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Tobacco Control Collection – August 7, 2024

Summaries of Articles

EDITORIAL

E-Cigarette Use in Adolescents and Adults—A JAMA Collection

Tracy A. Lieu, MD, MPH; Kirsten Bibbins-Domingo, PhD, MD, MAS

The collection of articles in the **Journal of the American Medical Association (JAMA)** highlights the evolving and complex landscape of e-cigarette use in both adolescents and adults. The introduction of e-cigarettes, also known as "vaping," has raised significant questions for both the clinical and research communities due to their dual potential as tools for smoking cessation and as gateways to nicotine addiction, particularly for young people. The long-term health effects of these products also remain largely unknown.

A recent Cochrane review suggests that e-cigarettes may produce higher smoking cessation rates than nicotine replacement therapy, but they may also lead to long-term e-cigarette use. For adolescents, the risk is heightened as e-cigarettes are more appealing, easily accessible, and addictive. Various articles and studies presented in this collection explore the complexities of e-cigarette use in both adults and adolescents, offering insights into cessation interventions, health impacts, regulatory concerns, and public health implications.

Overview of E-Cigarettes:

E-cigarettes are battery-powered devices that heat liquids containing nicotine, flavoring, and other chemicals to produce aerosols that are inhaled—a practice commonly known as "vaping." They have been marketed as safer alternatives to traditional combustible tobacco products, primarily because they do not contain many of the carcinogens found in cigarettes. However, the evidence surrounding e-cigarettes is mixed. While they may help adult smokers quit cigarettes, particularly through their high nicotine delivery systems, their long-term health effects remain uncertain. Moreover, they may act as a gateway to nicotine addiction, particularly among adolescents, who are more vulnerable to the appealing flavors and ease of access.

Prevalence of E-Cigarette Use:

Currently, 4.5% of U.S. adults, 10% of high school students, and 4.6% of middle school students report using e-cigarettes. These statistics highlight the growing concern, especially among youth, that e-cigarettes are often perceived as less harmful than traditional cigarettes while still carrying significant risks.

Contrasting Benefits and Risks:

The primary dilemma surrounding e-cigarettes stems from their contrasting potential benefits and risks:

- **For adult smokers**, e-cigarettes are seen as a possible harm reduction tool. The Cochrane review found with high certainty that e-cigarettes are more effective in helping smokers quit than nicotine replacement therapies (NRT). However, there are concerns that those who switch to e-cigarettes may end up using them long-term, potentially becoming dependent on nicotine through this new method.
- **For nonsmokers and adolescents**, e-cigarettes pose more risks than benefits. They increase the risk of nicotine addiction, particularly in young people, due to a variety of different flavors, the ability to use them discreetly, and the belief that they are safer than cigarettes. As adolescents are more susceptible to the addictive nature of nicotine there is concern that vaping could lead to long-term addiction and other developmental harms.

Articles within the Collection:

This JAMA collection includes various studies, clinical insights, and editorials that further explore issues on the use of e-cigarettes by adults and adolescents:

1. What are E-Cigarettes? by Malani and Walter:

This article provides an accessible overview of e-cigarettes, detailing their potential health risks and benefits. It highlights the complexity of e-cigarettes to help smokers quit while also posing risks for nonsmokers, particularly adolescents.

2. A Vaping Cessation Text Message Program for Adolescent E-Cigarette Users by Graham et al.:

This article discusses a randomized clinical trial studied a text-message intervention to promote vaping cessation in a diverse group of 1,503 adolescents. Recruited via social media, participants showed higher rates of self-reported abstinence in the intervention group than the control group. The study provides important evidence for an accessible, free intervention that clinicians can recommend to adolescents who wish to quit vaping. The findings align with similar results in young adult populations.

