



# American Academy of Pediatrics v. FDA (4th Cir.)

Topics Covered: Tobacco and Electronic Nicotine Delivery Systems

## **Outcome: Favorable**

### **Issue**

The issue in this case is whether the Food and Drug Administration (FDA) is properly regulating e-cigarettes, cigars, and other nicotine tobacco products under the Family Smoking and Tobacco Control Act.

### **AMA Interest**

The AMA recognizes the use of e-cigarettes and vaping as an urgent public health epidemic and will actively work with the Food and Drug Administration and other relevant stakeholders to counteract the marketing and use of addictive e-cigarette and vaping devices.

### **Case Summary**

By regulation effective August 8, 2016, the FDA deemed e-cigarettes, cigars, and related tobacco products to be subject to FDA regulation (the “Deeming Regulation”). However, in August 2017, the FDA issued a “guidance,” the effect of which would be to defer implementation of the Deeming Regulation for at least six more years.

The American Academy of Pediatrics, several other healthcare organizations, and five individual physicians sued the FDA for a declaration that the guidance is unlawful and that the Deeming Regulation should be strictly enforced. Both sides moved for Summary judgment. The district court granted the plaintiffs’ motion for Summary judgment and ordered that new tobacco products (including e-cigarettes) must complete an application for review by the FDA within ten months.

The FDA appealed to the Fourth Circuit. In the interim, the FDA promulgated new guidance banning flavoring from electronic cigarette products. The Fourth Circuit then dismissed the appeal as moot.

### **AMA Involvement**

The AMA, along with several specialty medical societies, filed a trial level *amicus* brief to support the plaintiffs. The Litigation Center, along with the specialty medical societies, also filed an *amicus* brief in the Fourth Circuit to support the plaintiffs.

Fourth Circuit Court of Appeals Brief