necsema
New England Convenience Store & Energy Marketers Association

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August 11, 2025

Town Council
Mansfield Town Hall
6 Park Row,
Mansfield, MA 02048

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Dear Members of the Mansfield Council, and Mansfield Board of Health,

I am writing on behalf of the New England Convenience Store and Energy Marketers Association (NECSEMA) to express our concern regarding the proposed restrictions on nicotine products. We urge rejection of this policy, as they unfairly restrict legal adults while failing to curb youth access. Policies should be based on reputable health data, prioritizing harm reduction over ineffective bans.

Selling tobacco to anyone under 21 is already illegal in Massachusetts, and flavored tobacco is banned, yet the Board of Health is considering further restrictions on nicotine pouches, limiting nicotine pouches to 6 milligrams per pouch. This move could have negative public health consequences, as studies show nicotine pouches are significantly less harmful than cigarettes. The FDA acknowledges a "continuum of risk," with cigarettes being the most dangerous and smoke-free alternatives posing much less harm.

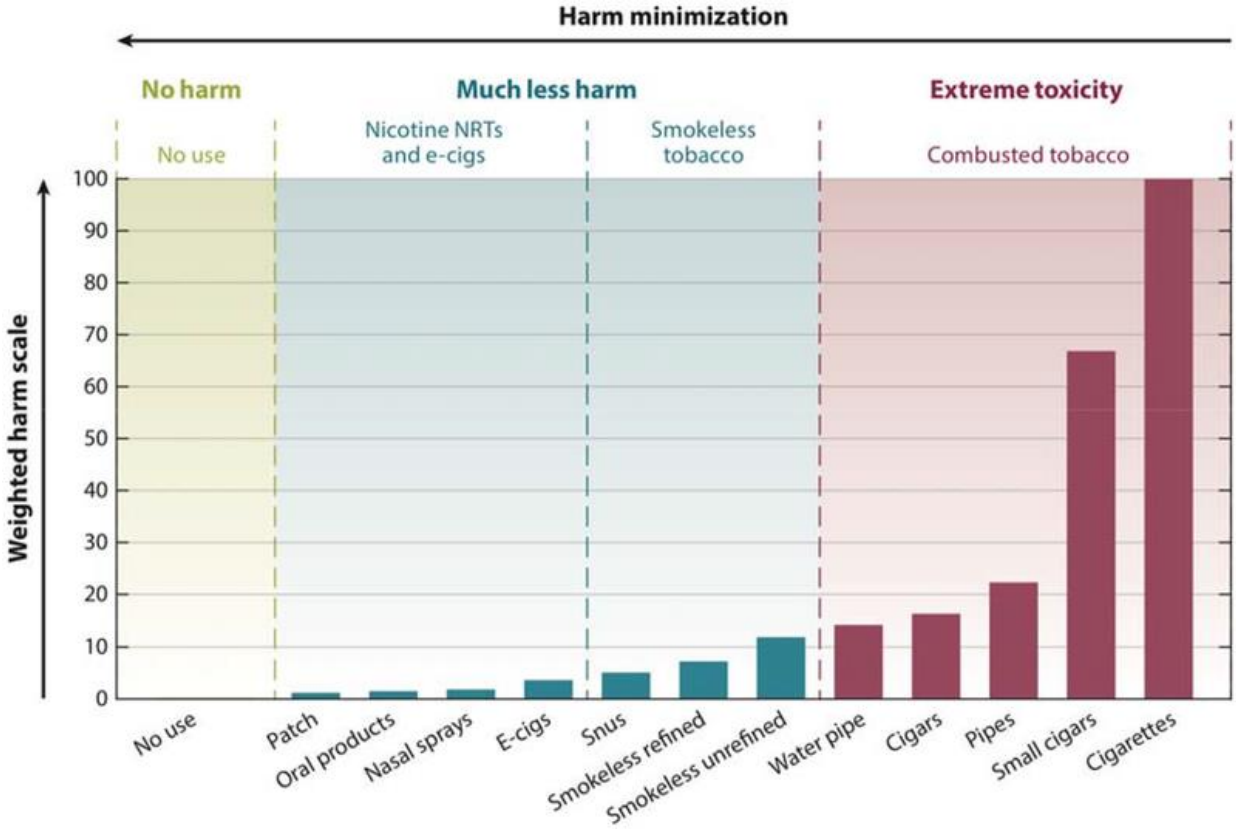
Ludlow, Massachusetts initially considered a nicotine cap of 6 milligrams but later amended the proposed regulation, raising the limit to 9 milligrams per pouch. This amendment recognized that the vast majority of products available in convenience stores are 9 milligrams or less which allows smokers' to switch to less harmful options. Instead of restricting access, policies should support harm reduction by ensuring adult smokers can easily transition to lower-risk products.

