

Anti-Smoking Advocacy Group Recognizes Kelly Dunbar for Leading Its E-Cigarette, Tobacco Legal Fight

OCTOBER 1, 2018

Partner Kelly Dunbar was recognized by the American Cancer Society Cancer Action Network for leading the legal team that has sued the Food and Drug Administration and Department of Health and Human Services under the Administrative Procedure Act aimed at reversing the FDA's regulatory exemption of e-cigarettes as well as cigars from a congressionally required pre-market review process for many years.

At a September 26, 2018 President's Recognition Breakfast, Mr. Dunbar received ACS CAN's 2018 Judicial Advocacy Initiative Award "which recognizes attorneys who generously donate their services to the cancer fight," the society said in a news release. A team of WilmerHale lawyers, led by Mr. Dunbar and including Ari Holtzblatt, Lynn Eisenberg, Kevin Lamb, Beth Neitzel and Alex Hemmer, has provided the anti-smoking advocacy groups with pro bono legal services.

In early 2018, several organizations, including ACS CAN, the Campaign for Tobacco Free Kids, the American Heart Association, the American Academy of Pediatrics, Truth Initiative, and the American Lung Association, joined several individual physicians in suing the FDA, HHS, and top agency officials in federal court in Maryland.

The plaintiffs challenged the FDA's decision to considerably extend the deadlines for pre-market reviews of certain products, including e-cigarettes, such as the candy-flavored products that appeal to adolescents and teenagers, as well as cigars.

Under the Tobacco Control Act, the pre-market review process requires manufacturers to submit to the FDA data and information about products regulated by the act. Under the act, pre-market review is designed to ensure FDA public health review of new tobacco products and it is a statutory prerequisite to the marketing of tobacco products.

The plaintiffs claim the agency exceeded its statutory authority in creating a multi-year exemption for nearly 25,000 new tobacco products from the statutory pre-market review process. In addition, the plaintiffs argue that the agency's decision has contributed to a fast-moving public health crisis with respect to youth use of e-cigarettes and that the agency failed reasonably to account for this foreseeable effect of its policy.

WilmerHale is co-counsel in the lawsuit with lawyers from Democracy Forward Foundation and the Campaign for Tobacco Free Kids.