PHILIPS

Progress update

Philips Respironics field action

January 30, 2023

innovation you

The Respironics recall remains highest priority

2022	2023	2023-2025
~90% production and 80% shipment of recall units	Finalize recall and testing	Manage impact of proposed Consent Decree
Encouraging test results for DS1 platform (within safety norms)	Manage litigation, DoJ investigation	Manage litigation, DoJ investigation
483 remediation in progress	483 remediation and clarity on proposed Consent Decree	Gradually restore position

Taking the learnings of Respironics recall
to raise Patient Safety and Quality to the highest standards across Philips

Extensive patient, clinician and regulator engagement

- **Driving patient engagement** and registrations with dedicated registration system and infrastructure
  - Continued patient outreach through mailing, call center, websites and direct contact with interest groups
  - Comprehensive DME outreach
  - Met the requirements in FDA's 518(a) order and continue to report progress
- **Ongoing engagement with regulators** to optimize the recall efforts
- **Sharing progress on testing program** to ensure patients and physicians fully informed

~90% production and 80% shipment of recall units in 2022

The task at hand

- Around 5.5M devices expected to be repaired or replaced
- Equivalent to over 5x previous annual production volume
- >1 thousand new product configurations released globally
- Partnering with DME's for patient delivery

Progress to date

- Quadrupled production capacity compared to pre-recall
- >1,000 people cross functional team engaged
- Dependency on supply of materials and global logistics capacity
- ~90% production and 80% shipment of recall units in 2022

Testing and literature review

Encouraging test results for DreamStation1 devices

VOC testing

Emissions within ISO limits (devices not exposed to ozone)

Visual inspection and assessment of the foam in used devices

- Low prevalence of significant visible foam degradation
- Even when significant visible particulates are formed, likely to accumulate inside the device

Particulate Matter testing

Foam degradation does not contribute to appreciable elevated levels of respirable particles; within ISO limits

Bioassay evaluation, chemical characterization and toxicological risk assessment

Exposure to particulates is unlikely to result in an appreciable harm to health in patients, even based on a worst-case assumption that the patient is exposed to 100% of the foam

Thorough consideration and mitigation of testing limitations that are inherent to any test standard and/or scientific research; very conservative assumptions taken

DreamStation1 represents ~68% of the total # of devices registered as part of the Respironics recall

More information on the latest testing results can be found here: https://www.philips.com/a-w/about/investor-relations/recall-sleep-and-respiratory/testing

Test & research program - next steps

- Finalize toxicological risk assessment of the VOC emissions resulting from ozone-induced foam degradation in DreamStation1 devices

  Expected in Q2 2023

- Complete testing for SystemOne (~26% of registered devices) and DreamStation Go (~1%), which contain the exact same foam as the DreamStation1 devices

  Expected in Q2 2023

- Complete VOC and PM testing, as well as chemical evaluation and toxicological assessments for Trilogy 100/200 (~3%) and OmniLab (~2%), where a different PE-PUR foam is used

  Expected in Q3 2023

- Ongoing engagement with FDA and other competent authorities

Summary of third-party epidemiological studies

- There were thirteen identified epidemiological studies, all of which found no consistent statistical association between use of PAP devices - including Philips Respironics'- and the risk of cancer in patients with obstructive sleep apnea (OSA)
- Two of the studies[1] showed no statistical difference in cancer risk between users of Philips Respironics PAP devices and users of other brands of PAP devices
- Eleven studies provided limited additional insights, but their results also suggested no excess risk of cancer associated with use of PAP devices
- The 2022 study by Palm and others reported more frequent prescription of respiratory relief medication among patients with both OSA and obstructive lung disease, but no statistical difference in hospitalization, i.e. health outcomes, was observed for OLD among OSA patients between the users or polyurethane PAP and non-foam PAP

1. An Association between Positive Airway Pressure Device Manufacturer and Incident Cancer? A Secondary Data Analysis; American Journal of Respiratory and Critical Care Medicine, 2021, Volume 204, Issue 12 pp. 1484–1488; Cancer risk in adherent users of polyurethane foam-containing CPAP devices for sleep apnea, European Respiratory Journal 2022.

