asap
Alliance of
Sleep Apnea Partners

RAISE YOUR VOICE

An Advocacy Toolkit for Patients Affected by the Philips Respironics Recall

LET'S GET STARTED

This material is based upon work supported by the American Academy of Sleep Medicine Foundation. Any opinions, findings, and conclusions or recommendations expressed in this publication are those of the authors and do not necessarily reflect the views of the American Academy of Sleep Medicine Foundation.

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 policies support person-centered care.

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

For inquiries, please email us at **info@apneapartners.org**.

You can find us on:

Support our work by donating today
apneapartners.org/donate

Introduction

Why We Created This Advocacy Toolkit

As sleep apnea patients and caregivers, we know the importance of advocating for our health and the health of our loved ones. Just as we are actively engaged in our own therapy in order to achieve a better outcome, we also can raise our collective voices for greater patient protections and improved, patient-centered processes and policies. This toolkit empowers sleep apnea patients and encourages advocacy for policies that put patients first. These include:

- allowing for efficient communications following a recall
- ensuring minimal health risks to those using respiratory devices
- removing any financial burden from the patients affected by a recall, and
- making certain that treatment is administered continuously without any interruptions.

The Philips Respironics Recall: What Happened and Its Effects on Patients

SLEEP APNEA AND PAP DEVICES

Obstructive sleep apnea (OSA) affects an estimated 54 million individuals in the United States between the ages of 30 and 70. 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, COPD, stroke, and cognitive problems—if left untreated.

Positive airway pressure (PAP) therapy, delivered through devices manufactured by companies like Philips Respironics, is considered the gold-standard treatment for managing OSA.

THE RECALL

In April 2021, Philips notified the FDA of potential health risks related to the polyester-based polyurethane sound-abatement foam in certain CPAP, BiPAP, and ventilator devices. 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 harmful gases.

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."

The recall affected more than 5 million CPAP devices in the United States.

According to the FDA, through September 30, 2023, there were more than 115,000 medical device reports, including both mandatory reports from Philips and voluntary

reports from health professionals, consumers, and patients. These include reports of 561 deaths. Symptoms reported on the FDA's website include cancer, pneumonia, asthma, infections, headache, cough, dyspnea (difficulty breathing), dizziness, nodules, and chest pain.

We believe several million sleep apnea patients 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.

THE RECALL'S IMPACT ON PATIENTS

The recall has had profound effects on patients who rely on PAP therapy for managing sleep apnea. Many patients and their healthcare providers initially were unaware of the recall and learned of it through news reports, friends, or social media. Even patients who were aware of the recall received conflicting information.

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, treatment disruptions, and the threat of additional health issues from either lack of treatment or continued use of a potentially dangerous Philip CPAP device.

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

Our Policy Goals

- We urge members of Congress to establish a centralized national registry for respiratory devices. This registry would enable efficient tracking and direct communication with patients affected by recalls, ensuring they receive timely notifications and necessary support. Implementing this measure will enhance patient safety, streamline recall processes, and improve overall public health outcomes.
- We urge Congress to require automatic subrogation for claims related to recalled respiratory devices. This policy change will relieve patients' financial burden and ensure they can quickly obtain necessary replacement devices, bypassing the usual replacement cycle. Implementing this measure will help maintain continuous care for patients affected by device recalls.

Getting Started with Advocacy

What Is Grassroots Advocacy and Why Is It Important?

"Grassroots advocacy" refers to efforts to mobilize ordinary citizens at the local level to influence public policy and decision-making. Through grassroots advocacy, individuals take collective action to raise awareness, engage in dialogue with their elected representatives and with the public, and advocate for awareness and specific changes around issues of importance to them. Grassroots advocacy typically relies on building a broad base of support among members of the general public and empowers them to directly engage with policymakers.

> "
>
> I have been waiting a year this month and still no replacement and no information as to when I can expect it. Can somebody help me? This is outrageous the way Philips has treated us. My health has suffered drastically.
>
> **– Carol P.**

Understanding the Legislative Process

The legislative process in the United States involves six key steps, from the introduction of a bill to its passage into law. Understanding these steps is essential for effective advocacy.

A video overview of the legislative process is available at **congress.gov/legislative-process**.

1. INTRODUCTION OF A BILL

- **Proposal:** A bill can be proposed by a member of Congress (either a Representative or a Senator).
- **Sponsorship:** The bill is sponsored by the member who introduces it and may gain co-sponsors who support it.

Advocates' role:
Grassroots advocates can bring issues to the attention of legislators and their staff, prompting those legislators to introduce new bills. By showing broad public support, advocates also can encourage legislators to sponsor or co-sponsor a bill.

