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Chapter

Regulatory and Policy-Making of E-Cigarettes Usage

Sharifa Ezat Wan Puteh, Norayuni Ismail and Nur Ismah Izzati Ismail

Abstract

Setting a suitable age limit of e-cigarette user should be established. This requirement considers the need for youth protection against e-cigarette misuse as such childproofing and age limits. Appropriate advertising without aiming for children to curb underage users. Advertisements could be done within sellers' or distributors' compound to keep vigilant control of appropriate or come of age users. Another reason for promoting e-cigarette use are to encourage smoking cessation and give information and incentives to smokers who are unable to stop to transition to less dangerous nicotine delivery methods. Addictive behaviors toward nicotine and complications from smoking e-cigarette should be warned and exposed to the public and users especially on newcomers as health warnings. Safety threshold of constituents should be complied and limit the strength of nicotine in the fluid could be done to reduce harm on users. An e-cigarette aerosol contains a variety of chemicals such as glycols, volatile organic compounds, and metals. The chemicals used have to be monitored for its safety threshold, where potential harm can be demoted. Harm causing effects of public vaping are considered for public vaping ban enforcement. While, many are opposed to the idea of vaping as medicinal treatment.

Keywords: age limit, advertising, health warning, safety threshold, public vaping, medicinal

1. Introduction

The tobacco pandemic is still very much alive and thriving, despite the fact that tobacco use is declining globally as shown statically. Initiatives to minimize the burden of diseases associated to tobacco use have been recognized and put into practise in order to end nicotine addiction. One of the well-recognized projects is the creation of nicotine replacement therapy (NRT), which temporarily replaces much of the nicotine from cigarettes to lessen incentive to use tobacco and nicotine withdrawal symptoms. This technique makes it easier to stop smoking cigarettes completely. Alternative nicotine delivery methods, such as gum, transdermal patches, nasal spray, inhalers, and sublingual tablets or lozenges, are increasingly included in programmes to aid people in quitting smoking [1]. Although long-term nicotine replacement therapy provides smokers an option, research has shown that it has no greater effect on harm reduction or stopping rates [2].

Soon after, it was reportedly intended that the invention of electronic cigarettes would make it possible to turn tobacco harm reduction from a theoretical idea into a practical alternative to smoking. A small percentage of smokers who support tobacco control view harm reduction as an even more crucial supplemental (rather than an alternative) method to conventional tobacco control [3]. According to the Centers for Disease Control and Prevention, "e-cigarettes" include electronic cigarettes, vapes, e-hookahs, vape pens, and other devices that electronically deliver nicotine [4]. While one study on vaping, which included seven countries—South Korea, Russia, Poland, Germany, the United Kingdom, and France—found that the number of vapers increased by up to 85% between 2013 and 2015, from 2.8 million to 5.1 million [5]. Adult vapers in Malaysia increased from 3.2 percent in 2016 to 4.9 percent in 2019 [6].

But there are a lot of concerns about how vaping will impact your health. It's important to realize that vape emissions include more than simply "harmless water vapour" [7]. Metals, glycols, and volatile organic compounds are among the substances in the aerosol that pure vapes emit. According to reports, the amount is normally considerably lower than that of a regular cigarette, but depending on the gadget used, it might still be greater. For instance, a device with an open system may be hotter, which might result in more e-liquid thermal breakdown [8]. Vapes can expose users to large amounts of ultrafine particles, which raise the risk of cardiovascular disease and non-cancerous lung illness similarly to traditional cigarette smoking [8]. Additionally, it could contribute to second-hand aerosol exposure, which is the passive inhalation of vape users' emissions [8], and indoor air pollution [7]. This rapid global uptake of electronic cigarette use, also known as vaping, has created a policy conundrum for public health, with opinions widely divided between those urging caution out of concern for safety and/or the potential for smoking to become more socially acceptable and those emphasizing the potential for harm reduction [8].

2. Childproofing and age limits

Different e-cigarette policies are developing over the world. E-cigarettes can now be regulated as either tobacco products, drugs, consumer goods, or none of the above. The Food and Drug Administration (FDA) in the U.S. has declared that it would extend its authority to regulate tobacco products to include e-cigarettes. To safeguard users and the general public, governments and the majority of public health professionals agree that e-cigarette regulation is necessary. However, how this should be accomplished is still a hotly debated topic. The majority of American smokers and vapers were found to support several of the proposed FDA regulations regarding safety and age, despite not being aware that the FDA does not regulate e-cigarettes. While Australian vapers' views on regulation indicated support for safeguarding those under the age of 18 but against the medical route of regulation, which limits access [9].

