JM 3rd; **ONMAP Technical Expert Panel**. Optimal NIV Medicare Access Promotion: Patients With Thoracic Restrictive Disorders: A Technical Expert Panel Report From the American College of Chest Physicians, the American Association for Respiratory Care, the American Academy of Sleep Medicine, and the American Thoracic Society. *Chest* 2021;160: e399-e408 [PMID: 34339688]. **I was a member of the Technical Expert Panel**

13. Hill NS, Criner GJ, Branson RD, Celli BR, MacIntyre NR, Sergew A; ONMAP Technical Expert Panel. Optimal NIV Medicare Access Promotion: Patients With COPD: A Technical Expert Panel Report From the American College of Chest Physicians, the American Association for Respiratory Care, the American Academy of Sleep Medicine, and the American Thoracic Society. *Chest* 2021; 160: e389-e397 [PMID: 34339684]. **I was a member of the Technical Expert Panel**
14. Chang JL, Goldberg AN, Alt JA, Mohammed A, Ashbrook L, Auckley D, Ayappa I, Bakhtiar H, Barrera JE, Bartley BL, Billings ME, Boon MS, Bosschieter P, Braverman I, Brodie K, Cabrera-Muffly C, Caesar R, Cahali MB, Cai Y, Cao M, Capasso R, Caples SM, Chahine LM, Chang CP, Chang KW, Chaudhary N, Cheong CSJ, Chowdhuri S, Cistulli PA, Claman D, Collen J, Coughlin KC, Creamer J, Davis EM, Dupuy-McCauley KL, Durr ML, Dutt M, Ali ME, Elkassabany NM, Epstein LJ, Fiala JA, Freedman N, Gill K, Gillespie MB, Golisch L, Gooneratne N, Gottlieb DJ, Green KK, Gulati A, Gurubhagavatula I, Hayward N, Hoff PT, Hoffmann OMG, Holfinger SJ, Hsia J, Huntley C, Huoh KC, Huyett P, Inala S, Ishman SL, Jella TK, Jobanputra AM, Johnson AP, Junna MR, Kado JT, Kaffenberger TM, Kapur VK, Kezirian EJ, Khan M, Kirsch DB, Kominsky A, Kryger M, Krystal AD, Kushida CA, Kuzniar TJ, Lam DJ, Lettieri CJ, Lim DC, Lin HC, Liu SYC, MacKay SG, Magalang UJ, Malhotra A, Mansukhani MP, Maurer JT, May AM, Mitchell RB, Mokhlesi B, Mullins AE, Nada EM, Naik S, Nokes B, Olson MD, Pack AI, Pang EB, Pang KP, **Patil SP**, Van de Perck E, Piccirillo JF, Pien GW, Piper AJ, Plawecki A, Quigg M, Ravesloot MJL, Redline S, Rotenberg BW, . . . International Consensus Statement on Obstructive Sleep Apnea. *Int Forum Allergy Rhinol* 2023;13:1061-1482 [36068685].
15. Donovan LM, Hoyos CM, Kimoff RJ, Morrell MJ, Bosch NA, Chooljian DM, McEvoy RD, Sawyer AM, Wagner TH, Al-Lamee RR, Bishop D, Carno MA, Epstein M, Hanson M, Ip MSM, Létourneau M, Pamidi S, Patel SR, Pépin JL, Punjabi NM, Redline S, Thornton JD, **Patil SP**. Strategies to Assess the Effect of Continuous Positive Airway Pressure on Long-Term Clinically Important Outcomes among Patients with Symptomatic Obstructive Sleep Apnea: An Official American Thoracic Society Workshop Report. *Ann Am Thorac Soc* 2023;20 :931-943 [PMID: 37387624].

Review Articles

1. **Patil SP**, Schneider H, Schwartz AR, Smith PL. Obstructive sleep apnea: pathophysiology and diagnosis. *Chest* 2007; 132:325 – 337 [PMID: 17625094].
2. Schwartz AR, Smith PL, Laffan AM, **Patil SP**. Obesity and obstructive sleep apnea: pathogenic mechanisms and therapeutic approaches. *Proc Amer Thoracic Society* 2008; 5:185-192 [PMID: 18250211].
3. **Patil SP***. What every clinician should know about polysomnography. *Resp Care* 2010; 55: 1179-1195 [PMID 20800000].*Remains an often referred to paper for understanding the application of amplifiers for polysomnography studies.
4. **Patil SP**. Preoperative evaluation of obstructive sleep apnea. Home sleep testing vs. laboratory testing. In *Sleep And Anesthesia* [Ed: Frances Chung]. *Sleep Med Clin* 2013; 8: 73-91.