3. Supporting Adolescents' Desire to Quit E-Cigarettes by Halpern-Felsher:

This editorial emphasizes that adolescent e-cigarette users are often addicted to nicotine and may express a desire to quit but struggle to do so. The authors stress the importance of recognizing adolescent vaping as a critical public health issue, especially in light of continued aggressive marketing and the appeal of e-cigarettes.

4. **E-Cigarette Use in Adults by Piper, Stein and Lasser:**

This article examines the contrasting impacts of e-cigarettes on different populations:

- **Winickoff and colleagues:** Focus on youth, highlighting concerns about nicotine addiction and the potential harms associated with vaping, such as impairments in attention, impulse control, and other issues like hypersensitivity pneumonitis caused by contaminants or simultaneous vaping of cannabis and nicotine.
- **Piper and colleagues:** Focus on adults, noting that although e-cigarettes are not FDA-approved for smoking cessation, they have been shown to produce higher quit rates than prescription nicotine replacement therapies. Adults often make multiple attempts to quit smoking, and switching to e-cigarettes may improve lung function, respiratory symptoms, and blood pressure. However, data on the long-term effects (beyond 12 months) are still limited.

5. **Variability in Constituents of E-Cigarette Products Containing Nicotine Analogues by Erythropel et al.:**

This research letter points out regulatory challenges in controlling the content of e-cigarettes, particularly the use of nicotine analogues. While the FDA has the authority to regulate tobacco and nicotine products, its jurisdiction does not extend to the chemical analogues used in some vaping liquids. These substances, often enhanced with sweeteners and flavorings, increase the appeal of e-cigarettes to new and young users, exacerbating public health concerns.

6. **Controversial FDA Decision Authorizes Menthol-Flavored E-Cigarettes Despite Risks to Youth by Rubin:**

This article reports on a significant FDA decision allowing the marketing of flavored e-cigarettes, raising concerns that this move prioritizes the benefits for current smokers over the risks to children and adolescents who are more likely to be drawn to flavored products.

Public Health Implications:

The ongoing debate surrounding e-cigarettes reflects broader public health challenges. On one hand, e-cigarettes may serve as an accessible tool for mitigating the harms of cigarette smoking among current smokers. On the other hand, their addictive potential, particularly for adolescents, is exacerbated by high nicotine delivery, incomplete regulation, and aggressive industry marketing. Educating nonsmokers, particularly young people, and protecting them from the harms of vaping must remain a priority in public health efforts.

Conclusion:

E-cigarettes may offer a pathway to reduce the harm caused by smoking for current smokers, yet they pose significant risks to public health, particularly for adolescents. The addictive power of nicotine, the appeal of flavored products, and the uncertainties around long-term effects mean that policymakers and healthcare providers must carefully weigh the benefits and risks when considering how to regulate and

recommend e-cigarettes. The strongest possible science must inform these public health decisions to ensure that nonsmokers, especially youth, are protected from the risks associated with vaping.

Citation: Lieu TA, Bibbins-Domingo K. E-Cigarette Use in Adolescents and Adults—A JAMA Collection. JAMA. Published online August 07, 2024. doi:10.1001/jama.2024.15912

JAMA PATIENT PAGE

What Are E-Cigarettes?

Authors: Preeti N. Malani, MD, MSJ; Kristi L. Walter, MD, MS

Key Points:

1. Definition and Description:

- E-cigarettes are battery-operated devices that heat liquid nicotine, flavoring, and other chemicals to create an aerosol.
- They come in various shapes, sizes, and colors, and their use is commonly referred to as "vaping."

2. Regulation and Terminology:

- E-cigarettes are considered "tobacco products" by the FDA and CDC, despite not containing tobacco.
- They are also known as vapes, vape pens, e-hookahs, hookah sticks, mods, and personal vaporizers.

3. Usage Statistics:

- E-cigarettes are the most commonly used tobacco product among US middle and high school students with significant usage reported among these groups (4.6% and 10% respectively).
- In 2021, 4.5% of US adults reported using e-cigarettes.

