2019

Inhalant Delivery System Laws and Rules Report to the 2019 Oregon Legislature

Review of Scientific Evidence and Regulatory Context

Oregon Health Authority

PUBLIC HEALTH DIVISION

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The content of this report draws from extensive literature reviews completed recently by the National Academy of Sciences and the U.S. Department of Health and Human Services. These reports are cited here and throughout this report as appropriate.

U.S. Department of Health and Human Services. *E-Cigarette Use Among Youth and Young Adults. A report of the Surgeon General*. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2016.

National Academy of Sciences. *Public Health Consequences of E-Cigarettes. A consensus study report of the National Academies of Sciences, Engineering, and Medicine*. Washington, D.C. National Academy of Sciences, Board on Population Health and Public Health Practice, Health and Medicine Division, 2018.

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Addendum to the Inhalant Delivery System Laws and Rules Report to the 2019 Oregon Legislature

Inhalant delivery systems (IDS), also called electronic cigarettes, e-cigarettes, or electronic nicotine delivery systems (ENDS), are devices that mimic the act of smoking conventional cigarettes. The 2015 Oregon State Legislature passed House Bill 2546, which defined IDS and incorporated these products into the state's tobacco regulatory structure. The Legislature also required the Oregon Health Authority to complete a report on the medical literature about IDS and existing IDS regulations for the 2019 Legislative Assembly.

To fulfill this requirement on the legislatively mandated timeline, the Oregon Public Health Division reviewed existing scientific literature and federal and state laws and regulations related to IDS between July 1 and September 28, 2018. In the months immediately following the Oregon Public Health Division's review, several national announcements expressed increased concern with e-cigarettes, especially among youth.

- The Centers for Disease Control and Prevention and the U.S. Food and Drug Administration released new data in November 2018 showing a rapid increase in youth e-cigarette use. The new data found that nationally, one in five high school youth used e-cigarettes in 2018. This is a 78% increase in use from 2017.(1) Oregon's most recent high school (11th grade) e-cigarette use data are from 2017. Updated data will be available in late 2019.
- In September 2018, the U.S. Food and Drug Administration called e-cigarette use among youth an "epidemic" that requires "historic action". In November 2018, in response to new data on youth e-cigarette use, the FDA announced that it would consider tighter regulations for flavored e-cigarettes.(2)
- In December 2018, the U.S. Surgeon General issued an advisory on e-cigarettes, declaring their use an "epidemic" among youth.(3) The Surgeon General urged parents; teachers; health professionals; and states, tribes and communities to act and protect youth from e-cigarettes.

The announcements from the FDA and the U.S. Surgeon General do not include broad regulatory action. Rather, they indicate a high level of concern with rapidly increasing rates of e-cigarette use among youth.

As this report details, Oregon has been a national leader in advancing policies that include IDS in youth sales restrictions and ban their use indoors. The Oregon Public Health Division will continue to monitor scientific and regulatory developments to inform public policy and decision making in the interest of the public's health.

Executive summary

Inhalant delivery systems (IDS), also called electronic cigarettes, e-cigarettes, or electronic nicotine delivery systems (ENDS), are devices that mimic the act of smoking conventional cigarettes. The 2015 Oregon State Legislature passed House Bill 2546, which defined IDS and incorporated these products into the state's tobacco regulatory structure.

House Bill 2546 required the Oregon Health Authority to report on the medical research on IDS and state and federal regulatory structures during the 2019 Legislative Assembly. According to Oregon Revised Statute (ORS) 431A.175, the objectives of this report are to:

- Review the medical research conducted on IDS and health impacts associated with IDS use;
- Review federal laws or regulations related to IDS, including labeling and packaging; and
- Review state laws and regulations related to IDS.

Oregon Public Health Division review activities

The Oregon Public Health Division completed the following activities between July 1 and September 28, 2018:

- Reviewed existing medical and public health scientific research on IDS and their associated short-term, long-term, and population-level health impacts. This included comprehensive research reviews from the National Academy of Sciences and the U.S. Surgeon General, as well as nearly 2,000 additional peer-reviewed research articles published after August 2017;
- Conducted a comparative regulatory review of federal and state laws and regulations related to IDS; and
- Developed recommendations to help the Oregon Legislature review the scientific evidence and associated laws and regulations.

Key findings

Science review

IDS use among youth and young adults is a serious public health concern.

- IDS are the most commonly used tobacco product among youth. There is

strong evidence to suggest that these products increase youth nicotine addiction and youth initiation of conventional tobacco products.

IDS have some short-term health harms and their long-term health effects are still unclear.

- Most IDS e-liquids contain nicotine. Nicotine is an addictive substance that increases heart rate and blood pressure, and is toxic at high doses.
- IDS contain or produce other chemicals that are identified as carcinogens or are otherwise harmful to health. There are few long-term studies on the devices' health impacts due to their recent development.

Combustible cigarettes are likely more harmful than IDS. However, current evidence regarding the effectiveness of IDS as smoking cessation aids is mixed.

- IDS users are likely exposed to fewer harmful substances than users of combustible cigarettes.
- There is not enough evidence to determine whether IDS help smokers quit. A growing body of research suggests that long-term IDS use may inhibit quit success.

Regulatory review

Federal regulation of IDS has developed gradually and focused on product standards and limiting youth access.

- The U.S. Food and Drug Administration issued its most significant IDS regulations in 2016. These regulations lay out rules regarding a federal minimum legal sales age of 18 years of age and some product standards.

Oregon laws and regulations pertaining to IDS are consistent with, and in some cases more protective than, federal laws and regulations.

- Oregon laws and regulations do more to prevent youth access to IDS than federal law. They do this through banning sales to youth under age 21 and limiting packaging that appeals to minors.

Conclusions and recommendations

- Substantial scientific evidence indicates that IDS cause adverse health effects to the user.
- One of the greatest IDS health concerns is increasing use by youth. Strong evidence links youth use, addiction and future use of combustible tobacco.
- Youth and young adults can be protected from the harms of IDS through actions such as comprehensive smoke and vape-free policies, price and tax policy, and further marketing and retail sale regulations. Oregon has taken several of these steps already and should consider more options as allowed by federal law.

Why examine inhalant delivery systems (IDS)?

What is this report's purpose?

The 2015 Oregon State Legislature passed House Bill 2546, which defined inhalant delivery systems (IDS) and incorporated these products into the state's tobacco regulatory structure. House Bill 2546 also required the Oregon Health Authority to report on the medical research on IDS, associated health impacts and a review of state and federal laws and regulations related to these devices. This report presents a science and regulatory review and makes recommendations to improve IDS regulation in Oregon.