Setting a suitable age limit of e-cigarette user should be established. This requirement considers the need for youth protection against e-cigarette misuse. Everyone agreed that childproofing beverages was essential from a safety standpoint. E-liquid bottle opening should be out of the reach of little children. The majority of vapers also concurred that 16–18 age limits were reasonable. The risk of nicotine addiction and having to be the same age as smoking were the main arguments made [9]. Before the FDA's "deeming" rule asserting authority over e-cigarettes was published in May 2016, there was no federal regulation of e-cigarettes in the United States. The law, which

came into force in August 2016, requires warning labels on e-cigarettes beginning in August 2018 and created a countrywide minimum age for purchasing of 18 starting immediately [10]. While the United Kingdom and Northern Ireland under the Medicines and Healthcare products Regulatory Agency (MHRA) whom an authority accountable for carrying out most of the requirements of Part 6 of the Tobacco and Related Products Regulations 2016 (TRPR), as amended requiring child-resistant and tamper-evident packaging for nicotine-containing products as well [11].

Between 2011 and 2015, comparisons of teen cigarette and e-cigarette usage in South Korea and the U.S. were observed. Adolescent e-cigarette usage stayed consistent at low levels in South Korea, where they were severely controlled between 2011 and 2015, while it surged in the United States, where they were subject to limited municipal controls but no federal ones. Both nations saw a decline in current cigarette usage, but South Korea had a decline in the combined prevalence of e-cigarette and cigarette use, while the U.S. saw a rise [10]. There are also worries that e-cigarettes might serve as a gateway into smoking among adolescents. A gateway impact has been recorded in certain regions in the U.S. although the data for this is still equivocal [12]. E-cigarettes were immediately controlled in South Korea once they were introduced to the market in 2007. By 2008, South Korea considered e-cigarettes a tobacco product and prohibited sales to minors [10].

3. Appropriate advertising and marketing

Stimson (Gerry Stimson is a sociologist who has been promoting a harm reduction approach to public health since 1987, first related to drug use and later to alcohol and tobacco control) hypothesizes that massive e-cigarette usage may be caused by the product being a consumer-driven factor rather than having its roots in the traditional areas of public health impact, such as medicine [13]. Whatever the cause, regulatory frameworks have lagged behind consumer behavior. For instance, more than 2 million people in the United Kingdom have used e-cigarettes [14]. Between 2010 and 2012, use more than doubled [15]. Although knowledge and use vary between nations, this commercial industry is also global and expanding quickly [16]. Since its inception, the electronically commercialized e-cigarette sector has also gained momentum and grown significantly [17]. Consequently, online purchases allow for the avoidance of national regulatory regimes.

In the United States, the implementation of various e-cigarette policy measures, ranging from restrictive to liberal, has started in certain jurisdictions. Retail access limits, which include legislation requiring a retail license to sell e-cigarettes over the counter, are one of the measures put in place by the United States. Other individual governments that are considering vaping regulations; for instance, Washington State has suggested prohibiting the sale of e-cigarettes online, banning flavors other than menthol/tobacco, and taxing all vaping goods by 95% [9]. Nonetheless, countrywide law enforcement of e-cigarette in the U.S. came into force in 2016. By 2018, there were no limitations on tastes or advertising, and no taxes were implemented under the law [10, 18].

The European Union's Tobacco Products Directive (EU-TPD), which was adopted in 2014 and put into effect in 2016, governs policy in the European Union (EU). This uses a "twin-track system," where goods are generally governed by tobacco laws, but stronger liquids (those containing more than 20 mg) or those with medicinal claims may be governed by laws governing pharmaceuticals. As a result, virtually all advertising is prohibited, and Member States are allowed to determine how to enforce

measures like online and cross-border sales and public vaping. Meanwhile. the majority of American smokers and vapers shown reduced support for limits on consumer choice, such as banning advertising and flavoring of e-juice. Internationally, there is also suspicion over the motives of regulators (such as governments eager to boost tax revenues and business entities eager to increase profit) [9].