4. Health Effects:

- E-cigarettes contain nicotine, which is highly addictive and can harm brain development in teenagers.
- Use during pregnancy is linked to preterm births and may affect fetal lung and brain development.
- Aerosol from e-cigarettes can contain harmful chemicals and heavy metals, posing various health risks, including cancer and lung disease.
- E-cigarettes can cause seizures as well as nicotine poisoning if e-liquid is swallowed, inhaled, or absorbed through the skin.
- There are risks of injuries from fires, and explosions due to defective batteries.
- Long-term health effects are still unknown.

5. Comparison with Smoking:

- Vaping is perceived as safer than smoking but can still lead to serious health issues.
- Both involve inhaling substances into the lungs, but cigarettes produce smoke from burning tobacco, while e-cigarettes produce an aerosol from heated liquid.

6. Smoking Cessation:

- E-cigarettes might help nonpregnant adults quit smoking if used as a complete substitute for smoked tobacco products. However, they are not currently FDA-approved for smoking cessation.
- Quitting all tobacco products is recommended for better health.

7. General Advice:

- There is no safe tobacco product, and planning to quit all tobacco use is crucial for protecting health.

Conclusion:

It is important to understand the risks associated with e-cigarettes and encourage quitting all forms of commercial tobacco products to ensure better health outcomes.

Citation: Malani PN, Walter KL. What Are E-Cigarettes? JAMA. Published online August 07, 2024. doi:10.1001/jama.2024.14334

ORIGINAL INVESTIGATION

A Vaping Cessation Text Message Program for Adolescent E-Cigarette Users A Randomized Clinical Trial

Authors: Amanda L. Graham, PhD; Sarah Cha, MSPH; Megan A. Jacobs, MPH; Michael S. Amato, PhD; Anna L. Funsten, MSN; Giselle Edwards, MHS; George D. Papandonatos, PhD

The objective of this randomized clinical trial was to evaluate the effectiveness of an interactive text message-based intervention to promote e-cigarette cessation among adolescents called “This Is Quitting.” The trial was conducted by Truth Initiative from October 2021 to October 2023 and involved 1,503 adolescents recruited through social media advertisements on platforms including Instagram, Facebook, and Snapchat.

Study Design:

- **Design:** This was a double-blind, parallel, 2-group randomized controlled trial with participants individually randomized to either the intervention or control groups.
- **Participants:** Adolescents aged 13 to 17 who used e-cigarettes within the past 30 days, were interested in quitting within the next 30 days, owned a mobile phone with an active text message plan, and resided in the US. About 87.3% of participants had

tried to quit in the past year, with 53.4% making three or more attempts to quit. In addition, 76.2% reported vaping within 30 minutes of waking.

- **Groups:**
 - **Intervention Group:** Received a tailored, automated, interactive text message program designed to help with vaping cessation. The messages delivered cognitive and behavioral coping skills training and social support. Messages were customized to the user's age, vaping habits, and whether they had set a quit date. All users received mental health support.
 - **Control Group:** Received only text messages to study participant retention, without any specific intervention for quitting.

Main Outcomes:

The primary outcome of the study was **30-day point-prevalence abstinence** from vaping at 7 months, based on self-reports from the participants. Participants who did not respond at follow-up were considered to still be vaping (missing data was treated as continued vaping). A secondary outcome was **repeated point-prevalence abstinence**, defined as reporting no vaping at both the 1-month and 7-month follow-ups.