5. Krishnan VK and **Patil SP**. Obstructive sleep apnea and transportation: Medicolegal issues. In Obstructive Sleep Apnea [Eds: Jones SF and Barker JA]. Sleep Med Clinics 2013; 8: 591-605.
6. Sowho M, Amatoury J, Kirkness JP, **Patil SP**. Sleep and respiratory physiology in adults. Clinics in Chest Medicine 2014; 35 (3): 469-481 [PMID 25156763].

Edited Books, Monographs, or Journal Volumes

1. **Patil SP** (Editor)*. Precision sleep medicine. Sleep Med Clin 2019; 14; 291-406.*I was the editor for this issue of Sleep Medicine Clinics and designed the content, invited authors, and edited submissions for publication.

Invited, Non-Peer Reviewed

1. Patil S. Abstracts & Analysis: Cardiovascular effects of continuous positive airway pressure in patients with heart failure and obstructive sleep apnea [Clinical Insights]. MD Consult Respiratory & Critical Care Medicine. June 17, 2003. Available at: <http://www.mdconsult.com>.

Book & Book Chapters

2. **Patil SP**, Schneider H, Smith PL, Schwartz AR. Upper Airway Obstruction and Sleep Apnea. In: Ward, Dahan and Teppema (Eds), Pharmacology and the Pathophysiology of the Control of Breathing. Lung Biology in Health and Disease series. Marcel-Dekker, Inc. Vol. 202, 2005.
3. Kirkness JP, Krishnan V, **Patil SP**, Schneider H. Upper airway obstruction in snoring and upper airway resistance syndrome. In Randerath, Sanner and Somers (Eds), Sleep Apnea. Prog Respir Res. Basel, Karger, Vol. 35: 79-89, 2006.
4. **Patil SP**. Technical aspects of sleep testing. In: ACCP Sleep Medicine Board Review. American College of Chest Physicians (Northbrook, IL). 2009.
5. **Patil SP**. Excessive daytime sleepiness: Medicolegal aspects. In: ACCP Sleep Medicine Board Review. American College of Chest Physicians (Northbrook, IL). 2009.
6. Gooneratne N, Rosen I, **Patil SP**. Sleep-Related Breathing Disorders. In: Barkoukis and Avidan (Eds), Review of Sleep Medicine. Elsevier, Inc. 2011.
7. Smith, PL, Kirkness, JP, **Patil SP**, Schneider H and Schwartz AR. Biomechanics of the Upper Airway During Sleep. In Pack (Eds), Sleep Apnea: Pathogenesis, Diagnosis, and Treatment. 2nd ed, p 27 – 52. New York, NY: Informa Healthcare, (2012).
8. Kirkness JP and **Patil SP**. Pathogenesis of obstructive sleep apnea in obesity. In: Dixon and Clerisme-Beaty (Eds), Obesity and Lung Disease: A Guide to Management. pages 71-98. Springer, Inc. (2012).

9. **Patil S.P.** and Kirkness J. (2013) Overview, Description, and Types of Sleep-Related Breathing Disorder. In: Kushida C.A. (ed.) The Encyclopedia of Sleep, Vol. 3, pp. 222-231. Waltham, MA: Academic Press.
10. Smith MT, Wincour E, Buenaver L, **Patil SP***. Chapter 153: Medication and Complementary and Alternative Medicine for Sleep Bruxism and Sleep Apnea. In: Kryger MH, Roth T, and Dement WC (eds) Principles and Practice of Sleep Medicine, 6th ed. St. Louis, MO: Elsevier Saunders.
*This textbook is considered to be the definitive clinical textbook for the field of sleep medicine.
11. **Patil SP***, Wincour E, Smith MT, Buenaver L. Medical Therapy for Sleep Apnea In: Kryger MH, Roth T, and Dement WC (eds) Principles and Practice of Sleep Medicine, 6th ed. St. Louis, MO: Elsevier Saunders. *This textbook is considered to be the definitive clinical textbook for the field of sleep medicine.
12. Smith MT, Wincour E, Buenaver L, **Patil SP***. Chapter XXX: Medication and Complementary and Alternative Medicine for Sleep Bruxism and Sleep Apnea. In: Kryger MH, Roth T, and Dement WC (eds) Principles and Practice of Sleep Medicine, 7th ed. St. Louis, MO: Elsevier Saunders. [Submitted for review] *This textbook is considered to be the definitive clinical textbook for the field of sleep medicine.
13. **Patil SP***, Wincour E, Smith MT, Buenaver L. Chapter XXX: Medical Therapy for Sleep Apnea In: Kryger MH, Roth T, and Dement WC (eds) Principles and Practice of Sleep Medicine, 7th ed. St. Louis, MO: Elsevier Saunders. [Submitted for review] *This textbook is considered to be the definitive clinical textbook for the field of sleep medicine.
14. Koch A and **Patil SP***. Chapter XXX: Pharmacotherapy for Sleep Apnea In: Kryger MH, Roth T, and Dement WC (eds) Principles and Practice of Sleep Medicine, 7th ed. St. Louis, MO: Elsevier Saunders. [Submitted for review] *This textbook is considered to be the definitive clinical textbook for the field of sleep medicine.