2. COMMITTEE REVIEW

- **Referral to Committee:** The bill is referred to a relevant committee that specializes in the bill's subject matter.
- **Subcommittee Review:** Often, the bill is further reviewed by a subcommittee where it may be studied in detail, amended, or subject to hearings.
- **Committee Vote:** If the subcommittee approves the bill, it returns to the full committee for further review and a vote. If the committee approves the bill, it moves forward.

Advocates' role:
Grassroots advocates can testify at committee hearings, providing personal stories and expert opinions. They can lobby committee members and their staff to support, amend, or reject a bill based on public interest.

3. FLOOR DEBATE AND VOTE

House of Representatives:

- **Rules Committee:** Sets the terms for debate (time limits, amendment rules).
- **Debate and Vote:** The bill is debated on the House floor and then voted on.

Senate:

- **Unanimous Consent or Filibuster:** Debates may involve procedures like unanimous consent agreements or the possibility of a filibuster.
- **Debate and Vote:** The bill is debated and then voted on by the full Senate.

Advocates' role:
Grassroots campaigns can mobilize constituents to contact their representatives, urging them to vote for or against a bill. They also can organize rallies and demonstrations that highlight public support or opposition, influencing legislative debate.

4. CONFERENCE COMMITTEE

If the House and Senate pass different versions of the bill, a conference committee made up of members from both chambers works to reconcile the differences. The revised bill is sent back to both the House and Senate for final approval.

Advocates' role:
Grassroots campaigns and members of the public can pressure legislators to adopt favorable compromises during the reconciliation process. An important part of this process is educating the legislative staff who help lawmakers formulate positions and write the detailed legislative language.

5. PRESIDENTIAL ACTION

- **Approval:** The President can sign the bill into law.
- **Veto:** The President can veto the bill, sending it back to Congress with reasons for the veto.
- **Override:** Congress can override a presidential veto with a two-thirds majority vote in both the House and Senate.

6. BECOMING LAW

If the President signs the bill or if Congress successfully overrides a veto, the bill becomes law and is implemented.

Advocates' role:
Grassroots advocates can petition the President to sign or veto a bill. In the case of a veto, they can rally supporters to pressure Congress to override the veto.

The Federal Rulemaking Process

Once a law is passed, Congress delegates authority to the federal agencies to enforce and implement the law. To do this, agencies create a detailed set of rules and regulations. The process usually involves several steps:

1. PROPOSAL

The agency drafts a proposed rule dictated by studies, public input, and the agency's expertise.

2. NOTICE OF PROPOSED RULEMAKING (NPRM)

The agency publishes the proposed rule in the Federal Register as a notice, including a summary of the rule, its objectives, and a request for public comments.

3. PUBLIC COMMENT PERIOD

The public (individuals, businesses, and other stakeholders) is given a set period (30-60 days) to submit comments, suggestions, or objections to the proposed rule.

4. REVIEW OF COMMENTS

All submitted comments are reviewed by the agency and changes are made to the proposed rule based on the public feedback.

5. FINAL RULE AND IMPLEMENTATION

The agency will publish the final rule in the Federal Register after making changes based on public input. This will include a summary of public comments, as well as the agency's responses. At a specified date, the rule will go into effect and the agencies will work on implementing the rule. They also may provide training, support, or guidance to those who are affected.

Advocates' role:
Grassroots advocates can submit comments to the agency during the public comment period. If the advocates believe that the rule is unlawful or exceeds an agency's authority, they can challenge the rule in courts, asking for judicial review.

"

My replacement was almost 5 years old and looked like it belonged to a smoker. The one it replaced was a few months old and pristine.

– Kathryn C.

Taking Action

Identifying Your Members of Congress

Begin your advocacy close to home: reach out to your own members of Congress first. This allows you to leverage constituent influence, build relationships with the people who directly represent you, and hold representatives accountable. Legislators are more closely attentive to their constituents' needs.

TOOLS TO USE

- **Senate.gov** – Select your state to find your state's senators.
- **House.gov** – Enter your ZIP code to find your representatives.

Local public libraries and community centers also can provide assistance and resources to help you engage with your federal representatives. Many libraries also offer free access to public computers and the internet.

Sign up for newsletters from your members of Congress. Attend local open houses and town hall meetings, where you can engage with your elected representatives while they are outside of Washington, D.C.

Key Committees and Subcommittees in Congress

In addition to reaching out to your own members of Congress, strategically focus on legislators on certain federal committees and subcommittees related to health and respiratory devices, because these legislators have direct influence over the issues highlighted by the Philips Respironics recall. Identify and reach out to members of these committees and subcommittees, especially those from your state or district. Explore opportunities to submit testimony for hearings related to health policy and medical device regulation. And attend and participate in public hearings relevant to issues around the Philips Respironics recall, which also will let you network with key stakeholders.

