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Lessons from Regulating E-Cigarettes: A Case of Coercive Paternalism, Nudging, or Behaviorally Informed Boosting

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Abstract

Background: After reports of alarming number of teen vaping and deaths associating with e-cigarettes, many countries around the world began imposing complete or partial ban on the sale of e-cigarettes. However, conflicting research claims the health risks of e-cigarettes are less than a tobacco-based cigarette (Traditional cigarettes). This has caused uncertainty in a uniform approach towards regulating the use and the sale of e-cigarettes.

Methods: Using behavioral economics findings, this article studies three policy making approaches to tackle the issue: Mandates, Nudges, and Boosts.

Results: When there is not a widespread social norm shaped by the use of e-cigarettes, coercive paternalism is the best way to eliminate the unwanted health risks associated with the product. In these instances, loss aversion is low, and people are more likely to comply with the new law. Moreover, allowing former smokers to use a prescription to purchase e-cigarettes from authorized drug stores can be helpful, indicating that e-cigarettes are safer alternatives to traditional cigarettes.

Conclusion: In protecting citizen's health in democratic states, early restrictive measures prevent the creation of new social norms for an unhealthy behavior, such as smoking e-cigarettes, and thus facilitate subsequent intervention by reducing the inertia associated with loss aversion.

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Introduction

In December 2018, the U.S. Surgeon General issued an advisory opinion declaring an e-cigarette use epidemic among youth (1). E-cigarettes had been in the market for almost a decade (2). Yet, in just one year, with a 78% increased use among high school students in the U.S, it caused a national health crisis (2). The advisory opinion singled out the most important player in the pandemic: Juul (3), a cartridge device introduced in 2017 (4). "The product became another word for vaping" (5). Juul offered a wide variety of flavored e-cigarettes, many of which are popular among teens.

In January 2020, the U.S. federal officials announced that in light of over 68 reported deaths associated with e-cigarettes, it would "forbid the sale of most flavored e-cigarette cartridges, but would exempt menthol and tobacco flavors, as well as flavored liquid nicotine sold in open tank systems at vape shops" (6). However, the guidelines created a loophole: disposable products were exempted from the ban (7). This exemption resulted in companies producing disposable flavored packages, like Puff Bar, targeting youth and largely rendering the FDA guideline ineffective (8). In July 2020, FDA asked companies to also remove fruity disposable cigarettes (9).

This article studied the U.S. approach to regulating e-cigarette to provide a guideline for policymakers across the world who continue to grapple with the issue. Studying the U.S. experience is especially important: the U.S. was the first country in the world to witness a youth epidemic of vaping. It was also the birthplace of one of the most popular brands of e-cigarettes–Juul (10). Unlike many countries that implemented stringent restrictions for regulating e-cigarettes, the U.S. moved slowly. And last but not least, the tobacco industry in the U.S. has a long active history across the world.

This article focuses on three policy and regulatory strategies informed by behavioral science as possible ways to address a public health crisis: mandates and bans, nudges, and boosting. It weighs each approach in light of regulating e-cigarettes to recommend the apt framework to address preventable deaths associated with it. This article argues for a paternalistic role of the democratic state in managing health crises that can ultimately save lives. Accordingly, this article first discussed the background of e-cigarettes, then briefly introduced the three behaviorally informed regulatory measures, and finally concludes with offering some thoughts on the bigger picture and lessons that states can learn from regulating e-cigarettes in managing health crises.

Background

While smoking has been around for a long time, vaping or electronic cigarettes are relatively new (11). In the U.S., it was not until 2007 that the early forms of e-cigarettes appeared in the market (2). According to the U.S. Centers for Disease Control and Prevention (CDC), "[e]-cigarettes produce an aerosol by heating a liquid that usually contains nicotine—the addictive drug in regular cigarettes, cigars, and other tobacco products—flavorings, and other chemicals that help to make the aerosol. Users inhale this aerosol into their lungs" (12). Initially marketed as a substitute for tobacco-based cigars, they soon turned out to be dangerous nicotine-based products.

