Rodney Mell
Head of Quality and Regulatory
Philips Respironics – Sleep and Respiratory Care
1740 Golden Mile Highway
Monroeville, PA 15146

Re: Philips Respironics Urgent Recall of Ventilators, CPAP, and Bi-Level PAP Medical Devices

August 25, 2021

Dear Mr. Mell:

The undersigned Philips Respironics device customers, disability advocates, and advocacy organizations submit the following response to the June 14, 2021 notice issued for the recall of thirteen models of ventilators, CPAP, and BiPAP machines.[1] While the recall advises that users immediately discontinue use of the affected machines, it provides a completely different advisory for users who rely on their devices for life-sustaining care. Philips advises those users not to stop using their devices but offers no concrete recommendation for their safety beyond consultation with their physicians.[2] Therefore, we write to request that Philips immediately develop and implement a device repair and/or replacement process and timeline that prioritizes users who depend on their equipment for survival or that Philips provide so-affected users with comparable devices from other manufacturers free-of-cost.

The notice states that the recall is due to the degradation of a polyester-based polyurethane sound abatement foam that "may enter the device's air pathway and be ingested or inhaled" by the user.[3] The foam particles can also release certain chemicals (known as "off-gassing").[4] Extreme heat and humidity or the use of certain cleaning methods can exacerbate the degradation of the foam.[5] Risks of potential exposure include, but are not limited to, irritation of the skin, eyes, and respiratory tract; headache, asthma, adverse effects to other organs such as the liver and kidneys, and "carcinogenic effects."[6]

As of the date of this letter, Philips users, especially those who depend on their devices for life-sustaining care, have been put on high alert about severe potential effects associated with the use of their devices with no clear explanation about what led to the discovery of these effects or ultimately to the recall of their devices. Philips Sleep and Respiratory Care Frequently Asked Questions (FAQs) states that Philips discovered the foam degradation and chemical emission problems through its "Quality Management system processes" in April 2021 but provides no

[1] Philips, *Urgent: Medical Device Recall*, https://www.philips.com (follow "Recalls" hyperlink at the bottom of the page; then click on "Field safety notice" and click on "Recall notification" under the Device registration and recall contact information heading) (last visited Aug. 19, 2021).

[2] *Id.* at 2.

[3] *Id.* at 1.

[4] *Id.* at 1.

[5] *Id.* at 1.

[6] *Id.* at 1.

details about what that process entails or how these issues were uncovered in the course of that process, leading to the recall notice issued approximately two months later in June 2021.[7] The FAQs also state that Philips has received reports and complaints about "possible patient impact" which it is "monitor[ing]"[8] but provides no details about specific reports, how this monitoring is occurring, or how users can access information being reported. Users deserve, require, and demand full transparency.

Additionally, Philips cannot adequately address the harms of medically necessary continued use of their recalled devices by simply telling users to talk to their doctors. In order for users to effectively take advantage of that recommendation, Philips must disclose what communications it has had with healthcare providers and professionals about the recall. Disclosure of such communications should also include what, if anything, Philips knows about adverse health effects potentially associated with continued or long-term use of their recalled equipment and how to mitigate those effects. Otherwise, users have no way of assessing their physicians' advice.

The information for physicians and other medical care providers listed on the Philips website includes only the aforementioned explanation about the degradation of the foam and the suggestion that patients use an inline bacterial filter that may "reduce exposure to degraded sound abatement foam particles" but "will not reduce exposure to potential Volatile Organic Compounds (VOCs)."[9] VOCs have also been found to be carcinogenic.[10]

Furthermore, some Philips users who have contacted their doctors or durable medical equipment (DME) providers have been unable to obtain definitive advice about the best way to protect themselves.[11] Some doctors and DME providers whose patients and users depend on Philips' devices for life-sustaining care have repeated Philips' suggestion that customers use a bacterial filter.[12] In addition to the uncertainty concerning whether bacterial filters effectively reduce exposure to the foam particles and the previously mentioned risks associated with VOCs, the FDA disputes the effectiveness of such filters in mitigating the risks of exposure to the foam.[13]

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[7]Philips, *Sleep and Respiratory Care Update: Frequently Asked Questions*, https://www.philips.com (follow "Recalls" hyperlink at the bottom of the page; then click on "Field safety notice" and click on "FAQs" under the Durable Medical Equipment Providers, Distributors, or Medical Institutions heading), 11 (last visited Aug. 19, 2021) [hereinafter "Frequently Asked Questions"]; *see also* Philip's First-Quarter Results 2021, PHILIPS NEWS CENTER-GLOBAL (April 26, 2021), https://www.philips.com/a-w/about/news/archive/corpcomms/news/press/2021/philips-first-quarter-results-2021.html (last visited Aug. 19, 2021).

[8]Frequently Asked Questions, *supra* note 7, at 2, 6, and 7.

[9]Medical Device Recall Notification: Information for Physicians and Other Medical Care Providers, https://www.usa.philips.com/healthcare/e/sleep/communications/src-update/information-for-physicians-and-providers (last visited Aug. 14, 2021).

