May 2022 Philips Recall Summary

In the summer of 2021, Philips Respironics issued a recall notification of a number of their CPAP, BiPap, and ventilators in the United States. A group of disabled people impacted by the recall organized and sent an open letter to the Head of Quality and Regulator at Philips Respironics USA on August 25, 2021. Below is a summary of events related to the recall, including a summary of a report by the Food and Drug Administration prepared by the Civil Rights and Disability Justice Clinic at New York Law School Legal Services, Inc.

DISCLAIMER: This summary is intended for informational purposes only. It is a collection of information from various cited publicly available sources. Nothing in this update should be construed as legal advice.

BRIEF SYNOPSIS

In August of 2021, many organizations signed onto a letter we wrote in conjunction with several Philips Respironics Users (Philips Users) to Rodney Mell, head of Quality and Regulatory at Philips Respironics ("Philips"), concerning the June 14, 2021 recall of numerous models of CPAP, BiPAP, and ventilator devices. The recall was due to the degradation of a polyester-based polyurethane (PE-PUR) sound abatement foam that may enter the device's air pathway and be ingested by the user.[1] The degraded foam may also release toxic chemicals known as Volatile Organic Compounds (VOCs).[2] In that letter, we requested that Philips develop and implement a repair and/or replacement process and timeline that prioritizes users who depend on their devices for life-sustaining care or, in the alternative, that Philips provide those users with comparable devices from other manufacturers without cost.

Although Philips never responded to the letter[3], we have continued to closely monitor Philips' management of the recall. This is a summary of these updates for the broader disability community. The major updates include the following:

- A November 2021 U.S. Food and Drug Administration ("FDA") report found that a silicone foam-containing CPAP device marketed outside of the U.S. failed safety testing for VOCs. This is important because Philips' repair and replacement plan–which was initially approved by the FDA and implemented by Philips–replaces PE-PUR foam with silicone foam. This information suggests that even the replacement devices could pose a health risk for device users.

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[1] Philips, *Urgent: Medical Device Recall*, https://www.usa.philips.com/c-dam/b2bhc/master/landing-pages/src/update/documents/en_US/philips-recall-letter-2021-11-16-a-cpap-a-ventilator-recall-letter-us-revised.pdf (last visited Apr. 22, 2022).

[2] *Id.*

[3] The physical letter was actually returned to us even though we sent it via priority mail and attempted to confirm the correct recipient and address. However, we also posted the letter online.

- The report also indicates that the FDA found that Philips knew about the foam breakdown since at least October 30, 2015 and decided not to change the devices' design and to continue using PE-PUR foam.

- Trilogy Evo ventilators, not included in the June recall, were recalled in December 2021.[4]

- Following testing, Philips–together with certified testing laboratories and other third parties–concluded that exposure to the level of VOCs in first generation DreamStation devices is "not typically anticipated to result in long-term health consequences" for users.[5]

- On March 8, 2022, Philips launched a patient prioritization process for the distribution of replacement devices.[6]

- The FDA found that Philips' notification efforts were inadequate and issued a notification order to the company, requiring it to notify users and health professionals of the recall and the "unreasonable risk of substantial harm" the degradation of the PE-PUR foam poses to the public health.[7]

SUMMARY OF EVENTS

Repair and Replacement Process

On September 1, 2021, Philips announced that the FDA authorized Philips to begin the repair and replacement process of first generation DreamStation CPAP and BiPAP machines that contain the defective foam.[8] The FDA-approved plan involves replacing the PE-PUR foam with

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[4] *Philips Respironics Recalls Certain Trilogy EVO Ventilators for Potential Health Risks from PE-PUR Foam*, U.S. Food & Drug Administration, https://www.fda.gov/medical-devices/medical-device-recalls/philips-respironics-recalls-certain-trilogy-evo-ventilators-potential-health-risks-pe-pur-foam (Jan. 26, 2022).

