

THE AMERICAN SLEEP APNEA ASSOCIATION  
PRESENTS:



**Raising our  
voices for  
progress in  
treatment  
and care**

**June 8, 2018  
10 a.m. until 4 p.m.**

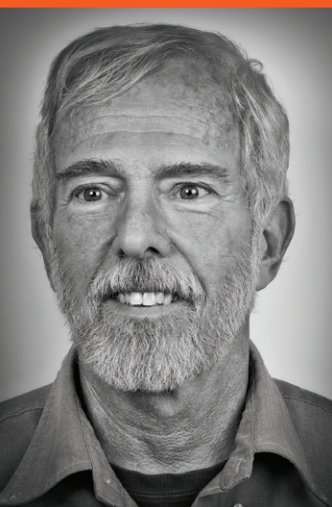
College Park Marriott Hotel & Conference Center  
College Park, Maryland

**#AWAKESleepApnea**

 **sleepapnea.org**  
American Sleep Apnea Association

## About the AWAKE Sleep Apnea Initiative

**AWAKE Sleep Apnea** is an education and empowerment initiative with several opportunities for sleep apnea patients, family members, and caregivers to help inform researchers, regulators, and life science companies about what it's like to live with sleep apnea. AWAKE Sleep Apnea is a strategic initiative of the American Sleep Apnea Association (ASAA) held in collaboration with the U.S. Food & Drug Administration (FDA) and with support from several life science companies and non-profit organizations. It is the first-of-its-kind initiative to accelerate progress in patient-focused medical product development for and patient-centered care of sleep apnea. Read more about the AWAKE initiative, ASAA, sponsors, and partners in this program.



## About Obstructive Sleep Apnea

The Greek word “apnea” literally means “without breath.” Sleep apnea is an involuntary cessation of breathing that occurs while the patient is asleep. There are three types of sleep apnea: obstructive, central, and mixed. Of the three, obstructive sleep apnea (OSA) is the most common. Despite the difference in the root

cause of each type, all three — if left untreated — cause people to stop breathing repeatedly during their sleep, sometimes hundreds of times during the night and often for a minute or longer. In most cases the sleeper is unaware of these breath stoppages because they don't trigger a full awakening. Left untreated, sleep apnea can have serious and life-shortening consequences: high blood pressure, heart disease, stroke, automobile accidents caused by falling asleep at the wheel, diabetes, depression, and other ailments.

Sleep apnea is seen more frequently among men than among women, particularly African-American and Hispanic men. A major symptom is extremely loud snoring, and gasping/snorting noises after periods of not breathing. Sometimes the sounds of these symptoms are so loud that bed partners find it intolerable. Other indications that sleep apnea may be present are obesity, persistent daytime

sleepiness, bouts of awakening out of breath during the night, and frequently waking in the morning with a dry mouth or a headache. But it can be possible that at times none of these symptoms are present. Only a sleep study in a sleep laboratory or a home sleep study can show definitively that sleep apnea is present and how severe it is.

Obstructive sleep apnea is caused by a blockage of the airway, usually when the soft tissue in the rear of the throat collapses and closes during sleep. In central sleep apnea, the airway is not blocked but the brain fails to signal the muscles to breathe. Mixed sleep apnea, as the name implies, is a combination of the two. With each apnea event, the brain rouses the sleeper, usually only partially, to signal breathing to resume. As a result, the patient's sleep is extremely fragmented and of poor quality.

Sleep apnea is very common — as common as type 2 diabetes — and researchers say it affects more than 18 million Americans. Risk factors include being male, overweight, and over the age of 40, but sleep apnea can affect anyone at any age, even children. Lack of awareness by the public and health care professionals leaves the vast majority of sleep apnea patients undiagnosed and therefore untreated, despite the fact that this serious disorder can have significant consequences.

Untreated, sleep apnea can cause high blood pressure and other cardiovascular disease, memory problems, weight gain, impotence, and headaches. Moreover, untreated sleep apnea may be responsible for job impairment and motor vehicle crashes. Fortunately, sleep apnea can be diagnosed and treated. Several treatment options exist, and research into additional options continues.