To find information about Senate committees, visit **senate.gov/committees**.

To find information about House committees, **house.gov/committees**.

Your Role

The citizen's voice is vital in the legislative process. Grassroots advocates amplify the voices of ordinary citizens whose lives are affected by legislation and policy, ensuring their perspectives and concerns are heard. They also demonstrate constituent support to lawmakers, who are then more likely to take action.

Grassroots advocacy can build public awareness and support for an issue, making it harder for politicians to ignore and pressuring them to hear their constituents and act. Citizens also contribute to policy innovation by bringing new ideas and perspectives to discussions around issues and by sharing their valuable expertise, insights, or experience with legislators. And grassroots advocates also serve as a counterweight to well-funded corporate or special interest groups, ensuring that policymakers hear a broader range of perspectives.

Key Messages and Talking Points

To develop your message to legislators, draw on the key messages and talking points that follow, adding your personal experience to illustrate and support them.

> I'm just extremely disappointed with how little protection there is for the patients. And how the whole industry seems to be focused on the corporations and maximizing their profits, as opposed to what it really should be, which is taking care of the patients. … We also need competitive products. We can't just have one company be the only one making something.
>
> **– Teri M.**

Our Key Messages

1. Creating a centralized national registry for tracking respiratory devices will help healthcare providers, device manufacturers, and durable medical equipment providers notify patients about a recall faster. Faster notification can help prevent illness or injury, disruptions to treatment, and deaths. We urge our legislators to hold a hearing on the need for a national registry and involve patient voices from those affected by the recall.

2. Requiring automatic subrogation (or "subro") for insurance claims on recalled respiratory devices will remove a substantial financial burden from patients and will allow them to acquire a replacement device outside the insurers' normal replacement cycle to maintain continuous care for those affected by the recall.

Talking Points

- **There currently is no national registry of PAP devices.** This makes it much harder for companies like Philips to contact patients in the event of a safety-related recall.
- **Under the current system, doctors often do not know what kind of CPAP machine their patients use, so they can't notify patients of a recall.** Requiring unique device identifiers (UDIs) to be logged into patients' electronic health records would make it possible for healthcare providers to alert patients to a recall.
- **A centralized national device registry will allow healthcare providers to reach their patients quickly** to inform them about a recall and provide needed support.
- **A national registry can aid collection of adverse effects** a recalled device has had on patients.
- **A national registry can be helpful in monitoring the long-term health consequences** of those affected by recalled devices.
- **A national registry will help prioritize and protect patients with critical health issues** who cannot interrupt treatment, as well as those in safety-sensitive jobs.
- **Having automatic subrogation of insurance claims for recalled devices frees patients from the costs and stress** of having to suddenly pay out of pocket to replace their recalled device.
- **Congress needs to provide the 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.
- **A new subrogation policy is needed so that patients can avoid high out-of-pocket expenses** for replacing their recalled devices and prevent potentially harmful treatment gaps when a medical device recall happens outside an insurer's normal replacement cycle.

The Power of Personal Stories

When contacting or speaking with your legislator or their staff, remember that personal stories are powerful. Personal experiences can illustrate the recall's real-world impact on patients and, by putting a human face on the issues, make the problem real to the legislator and sharpen the urgency to address it. In addition to presenting talking points, be prepared to briefly explain how the recall negatively affected your finances and physical or mental health.

Example: "As a sleep apnea patient affected by the Philips Respironics recall, I have faced significant health challenges due to the lack of reliable CPAP devices. My treatment was interrupted, causing severe fatigue and impacting my daily life. While waiting for a replacement device, I have had to take time away from my job. I have also had to take time out of my life to research where I could find a replacement—and then had to pay out of pocket to buy it."

TIPS FOR TELLING YOUR STORY

- **Be specific:** Provide details about your experience and how it affected you.
- **Be concise:** Keep your story clear and to the point.
- **Be honest:** Share your genuine concerns.

Contacting Legislators

Reaching out to legislators, especially those from your state or district, is a crucial step in grassroots advocacy. Here are some tips and best practices for connecting effectively with your elected representatives and their staff.

Use Multiple Channels

- **Email:** A formal, concise written record of your concerns and requests.
- **Phone calls:** Quick and direct, often allowing for immediate feedback or questions.
- **Social media:** Public messages that can raise broader awareness.
- **Letters:** Personalized and tangible, demonstrating a higher level of commitment.

Be Clear and Concise

- **Stay on topic.** Focus on one issue per communication.
- **Keep it brief.** Legislators and their staff are busy. A concise message is more likely to be read and remembered.
- **State your purpose.** Clearly explain why you are contacting them and what action you want them to take. Use the key messages provided in this guide.