[5] Philips, *Philips provides update on the test and research program in connection with the CPAP, BiPAP and Mechanical Ventilator recall notification* (Dec. 23, 2021), https://www.philips.com/a-w/about/news/archive/standard/news/press/2021/20211223-philips-provides-update-on-the-test-and-research-program-in-connection-with-the-cpap-bipap-and-mechanical-ventilator-recall-notification.

[6] Philips, *Important Information about patient prioritization* (Mar. 8, 2022), https://www.usa.philips.com/healthcare/resource-catalog/landing/experience-catalog/sleep/communications/src-update/news/important-information-about-patient-prioritization.

[7] *Update: Certain Philips Respironics Ventilators, BiPAP, and CPAP Machines Recalled Due to Potential Health Risks: FDA Safety Communication*, U.S. Food & Drug Administration, https://www.fda.gov/medical-devices/safety-communications/update-certain-philips-respironics-ventilators-bipap-and-cpap-machines-recalled-due-potential-health (Mar. 14, 2022).

[8] Philips, *Philips starts repair and replacement program of first-generation DreamStation devices in the US in relation to earlier announced recall notification* (Sept. 1, 2021), https://www.philips.com/a-w/about/news/archive/standard/news/press/2021/20210901-philips-starts-repair-and-replacement-program-of-first-generation-dreamstation-devices-in-the-us-in-relation-to-earlier-announced-recall-notification.html.

a silicone-based foam.[9] Philips has not yet provided the FDA with all the information the FDA needs to evaluate repair and replacement plans for all of the recalled devices.[10] Philips began the repair process in September 2021 and started to replace first generation DreamStations with DreamStation 2 devices.[11] Philips stated that it "intends to complete" the repair and replacement process by September 2022.[12]

FDA Investigation Report Findings

On November 12, 2021, the FDA released a report of its investigation of a Philips manufacturing facility that took place between August 26, 2021 and November 9, 2021.[13] The purpose of the report was to investigate what may have caused the foam to break down in its recalled devices and to determine whether Philips followed the FDA's quality system regulations, which outline the requirements concerning the design and manufacturing of medical devices.[14] A summary of the entire report can be found here.[15]

Among the FDA's major findings was the discovery of a test report, dated August 24, 2021, that showed Philips did not investigate after a singular silicone foam-containing CPAP device marketed outside of the United States failed safety testing for "chemicals of concern," including VOCs.[16] In response, the FDA requested that Philips retain an independent laboratory to perform testing to determine whether the silicone foam poses potential safety risks.[17] However, the FDA did not recommend that users who have received a replacement device with the silicone-based foam discontinue use because they did not have enough information to conclude whether the silicone-based foam posed any risk to users.[18]

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[9] *FDA Provides Update on Recall of Certain Philips Respironics Breathing Assistance Machines,* U.S. Food & Drug Administration (Nov. 12, 2021), https://www.fda.gov/news-events/press-announcements/fda-provides-update-recall-certain-philips-respironics-breathing-assistance-machines. The FDA's approval was based on testing information Philips provided to the FDA in June 2021. *Id.*

[10] *Philips Respironics CPAP, BiPAP, and Ventilator Recalls: Frequently Asked Questions*, U.S. Food & Drug Administration, https://www.fda.gov/medical-devices/safety-communications/philips-respironics-cpap-bipap-and-ventilator-recalls-frequently-asked-questions (Mar. 21, 2022).

[11] *Philips starts repair and replacement program of first-generation DreamStation devices in the US in relation to earlier announced recall notification*, *supra* note 8.

[12] *Id.* Of the 5.2 million recalled devices, at least 2 million are in the United States. 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. As of January 2022, Philips produced about 1.5 million repair kits and replacement devices, 750,000 of which have been distributed. Nick Paul Taylor, *Philips targets Q4 2022 end to recall as supply chain issues drag down results*, MedTechDrive (Jan. 24, 2022), https://www.medtechdive.com/news/philips-earnings-q4-2022-recall-supply-chain-issues/617553/.