---

## Patient-Focused Medical Product Development Meeting

### AGENDA | June 8, 2018

<b>9:00-10:00 AM</b>	Registration & Networking
<b>10:00-10:05</b>	Welcome & Agenda Overview Kim McCleary, Moderator, Founder & CEO, The Kith Collective
<b>10:05-10:15</b>	Welcome & Opening Remarks Adam Amdur, Chief Patient Officer, American Sleep Apnea Association
<b>10:15-10:25</b>	Overview of Sleep Apnea and Its Diagnosis Shelley R. Berson, MD, FACS, FAASM, FAAOA, Founder, ZZenter
<b>10:25-10:35</b>	Overview of Discussion Format & Polling Instructions Kim McCleary, Moderator
<b>10:35-11:00</b>	Panel 1: Patient Perspectives on Symptoms and Impacts on Daily Living Eugena Brooks; Brooklyn, NY Joelle Dobrow; Los Angeles, CA San Juanita Sanchez; San Juan, TX Peter Stein; Portland, ME Paul Zuccarini; Key Biscayne, FL
<b>11:00-12:00</b>	Polling & Facilitated Discussion Among Patients & Caregivers Kim McCleary, Moderator
<b>12:00-12:45 PM</b>	Lunch Break
<b>12:45-1:00</b>	Overview of Treatment of Sleep Apnea and Therapy Challenges Shelley R. Berson, MD, FACS, FAASM, FAAOA
<b>1:00-1:25</b>	Panel 2: Patient Perspectives on Current Approaches to Managing Sleep Apnea John Andrews; Virginia Beach, VA Paul Blumstein; Annandale, VA Rick Gordon; Upland, CA Celeste James; St. Albans, NY Erin Taylor; Colorado Springs, CO
<b>1:25-2:25</b>	Polling & Facilitated Discussion on Managing Sleep Apnea Kim McCleary, Moderator
<b>2:25-2:45</b>	Break
<b>2:45-3:30</b>	Polling & Focused Discussion of Challenges Adhering to Therapy Kim McCleary, Moderator
<b>3:30-3:50</b>	Summary of Day's Discussion by FDA Kathryn O'Callaghan, CDRH Assistant Director, Strategic Programs
<b>3:50-4:00</b>	Wrap Up and Closing Remarks ASAA Board Members Adam Amdur & Carl Stepnowsky, PhD
<b>4:00</b>	Adjourn

# About Patient-Focused Medical Product Development & Sleep Apnea

The AWAKE Sleep Apnea meeting is part of a meeting series initiated by FDA in 2013 designed to better align medical products with patients' needs.



## FDA's Commitment to Patients

The U.S. Food and Drug Administration (FDA) has placed a high priority on hearing directly from individuals with lived experience about what it's like to live with medical conditions. To bring this important information to FDA leaders and review staff, FDA created the Patient-Focused Drug Development (PFDD) initiative within the Center for Drug Evaluation and Research (CDER). Nearly 40 PFDD meetings have been held since 2013, focusing on a wide range of prevalent and rare diseases where there is substantial unmet medical need.

In 2013, FDA's Center for Devices and Radiologic Health (CDRH) launched the Patient Preference Initiative to develop methods of understanding patients' expectations for benefits and tolerance for harms and risks related to interventions that involve medical devices. In 2016, CDRH established "partnering with patients" as one of its three strategic priorities and leadership set aggressive goals to measure its progress. In 2017, it convened a Patient Engagement Advisory Committee to guide the agency's continued interactions with patients and patient organizations.

These programs have created new opportunities for patient perspectives to inform decisions about clinical trials and regulation of medical products.

## Breaking New Ground for Sleep Apnea

The American Sleep Apnea Association (ASAA) applied to FDA's PFDD program in November 2017, proposing to host a meeting focused on the full range of treatment approaches used by people with sleep apnea, including medications, medical devices, and a range of other approaches. Today's meeting is the culmination of a collaborative effort with FDA to involve staff and reviewers from CDER and CDRH. This is the first meeting identified as a Patient-Focused Medical Product Development (PFMPD) meeting.

A report combining patient and caregiver experience shared at the meeting, through the polling questions, and via the AWAKE Sleep Apnea Patient & Caregiver Survey will be issued to participants, FDA, sponsors, and the public. It will also be submitted to FDA's online repository for patient experience information as an evergreen resource. Meeting participants will receive an email with a link to the final report later this summer and it will be posted to [www.awakesleepapnea.org](http://www.awakesleepapnea.org) and [www.sleepapnea.org](http://www.sleepapnea.org).

