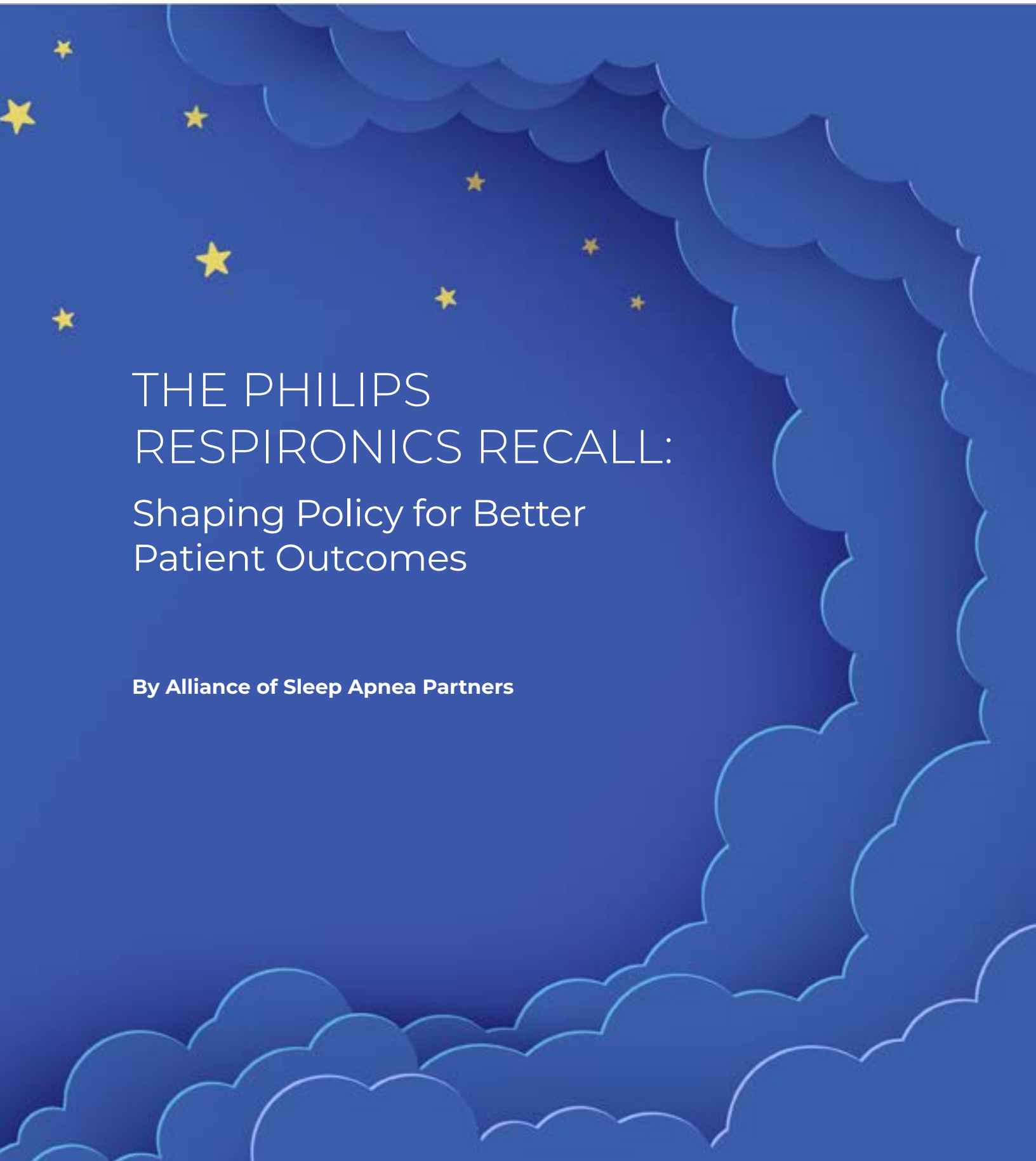
Alliance of
Sleep Apnea Partners



THE PHILIPS RESPIRONICS RECALL:

Shaping Policy for Better Patient Outcomes

By Alliance of Sleep Apnea Partners

About Alliance of Sleep Apnea Partners (ASAP)

We are a patient-oriented nonprofit 501(c)(3) advocacy organization founded in 2018 by patient volunteers. Our mission is to promote and advocate for screening, diagnosis, treatment and management for optimal health of those who suffer from sleep apnea.

As a trusted partner with patients, healthcare providers, industry, governmental agencies and other advocacy organizations, we want to ensure that sleep apnea is a national priority and at the same time make sure that the policies support person-centered care.

For more information on ASAP, please visit us at **apneapartners.org**.

Email us at **info@apneapartners.org**.

You can find us on:

Support our work by donating today
apneapartners.org/donate

Oct. 30, 2024

Dear Readers,

On June 14, 2021, the Food and Drug Administration (FDA) recalled several Philips Respironics products, including ventilators and positive airway pressure (PAP) devices over safety concerns. This is one of the most serious device recalls in recent times. Furthermore, it has also been the worst recall affecting the sleep apnea patient community, and we will continue to see its impact in the years ahead.

As a patient-oriented advocacy organization, we felt it was important for the Alliance of Sleep Apnea Partners (ASAP) to truly understand what led to the recall and how some of the healthcare delivery processes that had been working for years finally failed patients. Our goal was not to place blame on any one organization or entity, but to simply examine the scope of the problem and hopefully find workable solutions to ensure that the impact of another potential recall in the future is minimal on the patient community and that patients' care is not interrupted as a result of any such recall.

As we set out to speak with a diverse group of stakeholders who were affected by the recall, we ran into a number of roadblocks due to the ongoing legal issues between several organizations and Philips Respironics. In spite of these roadblocks, we still managed to have rich conversations around the impact of the recall on patients and providers and also were able to discuss the policy implications pertaining to the recall. We have made these conversations available to the public for free via ASAP's **YouTube channel** and **website**. In total, there are four episodes in this series called "Breathing Easier": 1) Patient Perspectives, 2) Physician Perspectives, 3) Policy Perspectives and 4) Frontline provider perspectives.