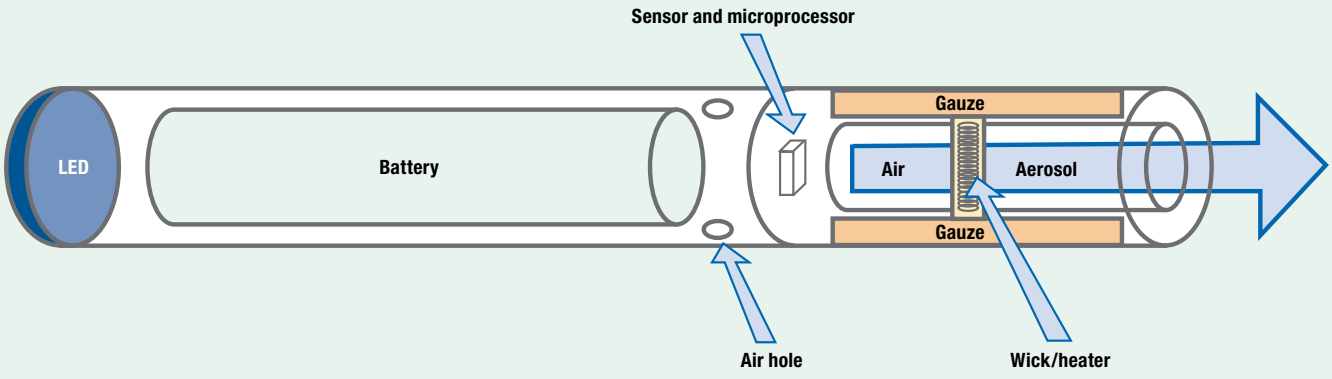
What are IDS?

IDS, also called electronic cigarettes or e-cigarettes, are devices that allow users to mimic the act of smoking conventional cigarettes. IDS are an evolution of the tobacco products that have been in the U.S. for many years. IDS users inhale an aerosol that generally contains flavor additives and other chemicals, dissolved in a liquid known as a "carrier solvent". They usually contain nicotine, the same addictive ingredient in conventional cigarettes. IDS can also be used for marijuana, tetrahydrocannabinol (THC) concentrates and other substances.

IDS are a diverse group of products that usually share several key parts:(5)

- Battery;
- Heating coil;

Figure 1: Typical e-cigarette configuration. This shows a wick/heater as aerosol generator, gauze saturated with e-liquid, a microprocessor (optional) to control operations and an LED (optional) to imitate a burning coal.(4)



- Atomizer that converts e-liquid to aerosol;
- Cartridge that holds e-liquid; and
- Mouthpiece.

Each component can affect health outcomes independently and interact with others, making research complicated. IDS users consume varying amounts of nicotine depending on the user and device. Also, some IDS users modify their devices after purchase to increase device power and nicotine delivery.

IDS emissions are an aerosol made up of gases, vapors, and aqueous particles. IDS aerosol contains lower levels of toxicants than combustible tobacco cigarette smoke. Experienced IDS users inhale more (volume and duration) than combustible cigarette users. When IDS users exhale, secondhand aerosol is released into air, exposing non-IDS users to particulate matter, airborne nicotine, and volatile organic compounds.

What is the history of IDS?

Research has strengthened the link between conventional cigarettes and adverse health effects over the past century. Manufacturers, scientists, and entrepreneurs have then promoted product changes to reduce the harmful elements in cigarette smoke. IDS are among these current innovations. The first IDS came to the U.S. market in the mid-2000s and by 2010 additional products emerged. Since that time, IDS sales have increased dramatically. E-cigarette sales grew by 14% between 2014–2015, although cigarette sales are still greater than IDS sales in outlets such as convenience stores, supermarkets, and drug stores.(6) IDS marketing on television — where cigarette ads have been banned since 1971 — could undermine decades of efforts to deglamorize smoking.(7) Spending on e-cigarette advertising jumped from $6.4 million in 2011 to about $115 million in 2014.(7) Nearly seven out of ten middle and high school students reported seeing e-cigarette ads in stores, online, or in other media in 2014.(9)

Why are IDS a public health concern?

IDS use among youth and young adults is a serious public health concern. IDS are heavily marketed and are now the most commonly used tobacco product among youth, surpassing conventional cigarettes.(9) The U.S. Preventive Services Task Force, an independent panel of health experts that makes evidence-based recommendations about preventive health care services, found that there is not enough evidence to support the use of IDS to quit smoking in adults, including pregnant women.(10)

There is a growing body of evidence that IDS are increasing youth initiation of nicotine and combustible tobacco use, setting the stage for potential dependence and health problems later in life.(5)

In Oregon, IDS use among 11th graders nearly tripled from 2013 to 2017, from 5% to 13%(**11**). Among 8th graders, 6% reported using IDS in 2017. 11th and 8th grade e-cigarette use were slightly lower in 2017 than in 2015 (17% and 9%), which was the first year there was a decline in e-cigarette use among Oregon youth. Oregon data typically follow national trends. National data also showed a leveling-off in 2017, followed by a 78% increase in high school e-cigarette use in 2018.(1)

Approximately 4 in 10 Oregon high school students who are current IDS users report that they never smoked conventional cigarettes and therefore are being introduced to nicotine through IDS.(**11**) A survey released by the Centers for Disease Control and Prevention (CDC) found that youth who had tried e-cigarettes were nearly twice as likely to say they would try a conventional cigarette.(**12**)

In Oregon, youth IDS use overlaps with use of conventional tobacco and flavored tobacco products. More than half of Oregon 8th and 11th graders who use tobacco use flavored tobacco. Roughly half of all youth who currently use conventional tobacco products started with IDS. Nearly 2 in 5 Oregon 11th grade IDS users also currently smoke conventional cigarettes.(**11**)

Current IDS use in Oregon

- Adults: 4% (2016)(**13**)
- Youth in 11th grade: 13% (2017)(**11**)
- Youth in 8th grade: 6% (2017)(**11**)

Youth transition from IDS to conventional tobacco products

- Roughly half of all youth who currently use conventional tobacco products started with IDS.(**11**)

Science review

Direct health effects of IDS use

Nicotine addiction

Nicotine is addictive. Among Oregon adults who smoke cigarettes, most say they want to quit and more than half report trying to quit during the past year.(**14**) The addictive properties of nicotine are why it takes tobacco users seven or eight quit attempts, on average, before they are able to quit for good.