**Meeting participants will receive an email with a link to the final AWAKE Sleep Apnea report later this summer**

## About the American Sleep Apnea Association

Founded in 1990, the American Sleep Apnea Association (ASAA) is a patient-led, nonprofit organization dedicated to the promotion of sleep health through research, advocacy, and education. Each year ASAA responds to thousands of requests for information and provides answers to a multitude of questions about the diagnosis of and treatment options for sleep apnea. ASAA works collaboratively with non-profit organizations and professional societies to further its mission.

The ASAA engages patients, physicians, and the public through several programs and research related activities. Its key initiatives include: the CPAP Assistance Program (CAP); a national patient engagement network called Alert, Well and Keeping Energetic (A.W.A.K.E); a closed A.W.A.K.E Facebook page for patients; monthly webinars; a Sleep Health app (available at no cost on iTunes); and a month-long awareness campaign conducted in September called Sleeptember.

ASAA is currently involved in three primary sleep-related research projects: the COPD O2VERLAP Study; a PCORI-funded project on sleep-related questions in comparative effectiveness research; and a project being conducted with the Veterans Health Administration.

## Board of Directors & Staff

Only patients and established patient advocates serve on the Association's Board of Directors. The Board ensures that ASAA maintains the highest standards of performance, governance, accountability, transparency and cost-to-fundraising ratios. Additionally, the Board ensures that the patient's voice is reflected in all major decisions and program implementation. All board members contribute financially to the organization.

Staff include patients diagnosed with sleep disorders, patient-advocates, and researchers. The highly qualified staff works to advance the ASAA's mission through research, program development and implementation, fundraising, networking, marketing, and administration.

---

### Board Members:

- Adam Amdur – Chairman and Chief Patient Officer
- Joe Borelli, MD
- Rich Bren
- Bill Clark
- Will Headapohl – Chairman Emeritus
- Paul Jannace
- Andy Mendoza – Secretary
- Zack Miller
- Theresa Shumard
- Carl Stepnowsky, PhD – Chief Science Officer

---

### Staff:

- Adam Amdur – Chief Patient Officer
- Justine Amdur – Program Coordinator
- Kevin Bradley – Community Engagement
- Valerie Danielson – CAP Program Manager
- Sean Deering – Information Technology
- Megan Gramstad – CAP Program Coordinator
- Elizabeth Johnson – Finance Manager
- Elizabeth Korfmacher – Marketing/Communications Consultant
- Sergio Martinez – Research Assistant
- Christina Piazza – Community Reporting & Analytics
- Theresa Shumard – Community Leader
- Carl Stepnowsky, PhD – Chief Science Officer
- Tania Zamora – Relationship Coordinator

# Patient & Caregiver Perspectives:

## INTERIM SURVEY RESULTS

In preparation for the June 8, 2018 AWAKE Sleep Apnea meeting, ASAA fielded a Patient & Caregiver Survey to capture a broad set of patient experiences and inform the discussion at the meeting. As of May 29, 2018, the 31-item survey attracted responses from 2,221 people, 98% of whom are patients diagnosed with sleep apnea by a medical professional.

### Demographics

Sixty-one percent of respondents identified as being female, notable because men are considered to be at higher risk for sleep apnea. The geographic distribution of responses resembled the U.S. as a whole, with slight over representation of the southeast; 2% of responses came from individuals living outside the U.S. More than half of the respondents are currently age 55 or older. Nearly half reported being between the ages of 35 and 54 at the time of onset.

### Diagnosis

The primary motivating factor for pursuing a formal diagnosis was symptoms becoming bothersome or intolerable (42%), followed by concern expressed by a family member or friend (25%). For 6%, a diagnosis was sought following an episode where their own life or someone else's was put in jeopardy by sleep apnea. When asked how long it took to get diagnosed, slightly more than half indicated within a year of recognizing symptoms. The other half were split relatively evenly between 1-2 years, 3-5 years, and more than 6 years after recognition of symptoms. Open text comments indicated, however, that in retrospect many suspect they had sleep apnea far longer. An overnight sleep study was involved in diagnosing sleep apnea for 86% of respondents. A home sleep study was involved for about 27%, with some individuals reporting having both.