Regulatory and legal

Regulatory and legal update - FDA/DOJ

- Philips Respironics continues to engage with the US Food and Drug Administration (FDA) on the steps it has taken in response to the FDA's Form 483 observations.

- Since July 2022, Philips Respironics has been in discussions with the US Department of Justice (DOJ), acting on behalf of the FDA, regarding the terms of a proposed consent decree to address many of the identified issues on a forward-going basis.

- In addition, on April 8, 2022, Philips Respironics and certain of Philips' subsidiaries in the US received a subpoena from the DOJ to provide information related to events leading to the Philips Respironics recall. The relevant subsidiaries are cooperating with the agency. The criminal and civil investigation is being conducted by the DOJ's Consumer Protection Branch and Civil Fraud Section and the US Attorney's Office for the Eastern District of Pennsylvania.

Regulatory and legal update- Civil litigation

- Collective and individual civil complaints have been filed in various jurisdictions globally, including but not limited to the United States, Australia, Canada, Israel and Chile. The complaints variously allege economic loss, personal injury and, in some cases, the need for medical monitoring related to devices subject to the Philips Respironics recall
    - In the United States, as of January 2023, putative economic loss and medical monitoring class actions and approximately 320 personal injury lawsuits have been consolidated into a multidistrict litigation (MDL) in Pennsylvania and are currently pending.
    - In September 2022, the MDL court established a voluntary, court-approved census registry, and associated tolling, for potential claimants who have not filed claims, but may file claims in the future, relating to the recalled devices. As of January 27, 2023, approximately 20,000 individuals had joined the census registry. The company anticipates that the number of individuals on the census registry will increase in 2023.
    - In September 2022, the Court requested that plaintiffs resubmit consolidated or master complaints for their economic loss, medical monitoring and personal injury claims. Since then, the various Philips defendants have filed motions to dismiss each of these complaints on numerous grounds.
    - Formal discovery has started, and it is expected to continue throughout 2023 and beyond.
- SoClean, a manufacturer of ozone-based CPAP cleaning devices, filed an amended complaint against Philips and certain of its U.S. affiliates, including Philips Respironics, in October 2022 for alleged unfair competition, tortious interference with business relationships, defamation and commercial disparagement. Philips believes SoClean's claims have no basis in fact or law and is seeking dismissal of the case in its entirety, including on the basis that the FDA has stated that CPAP ozone cleaners, like SoClean's products, "are not legally marketed for this use."
- In the Eastern District of New York, a securities class action suit was filed against the company in August 2021, alleging Philips' statements in connection with the recall triggered a fall in stock price. Plaintiffs filed a Second Amended Complaint in November 2022. Philips will be moving to dismiss the Second Amended Complaint.
- Given the uncertain nature the relevant events, and of their potential impact and associated obligations, if any, the company has not provided for these matters.

Medical Device Reporting

Process

- Medical device manufacturers are required to submit medical device reports (MDRs) to the FDA when they receive complaints for certain types of device malfunctions and safety issues.
- These complaints may be submitted to the manufacturer by health care professionals, patients, caregivers and consumers
- The FDA acknowledges that "the submission of an MDR itself is not evidence that the device caused or contributed to the adverse outcome or event" and that the "cause of an event cannot typically be determined from this reporting system alone"

Background

- Following Philips' public statements on possible risks to users in April 2021 and the June 2021 recall notification/field safety notice, Philips Respironics received a steep increase in complaints allegedly associated with possible foam degradation.
- This led to approximately 90,000 MDRs filed by Philips Respironics to the FDA from April 2021 through October 31, 2022.
- As previously disclosed by Philips, the vast majority (93% as of November 2022) of the MDRs filed since April 2021 are alleged technical malfunctions that do not involve serious injury.


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