There is strong evidence that IDS use results in symptoms of addiction, including cravings, short time-to-use after waking up, and trouble not using IDS in prohibited areas.(**5,15,16**) A recent study found that IDS with higher nicotine concentrations were associated with greater frequency of use.(**17**) More frequent users are at risk for stronger addiction and dual users report more severe symptoms than those who are exclusive IDS users. "Dual use" is generally defined as current 30-day use of IDS and another tobacco product; for example, individuals who use both combustible cigarettes and IDS. A study of nearly 40,000 people found that dual users smoked more cigarettes per day and reported more breathing difficulty compared to cigarette-only users.(**18**) Being exposed to e-cigarette aerosol has been shown to increase youth susceptibility to using e-cigarettes.(**19**)

There is also evidence that IDS characteristics such as e-liquid nicotine concentration, type of IDS and flavors influence the risk of addiction.(**5**) Studies suggest that IDS use has a lower risk of severe nicotine addiction than combustible tobacco. However, sweet or fruity IDS flavors, as well as menthol and menthol-mint flavors, have significantly higher potential for addiction since users perceive the flavors as enjoyable and may use the device more frequently.(**5**)

Health effects of nicotine and other IDS components

Nicotine is an addictive substance that increases heart rate and blood pressure. High doses of nicotine can cause acute toxicity, including seizures, gastrointestinal distress, difficulty breathing and altered heart rate.(**5**)

Conclusive evidence shows that nicotine exposure by IDS varies widely depending on device and e-liquid characteristics, as well as how the device is used. For example, studies done with early production, lower-power devices often show lower nicotine

exposures than studies done with new, higher-power devices. It is also clear that experienced adult IDS users can get nicotine doses comparable to those from conventional cigarettes.(5)

Other than nicotine, the levels of toxic compounds in IDS aerosol is lower than for combustible cigarettes. IDS emissions do contain numerous toxic chemicals, such as formaldehyde and acetone, that are known carcinogens and irritants and can damage cells and tissues in the body. At least 11 recent studies have found toxic metals in IDS aerosols, including lead, nickel, chromium, cadmium, aluminum, and tin; these metals can leach from device components in significant amounts.(20) Many flavorings and carrier solvents in e-liquids have been tested for safety when consumed as food, but little research has been done on the health effects when they are heated and inhaled. Establishing the safety of e-liquids and heated aerosols is complicated by the fact that there are over 15,400 different e-liquid flavors documented to date.(21)

Respiratory disease

Respiratory diseases include asthma, chronic obstructive pulmonary disease (COPD), and decreased lung function. Studies on the short-term effects of IDS use on respiratory disease do not show better respiratory health outcomes for smokers who switch to IDS.(2) IDS are emerging products, and there are no studies covering a time frame long enough to establish a causal link between IDS use and respiratory diseases.(5,22)

Studies of adolescents have generally found that IDS use increased the severity of asthma symptoms, chronic bronchitis, and respiratory symptoms, including cough and wheezing. Also, studies using young mice found that those exposed to IDS had pulmonary function abnormalities and a depressed immune response, particularly for lung and sinus infections.(22)

Cardiovascular disease

Unlike combustible tobacco, IDS do not emit potentially toxic products of combustion such as carbon monoxide. IDS emit ultrafine particles (smaller than PM2.5) and liquid particles that could affect cardiovascular health.(5) Some evidence links IDS use with cardiovascular disease risk factors. For example, heart rate increases immediately after IDS use, and the amount of the increase is tied to nicotine dose. Studies have found consistent short-term increases in diastolic blood pressure after using IDS. The effects are similar to combustible cigarettes and nicotine replacement products.(5) Evidence on the long-term effects of IDS use on blood pressure is limited. Some studies suggest that IDS use increases short-term cardiovascular risk factors like oxidative stress and arterial stiffness; however, other studies have found that IDS users with high blood pressure may have better blood pressure and blood pressure control than cigarette smokers with high blood pressure.(5)

A recent observational study using data from national surveys of more than 69,000 people found that daily e-cigarette use was associated with a nearly 80% greater risk of heart attacks compared to non-users.(23) More studies are needed to firmly establish the cardiovascular effects of IDS.(5) These should measure clinical cardiovascular outcomes (including coronary heart disease, heart attack, sudden cardiac death and stroke) or established subclinical outcomes such as coronary artery calcification.

Cancer

The cancer risk from IDS use is expected to be lower than that of combustible cigarettes. Given the relatively recent introduction of IDS, there is not enough long-term evidence to show whether there is an association between IDS use and cancer in humans. Some components of IDS aerosol, including formaldehyde, arsenic and acrolein, are known carcinogens or are known to damage DNA. A recent study reported higher concentrations of carcinogens in the urine of IDS users compared to non-users.(24) It is uncertain whether other substances found in IDS, such as flavors and carrier solvents, become carcinogenic when heated and aerosolized.(5)

Developmental and reproductive effects

There is little or no scientific evidence to determine the effects of IDS use on pregnancy outcomes, reproductive health and fetal development.(5) Research on combustible cigarettes has found that newborns of mothers who smoked during pregnancy have elevated levels of nicotine in blood samples. Nicotine has adverse effects on fetal development, including stillbirth, infant mortality, impaired fetal growth, preterm birth and low birth weight. Animal studies evaluating the effects of e-cigarettes with and without nicotine on pregnant rodents and their offspring have found that some of the newborn mice experienced developmental, cognitive(25) or metabolic(22) abnormalities.(5)

Injury and poisonings

The most commonly reported injuries from IDS are severe burns (often deep second- and third-degree burns)(26) from overheating or exploding batteries or resistors and injuries to eyes and face from exploding devices. Devices that are modified by users are more likely to malfunction.(5)

IDS also pose a risk of nicotine poisoning, especially for children.(5) Drinking or injecting e-liquids can be fatal. Children are at a greater risk than adults for unintentional poisoning from e-liquids. In the United States, children age five and under accounted for 51% of all e-cigarette-related poison center calls between September 2010 and February 2014. Additionally, between January 2012 and April 2015, poison center calls related to e-cigarette exposures increased nearly 1500%

nationally.(**5**) In Oregon, e-cigarette related poisonings more than doubled between 2014 and 2017, from 19 exposures in 2014 to 48 in 2017. Of the 48 exposures in 2017, 67% occurred in children age five and under.(**27**)

Oral health

Smoking and smokeless tobacco use are well-established as major risk factors for dental disease. Similar research on the oral health effects of IDS is lacking. While some studies have found that switching to IDS may improve dental disease in smokers, other studies suggest that both nicotine and non-nicotine containing aerosols cause inflammation and can damage oral tissue cells in non-smokers. Both nicotine and IDS flavors (including menthol) have been shown to independently harm periodontal cells. No long-term epidemiological studies have examined IDS use and dental disease.(**5**)

IDS and tobacco cessation

Smoking cessation among adults

The FDA has approved seven cessation medications for quitting tobacco entirely; these medications have been identified as effective through stringent clinical trials. FDA-approved cessation medications include five forms of nicotine replacement therapy (NRT) and two non-NRT medications (bupropion SR and varenicline).