This report captures key highlights of these conversations and lays out potential recommendations on how to change the current landscape from medical device regulation to patient engagement in regulatory decision-making and to promote more effective communication. It also serves as a call to action and encourages the

- Industry to ensure that medical products are safe and efficacious for patients and to include patient feedback and engagement throughout the product lifecycle, including post-market phases.
- FDA to work closely and effectively with patient organizations to ensure better communications, including making patients aware of their opportunities to provide feedback and perspectives during the device approval and post-market surveillance processes.
- Congress to ensure that FDA's regulatory policies favor innovation and at the same time support patient protection.
- Public to understand their role as an effective advocate for change and to contact their members of Congress using ASAP's advocacy toolkit to raise awareness of any adverse impacts this recall has had on their or their loved ones' health.

We thank all our collaborators and colleagues who have supported us on this initiative. We are also grateful to the American Academy of Sleep Medicine Foundation for a grant that has made this project possible.

Sincerely,

Monica P. Mallampalli, PhD
Executive Director, Alliance of Sleep Apnea Partners

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Acknowledgments

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- Muhammad Adeel Rishi, MD, Chair of the Public Safety Committee of the American Academy of Sleep Medicine & Associate Professor of Medicine at Indiana University School of Medicine
- Andre Puleo, Business Development Consultant
- Emma Cooksey, Podcast Host of *Sleep Apnea Stories*
- Frank Salvatore, System Director for Sleep and Wound Care/ Hyperbaric Medicine at Nuvance Health
- Kushal Kadakia, Medical Student and Health Policy researcher at Harvard University
- Laura DeFelice, former Manager of the Connecticut Center for Sleep Medicine at Stamford Hospital
- Madris Kinard, Founder and CEO of Device Events, LLC
- Michael Twery, PhD, Independent Consultant and ASAP Scientific Advisor
- Nicole Sondermann, NBC-HWC, CCSH, RPSGT, Founder of Sleep Health Coach
- Randy Bosin, Founder, Philips CPAP, BiPAP Recall Support and Advocacy
- Rebecca Robbins, PhD, Assistant Professor in Medicine at Harvard Medical School and an Associate Scientist at the Brigham and Women's Hospital
- Tetyana Kendzerska, MD, PhD, Associate professor in the Department of Medicine, Division of Respirology at the University of Ottawa
- Tom Wilson, Founder, Philips CPAP Recall Support Group
- Vaishnavi Kundel, MD, Member of American Thoracic Society's Sleep and Respiratory Neurobiology Assembly & Assistant Professor of Medicine in the Division of Pulmonary, Critical Care and Sleep Medicine at the Icahn School of Medicine at Mount Sinai

We also thank ASAP board of directors, community leadership council and consultants in contributing and producing this project.

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Executive Summary

The 2021 Philips Respironics recall of CPAP, BiPAP, and ventilator devices 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.

The recall, which was due to potential health risks associated with the degradation of polyester-based polyurethane (PE-PUR) sound-abatement foam in the devices, continues to reverberate throughout the healthcare industry, significantly impacting both sleep apnea patients and healthcare providers.

The recall has highlighted significant challenges in patient care and healthcare provider management during medical device recalls. Based on a series of public discussions that the Alliance of Sleep Apnea Partners (ASAP) conducted with patients, healthcare providers, sleep researchers, former FDA representatives, and policy analysts, this white paper examines the impact of the recall on patient care, the challenges faced by both patients and their healthcare providers, the systemic gaps and lack of communication that exacerbated those challenges, and policy changes that can help address these issues.

The recall has had profound implications for sleep apnea patients, disrupting their treatment, contributing to or worsening their existing health concerns, and undermining their faith in CPAP as a treatment modality. Financial barriers and supply shortages also have presented obstacles for patients, particularly those from underserved communities, who have sought to have their machines replaced. Meanwhile, healthcare providers also have wrestled with shortages, safety concerns, patient questions, and disparities in device distribution, underscoring systemic vulnerabilities in the management of medical device recalls.

Policy and communication failures have added to patients' and providers' difficulties, making it even harder to manage the recall effectively. Poor communication between stakeholders and a lack of transparency in reporting adverse events also have undermined patient trust and hindered timely notification and follow-up during recalls.

To address these shortcomings, ASAP proposes several policy recommendations, including

- creating a national device registry to communicate and track medical devices used by patients when a recall is initiated
- improving communication protocols between device industry and patients as well as the FDA and patient community.
- enhancing FDA's authority on post-market surveillance of FDA-cleared devices
- reforming Medicare and Medicaid rules to facilitate timely replacement of recalled devices
- amplifying patient voices in the regulatory decision-making process
- increasing support for research, innovation, and education around sleep apnea therapies

This report aims to highlight key issues and offer strategic steps to stakeholders for mitigating risks and safeguarding patient health. By implementing these recommendations, regulatory agencies along with patient organizations can raise patient awareness and promote better safety measures, support healthcare providers' efforts to protect patients, and improve the management of future medical device recalls. By exploring the failures and gaps that hamper sleep apnea patients' ability to get appropriate treatment, ASAP also intends to arm those patients with the knowledge to help them advocate for themselves to secure better policies and care.

Background

Obstructive sleep apnea (OSA) affects an estimated 54 million individuals in the United States between the ages of 30 and 70.[1] The condition leads to disruptions in breathing during sleep and is related to a number of potentially severe health problems—including high blood pressure, type 2 diabetes, heart disease, atrial fibrillation, pulmonary hypertension, stroke, and cognitive problems—if left untreated.[2]

CPAP therapy, delivered through devices manufactured by companies like Philips Respironics, is considered among the leading treatments for managing OSA. However, in April 2021, Philips notified the FDA of potential health risks related to the breakdown of the polyester-based polyurethane (PE-PUR) sound-abatement foam in certain CPAP, BiPAP, and ventilator devices.[3] Two months later, on June 14, 2021, the company initiated a voluntary recall due to concerns over the breakdown of the sound-abatement foam, which could release inhalable particles and gases harmful to users' health.