Results:

- **Demographics:** The average participant age was 16.4 years, with 50.6% female, 42.1% male, and 7.4% identifying as nonbinary or other. The sample was racially diverse, with 10.2% Black/African American, 62.6% White, 18.5% multiracial, and 16.2% Hispanic. Additionally, 42.5% of participants identified as LGBTQ+.
- **Follow-Up Rates:** At the 7-month follow-up, 70.8% of participants completed the assessments.
- **Abstinence Rates:** At the 7-month mark, the **intervention group** had a **37.8% abstinence rate**, while the control group had a **28.0% abstinence rate**, indicating a significant improvement in cessation rates among those who received the text message intervention. The relative risk for abstinence in the intervention group compared to the control group was 1.35, suggesting that participants in the intervention group were 35% more likely to be abstinent from vaping.
- **Repeated Point-Prevalence Abstinence:** The intervention group more than doubled the quit rate compared to the control group (17.3% vs. 8.2%).
- **No Transition to Combustible Products:** There was no evidence that participants who quit vaping switched to using combustible tobacco products (such as cigarettes or cigars) during the trial.

Conclusion:

The “**This is Quitting**” text message intervention was effective in helping adolescents quit vaping, significantly increasing the self-reported vaping cessation rates at 7 months. This study is the first randomized controlled trial to demonstrate an effective vaping cessation intervention specifically for adolescents. The **tailored, interactive approach** provided support through cognitive and behavioral strategies, social reinforcement, and mental health support, such as mindfulness and stress management. This low-cost, scalable digital intervention shows promise as a public health tool to address the high prevalence of e-cigarette use among adolescents.

The findings indicate that text messaging is an effective and accessible method for promoting health behavior changes in adolescents, especially considering the growing concerns about the impact of nicotine on adolescent brain development and overall health. The absence of transition to combustible tobacco products suggests that the intervention did not unintentionally cause harm by leading to other forms of tobacco use.

Implications for Public Health:

The study highlights the potential of mobile-based interventions as a **scalable solution** to combat adolescent vaping, which has become a pressing public health issue. The intervention could be integrated into pediatric and adolescent healthcare settings as a recommended resource for clinicians to use when counseling young patients about vaping cessation. Additionally, given the large sample size and diversity of the participants, the findings support the idea that such interventions could be broadly applicable across different demographic groups. Overall, this study provides strong evidence that a **digital, text message-based approach** can significantly reduce vaping among adolescents and suggests that similar methods could be effective in broader tobacco control efforts.

Citation: Graham AL, Cha S, Jacobs MA, et al. A Vaping Cessation Text Message Program for Adolescent E-Cigarette Users: A Randomized Clinical Trial. JAMA. Published online August 07, 2024. doi:10.1001/jama.2024.11057

EDITORIAL

Supporting Adolescents' Desire to Quit E-Cigarettes

Author: Bonnie Halpern-Felsher

Key Points:

1. Prevalence and Health Risks:
 - High Usage Rates: E-cigarettes are the most commonly used nicotine product among U.S. adolescents, with 2 million middle and high school students reporting recent use. This widespread use is particularly concerning given the developing brains of adolescents, which are more susceptible to addiction.
 - Health Consequences: E-cigarette use poses several health risks, including damage to lung and cardiovascular health. Moreover, adolescents who start with e-cigarettes are more likely to transition to traditional cigarettes, further increasing their risk of long-term health issues.
2. Nicotine Addiction:
 - Addiction Levels: Research indicates that adolescents using e-cigarettes show significant signs of nicotine dependence, with some using e-cigarettes within minutes of waking—a strong indicator of addiction. The nicotine content in modern e-cigarette devices is particularly high, often exceeding the amount found in a pack of traditional cigarettes.

- **Adolescents' Vulnerability:** Due to their developing brains, adolescents are more vulnerable to nicotine addiction. Many lack awareness of the addictive nature of nicotine and the difficulties associated with quitting.

3. Desire to Quit:

- **Widespread Intentions:** Adolescents who use e-cigarettes express a strong desire to quit but have difficulty doing it. Surveys show that a significant proportion of high school students have attempted to quit e-cigarettes and many are seriously considering quitting due to health concerns, particularly related to lung health.
- **Ineffective Quitting Methods:** Common strategies used by adolescents, such as quitting "cold turkey," are generally ineffective. However, digital cessation tools, which adolescents are more likely to endorse, show promise.