### Impacts on Daily Living

Topping the list of symptoms that are most problematic for respondents are fatigue (80%), daytime sleepiness (77%), unrefreshing sleep (71%), dry mouth in the morning (55%) and cognitive difficulties (49%). Among those treated with CPAP, 81% reported moderate to severe fatigue and 78% reported moderate to severe daytime sleepiness. Respondents longed to awaken feeling refreshed (66%), sleep through the night (55%), and perform as they'd like to at work or at school (32%). The top concern among those living with sleep apnea is the potential long-term consequences on health and lifespan (62%) and the effect of symptoms on physical and/or mental performance (48%). When asked about the biggest impact on their lives, here are some statements offered by respondents:

*"I am worried about my risk for congestive heart failure, heart attack, or stroke."*

*"I am scared to fall asleep without machine, scared I won't wake up. I am worried about how it will affect my life, too."*

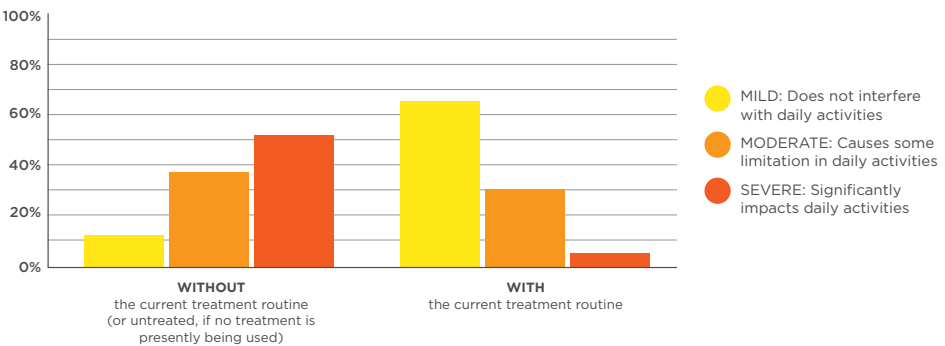
*"Every day I struggle with a lack of concentration, motivation, and energy to get the things done I need to do."*

*"I once fell asleep while driving. It's very scary."*

### Management

A large majority of respondents (89%) were currently using positive airway pressure (including CPAP, BiPAP, and APAP) to manage their sleep apnea. While there was some variability, most reported use 7 nights a week and 6-8 hours per night. There was much less utilization of oral appliances, with more respondents indicating past use (12%) than current use (8%), and a much lower rate of utilization (3 nights per week on average). Medication use included a wide array

### In general, how would you describe the impact sleep apnea symptoms on the person living with sleep apnea's daily life?



of pharmacologic agents, both currently and in the past, with nasal corticosteroids being the most utilized, followed by serotonin reuptake inhibitors (SSRIs) and anticonvulsants. There were relatively few respondents who had undergone surgery to treat sleep apnea; among those who did, tonsillectomy and/or adenoidectomy was the most reported surgical procedure (9%). Weight loss through diet and/or activity, sleep position training, and alcohol avoidance were the three most often reported supportive strategies currently used.

In describing the impact of sleep apnea symptoms as currently treated compared to not treated, respondents shifted from 52% reporting "severe" impact (significantly impacts daily activities) when not treated to 64% reporting "mild" impact (does not interfere with daily activity) when treated. When asked what helps the most, here are a few of the statements provided by respondents:

*"Keeping my [CPAP] machine clean, using it even when I nap, and getting as much sleep as possible."*

*"Side sleeping with my CPAP machine and elevating my head and chest. Yet nothing is completely effective; it's always a challenge."*

*"Getting a mask with a good seal and learning how to adjust the machine settings; education and support are essential."*

*"Practicing good sleep hygiene, although it's hard because I do shift work."*

*"Using my machine regularly and taking a daytime stimulant when needed."*

*"Losing weight, getting physical activity, and tending to allergy symptoms make a big difference."*

## Barriers to Treatment

Barriers respondents encounter in either starting or sticking with therapy include therapies that are "uncomfortable" (56%) or "inconvenient" (47%), or there being financial barriers (37%, including lack of insurance, lack of coverage, or high out of pocket costs). Many of the free text responses focused on finding well-fitting equipment; getting good service from equipment suppliers; and accessing new models not covered by insurance plans. There were also multiple comments about challenges that arose in relationships with bed partners, including being self-conscious about the way masks made them look, and general stigma and embarrassment attached to sleep apnea and its treatment.

## Looking Ahead

The most important result that a treatment could provide was "feel better and go about daily life more easily" for 43% of respondents. Another 20% sought to experience a significant improvement of the symptoms that present the biggest problem for them, and 18% looked to have fewer long-term

health problems. Slightly more than one-third expressed interest in participating in research. Only 4% had ever participated in a sleep apnea study; an overwhelming majority – 78% – had never been asked to participate in research.