Personalize Your Message

- **Share your story.** Personal anecdotes are powerful. Explain how the issue affects you and others.
- **Connect locally.** If you are a constituent, mention that and include your address to show you live in their district.
- **Be respectful, polite, and professional.** Always be courteous, even if you disagree with their stance.
- **Use correct titles.** Address them appropriately (e.g., Senator Smith, Representative Jones).

Follow Up

- **Acknowledge responses.** Thank them for any response you receive and provide further information if requested.
- **Keep in touch.** Regularly update your legislator's office on the issue and continue to advocate for change. Doing so can help you become a trusted resource on the issue, especially if you also are active at local town hall meetings or other events the legislator holds while at home in your state or district. And it lets your legislator and their staff know that you are staying engaged on the topic and will continue to follow up on your request's progress.

SAMPLE EMAIL TEMPLATE

Subject: Urgent Need for National Registry for CPAP Devices

Dear [Representative/Senator] [Name],

My name is [Your Name], and I am a constituent from [City, State, ZIP Code]. I am writing to express my deep concern about the recent Philips Respironics CPAP device recall and its significant impact on patients like me.

As a sleep apnea patient, I rely on my CPAP device for my health and well-being. The recall has disrupted my treatment and caused considerable stress and health complications. I urge you to support legislation that establishes a national registry for better tracking of these devices and allows subrogation of insurance claims for recalled devices so patients can continue therapy without taking on high out-of-pocket expenses to replace their recalled machines.

Your leadership on this issue is crucial for ensuring the safety and well-being of many constituents. Thank you for your attention to this important matter.

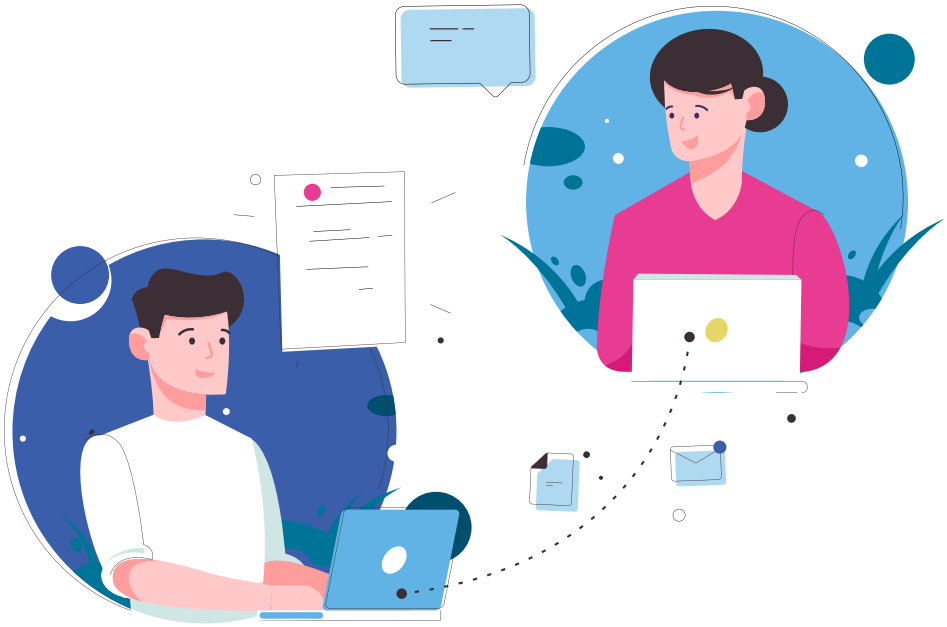
Sincerely,
[Your Name]
[Your Address]
[Email Address]
[Phone Number]

SAMPLE CALL SCRIPT

Hello, my name is [Your Name], and I am a constituent from [City, State, ZIP Code]. I am calling to express my concern about the Philips Respironics CPAP device recall and its impact on patients with sleep apnea.

I urge [Representative/Senator] [Name] to support establishing protocols or processes at the FDA that allow for better communication during recalls, and the establishment of a national registry for these devices that allows efficient tracking of recalled respiratory devices. This issue is critical for my health and the health of many others.

Thank you for your attention to this important matter.



SAMPLE SOCIAL MEDIA POSTS

Twitter/X:
@[Representative's Twitter/X Handle], as a sleep apnea patient affected by the Philips Respironics recall, I urge you to support a national registry for CPAP devices. The recall has disrupted many patients' treatment and health.