The FDA declared the Philips recall a Class I recall, the administration's most serious designation, indicating "a situation where there is a reasonable chance that a product will cause serious health problems or death."[4]

According to the FDA website, fda.gov, from April 1, 2021, through September 30, 2023, there were more than 115,000 medical device reports (MDRs), including both mandatory reports from Philips and voluntary reports from health professionals, consumers, and patients. Symptoms reported to the FDA include cancer, pneumonia, asthma, infections, headache, cough, dyspnea (difficulty breathing), dizziness, nodules, and chest pain including more than 561 deaths.[5]

Previous internal concerns at Philips Respironics about device safety and adverse events had not been reported promptly to the FDA, raising questions about transparency and accountability within the medical device industry.[6] These delays also contributed to a prolonged period of uncertainty both for patients and their healthcare providers.

The recall affected more than 15 million devices globally, including 5.6 million CPAP and BiPAP therapy devices. [7,8] Unfortunately, it also came during the SARS-COV-2 pandemic, a time when breathing-related devices were in high demand and already subject to supply-chain problems compounding the issue further.[9] This left sleep apnea patients and their providers seeking answers, with little guidance on their treatment options and

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1 Benjafield AV, Ayas NT, Eastwood PR, et al. Estimation of the global prevalence and burden of obstructive sleep apnoea: a literature-based analysis. Lancet Respir Med. 2019;7(8):687-698. doi:10.1016/S2213-2600(19)30198-5

2 Yeghiazarians Y, Jneid H, Tietjens JR, et al. Obstructive Sleep Apnea and Cardiovascular Disease: A Scientific Statement From the American Heart Association [published correction appears in Circulation. 2022 Mar 22;145(12):e775]. *Circulation*. 2021;144(3):e56-e67. doi:10.1161/CIR.0000000000000988

3 U.S. Food and Drug Administration, **FDA Activities Related to Recalled Philips Ventilators, BiPAP Machines, and CPAP Machines**.

4 U.S. Food and Drug Administration, **"What Is a Medical Device Recall?"** fda.gov, retrieved June 10, 2024.

5 U.S. Food and Drug Administration, **"Problems Reported with Recalled Philips Ventilators, BiPAP Machines, and CPAP Machines"**. fda.gov, retrieved June 10, 2024.

6 U.S. Food and Drug Administration letter to Philips Respironics on proposal for FDA to issue an order for device repair, replacement, and/or repair. **"Notice for opportunity for hearing"**. fda.gov, May 2, 2022.

7 U.S. Food and Drug Administration, **"Recalled Philips Ventilators, BiPAP Machines, and CPAP Machines"**. fda.gov, retrieved June 10, 2024.

8 Philips Respironics, **"Explained: The voluntary Philips Respironics sleep and respiratory care devices recall"** Philips.com, retrieved June 15, 2024.

9 Chip shortages threaten diminished supply of CPAP machines. **Chestnet.org**. March 1, 2022.

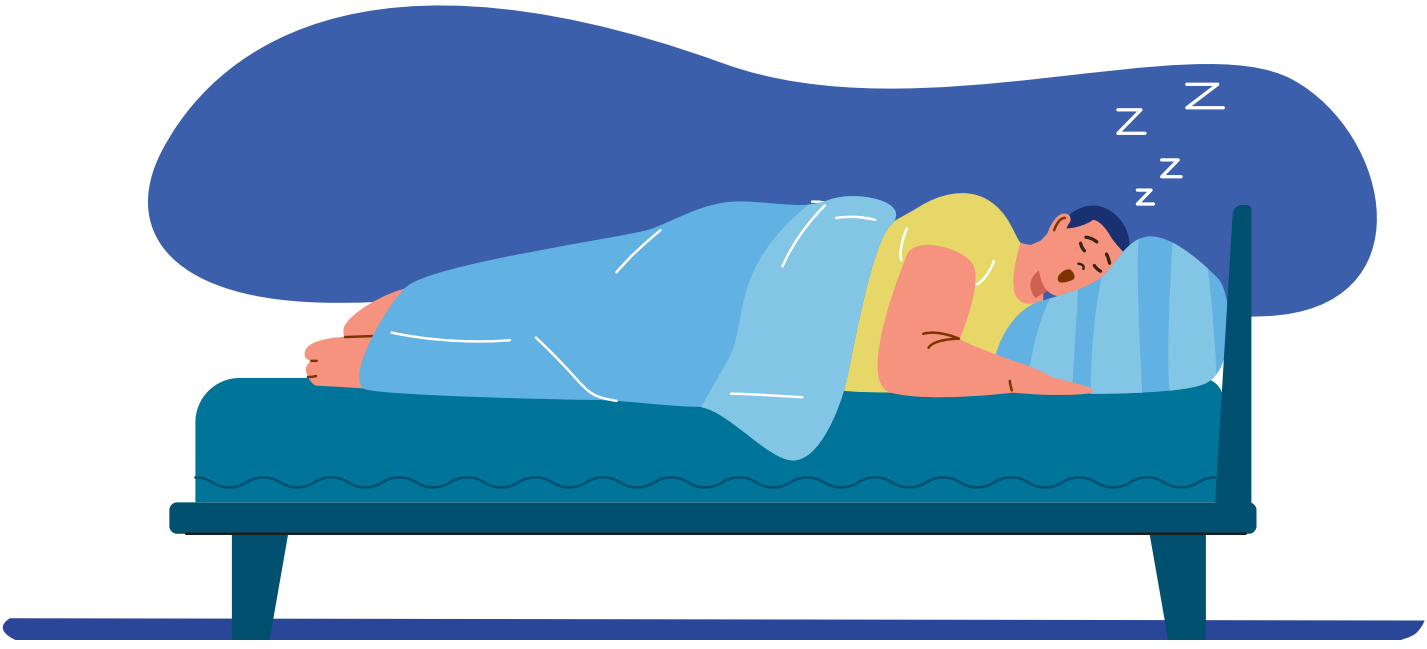
a painfully short supply of replacement devices, even for patients who could afford to replace their recalled devices out of pocket.

