OFFICE OF THE ATTORNEY GENERAL
CONNECTICUT

WILLIAM TONG
ATTORNEY GENERAL

August 3, 2021

By U.S. Mail

Rodney D. Mell
Head of Quality and Regulatory
Philips Respironics – Sleep and Respiratory Care
Philips Medical Systems International BV
1740 Golden Mile Highway
Monroeville, PA 15146

Re: *Medical Device Recall of Philips Respironics CPAP and Bi-Level Pap Devices*

Dear Mr. Mell:

My Office is receiving a growing number of complaints from patients and medical providers concerning a voluntary recall by Philips Respironics of certain ventilator devices (the "Defective Devices") that have a defect which your company and the Food and Drug Administration have determined is potentially life-threatening.

The voluntary recall identifies two issues with the Defective Devices related to polyester-based polyurethane ("PE-PUR") sound abatement foam. The issues are particulate release from degrading PE-PUR foam into the device's air pathway and off-gassing of chemicals from degrading foam that are toxic and potentially carcinogenic. On its face, the recall statement makes it clear that the risks related to continued use of any of the identified ventilators presents a serious and unacceptable risk to the patient.

Philips Respironics sent notification to patients and providers about these issues and encouraged patients to register their device on a recall website. It also provided a toll-free phone number and a website address for further information about the recall. Unfortunately, the website does not describe the claim process or, most importantly, the time frame necessary for repair or replacement of the Defective Devices. Patients have also reported to my Office that the dedicated phone number does not afford them the ability to speak directly with a person knowledgeable about the recall and that requests for return phone calls are not fulfilled.

Patients are justifiably alarmed that the defect and lack of an immediate replacement have thwarted their use of a life-sustaining device. It is with this concern in mind that I request answers to the following questions:

165 Capitol Avenue
Hartford, Connecticut 06106

1) Will all of the Defective Devices be replaced at no charge to patients by Philips Respironics?
2) What is the time frame for replacement of the Defective Devices?
3) Has Philips Respironics notified all durable medical equipment suppliers about the need to stop distributing the Defective devices?

Please provide your responses as soon as possible, but no later than ten (10) days from your receipt of this letter. Additionally, I urge you to improve the information provided on your website and the toll-free phone access identified in your recall notification.

Your responses and any communication with my Office should be directed to Assistant Attorney General Tom Ryan. He may be reached at (860) 808-5368. Thank you.

Very truly yours,

WILLIAM TONG