[13] *Form FDA-483*, U.S. Food & Drug Administration (Nov. 9, 2022), https://www.fda.gov/media/154099/download.

[14] *FDA Provides Update on Recall of Certain Philips Respironics Breathing Assistance Machines, supra* note 9.

[15] *Update on Philips CPAP, BiPAP, and Ventilator Recall*, Disability Visibility Project (Jan. 17, 2022), https://disabilityvisibilityproject.com/2022/01/17/update-on-philips-cpap-bipap-and-ventilator-recall/.

[16] *FDA Provides Update on Recall of Certain Philips Respironics Breathing Assistance Machines, supra* note 9.

[17] *Id.*

[18] *Id.*

The investigation also found that between April 1, 2016 and January 22, 2021, there were at least 14 instances where Philips' risk analysis was inadequate or where Philips did not conduct a risk analysis when appropriate even though it was aware of potential foam breakdown and/or VOC emission concerns in various devices.[19] Moreover, the FDA uncovered emails beginning on October 30, 2015 between Philips and its raw foam supplier that showed that Philips was aware of the foam breakdown issues.[20] Despite this knowledge, emails from August 24, 2018 showed that Philips decided not to change their device design and to continue using PE-PUR foam.[21]

A New Recall

In December 2021, Philips initiated a recall of Trilogy Evo ventilators with specific serial numbers distributed between April 15, 2021 and May 24, 2021, which were not included in the original recall,[22] because a Philips manufacturer "incorrectly used" PE-PUR foam in the muffler assembly of the devices.[23] This issue was discovered during lab testing of the ventilators.[24]

Philips issued another recall about a separate problem in V60 and V60 Plus ventilators on April 22, 2022 and the FDA announced it on May 2, 2022.[25] The announcement indicates that there is an issue with the electrical circuit that controls the power supply to the ventilator and alarm, such that the ventilator may cease to operate potentially without setting off the alarm and the patient may no longer receive respiratory assistance.[26] Philips is investigating one death potentially linked to this issue and the FDA is working with Philips on this.[27]

Testing Results Released

Since June 2021, Philips, "together with certified testing laboratories and other qualified third parties," has been conducting tests on the PE-PUR foam to assess health risks related to the degraded foam particulates and the VOCs the foam emits.[28] On December 23, 2021, Philips released the results of their testing of VOC emissions in first-generation DreamStation devices. Their conclusion was that exposure to the level of VOCs in those devices is "not typically

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[19] *Form FDA-483*, *supra* note 13, at 3.

[20] *Form FDA-483*, *supra* note 13, at 18.

[21] *Id.*

[22] *Philips Respironics CPAP, BiPAP, and Ventilator Recalls: Frequently Asked Questions, supra* note 10.

[23] *Philips Respironics Recalls Certain Trilogy EVO Ventilators for Potential Health Risks from PE-PUR Foam*, *supra* note 4.

[24] *Id.*

[25] *Philips Respironics Issues Voluntary Recall Notification/Field Safety Notice for the V60 Ventilator Product Family*, U.S. Food & Drug Administration (May 2, 2022), https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/philips-respironics-issues-voluntary-recall-notificationfield-safety-notice-v60-ventilator-product.

[26] *Id.*

[27] Nick Paul Taylor, *Philips investigates reports of 1 death, 4 injuries potentially tied to ventilator recall,* MedTechDive (Apr. 20, 2022), https://www.medtechdive.com/news/another-class-i-recall-philips-ventilators/622350/.

