E-Cigarette Use and Regulation: A Comparative Analysis between the United States, the UK, and China

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Svirsky, Howard, and Berman (2022) have enumerated a variety of U.S. FDA (Food and Drug Administration) roles, arguing that although the public possess a “right to information” about health risks, the FDA should be hesitant about endorsing e-cigarette use given scientific uncertainty. In the authors’ view, as a knowledge purveyor, the FDA has a responsibility to inform the public about the harms and benefits of e-cigarettes; however, its roles as information producer, advisor, and market agent require that FDA be cautious in the way it interprets and communicates available evidence. Compared with disseminating information regarding the health risks and benefits of e-cigarettes, the FDA can make its most important contribution to public health by reducing combustible tobacco use, making such products less appealing while simultaneously making e-cigarette products safer.

In this commentary, we aim to supplement the authors’ opinion by comparing the trends in e-cigarette use and governmental regulation in the U.S., the UK, and China. We selected these three typical countries because the U.S. is the world’s biggest vaping market (Knowledge Action Change 2020), China has the world’s largest smoking population (China Briefing 2022), and no country in the world other than the UK has announced support for medicinal licensing of e-cigarettes (Hopkinson et al. 2022).

Although the e-cigarette was first invented by H. A. Gilbert in 1963, the subsequent commercially viable design was patented in 2003 by Chinese pharmacist, Hon Lik, who brought it to the Chinese domestic market the next year. Subsequently, e-cigarettes entered the U.S. and European markets in 2006 and 2007, respectively (Gupta et al. 2020). Governments generally categorize e-cigarettes as tobacco, imitation tobacco, medicinal, pharmaceutical, or consumer products, poisons, or electronic nicotine delivery systems (ENDS), and how e-cigarettes are defined affects its policies and regulations. Currently, there is no global standard for e-cigarette regulation, which varies from one country or region to another (Bianco et al. 2021). Thus far, different approaches to regulating e-cigarettes have been adopted internationally. First, we analyze the regulation of e-cigarettes in the U.S., the UK, and China.

In mainland China, since e-cigarettes first emerged in 2004, their regulations have gone from relaxed to strict. Back then, with little international regulatory experience, the classification of e-cigarettes had not yet been determined. E-cigarette companies marketed their products as a safer alternative to tobacco and as a tool to facilitate quitting smoking. Since there is little evidence of health effects, government agencies started to pay attention to the regulation of e-cigarettes and gradually tightened it (Xu et al. 2016). In August 2018, the State Administration for Market Regulation (SAMR) and the State Tobacco Monopoly Administration (STMA) released a notice banning the sale of e-cigarettes to minors and online sales of e-cigarettes in November 2019 (Zhao et al. 2020). In November 2021, China’s State Council announced it had revised Regulations for the Implementation of the Tobacco Monopoly Law to include e-cigarettes and related products, making them subject to the same rules as tobacco products. In March 2022, the STMA released the

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final version of the Administrative Measures for E-Cigarettes, which made new regulations on their production, marketing, and sales in China. In April 2022, the SAMR approved a technical standard that bans the sale of e-cigarettes of any flavor other than tobacco. To summarize, the new administrative measures mark a stricter regulation of e-cigarettes in mainland China (China Briefing 2022).

In the U.S., the FDA has been regulating tobacco products dating from 2009. In its early stages, light regulation of e-cigarettes led to very limited control of the market and an epidemic of the use of these products by the youth (Gottlieb 2019), following which, its regulation became stricter. Since beginning to treat e-cigarettes as tobacco products in 2016, the FDA has had extensive powers to reduce their availability to young people and require manufacturers to obtain premarketing approval on safety grounds (McKee 2020). Since the availability of flavors is the main reason for use of e-cigarettes among teens, in January 2020, the FDA issued a policy prioritizing enforcement against the sale of certain flavored cartridge-based e-cigarettes other than tobacco or menthol flavors and, in April 2021, announced its intention to ban menthol cigarettes and flavored cigars (Ali et al. 2022).