E-cigarette or vaping products, unfortunately, became popular among teens (chart 1). According to CDC, 40% of e-cigarette smokers aged 18-24 had never even been regular cigarette smokers. With targeted advertisement, social media marketing, and over 7,700 flavors, the large number of teen e-cigarette smokers in the U.S. should not have come as a surprise (13). Many of the flavors were marketed by names such as "cotton candy, bubble gum, coffee, Belgian waffle", appealing to teens and young adults (14).

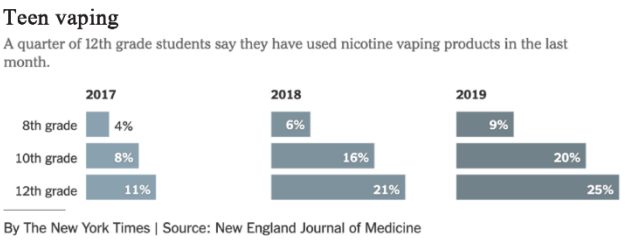

Chart 1. By the New York times (15)

One of the most popular companies that helped spark teen vaping was Juul (3). The company was formed by two Stanford graduates who initially thought of creating a product that could help tobacco smokers quit (5). With strong marketing strategies and sleek design, Juul quickly dominated the market. In just about a year, Juul sales raised from 200 million in 2017 to 1.3 billion in 2018 (3). FDA had not allowed the company to advertise its product as a product that would help smokers quit, but it had allowed them to remain in the market without fully knowing its health effects. The FDA's initial hope was to see a product that would

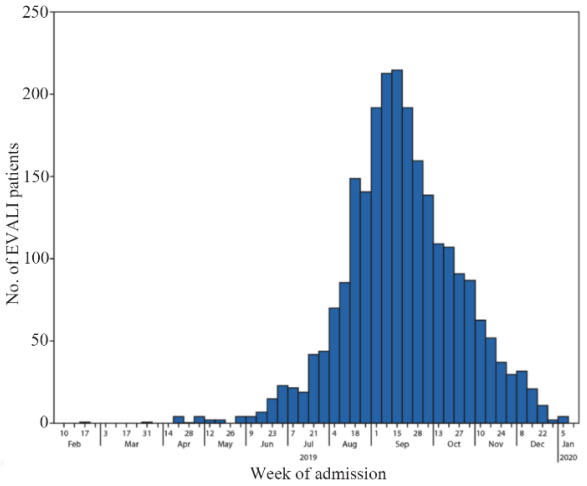

Figure 1. Number of patients (n=2.398) with e-cigarette, or vaping, product use-associated lung injury (EVALI) by week of hospital admission-United States, February 10, 2019-January 14, 2020 (16)

reduce the large number of annual deaths caused by tobacco and smoking (7).

With the spike of the use of Juul among teens, the FDA gave Juul and similar companies a 30-day ultimatum for a plan to keep the product away from teens (7). Juul initially changed the name of its flavors in an effort to make them less attractive to young users. However, around the same time, it was trying to sell part of the company's share to the most powerful tobacco company in the U.S., a move that seemed to be in contrast to their initial stipulated mission (3). Altrias finally invested 13 billion dollars in Juul and purchased a 35% stake of the company (17).

Summer of 2019 (Figure 1) marked the outbreak of lung related diseases and deaths associated with e-cigarette or vaping. CDC called the new disease EVALI (E-cigarette or Vaping Product Use-Associated Lung Injury) (18).

The U.S. federal investigators stated that testing shows "tetrahydrocannabinol (THC)-containing e-cigarette, or vaping products, particularly from informal sources like friends, family, or in-person or online dealers, are linked to most EVALI cases and play a major role in the outbreak" (19). According to CDC: "Vitamin E acetate is strongly linked to the EVALI outbreak. Vitamin E acetate has been found in product samples tested by FDA and state laboratories and in-patient lung fluid samples tested by CDC from geographically diverse states. Vitamin E acetate has not been found in the lung fluid of people that do not have EVALI. *Evidence is not sufficient to rule out the contribution of other chemicals of concern, including chemicals in either THC or non-THC products, in some of the reported EVALI cases (emphasis added)*" (16).