#CPAPSafety #PatientAdvocacy #ApneaPartners @OfApnea

Facebook:
Dear [Representative/Senator] [Name], I am a constituent from [City, State] affected by the recent Philips Respironics CPAP device recall. This issue has disrupted my treatment and impacted my health. Please support establishing protocols or processes at the FDA that allow for better communication during recalls, and tracking of respiratory devices affected by a recall by establishing a national registry for these devices. Thank you. @ApneaPartners

> My first replacement was delivered to my old address 10 months ago. I discovered it four months later. A replacement was never seen again. Zero communication from Philips prior to and after delivery. I'm waiting on a ResMed so I didn't even want a Philips replacement, since I figured it might reset the five-year replacement from my insurance company.
>
> **– Matt S.**

SAMPLE LETTER TEMPLATE

[Your Name]
[Your Address]
[City, State, ZIP Code]
[Email Address]
[Phone Number]

[Date]

The Honorable [Representative/Senator's Name]
[Office Address]
Washington, DC 20515

Dear [Representative/Senator] [Name],

I am writing to you as a concerned constituent and a sleep apnea patient affected by the recent Philips Respironics CPAP device recall. This recall has had a significant impact on my health and well-being, disrupting my treatment and causing serious complications.

I urge you to support legislative efforts to improve processes at the FDA that will enhance communication protocols during medical device recalls, and establish a national registry allow for efficient tracking of these devices. This is vital for protecting the health and safety of patients who rely on CPAP therapy.

Thank you for your attention to this critical issue. I look forward to your support and action.

Sincerely,
[Your Name]

Meeting with Legislators

Meeting with legislators is one of the most effective ways to advocate for change. Getting a meeting with a legislator can take time and often involves working initially with their staff to provide a summary of the issue and your concerns, as well as some supporting materials. Don't be discouraged, and understand that meeting with Congressional staffers is also important and can be as effective as meeting with elected representatives.

Here are some best practices to prepare for, conduct, and follow up on a meeting with your elected representatives or their staff.

Requesting a Meeting

1. IDENTIFY YOUR REPRESENTATIVES

- **Senate.gov** – Select your state to find your state's senators.
- **House.gov** – Enter your ZIP code to find your representatives.

2. CONTACT THEIR OFFICES

Call the local or Washington, D.C., office of your representative or senator to request a meeting. Be prepared to explain who you are, what issue you want to discuss, and why it's important. Most members of Congress also have local offices in the state or district they represent and which they use when Congress is not in session. Once you have identified your elected federal representatives, visit their website and sign up for their mail or email lists, which will alert you to their local open houses or constituent meetings. Meeting your senator or representative locally can be highly effective.

3. SEND A FORMAL REQUEST

Follow up your phone call with an email or letter. Here's a template you can use:

> [Your Name]
> [Your Address]
> [City, State, ZIP Code]
> [Email Address]
> [Phone Number]
>
> [Date]
>
> The Honorable [Representative's/Senator's Name]
> [Office Address]
> Washington, DC 20515
>
> Dear [Representative/Senator] [Name],
>
> I am writing to request a meeting with you to discuss an urgent issue that affects many of your constituents, including me. As a sleep apnea patient affected by the recent Philips Respironics CPAP device recall, I would like to talk about the need for better communication during recalls and stronger post-market tracking of medical devices.
>
> I would appreciate the opportunity to meet with you or a member of your staff at your earliest convenience.
>
> Thank you for considering my request. I look forward to your response.
>
> Sincerely,
> [Your Name]

Preparing for the Meeting

RESEARCH YOUR LEGISLATOR

Understand their positions on healthcare and medical device regulation. Look up recent statements, votes, and sponsored legislation.

PREPARE YOUR KEY MESSAGES

Identify three main points you want to communicate, using the key messaging in this guide. Keep your message clear and concise. For example:

- The impact that the Philips Respironics recall has had on you or someone close to you.
- The need for a national device registry and relief for patients from out-of-pocket costs for replacing recalled machines.
- The importance of better communication during a recall and tracking of medical devices.

BRING SUPPORTING MATERIALS

- Fact sheets, personal stories, and data that highlight the issue. Check ASAP's **Philips Respironics recall web page** for information, and download ASAP's handout, **Fast Facts About the Philips CPAP Recall**, at the apneapartners.org website. Click the Advocacy tab, then select Philips Recall Information.
- A one-page summary of your key points to leave with the legislator or their staff.

PRACTICE YOUR TALKING POINTS

Rehearse what you plan to say. Be ready to share your personal story and how the issue affects you and others. Keep in mind that your meeting with your legislator or their staff might be as brief as 15 minutes.

During the Meeting

INTRODUCE YOURSELF

Briefly introduce yourself and any other advocates with you. Explain why you are there, but be succinct.

TELL YOUR STORY

Share your personal experience with sleep apnea and how the CPAP device recall has impacted your health. Personal stories are compelling and memorable.