This created a perfect storm, leading to shortages, rationing, and disruptions in patient care. The situation was made worse by sometimes conflicting advice from Philips and by systemic gaps that prevented Philips, care providers, or other stakeholders from easily contacting the devices' users directly to alert them to the recall and any steps they should take.

The recall was to end on December 31, 2024, highlighting persistent challenges in addressing the issue effectively. In the meantime, we believe several million sleep apnea patients, including those belonging to lower socio economic status, either remain uncontacted and potentially unaware of the recall, are still waiting for replacement machines, or are uncertain whether to stop or continue their CPAP treatment.

As of March 27, 2024, Philips Respironics has acknowledged on their website that they have remediated 2.59 million patients within the U.S., meaning these patients have either received new, recertified or an alternative device sent as replacements in lieu of the affected units (either directly or via their DMEs) or have received financial payments from the company.[10]

Addressing these issues of availability, access, and communication will require coordinated efforts across stakeholders and must include manufacturers, regulators, healthcare providers, patient organizations, and policymakers to ensure continued access to essential sleep apnea treatment and mitigate the ongoing negative impact on patients' health and well-being.



10 Voluntary Recall Information for Philips Respironics Sleep and Respiratory Care Devices. Remediation Progress Update. **usa.phillips.com**. April 10, 2024.

The Impact on Patients

The recall has had profound effects on patients who rely on CPAP therapy for managing sleep apnea. Many patients initially were unaware of the recall and often received word from non-medical sources. "Patients, according to their providers, most commonly heard about the recall through news," said Dr. Rebecca Robbins, an assistant professor at Harvard Medical School, associate scientist at Brigham and Women's Hospital, and lead author of "Quantifying the Impact of the Philips Recall on Patients with Sleep Apnea and Clinicians," which collected data until July 2022. "I think that that sheds a little bit of light on opportunities, should there be another instance of this, to better communicate to patients and providers instead of having this kind of what we call in the health communication world 'a two-step flow of information,' not directly from the provider or from the manufacturer but instead through a news outlet where the information the messages might not be as accurate as one would hope."

Many of those patients who were aware of the recall encountered conflicting information.

"When Philips initially put out this recall, they actually told patients to stop using their devices," said Dr. Muhammad Adeel Rishi, chair of the American Academy of Sleep Medicine's Public Safety Committee. "That was the initial communication that went out. And that was a huge problem.

"Some of the patients showed up three, four, five months after the recall, and they should not have been using devices. Some of them probably should not have stopped using their devices. It is a decision that should be very customized to the patient's needs, and that initial instruction from Philips was not appropriate."

This contributed to confusion and anxiety among patients about the safety of their devices. Difficulty obtaining replacements, compounded by insurance limitations and Medicare rules (including a policy to replace CPAP machines only every five years in most circumstances), left patients facing financial burdens and treatment disruptions.

> "There were a lot of people who had all these dilemmas: should I continue to use my device that I've been told is unsafe or should I ... go out and buy a new machine? ... I didn't have $1,400 to go out and buy a new BiPAP. So I kept using it for several months until I then became eligible on Medicare to help pay for a new machine. But a lot of people were faced with a lot of these dilemmas and had really little guidance from the medical suppliers or doctors. There were a lot of people fending for themselves."
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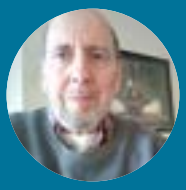
> 
>
> **Randy Bosin**
> sleep apnea patient and patient advocate

The lack of clear communication and guidance further eroded patients' trust in medical devices, healthcare providers, and regulatory agencies.

"They did, in my opinion, an extremely poor job communicating to not only consumers, but all the constituencies: the doctors, the DMEs," said Tom Wilson, who established the Philips CPAP Recall Support Group in June 2021 for patients like him who were affected by the recall. "Frankly, nobody really knew what was going on, and everyone was upset. That, I think, was the biggest problem."

"Definitely, the communication was so lacking," added Emma Cooksey, a sleep apnea patient who also hosts the Sleep Apnea Stories podcast. "I first heard about the recall from one of my podcast listeners emailing me and saying, 'I heard there was a recall. What should I do?' I went and read what Philips had put out and thought to myself, 'Well, just go to your doctor.' Because I just assumed as a patient that a large recall of this kind could never happen without them giving the doctors lots of information ahead of time so that they could actually advise their patients on what to do. But over the weeks, it became clear that the doctors really hadn't had any communication from Philips, and similarly with the DME companies. There are an awful lot of patients just having to deal with this, trying to contact the DME company, trying to contact Philips, and trying to contact their doctors and not really getting anywhere. The communication, I think, really has been the biggest problem.

"I hear a lot from family members at all the different stages," Cooksey added. "So family members of people who are pre-diagnosis, whether it's a partner or an older relative that they're trying to get to go to the doctor about sleep apnea symptoms. I feel like, with the recall, there was a big erosion of trust to the point where some of those people who were just reluctant because they didn't want to take a sleep study or go see the doctor at all were now saying, 'Well, it seems like there's this recall and bad things could happen if I use a CPAP machine anyway, so I may as well not get tested. I think it just had a cooling effect on anybody actually going and getting a diagnosis in the first place."

For those patients who were aware of the recall and knew that they had a recalled machine, the dilemma was stark: to continue treatment on a machine deemed potentially dangerous or to stop life-improving, and potentially life-saving, treatment.