In the UK, after Public Health England published its “95% less harmful” landmark review of evidence about e-cigarettes in 2015, the government’s stance on e-cigarettes has shifted from neutral to advocacy. On October 29, 2021, the UK Medicines and Healthcare products Regulatory Agency released guidance on how to license electronic cigarettes and other nicotine-containing products as medicines, meaning that England could be the first country to prescribe e-cigarettes licensed as a medical product to help reduce smoking rates (GOV.UK 2021).

Next, we analyze e-cigarette use in these three countries. In two nationally representative surveys in 2015–2016 and 2018–2019 involving e-cigarette use among adults in mainland China (Zhao et al. 2020), the estimated prevalence of e-cigarette use in the past 30 days rose from 1.3% in 2015–2016 to 1.6% in 2018–2019, and the prevalence of e-cigarette use among young adults aged 18–29 years rose from 2% in 2015–2016 to 2.7% in 2018–2019. Although the prevalence of e-cigarette use in China was still lower than in some developed countries (such as the U.S., the UK, and France), the estimated number of adults who were using e-cigarettes in 2018–2019 was 16.9 million according to the population size of China, with 16.2 million current smokers and more than a quarter of a million who never smoked.

Similar to China’s situation, studies in the U.S. revealed that e-cigarettes gained popularity among children and adolescents. The use of e-cigarettes among high school students rose from 1.5% in 2011 to 19.6% in 2020. Despite the recent dip in the prevalence of users, the rates continue to be alarmingly high (WHO 2021).

In the UK, although recently relatively stable, vaping prevalence among adults increased from 1.7% in 2012 to 7.1% in 2019 (Jerzyński et al. 2021). Between 2013 and 2020, the proportion of people who use nicotine replacement therapy declined and that of people who use vaping products increased among long-term former smokers. The proportion of long-term vapers increased over time. Between 2018 and 2020, the proportion of people who smoked e-cigarettes for more than 3 years was 23.7, 29.3, and 39.2%, respectively (McNeill et al. 2021).

In addition, the global e-cigarette market has grown significantly over the past (nearly) two decades. According to data from Statista (Statista 2017, 2022), e-cigarette sales worldwide increased from US $20 million in 2008 to US $20.7 billion in 2021, and are expected to grow to US $26.6 billion by 2025.

The findings of the comparative analysis of relevant data and policies of the three countries show that the trend of e-cigarette sales worldwide and the proportion of the overall trend of e-cigarette users (adults or adolescents) in the U.S., the UK, and China are rising upward, despite differences in regulation and control policies: the UK, for example, disseminates the harm-reduction function of e-cigarettes, while the U.S. and China do not. Furthermore, WHO’s latest report on the global tobacco epidemic also stated that “until independent research shows the real risk profile of ENDS, governments should be cautious” (WHO 2021). Therefore, given the current uncertainties and emerging new evidence, disseminating information about the health risks and benefits of e-cigarettes should not be a priority. According to Beauchamp and Childress (2019), in biomedical ethics, principles, rights, and obligations should be balanced in circumstances of the contingent conflict. We think that the principle of beneficence (providing benefits) and non-maleficence (avoiding harm) should be given more weight than respect for the right to know and autonomy where the evidence is not very clear. A rigorous regulatory framework should include oversight of product standards, effective restrictions on sales to the youth, appropriate taxation, and ongoing monitoring.
and surveillance to ensure that public health objectives are met (Laura 2022). The important function of the FDA and other relevant government departments should take into account the above framework for the scientific regulation of e-cigarettes.

To summarize, we agree with Svirsky, Howard, and Berman (2022) that informing the public is only one of many obligations and it should not interfere with the administration’s other necessary roles to provide meaningful benefits to public health. Much more effort is required by countries worldwide to reduce the harm caused by tobacco use and thereby, improve public health. The applicability of certain regulatory frameworks should be considered with the particular national and local context in mind. We hope our commentary will stimulate more discussion around e-cigarettes.

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