Thank you for your attention to this matter. If you have any questions, please do not hesitate to contact me.

Sincerely,

Peter A. Brennan

Diagram of Harm Minimization Through Nicotine Products



David Abrams et al. (2018)[1]

Attachments

1. David Abrams, et al., "Managing nicotine without smoke to save lives now: Evidence for harm minimization." Prev Med. 2018 Dec; 117:88-97. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6934253/
2. FDA, "The Relative Risks of Tobacco Products," https://www.fda.gov/tobacco-products/health-effects-tobacco-use/relative-risks-tobacco-products
3. Devi Shastri, "What to know about delta-8 and other common vape shop drugs," LA Times, Sept. 8, 2024, https://www.latimes.com/business/story/2024-09-08/what-to-know-about-delta-8-and-other-common-vape-shop-drugs
4. CBS San Francisco, "Undercover Study: Half Of California Tobacco And Vape Shops Don't ID Teens," https://www.cbsnews.com/sanfrancisco/news/undercover-study-tobacco-vape-shops-no-id-check-teens

CC: Amy Donovan-Palmer, Board of Health Director
Kevin J. Dumas, Town Manager

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Managing Nicotine Without Smoke to Save Lives Now: Evidence for Harm Minimization

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Abstract

Tobacco control has made strides in prevention and cessation, but deaths will not decline rapidly without massive behavior change. Currently, inhaled smoke from combusting tobacco is chiefly responsible for prematurely killing 7.2 million people worldwide and 530,000 in the United States annually. An array of noncombustible nicotine products (NNPs) has emerged and has disrupted the marketplace. Saving lives more speedily will require societal acceptance of locating a “sweet spot” within a three-dimensional framework where NNPs are simultaneously: 1. Less toxic, 2. Appealing (can reach smokers at scale), and 3. Satisfying (adequate nicotine delivery) to displace smoking. For this harm minimization framework to eliminate smoking, a laser focus on “smoking control” (*not general tobacco control)* is needed. By adopting these economically viable NNPs as part of the solution, NNPs can be *smoking control’s* valued

ally. Synthesis of the science indicates that policy and regulation can sufficiently protect youth while speeding the switch away from smoking. Despite some risks of nicotine dependence that can be mitigated but not eliminated, no credible evidence counters the assertion that NNPs will save lives if they displace smoking. But scientific evidence and advocacy has selectively exaggerated NNP harms over benefits. Accurate communication is crucial to dispel the misperception of NNPs harms and reassure smokers they can successfully replace smoking cigarettes with NNPs. Saving more lives now is an attainable and pragmatic way to call for alignment of all stakeholders and factions within traditional tobacco control rather than perpetuate the unrealized and unrealizable perfection of nicotine prohibition.

Keywords: Harm reduction, tobacco, nicotine, electronic nicotine delivery systems, non-combusted tobacco, smoking, mortality, harm minimization, public health impact

1. INTRODUCTION

1.1. Reframe nicotine use in society or stay the course?

We often attribute smoking's incredible toll on public health to tobacco products in general. However, the overwhelming majority of tobacco-related deaths are caused by inhaling lethal smoke chiefly from cigarettes as well as from all types of cigars, hookah, roll your own, pipes and bidis. In 2017, smoking prematurely killed over 7 million people worldwide.[1] At this rate, over 1 billion premature deaths will accrue globally during the 21st century.[2] In the United States (US), 530,000 smokers per year die prematurely, and about 16 million more smokers suffer debilitating chronic disease burdens.[3] Despite 50 years of concerted and successful tobacco control efforts to eliminate all tobacco products, the death caused by smoking persists at unacceptable levels.[4] Several endgame strategies have been proposed to stay the course, eliminate all tobacco use, and destroy the tobacco industry.[5] The stay-the-course framework strives to protect non-users, especially youth at any costs, and also expects all smokers to quit in this Utopian vision of a world without nicotine. But the implementation of this endgame is slow, difficult to attain and remains unrealized.

