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Session 8: The pros and cons of differing approaches to e-cigarette regulation: PHE and the FDA

While in the United States electronic nicotine-delivery systems (ENDS) are regulated under the Family Smoking Prevention and Tobacco Control Act, signed into law in 2009, in the United Kingdom these products are subject to the revised Tobacco Products Directive (TPD2), which entered into force in May 2014. The approaches to regulation of ENDS in the two countries could hardly be more different: While Public Health England (PHE), an executive agency of the department of health in the U.K., is driving a migration from smoking to vaping, the U.S. Food and Drug Administration (FDA), which oversees tobacco control in the U.S., uses a precautionary principle against e-cigarettes.

PHE, in line with the Royal College of Physicians' April 2016 report that concludes that e-cigarettes are likely to be beneficial to U.K. public health, sees sufficient evidence at this time to conclude that ENDS pose substantially less risk to health than smoking cigarettes and can be an effective aid to smoking cessation. The organization also sees an opportunity to improve smokers' health by explicitly encouraging and assisting ENDS use. The changes PHE seeks to effect include increased acceptability of ENDS to smokers, reduced misperceptions of the absolute and relative harmfulness of ENDS, and increasing prevalence of evidence-based perceptions of harmfulness. The organization aims at an increased displacement of cigarette smoking by e-cigarette use. In July 2016, PHE and other U.K. health organizations published a joint statement encouraging smokers to try vaping. In addition, a technical guidance document, produced in partnership with PHE, was released, which reflects a multi-organization commitment to empowering smoking cessation counselors to increase smokers' capabilities, opportunities and motivation to switch to e-cigarettes. The document also contains recommendations for practice, referring, for example, smokers willing to quit to e-cigarette dealers.

In August 2016, the FDA finalized its deeming regulations for ENDS. Based on the view that there is yet insufficient evidence for manufacturers and physicians to recommend e-cigarettes as a safe and effective aid to smoking cessation, the agency sees its duty in protecting citizens' health by implicitly and explicitly discouraging e-cigarette use. The long and costly application procedure required for premarket authorization for vaping products launched after the grandfather date of 2007 as well as the agency's slow processing of applications mean a long time to market for new product launches. Currently, around 3,500 applications are still with the FDA. The agency estimates that at present 1,100 e-cigarette products are on the U.S. market; it expects 99 percent of all devices not to pass the application procedure.

With the deeming regulations, experts claim the FDA has overreached its authority and stifled innovation in the field of potentially less harmful products. Several lawsuits have been filed by manufacturers and vaping advocacy groups against the legality of the FDA e-cigarette regulations.