[28] *Philips provides updates on the test and research program in connection with the CPAP, BiPAP and Mechanical Ventilator recall notification*, *supra* note 5.

anticipated to result in long-term health consequences" for users.[29] However, these results have limitations because the tested devices were not exposed to ozone cleaning in accordance with instructions for use, the testing did not evaluate the risks associated with the degraded foam particulates, and the testing did not include VOC testing of devices other than the first-generation DreamStation.[30] Ongoing testing will address those limitations.[31]

Patient Prioritization Process

On March 8, 2022, Philips announced that it will begin distributing replacement devices based on a new patient prioritization process.[32] The process allows users who have already registered their devices to update their registration information to include information such as their age, related health conditions, obstructive sleep apnea severity, if the user identified foam particulates in their device, and if they used ozone for device cleaning purposes.[33] However, this does not guarantee that users will receive their devices faster.[34] Philips stated that they are unable to confirm individual timeframes and notes that the repair and replacement process will take until about the end of 2022 for the "vast majority" of users.[35]

FDA Notification Order

On March 10, 2022, the FDA issued a notification order to Philips pursuant to Section 518(a) of the Federal Food, Drug, and Cosmetic Act requiring it to notify users and health professionals, among others, of the June 2021 recall and the "unreasonable risk of substantial harm" the degradation of the PE-PUR foam poses to the public health.[36] The FDA concluded that this notification order was necessary to eliminate the unreasonable risk of harm the recalled products pose to users because Philips' notification efforts thus far have been inadequate.[37] The notification also requires Philips to provide access to all available testing results and conclusions regarding PE-PUR foam degradation and VOCs in Philips-manufactured devices.[38] Philips must provide the ordered notification within 45 days of its issuance.[39]

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[29] *Id.*

[30] *Id.*

[31] *Id.*

[32] *Important Information about patient prioritization*, *supra* note 6.

[33] *Id.*

[34] Philips cites other factors that must be met such as "sufficient inventory availability" and receipt of information from users and DMEs concerning therapy settings. *Id.*

[35] *Id.*

[36] *Update: Certain Philips Respironics Ventilators, BiPAP, and CPAP Machines Recalled Due to Potential Health Risks: FDA Safety Communication*, *supra* note 7.

[37] *Id.* Based on information Philips provided, the FDA estimated that only approximately 50% of device users who purchased or received a recalled device in the last 5 years have registered their devices since the recall's announcement 9 months ago. *518(a) Notification Order*, U.S. Food & Drug Administration, https://www.fda.gov/media/156811/download (last visited Apr. 21, 2022).

[38] *Id.*

[39] *Id.*

On May 2, 2022, the FDA's Center for Devices and Radiological Health proposed an order under 518(b) of the Federal Food, Drug, and Cosmetic Act to require Philips to submit a plan for the repair, replacement, or refund of the purchase price of the recalled devices. Philips has an opportunity for an informal hearing before the FDA issues the order.[40]

DOJ Subpoena

On April 25, 2022, the U.S. Department of Justice issued a subpoena to Philips for information related to events leading to the recall.[41]

For More Information

1) Please share the link of this update with everyone you know, especially other people impacted by the recall https://disabilityvisibilityproject.com/2022/05/10/may-2022-philips-recall-summary/

2) You can find and read existing reports submitted by people impacted by the recall from MAUDE (Manufacturer and User Facility Device Experience), a database of medical device reports submitted to the FDA by mandatory and voluntary reporters. You can do a search with the terms "Philips Respironics": https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/search.cfm

3) Meeting minutes and documents from the FDA's Patient Engagement Advisory Committee from October 2021 on medical device recalls: https://www.fda.gov/advisory-committees/advisory-committee-calendar/october-6-2021-patient-engagement-advisory-committee-meeting-announcement-10062021-10062021

[40] *Philips Respironics CPAP, BiPAP, and Ventilator Recalls: Frequently Asked Questions*, *supra* note 10.

[41] *Philips receives subpoena from US Department of Justice, provides recall updates*, American Academy of Sleep Medicine (Apr. 28, 2022), https://aasm.org/philips-subpoena-department-justice-recall/.