[10]*Volatile Organic Compounds*, AMERICAN LUNG ASSOCIATION, https://www.lung.org/clean-air/at-home/indoor-air-pollutants/volatile-organic-compounds (last visited Aug. 19, 2021).

[11]Kait Sanchez, *A Recall of Philips Respiratory Devices Has Left Users Stranded*, VERGE (Aug. 5, 2021), https://www.theverge.com/2021/8/5/22609651/philips-recall-respironics-ventilators-cpap-bipap.

[12]*See* Sanchez, *supra* note 11.

[13]*Certain Philips Respironics Ventilators, BiPAP, and CPAP Machines Recalled Due to Potential Health Risks: FDA Safety Communication*, U.S. Food & Drug Administration (June 30, 2021), https://www.fda.gov/medical-

Nevertheless, users who depend on their devices to live, many of whom are people with disabilities who cannot afford new devices or alternative treatments, have been forced to pay out-of-pocket for additional filters they cannot guarantee will help them.[14]

Finally, Philips' registration process for the repair and replacement of affected machines is an important first step, but this step is insufficient and incomplete without a definitive timeline that prioritizes users who depend on their devices to live. While Philips has previously stated a desire to "prioritize patients with 'more advanced clinical needs'"[15] in the repair and replacement process, it must articulate a concrete plan with timetables for how that will be done.

Philips acknowledges that extreme heat and humidity exacerbate the degradation of the foam particles.[16] Yet, as of the date of this letter, in the middle of the summer months and more than two months after the issuance of the recall, many users of Philips equipment have been left with their recalled devices in conditions of intense heat, humidity, and even wildfires[17] that further jeopardize their equipment and health. After registering their devices, some users have been told to expect as long as a 12-month wait for a repair or replacement of their ventilators.[18] This is unacceptable.

In addition to being timely and prioritizing users who depend on their devices to live, Philips must implement a registration and repair process that is orderly and informative. Instead, several users who have contacted Philips about the recall have been redirected to apparent third-party contractors who have been either uninformed or unable to assist them.[19] However, just as users' healthcare providers and their contracted DME providers have records of what and how many products they have sold or provided to patients, Philips should partner with these and other healthcare providers to identify and target users who rely on their equipment for life-sustaining care for immediate repairs and replacements.

Thus, based on the foregoing we request that Philips issue an updated and public statement about the recall that prioritizes the replacement and/or repair of devices of users who depend on their equipment for life-sustaining care by September 14, 2021. The statement should include an explicit plan detailing how the prioritization will be accomplished and a timeline for the initiation and completion of this repair or replacement process. This process must also be staffed by operators with up-to-date and accurate information. Additional or updated public information about the recall should also address the issues raised herein, including but not limited to, the following:

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devices/safety-communications/certain-philips-respironics-ventilators-bipap-and-cpap-machines-recalled-due-potential-health-risks?#actions.

[14] *See* Sanchez, *supra* note 11.

[15] Joshua Brockman, *Breathing Machine Recall Over Possible Cancer Risk Leaves Millions Scrambling for Substitutes*, N.Y. TIMES (Aug. 17, 2021), https://www.nytimes.com/2021/08/17/health/cpap-breathing-devices-recall.html.

[16] Frequently Asked Questions, *supra* note 7, at 12.

[17] *See* Sanchez, *supra* note 11.

[18] @AndersenFields, TWITTER (Aug. 19, 2021, 6:32 PM), https://twitter.com/AndersenFields/status/1428484976312344577.

[19] *See* Sanchez, *supra* note 11.

- Information concerning how the identified issues that led to the recall were discovered in the Quality Management System process and what that process entails
- How the findings of that process reported in April 2021 led to the recall of the affected devices in June 2021
- How Philips has monitored/is monitoring reports and/or complaints about health effects associated with the use of the recalled devices and where users can access these reports and complaints
- What specific information about the recall and potential health effects associated with the continued or long-term use of the affected devices has been communicated to healthcare providers and professionals.

We appreciate your attention to our concerns and anticipate continued communication as we continue to monitor your response to this dire issue that so gravely impacts Philips' users in the communities we serve and represent.

Regards,

Alice Wong
Sandy Ho
Diane Coleman
Ingrid Tischer
Kathy Flaherty
Mike Volkman
Rachel Tanenhaus
Finn Gardiner
Heather Watkins

American Association of People with Disabilities
Association of Programs for Rural Independent Living
Autistic Women & Non-Binary Network
Autistic Self Advocacy Network
Center for Independence of the Disabled, New York
Civil Rights and Disability Justice Clinic, New York Law School
Civil Rights Education and Enforcement Center (CREEC)
Disability & Intersectionality Summit
Disability Rights Advocates
Disability Rights California
Disability Rights Education and Defense Fund (DREDF)
Disability Rights New York
Disability Policy Consortium
Disability Visibility Project
Fat Legal Advocacy, Rights, and Education (FLARE) Project
Little Lobbyists
National Association of the Deaf
National Center for Law and Economic Justice

National Council on Independent Living
National Disabled Law Students Association
NMD United
#NoBodyIsDisposable Coalition
Not Dead Yet
Paralyzed Veterans of America
Senior & Disability Action
United Spinal Association