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October 10, 2023

Dr. Robert Califf, MD
Administrator
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, Maryland 20993

The Honorable Merrick Garland
Attorney General of the United States
U.S. Department of Justice
950 Pennsylvania Avenue NW
Washington, D.C. 20530

Dear Administrator Califf and Attorney General Garland,

I write to urge the U.S. Food and Drug Administration (FDA) and the U.S. Department of Justice (DOJ) to take immediate action against Philips Respironics ("Philips") after an explosive investigation by *ProPublica* and the *Pittsburgh Post-Gazette* revealed the company withheld thousands of complaints about their popular breathing machines from the FDA for years, likely in violation of federal law, and ignored testing and warning signs suggesting the devices were dangerous.[1] It was not until 2019 – nearly a decade after the first complaints were received – that Philips finally initiated a formal investigation.[2] It would be two years before Philips would alert FDA that it was recalling the 15 million impacted devices in 2021.[3]

FDA and DOJ must urgently use all of their authorities to protect current and future patients by investigating these allegations thoroughly, taking the strongest enforcement action possible, including criminal charges, if the allegations are substantiated.

On April 26, 2021, Philips issued its first quarter earnings update with information regarding "possible risks to users related to the sound abatement foam used in certain Philips' sleep and respiratory care devices currently in use."[4] Several months later, on June 14, 2021, Philips issued a recall notification in the United States for impacted devices.[5] Later in June, FDA classified this "device problem as a Class I recall, the most serious type of recall,"[6] which is reserved for "a

[1] Debbie Cenziper, et al, *Philips Kept Complaints About Dangerous Breathing Machines Secret While Company Profits Soared*, PROPUBLICA AND PITTSBURGH POST-GAZETTE (Sep. 27, 2023), https://www.propublica.org/article/philips-kept-warnings-about-dangerous-cpaps-secret-profits-soared.
[2] *Id.*
[3] *Id.*
[4] *Philips' First-Quarter Results 2021*, PHILIPS (Apr. 26, 2021), https://www.philips.com/a-w/about/news/archive/corpcomms/news/press/2021/philips-first-quarter-results-2021.html.
[5] *Medical Device Recall Notification: Philips Respironics Sleep and Respiratory Care devices*, PHILIPS (June 14, 2021), https://wwspecificw.usa.philips.com/healthcare/e/sleep/communications/src-update#section_3.
[6] *FDA Activities Related to Recalled Philips Ventilators, BiPAP Machines, and CPAP Machines*, U.S. FOOD AND DRUG ADMINISTRATION (Oct. 5, 2023), https://www.fda.gov/medical-devices/recalled-philips-ventilators-bipap-machines-and-cpap-

situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious adverse health consequences or death."[7] The recall – caused by the breakdown of unsafe foam used to make the devices quieter – impacted devices manufactured between 2009 and 2021[8] and resulted in serious complications such as vomiting, headaches, respiratory infections and cancers of the lungs, throat, and esophagus.[9]

Following the recall, FDA began an inspection of a Philips facility and released an inspection close-out report outlining its observations. The observations, highlighted in a report by *Medtech Insight*, found in part that Philips inadequately assessed risks and had insufficient procedures for corrective and preventive actions and design changes.[10] Further, those at the top failed to ensure "that the quality policy is understood, implemented and maintained at all levels of the organization".[11] The investigation also reviewed a "query of [Philips'] consumer complaints from 01/01/2008 to current, for keywords contaminants, particles, foam, debris, airway, particulate, airpath, and black,…[which uncovered]…over 220,000 complaints."[12] Despite Philips' awareness of widespread consumer concerns, the FDA investigation found, "[n]o formal investigation, risk analysis, or [corrective and preventive actions] were initiated, performed, or documented" for nearly a decade.[13]

The investigation and subsequent reporting found that on multiple occasions between 2015 and 2021 Philips was "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 the risk analysis needed to assess the problem was either "inadequate or was not performed when appropriate or within an appropriate timeframe."[14]

During this time, email messages between Philips and its foam supplier further show that the company "was made aware of polyester polyurethane foam degradation issues in/around October 2015."[15] The supplier confirmed the issues in August 2016.[16] No corrective action plan was taken by Philips.[17] Additional testing done by 2018 further confirmed "that the affected foam breaks down in high heat and high humidity environments."[18] No formal investigation into the

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machines/fda-activities-related-recalled-philips-ventilators-bipap-machines-and-cpap-machines#:~:text=In%20July%202021%2C%20the%20FDA,adverse%20health%20consequences%20or%20death.

[7] *Recalls, Corrections and Removals (Devices)*, U.S. FOOD AND DRUG ADMINISTRATION (Sep. 9, 2020), https://www.fda.gov/medical-devices/postmarket-requirements-devices/recalls-corrections-and-removals-devices.

[8] *Philips Respironics Recalls Certain Continuous and Non-Continuous Ventilators, including CPAP and BiPAP, Due to Risk of Exposure to Debris and Chemicals*, U.S. FOOD AND DRUG ADMINISTRATION (July 22, 2021), https://www.fda.gov/medical-devices/medical-device-recalls/philips-respironics-recalls-certain-continuous-and-non-continuous-ventilators-including-cpap-and.

[9] PROPUBLICA, *supra* note 1.

[10] Shawn M. Schmitt, D*amning FDA-483: Philips Didn't Investigate 222,000 Complaints Of Possible Degraded Foam In Breathing Devic*es, MEDTECH INSIGHT (Nov. 15, 2021) https://medtech.pharmaintelligence.informa.com/MT144720/Damning-FDA483-Philips-Didnt-Investigate-222000-Complaints-Of-Possible-Degraded-Foam-In-Breathing-Devices.

[11] *Id*.

[12] *Id*.

[13] *Id*.

[14] Rodney D. Mell, *Form FDA-483 Report on Philips Respironics, Inc's. Murrayville, PA Facility*, U.S. FOOD AND DRUG ADMINISTRATION (Nov. 9, 2021), https://www.fda.gov/media/154099/download.

[15] *Id*.

[16] *Id*.

[17] *Id*.

[18] *Id*.

problem was launched until 2019 and it would be two more years before Philips would alert the FDA and public of its recall plans.[19]

This delay in action is made even more alarming by the fact that, in 2015, the company received complaints similar to those it had already received in the United States from a subsidiary in Japan. In that case, the subsidiary quickly moved to replace the foam in those breathing machines.[20] Of course, despite this information and action in Japan, Philips continued using the foam in the United States without warning patients or alerting the FDA until 2021.[21]

Further, when additional reports surfaced in Australia in 2018, a Philips engineer outlined the safety risk in an email to the foam suppliers explicitly stating that they "[…] flagged this message with high importance since [they] are addressing a potential safety concern."[22] Despite the increasingly clear understanding that this foam posed a serious safety risk, Philips still took no action to alert consumers or immediately seek out different foam in their devices.

These persistent problems show that for over a decade, safety policies and procedures in place at Philips were inadequate, complaints were not timely acted on or fully disclosed, and alarming test results were ignored. Even after a formal investigation was finally initiated in 2019, no substantive action was taken until the dangerously defective breathing devices were subject to a mass recall in the middle of 2021.

As a result, we may not know the full impact of Philips' negligence for years to come. That is why it is imperative for FDA and DOJ to take swift and aggressive investigatory and enforcement action against Philips to deter future wrongdoing and hold the company accountable for past violations.

Sincerely,

RICHARD BLUMENTHAL
United States Senate

[19] PROPUBLICA, *supra* note 1.
[20] *Id.*
[21] *Id.*
[22] *Id.*