"The other big issue is that, even when people get a replacement device, what are the potential health issues going forward?" asked sleep apnea patient and patient advocate Randy Bosin. "I haven't really heard or seen that that's been addressed in any consequential manner by anybody so far. And some of those [issues], of course, may not develop for a long time. We could be looking at a long-term situation. There certainly have been a lot of people who believe they've already become sick because of using these devices, but who knows what the future is going to hold? Things like cancer can possibly take years to develop."

Those who were required to maintain consistent CPAP treatment as part of their employment in safety-sensitive occupations also experienced anxiety over possible job loss if they stopped treatment on their recalled machines.

"Someone I heard from was a pilot, and they were in a situation where they had to show compliance," Cooksey noted. "If your CPAP has been recalled, it's very difficult to show the compliance."

Nicole Sondermann, a board-certified clinical sleep health educator and a nationally board-certified health and wellness coach. Sondermann also noted that employees in safety-sensitive positions,

such as first responders, airline pilots, truck drivers, school bus drivers, were under particular pressure.

"When I had patients call and they were asking about using the equipment or running the risk of losing their job, the recommendation that I made was for them to speak to their managers, to their HR department, employee health, and just explain the scenario," Sondermann explained. "It was up to … the leadership within organizations to then make decisions on are we going to look at the compliance or are we going to put out a notification regarding CPAP and the employees. …

"If something like this does happen, have a plan B," she said, "and not just empower the patients, but empower the employers. … Let those institutions assist the patient with a plan. So you're using the equipment because you need it, you have to stay compliant so you stay compliant for work. Let the companies get involved. And then the insurance cost won't be as big a burden as it initially was for people that have to use it for work. Maybe their EAP [employee assistance program] can have an extra plan where you send the equipment in and get a new one or have it at least evaluated. … I think having the option of corporate standing behind you, it eases the burden on the patient and on the medical system."

Dr. Tetyana Kendzerska, an associate professor in the Department of Medicine, Division of Respirology, at the University of Ottawa noted that the lack of communication, device shortage, and confusion over whether to use or not use CPAP did more than frustrate patients.

"Anxiety and depression were not listed as potential side effects associated with the devices," she said. "But this is what we see in our patients. We can see this anxiety and fear associated with using the device and having this decision-making process, if I should continue using the device, if I should stop using this device."

Paying for a new machine out of pocket was a potential option for those patients who could afford it—and who could find another machine. But as prices climbed for scarce machines, more patients struggled to decide what to do. There were stark disparities, as Dr. Rishi, who works in a county hospital in Indianapolis noted.

"I can tell you that, at the place where I'm at, it's a county hospital, most of my patients are poor, are minority communities, indigent, a lot of patients who are uninsured or underinsured, undocumented," he said. "I think maybe 50 % who had the recalled devices still have recalled devices.

"Patients who had the means are not on recalled devices. They were not on recalled devices within a couple of months of having the recall. They just went out there and bought the machine, like a thousand-dollar machine. … So two, three years out, the only patients who have the recalled machine are those who don't have the means or did not have the ability to get on the internet and get devices, which is just our old and the elderly and those who don't speak English, and those who don't have access to internet, or those who are in jails, those who can't advocate for themselves. Those are the patients who are without devices right now. And unfortunately, when you work in a county hospital, those are the patients that you serve. Those are the patients you're trying to advocate for."

The recall had a much broader impact than has been reported in the media, especially in vulnerable populations, leaving patients to deal with the fallout by themselves—without effective communications protocols to help them find and receive important information.

The Impact on Healthcare Providers and DMEs

The lack of timely communication and guidance from Philips and regulatory agencies also disrupted healthcare providers and durable medical equipment (DME) suppliers.

During the recall, frontline healthcare providers have been tasked with identifying affected patients, communicating safety risks, and facilitating device replacements or alternative treatment options. But limited communication and coordination between stakeholders has hindered these efforts, leading to delays in patient care and a heavy administrative burden for providers.

According to research led by Harvard Medical School's Dr. Robbins, clinicians primarily heard about the recall through Philips. But still only 25% of them reported that they initially heard about the recall from the manufacturer; slightly fewer, 23%, reported hearing through the clinic, and 14% said they first heard via the news.[11]

"There was a pandemic going on, and then you get a big recall that hit the sleep medicine community," recalled. Dr. Rishi, the American Academy of Sleep Medicine Public Safety Committee's chair, who described the situation as seeming "like it was the second pandemic in the pandemic."

"That's what it felt like, at least to the providers who work with me and to our patients," he said. "The size of the recall, I think, was a huge problem, and the fact that it was so hard to ramp up production because of everything that was going on with the pandemic itself made responding to this recall so much harder. … The second big issue that I would point out was the communication.

"We've kind of suffered through these last two years partly because the communication was not good from Philips, but I think Philips is not the only one to blame. I think the way FDA handles these types of recalls, now that we've gone through this once, I think it's easy to see that that's not optimal. Something has to change there as well, if we are to improve this type of situation, if it ever happens again, which I hope it doesn't."

> "Many providers themselves were forced to do this challenging kind of trade-off, and discussion with patients was like, 'This is an uncertainty. There may be carcinogens and it may be cancer-causing, but it's also a life-saving treatment.' How are we supposed to and how are patients supposed to make sense of that?"
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> **Dr. Rebecca Robbins**
> assistant professor, Harvard Medical School and lead author of *Quantifying the Impact of the Philips Recall on Patients With Sleep Apnea and Clinicians*

Frontline healthcare providers speaking publicly with ASAP noted that, because the distribution of CPAP machines is handled largely through DMEs, often is based on the particular stock a DME has available at the time, and is not recorded in a national registry of devices and patients, providers often were unable to identify which machine their patients had in order to alert them proactively

11 Robbins R, Epstein LJ, Pavlova MK, Iyer J, Batool-Anwar S, Bertisch SM, Quan SF. Quantifying the impact of the Philips recall on patients with sleep apnea and clinicians. *J Clin Sleep Med.* 2023 Sep 1;19(9):1677-1683. doi: 10.5664/jcsm.10652. PMID: 37143357; PMCID: PMC10476045.

about the recall. This shut off another avenue for patients to receive both the recall alert and any subsequent guidance.

