



February 14, 2022

Acting Commissioner Janet Woodcock
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, Maryland 20993

Dear Acting Commissioner Woodcock,

We strongly urge the U.S. Food and Drug Administration's (FDA) immediate enforcement action against Philips Respironics following a devastating FDA investigation into the abrupt recall of over 15 million Philips breathing devices, which showed the company failed to investigate hundreds of thousands of complaints dating back to 2008.^[1] Further, the investigation also revealed that the silicone-based foam Philips has been providing to consumers to replace the recalled foam is potentially unsafe, possibly renewing the risk to consumers.^[2] FDA must now urgently use all of its enforcement authorities to protect current and future patients.

Our offices have received dozens of complaints from concerned constituents and patients, many of whom suffer from sleep apnea and have been unable to use their life-sustaining devices.

Connecticut constituents have expressed alarm that the FDA and Philips have failed to put in place a transparent plan to mitigate the now-clear carcinogenic risks associated with these devices, despite multiple warnings to consumers. They have also reported increases in secondary weight gain, blood pressure, anxiety, and insomnia as a result of their inability to use their C-PAP devices. Others are considering paying hundreds of dollars to replace their devices, while running into supply shortages of alternatives. Furthermore, despite making repeated calls to Phillips, these constituents report receiving inadequate answers from the company as to when they can expect a replacement device. Our offices have also heard from doctors who say that the failure to provide timely replacement of the recalled machines will continue to dramatically worsen comorbid conditions such as hypertension, obesity, diabetes, coronary artery disease, and congestive heart failure.

The brief history of Philips' actions and FDA investigations below illustrates the company's negligent, even reckless, behavior, seemingly ignorant of the impact their dangerous product has on their own customers:

- On April 26, 2021, Philips issued its first quarter earnings results update with information regarding "possible risks to users related to the sound abatement foam used in certain of Philips' sleep and respiratory care devices currently in use."^[3] Several months later, on

June 14, 2021, “Philips issued a recall notification for the United States for specific affected ventilation and sleep apnea devices.”^[4] Later in June, FDA classified this “device problem as a Class I recall, the most serious type of recall,”^[5] which is reserved for “a situation in which there is a reasonable probability that the use of, or exposure to, a volatile product will cause serious adverse health consequences or death.”^[6] The recall impacted devices manufactured between 2009 and 2021.^[7]

- Following the recall, FDA began an inspection of a Philips facility. Following this investigation, the FDA released an inspection close-out report outlining its observations. The observations, highlighted in a report by *Medtech Insight* which called them “damning”, found in part that Philips inadequately assessed risk and had inadequate procedures for corrective and preventive actions and design changes.^[8] Further, those at the top failed to ensure “that the quality policy is understood, implemented and maintained at all levels of the organization.”^[9]
- The summarized observations are bad enough, but the details are worse. The FDA investigation found that on multiple occasions between 2016 and 2021 Philips was made “aware of issues and concerns related to potential foam degradation and/or Volatile Organic Compound (VOC) emissions, with various Sleep and Respiratory Care devices” but that the risk analysis needed to assess the problem was either “inadequate or was not performed when appropriate or within an appropriate timeframe.”^[10]
- Further, the FDA investigation found that a “query of [Philips’] consumer complaints from January 1, 2008 to current, for keywords contaminants, particles, foam, debris, airway, particulate, airpath, and black, resulted in over 220,000 complaints.”^[11] Despite Philips being aware of widespread consumer concerns beginning in at least 2008, the FDA investigation found, “[n]o formal investigation, risk analysis, or [corrective and preventive action] were initiated, performed, or documented” for nearly a decade.^[12]
- During this time, email messages between Philips and its foam supplier showed that the company “was made aware of polyester polyurethane foam degradation issues around October 2015.”^[13] The supplier confirmed the issues in August 2016.^[14] Even though testing further confirmed “that the affected foam breaks down in high heat and high humidity environments,” the FDA investigation shows that Philips decided not to change the device design, and instead continued to use the dangerous foam in question.^[15]
- More alarming is that Philips’ management, “including management with executive responsibility,” knew and did nothing for over a year. Despite the fact that “[p]olyester polyurethane foam degradation issues concerning CPAPs, BiPAPs, and Trilogy Ventilators were discussed at all [redacted] management review meetings, since the 2019 [redacted], dated 01/31/2020,” no further corrective actions were taken until April 2021.^[16]
- The FDA has recommended that patients who have yet to receive replacement devices consult with their physicians about whether to continue using the devices. It seems highly inappropriate for the FDA and Philips to place the responsibility for this risk-benefit


analysis on the shoulders of prescribing physicians as they have done in this case. Doctors are not trained to assess the actual risks posed by the chemicals and particulates that can be released by these machines. Due to limited insurance coverage and supply shortages of alternatives, patients have limited options. Under these circumstances, it appears that the patients have the option to either continue to use the machine and risk various cancers and respiratory issues, or stop using the machine and risk the health consequences associated with breathing diminishment or cessation during sleep.

- Unfortunately, the challenges to patients continue. FDA approved a mitigation plan allowing Philips to replace the recalled foam with a new, silicone-based foam “based, in part, on testing the company provided to the FDA in June on the new foam.”^[17] However, during a recent inspection, “FDA obtained additional information, not previously available to the agency, regarding the silicone-based foam” showing that it also failed a safety test.^[18] While FDA is recommending patients with the repaired devices continue to use them based on an overall risk-benefit analysis, the uncertainty and potential risk to patients, as outlined above, continues.

FDA must take swift and aggressive enforcement action against Philips, including steps necessary to remedy this situation as quickly as possible, so that device users now and into the future can trust that the life-saving and life-sustaining products they use are safe.

Sincerely,


RICHARD BLUMENTHAL
United States Senate


WILLIAM TONG
Attorney General
State of Connecticut