In response to the outbreak, many states took matters in their own hand. While the FDA is the main authority in regulating the sale of e-cigarettes on the national level, states also have certain authority. The Tobacco Control Act preserves, with certain limitations, the authority of states and local authorities "to enact, adopt, promulgate, and enforce any law, rule, regulation, or other measure with respect to tobacco products that is in addition to, or more stringent than, requirements established under this chapter, including a law, rule, regulation, or other measure relating to or prohibiting the sale, distribution, possession, exposure to, access to, advertising and promotion of, or use of tobacco products by individuals of any age, information reporting to the State, or measures relating to fire safety standards for tobacco products".

Although some state actions are restricted, states have the authority to regulate the "sale, distribution, possession, information reporting to the State, exposure to, access to, the advertising and promotion of, or use of, tobacco products by individuals of any age".

Consequently, San Francisco, the corporate home of Juul, became the first city to ban all forms of e-cigarettes (10). Massachusetts, too, initially imposed a temporally four month ban on the sale of e-cigarettes (20). However, it removed the ban and instead enforced additional restrictions on the sale of e-cigarettes (21). Several other states including Oregon, Rhode Island, Washington, and Montana (22), also enforced temporary bans to decide how to deal with the outbreak in their states.

As of February 2020, 2, 807 hospitalized EVALI cases or deaths have been reported to CDC, and 68 deaths have been confirmed (19). Among the 2,668 hospitalized EVALI cases or deaths reported to CDC, the median age of patients was 24 years and ranged from 13–85 years (19).

Method

There are many approaches in policymaking and regulating health products; three forms discussed in this article are: A) mandates, B) nudges, and C) boosts. The latter two stem from the recent reliance of regulators and public officials on psychology and behavioral science (23). The discussion of such alternatives to outright bans and mandates became popular among legal scholars largely by the work of Cass R. Sunstein and Richard H. Thaler (24, 25).

In their famous book, Nudge, (26), the authors argue for nudges that help actors make smart choices. They argue that having a choice architecture is inevitable (26). Therefore, the choice architecture should choose defaults that will nudge people into making wiser decisions. The choice architecture must have "a good understanding of how humans behave", and design such defaults with those behavioral insights in mind (26). The theory called "libertarian paternalism" (24) falls short of being paternalistic since the chooser is able to choose a different option, should she actively seek to do so (27). This way, the choice architecture, which is in many instances the government, can help promote the "health, wealth, and happiness" of citizens. This theory notes that people are not always rational decision makers. They make mistakes, but those mistakes can be mitigated by good choice architecture (24).

Another behaviorally informed approach in policy making is "boosting" as discussed by Ralph Herwig (27). The goal of "boosts" is "to improve people's competence to make their own choices" (27). What distinguishes boosts from nudges is the emphasis of boosts on personal agency by explicitly seeking to "foster existing decision-making competences and develop new ones". It emphasizes on the power of choice, and values educative efforts (27).

Moreover, boosts have the potential of creating lasting behaviors by emphasizing on literacy rather than passive nudging. Examples of boosts include improving risk literacy or financial literacy. Boosts are non-regulatory, and instead, hope to help policymakers implement behaviorally informed interventions (28).

The third approach in policy making is enforcing mandates. Mandates are a form of coercive paternalism by which the state believes there should be no preservation of individual choice. Coercive paternalism assumes that the individual decision-making is "not to be trusted ", and thus says that "somethings are not allowed". For example, the mandatory rule to fasten seatbelt is a form of paternalism. However, eliminating individual choices is not a popular approach as it may lead to abuse of power (29).

To arrive at a balancing scale, Sarah Conoly offers several guidelines that can help in deciding when paternalism is justified. When (29):

"1. The activity to be prevented on paternalistic grounds is really one that is opposed to our long-term ends.
2. Coercive measure actually has to be effective.
3. The benefits have to be greater than the costs.
4. The measure in question needs to be the most efficient way to prevent the activity".

Does smoking fit within these parameters? Conoly contends the answer is yes. What about e-cigarettes? The next section discusses the options in answering this question.

Results and Discussion

This section applies the three suggested methods discussed above to the case in question: e-cigarettes.

A) Boosts: There are many educational programs that aim to prevent the use of e-cigarette and vaping products among youth (30). In the U.S., some take place at federal levels (31), while others are grassroot organizations such as "Parents Against Vaping e-cigarettes (PAVe)". States also provide educational sources and online programs for local citizens (32). However, "[i]f public education were effective, we would have no new smokers, but we do" (32). Boosts can function as additional tools in the policy making toolbox; they are used to make sure those who do not smoke do not start smoking e-cigarettes. However, on their own, boosts are insufficient to reduce the health risk associated with e-cigarette smoking.