Appropriate advertising without aiming for children to curb underage users. Advertisements could be done within sellers' or distributors' compound to keep vigilant control of appropriate or come of age users. Another reason for promoting e-cigarette use are to encourage smoking cessation and give information and incentives to smokers who are unable to stop to transition to less dangerous nicotine delivery methods [19]. On the other hand, opinions on a ban on e-cigarette advertising varied significantly. Both for and against limiting e-cigarette ads, several analogies with gambling, alcohol, and tobacco advertisements were made. Few believed that it was appropriate to outlaw commercials on the grounds that the hazards were not yet understood, but the majority said that marketing to adults should be promoted for the sake of the public health [9].

The updated EU-TPD provided the foundation for e-cigarette regulation at the EU level. It contained requirements for the permitted nicotine levels in e-liquids as well as standards for packaging and labelling. In 2016, when the Tobacco Act (TA2016) was updated, Finland incorporated the EU-TPD rules into domestic law. A significant regulatory change for e-cigarettes was included in the renewal of the TA2016 in addition to the implementation of the new EU-TPD standards. In 2014, under the previous regulatory framework (TA2016), 2% of the general population of Finland currently used e-cigarettes. Other Nordic nations, such Denmark (3%) and Sweden (1%), have likewise seen around the same amount of e-cigarette use. It is important to note that although e-cigarettes were rigorously controlled, they were allowed to join the market with licensing. Vaping prohibitions and restrictions on point-of-sale displays were among the rules. Additionally, the selling of e-cigarettes and nicotine liquids over international borders as well as domestically, including online, was prohibited. For example, in Finland, by the end of 2019, a total of 8061 retail sale permits for tobacco products had been awarded, 362 for both tobacco products and nicotine liquids, and 59 for nicotine liquids solely, according to the national registry kept by the National Supervisory Authority for Welfare and Health (Valvira). Therefore, the majority of metropolitan towns across the country have at least one retail location with a nicotine liquids license. The EU-TPD left it up to the Member States to take into consideration in their domestic law any potential regulation of e-liquid flavors. Few nations have laws governing e-liquid flavors, but the TA2016 in Finland includes a restriction on flavors other than tobacco (including menthol) [20].

Although several nations, like Estonia, Hungary, and some U.S. counties, have enacted flavor bans or limitations, these policies are still uncommon internationally [20]. Most nations that ban or limit the sale of e-cigarettes also forbid or restrict sponsorship, marketing, or advertising. The U.K.'s current regulations state that e-cigarette advertisements must explicitly state that the product is not a tobacco product and may not cross-promote tobacco brands or tobacco goods. Additionally, advertisements cannot include actors who are or appear to be under 25 smoking e-cigarettes or otherwise having a key role in the product or service [21]. To add some more, sellers are compelled by MHRA to notify and publish all information about e-cigarettes and e-liquids before they may be sold [11]. In contrast, Southeast Asian nations are attractive targets for the e-cigarette sector due to their high smoking population and underdeveloped e-cigarette marketplaces. For instance, Southeast Asian markets are targets

for Juul Labs (is an American electronic cigarette company which once reached its highest peak at $38 billion in market value), partially controlled by Altria Group (formerly Philip Morris). In a 2019 interview, the president of Juul's Asia-Pacific South division referred to Asia as a "high-priority region". Southeast Asian nations have a wide range of e-cigarette policy responses, from outright bans to minimal or no controls. Additionally, the countries' approaches to regulation vary. It also been observed that advertisements showcasing young female models and point-of-sale promos heavily targeted young people in the area with fashionable vape pen designs and a broad range of e-liquid flavors. Given the low frequency of female smoking in Southeast Asia, the targeting of youth, particularly female youth, is at odds with the idea that e-cigarettes are meant to aid current smokers in quitting [12].

