August 9, 2023

Letise Williams
Center for Devices and Radiological Health
Food and Drug Administration
SENT VIA EMAIL: letise.williams@fda.hhs.gov

RE: FDA Patient Engagement Advisory Committee meeting, "Advancing Health Equity in Medical Devices," Docket No. FDA-2023-N-0008

Dear Ms. Williams:

On behalf of the American Academy of Sleep Medicine (AASM), we are submitting comments to address health equity concerns related to the ongoing Philips Respironics positive airway pressure (PAP) device recall. The AASM is a professional society that represents a membership of 12,000 physicians, scientists, allied health professionals, and accredited sleep centers. The AASM is committed to advancing sleep care and enhancing sleep health to improve lives.

About 5.5 million ventilatory and PAP devices used to treat sleep apnea were affected by the Phillips recall, which was announced June 14, 2021, due to concerns about the potential health risks posed by exposure to the particulates released from the polyester-based polyurethane sound-abatement foam in these devices, as well as off-gassing of potentially toxic concentrations of volatile organic compounds (VOCs). This was later categorized by the FDA as a class 1 recall - with reasonable probability that the use of or exposure to a violative product will cause serious, adverse health consequences or death.

Given the magnitude of the recall, replacement or refurbished machines were not immediately available for several months to years for many patients with these recalled sleep and respiratory care devices, and many were left with the following choices: continuing therapy with potentially deleterious health consequences, enduring significant costs to acquire alternative therapies out of pocket, or discontinuing therapy with associated risk of cognitive decline, heart problems and death from non-treatment. Unfortunately, however, as is often the case, some patient populations were impacted more than others. Indeed, as early as June 25, 2021, members of the AASM expressed concerns regarding the potential impact of the recall on vulnerable populations during a webinar organized by the AASM, along with the American Academy of Neurology (AAN), American College of Chest Physicians (CHEST), and American Thoracic Society (ATS).

It was recognized that engagement with vulnerable populations would warrant special attention. This includes the elderly, the uninsured, and the underserved (including individuals who have dropped in and out of the health care system due to social, medical, and psychiatric issues), individuals with low socioeconomic status or physical impairment who may have difficulty accessing information regarding the recall and risk mitigation strategies, people with low technological literacy, people who are pregnant, and pediatric patients who require coordinated family-based discussions. Given the scarcity of replacement equipment, medical triaging of resources would be required to disperse these devices in an equitable fashion.

Despite attempts at triaging, these medically and socially vulnerable populations remain behind in the device replacement process, at least partly due to inadequate and delayed use of data identifying these populations. The assumption that every affected consumer would be notified or otherwise become aware, have access to a computer, and be able to navigate the device registration process was erroneous. Indeed, anecdotal evidence suggests that some of these patients remain unaware of the recall. The recall has unfortunately exposed stark inequities in our health care system and the absence of an industry-wide device-tracking standard. It also has become apparent that no guidelines exist to ensure that mitigation of any recall occurs in an equitable fashion.

Those with the means were able to circumvent supply issues by purchasing machines out of pocket. Similarly, the recall further amplified the preexisting inequity in access to alternative therapies including oral appliance and surgical interventions. Lack of transparency regarding wait times and difficulties with the registration process, as well as data about when, where and to whom the refurbished/replacement machines were delivered, continues to further erode public confidence in the process.

This failure also raises concerns about the responsibility of the manufacturer's ethical obligation to disclose safety issues and the ability of the FDA or other regulatory bodies to enforce corrective action in a more equitable manner. There is clearly a need for more regulatory oversight and post-marketing surveillance with medical devices to protect the most vulnerable among us.

Amara Okoli, MD; Jocelyn Cheng, MD; Muhammad Rishi, MD and Indira Gurubhagavatula, MD MPH, FAASM on behalf of the The Public Safety Committee of the American Academy of Sleep Medicine

References

Philips. Philips issues recall notification to mitigate potential health risks related to the sound abatement foam component in certain sleep and respiratory care devices. June 14, 2021. Accessed Aug. 9, 2023. https://www.philips.com/a-w/about/news/archive/standard/news/press/2021/20210614-philips-issues-recall-notification-to-mitigate-potential-health-risks-related-to-the-sound-abatement-foam-component-in-certain-sleep-and-respiratory-care-devices.html.

Philips Respironics. Urgent: medical device recall. Accessed Aug. 9, 2023. https://www.philips.com/c-dam/b2bhc/master/landing-pages/src/update/documents/philips-recall-letter-2021-05-a-2021-06-a.pdf.

Philips Respironics. Medical device recall information. Updated July 31, 2023. Accessed Aug. 9, 2023. https://www.usa.philips.com/healthcare/e/sleep/communications/src-update.

U.S. Food and Drug Administration. Update: certain Philips Respironics ventilators, BIPAP machines, and CPAP machines recalled due to potential health risks: FDA safety communication. Updated June 2, 2023. Accessed Aug. 9, 2023. https://www.fda.gov/medical-devices/safety-communications/update-certain-philips-respironics-ventilators-bipap-machines-and-cpap-machines-recalled-due.

American Academy of Sleep Medicine. AASM guidance in response to Philips recall of PAP devices. Updated July 24, 2023. Accessed Aug. 9, 2023. https://aasm.org/clinical-resources/guidance-philips-recall-pap-devices/.

Kinard M, McGiffert L. Medical device tracking—how it is and how it should be. *JAMA Intern Med*. 2021;181(3):305-306. https://doi.org/10.1001/jamainternmed.2020.7797.

Owens RL, Wilson KC, Gurubhagavatula I, Mehra R. Philips Respironics recall of positive airway pressure and noninvasive ventilation devices: a brief statement to inform response efforts and identify key steps forward. *Am J Respir Crit Care Med*. 2021;204(8):887-890. https://doi.org/10.1164/rccm.202107-1666ED.

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. https://doi.org/10.1001/jamainternmed.2022.5141.

Robbins R, Epstein LJ, Pavlova M, 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 May 5. https://doi.org/10.5664/jcsm.10652