B) Nudges: Nudges can lead to positive change in behavior (33). They can thus also reduce the number of smokers, whether e-cigarette or tobacco-based products. For example, warnings that appear on smoking packages are one form of nudging (34). Although such nudges are effective in reducing the toll (35), high number of deaths associated with tobacco use suggest that nudges are not enough to combat such health crises. Similar to the discussion on boosting, nudges can also serve as an effective option in changing smoking behaviors when there are no other alternatives. But how about mandates? Could they serve as better alternatives for regulating e-cigarettes?

C) Mandates: At this point, 29 countries, such as Iran (36), Brazil (37), and India (38) have chosen to enforce mandates; they have placed an outright ban on all sales of e-cigarettes. There are also countries with partial mandates, such as the U.S. with its mandates on certain flavors. Individual U.S. states have also implemented various methods, from mandates to nudges (39).

Nevertheless, even partial mandates appear to be inadequate. Traditional cigarette smoking is the number one preventable death in the U.S., killing

480,000 each year (40). That is why some scholars like Sarah Conoly (29) advocates for a complete ban on the product (41). What about e-cigarettes? Would an absolute ban on the product, like those already implemented in many countries around the globe, be the best option? Applying Conoly's framework to e-cigarette is helpful in answering these questions:

1) Does a total ban on all forms of e-cigarettes promote long-term goals? With the outbreak of EVALI disease and the unknown health risks associated with e-cigarette (41), it may just be another dangerous product that puts people at health risks. Despite a decline in the number of EVALI patients, the full scope of the harms associated with e-cigarette products are not fully known. Moreover, given that e-cigarettes contain nicotine, they promote an undesirable habit that may also result in encouraging many non-smokers to also pick up tobacco smoking.

2) Is it effective? The answer is yes. As the chart presented at the outset indicates, after the outbreak and the measures taken at the state and federal level, there have been fewer reported EVLI cases (41). Therefore, a total ban may work even better than partial bans in eliminating the health risks associated with e-cigarettes.

3) and 4) Do the benefits outweigh the cost, and is an absolute ban the most effective way? There are many costs associated with e-cigarette smoking. The gateway effect of e-cigarettes, for one, is alarming. Dr. Ulysses Dorotheo, the executive director of the Southeast Asia Tobacco Control Alliance in Malaysia states: "We have enough problems with cigarettes and now we have 9-year-olds vaping because they think it's fun … More than half our population is under 30. The last thing we need is for young people to get hooked on vaping" (42).

In terms of financial costs on consumers, there are also outstanding lawsuits against e-cigarette companies such as Juul. The attorney generals of New York and California have claimed that Juul "deliberately marketed and sold vaping products to young people—and helped create a public health crisis" (43).

However, as of April 2020, CDC concluded that "[e]-cigarettes have the potential to benefit adult smokers who are not pregnant if used as a complete substitute for regular cigarettes and other smoked tobacco products" (15). This finding can make the product desirable for adult smokers to switch to e-cigarettes. This finding makes the outright ban on e-cigars hard to justify. Furthermore, when the society already allows the marketing of tobacco, a dangerous cancer-causing product, what could justify a total ban on a product that offers lower risks? While this objection is plausible, a complete ban on e-cigars except for prescription purchase should be the chosen policy for the reasons set forth below.

Although the health risks associated with e-cigarettes and their aerosol are less than traditional tobacco cigars, they are not trivial. A temporary ban on e-cigarettes can give companies the time and the incentive to improve their product's safety. If the companies cannot make e-cigarettes hazardless, they can make it less dangerous. Once the state has adequate information on the harms associated with the product, it can go forward with the permission for a limited sale, and only to traditional cigar smokers. Any confidence in the level of harm is relative confidence, similar to the licenses given to new medicines, which are not ultimately risk-free. However, institutions in charge of this mission reach an acceptable level of confidence in a given drug or product before allowing it to enter the market, unlike e-cigarettes, which initially were in the market, unchecked by authorities (2).

