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FDA Orders Philips To Bolster Communications Around Recalled Breathing Machines, Calls Notification Efforts 'Inadequate'

by Shawn M. Schmitt

The US FDA on 10 March sent a letter to Philips Respironics that orders the company to beef up its recall communications, among other directives. The agency is worried about what it perceives as the firm's lackluster notification activities around the June 2021 recall of millions of BiPAP, CPAP, and other mechanical ventilator devices.

Calling the company's efforts to notify customers about its recall of breathing machines "inadequate," the US Food and Drug Administration on 10 March sent a letter to *Philips Respironics* that orders the manufacturer to beef up its recall communications, among other directives.

Philips in June 2021 recalled millions of bi-level positive airway pressure (BiPAP), continuous positive airway pressure (CPAP), and other mechanical ventilator devices because there's a risk that users of the products could inhale degraded sound abatement foam. The FDA gave the recall a high-risk class I designation roughly a month later. (*See timeline below.*)

In a pointed six-page notification order, the FDA's Malvina Eydelman told Philips Respironics' head of quality for sleep and respiratory care, Tom Fallon, that the agency is worried about what it perceives as the company's lackluster notification activities around the recall.

"Throughout the process of the recall, FDA has maintained regular communication with Philips, and on multiple occasions has informed Philips that FDA was concerned that Philips' efforts to notify patients and consumers, health care providers and consignees regarding the recall have been insufficient, and that it is likely that a significant portion of patients and consumers using

the recalled products are unaware of the health risks presented by those products," Eydelman wrote.

Eydelman is director of the Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices (*OHT1*) in the FDA's Office of Product Evaluation and Quality. *OPEQ* resides within the agency's device center.

> ***"Patients and consumers are frustrated due to the slow progress of the recall." – Malvina Eydelman***

"Despite FDA's efforts to encourage Philips to voluntarily expand its communications strategy regarding the recall, and to provide clearer information to the public regarding the health risks posed by the recalled products, FDA has continued to receive communications from patients and consumers who are unaware of the recall," Eydelman's letter says.

The FDA says it used data from Philips to deduce that only half of users of the recalled devices registered with the company to get a replacement. Philips said last September that it would take a year to repair and replace the devices, and on 10 March the company said it has shipped more than 650,000 replacements to US customers.

Eydelman says it's "unclear whether the remaining patients and consumers have not registered because they are unaware of the need to register, or because they do not want or need a replacement device from Philips."

Philips' Recall Quagmire: A Timeline

- *14 June 2021*: Philips initiates recall of certain BiPAPs, CPAPs, and other ventilation devices
- *22 July 2021*: The FDA gives the recall a high-risk class I designation
- *24 August 2021*: Powerful US Sen. Richard

Blumenthal sends a letter to Philips demanding answers about the recall

- *1 September 2021*: Philips begins its repair-and-replace program, which the company says will take a full year to complete
- *9 November 2021*: After an FDA inspection of Philips Respironics' Murrysville, PA, plant, the firm is given a scathing inspection observation report by the agency's investigator that says the manufacturer failed to open formal investigations after receiving hundreds of thousands of complaints of particles and other contaminants when the recalled devices were used
- 22 November 2021: The FDA holds a call with Philips to discuss what the agency calls "ineffective recall audit checks" by the company
- *24 November 2021*: *Royal Philips* CEO Frans van Houten says complaints were wildly overcounted by the FDA's investigator during the 26 August-9 November inspection
- *23 December 2021*: Philips says a first round of toxins testing on its DreamStation breathing machine found that the level of volatile organic compounds put off by the recalled device probably won't cause long-term health effects for users
- 8 March 2022: The FDA warns Philips during a teleconference that it's considering issuing the company a 518(a)

FDA Tests Philips' Recall Communications

The letter says the FDA tested Philips' recall efforts by contacting a sample of 182 consignees to find out if they were aware of the recall.

The FDA sent emails to Philips in September and October 2021 that said 28 of the 182 consignees didn't know about the recall. The agency says Philips failed to respond to those two emails.

Notification Order

- 9 March 2022: In a second teleconference, Philips asks the FDA "whether an order under section 518(a) is necessary"
- 10 March 2022: The FDA sends a 518(a) Notification Order to Philips

Then, in November 2021, the FDA called Philips "to discuss the ineffective recall audit checks," Eydelman's letter says. "During that call, Philips stated that, as of November 22, 2021, 23 of the 28 consignees identified by FDA had received written notification of the recall, and presented a spreadsheet identifying the consignees for which Philips had received 'delivery confirmation.'"