4. Need for Targeted Cessation Programs:

- **Lack of Effective Resources:** Nicotine replacement therapies (NRTs) are not FDA-approved for those under 18, though they are sometimes prescribed off-label. There is also a lack of NRT studies for adolescents. This gap highlights the urgent need for effective, evidence-based cessation programs tailored to adolescents.
- **Successful Interventions:** The Truth Initiative's "This is Quitting" program is highlighted as a successful intervention. The program, which uses text messaging to support adolescents in quitting e-cigarettes, was shown to significantly increase the likelihood of quitting compared to a control group. This program's success is attributed to its accessibility, evidence-based design, and focus on mental health, which is crucial given the high rates of mental health issues among adolescents who use e-cigarettes.

5. Policy and Future Directions:

- **Call for Broader Implementation:** Interventions like "This is Quitting" that are accessible, free, confidential, and tailored to the developmental needs of adolescents should be implemented widely.
- **Continued Need for Research:** There is a continued need for research into effective adolescent-specific cessation methods, especially given the evolving landscape of e-cigarette products and marketing strategies targeting youth.

Conclusion:

Adolescent e-cigarette use and the need for targeted, effective cessation programs represent a critical public health challenge. Studies show that adolescents are both highly susceptible to nicotine addiction and highly motivated to quit, but they require tailored and effective cessation resources and digital support to do so successfully. Interventions like "This is Quitting" represent a promising approach, but broader implementation and further research are necessary to address the public health crisis of youth nicotine addiction effectively.

Citation: Halpern-Felsher B. Supporting Adolescents' Desire to Quit E-Cigarettes. JAMA. Published online August 07, 2024. doi:10.1001/jama.2024.13142

JAMA INSIGHTS

E-Cigarette Use in Adults

Authors: Megan E. Piper, PhD; James H. Stein, MD; Karen E. Lasser, MD, MPH

Key Points:

a) Prevalence:

- 4.5% of US adults aged 18 years or older use e-cigarettes.
- Approximately 1 million adults use both e-cigarettes and traditional cigarettes.

b) Regulation and Use:

- The FDA has authorized 10 e-cigarette devices and 13 tobacco-flavored e-liquids for sale in the US, but e-cigarettes are not approved for smoking cessation.

c) Health Effects:

- E-cigarettes do not contain many toxic combustion or carcinogenic products found in traditional cigarettes.
- Short-term effects from e-cigarette use include increased heart rate, blood pressure, oxidative stress, and impaired lung function.
- Switching from traditional cigarettes to e-cigarettes may improve lung function and reduce respiratory symptoms in some individuals; however, long-term health effects are still largely unknown.

d) Smoking Cessation:

- E-cigarettes can help adults quit smoking traditional cigarettes and may be more effective than nicotine replacement therapy (NRT).
- A 2024 Cochrane review found that e-cigarettes with nicotine produced higher quit rates compared to NRT.
- study in Switzerland showed higher abstinence rates at 6 months in the e-cigarette group compared to the control group using NRT. The study also showed the e-cigarette group reported higher adverse events compared to the control group.

e) Continued Use:

- Long-term use of e-cigarettes after quitting traditional cigarettes is common.
- Dual use of e-cigarettes and traditional cigarettes is not recommended due to continued health risks.

Conclusions:

1. Effectiveness for Smoking Cessation:

- E-cigarettes may be considered for smoking cessation, especially for those who have not succeeded with FDA-approved pharmacotherapies.

- If used as a smoking cessation aid, they should be used as a complete substitute for traditional cigarettes and in conjunction with smoking cessation counseling.
2. Health Risks and Recommendations:
 - Despite some benefits in aiding smoking cessation, the long-term health risks of e-cigarette use remain uncertain.
 - Smoking cessation should ultimately be followed by e-cigarette cessation to minimize potential health risks.
 - For those unable to stop vaping after quitting smoking, similar strategies used for smoking cessation, such as pharmacotherapy and behavioral therapy, may be beneficial.
 3. Public Health Implications:
 - Smoking remains the leading preventable cause of death, disease, and disability.
 - All individuals who use tobacco should be offered evidence-based treatments for cessation.
 - The goal is to quit all tobacco products to ensure better health outcomes.