In Asia, some nations have legalized e-cigarettes, including the Philippines, South Korea, while others—including the United Arab Emirates, Thailand, and Singapore—have not, including Japan, which only regulates the sale of e-cigarettes that do not contain nicotine. Therefore, public health policy makers in nations where e-cigarettes are still regulated, like Singapore, are faced with a conundrum: legalize e-cigarette use with the goal of enticing smokers of traditional cigarettes to switch to the ostensibly lower risk product despite the potential risk of creating a new generation of e-cigarette users, or keep e-cigarette prohibition in place and work toward an endgame for traditional cigarettes [22]. But now, for Singapore, Singapore has modified its laws to prohibit the sale, possession for sale, import, and distribution of e-cigarettes. Selling, keeping anything for sale, importing, or distributing e-vaporizers and associated parts is illegal. Anyone found guilty might be sentenced to a fine of up to S$10,000 and up to six months in prison. The penalties for using and having a vape is up to S$2000 [23].

In 2008, South Korea has taken the step to prohibit advertisements on television, radio, and billboards. Not to mention, that nation also prohibited sales by Internet and mail, and levied excise taxes. A regulation stating that e-cigarette parts, such as the battery, atomizer, and cartridge, are dangerous to adolescents under the Adolescent Protection Act 14 was published by the Korean Ministry of Gender Equality and Family in November 2011. As a result, the sale, rental, and distribution of the dangerous instruments to adolescents was outlawed. Violators may face fines or imprisonment. Additionally, this rule mandates that sellers of such commodities designate their goods as "hazardous to adolescents" [11].

4. Health warnings and complications

Addictive behaviors toward nicotine should be warned and exposed to the public and users especially on newcomers. Advertising was the subject of two questions: whether commercials ought to be outlawed, and if e-cigarette goods ought to have health warnings. Most people believed that if they linked to addiction, health warnings should be included. Many vapers underlined that warnings ought to be supported by evidence, provided that the evidence is based on science rather than guesswork [9].

Another study revealed nicotine dependence affects cigarette smokers' pulmonary functioning condition [24]. According to one study, adolescent smokers who vape propylene glycol/glycerol aerosol at high wattage with or without nicotine suffer prolonged transcutaneous oxygen tension declines and airway epithelial damage [25]. Additionally, it was shown that vape users had significantly worse lung function characteristics than the control group, which had peripheral obstructive airway impairment [26].

A recent Polish research raised the possibility that vapes are extremely addictive since younger people who use vapes have greater levels of nicotine dependency than those who use traditional cigarettes. Additionally, dual users have been found to have a greater reliance on vapes than regular cigarettes [27]. The use of vapes can expose those who have never used tobacco to nicotine, perhaps predisposing them to nicotine dependency. This would therefore result in the usage of further tobacco products in the future [28].

In addition, particulate matter from second-hand aerosol (SHA), which comes from vapes, includes fine and ultrafine particles, 1,2-propanediol, volatile organic chemicals, certain harmful metals, and nicotine, is a new form of air pollution. It has been demonstrated that SHA contains more metals than second-hand smoke (SHS), such as nickel and chromium. When compared to background air levels, PM 1.0 and PM 2.5 concentrations in SHA are between 14 and 40 times and 6 to 86 times higher, respectively [8].

E-liquids with flavorings and related aerosols include a number of hazardous ingredients and have the potential to be cytotoxic. The flavors of e-cigarettes make them more appealing to young people and are a major factor in the beginning of e-cigarette usage. Young people favor sweet flavors over other flavors, and teenagers are more likely than adults to use flavor-enhanced e-cigarettes. However, flavors make products more appealing to adults as well, and they greatly contribute to prolonged e-cigarette usage. E-cigarettes with a tobacco flavor or without one may be used more frequently by older people and dual users than by younger persons and ex-smokers. The most popular flavor among adult current e-cigarette users in the U.S., Canada, the U.K., and Australia has been fruit flavor, however variety-seeking, flavor transitions, and multiple flavor usage may occur [29].

An exemplary action by South Korea where right after marketization of e-cigarette, the requirement of health warning labels made mandatory. On nicotine cartridges, written health warnings started to appear in 2015 nation widely. The South Korean's Fair Trade Commission issued an order in October 2012 requiring two e-cigarette producers to retract their fraudulent health claims in accordance with the Act on Fair Labeling and Advertising, which forbade e-cigarette manufacturers from making such claims about their products [10].

