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Philips Implements Plan To Address FDA Concerns Following Harsh Inspection Report

by Brian Bossetta

After a lengthy inspection of a Philips facility that manufactured several recalled breathing and ventilator devices, the US Food and Drug Administration delivered a pointed report to the company highlighting multiple risk management and quality systems issues. In response, Philips wrote to the FDA outlining steps it plans to take to fix the problems.

After recalling more than 2 million breathing devices in June 2021, Royal Philips found itself in royal trouble with the US Food and Drug Administration.

The class I recall of the company's bi-level positive airway pressure (BiPAP), continuous positive airway pressure (CPAP), and other mechanical ventilator devices triggered an agency inspection of the company's facility in Murrysville, PA, where the devices where made.

When the FDA wrapped up its inspection, which ran from 26 August 2021 through 9 November 2021, it delivered an incriminating FDA-483 report to the plant's head of quality.

In the 29-page report, the FDA rebuked Philips Respironics for failing to investigate "at least" 222,000 complaints about the breakdown of noise-abatement foam in the devices – the issue that prompted the recall.

When Philips first initiated the June 2021 recall, the company said the foam "may degrade into particles which may enter

Damning FDA-483: Philips Didn't Investigate 222,000 Complaints Of Possible Degraded Foam In Breathing Devices

By Shawn M. Schmitt

the device's air pathway and be ingested or inhaled by the user, and the foam may off-gas certain chemicals." (Also see "*Polyurethane Foam Problems Nudge Philips To Recall Certain Sleep, Mechanical Ventilator Devices*" - Medtech Insight, 14 Jun, 2021.)

Upon completion of the Murrysville facility inspection, FDA investigator Katelyn Staub-Zamperini said in the 483: "Analysis of quality data, such as complaints and Medical Device Reports, was not adequately performed to identify or detect quality problems" and further noted the company failed to take corrective and preventive action (CAPA), risk analysis, and did not formally investigate the thousands of complaints potentially linked to the degradation of the foam.

15 Nov 2021
Royal Philips has been reeling from a June recall of millions of breathing machines, and now it's been slapped by the US FDA with multiple observations after an on-site inspection. One observation says the company didn't open formal investigations after receiving hundreds of thousands of complaints of particles and other contaminants when the recalled devices were used.

Read the full article here

The violations noted in the 483 seemed consistent with customer claims that Philips was aware of the foam risk but didn't act. In July 2021, patients in the US and Canada filed a class action lawsuit against Philips alleging the company failed to properly investigate customer complaints about the devices, which are most often used to treat obstructive sleep apnea. (Also see "*Recall Of Sleep, Ventilator Devices Lead To International Patient Suits For Philips*" - Medtech Insight, 28 Jul, 2021.)

In total, Staub-Zamperini detailed eight observations in the 483. In addition to noting the company's inadequate risk analysis and CAPA procedures, these included charges that the design validation of the devices did not conform to defined user need and intended use, that there was no established procedure for design change, and that executive management failed to ensure that the quality policy was "understood, implemented and maintained at all levels of the organization."

Philips Responds

A month after receiving the 483 report, however, Philips responded to the FDA in a detailed *91-page letter* outlining a series of corrective measures it was implementing to "fully address" the agency's concerns after investigating Staub-Zamperini's observations.

In the letter, Tom Fallon, Philips Respironics' head of quality, sleep and respiratory care, said the company was creating a team of "internal subject-matter experts within Respironics that focuses on biocompatibility, cleaning and disinfection, and toxicology" and adding personnel to evaluate

risk while implementing several "over-arching changes" to further promote compliance with FDA's regulations.

> *"Respironics has coordinated with FDA to ensure that Respironics executes the remediation plan for affected devices efficiently, effectively, and promptly." – Tom Fallon*

Additionally, Fallon noted that Philips was in the process of engaging outside quality system experts to help ensure the company's improvements "meet FDA requirements and expectations."

The team's purpose, according to Fallon's letter, was to create centralized oversight, accountability, and information sharing for all company matters that concern biocompatibility, cleaning and disinfection, and toxicology.

Specifically, Philips said it was going to add "full-time, subject-matter" experts to provide data for evaluating risk, such as toxicologists and engineers to support biocompatibility as well as a director of the biocompatibility, cleaning and disinfection, and toxicology team. The company also said it was going to add personnel to support "quality, regulatory, design quality, supplier management, post-market, and medical affairs."

As of publication date, Philips did not provide *Medtech Insight* with the number of employees added meet these objectives.

In its response to the FDA, Philips said it initiated the June recall after conducting a voluntary field action a month before and reporting that action to the agency.

Fallon wrote: "As explained in the May 7, 2021 and subsequent reports, Respironics became aware of two issues regarding the affected devices: (1) the polyester-based polyurethane (PE-PUR) sound abatement foam used in the affected devices may degrade and enter the air pathway; and (2) based on testing completed as of the May 7, 2021 report, the PE-PUR sound abatement foam used in these devices may emit certain chemicals. Since submission of the May 7, 2021 report, Respironics has coordinated with FDA to ensure that Respironics executes the remediation plan for affected devices efficiently, effectively, and promptly."

Some of those specific actions, according to Fallon, include the company submitting three 510(k) premarket notifications to the FDA regarding a change to the sound abatement foam, a protocol

regarding the remediation of returned recalled devices, and attending bi-weekly calls with the FDA to provide updates regarding the remediation plan and ongoing testing, and to ensure the agency's follow-up questions are fully addressed.

