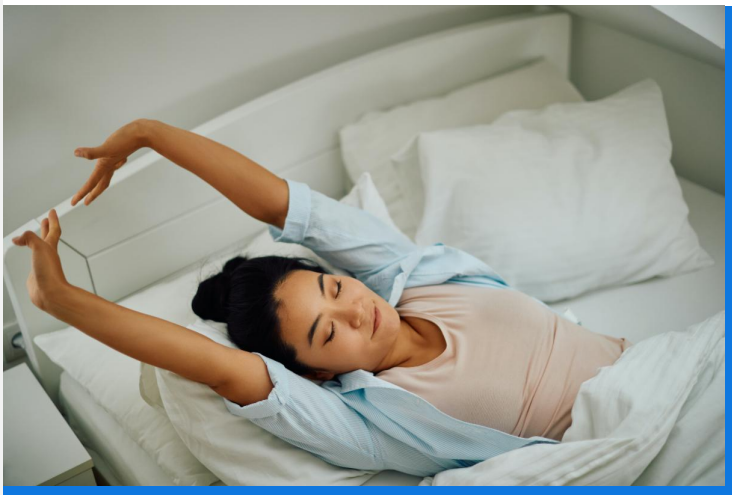
Alliance of Sleep Apnea Partners

OCTOBER 2024



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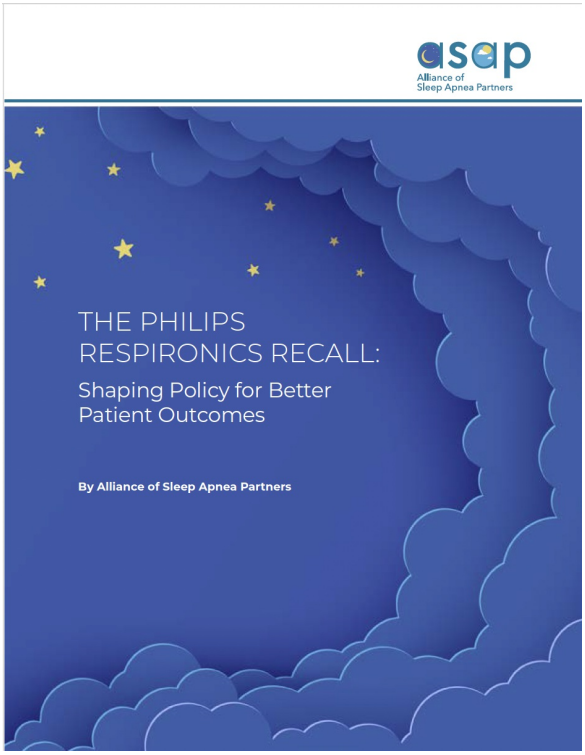
New ASAP White Paper Spotlights Harmful Failures During Philips Recall

Report details recall's impact on patients and healthcare providers, includes policy recommendations

ASAP has released a comprehensive white paper, "The Philips Respironics Recall: Shaping Policy for Better Patient Outcomes." This report examines the far-reaching consequences of the Food and Drug Administration's 2021 recall of Philips Respironics CPAP, BiPAP, and ventilator devices. This is one of the largest medical device recalls in history, involving an estimated 15 million devices worldwide and 10 million in the United States alone.



Key highlights of the ASAP white paper include:

- Analysis of the recall's negative impact on patient care and healthcare provider management
- Identification of systemic gaps and communication failures that exacerbated challenges
- Policy recommendations to improve

respiratory device regulation and patient safety
- Insights from discussions with patients, healthcare providers, sleep researchers, former FDA representatives, and policy analysts

The white paper's proposed policy recommendations include:

1. Creating a national respiratory device registry for improved recall communication and tracking
2. Enhancing FDA authority on post-market surveillance of respiratory devices
3. Reforming Medicare and Medicaid rules to facilitate timely replacement of recalled respiratory devices
4. Amplifying patient voices in regulatory decision-making processes
5. Increasing support for research, innovation, and education around sleep apnea therapies