IDS are not FDA-approved cessation devices. The National Academy of Sciences has systematically assessed studies on IDS effectiveness for smoking cessation.(**5**) Their review considered whether smokers quit entirely, relapsed or became dual users.

Current evidence regarding the effectiveness of IDS as smoking cessation aids is mixed.(**5**) Some studies show that IDS can support long-term cessation, and some suggest that cessation is more likely among those who use IDS more frequently. (**28,29,30,31**) Other studies have conflicting findings; for example, one prospective study found that smokers who also used IDS were 70–75% less likely to quit smoking than those who did not use IDS.(32) Limitations of cessation studies include small sample sizes, short-term follow-up, self-reported results in some studies, lack of statistically significant results, and a small number of trials.(**5**) In addition, studies define "cessation" differently. Some consider quitting combustible tobacco to mean cessation even if the individual continues to use IDS. Other studies consider cessation to be ceasing to use any nicotine product.

Frequent IDS use for smoking cessation could increase health risks due to additional exposure to aerosol components, compared to FDA-approved cessation aids; however, it is possible that some smokers unable or unwilling to quit smoking

using FDA-approved aids may have success using IDS. At this time, there is not sufficient evidence that IDS are an effective way to quit combustible cigarettes or end an individual's nicotine addiction entirely. The U.S. Public Health Service maintains the clinical practice guidelines for treating tobacco use and dependence, which includes the seven medications approved by the FDA for tobacco cessation.(33) These guidelines remain evidence-based best practice for tobacco cessation for tobacco users who would like to quit.(5)

Harm reduction

A harm reduction approach to tobacco use aims to decrease tobacco-related health risks among individuals and the whole population. Switching from combustible tobacco to other tobacco products, including IDS, with the intention to quit is not a proven method for smoking cessation or harm reduction.(5)

No long-term studies have identified health benefits from using IDS concurrently with combustible tobacco. There is also no available evidence that IDS use among cigarette smokers improves long-term health outcomes compared to those who are cigarette smokers only. Several studies have reported that most dual users return to using only combustible tobacco within one year.(5)

There may be some health benefits to completely switching to IDS from combustible tobacco. Several studies have found that exposure to carbon monoxide and several other toxins and carcinogens found in combustible tobacco decreased significantly when combustible tobacco users switched completely to IDS. Nicotine intake did not change, however. There is moderate evidence that secondhand exposure is lower with IDS aerosol compared with combustible tobacco smoke.(5)

Youth tobacco initiation and use

Most addiction to tobacco starts in adolescence, and nine of 10 adults who smoke report that they started smoking before turning 18.(34) Studies show that the younger someone is when they start smoking, the harder it is to quit.(34,35) In the last few decades, public health has made great strides in decreasing youth tobacco use. From 1996 to 2017, smoking among Oregon 11th-graders declined by 72% and among eighth-graders by more than 86%.(14)

The rise in other tobacco product use, such as IDS, little cigars and hookah, could potentially undo decades of public health progress in decreasing youth smoking. In Oregon, e-cigarette use among 11th graders nearly tripled from 2013 to 2017 from 5% to 13%.(14) Use of nicotine-containing products such as IDS is unsafe for youth, and the aerosol produced by IDS is not harmless.(5) Flavors appear to be a key component for youth to start using tobacco.(36) IDS marketing targets youth through flavors and advertising similarly to cigarette advertisements in the past.(5,21)

IDS and combustible tobacco cigarette smoking among youth and young adults

Substantial evidence indicates that IDS use among youth and young adults increases the likelihood of combustible cigarette experimentation. Across multiple studies, youth and young adults who had ever used an IDS were 2.5 times more likely to have also ever used combustible cigarettes compared to those who had never used an IDS. Among studies reviewed by the National Academy of Sciences, the probability of youth and young adult IDS users transitioning to cigarette smoking during the studies ranged from eight to 40%. This was much higher than the range of three to 11% among youth and young adults who had never used IDS.(5)

Evidence indicates that youth and young adult IDS use increases the frequency and intensity of subsequent cigarette smoking.(5,37,38,39,40,41,42) A recent study estimated that IDS use results in more harm than benefit on the population level because the number of adolescent and young adult e-cigarette users who will later start cigarette smoking is much greater than the number of adult smokers who will quit through e-cigarette use.(43)