Leadership And Resource Changes

To further promote compliance with FDA's requirements and address the issues identified by the agency in its Murrysville inspection, Respironics said it invested in new personnel to manage its Quality Management System (QMS), including changes to Respironics' top management and investment in additional resources to support the QMS and related activities.

Those top management changes include Fallon, who started his current role in November 2021, David Ferguson, a health tech veteran the company hired in March as Respironics' "business leader," a new position defined as "management with executive responsibility."

Respironics also created a team of internal subject-matter experts within the company to focus on biocompatibility, cleaning and disinfection, and toxicology. Specifically, the company added toxicologists and engineers to support biocompatibility evaluations, including a team director.

Fallon's letter also noted "broader actions" the company was taking in response to the 483, such as enhancing the knowledge of Respironics personnel by engaging outside experts to perform in-depth, company-wide training on the Quality System Regulation (QSR); Medical Device Reporting (MDR); and reporting of corrections and removals.

"As part of the training, the outside experts will provide guidance on FDA's current expectations related to specific regulatory requirements," Fallon said in the letter. "In addition, the training will help make personnel aware of potential risks/failures that could result from the improper performance of their specific job."

Problems Persist

Still, issues with the breathing machines continued.

On 16 August 2022, the FDA issued a *safety communication* noting it had received more than 48,000 MDRs between 1 May and 31 July, including 44 reports of death associated with the breakdown – or suspected breakdown – of the foam. (Also see "*US FDA Adds More MDRs To Philips Recall, Including Deaths*" - Medtech Insight, 19 Aug, 2022.)

On that same day, Royal Philips also announced long-time CEO Frans van Houten was leaving the company and being replaced by Roy Jakobs. (Also see "*Philips Announces CEO Succession In Midst Of Massive Recall*" - Medtech Insight, 16 Aug, 2022.)

Since April 2021, the FDA has received more than 90,000 MDRs, including 260 reports of death,

reportedly associated with the PE-PUR foam breakdown or suspected foam breakdown.

Responding to the increase in MDRs, Philips *said* that at the time of the June 2021 recall the company relied on a "limited data set and toxicological risk assessment and assumed a reasonable worst-case scenario" for the possible health risks.

> ***"Patients with affected products may learn about a recall long after it was issued, and potentially from an unreliable source." – ECRI***

After issuing public statements on the risks from the devices in April 2021 and the subsequent June recall, the company said it received a "steep increase" in complaints associated with possible foam degradation, which, the company claimed, led to the sharp rise in MDRs – more than 20,000 from April 2021 to April 2022.

In the following months through October 2022, Philips said it filed an additional 70,000 MDRs and noted "the vast majority (93%) of the approximately 90,000 MDRs filed since April 2021 are alleged technical malfunctions that do not involve serious injury."

Speaking to the drastic jump in MDRs, Ben Zwirs, Philips global press officer, told *Medtech Insight* that an MDR submission alone does not prove the device was the reason for the adverse outcome.

Failure to Communicate

Throughout the recall saga, Philips also faced criticism for its efforts – or lack thereof – in notifying customers about the recalls and issues with the devices in question.

In March, the FDA rebuked the company for how it communicated the recall, calling it "inadequate" and invoking its regulatory authority to order Philips to notify all health professionals and patients about the risk associated with the breakdown of the foam. (Also see "*FDA Orders Philips To Bolster Communications Around Recalled Breathing Machines, Calls Notification Efforts 'Inadequate'*" - Medtech Insight, 10 Mar, 2022.)

In August 2021, US senator Richard Blumenthal, D-CT, sent a scathing letter to Philips calling the problems with the breathing devices as "untenable" and "unacceptable" and berating the company for dragging its feet in notify customers about the issues.

"While Philips apparently first made patients aware of this problem, which may impact devices as far back as 2009....many patients did not learn about the issue from Philips at all, instead finding out through social media or family and friends," Blumenthal wrote.

And in a recent special report, "The Top 10 Health Technology Hazards for 2023," the Emergency Care Research Institute (ECRI), which ranks "gaps in recalls for at-home medical devices" as the No. 1 issue posing harm to patients, says device manufacturers seldom have direct communication with home care patients, and healthcare providers may not proactively contact patients about recalls.

"Patients with affected products may learn about a recall long after it was issued, and potentially from an unreliable source," the report says, citing the Philips recall as an example. ECRI's report not only points out the delay, but also the methodology. "Because of the language used in the recall notice, patients were confused about whether to continue to use the device and what actions they needed to take," ECRI says.

DOJ

The FDA inspections also resulted in the Department of Justice issuing a subpoena to Philips in July seeking information related to events leading up to the June recall. Philips announced the company was in negotiations with the DOJ on a consent decree to resolve the issues associated with the recall and the agency's observations highlighted in the 483.

Philips did not provide *Medtech Insight* with an update on the status of the consent decree.

Philips did, however, announce in July its progress in the repair and replacement of the devices affected by the June 2021, noting at that time it had produced 3 million replacement devices and repair kits with aims to increase capacity and complete "around 90% of the production and shipments to customers in 2022."

In December, the company also provide an update on Philips Respironics' test and research program following the initial June 2021 recall to address the risks associated with the foam breakdown in the breathing devices.

The program, according to Philips, was conducted with five independent, certified testing laboratories, and the results reviewed and assessed by third-party qualified experts, along with the company, and an external medical panel.

While Philips posted the complete test *results*, the company says they indicate that exposure to particulates from the downgraded foam is "unlikely" to cause appreciable harm to patients, that exposure to volatile organic compound emissions is "not anticipated" to result in long-term health consequences for patients, and prevalence of visible foam degradation in inspected

devices was “found to be low.”