"This white paper serves as a call to action for industry, regulators, and policymakers to prioritize patient safety and improve communication during medical device recalls," said ASAP Executive Director Dr. Monica Mallampalli. "And it empowers patients to become effective advocates for awareness and change, both in policy and regulation, as well as during the development and post-market surveillance of these devices."
The report is based on a series of public panel discussions conducted by ASAP, which are available for free on the organization's YouTube channel (@ApneaPartners).
This project was made possible through a generous grant from the American Academy of Sleep Medicine Foundation.
For more information about the Alliance of Sleep Apnea Partners and to access the full white paper, please visit apneapartners.org.

Read the Report

New Survey Reveals Hidden Impact of OSA

Apnimed, Inc., has announced the results of its Sleep Health Inquiries on Needs and Emotions (SHINE) survey of 1,500 people living with obstructive sleep apnea (OSA).

The survey results revealed the significant and often devastating impact that people living with OSA experience daily. Many respondents reported feeling worn out or exhausted from fatigue, with 74% indicating this issue. Additionally, 67% feared long-term health consequences, while 34% expressed a fear of dying due to their OSA.

"The SHINE survey has powerfully captured the voices and challenges faced by individuals living with OSA, a chronic illness that has failed to receive the public attention it deserves," said Monica P. Mallampalli, PhD, Executive Director, Alliance of Sleep Apnea Partners. "The real-life experiences of living with OSA spotlighted in the results emphasize the need for greater awareness, both for the public and for healthcare providers, to improve recognition and management of this often-overlooked condition."

ASAP, the American Sleep Apnea Association, and Project Sleep collaborated with Apnimed to review the survey results and have joined forces to distribute the findings.
Download a SHINE survey infographic here.
Visit OSAsurvey.com to read personal stories of four people living with OSA that shine further light on the challenges of this disease, as well as the full results of the survey.

See Survey Results

SCIENCE CORNER

Tirzepatide Study Shows Promise for Some Patients With Moderate to Severe OSA

Photo: Marcelo Leal/Unsplash

A study recently published in the New England Journal of Medicine concluded that, in adults with moderate to severe obstructive sleep apnea and obesity, once-weekly tirzepatide led to a significantly greater reduction in apnea-hypopnea index (AHI) after a year than a placebo did.

The published conclusions noted that the drug "reduced the AHI, body weight, hypoxic burden, hsCRP concentration, and systolic blood pressure and improved sleep-related patient-reported outcomes."

The group of researchers conducting the study included ASAP board member Dr. Susan Redline.

The study was funded by pharmaceutical company Eli Lilly, which currently markets tirzepatide under the name Zepbound® for weight loss and Mounjaro® for type 2 diabetes.

In April, ASAP expressed interest in learning more about how treatments like Zepbound might work in conjunction with other strategies to help improve sleep apnea patients' health and quality of life. "The next step is to ensure that this treatment is accessible and available to patients who need it upon its approval by the FDA as a sleep apnea therapy," ASAP Executive Director Monica Mallampalli, PhD, said then.

Research has shown that weight loss can help reduce the severity of OSA symptoms and related cardiometabolic abnormalities associated with both OSA and obesity. Obesity is a risk factor for OSA, though patients who are not overweight can have or continue to have OSA.

Read Study on NEJM.org Website

Download Plain-Language Summary

Apnimed Completes Enrollment in Phase 3 SynAIRgy Study for Potential Oral Treatment

Apnimed has announced early completion of patient enrollment in its Phase 3 SynAIRgy study of AD109, a potential oral treatment that Apnimed says addresses the neuromuscular cause of OSA.

The study is designed "to examine the efficacy and safety of Apnimeed's lead candidate AD109 (aroxybutynin/atomoxetine) compared to placebo at six months in adults living with mild to severe OSA.

The pharmaceutical company's Phase 3 studies include more than 1,300 patients in total,

the company said in a September press release.

Earlier this year, Apnimed also completed enrollment for its LunAIRo Phase 3 study examining AD109 in OSA. Topline Phase 3 data for both the SynAIRgy and LunAIRo studies are expected in mid-2025.