Areas for future research

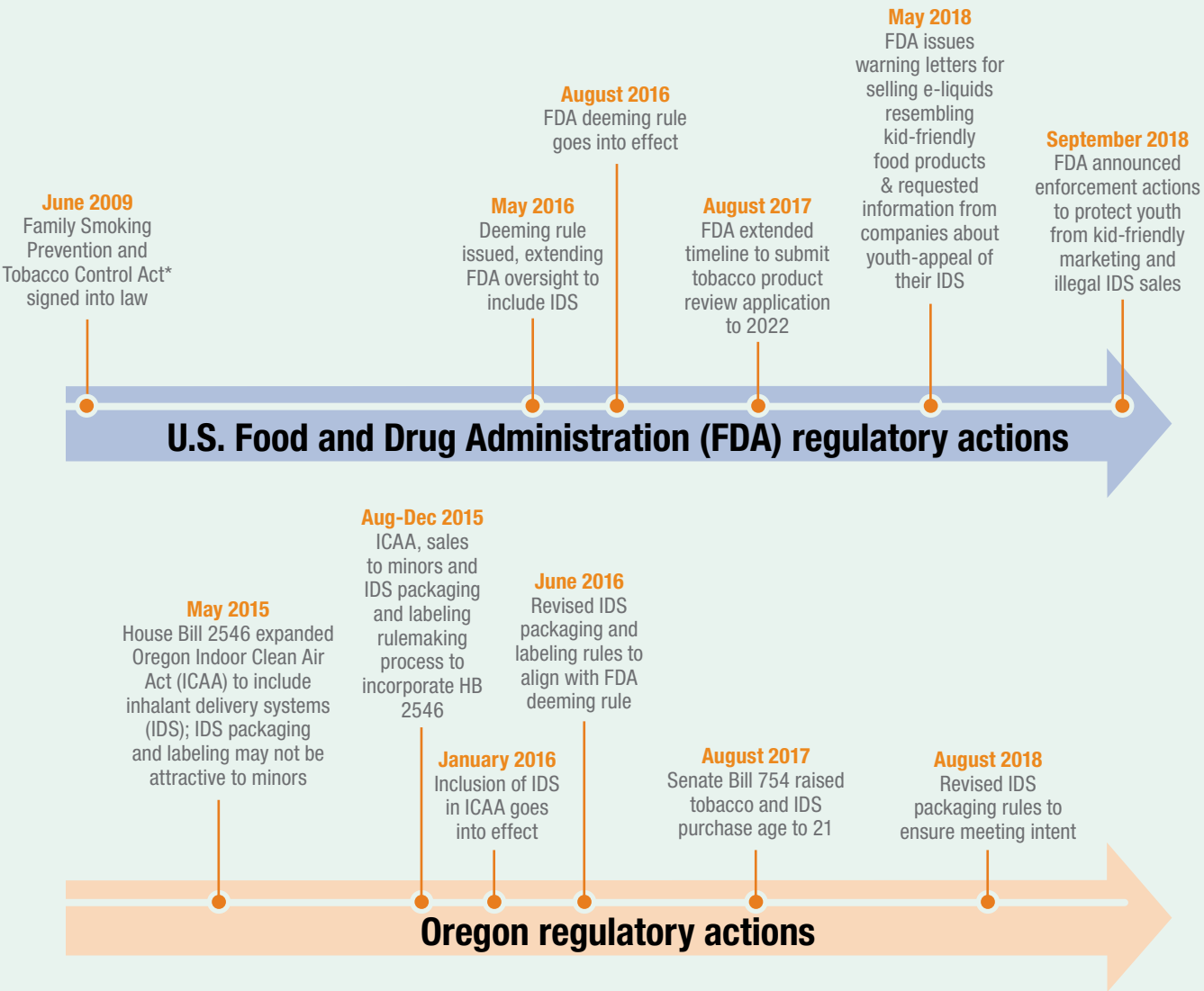
Enough evidence exists to justify public health regulations to mitigate the negative effects of IDS. However, IDS are still relatively new products and more research is needed on their health effects. A recent systematic review of the impacts of industry tactics on IDS research found that journal articles declaring a conflict of interest were more than twice as likely to have favorable conclusions towards IDS use for harm reduction and cessation.(44) As devices and use patterns continue to evolve, well-designed, independent studies will be important to understand both specific health effects and broader implications for public health.

Regulatory review

Federal and state laws and regulations related to IDS

Figure 2 illustrates a timeline of significant federal and state IDS regulatory actions. Each action is described in greater detail below.

Figure 2: Federal and state inhalant delivery system regulatory timeline



* Allows FDA to regulate manufacturing, marketing and distribution of cigarettes, cigarette tobacco, smokeless tobacco and roll-your-own tobacco; gives FDA authority to extend jurisdiction over "other tobacco products" by issuing a regulation deeming those products subject to statute.

2009: Family Smoking Prevention and Tobacco Control Act

On June 22, 2009, President Obama signed the Family Smoking Prevention and Tobacco Control Act (TCA) into law.(**45**) The law allowed the U.S. Food and Drug Administration (FDA) to regulate the manufacturing, marketing and sale of tobacco products to protect the public's health and reduce tobacco use by anyone under 18 years of age. Tobacco products include cigarettes, cigarette tobacco, smokeless tobacco and roll-your-own tobacco. The TCA also gave FDA the authority to extend its jurisdiction over other tobacco products by issuing a regulation deeming those products subject to the statute.

2015: Oregon House Bill 2546

On May 26, 2015, Oregon Governor Kate Brown signed House Bill 2546 into law.(**46**) House Bill 2546 created the IDS definition for electronic cigarettes in Oregon statute, which is inclusive of non-nicotine products. The bill also expanded the Oregon Indoor Clean Air Act to include IDS and amended existing laws related to youth tobacco product sales and use to equally apply to IDS. In addition, House Bill 2546 required IDS to be in child-resistant safety packaging, packaged in a manner that is not attractive to minors and labeled in accordance with rules adopted by the Oregon Health Authority (OHA).

Between August and December of 2015, OHA adopted rules incorporating IDS regulations into the Indoor Clean Air Act,(**47**) youth tobacco product sales laws(**48**) and packaging and labeling of IDS laws.(**49**)

2016: Expanded State Protections and the Federal Deeming Rule

On January 1, 2016, provisions that included IDS in Oregon's Indoor Clean Air Act went into effect, prohibiting IDS use in all workplaces and enclosed public places.

On May 10, 2016, FDA issued the final "Deeming Rule" (Deeming Tobacco Products to be subject to the Federal Food, Drug and Cosmetic Act, as Amended by the TCA) extending its regulatory oversight to electronic cigarettes (not inclusive of all non-nicotine products), cigars, hookah, pipe tobacco, nicotine gels and, dissolvable tobacco products.(**50**)

The Deeming Rule laid out several provisions with which manufacturers, retailers, importers and distributors must comply (Table 1). It also included a set of deadlines by which manufacturers, retailers, importers and distributors would need to meet specific rule provisions. The deadline dates for these provisions ranged from August 2016 to August 2019.

In addition to these regulations, FDA preempted states from regulating deemed tobacco product labeling and product standards.

In June 2016, OHA revised rule text for IDS labeling and product standards to align with federal labeling and product standard regulations, as House Bill 2546 specified that Oregon's IDS packaging and labeling regulations must be consistent with any regulation adopted by the FDA.

2017: Federal deadline extensions and Oregon tobacco 21

In August 2017, FDA extended the timeline for IDS manufacturers to submit tobacco product review applications for regulated products that were on the market as of August 8, 2016. The IDS timeline was extended from August 2017 to August 2022.(**51**)

On August 9, 2017, Governor Kate Brown signed Senate Bill 754 into law, raising the required minimum age for a person to legally buy tobacco products and IDS from 18 to 21.(**52**) Existing laws related to retail tobacco product sales were amended to reflect the increase in legal sales age.

2018: Federal warnings for products appealing to youth

In May 2018, FDA and the Federal Trade Commission issued warning letters to manufacturers, distributors and retailers for selling e-liquids labeled or advertised in a manner resembling kid-friendly products, such as cookies or candy. Section 5 of the Federal Trade Commission Act prohibits unfair or deceptive advertising.(**53**)

In May 2018, FDA issued letters to four IDS manufacturers requiring them to submit documents to help FDA better understand youth appeal of these products.(**54**)

In August 2018, OHA revised IDS rules related to packaging attractive to minors. The revised rules clarified what packaging is considered attractive to minors with the goal of preventing youth access to and use of IDS.

In September 2018, FDA announced an enforcement plan to protect youth from the dangers of tobacco products and IDS.(**55**) FDA issued over 1,300 warning letters and fines to retailers across the nation who sold IDS to people under 18 and asked several IDS manufacturers to submit a plan describing how they will reduce youth access and use of their products.