The problem was worse for rural and traditionally underserved areas and populations, noted Dr. Rishi, who works at a county hospital in downtown Indianapolis. “Larger cities and those DMEs which are high-volume DMEs tend to get devices earlier and then the smaller towns, the center of the country and smaller DMEs, had to wait longer,” he said.

Recall notifications from Philips relied, at least in part, on patients to have registered their CPAP machines—a burden on patients and another gap in their care, which also added to frontline providers’ hardship, as recounted by Laura DeFelice, former manager of the Connecticut Center for Sleep Medicine at Stanford Hospital.

“Philips waited for the patients to do that before they took action on anything,” she said. “And so many patients still … don’t have their machines, didn’t get a new machine yet. Which impacted on patient care, and also put a hardship on the doctor’s offices and on the doctor themselves, because now you had a volume of phone calls coming in that they didn’t have the staff to really manage, and the doctor was put in a hot seat for what to do for the patient. Do you keep them on a machine because they’re so severe they really shouldn’t be without it? The other options are not for everybody, and oral appliances are not for a severe patient. Positional therapy doesn’t work for everybody. Weight loss is not a quick fix. So … what do you do? Do you keep the patient? If there’s no indication that something’s wrong with the machine, do you keep the patient on the machine? Do you take them off and have them see if they could buy another machine? As we all know, prices went sky high after that. So, it was a very, very sad moment. And patients got caught in the middle of that.”

DeFelice and others, including former sleep

technologist Andre Puleo, now a consultant for sleep-related medical devices and software, called for a registry that does not require patients to submit information themselves and which would allow better, faster tracking of recalled machines and affected patients.

“Have a registration system across all medical devices, especially devices to go into patients’ homes, to be able to track that and have communication,” Puleo said.

“It was even really difficult to find patients, because we don’t have a registry of patients on positive airway pressure therapy,” explained Dr. Tetyana Kendzerska of the University of Ottawa. “We don’t document the manufacturer of those positive airway pressure therapy devices. So this is why we need that registry. We cannot find patients. We cannot work with those patients. We tried our best. …

“The second issue was the very limited—I would even say a lack of—information at the beginning of the recall. It was very difficult to have those conversations with our patients and very difficult to make informed decisions: should we continue with the therapy or should we stop the therapy?”

Patients who had heard about the recall inundated their physicians, sleep coaches, and sleep clinics in

search of reliable information, many of whom were short-staffed or only had limited information to provide.

"Our problem was the number of people calling the sleep center because they just couldn't get the information elsewhere," said Frank Salvatore, Systems Director for Sleep and Wound Care Hyperbaric Medicine at Nuvance Health. "We had to actually create a frequently asked questions list for those who answered the phones so that they could help answer the questions because we would just need one full-time equivalent just to answer the phones at that time."

Among clinicians who reported that they and their patients shared decision-making about whether to continue CPAP therapy, 62.4% reported advising their patients to continue using their devices, with 9% advising against. But providers also noted that they estimated a high proportion of their patients, 26%, stopped using their machines.

Providers reported that they felt their patients' health and well-being had been most significantly impacted, followed by the clinicians' own stress level, which they felt had risen due to the recall. Importantly, Dr. Robbins noted, 83.3% of providers reported feeling that their patients' trust in medicine had been disrupted to some degree.

"Where there's flip-flopping … 'Now we're recommending this, but before it was this,' I think that's really hard for patients to understand," Dr. Robbins said. "And then you add in the fact that sleep apnea is already an extremely complicated condition and patients are already reluctant and demonstrate low rates of adherence [to treatment].

"It's complicated. They have to maintain a certain level of usage. They have to engage in trial and error. And so to add this on top of all of those challenges, to sleep apnea, really just further raised concerns and barriers that patients face to getting successful treatment."

Simply determining whether patients had an affected device could be challenging, said Dr. Vaishnavi Kundel, an assistant professor of medicine in the Division of Pulmonary Critical Care and Sleep Medicine at the Icahn School of Medicine at Mount Sinai in New York.

"There were so many devices floating around," she said. "And then instructions to then register your device for replacement, that wasn't always easy, especially often in the elderly population, so that was very difficult to communicate."

DMEs, who were on the front lines of the supply chain problems, had trouble sourcing machines and components. Like the DMEs, physicians also were struggling to meet patient demand for replacement devices.

"This was the perfect storm: a recall in the middle of a pandemic," sleep clinic operator Frank Salvatore said. "And now we couldn't get the parts, we couldn't get the pieces, we couldn't get supply. It became a big issue. We've got to start standing up and saying, you know what, we need to manufacture this stuff in the United States. We need to be able to supply our healthcare population with the goods that they need."

"I think the most frustrating thing on my end was really the supply chain shortages and getting them a new device," Dr. Kundel said. "We often had patients that were maybe diagnosed six months ago. They just got that device, and now they're technically not eligible for a new device for five years through their insurance."

Sleep clinic manager DeFelice agreed that insurance was a stumbling block for patients, who also faced steeper private-purchase costs during the shortage. "With a recall, the manufacturer is responsible for replacing that machine. But unlike a recall on pharmaceuticals, if your medication gets recalled, you can go your doctor can order another medication similar to that, and you can go to the pharmacy and get it covered. That's not the case

for the criteria for insurance coverage on CPAP is very different than on other medical equipment or medications.

"So a lot of this had come out of the patient's pocket to replace that machine. Maybe we have to look at exceptions to crises like this, too, where patients would be able to get coverage because a lot of patients would not take money out of pocket to replace the machine, especially when the price is doubled."

