United States Senate
WASHINGTON, DC 20510

August 24, 2021

Vitor Rocha
Chief Executive Officer
Philips North America
222 Jacobs Street
Cambridge, Massachusetts 02141

Dear Mr. Rocha,

I write with grave concern regarding the recent recall of millions of ventilators, CPAPs, and BiPAPs manufactured by Philips Respironics, a subsidiary of Philips North America. I have heard from a number of my constituents that this massive recall has left them and many others around the country struggling to find a safe, effective alternative. Further, it has prompted the U.S. Food and Drug Administration (FDA) to classify the problem as a Class I recall,[1] the most serious type of recall, which is reserved for "a situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious adverse health consequences or death."[2] I am requesting that Philips immediately provide information regarding the number of patients who have been impacted by this recall, including figures on the number who have been provided a repair or safe, effective replacement device, and Philips' timeline for submitting a mitigation plan with sufficient evidence to FDA for authorization of a permanent solution.

On April 26, 2021, Philips issued its first quarter earnings results update with information regarding "possible risks to users related to the sound abatement foam used in certain of Philips' sleep and respiratory care devices currently in use."[3] Several months later, on June 14, 2021, "Philips issued a recall notification for the United States for specific affected ventilation and sleep apnea devices."[4] Then, in July, FDA classified this "device problem as a Class I recall, the most serious type of recall."[5]

---

[1] *Certain Philips Respironics Ventilators, BiPAP, and CPAP Machines Recalled Due to Potential Health Risks: FDA Safety Communication*, U.S. FOOD AND DRUG ADMINISTRATION (June 30, 2021), https://www.fda.gov/medical-devices/safety-communications/certain-philips-respironics-ventilators-bipap-and-cpap-machines-recalled-due-potential-health-risks.

[2] *Investigations Operations Manual 2021: Chapter 7*, U.S. FOOD AND DRUG ADMINISTRATION (2021), https://www.fda.gov/media/75263/download#:~:text=Class%20I%20Recall%20is%20a,adverse%20health%20consequences%20or%20death.

[3] *Philips' First-Quarter Results 2021*, PHILIPS (Apr. 26, 2021), https://www.philips.com/a-w/about/news/archive/corpcomms/news/press/2021/philips-first-quarter-results-2021.html.

[4] *Medical Device Recall Notification: Philips Respironics Sleep and Respiratory Care devices*, PHILIPS (June 14, 2021), https://www.usa.philips.com/healthcare/e/sleep/communications/src-update#section_3.

[5] *Certain Philips Respironics Ventilators, BiPAP, and CPAP Machines Recalled Due to Potential Health Risks: FDA Safety Communication*, U.S. FOOD AND DRUG ADMINISTRATION (June 30, 2021), https://www.fda.gov/medical-devices/safety-communications/certain-philips-respironics-ventilators-bipap-and-cpap-machines-recalled-due-potential-health-risks.

While Philips apparently first made patients aware of this problem, which may impact devices as far back as 2009, on June 14, many patients did not learn about the issue from Philips at all, instead finding out through social media or family and friends.[6] This is despite the fact that the problem has been identified by Philips since at least April. That's why I am so alarmed that even after several months, too many patients have yet to receive the promised repair kits and replacements, leaving users "stranded," and many patients may not even know of the recalled status of their device.[7] For these patients, Philips has presented a false choice of foregoing essential, sometimes life-saving care or using a defective product that could itself result in death. One patient, quoted in an article by *The Verge*, said, "I have to breathe, but breathing from a machine pumping carcinogenic particles into my lungs is my only option?"[8] I have heard from a number of my constituents in Connecticut with similar concerns, such as a lack of information from Philips, first learning about the recall second hand, and no help in accessing the promised replacements or repairs that Philips continues to reference.

Therefore, I am requesting answers to the below questions by September 7, 2021:

- How many devices have been impacted by this recall, and how many patients are believed to have been impacted by this recall?

- What percentage of impacted patients have used the Philips established registration process to register a recalled device? Please also provide the total number of impacted patients who have registered.

- How has Philips reached out to affected patients to alert them to this problem and how is Philips continuing to ensure all affected patients learn of this problem?

- What percentage of impacted patients who have registered their device have received a response from Philips regarding their recalled device? Please also provide the total number of impacted patients who have received any response.

- What percentage of impacted patients have had their recalled device repaired or replaced by Philips' "comprehensive repair and replacement program"? Please also provide the total number of impacted patients who have had the issue completely resolved through replacement or repair.

- When does Philips expect to have repaired or replaced all impacted devices?

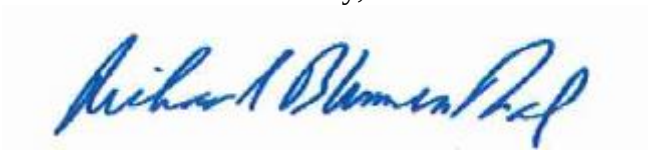
- When does Philips expect to submit a mitigation plan to FDA for authorization to permanently resolve this problem? If it has done so, has it provided FDA with sufficient evidence to show that the mitigation plan eliminates the product defect and the product is now safe and effective for use?

---

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

The current situation is untenable, unacceptable, and must be immediately rectified. I look forward to reviewing your answers to these questions. In the meantime, I urge Philips to continue its outreach to impacted patients, immediately expedite its replacement and repair program, submit a mitigation plan with sufficient evidence to FDA for authorization, and work to ensure that such a mass recall does not occur again in the future.

Sincerely,



RICHARD BLUMENTHAL
United States Senate