OFFICE OF THE ATTORNEY GENERAL
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ATTORNEY GENERAL

October 5, 2021

By Email and U.S. Mail

Janet Woodcock, MD
Commissioner
Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20993

Re: *Philips Respironics Recall*

Dear Commissioner Woodcock:

I am writing to request that the FDA take more aggressive regulatory action pertaining to the voluntary recall by Philips Respironics of certain Continuous Positive Airway Pressure ("CPAP"), Bilevel Positive Airway Pressure ("BiPAP") and ventilator devices, which contain a degrading foam that has been determined by the FDA to be potentially life threatening.

I wrote directly to Philips on August 5, 2021 about its voluntary recall, at a time when it was unclear what corrective measures Philips intended to take, whether Philips intended to replace the affected machines and, if so, how long that process would take. The response I received was less than reassuring. Philips responded that it would replace the devices, but the process will take as much as 12 months to complete. In the meantime, it has not offered any interim steps to be taken to protect individuals who need to use the machines while awaiting replacement under the recall.

It is abundantly clear to me that millions of people who rely on these devices are scared, upset and woefully lacking understanding of what to do. The corrective action plan approved by your agency, to be followed by Philips, has not been disclosed either by the FDA or by Philips. This lack of transparency leaves patients at risk. On the one hand, they do not want to expose themselves through continued use of the affected machines to the particulates and carcinogens released by the degrading foam. On the other hand, they require assistance in breathing and are unable in many cases to either locate or invest in alternative machines. Making matters worse, replacement machines are reportedly scarce in light of the heightened demand caused by the recall itself.

My office reached out via email to James Nick Walker Assistant Director of CDRH Recalls & Shortages at your agency on September 2, 2021 to open a discussion about issues relating to the recall. My office has received a promise from a government relations spokesperson that we will

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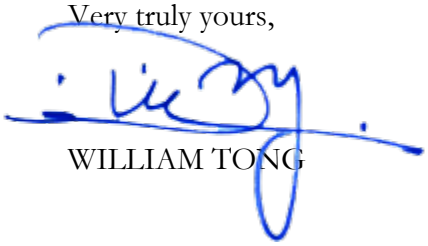
receive a response, but no response or substantive communication has occurred. We had hoped to provide feedback to the FDA about issues relating to patient notice, short term replacement strategies, and suggestions about overall transparency actions that would enhance patient confidence in the measures being taken on their behalf.

My office has suggested to Philips via its outside counsel that it consider the following:

- Reimbursing health plans that provide coverage for replacement machines before the end of the typical five-year coverage period required by many if not most plans.
- Examining whether filtration methods could be employed to reduce exposure risk prior to replacement.
- Sponsoring the issuance of loaner machines through DME providers prior to replacement.
- Reimbursing patients who are able to replace machines at their own expense before Philips is able to do so.
- Improving public awareness and patient notification through direct outreach to sleep centers and hospital systems where these devices are commonly used and recommended.
- Prioritizing those in need by ensuring that the most medically compromised patients get their replacements sooner.
- Considering certified methods of local repair of affected machines.
- Making progress toward the goal of replacing machines more transparent to the public by issuing biweekly reports containing, at minimum, the number of machine registrations and the number of replaced machines, segmented by state.

These are by no means an exhaustive list of suggestions. Nevertheless, it is abundantly clear that while Philips has acknowledged these suggestions it is truly up to the regulator, i.e., the FDA, to select strategies that will work to shorten this crisis, protect vulnerable patients in the interim and keep all affected citizens apprised of their rights and the progress of the corrective action plan. Please give this matter the urgent and focused attention it deserves.

Very truly yours,



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