Philips provided little information, and some of what it did release was too vague to be helpful for physicians, Dr. Kundel said. "Some of the symptomatology they mentioned was vague," she said. "It was very non-specific: headaches, congestion—often my patients have congestion or headaches, so it's really hard to pinpoint to say, 'It's your CPAP.' There was no scientific guidance, like how long should you have been using the CPAP to have been experiencing these symptoms. There was really no science backing for some of these kinds of symptoms, and it put the physicians in a hard place because we don't have the answers; we just have the information that was provided by the FDA and Philips.

"I feel like I had kind of a lot of patients in two buckets," Dr. Kundel added. "One [bucket] was there was a lot of mistrust and so they essentially were absolutely against using the recalled unit at all, which I totally understand. It was very much a shared decision-making process with each patient, a very individualized process. And then there was another bucket of patients that had been on CPAP for 10 years or five years or two years. And they said, 'Hey, doc, look, I can't live without my CPAP. I haven't noticed any of these symptoms.' We reviewed everything and then they made the decision to continue using the unit because they felt the benefit was more pronounced than the risk."

Physicians and frontline healthcare providers faced device shortages and a flood of patient inquiries that they often did not have enough information to answer. Appropriate tools like a medical device tracking system could have supported them in helping their patients, but these were nonexistent. This added more strain to an already fractured healthcare delivery system and led to a complete breakdown following the recall. As physicians and healthcare providers struggled with the situation, their patients faced dilemmas about whether or not to continue using recalled Philips devices, how to find or pay for replacements, and where to get reliable information as the recall continued.

How Current Policy Contributed to Failures

Kushal Kadakia labeled the Philips Respironics recall as an ongoing public health crisis in an opinion piece he co-authored with other policy experts. Together they called for a better device regulation by the FDA and the need for systemic reform when it comes to oversight of medical devices.[12] It is clear that the Philips Respironics CPAP recall has underscored several policy and communication failures within the medical device regulatory framework. These include:

- **Regulatory loopholes and understaffing:** The FDA's 510(k) clearance pathway, which allows devices that are considered substantially equivalent to previously cleared (or "predicate") devices to be marketed without rigorous clinical testing, may have contributed to oversight of safety issues in the Philips CPAP machine and/or its components. And as former FDA official Madris Kinard noted during "Policy Perspectives: Philips Respironics Recall," hosted by ASAP, although the agency previously had added 80 new scientists to assess devices, it did not increase staff to handle reports of problems, creating a gap in addressing issues promptly.
- **Lack of proactive surveillance and use of mandatory-recall power by the FDA:** The recall highlighted deficiencies in post-market surveillance systems, with reports of adverse events and device malfunctions going unnoticed or unaddressed for extended periods, even though FDA has the power to call a mandatory recall.[13] "FDA could take a more active role in recalls," noted health policy researcher Kushal Kadakia. "We would want the agency that tasked with protecting the health of Americans to not be the one waiting for information, but being more proactive in terms of going out and resolving recalls, and also setting standards and precedent for how it expects manufacturers to be moving in these situations."

> "What really caught our eye was the scope of the recall. There are thousands and thousands of medical devices on the market, but Philips devices stand out for how widely they are used and how important they are to patients' everyday care. And the recall encompassed over 15 million units of devices worldwide. So certainly that scale, which would rank it among one of the largest medical device recalls in history, coupled with the severity of the FDA's assessment of the situation, raised our concerns and got our interest into this process."

Kushal Kadakia
health policy researcher, Harvard Medical School, co-author of *The Philips Respironics Recall of Ventilators and Positive Airway Pressure Machines–Breakdowns in Medical Device Surveillance*

12 Kadakia KT, Ross JS, Rathi VK. The Philips Respironics Recall of Ventilators and Positive Airway Pressure Machines-Breakdowns in Medical Device Surveillance. *JAMA Intern Med.* 2023 Jan 1;183(1):5-8. doi: 10.1001/jamainternmed.2022.5141. PMID: 36374487.

13 U.S. Food and Drug Administration, "Recalls, Corrections and Removals (Devices)". fda.gov. Retrieved June 15, 2024.

- **Challenges in updating administrative forms.** Bureaucratic hurdles can slow updates to administrative forms, such as the need to incorporate a field for unique device identifiers (UDIs), which are necessary for tracking devices.
- **Lack of a national registry to track devices.** Without a national registry, neither Philips, the FDA, nor frontline healthcare providers had an adequate means to identify and communicate directly with patients whose devices were subject to the recall.
- **Under-reporting of safety concerns:** Internal concerns at Philips went unreported to the FDA for a significant period of time until the devices were recalled.[14] This delay in reporting contributed to a failure to address the safety issues promptly.
- **Inadequate risk communication:** Patients and healthcare providers received conflicting or insufficient information about the recall, leading to confusion and distrust in the healthcare system.
- **Inflexible Medicare and insurance policies regarding device replacement.** "We often had patients that were maybe diagnosed six months ago," explained Dr. Kundel from the Icahn School of Medicine at Mount Sinai. "They just got that device. And now they're technically not eligible for a new device for five years from their insurance."

Systemic issues such as these made it difficult for patients to access reliable, timely notifications about the recall or find information about steps they should take in response to it. The result was a patchwork of advice from healthcare providers (who often were not fully informed themselves about the recall and risks associated with specific devices), from Philips, and from the FDA, which patients who knew about the recall tried to piece together in the effort understand their treatment options and secure a new CPAP device. The stakes—their health and, particularly for those in safety-sensitive positions, their livelihoods—could not have been higher.

In addition to noting the systemic issues, experts also called for a federal push for innovation that could improve both patient safety and patient options. Kinard, formerly of the FDA, noted that the FDA has publicly called for innovation in other situations and could do so again. Independent consultant Michael Twery similarly called for an examination of the manufacturing culture and how a responsible, patient- and safety-centered culture might be strengthened to prevent future recalls of the kind affecting Philips PAP users.

"Is it possible to communicate with the manufacturers to incentivize those manufacturers, in terms of being good citizens, meeting those standards, and testing for those standards?" he concluded. "Because there's no profit in taking shortcuts, as Philips might find out."

