

September 17, 2019

Norman E. "Ned" Sharpless, M.D.
Acting Commissioner of the Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Director Sharpless:

As the nation's leading organization for the consumer safety of medical cannabis patients, we write to you with great concern about the recent news of illnesses and deaths associated with the vaping of e-cigarette products. In response to these recent events, we strongly urge you to develop federal oversight at the FDA that ensures individuals using vaporized products, particularly those who are state-legal medical cannabis patients, are not subjected to the harmful dangers that result from unregulated products.

The ongoing reports of illnesses and deaths associated with vaping are clearly a public health crisis. As of September 17, 2019, 380 confirmed cases of lung illness have been reported to the CDC from 33 states and one U.S. territory.¹ Additionally, six deaths have been attributed to alleged complications associated with vaping. Even though cases appear similar, it is not immediately clear whether these cases have a common cause, and to suggest otherwise is inappropriate. While a single cause for these illnesses has not been identified, vitamin E oil (tocopheryl-acetate) has been implicated in a number of cases, with this oil frequently appearing in tested samples of illicit cartridges that also contain THC (tetrahydrocannabinol). As many of our members utilize vaping as the mechanism to deliver their medicine, they share a fear that the FDA will outright ban vape cartridges and vaping or impose restrictions so onerous as to seriously disrupt their treatment regimen. Medical cannabis patients often prefer vaporization because dosing and administration is often easier with vaping than with other delivery methods.

While states continue to pass laws that legalize the use of vaporized and non-vaporized cannabis, we urge the FDA to use its regulatory authority to, at minimum, issue guidance that encourages consumers to only buy vaporization products in legal, licensed stores and not on the illicit market. We further suggest that the FDA develop 1) A recall and adverse event reporting procedure for cannabis and other vape cartridges consistent with other consumer protection laws; 2) Promulgate good manufacturing for vape cartridges processes similar to those adopted by the American Herbal Products Association for plant-based material; 3) Enforce OSHA guidance and

¹ https://www.cdc.gov/tobacco/basic_information/e-cigarettes/severe-lung-disease.html

other workplace safety regulations, including sanitization for vape cartridge manufacturers; and
4) Mandate that vape products undergo third-party laboratory testing and certification.

Americans for Safe Access has developed many education and training tools as well as an independent Patient Focused Certification (PFC) compliance program for businesses and would welcome the opportunity to discuss compliance with the FDA. We previously presented safety information at the FDA's meeting for Scientific Data and Information about Products Containing Cannabis or Cannabis-Derived Compounds and would be happy to share this information again.

We look forward to working together to ensure the safety of medical cannabis patients.

Respectfully Submitted,

Americans for Safe Access

CC: Secretary Alex Azar, Department of Health and Human Services; Robert Redfield, M.D.,
Director of the Centers for Disease Control