## Final Words

Respondents had the opportunity to express themselves in response to the question "What else would you like us to know about your experience with sleep apnea?" Here are a few of the comments received:

*"Until I started researching it more, I didn't realize all the health problems resulting from sleep deprivation. I suffered from major depressive disorder, high blood pressure, and obesity. I thought my weight was to blame, but I couldn't stick to a weight loss plan while being so exhausted. CPAP therapy is literally saving my life!"*

*"I wish I had pursued treatment sooner. I let others tell me I was reading too much into symptoms until my daughter spoke up and I acted on her concern. More information and education is needed so my story doesn't happen to others."*

*"It takes 3-4 months to get an appointment at the local sleep center; it's frustrating not to be able to get help sooner than that."*

*"Equipment suppliers are not as helpful as they could be in finding the right mask and settings."*

*"It's embarrassing to talk about and I dislike having to take a lot of equipment with me when I travel or visit family. Sometimes I just don't sleep when I'm away from home."*

*"General medical practitioners need to be trained to ask about snoring and other sleep problems; maybe then I wouldn't have gone so long with poor sleep and problems it caused at my job and in my life."*

*"Having sleep apnea is a miserable and lonely experience."*

*"If I didn't start treating it when I did, I sincerely believe I wouldn't be sitting here typing this. I would have had a massive heart attack long before now."*

**"Every day I struggle with a lack of concentration, motivation, and energy to get the things done I need to do."**

---

**The Patient & Caregiver Survey will remain open until June 29, 2018;** a link to it can be found at [www.awakesleepapnea.org](http://www.awakesleepapnea.org). Final results will be tallied and included in the wrap-up report on the June 8 meeting, to be published later this summer. The report will also be submitted to the FDA.

# SPONSORS

---

The American Sleep Apnea Association thanks corporate sponsors of the AWAKE Sleep Apnea initiative for the unrestricted educational grants that helped make this meeting possible.

## PLATINUM



**Jazz Pharmaceuticals<sup>®</sup>**  
Innovation that performs

# SPONSORS

---

The American Sleep Apnea Association thanks corporate sponsors of the AWAKE Sleep Apnea initiative for the unrestricted educational grants that helped make this meeting possible.

## SILVER



**ResMed**

*Changing lives  
with every breath*

## BRONZE

**Fisher & Paykel**  
HEALTHCARE

**PHILIPS**

## FRIENDS OF AWAKE

CMB Solutions  
Evidation Health  
RemZzzs  
RT Sleep World

# PARTNERS

---

The American Sleep Apnea Association thanks partners of the AWAKE Sleep Apnea initiative for assistance with community outreach and education about this meeting and the Patient & Caregiver Survey.



## Get Involved!

### AWAKE Sleep Apnea Patient & Caregiver Survey

If you haven't done so yet, please complete the anonymous survey that covers six key areas of the patient experience, including: diagnosis, symptoms, daily impacts, treatment approaches, and greatest concerns. It takes just 15 minutes or so to complete. Survey results will be included in the final AWAKE Sleep Apnea report published later this summer to capture the voices of patients & caregivers from across the country. The report will be shared with FDA, life science companies, the patient community, and the public.



#### SleepHealth App for iPhone

SleepHealth is a mobile application study and wellness tool from the American Sleep Apnea Association and powered by Apple's ResearchKit and IBM Watson Health Cloud.

The SleepHealth study is being conducted by the American Sleep Apnea Association and

researchers at the University of California, San Diego. The app and study was designed and funded through the contributions of a small all-patient team of scientists, physicians, advocates and technology experts dedicated to health and data discovery in order to accelerate patient-centered and citizen research related to heart disease, hypertension, obesity, cancer, COPD, depression, Alzheimer's, motor-vehicle crashes, and reduced quality of life, among others.

The SleepHealth app is also a personalized tool that helps you gain greater insight into your sleep habits and sleep issues, learn how sleep is associated with other conditions you may have, and take charge of your health. You can keep track of your daily activity, sleep habits and daytime alertness in order better understand how your sleep impacts your health, safety, productivity, and well-being. Download the app on iTunes, contribute your data to research, and become more empowered today!



#### Sleeptember

Our annual Sleeptember campaign harnesses the power of social media to prioritize healthy sleep and raise awareness of the risks of untreated sleep apnea.

During the month of September, the initiative encourages the public to take healthy sleep actions and raise funds for and awareness of sleep disorders. This helps advance research on sleep apnea, educates people on the importance of sleep, and promotes healthy sleep habits.