14 FDA Form 483, Inspectional observations of Philips Respironics, Inc facility. **fda.gov.** Retrieved June 15, 2024.

Recommendations

1. **Strengthen FDA oversight to ensure transparency and reporting.**

   Ensure transparency and strict reporting requirements for medical device manufacturers to prompt timely and comprehensive reporting of adverse events, safety concerns, and product changes. This could include stronger penalties for non-compliance.

2. **Establish a national device registry.**

   Create a centralized database of medical devices like CPAP devices to enable manufacturers and/or FDA to quickly identify and contact affected patients and healthcare providers during recalls. As part of this, update administrative forms to facilitate device registration and tracking.
   Require that UDIs be logged into patients' electronic health records for use in recalls.

3. **Update the 510(k) clearance process.**

   Revise criteria for "substantial equivalence" for CPAP and BiPAP machines. Require clinical testing for certain device types and/or closer review of predicate devices to ensure that the comparison to new devices is adequate. Ensure that any review takes into consideration ISO standards for component parts made by third party companies, as well as overall design, safety and function, into account.

4. **Strengthen post-market monitoring.**

   Implement rigorous tracking, including for device performance and adverse events, and increase the frequency and thoroughness of inspections for manufacturing facilities. This could include tighter monitoring of supply chains and supplier qualification and inspection, as well as increased scrutiny of materials and manufacturing processes.

> "I would say the whole process, from the FDA to the manufacturers, to the communication, to the development of the device, everything needs to be revamped."

Dr. Muhmmad Adeel Rishi
chair of the American Academy of Sleep Medicine's Public Safety Committee

5. **Improve communication protocols.**

   Establish clear communication channels and protocols between manufacturers, healthcare providers, patients, and regulatory agencies during recalls to facilitate distribution of information and guidance.

6. **Develop patient and provider educational materials.**

   Patient-focused groups should provide comprehensive information to patients about device safety and recalls, but also about treatment alternatives. Create initiatives and communications products to improve patient and healthcare provider awareness of the range of available sleep apnea treatments, including CPAP and alternatives. This could involve developing educational materials, training programs, and awareness campaigns to empower both patients and their providers to make informed decisions about device suitability, use, and safety for particular patients.

7. **Allow subrogation for insurance claims to allow replacement of recalled devices outside of normal replacement schedules.**

   Subrogration (sometimes referred to as "subro") allows your insurer to request reimbursement from the at-fault party. This mechanism should cover out-of-pocket costs for patients with critical health needs who cannot interrupt their treatment. It also should prioritize patients in safety-sensitive jobs that require compliance in using medical devices.

8. **Provide FDA with the authority and appropriate tools to address supply chain disruptions in the event of a shortage of respiratory devices or their components, ensuring that critical medical devices remain available to those who need them most. Such authority should also remove reliance on foreign-made components.**

   "Inspections of foreign facilities are requests," explained former FDA official Madris Kinard. "So any time you're sourcing from outside the country, you run the risk of not knowing as much about the materials as you most likely would if it was sourced inside the U.S."

9. **Increase funding for research and incentivize innovation.**

   Federal agencies and industry should invest in research to identify and mitigate risks associated with medical device materials and design. Federal agencies such as the FDA should provide incentives for medical device manufacturers to prioritize both innovation and safety in product development. "This over-reliance on only CPAP is a huge problem," sleep apnea patient and advocate Emma Cooksey said. "The recall and some of the supply problems, as well, that happened during the pandemic have really made me realize that you can't just rely on one treatment option for everybody." Outside of potential financial incentives, the FDA also can use its position as a bully pulpit. As health policy researcher Kushal Kadakia noted, the recall presents an opportunity for the agency "to use this public health crisis as an opportunity to say, 'This is what innovation should look like for patients in this space, and these are the new standards that we hope all device makers will meet."

10. **Facilitate patient advocacy in decision-making.**

    Involve patient advocacy organizations in raising awareness of device safety issues and amplifying patient voices in regulatory decision-making processes. Alliance of Sleep Apnea Partners calls on industry to work directly with patient groups like ASAP to create protocols that include patient feedback in products' development and post-market phases. ASAP also calls on the FDA to work closely with patient organizations to ensure that patients are aware of their opportunities to provide feedback and perspectives during the approval and post-market surveillance processes.

Resources

Impact of the Philips PAP recall on patient care and sleep center operations. American Academy of Sleep Medicine. June 18, 2021. **https://www.youtube.com/watch?v=H80vyhFb5vc**

Adapting to the Philips Respironics Sleep & Respiratory Product Portfolio Changes. American Academy of Sleep Medicine. June 18, 2021. **https://www.youtube.com/watch?v=eIk9DDMHToE**

With Every Breath: Millions of Breathing Machines. One Dangerous Defect," ProPublica and the Pittsburgh Post-Gazette. Sept. 27, 2023-April 30, 2024. **https://www.propublica.org/series/with-every-breath**

Impact of the Philips PAP Recall on Vulnerable Populations. American Academy of Sleep Medicine. June 25, 2021. **https://www.youtube.com/watch?v=Mj6Tamcd6zc**

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Patient perspectives on Philips Respironics recall. Mallampalli M, Wilson T, Bosin R, Cooksey E. Alliance of Sleep Apnea Partners webinar. December 5, 2023. Accessed April 29, 2024. **https://www.youtube.com/watch?v=ENoC3JQ9rmI**

Physician perspectives: Philips Respironics recall. Mallampalli M, Robbins R, Kundel V, Rishi M A, Kendzerska T. December 14, 2023. Accessed April 30, 2024. **https://www.youtube.com/watch?v=917Ax9fWfvU**

Policy perspectives: Philips Respironics recall. Mallampalli M, Kadakia K, Kinard M, Twery M. Alliance of Sleep Apnea Partners webinar. February 21, 2024. Accessed April 29, 2024. **https://www.youtube.com/watch?v=NZhBef3Le9I**

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