PRESENT YOUR KEY MESSAGES

Clearly and concisely explain your main points. Use your supporting materials to reinforce your message.

BE CLEAR ABOUT YOUR ASK

Specify what you want the legislator to do. For example:

- "We call on you for legislation that requires establishment a national device registry to allow efficient post-market tracking of respiratory devices."
- "We ask you to support a Congressional hearing on the need for a national registry, involving patient voices from those affected by the recall."
- "Please advocate for automatic subrogation of claims to relieve patients of the need to unexpectedly pay out of pocket for recalled machines."

If there is current legislation that you would like them to support or oppose, include the specific bill or resolution number.

LISTEN AND RESPOND

Pay attention to the legislator's or staff member's questions and comments, and be prepared to answer questions or provide additional information. Do not be afraid to say, "I don't know. I will look into that and get back to you."

LEAVE MATERIALS FOR CONSIDERATION

Provide a one-page summary of your key points and any other relevant materials.

THANK THE LEGISLATOR OR STAFFER

Express your appreciation for their time and attention.

> "
>
> I've been waiting 10 months for a replacement. I have called several times to Philips, as well as the provider where I originally received the machine. I receive no information or help.
>
> **– Janette Z.**

After the Meeting

SEND A THANK-YOU NOTE

Follow up with a thank-you email or letter. Reinforce your key messages and provide any additional information requested during the meeting.

SAMPLE FOLLOW-UP NOTE

> [Your Name]
> [Your Address]
> [City, State, ZIP Code]
> [Email Address]
> [Phone Number]
>
> [Date]
>
> The Honorable [Representative's/Senator's Name]
> [Office Address]
> Washington, DC 20515
>
> Dear [Representative/Senator] [Name],
>
> Thank you for taking the time to meet with me on [date] to discuss the critical issue of establishing a national registry for respiratory devices and enhancing FDA communication and tracking of these devices.
>
> I appreciate your willingness to consider our concerns and the potential impact on patients like myself. Please let me know if there is any additional information I can provide.
>
> Thank you again for your attention to this important matter.
>
> Sincerely,
> [Your Name]

MAINTAIN CONTACT

Keep in touch with the legislator's office. Provide updates on the issue and continue to advocate for change.

ENGAGE YOUR COMMUNITY

Share your experience with other patients and encourage them to get involved. Collective voices are more powerful. Do not underestimate the influence social media can have on your messaging.

Using Social Media for Advocacy

Social media can amplify a campaign and the issues it is addressing. It also can build a following and momentum for policy change. As with other communications tools, social media requires concise, disciplined messaging to get your point across to a wide public audience, clearly and succinctly. Using an image or graphic helps make your post on any platform more eye-catching and engaging to your audience.

Choosing a Platform

Start your grassroots advocacy where you already are active on social media—the people who already follow you are likely to be most receptive to your message and your experience or perspective.

Twitter/X: Great for quick updates, following and engaging with journalists, and using hashtags like #SleepApnea, #CPAP, #CPAPRecall, #PatientSafety, and #ApneaPartners to help people find related content. Tag ASAP: @OfApnea.

Facebook: Useful for sharing longer posts, creating event pages, and engaging with groups. Take the time to be an active member of groups answering questions and helping others. Each Facebook group will have its own rules and etiquette. If in doubt, send a private message to the group admin or moderator to ask about any policies before posting. Tag ASAP by typing @ApneaPartners in the text of your post.

Instagram: Photo- and image-based, ideal for visual content and personal stories. Tag ASAP (type @ApneaPartners) in the text of your post.

SAMPLE SOCIAL MEDIA POSTS

> **Twitter/X:**
> Thousands of #SleepApnea patients are affected by the #CPAP Recall. We @ApneaPartners need a national respiratory device registry and better communication protocols during recalls. @YourRep @YourSenator, please take action! @OfApnea #PatientSafety #CPAP #ApneaPartners

> **Facebook:**
> The Philips Respironics CPAP device recall has left many sleep apnea patients, including me, without crucial treatment. We need a national respiratory device registry and better communication during recalls. Join us @ApneaPartners in urging Congress to take action! #CPAPRecall #PatientSafety #ApneaPartners

> **Instagram** [post a photo of yourself or your Philips CPAP device]:
> CPAP is my lifeline for managing sleep apnea. Like thousands of others, my treatment has been disrupted by the recent Philips Respironics recall. We need a national respiratory device registry and better communication during recalls. Let's make our voices heard @ApneaPartners! #CPAPRecall #PatientAdvocacy #ApneaPartners

Resources and Tools

For downloadable copy to leave behind with your legislators, use the QR code

> They did, in my opinion, an extremely poor job communicating to not only consumers, but all the constituencies: the doctors, the DMEs. Frankly, nobody really knew what was going on, and everyone was upset. That, I think, was the biggest problem.
>
> **– Tom Wilson**
> **Philips CPAP Recall Support Group**

Fast Facts About the Philips CPAP Recall

An estimated 54 million individuals in the United States between the ages of 30 and 70 have obstructive sleep apnea (OSA). OSA can affect men, women, and children. OSA leads to disruptions in breathing during sleep.