Table 1. Comparison of federal and state inhalant delivery system regulations

Regulatory area	Federal law or regulation[53]	Oregon law or regulation
Minimum sales age	18 years of age	21 years of age (ORS 167.755)
Minimum possession age	18 years of age	18 years of age (ORS 167.785)
Age verification	Under 27 years of age	No state regulation
Prohibition on vending machine sales	Allowed in adult-only facilities (18 years and older)	Allowed in facilities entirely off-limits to people under 21 years of age (ORS 167.780)
Free samples	Prohibited	No state regulation
Regulation of adulterated products	In place	No state regulation
False or misleading advertising	Prohibited	No state regulation
Premarket review of modified risk tobacco products	In place	No state regulation
Disclosure of health-related documents	Required	No state regulation
Registration of manufacturers	In place	No state regulation
Disclosure of product lists	Required	No state regulation
"Light," "mild," "low" descriptors	Prohibited	No state regulation
Disclosure of ingredients, substances, compounds and additives	Required	No state regulation
Warning labels on packages and advertisements	Required: "WARNING: This product contains nicotine. Nicotine is an addictive chemical."	Required warning consistent with federal regulations (ORS 431A.175)
Packaging attractive to minors	No law in place	Prohibits packaging attractive to minors (ORS 431A.175)
Child-resistant safety packaging	Protocol describing test to ensure child-resistant	Required child-resistant safety packaging consistent with federal regulations (ORS 431A.175)
Disclosure of harmful and potentially harmful constituents	Required	No state regulation
Marketing applications for products on the market as of August 8, 2016	Required	No state regulation
E-liquid regulation	Must contain or be derived from tobacco or nicotine	Applies to nicotine and to non-nicotine products (ORS 431A.175)
Self-service displays	No law in place	Employee must assist in accessing, unless off-limits to people under 21 years of age (ORS 167.765)

Same **State stronger** **Federal stronger**

State opportunities to regulate IDS

States retain the authority to regulate deemed tobacco products, including IDS, in the interest of protecting the public's health. Possible policies to decrease youth initiation of tobacco products and IDS include:

- Establishing an IDS tax;
- Establishing minimum package size requirements;
- Establishing minimum prices;
- Prohibiting flavors, including menthol;
- Limiting where tobacco and IDS can be sold, for example by prohibiting sales in pharmacies; and
- Prohibiting price promotions and coupons.

Conclusion

The effect of IDS on the population's health depends on both their direct health effects and their effects on youth initiation and adult cessation of conventional tobacco products. Early evidence points to a net negative public health impact due to youth initiation.

Scientific evidence is clear that IDS cause health harms to users. The nicotine and toxins in inhaled aerosol cause cumulative, long-term harms. IDS contain nicotine in amounts comparable to conventional tobacco products and likely pose a similar risk of addiction. E-liquid poisonings and device injuries are immediate IDS health harms. Early evidence suggests that IDS have generally lower health risk than conventional cigarettes. A full understanding of IDS health risks requires more scientific research, especially large, long-term studies.

Nationally and in Oregon, IDS are a serious public health concern due to the risk of nicotine addiction for youth and young adults. There is also substantial evidence that youth and young adults who use IDS are more likely to start using combustible tobacco products. Youth and young adults who start using IDS are at the greatest risk for harm given their potential for addiction and long-term use.

Recommendations

Youth and young adults can be protected from the harms of IDS through actions such as comprehensive smoke-free policies inclusive of aerosol, price and tax policies and further regulation of marketing and retail IDS sales. Oregon has taken several steps to reduce IDS public health harms through restrictions on sales to those under age 21 and packaging that appeals to youth. State policymakers should consider other options as supported by evidence and allowed by federal law.

End notes

1 Cullen KA, Ambrose BK, Gentzke AS, Apelberg BJ, Jamal A, King BA. Notes from the Field: Use of Electronic Cigarettes and Any Tobacco Product Among Middle and High School Students — United States, 2011–2018. MMWR Morb Mortal Wkly Rep 2018;67:1276–1277. DOI: http://dx.doi.org/10.15585/mmwr.mm6745a5

2 U.S. Food and Drug Administration. Statement from FDA Commissioner Scott Gottlieb, MD, on proposed new steps to protect youth by preventing access to flavored tobacco products and banning menthol in cigarettes. Available at: https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm625884.htm. Accessed January 23, 2019.

3 U.S. Surgeon General's Advisory on E-cigarette Use Among Youth. Available at: https://e-cigarettes.surgeongeneral.gov/documents/surgeon-generals-advisory-on-e-cigarette-use-among-youth-2018.pdf. Accessed January 22, 2019.

4 Brown CJ, Cheng JM Electronic cigarettes: product characterisation and design considerations. Tobacco Control 2014;23:ii4-ii10.

5 National Academy of Sciences. *Public Health Consequences of E-Cigarettes. A consensus study report of the National Academies of Sciences, Engineering, and Medicine.* Washington, D.C. National Academy of Sciences, Board on Population Health and Public Health Practice, Health and Medicine Division, 2018.

6 National and State Trends in Sales of Cigarettes and E-Cigarettes, U.S., 2011-2015 American Journal of Preventive Medicine.

7 Warner KE, Goldenhar LM. The cigarette advertising broadcast ban and magazine coverage of smoking and health. (1989) J Public Health Policy. 10(1):32-42.

8 Singh T, Marynak K, Arrazola RA, Cox S, Rolle IV, and BA King (2014) Vital Signs: Exposure to Electronic Cigarette Advertising Among Middle School and High School Students — United States, 2014. MMWR 64(52): 1403-1408.

9 U.S. Department of Health and Human Services. E-Cigarette Use Among Youth and Young Adults: A Report of the Surgeon General—Executive Summary. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2016. https://e-cigarettes.surgeongeneral.gov/documents/2016_SGR_Exec_Summ_508.pdf

10 "Final Recommendation Statement: Tobacco Smoking Cessation in Adults, Including Pregnant Women: Behavioral and Pharmacotherapy Interventions - US Preventive Services Task Force." Accessed October 24, 2018. https://www.uspreventiveservicestaskforce.org/Page/Document/RecommendationStatementFinal/tobacco-use-in-adults-and-pregnant-women-counseling-and-interventions1.

11 Oregon Healthy Teens (OHT) Survey, 2017. Oregon Health Authority. Unpublished data.

12 Bunnell RE, Agaku IT, Arrazola R, Apelberg BJ, Caraballo RS, Corey CG, Coleman B, Dube SR, King BA. "Intentions to smoke cigarettes among never-smoking U.S. middle and high school electronic cigarette users." National Youth Tobacco Survey, 2011-2013. Nicotine and Tobacco Research. 2014 Aug 20.