But the agency says the spreadsheet was inadequate because it didn't include the dates that the 23 consignees received notification. The spreadsheet didn't "indicate whether the consignees identified by FDA had been sent notification before, or only after, they had been identified by FDA as being unaware of the recall," the letter says.

Eydelman points out that "delivery confirmation receipts generally do not confirm that a recall notification communication has been effective," and that a "delivery confirmation receipt, by itself, does not confirm that the targeted entity or individual received the notice and is aware of the instructions therein."

The letter goes on: "The fact that 23 consignees who purportedly received a recall notification reported to FDA that they were not aware of the recall, and that as of November 22, 2021, Philips could not confirm delivery of a notification to four of the 28 consignees, also raises concerns about the overall effectiveness of Philips' notification efforts."

518(a) Notification Order

The letter from the FDA and signed by Eydelman is a so-called 518(a) Notification Order.

Sec. 518(a) of the Food, Drug, and Cosmetic Act gives the agency the authority to place demands on a company when a product poses an "unreasonable risk of substantial harm to the public health" and "notification is necessary to eliminate the risk."

The letter says the FDA informed the manufacturer on 8 March that a 518(a) Notification Order could be on the horizon because of the "lack of effectiveness of Philips' communications with the public regarding the risks presented by the recalled products."

The next day, on 9 March, the FDA and Philips held another teleconference, during which time the company wanted to "discuss whether an order under section 518(a) is necessary" given that the firm "is willing to voluntarily undertake the actions outlined in the March 8, 2022, teleconference that FDA was considering ordering Philips to complete," Eydelman wrote.

Despite Philips' plea – and despite giving the FDA written feedback on 9 March – the agency moved ahead anyway with issuing its 10 March notification order.

Eydelman explains: "Given the extensive time that has passed without effective notification to the public, FDA has determined that the standard for issuing this order under section 518(a) of the FD&C Act is met and taking action pursuant to section 518(a) is warranted."

Under the order, Philips *must* take these steps within 45 days:

- Notify consignees and users of the recalled products, including patients, consumers and health care providers, regarding the recall and the health risks posed by the products;

- Maintain prominently displayed information on the risk of using ozone cleaners on the recalled products on the firm's recall webpage;

- Provide a link for health care providers and registrants to access all available testing results and third-party confirmed conclusions on results and findings from testing polyester-based polyurethane (PUR-PE) foam used in devices manufactured by Philips for volatile organic compounds (VOCs) and particulates, regardless of the device that the foam may have been tested in; and

- Continue using the company's DreamMapper app to track use of the recalled products, and send notifications to patients and others that use the app with information regarding the recall and the process for registering, and maintaining registration, for a replacement device.

Philips said on 10 March that roughly 2.6 million devices have been registered with the firm. The company further said it's already using its DreamMapper app to "send notifications to patients and consumers utilizing the application with information regarding the field action."

The FDA is giving the manufacturer two weeks to provide the agency with a plan for how the company will comply with the four orders listed above.

Philips Agrees To 'Prioritization Approach'

Eydelman says in her letter that Philips has agreed to a "prioritization approach" to get replacement devices into the hands of those who need them quickly.

"Patients and consumers are frustrated due to the slow progress of the recall, and have resorted to frequently contacting FDA for answers and requesting that the agency take action," the letter explains.

Recalls 101: New FDA Guidance Gives Basic Advice On Prepping For, Executing A Recall

By Shawn M. Schmitt

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The US FDA's final guidance is a basic how-to guide for manufacturers to prepare for and roll out a product recall action.

Read the full article here

To keep patients and others abreast of the latest news on the recall and how to get a replacement device, the FDA says it's *recommending* that Philips:

- Develop a strategy to increase patient and consumer registration of recalled products on the company's website and provide regular updates to the FDA on the number of new registrants;
- Improve communication with those who register a recalled product on Philips' website;
- Respond to those who contact the manufacturer through the recall assistance phone number provided on Philips' website within 24 hours of receipt;
- Provide detailed information regarding the process for obtaining a replacement device; and
- Provide language on the firm's website, and to patients and consumers after registration, that emphasizes the importance of keeping track of the registration number and confirmation number provided by Philips during the registration process, so those numbers can be used to determine the status of replacement devices.

In a 10 March release, FDA device center director Jeff Shuren said the agency "has heard the frustration" of those who have the recalled devices.

He added that the notification order "enables the FDA to mandate that Philips Respironics improve its communication about the recall and the serious risk posed by the foam used in the recalled products with patients and the public, and to ensure that individuals who rely on these essential devices are receiving the important information they need from the company."