If left untreated, OSA 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 such as early-onset dementia. Continuous positive airway pressure (CPAP) therapy is considered the gold standard for treatment.

The 2021 recall of Philips Respironics positive airway pressure devices affected 15 million devices globally, including more than 5 million in the U.S., according to the Philips Respironics website. Many patients and their doctors were unaware of the recall. Even among those who were aware, poor communication from Philips led to confusion about whether patients should continue using recalled devices, leading to treatment disruptions.

According to Philips Respironics, only 2.59 million of the affected U.S. devices have been remediated. Remediated patients include those who received a financial payment or whose devices were replaced with either a new or a repaired device.

There currently is no national registry of PAP devices. This makes it much harder for companies like Philips to contact patients in the event of a safety-related recall.

Under the current system, doctors often do not know what kind of CPAP machine their patients use, so they can't notify patients of a recall. Requiring unique device identifiers (UDIs) to be logged into patients' electronic health records would make it possible for healthcare providers to alert patients to a recall.

The FDA protocol by which CPAP devices are approved—the 510k pathway—does not currently require rigorous clinical testing or testing of component parts like the foam that degraded in Philips devices and prompted the recall. Revising and strengthening the 510k clearance pathway's criteria could better protect patients.

The FDA has the authority to take a more active role in device recalls under 21 CFR 810, Medical Device Recall Authority. Philips recalled these devices voluntarily, but reports of adverse events and device malfunctions went unnoticed or unaddressed for extended periods.

Philips Respironics Recall Timeline

2021

APRIL 23
Philips Respironics notifies the FDA of potential health risks related to the PE-PUR sound-abatement foam in CPAP, BiPAP and ventilators

JUNE 14
Philips initiates Class I voluntary recall due to PE-PUR degradation

JUNE 30
FDA safety communication alerts the public of Philips voluntary recall

JULY 23
FDA identifies certain Philips ventilators, BiPAP machines, and CPAP machines as a Class I recall, the most serious type of recall

JULY 26
- Philips stops taking orders
- Class action suits filed in the US and Canada
- Ventilators recalled

JULY 29
FDA posts FAQs on its website after working with patient and professional groups (ASAP was not involved in those conversations)

SEPTEMBER 1
Philips announces repair and replacement program for DreamStation Devices with silicone-based foam

Complete repair and replacement program required in 12 months

OCTOBER 8
Federal lawsuits filed against the company centralized in a multidistrict litigation in western Pennsylvania

NOVEMBER 12
FDA inspection of manufacturing facility revealed that the silicone-based foam in singular similarly marketed device failed one safety test for release of volatile organic compounds.

FDA asks Philips Respironics to have an independent lab to perform safety test to determine risks by silicone-based foam, used in the repair-and-replace program

2022

APRIL 25
US Department of Justice subpoenas Philips in Respironics recall

MARCH 8 & 9
FDA and Philips meet twice to discuss 518(a) notification.

Philips meets with the FDA to take actions proposed by the FDA

FDA concludes that extensive time has passed without effective communication to the public

MARCH 10
FDA issues 518(a) notification letter to all health professionals and other industry stakeholders within 45 days to "eliminate unreasonable risk of harm"

MAY 2
FDA provides notice for an opportunity for hearing according to section 518(b) of the FD&C Act

Requires a plan from Philips to repair, replace, or refund

JUNE 28
Philips says small portion of returned devices displayed foam degradation.

Repeated ozone cleaning made problem worse

JULY 25
DOJ announces that it is in consent decree talks with Philips

AUGUST 29
FDA alerts that BiPAP machines may be contaminated with material that may release volatile organic compounds or cause the device to fail

SEPTEMBER 1
Philips and DOJ settle for $24.8 M on kickback allegations

SEPTEMBER 6
FDA alerts healthcare providers that magnets in masks can interfere with implanted devices (based on 14 reports)

SEPTEMBER 22
Philips recalls certain masks with magnets and BiPAPs with non-compatible plastics

OCTOBER 15-20
Roy Jakobs appointed as the new CEO of Philips. He apologizes to the public as "deeply sorry" and says company will re-align with people-centered ideology. Company begins major global layoffs.