POLICY NOTES

FDA Classifies SoClean 3+, ASAP Reminds Patients to Use Caution with CPAP Cleaners

In late August, the Food and Drug Administration classified the SoClean 3+ as a Class II (moderate to high risk) respiratory accessory microbial reduction device, subject to general and special controls that "provide reasonable assurance of the safety and effectiveness of the device type."

SoClean 3+ is intended for CPAP users to apply as an additional, anti-microbial agent after cleaning their CPAP masks and ventilation hoses. According to the FDA classification letter, it has been tested for use only on ResMed Mirage FX (nasal mask), ResMed ClimateLine Air (tubing), and SlimLine (tubing) for ResMed AirSense 10 CPAP devices.

The FDA noted that SoClean 3+ had shown reduction of several bacteria *in vitro* but that "any correlation between *in vitro* results and clinical outcome has not been established." "This device must not be used to replace the cleaning procedures as recommended by the CPAP mask and hose manufacturers," the FDA said in its letter to SoClean, Inc., classifying SoClean 3+.

ASAP reminds CPAP users to follow their device manufacturers' cleaning instructions, as well as the FDA's previous recommendations for using SoClean2 and SoClean3 products. The FDA provided those recommendations as part of information it issued after SoClean's voluntary recall related to the use of SoClean2 and SoClean3 equipment used to clean, sanitize, or disinfect CPAP devices and accessories.

Read Recommendations

ASAP Comments on Proposed CMS Rule-Making

ASAP recently commented on proposed rule making by the Centers for Medicare & Medicaid Services (CMS) regarding Medicare programs and services. ASAP provided comments on caregiver training and audio-only telecommunications technology and on services related to oral appliances for OSA.

To read this and other comment letters submitted by ASAP, visit the **Policy Engagement page** under the Advocacy tab on **apneapartners.org**.

Read the Comment Letter

ASAP NEWS

ASAP Executive Director Mallampalli Sharing

Patient Perspectives Around the U.S.

Alliance of Sleep Apnea Partners Executive Director Monica Mallampalli, PhD, continues to represent patient voices and perspectives at conferences and in media around the country.

On Nov. 9, she'll present at the Florida Association of Sleep Technologists conference on the topic "A Breath of Fresh Care: Advocating for Sleep Apnea Patients." That month she'll also participate in a National Institutes for Health workshop on personalized approaches to OSA, where she'll discuss sex differences and the importance of including patients.

In October, she visited the Carolina Sleep Society in South Carolina to give a presentation about the Philips Respironics Recall's impact on patients and providers in the lead-up to the release of ASAP's white paper, "The Philips Respironics Recall: Shaping Policy for Better Patient Outcomes."

She also joined Italian sleep apnea patient advocate Luca Roberti of Associazione Apnoici Italiani-ETS to moderate an online discussion with sleep medicine doctor and sleep apnea researcher Dr. Atul Malhotra, the director of research for pulmonary, critical care, sleep medicine, and physiology at the University of California, San Diego's medical school.

Well+Good Interviews Founding Board Member Redline About Sleep Apnea in Women

In an article published in October on WellAndGood.com, ASAP founding board member Dr. Susan Redline, a Harvard professor of epidemiology and sleep medicine, talked about the "diagnosis gap" between men and women who have obstructive sleep apnea.

The article by Jenn McKee, noted, "While it's still true that more men than women have apnea ... the estimated gender disparity has shrunk in recent years from 8:1 to 3:1 (if not even less). Dr. Redline believes this narrowing gap is not because more women are developing apnea but because more are being accurately diagnosed."

"I've had [female] patients tell me, after they got diagnosed and treated and felt so much better, how many years a doctor was just saying to them, 'Oh, you're not getting enough sleep.' 'You're working too hard.' 'You're eating too much.' 'You're too fat,'" Dr. Redline said in the article. "And, lo and behold, they had something very treatable."