Citation: Piper ME, Stein JH, Lasser KE. E-Cigarette Use in Adults. JAMA. Published online August 07, 2024. doi:10.1001/jama.2024.8759

JAMA REVISITED

“Denicotinized” Tobacco

August 18, 1928; revisited August 7, 2024

Published in JAMA in 1928 and revisited in August 2024, this article discusses the ongoing efforts and challenges in creating tobacco products with reduced nicotine content. It places the discussion of nicotine within the broader context of how humans have long used various substances—such as alcohol, caffeine, and nicotine—that are not essential nutrients but are consumed for their stimulant effects.

Key Points:

1. Non-Nutritional Substances and Stimulants:
 - Humans have historically consumed substances like coffee, tea, and tobacco, which are not foods but provide specific effects, such as stimulation. Efforts have been made to eliminate undesirable elements from these substances, such as caffeine from coffee or alcohol from beverages, to retain the pleasure of consumption while reducing harm.
2. Nicotine and Health Concerns:
 - Nicotine, a potent alkaloid found in tobacco, is the central ingredient responsible for the stimulant effects of smoking. However, it is also associated with harmful physiological effects, leading many smokers to seek alternatives that allow them to continue using tobacco without the adverse health impacts. Other harmful

compounds found in tobacco smoke, such as carbon monoxide, volatile sulfide, methyl alcohol, and hydrocyanic acid contribute to tobacco smoke's overall toxicity.

3. The Advent of Denicotinized Tobacco:

- To address nicotine's health risks, there has been a movement toward producing "denicotinized" tobacco. These products are designed to retain the experience of smoking while reducing nicotine levels. Labels often claim "special treatment for the reduction of nicotine" or "removal of bulk nicotine," attracting smokers who want to reduce their intake. These products have become of particular interest to physicians advising patients to reduce or quit smoking due to nicotine-related health concerns.

4. Methods of Nicotine Reduction:

- The processes used to reduce nicotine in tobacco are primarily through superheated steam treatment, heating in vacuum chambers, or adding nicotine-free leaves to dilute the nicotine content. However, an analysis conducted by the Connecticut Agricultural Experiment Station found that the nicotine content of "denicotinized" products varied widely. While some products did contain less nicotine than regular tobacco, others had nearly as much nicotine as untreated tobacco.

5. Consumer Perception and Risk:

- It is concerning that smokers might overestimate the safety of denicotinized products by believing these products to be largely nicotine-free, and consequently smoking more to achieve the desired stimulant effect. This behavior could paradoxically increase their overall nicotine intake rather than reducing it. Therefore, the perception of safety could lead to unintended outcomes, such as increased consumption of harmful tobacco smoke.

6. The Limitations of Denicotinized Tobacco:

- While there is potential to further reduce nicotine content in tobacco through advanced processes, it is uncertain whether tobacco can retain its desirable qualities as a smoking product once nicotine is removed. Nicotine plays a crucial role in providing the satisfaction smokers seek, and its removal may lead smokers to compensate by smoking more. Thus, the reduction of nicotine might not necessarily solve the health problems associated with smoking, as smokers might inadvertently consume more toxic substances in pursuit of nicotine-like effects.

Conclusion:

Although the reduction of nicotine may seem like a solution for health-conscious smokers, it is not a foolproof approach. The variability in nicotine content across different products, combined with the potential for smokers to increase consumption due to perceived safety, suggests that denicotinized tobacco may not be as safe as it is marketed. This calls for a measured understanding of the risks associated with these

products and the acknowledgment that nicotine is only one of many harmful substances found in tobacco smoke.

