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January 3, 2018

The Honorable Scott Gottlieb, M.D. Commissioner, Food and Drug Administration 5630 Fishers Lane, Rm. 1061 Rockville, MD 20852

ATTN: Division of Dockets Management (HFA-305), Docket ID: FDA-2017-D-3001

Dear Commissioner Gottlieb,

Every individual should understand that smoking is hazardous to health, but nursing facilities face substantial additional safety risks from cigarette smoking. In addition to the serious personal health risk, cigarette smoking continues to pose a significant danger to the residents, guests and staff of senior living facilities. Fire safety is a paramount concern for senior living facilities, because older adults face the greatest relative risk of dying in a fire according to the National Fire Protection Association.¹

Recognizing that seniors may take longer to evacuate in an emergency, senior living communities are built to the highest life safety standards. Nevertheless, according to the National Fire Protection Administration, during 2009-2013, U.S. fire departments responded to an estimated average of 1,830 structure fires in residential board and care facilities or similar properties per year. These fires caused annual averages of six civilian deaths, 46 civilian injuries, and \$8.4 million in direct property damage.²

On May 24, 2017 FDA accepted a Modified Risk Tobacco Product Application for substantive scientific review of a "heat-not-burn" tobacco product In order to promote and protect public health, we encourage FDA to rigorously evaluate the scientific and health claims made in this application, and any subsequent applications for Modified Risk Tobacco Products. Since the product does not combust tobacco and is not lit on fire, it could result in significant reduction of any fire-related hazards for those seniors who would replace combustible cigarettes with the heat-not-burn product.

¹ https://www.usfa.fema.gov/prevention/outreach/older_adults.html

² http://www.nfpa.org/news-and-research/fire-statistics-and-reports/fire-statistics/fires-by-property-type/residential/structure-fires-in-residential-board-and-care-facilities

Clearly, the Rhode Island Health Care Association is unable to comment or offer clinical or technical comments on this application, and is unable to support or endorse this product, or any other product under FDA review. But we note that the FDA's new direction calls for leveraging new technology to provide alternatives for adults who want access to nicotine, but want to quit cigarettes.³

For those individuals who might choose to stop using conventional combustible cigarettes and use noncombustible forms of nicotine delivery instead, a noticeable reduction in fire-related hazards would be a significant achievement, particularly in long-term care facilities.

Sincerely,

Virginia M. Burke, President and CEO Rhode Island Health Care Association

³ https://www.fda.gov/NewsEvents/Speeches/ucm581314.htm