13 Oregon Health Authority, Public Health Division, Health Promotion and Chronic Disease Prevention section. Oregon Behavioral Risk Factors Surveillance System. 2016.

14 Oregon Health Authority Public Health Division, Health Promotion and Chronic Disease Prevention Section. 2018. Oregon tobacco facts. Available at https://public.health.oregon.gov/PreventionWellness/TobaccoPrevention/Pages/pubs.aspx.

15 Case, Kathleen, Dale Mantey, MeLisa Creamer, Melissa B. Harrell, Steven Kelder, and Cheryl Perry. "E-Cigarette- Specific Symptoms of Nicotine Dependence among Texas Adolescents." Addictive Behaviors 84 (March 1, 2018). https://doi.org/10.1016/j.addbeh.2018.03.032.

6 Morean, Meghan E., Suchitra Krishnan-Sarin, and Stephanie S O'Malley. "Assessing Nicotine Dependence in Adolescent E-Cigarette Users: The 4-Item Patient-Reported Outcomes Measurement Information System (PROMIS) Nicotine Dependence Item Bank for Electronic Cigarettes." Drug and Alcohol Dependence 188 (01 2018): 60–63. https://doi.org/10.1016/j.drugalcdep.2018.03.029.

17 Goldenson NI, Leventhal AM, Stone MD, McConnell RS, Barrington-Trimis JL. Associations of Electronic Cigarette Nicotine Concentration With Subsequent Cigarette Smoking and Vaping Levels in Adolescents. JAMA Pediatr. 2017 Dec 1;171(12):1192-1199. doi: 10.1001/jamapediatrics.2017.3209. PubMed PMID: 29059261; PubMed Central PMCID: PMC5779618.

18 Wang, Julie B., Jeffrey E. Olgin, Gregory Nah, Eric Vittinghoff, Janine K. Cataldo, Mark J. Pletcher, and Gregory M. Marcus. "Cigarette and E-Cigarette Dual Use and Risk of Cardiopulmonary Symptoms in the Health EHeart

Study." PLoS ONE 13, no. 7 (July 25, 2018). https://doi.org/10.1371/journal.pone.0198681.

19 Kowitt SD, Osman A, Ranney LM, Heck C, Goldstein AO. E-Cigarette Use Among Adolescents Not Susceptible to Using Cigarettes. Prev Chronic Dis 2018;15:170368. DOI: http://dx.doi.org/10.5888/pcd15.170368.

20 Gaur, Sumit, and Rupali Agnihotri. "Health Effects of Trace Metals in Electronic Cigarette Aerosols-a Systematic Review." Biological Trace Element Research, July 4, 2018. https://doi.org/10.1007/s12011-018-1423-x.

21 "Flavors Hook Kids." California Tobacco Control Program - English. Accessed October 24, 2018. https://www.flavorshookkids.org/.

22 Chen H, Li G, Chan YL, Nguyen T, van Reyk D, Saad S, Oliver BG. Modulation of neural regulators of energy homeostasis, and of inflammation, in the pups of mice exposed to e-cigarettes. Neurosci Lett. 2018 Sep 25;684:61-66. doi: 10.1016/j.neulet.2018.07.001. Epub 2018 Jul 4. PubMed PMID: 29981356.

23 Alzahrani, Talal, Ivan Pena, Nardos Temesgen, and Stanton A. Glantz. "Association Between Electronic Cigarette Use and Myocardial Infarction." American Journal of Preventive Medicine 55, no. 4 (October 1, 2018): 455–61. https://doi.org/10.1016/j.amepre.2018.05.004.

24 Fuller, Thomas W., Abhinav P. Acharya, Thiagarajan Meyyappan, Michelle Yu, Godugu Bhaskar, Steven R. Little, and Tatum V. Tarin. "Comparison of Bladder Carcinogens in the Urine of E-Cigarette Users Versus Non E-Cigarette Using Controls." Scientific Reports 8 (January 11, 2018). https://doi.org/10.1038/s41598-017-19030-1.

25 Nguyen, Tara, Gerard E. Li, Hui Chen, Charles G. Cranfield, Kristine C. McGrath, and Catherine A. Gorrie. "Maternal E-Cigarette Exposure Results in Cognitive and Epigenetic Alterations in Offspring in a Mouse Model." Chemical Research in Toxicology 31, no. 7 (July 16, 2018): 601–11. https://doi.org/10.1021/acs.chemrestox.8b00084.

26 Hickey, Sean, Jeremy Goverman, Jonathan Friedstat, Robert Sheridan, and John Schulz. "Thermal Injuries from Exploding Electronic Cigarettes." Burns: Journal of the International Society for Burn Injuries 44, no. 5 (August 2018): 1294–1301. https://doi.org/10.1016/j.burns.2018.02.008.

27 Oregon Poison Center. E-cigarette Exposures 2017. Unpublished data.

28 Pasquereau A, Guignard R, Andler R, Nguyen-Thanh V. Electronic cigarettes, quit attempts and smoking cessation: a 6-month follow-up. Addiction. 2017 Sep;112(9):1620-1628. doi: 10.1111/add.13869. Epub 2017 Jun 26. PubMed PMID: 28504457.

29 Kulik MC, Lisha NE, Glantz SA. E-cigarettes Associated With Depressed Smoking Cessation: A Cross-sectional Study of 28 European Union Countries. Am J Prev Med. 2018 Apr;54(4):603-609. doi: 10.1016/j.amepre.2017.12.017. Epub 2018 Feb 12. PubMed PMID: 29449132; PubMed Central PMCID: PMC5860982.

30 Curry E, Nemeth JM, Wermert A, Conroy S, Shoben A, Ferketich AK, Wewers ME. A Descriptive Report of Electronic Cigarette Use After Participation in a Community-Based Tobacco Cessation Trial. Nicotine Tob Res. 2017 Dec 13;20(1):135-139. doi: 10.1093/ntr/ntx013. PubMed PMID: 28339576; PubMed Central PMCID: PMC5896449.

31 Young-Wolff KC, Klebaner D, Folck B, Tan ASL, Fogelberg R, Sarovar V, Prochaska JJ. Documentation of e-cigarette use and associations with smoking from 2012 to 2015 in an integrated healthcare delivery system. Prev Med. 2018 Apr;109:113-118. doi: 10.1016/j.ypmed.2018.01.012. Epub 2018 Jan 31. PubMed PMID: 29360481.