*Citation: "Denicotinized" Tobacco. JAMA. Published online August 07, 2024.
doi:10.1001/jama.2023.18403*

RESEARCH LETTER

Variability in Constituents of E-Cigarette Products Containing Nicotine

Analogues Authors: Hanno C. Erythropel, PhD; Sairam V. Jabba, DVM, PhD; Peter Silinski, PhD; Paul T. Anastas, PhD; Suchitra Krishnan-Sarin, PhD; Julie B. Zimmerman, PhD; Sven E. Jordt, PhD

The study investigates the composition and safety of e-cigarettes that contain nicotine analogues, which are currently exempt from FDA regulation. It focuses on two products: "Spree Bar," which contains 5% 6-methylnicotine (6MN), a nicotine analogue, and another product line with nicotine replacements marketed under the names Nixotine, Nixodine, Nixamide, and Nic-Safe, which contain nicotinamide, a compound claimed to target nicotinic receptors that traditional nicotine stimulates.

Key Points:

1. Product Composition and Mislabeling:

The study confirmed that **6MN was present in all flavors of "Spree Bar"** (product 1), but at concentrations significantly lower than labeled (5.8 to 6.3 mg/g instead of the labeled 50 mg/g—87% to 88% less than expected). **Product 2 samples** contained 7% to 46% less nicotinamide than labeled, particularly at higher concentrations. Nicotinamide was detected in 6 out of 8 samples. Interestingly, **6MN was also detected** in some product 2 samples despite not being listed as an ingredient. None of the products contained nicotine, only nicotine analogues.

2. Nicotine Analogues:

6MN is **more potent and toxic than nicotine** in animal studies, raising concerns about its potential addictive properties and unknown health risks. Human toxicological data is lacking, making risk assessments difficult.

3. Stereoisomers and Addictiveness:

Product 1 samples contained only the **(S)-6MN stereoisomer**, which is known to be more potent and addictive than the (R)-6MN isomer.

4. Additives:

Product 1 also contained **neotame, a high-intensity artificial sweetener, and WS-23, a synthetic coolant**. Neotame is 7,000 to 13,000 times sweeter than sucrose, and WS-23 is widely used in disposable e-cigarettes. The presence of these additives, especially in youth-appealing flavors, enhances the product's appeal but raises concerns about the unknown risks of inhalation exposure to these compounds.

5. Discrepancies and Regulatory Gaps:

The significant differences between labeled and measured concentrations create **uncertainty about user exposure**, complicating risk assessments. The regulatory loophole that exempts nicotine analogues from FDA oversight allows these products to be marketed with potentially harmful ingredients and misleading labels.

6. Health and Regulatory Concerns:

There are unknown health risks associated with nicotine analogues, particularly in the context of e-cigarettes being used for smoking cessation. The presence of unregulated, potent analogues, combined with the appeal of youth-targeted flavors and additives, highlights the need for urgent regulatory action. Lawmakers need to grant the FDA authority to regulate products containing nicotine analogues as tobacco products.

Conclusion:

The significant variability in the chemical composition of e-cigarettes containing nicotine analogues pose a potential risk and uncertainty about user exposure. These products, marketed as safer alternatives or smoking cessation aids, have unknown risks, both in terms of addiction potential and the health effects of inhaling synthetic additives like neotame and WS-23. These discrepancies and potential hazards should prompt immediate regulatory intervention to protect consumers, especially younger users. The current regulatory gap must be closed, and nicotine analogues should be treated similarly to nicotine under FDA oversight. The inclusion of compounds that enhance the product's appeal without sufficient understanding of their health impacts further underscores the need for better regulation and monitoring.