5. Safety threshold of constituents

Limit the strength of nicotine in the fluid could be done to reduce harm on users. An e-cigarette aerosol contains a variety of chemicals such as glycols, volatile organic compounds, and metals. The chemicals used have to be monitored for its safety threshold, where potential harm can be demoted. The idea that vaping should be confined to certain flavors in order to avoid tempting minors was contested by several vapers from the U.S. and the E.U. as well. A restriction of nicotine to 20 mg for sale in normal stores in accordance with the EU Tobacco Products Directive (EU-TPD) was another topic of discussion. Some vapers expressed agreement or ambivalence. Many vapers were worried that this would not completely satiate the nicotine needs of heavy smokers. Regulation to increase safety, both for batteries and chargers as well as the components of liquids, was, nevertheless, welcomed [9]. Meanwhile, the MHRA has restrict the use of certain compounds, such as colorings, caffeine, and taurine for U.K. and Northern Ireland [11].

In the United States in 2019, 68 e-cigarette users died and over 2800 were hospitalized with e-cigarette or vaping product use associated lung injury (EVALI), a condition that resembles acute pneumonia. These events were due to vaping e-liquids in combination with a fatal constituent namely marijuana oil, which is frequently obtained informally, has the potential to be deadly. Stringent control in constituents used to produce e-liquids needs to be monitored to avoid these kind of incidence [12].

6. Ban on public vaping

Harm causing effects of public vaping should be measured to consider public vaping ban enforcement. For example, in Farrimond's study that in terms of public usage, the participants of the study advocated against a blanket prohibition due to a perceived lack of scientific proof of damage. The participants did, however, accept the autonomy principle, which states that people and organizations have the authority to limit vaping. In keeping with current smoking regulations, some of the participants advised prohibiting vaping in locations like schools, hospitals, and around food [9]. It is also found that e-cigarettes also expose users to high levels of ultrafine particles that pose disease risks similar to exposure with conventional cigarettes [29]. It can also be a source of indoor air pollution [7] and second-hand aerosol exposure to emissions from e-cigarette users [8]. There is minimal proof that secondhand exposure to e-cigarette vapor or aerosol is harmful to their health. There is evidence to support the claim that using e-cigarettes raises the level of fine particulate matter dispersed in the air. However, the particulate matter's makeup is different from that of cigarette smoke, its concentrations are far lower than those brought on by cigarette smoke, and sometimes it can be difficult to tell them apart from airborne particles in non-smoking and non-vaping surroundings [21].

Furthermore, a limited number of nations outlaw the use of e-cigarettes entirely, while others just forbid its use in particular types of enclosed public venues or on public transit. Policies might differ even between nations. Similar to how different a nation's states have different legislation from each other [21]. However, in Farimond's study, total banning of vaping has vapers claimed that it would simply benefit tobacco businesses as regular cigarettes are currently not outlawed. They also pointed out the danger that switching from smoking to e-cigarettes posed. A few people also mentioned "stealth vaping," which refers to using a vape device in places where it is illegal or where the rules are hazy. Vaping was believed to make this simpler because there is no scent, which improves discretion. Several European nations have considered banning public vaping, and some study has looked into opinions regarding these proposals (for example, France and Wales). Approximately half of the Spanish people disapproved of vaping in public, whereas slightly over half approved of it in the workplace. They also noted that the least support for public usage was seen in health care facilities, hospitals, and schools. Support for prohibitions on using e-cigarettes inside closed spaces has also been connected to perceptions of high danger [9].

Both conventional and social media have been used to discuss the public health conundrum around e-cigarette legislation and regulation. They may be discovered online, in blogs, vape forums, and on websites like Twitter as well as in newspapers. A

"right to vape" is the focus of a revived social advocacy movement. Even vapers who have no interest in politics are probably aware of the political agenda. There might be regional variations in this political drive. Given that e-cigarette usage is rather substantial due to their ubiquitous availability, the policy agenda may be especially obvious in the United Kingdom. Public controversy has also been sparked by the adoption of Article 20 of the EU-TPD in 2016 and suggested restrictions on vaping in public. The views of vapers toward law and policy may be viewed not just as a question of politics but also as an issue of identity. It has been noted that smoking has become moralized as a social sin as opposed to a personal lifestyle decision. Similar to what was discovered in Australia, the majority of vapers opposed the licensing of medical devices, and some even rejected the idea of a medicalized conception of vaping. This resemblance to other contemporary works leads one to believe that the transnational nature of the 21st-century vaper's policy position. Through social media (such as forums), vapers communicate with one another across international borders to exchange information on goods and technology as well as, for some, to serve as political activists for the "right to vape" [9].