32 Weaver, Scott R., Jidong Huang, Terry F. Pechacek, John Wesley Heath, David L. Ashley, and Michael P. Eriksen. "Are Electronic Nicotine Delivery Systems Helping Cigarette Smokers Quit? Evidence from a Prospective Cohort Study of U.S. Adult Smokers, 2015–2016." PLOS ONE 13, no. 7 (July 9, 2018): e0198047. https://doi.org/10.1371/journal.pone.0198047.

33 Treating Tobacco Use and Dependence. Content last reviewed April 2013. Agency for Healthcare Research and Quality, Rockville, MD. http://www.ahrq.gov/professionals/clinicians-providers/guidelines-recommendations/tobacco/clinicians/update/index.html

34 U.S. Department of Health and Human Services. Preventing tobacco use among youth and young adults: A report of the Surgeon General, U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2012.

35 Hegmann KT, et al. The effect of age at smoking initiation on lung cancer risk. Epidemiology 4(5):444-48, September 1993; Lando HA, et al. Age of initiation, smoking patterns, and risk in a population of working adults. Preventive Medicine 29(6 Pt 1):590–98, December 1999.

36 Myers ML. New study finds over 40 percent of youth smokers use flavored little cigars or cigarettes, shows need for FDA to regulate all tobacco products. Campaign for Tobacco-Free Kids. Oct. 22, 2013.

37 Wills TA, Sargent JD, Gibbons FX, Pagano I, Schweitzer R. E-cigarette use is differentially related to smoking onset among lower-risk adolescents. Tobacco control. 2016;26(5):534-539. doi:10.1136/tobaccocontrol-2016-053116.

38 Chaffee BW, Watkins SL, Glantz SA. Electronic Cigarette Use and Progression From Experimentation to Established Smoking. Pediatrics. 2018;141(4):e20173594.

39 Primack BA, Shensa A, Sidani JE, Hoffman BL, Soneji S, Sargent JD, Hoffman RM, Fine MJ. Initiation of Traditional Cigarette Smoking after Electronic Cigarette Use Among Tobacco-Naïve US Young Adults. Am J Med. 2018 Apr;131(4):443.e1-443.e9. doi: 10.1016/j.amjmed.2017.11.005. Epub 2017 Dec 11. PubMed PMID: 29242110.

40 Miech R, Patrick ME, O'Malley PM, Johnston LD. E-cigarette use as a predictor of cigarette smoking: results from a 1-year follow-up of a national sample of 12th grade students. Tob Control. 2017 Dec;26(e2):e106-e111. doi: 10.1136/tobaccocontrol-2016-053291. Epub 2017 Feb 6. PubMed PMID: 28167683; PubMed Central PMCID: PMC5545162.

41 East K, Hitchman SC, Bakolis I, Williams S, Cheeseman H, Arnott D, McNeill A. The Association Between Smoking and Electronic Cigarette Use in a Cohort of Young People. J Adolesc Health. 2018 May;62(5):539-547. doi: 10.1016/j.jadohealth.2017.11.301. Epub 2018 Mar 2. PubMed PMID: 29499983; PubMed Central PMCID: PMC5938086.

42 Hammond D, Reid JL, Cole AG, Leatherdale ST. Electronic cigarette use and smoking initiation among youth: a longitudinal cohort study. CMAJ. 2017 Oct 30;189(43):E1328-E1336. doi: 10.1503/cmaj.161002. PubMed PMID: 29084759; PubMed Central PMCID: PMC5662449.

43 Soneji SS, Sung HY, Primack BA, Pierce JP, Sargent JD. Quantifying population-level health benefits and harms of e-cigarette use in the United States. PLOS One. 2018:13(3): e0193328. https://doi.org/10.1371/journal.pone.0193328.

44 Martínez C., Fu M., Galán I., et al. Conflicts of interest in research on electronic cigarettes: a cross-sectional study. Tobacco Prevention & Cessation. 2018;4(Supplement):A52. doi:10.18332/tpc/90465.

45 Family Smoking Prevention and Tobacco Control Act 2009: https://www.gpo.gov/fdsys/pkg/PLAW-111publ31/pdf/PLAW-111publ31.pdf.

46 Oregon Indoor Clean Air, HB 2546, Chapter 20 (Cal. State. 2015): https://olis.leg.state.or.us/liz/2015R1/Downloads/MeasureDocument/HB2546/Enrolled.

47 ICAA OAR 333-015-025 to 333-015-0090: https://secure.sos.state.or.us/oard/displayDivisionRules.action;JSESSIONID_OARD=r_wVZhodSCP2Fsp4RHtG0jLSHlBKJwMKkSfkr6ayNjFZyzCfiPhy!-1397433681?selectedDivision=1230.

48 ICAA OAR 333-015-0200 to 333-015-0220: https://secure.sos.state.or.us/oard/displayDivisionRules.action;JSESSIONID_OARD=r_wVZhodSCP2Fsp4RHtG0jLSHlBKJwMKkSfkr6ayNjFZyzCfiPhy!-1397433681?selectedDivision=1230

49 ICAA OAR : 333-015-0300 to 333-015-0375: https://secure.sos.state.or.us/oard/displayDivisionRules.action;JSESSIONID_OARD=r_wVZhodSCP2Fsp4RHtG0jLSHlBKJwMKkSfkr6ayNjFZyzCfiPhy!-1397433681?selectedDivision=1230

50 Deeming tobacco products to be subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products; Final Rule: https://www.federalregister.gov/documents/2016/05/10/2016-10685/deeming-tobacco-products-to-be-subject-to-the-federal-food-drug-and-cosmetic-act-as-amended-by-the

51 FDA Extension of Certain Tobacco Product Compliance Deadlines Related to the Final Deeming Rule: https://www.fda.gov/downloads/TobaccoProducts/Labeling/RulesRegulationsGuidance/UCM557716.pdf

52 SB 754: https://olis.leg.state.or.us/liz/2017R1/Downloads/MeasureDocument/SB754/Enrolled

53 E-liquids misleadingly labeled or advertised as food products: https://www.fda.gov/TobaccoProducts/NewsEvents/ucm605729.htm

54 https://www.fda.gov/TobaccoProducts/Labeling/RulesRegulationsGuidance/ucm281784.htm

55 https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm620184.htm

56 FDA Deeming Regs https://www.federalregister.gov/documents/2016/05/10/2016-10685/deeming-tobacco-products-to-be-subject-to-the-federal-food-drug-and-cosmetic-act-as-amended-by-the

57 FDA Deeming Regs; 16 CFR 1700.20 (1995) https://www.gpo.gov/fdsys/granule/CFR-2012-title16-vol2/CFR-2012-title16-vol2-sec1700-20/content-detail.html

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