Throughout September, we will encourage our community and the general public to follow the ASAA on Facebook, Instagram, and Twitter, and visit our website [www.sleepapnea.org](http://www.sleepapnea.org) to learn, educate, and engage in information about sleep. Mark your calendar now to participate and build awareness!



follow the ASAA on Facebook, Instagram and Twitter, and visit our website [www.sleepapnea.org](http://www.sleepapnea.org) to learn, educate, and engage in information about sleep

# Need Assistance or Support?

## CPAP Assistance Program

The ASAA's CPAP Assistance Program (CAP) has provided over 5,000 continuous positive airway pressure (CPAP) equipment packages to patients in need over the last three years. Patients come to us with a variety of hardships that make purchasing a CPAP machine prohibitive – loss of job or insurance, high-deductible insurance coverage, living on a fixed income, and other circumstances. We believe no one's sleep apnea should go untreated and our mission is to help as many patients as possible get the treatment that they need.

Under this program, we offer to those in need a one-time equipment package that consists of a CPAP machine, new tubing, a filter, a carrying case, and a data card. Applicants must provide a valid prescription and pay a \$100 program fee. We also offer a Yearly Supply Program (YSP) for replacement parts. The YSP package includes four masks, four filters, and two tubes for a \$100 program fee. Online applications for the CAP and YSP Program can be found at [www.sleepapnea.org](http://www.sleepapnea.org).

### These testimonials underscore the value of this vital program:

*"Even with insurance, buying a machine can be impossible. Programs like these allow people to get the treatment they need without the stress of going without. Thank you!"*

*"Thank you so much for this amazing program. I went eight months after being diagnosed with sleep apnea without a machine because I could not afford it. The lack of sleep was really wearing my body down and I have two young children to care for. I had no idea you could actually die from sleep apnea! I had almost lost hope when I was given your information. You are truly a Godsend! Thank you so much for helping me!"*

*"I was laid off from my job and lost my insurance coverage. My CPAP machine finally gave out after several years of use. I have not had a machine for four months now. I fall asleep throughout the day. I fall asleep while driving and have severe headaches all day. I never feel rested. I wake up several times a*

*night from my breathing stopping. I have not had a good night's sleep in four months. My mental health and mental clarity have suffered. Thank you for helping me return to a normal night of sleep."*

ASAA accepts donations of new or gently used devices and factory sealed supplies. Your donations allow us to provide PAP devices and supplies to those in need. To donate a machine or supplies, please contact our CAP Program Manager, Valerie Danielson at [vdanielson@sleepapnea.org](mailto:vdanielson@sleepapnea.org).

## A.W.A.K.E. Support Network

The Alert, Well, and Keeping Energetic (A.W.A.K.E.) program of the American Sleep Apnea Association dates back to 1986. Currently, there are more than 80 A.W.A.K.E. groups meeting throughout the U.S. to serve anyone having difficulty with sleep disorders or daytime sleepiness. To locate or start an A.W.A.K.E. group in your area, please email [asaa@sleepapnea.org](mailto:asaa@sleepapnea.org).

In addition to groups that meet in person in communities across the country, a private (closed) A.W.A.K.E. Sleep Health group on Facebook offers a patient-centered support community for anyone suffering from sleep-related conditions. Find us by visiting the ASAA's Facebook page and requesting permission to join.

---

## ACKNOWLEDGEMENTS

The American Sleep Apnea Association wishes to thank the following for their services in conjunction with AWAKE Sleep Apnea Initiative:

**Gilles Frydman** at @notadrawing for capturing the portraits of individuals living with sleep apnea featured in this program booklet and in the gallery at the meeting

**Kim McCleary** at the Kith Collective for consulting and program management services to prepare for patient-focused medical product development activities

**Julie Rathjens** for design and creative services for the AWAKE initiative



AWAKE Sleep Apnea is a strategic initiative of the American Sleep Apnea Association

641 S Street, N.W. Third Floor  
Washington, D.C. 20001-5196  
Phone: 888-293-3650  
Email: [info@sleepapnea.org](mailto:info@sleepapnea.org)  
Web: [www.sleepapnea.org](http://www.sleepapnea.org)



The American Sleep Apnea Association, founded in 1990, is a patient-led 501(c)(3) nonprofit organization that promotes sleep health and awareness of sleep apnea, works for continuing improvements in treatments and care, and advocates for the interests of sleep apnea patients.