Patents

NA

Media Appearances & Coverage/Podcasts

NA

Other Media

1. **Patil SP** and Schneider H. Fun with Filters. Sleep Fragments. A Publication of the American Thoracic Society. July 2008. Available at: <http://www.thoracic.org/clinical/sleep/sleep-fragment/pages/july-2008..php> [Last accessed on October 13, 2011].
2. Braidy J and **Patil SP**. A man is unable to sleep in bed. A Publication of the American Thoracic Society. May 2009. Available at: <http://www.thoracic.org/clinical/sleep/sleep-fragment/pages/man-unable-to-sleep-in-bed.php>. [Last accessed on October 13, 2011].

3. **Patil SP.** Vital Signs – What is the Arrhythmia? A Publication of the American Thoracic Society. July 2009. Available at: <http://www.thoracic.org/clinical/sleep/sleep-fragment/pages/41yroid-african-american-male-with-hypertension.php>. [Last accessed on October 13, 2011].
4. Johns Hopkins Medicine Healthy Sleep Portal* at <https://www.hopkinsmedicine.org/health/wellness-and-prevention/sleep>. Member of the Expert Sleep Panel. * I was one of several physicians that served as a content expert to develop and review materials included related to sleep medicine that were planned to be published as part of the Johns Hopkins Health Library portal.

Software/Application Development

NA

Editorials/Commentaries

1. Schwartz AR, **Patil SP**, Schneider H, Smith PL. Modeling pathogenic mechanisms of upper airway dysfunction in the molecular age. *Eur Respir J.* 2008; 32(2):255-8 [PMID: 18669783].
2. Schwartz AR, **Patil SP**, Squier S, Schneider H, Kirkness JP, Smith PL. Obesity and upper airway control during sleep. *J Appl Physiol.* 2010; 108 (2):430-435 [PMID 19875707].
3. Schwartz AR, Schneider H, Smith PL, McGinley BM, **Patil SP**, Kirkness JP. Physiologic phenotypes of sleep apnea pathogenesis. *Am J Respir Crit Care Med* 2011;184 (10): 1105-1106 [PMID: 22086988].
4. Schwartz AR, Smith PL, Schneider H, **Patil SP**, Kirkness JP. Lung volume and upper airway collapsibility – what does it tell us about pathogenic mechanisms (invited editorial). *J Appl Physiol* 2012; 113 (5): 689-690 [PMID 22858622].
5. Punjabi NM, Aurora RN, **Patil SP**. Home sleep testing for obstructive sleep apnea: One night is enough for now! *Chest* 2013; 143 (2):291-294 [PMID 23381307].
6. Dobrzielski DA and **Patil SP**. Weight loss and obstructive sleep apnea: What lies AHEAD (Invited editorial). *Sleep.* 2013; 36 (5):627-9 [PMID: 23633741].
7. Perry GS, **Patil SP**, Presley-Cantrell LR. Raising awareness of sleep as a healthy behavior. *Prev Chron Dis* 2013; 10:130081. <http://dx.doi.org/10.5888/pcd10.130081> [PMID: 23928458].
8. Ayas NT, **Patil SP**, Stachina M, Malhotra A. Treatment of central sleep apnea with adaptive servoventilation in chronic heart failure (editorial). *Am J Respir Crit Care Med.* 2015;192 (2):132-133 [PMID: 26082979].
9. Malhotra A, **Patil S**, Sands S, Ayas N. Central sleep apnoea in congestive heart failure (editorial). *Lancet Respir Med.* 2015; 3 (7):507-508 [PMID: 26074186].
10. Gurubhagavatula I, **Patil S**, Meoli A, Olson R, Sullivan S, Berneking M, Watson NF; Sleep and Transportation Safety Awareness Task Force of the American Academy of Sleep Medicine. *Sleep*