A ban on e-cigarettes that would also carve out an exception for purchase with prescription can limit the "gateway effect"–the possibility of new smokers and nicotine addicts (44, 45). While the required prescription will create an impediment, or "sludge," (46) for smokers who want to make the switch, the benefits of reducing the numbers of new smokers outweigh the costs associated with the sludge.

What justifies such a ban on e-cigarettes in contrast to continuing the permission of tobacco cigars purchases? There are strong norms and social practices already shaped around tobacco-based cigars that have created a sense of entitlement to being free to smoke. People are loss averse, meaning that "losses loom larger than gains" (47). This psychological finding is extremely helpful in designing effective policies and regulations. It explains why the costs of relaxed policies are high. Loss aversion creates inertia, meaning "a desire to stick with your current holdings" and a reluctancy to give up what you already have (48). Once the state allows a product to enter the market, it will be more difficult to create a ban on the product later and try to pull it out of the market. Because of loss aversion and the inertia associated with it, people are more likely to oppose the law. Therefore, such policy making will not be as effective.

The fact that there is a strong sense of entitlement to tobacco smoking does not mean that governments cannot take effective measures to change the norm and help people quit smoking. The purpose of its discussion here is to illustrate a contrast to norms on smoking e-cigarettes. Governments still have the chance to shape the norms around e-cigarettes; it is not yet too late. There is no strong sense of entitlement to e-cigarette smoking, at least not as strong as that of tobacco cigars. Therefore, instead of a total ban on e-cigarettes, banning the sale of e-cigarettes except for traditional smokers who can provide a prescription for the product is the most effective way to reduce the number of deaths associated with e-cigarette smoking. At the same time, the policy allows traditional tobacco smokers to make the switch to a product that, though still dangerous, is less harmful than traditional tobacco cigars.

The Bigger Picture

When facing new public health threats, coercive paternalism, within the constitutional boundaries, is the best way to eliminate or decrease the potential death cases (49). Whether the fatal harm comes slowly like developing cancer or lung disease after months of vaping, or fast, early interventions in forms of mandates will decrease preventable deaths (50).

Early interventions stop the creation of a new social norm surrounding a health-related issue such as vaping. This way, policymakers and state regulators can enact effective measures, should time reveal the health risks of a product are even worse than initially estimated. And should time show the issue in questions to be less harmful than expected, the state has not sacrificed any lives and can then regulate based on the new findings.

There is cost-benefit analysis at play here: Do the benefits outweigh the cost in stopping a company from running its business because the product may impose health risks to users? Is a short-term mandate worth its costs? In balancing the lives and health of citizens against potential economic downfalls, or possible loss of profit, time and again with different health crisis–from the deaths of e-cigarette pandemic to those of COVID-19– experience has shown a short-term mandate (such as a mandate to wear masks in the case of COVID-19), will serve the public interest more effectively than downplaying health risks that can become hard to compensate (51).

Moreover, agencies in charge of public health are among the less funded agencies (52). As such, precautionary steps are less costly. Public health messages are also difficult to get across. Therefore, sending the wrong initial signal about a public health issue will become costly and difficult to alter.

Scholars note that any alternation in public behavior regarding health needs to take place at a collective level (53). Regulators and policymakers need to be very careful in shaping social practice with their messages and regulations. Initial cautionary notes can decrease the risk associated with establishing the wrong social norm. For example, after the e-cigarette epidemic outbreak and news coverage in the U.S. largely attributed to Juul, the company failed to build a successful market outside the U.S (42). Even Indonesia–a country with relaxed smoking laws, no regulation concerning e-cigarettes, and one of the highest percentage of smokers in the world–was not a success story for Juul; the company decided to ultimately pull out its products (42). Thus, preventing the establishment of an unhealthy social norm reduces human cost (54).

Last but not least, this article does not advocate for a general paternalistic approach to regulations, but for a narrow approach when dealing with public health crises in democratic societies. As noted by scholars, common objections to paternalism are that such laws are against the autonomy of the individual or intend to work against autonomy by taking away the right to choose (55). But most importantly, as argued by Nicolas Cornell, paternalism "is suspect because it implies that the other party is not capable of making good judgments for herself". Public health concerns are issues that require expertise. Note that smoking is also an issue of public health (52). It not only puts the health of the user of e-cigarettes or vaping products at risk but also the health of other citizens since "bystanders can also breathe in this aerosol when the user exhales into the air".

