

YOUR ORGANIZATION IS INVITED TO PARTNER WITH THE  
AMERICAN SLEEP APNEA ASSOCIATION IN SUPPORT OF:

The AWAKE Sleep Apnea initiative offers a unique opportunity for organizations dedicated to better sleep health to join efforts in support of better treatment and care for sleep apnea. Participating organizations will be publicly recognized as initiative partners in exchange for active promotion of participation opportunities.



Raising our voices for progress in treatment and care

**June 1, 2018 10 a.m. until 4 p.m.**

College Park Marriott Hotel & Conference Center College Park, Maryland  
(located in the Washington, D.C. metro area)

## 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, focused on a wide range of chronic and terminal conditions, including both prevalent and rare diseases. Narcolepsy was the first rare disease featured in the series. The "Unite Narcolepsy" initiative is regularly cited by FDA for its effective community engagement. The "AWAKE Sleep Apnea" initiative will employ the same approaches.

## Breaking New Ground for Sleep Apnea & FDA

The American Sleep Apnea Association (ASAA) applied to FDA's PFDD program in November 2017. It proposed to host a meeting focused on the full range of treatment approaches used by people with sleep apnea. FDA approved ASAA's application in late February 2018 and endorsed its request to actively involve staff and reviewers from the FDA's Center for Devices and Radiologic Health (CDRH) in addition to CDER staff in this June 1, 2018 meeting, making this **the very first Patient-Focused Medical Product Development (PFMPD) meeting**.

## The AWAKE Sleep Apnea Initiative

Sleep apnea is an extremely common condition, affecting as many as 18 million individuals of all ages in the U.S. In spite of its high prevalence, there have been few forums for individuals affected by sleep apnea to share their experiences, express their treatment needs, and be heard by individuals directly involved in research, development, and regulation of medical products. ASAA created the AWAKE SLEEP APNEA education and empowerment initiative to inform patients and caregivers about this first-of-its-kind PFMPD opportunity. The initiative will also prepare the community to accelerate progress in care and treatment of sleep apnea and promote the importance of sleep health.

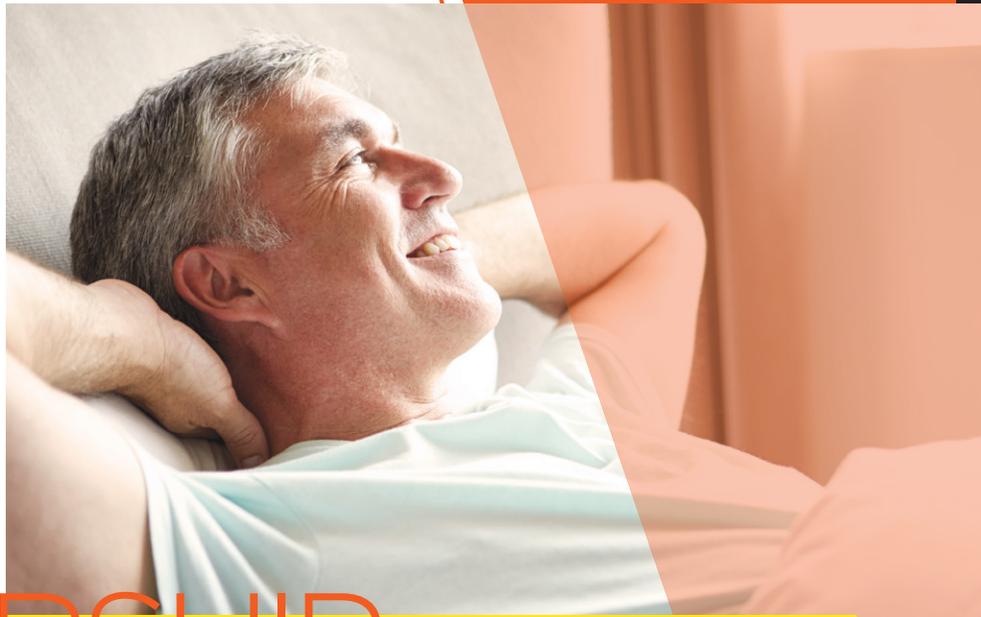
The AWAKE Sleep Apnea PFMPD initiative includes several participation opportunities for patients, caregivers, and other stakeholders:

- In-person attendance at the June 1 meeting in College Park (near the FDA) where participants will have the chance to take part in moderated group discussions and live polling questions;
- Remote attendance via live webcast at the June 1 meeting with the ability to respond to live polling questions (patients and caregivers only);
- Response to a pre-meeting patient/caregiver survey about symptoms, impacts on daily living, treatment approaches used, and unmet treatment needs; and,
- Submission of written comments by email or postal mail.

Following the June 1 meeting, a report combining all these forms of patient and caregiver experience input will be issued to participants, FDA, sponsors, and the public. It will also be submitted to FDA's online Patient Experience Repository.



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# PARTNERSHIP OPPORTUNITIES

## Initiative Sponsorship Opportunities

ASAA invites non-profit patient organizations and professional societies to support the AWAKE SLEEP APNEA initiative. In exchange for actively promoting the initiative, partners will receive visibility and recognition throughout all initiative activities including onsite at the June 1 meeting and in the enduring report.

### PRE-MEETING ENGAGEMENT & PROMOTION (April & May 2018)

Your organization will receive name and logo recognition as an AWAKE Sleep Apnea Partner via:

- Dedicated AWAKE SLEEP APNEA initiative website (under development);
- ASAA's campaign webinars; and,
- ASAA's community outreach and educational activities.

Contact Karen Misantone at [karen@sleeptember.org](mailto:karen@sleeptember.org) to arrange a call to discuss partnership opportunities in more detail.

## On-Site at the June 1 Meeting

Partnering organizations receive seating and meals for up to 2 representatives at the June 1 meeting. They will also be included in a special invitation-only briefing on the afternoon of May 31 to recap the initiative, report data collected in the pre-meeting patient/caregiver survey, and preview the meeting agenda & participants.

Partners receive name and logo recognition via:

- Print meeting program;
- Introductory and closing remarks; and,
- Acknowledgement in the enduring meeting report.

In exchange for these visibility and participation benefits, partners are expected to actively promote the AWAKE Sleep Apnea initiative using their traditional and social communication channels. Template messaging about participation opportunities for patients, caregivers, and other stakeholders will be provided by ASAA to encourage consistency and for ease of adoption.

ASAA is seeking paid sponsorship from a variety of companies that serve individuals with sleep disorders, including pharmaceutical and medical device innovators, companies facilitating research, distributors of medical equipment and supplies, and sleep-related consumer brands. Sponsors will receive recognition and participation benefits in consideration of unrestricted educational grants to the American Sleep Apnea Association to defray costs associated with the meeting events, survey, community outreach and educational activities, and report production. Sponsorship will also support a select number of travel scholarships for sleep apnea patients and caregivers to attend the June 1 meeting, the recipients of which will be chosen solely by ASAA.

### The June 1 Meeting Facilitates Interactions with:

- Patients diagnosed with or at-risk for sleep apnea
- Caregivers and family members of patients
- Staff and reviewers from FDA's Center for Drug Evaluation and Research (CDER) and Center for Devices and Radiologic Health (CDRH)
- Patient organizations and professional societies dedicated to improving sleep health
- Life science industry partners, researchers, and clinicians