Read the Article

Board Members Hanson, Merrell Speak About Sleep Disorder Experiences

ASAP founding board member Mark Hanson and patient advocate Ray Merrell, both dedicated and long-term patient advocates, have been sharing their stories to the wider community in recent weeks.

In August, they both joined ASAP medical and scientific advisor Michael Grandner, PhD, online to share their sleep disorder experiences as part of the University of Arizona Sleep and Health Research Program's Patient Panel series. For instructions to access this archived video discussion, click here and select "Essentials series" when asked which recordings you are interested in.

In October, Merrell also gave a presentation, "When Dreams Break Through: Living with REM Sleep Behavior Disorder," at the Society of Anesthesia and Sleep Medicine's annual conference in Philadelphia as of Project Sleep's Rising Voices program, which empowers patients to share their sleep disorder experiences

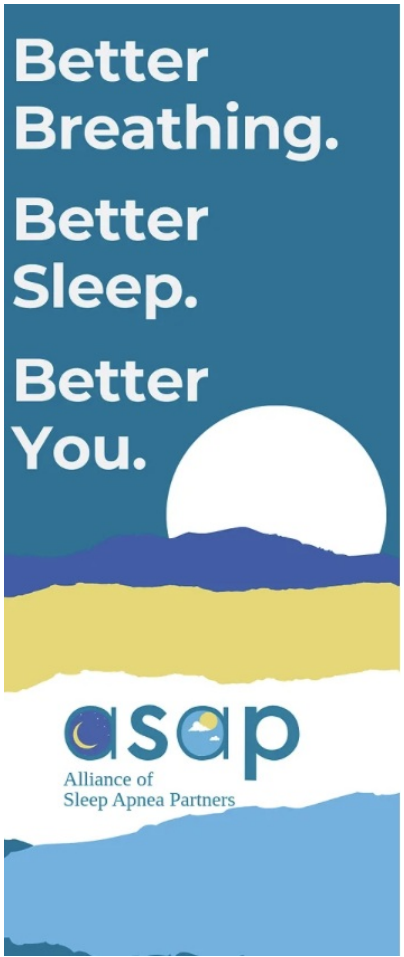
Apnea Story by Sue Roberts: "I Have Never Slept Better"

When her husband developed sleep apnea, Sue endured a lot of sleepless nights due to his snoring. In the year since he began oral appliance therapy, both Sue and her husband are finally getting their rest.

This blog post originally as written for the American Academy of Dental Sleep Medicine, the only national non-profit professional society dedicated exclusively to the practice of dental sleep medicine, and is published here with their permission. The AADSM represents thousands of dentists across the U.S. who are specially trained to provide snoring and sleep apnea solutions.

Would you like to share your own sleep apnea experience with other patients in the sleep apnea community? Submit your story to info@apneapartners.org.

Read Sue's Apnea Story



Help ASAP's Patient Advocacy Mission

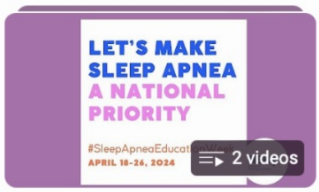
The Alliance of Sleep Apnea Partners is a patient-centered 501(c)(3) nonprofit working to ensure not only that patient voices are heard, but that health care policies benefit patients and improve their health outcomes.

We're dedicated to serving those living with sleep-disordered breathing or who have been diagnosed with obstructive sleep apnea. We strive to represent diverse patient voices at the local, regional, and national levels through education, advocacy, and support to eliminate gaps in patient care.

Your donation helps ASAP carry out this work to create a brighter future for everyone living with sleep apnea.

DONATE TO ASAP

Explore ASAP and Our Resources Online



Sleep Apnea Education Week

View full playlist

Breathing Room

View full playlist

Laura Explains

View full playlist

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- YouTube: youtube.com/@apneapartners
- LinkedIn: @ApneaPartners
- Twitter/X: @OfApnea
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We Want to Hear From You!

Do you have questions or concerns about sleep apnea? Do you have a sleep apnea story to share?
Email ASAP and let us know!

Email ASAP