The situation of the modern vaper with regard to regulation is both political and psychological. Insistence on their "right to vape" at the cost of others was not common among vapers. The concept of autonomy—which states that groups and people have the freedom to decide for themselves whether to permit vaping—was used to handle the conflict between the "right to vape" and "the rights of others." Additionally, several participants recommended refraining from vaping in public in places where smoking norms or restrictions already exist, such as around children, food, or hospitals. This might be seen as a strategy to lessen social stigma, similar to that associated with smoking, by positioning oneself as a "pro-social," "considerate," and socially conscious vaper. Participants also accomplished this by highlighting the value of "protecting youngsters," since "damage to innocents" is a significant factor in the stigma associated with smoking. The vapers in this group were actively concerned about preventing nicotine addiction in the next generation and supported a number of regulations (childproofing, age restrictions on sale, advertising restrictions, health warnings, etc.) to achieve this. It is important to note that this is not just a rhetorical device [9].

7. Medicinal regulation

Whether e-cigarettes should be controlled "as medications (like nicotine gum/patches) rather than consumer items" was the question put to the vapers in Farrimond study. Most participants opposed such restriction. Because they did not view their vaping as a medicinal treatment, several participants opposed medical regulation. Others expressed worry about the lack of variety and product availability if supplied solely via medical practitioners. Some people had more favorable opinions of the advantages of medical regulation [9].

8. Comparative table of legislative actions between countries mentioned

Based on the subjects mentioned above, a comparative table of legislative actions taken between the countries is shown the **Table 1**.

Subject	Country involved	Actions taken	References
Childproofing and age limit	United States	Countrywide minimum age for purchasing of 18	[10]
	United Kingdoms & Northern Ireland	Child-resistant and tamper-evident packaging for nicotine-containing products	[11]
	South Korea	• Prohibited sales to minors • Prohibit advertisements on television, radio, and billboards • Prohibited sales by Internet and mail, and levied excise taxes	[10]
Appropriate advertising and marketing	United States	• Retail access limits, which include legislation requiring a retail license to sell e-cigarettes over the counter	[9, 10, 18]
	European Union	• Requirements for the permitted nicotine levels in e-liquids • Were allowed to join the market with licensing • Vaping prohibitions and restrictions on point-of-sale displays • Prohibit selling of e-cigarettes and nicotine liquids over international borders as well as domestically • Including virtual advertising prohibition	[9, 20]
	United Kingdoms & Northern Ireland	• Advertisements must explicitly state that product is not a tobacco product, no cross-promote tobacco brands or tobacco goods • Advertisements cannot include actors who are or appear to be under 25 • Sellers to notify and publish all information about e-cigarettes and e-liquids before sold	[11, 25]
	South Korea	Stating that e-cigarette parts are dangerous to adolescents	[11]
Health warnings and complications	United States	Warning labels on e-cigarettes	[10]
	European Union	Standards for packaging and labelling	[11]
	South Korea	• Health warning labels made mandatory • Forbade fraudulent health claims	[10]
Safety threshold of constituents	European Union	Restriction of nicotine to 20 mg for sale in normal stores	[11]
	United Kingdoms & Northern Ireland	Restrict the use of certain compounds, such as colorings, caffeine, and taurine	[11]
Ban on public vaping	Still debated in e-cigarettes legalized countries		
Medicinal regulation	Still debated in e-cigarettes legalized countries		

Table 1.
Comparative table of legislative actions taken between the countries.

9. Conclusions

Similar to smoking, reduced e-cigarette usage may be predicted by more stringent e-cigarette legislation. It is conceivable that stringent laws against smoking and using e-cigarettes, such as taxes, marketing restrictions, use limits, prohibitions on remote sales and point-of-sale transactions, and flavor limitations, will make e-cigarette use less common. Increased regulations on flavoring tobacco products can reduce teen cigarette and e-cigarette usage. E-cigarettes may have distinct smoking cessation effects when used as consumer and therapeutic goods, underscoring the importance of the regulatory framework in outcomes associated with nicotine and tobacco use. It is recommended that countries with lax rules, big populations, and high smoking rates control e-cigarettes before their usage becomes established in their cultures, especially among the younger generation.

Conflict of interest

The authors declare no conflict of interest.

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