Moreover, paternalistic approaches in regulating health crises advocated in this article must be preceded by a caveat that they are taking place in a democratic country in which individuals have had, either directly or indirectly, played a role in the selection of the experts. Under such circumstances, there is also the possibility of voting for new representatives, should there be any abuse of power.

Conclusion

Reviewing the process of regulating e-cigarette in

the U.S. can help other counties learn from the mistakes and think ahead. This article described and applied three policy approaches to regulating e-cigarettes: bans (paternalism), nudges (soft paternalism), and boosts. It argued that to reduce the number of preventable deaths associated with e-cigarettes, a ban on popular youth flavors is not adequate. Instead, a total ban with an exception is the right approach. The exception would allow traditional tobacco smokers to purchase e-cigarettes by providing a copy of their prescription. This is in line with the findings that "cigarettes have the potential to benefit adult smokers who are not pregnant if used as a complete substitute for regular cigarettes and other smoked tobacco products".

Early paternalistic interventions in democratic countries are the most effective policy and regulatory approaches in addressing public health crisis. Such early interventions slow down and can even stop creating new social norms around the use of harmful products. They reduce the inertia associated with loss aversion among consumers that can hinder subsequent regulatory measures. Such interventions are especially important in fluid circumstances that require a rapid change of laws and guidelines as policymakers learn more about the harms or benefits of a product.

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Conflict of Interest

Authors declare no conflict of interest.

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مجله ایرانی حقوق و اخلاق زیست پزشکی

مقالهٔ پژوهشی

ضرورت نظام دهی استفاده از سیگارهای الکترونیکی: مقایسه نقش قدرت پدرسالارانه، ترغیب نوجوانان و یا تقویت رفتار آگاهانه

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چکیده

مقدمه: پس از گزارش‌های مربوط به نرخ بالای استفاده از دستگاه ویپ و مرگ ناشی از سیگار الکترونیکی در بین نوجوانان، بسیاری از کشورها، منع کامل یا جزئی فروش سیگار الکترونیکی را در دستور کار خود قرار دادند. با این حال، تحقیقات متعدد و گاه متناقض ادعا می‌کنند که خطرات سلامتی ناشی از سیگارهای الکترونیکی کمتر از سیگارهای حاوی تنباکو (سیگارهای سنتی) است. این امر باعث ایجاد عدم اطمینان و شکل‌گیری رویکردی یکپارچه نسبت به تنظیم میزان استفاده و فروش سیگارهای الکترونیکی شده است.

روش‌ها: این مقاله با استفاده از یافته‌های اقتصاد رفتاری، سه روش سیاستگذاری برای حل این مسئله را بررسی می‌کند که عبارتند از تحکم، ترغیب، آگاهی و تعالی.

نتایج: در این مقاله براساس یافته‌های اقتصاد رفتاری، استدلالی ارائه شده که توضیح می‌دهد هنگامی که هنجار اجتماعی گسترده‌ای در استفاده از سیگار الکترونیکی شکل نگیرد، قدرت پدرسالارانه بهترین راه حل برای از بین بردن خطرات سلامتی ناخواسته مرتبط با استفاده از محصول است. در این موارد، میزان انزجار از ضرر اندک است و افراد به احتمال زیاد از قانون جدید پیروی می‌کنند. علاوه بر این، اجازه دادن به افراد سیگاری سابق در ارائه نسخه جهت خرید سیگار الکترونیکی از داروخانه‌های مجاز، راه حل مفیدی است که سیگارهای الکترونیکی را جایگزین‌های ایمن‌تری برای سیگارهای سنتی می‌پندارد.

نتیجه‌گیری: برای محافظت از سلامت شهروندان در جوامع دموکراتیک، اقدامات محدود کننده اولیه، از ایجاد هنجارهای جدید اجتماعی برای یک رفتار ناسالم مانند کشیدن سیگار الکترونیکی جلوگیری می‌کند و بدنبال کاهش اینرسی تمایل به انزجار از ضرر، مداخله بعدی را تسهیل می‌نماید.

واژه‌های کلیدی:
نظام‌دهی، سیگاری‌های الکترونیکی، ارتقاء سلامت شهروندان.

نحوهٔ استناد به مقاله:
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