



Nita M. Lowey
Congress of the United States
17th District, New York

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The Honorable Ned Sharpless
Acting Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Acting Commissioner Sharpless:

At least 193 individuals in 22 states, mostly teens and young adults, have been treated for vaping related lung illnesses in recent weeks. On Friday, health officials in Illinois announced that one of these patients had lost his life from what doctors believe are respiratory illnesses caused by vaping. This tragic news underscores the failure of the federal government to protect the public against the harms of vaping.

The U.S. Food and Drug Administration (FDA) is charged with protecting consumers. I believe that you and I share a mutual goal of protecting young people from the dangers of nicotine addiction. Yet, I continue to be frustrated by FDA's slow-walking of enforcement actions for tobacco products that violate federal law. Actions to date simply are not enough to combat this epidemic.

Earlier this month, FDA issued warning letters to four companies for illegally selling products without required marketing authorizations. Your own statement issued with the warning letters stated, "The marketing of illegal tobacco products is particularly concerning given the epidemic of youth vaping that we're facing, which we know has resulted in part from irresponsible practices of manufacturers, importers and retailers who have targeted kids in their marketing of these practices."

In the weeks since that announcement, a number of concerning tobacco products have been brought to my attention. Given the vast number of vaping products available online, FDA clearly must redouble its efforts to promptly remove illegal products from the market. If a teen can do a simple online search to find vaping products that could easily be hidden from parents and teachers, then FDA can similarly search out these products and bring enforcement actions.

One of these troubling products is the UWELL Amulet Watch Style Pod System, sold online through Element Vape and advertised on Facebook and YouTube. A screenshot of Element Vape's Facebook advertisement is enclosed. The manufacturer's YouTube video¹ advertises the UWELL Amulet Watch

¹ <https://www.youtube.com/watch?v=lGgp9ZtpdVc&feature=youtu.be>

Style Pod System as “Apple-esqe” and highlights that users can “easily take the pod, throw it in your pocket, and you have a tiny little device at your every need.” The video, published on July 2, 2019, repeatedly refers to the product as brand new, which without an FDA marketing authorization order would violate federal law. With students nationwide preparing to start a new school year, this product raises alarms as it could be easily disguised and used by teens throughout the school day. FDA should immediately remove the device from the market.

The FDA must do much more to address the public health emergency of e-cigarettes as a new generation is getting hooked on nicotine, which can lead to a lifetime of health challenges, and as vaping related illnesses are urgently threatening the health and safety of Americans of all ages. I urge you to bring aggressive enforcement actions against illegal products such as the UWELL Amulet Watch Style Pod System and to swiftly remove it from the market.

Sincerely,


Nita M. Lowey
Member of Congress

CC: Secretary of Health and Human Service Alex Azar


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