Citation: Erythropel HC, Jabba SV, Silinski P, et al. Variability in Constituents of E-Cigarette Products Containing Nicotine Analogues. JAMA. Published online August 07, 2024. doi:10.1001/jama.2024.12408

MEDICAL NEWS & PERSPECTIVES

Controversial FDA Decision Authorizes Menthol-Flavored E-Cigarettes Despite Risks to Youth

Author: Rita Rubin, MA

This article examines the controversial FDA decision to authorize the marketing of menthol-flavored e-cigarettes by NJOY, a subsidiary of tobacco giant Altria, despite the known risks of such products to youth. The decision marked the first time non-tobacco-flavored e-cigarettes received FDA authorization, highlighting a complex balance between potential public health benefits for adult smokers and the risks of enticing youth.

Key Points:

1. FDA Authorization:

NJOY succeeded where its rival, RJ Reynolds, failed. While RJ Reynolds' menthol and fruit-flavored Vuse products were denied authorization by the FDA in 2023, NJOY's menthol e-cigarettes were approved in 2024. The FDA justified this by stating that NJOY provided sufficient scientific evidence showing a potential benefit for adult smokers transitioning away from traditional cigarettes, which outweighed the risks posed to youth.

2. Health Risks and Benefits:

The FDA acknowledged that menthol-flavored e-cigarettes might help some smokers reduce or quit smoking combustible cigarettes. However, there is a substantial risk that flavored products, including menthol, appeal to children and adolescents, who are less likely to smoke combustible cigarettes but may be drawn to vaping. The FDA remains concerned about the potential for youth initiation with flavored products, noting that e-cigarettes still carry significant risks, including nicotine addiction.

3. Scientific Uncertainty:

Although e-cigarettes produce fewer toxic compounds than traditional cigarettes, they are not risk-free, especially since most contain nicotine. Long-term effects remain unknown due to the relative novelty of these products in the market. Research is mixed regarding whether menthol-flavored e-cigarettes are more effective than tobacco-flavored ones in helping smokers quit. NJOY's data suggested higher switching rates from combustible cigarettes with menthol e-cigarettes, but these results were based on comparisons to its tobacco-flavored products rather than established cessation aids.

4. Youth Vaping Concerns:

Health advocates, including the American Academy of Pediatrics, condemned the FDA's decision, pointing to surveys that show flavored e-cigarettes are most popular among young people, with menthol playing a significant role in their appeal. Despite a decline in youth vaping rates, advocates fear this decision could reverse recent progress.

5. Regulatory and Legal Context:

The FDA's authority over e-cigarettes has evolved since the Family Smoking Prevention and Tobacco Control Act of 2009, which initially only covered traditional cigarettes. In 2016, the FDA extended its regulatory scope to e-cigarettes and prohibited the sale of these products to minors. Yet, enforcement of these regulations has been inconsistent, with many unauthorized flavored e-cigarettes still available on the market.

6. The Debate Over Menthol:

While the FDA is moving toward banning menthol cigarettes due to their harmful public health impact, its approval of menthol e-cigarettes raises questions about its regulatory stance. Some researchers believe that menthol's cooling effect makes smoking them more harmful by facilitating deeper inhalation of nicotine and other chemicals into the lungs.

7. Future Implications:

It is possible that more menthol e-cigarette products could be approved in the future. The FDA's rescinding of previous marketing denials for JUUL's menthol products suggests that the regulatory landscape for flavored e-cigarettes remains in flux. Public health experts continue to debate whether menthol e-cigarettes offer any significant benefit, with many arguing that public health would be better off without menthol in any form.

Conclusion:

The FDA's decision underscores a delicate balance between harm reduction for adult smokers and the ongoing risks of youth vaping. While NJOY's menthol-flavored e-cigarettes have been authorized for the market, concerns about youth exposure, regulatory consistency, and the long-term public health impacts remain contentious.

Citation: Rubin R. Controversial FDA Decision Authorizes Menthol-Flavored E-Cigarettes Despite Risks to Youth. JAMA. Published online August 07, 2024. doi:10.1001/jama.2024.14243