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11. Hernandez AB, **Patil SP**. Pathophysiology of central sleep apnea. Sleep Breath 2016; 20 (2): 467-482 [PMID: 26782104].
12. Dobrosielski DA, Papandreou C, **Patil SP**, Salas-Salvadó J. Diet and exercise in the management of obstructive sleep apnoea and cardiovascular disease risk. Eur Respir Rev 2017; 26 (144): 160110.doi: 10.1183/16000617.0110-2016 [PMID: 28659501].
13. **Patil SP***. Precision medicine in the field of sleep medicine: Early days. Sleep Med Clin 2019; 14: xiii-xiv [PMID31375209].*I was the primary editor of this issue of Sleep Medicine Clinics
14. **Patil SP***, Gay P, Johnson K, Kimoff RJ, Pack A. Response to: Draft Technology Assessment – “Continuous Positive Airway Pressure Treatment for Obstructive Sleep Apnea” at <https://www.ahrq.gov/research/findings/ta/draft-review-form.html>. Published online at <https://aasm.org/ahrq-draft-cpap-sleep-apnea-technology-assessment-comment/>. Last accessed on 5/4/21. *I was the chair of writing committee that responded to this AHRQ report on behalf of more than 20 international, national, and state professional societies and patient support groups.
15. **Patil SP**, Billings ME, Bourjeily G, Collop NA, Gottlieb DJ, Johnson KG, Kimoff RJ, Pack AI. Long-term health outcomes for patients with obstructive sleep apnea: placing the Agency for Healthcare Research and Quality report in context-a multi-society commentary. J Clin Sleep Med. 2023; Oct 31. doi: 10.5664/jcsm.10832 [PMID: 37904571].

Letters

1. **Patil SP**, Krishnan JA, Lechtzin N, Diette GB. In-hospital mortality and long-term use of inhaled corticosteroids. Arch Int Med 2004; 164: 222-223.

CLINICAL ACTIVITIES

Clinical (Service) Responsibilities

2005-2006	Pulmonary & Critical Care Medicine (1.0 months inpatient care)
2006-2007	Pulmonary & Critical Care Medicine (2.0 months inpatient care)
2007-2008	Pulmonary & Critical Care Medicine (1.5 months inpatient care)
2008-2009	Pulmonary & Critical Care Medicine (2.0 months inpatient care)
2009-2010	Pulmonary & Critical Care Medicine (2.0 months inpatient care)
2010-2011	Pulmonary & Critical Care Medicine (2.0 months inpatient care)

2011-2012	Pulmonary & Critical Care Medicine (1.0 months inpatient care)
2012-2013	Pulmonary & Critical Care Medicine (1.0 months inpatient care)
2013-2014	Pulmonary & Critical Care Medicine (1.0 months inpatient care)
2014-2015	Pulmonary & Critical Care Medicine (1.5 months inpatient care)
2015-2016	Pulmonary & Critical Care Medicine (2.5 months inpatient care)
2016-2017	Pulmonary & Critical Care Medicine (3.0 months inpatient care)
2017-2018	Pulmonary & Critical Care Medicine (3.0 months inpatient care)
2018-2019	Pulmonary & Critical Care Medicine (3.0 months inpatient care)
2019-2020	Pulmonary & Critical Care Medicine (3.0 months inpatient care)
2020-2021	Pulmonary & Critical Care Medicine (3.0 months inpatient care)

CERTIFICATE OF SERVICE

The undersigned certifies, in accordance with 37 C.F.R § 42.6(e), that
service was made on the Petitioner as detailed below.

<i>Date of service</i>	July 29, 2024
<i>Manner of service</i>	Electronic Mail (tiffany.miller@us.dlapiper.com; ed.sikorski@us.dlapiper.com; jim.heintz@us.dlapiper.com; DLA-ResMed-CleveMed-IPR@us.dlapiper.com)
<i>Documents served</i>	DECLARATION OF DR. SUSHEEL PATIL IN SUPPORT OF PATENT OWNER'S RESPONSE
<i>Persons Served</i>	DLA Piper LLP (US) Tiffany C. Miller Edward H. Sikorski James M. Heintz

/James Hannah/
James Hannah
Registration No. 56,369
Lead Counsel for Patent Owner