DECEMBER 21
Philips says recalled DreamStation tests show unlikely harm to health

2023

JANUARY 30
Philips reduces global workforce by 6,000

Philips gradually restoring its place in respiratory device market through 2025

FEBRUARY 10
Philips appoints a new chief patient safety and quality officer

APRIL 7
FDA issues recall summary on reworked DreamStations; these were assigned incorrect or duplicate serial numbers during initial programming (wrong prescription, factory settings or no therapy at all)

APRIL 13
Misinformation on Philips website leads to another announcement by the FDA on the need for transparency

2.4 million devices shipped to repair facilities and not consumers

JULY 24
Consent decree talks with DOJ continue

AUGUST 15
Exor buys a 15% stake in Philips to become largest shareholder

SEPTEMBER 7
Philips announces $479M payment to settle claims

Covers only economic costs incurred by the users of CPAPs and other respiratory devices recalled over sound-abatement foam

Philips did not admit liability, wrongdoing or fault in settlement and still faces lawsuits claiming deaths, injuries and medical costs related to the recall

SEPTEMBER 27
ProPublica and Pittsburgh Post-Gazette publish investigation summary

Philips allegedly withheld majority of warnings about contaminants in device airway chambers from FDA

Philips disagrees

OCTOBER 5
FDA calls on Philips for more testing in the sound-abatement foam recall

NOVEMBER 21
Voluntary recall of SoClean equipment 2 & 3 – new user manual and with a hose and mask adapter

NOVEMBER 28
FDA informs patients to monitor their DreamStation 2 for signs of overheating.

2024

JANUARY 29
Philips suspends sale of CPAP and ventilators in the US until the terms of the consent decree are met but will service devices and sell accessories

JANUARY 31
FDA Update: Additional >7,000 medical device reports received and 111 deaths reported between July 1–September 30, 2023

APRIL 9
A federal district court entered a consent decree against Philips that requires implementation of a Recall Remediation Plan jointly agreed to by FDA and Philips.

This plan is to help ensure relief is provided to patients impacted by recall by way of receiving a new or reworked/remediated device or, for certain devices, providing the option for a partial refund.

Restricts production and sale of new CPAP and BiPAP machines in Pennsylvania and California until certain requirements are met

Prohibits Philips from exporting for commercial distribution CPAP and BiPAP devices that are being used to remediate patients impacted by the recall unless certain conditions are met, as detailed in the consent decree.

Requires Philips to contract with an independent testing expert to review and evaluate their testing, including biocompatibility data, on the new, silicone-based foam that the company is using to replace and rework some machines impacted by the June 2021 recall.

Requires Philips to retain an independent expert to inspect their other Sleep and Respiratory Care facilities (besides facilities in Pennsylvania and California) to evaluate whether those facilities are operating in compliance with the Federal Food, Drug, and Cosmetic Act and to correct any deficiencies that are identified.

Useful links

> I have been registered since last August but do not receive these "frequent updates" that they say they are providing on their site. ... I am in such a fog and desperate to speed up the process.
>
> **– Tracey F.**

- Alliance of Sleep Apnea Partners: **apneapartners.org**
- Alliance of Sleep Apnea Partners Philips Respironics Recall webpage: **apneapartners.org/philips-recall-information**
- Alliance of Sleep Apnea Partners social media handles:
  1. Twitter/X: **@OfApnea**
  2. Facebook: **@ApneaPartners**
  3. Instagram: **@ApneaPartners**
  4. LinkedIn: **@ApneaPartners**
- FDA Recommendations for Recalled Philips Ventilators, BiPAP Machines, and CPAP Machines: **fda.gov/medical-devices/recalled-philips-ventilators-bipap-machines-and-cpap-machines/recommendations-recalled-philips-ventilators-bipap-machines-and-cpap-machines#risk**
- Medical Device Reports for Philips Respironics Device: **fda.gov/medical-devices/recalled-philips-ventilators-bipap-machines-and-cpap-machines/problems-reported-recalled-philips-ventilators-bipap-machines-and-cpap-machines#medical**
- Philips Respironics Recall Information webpage: **usa.philips.com/healthcare/e/sleep/communications/src-update**
- Philips Recall Patient Portal: **philipspatientportal.expertinquiry.com**
- Philips Respironics device registration: **philipssrcupdate.expertinquiry.com/?ulang=en**
- FDA recall alert sign-up: **public.govdelivery.com/accounts/USFDA/subscriber/new**
- **Senate.gov** – Select your state to find your state's senators.
- **House.gov** – Enter your ZIP code to find your representatives.
- Legislative Process videos: **congress.gov/legislative-process**

Alliance of
Sleep Apnea Partners

apneapartners.org
info@apneapartners.org

You can find us on:

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apneapartners.org/donate