1.2. Recent developments in tobacco control

There have been enormous changes in the tobacco and nicotine product landscape over the last decade, culminating in a fundamental re-thinking of the role of nicotine and tobacco in society. In July 2017, the US Food and Drug Administration (FDA) announced a new national comprehensive nicotine management strategy: "The FDA agency's new tobacco strategy has two primary parts: reducing the

addictiveness of combustible cigarettes while recognizing and clarifying the role that potentially less harmful tobacco products could play in improving public health…***The availability of potentially less harmful tobacco products could reduce risk while delivering satisfying levels of nicotine for adults who still need or want it*** [emphasis added]."[6] (p.1). Strategies to reduce the addictiveness of combustible tobacco products are discussed in detail elsewhere,[7,8] but it is important to note that the two parts are complementary. Reduced risk noncombustible nicotine products (NNPs) can provide smokers with an alternative source of enjoyable nicotine and preferably some time before introducing a product standard for reducing addictiveness in combustibles to accelerate a mass-migration away from smoked tobacco/cigarettes.[8,9]

The last 10 years have witnessed other unprecedented changes in the nicotine and tobacco product marketplace.[10] New innovations in electronic cigarettes, heat-not-burn tobacco products and other substantially less harmful products are emerging. The world has not seen such technology-driven disruption in nicotine delivery since the 1880's, with the invention of the cigarette rolling machine.[4,11]

Another recent development is the emergence of the new field of tobacco and nicotine regulatory science,[12,13] which focuses on research directly relevant to informing policy and regulation of tobacco and nicotine products. Regulation of tobacco-derived nicotine (both medicinal cessation therapy and consumer products for adult recreational use) by the US FDA[14] is now a critical part of any reframing of nicotine and tobacco use in society. In 2018, Public Health England (PHE)[15] and the US National Academies of Sciences, Engineering and Medicine (NASEM)[16] updated and synthesized the science base. There was increasing convergence in the science with some differences in emphasis derived from different predisposing ideological conviction (i.e., stay-the-course or harm reduction) in the interpretation of some of the scientific data. Warner summarized differences as being possibly driven more by emotion rather than rationality in his Doll-Winder Public Health Theme Address: How to Think - Not Feel - about Tobacco Harm Reduction.[17]

Rapid technological innovation in the nicotine and tobacco product marketplace, the new regulatory climate, and the stronger science focus is on maximizing benefits and minimizing harms for public health at a population level.

1.3. Division in the tobacco control community

A troubling divisiveness has emerged about rethinking the tobacco control framework. When disruptive change occurs, diffusion of innovation (theory about how new technologies spread) involves multiple streams of influence (e.g., Kingdon's model where policy, politics, and problem focus converge in a "window of opportunity"[18]). During the early stages of responding to disruption, hypothetical fears

about unknown consequences abound, coupled with an instinctive resistance to changing course.[19,20] Over 400 years ago, Sir Francis Bacon warned about divisiveness based on prior ideological beliefs of the types being experienced by the tobacco/nicotine community today:[21] "The human understanding when it has once adopted an opinion draws all things else to support and agree with it. And though there be a greater number and weight of instances to be found on the other side, yet these it either neglects and despises, or else by some distinction sets aside and rejects, in order that by this great and pernicious predetermination the authority of its former conclusion may remain inviolate." As scientific evidence accumulates, reason prevails over emotional attachment to prior preconceived ideology. Tobacco control's struggle with change is no different than in other fields.

Divisiveness and uncertainty aside, the opportunity lost by not changing course must also be considered. In light of the dramatic changes in the product landscape, by not taking some risks to speed the demise of deadly smoked tobacco, then worldwide over the next century the lives of a billion smokers are ultimately at stake. While all agree that saving lives from smoked tobacco is paramount, the tactics of how to move forward are unclear as long as the differences in the core underlying framework remain unresolved.[15,16] The deep question boils down to whether one can accept that NNPs are less harmful, can displace smoked tobacco and that the makers and marketers of NNPs can profit from a legal product provided they comply with reasonable rules of the road (e.g., are regulated, sell to adults only, do not sell or engage in marketing to underage youth). In the next sections we explore what specific frameworks and scientific evidence provide a roadmap for maximizing the benefits and minimizes the risks of NNPs.

2. A New Framework

2.1. Overview

In considering a new framework for harm minimization, some prior tobacco control strategies will be continued, others modified, and some abandoned as iatrogenic. For example, effective policies such as taxing cigarettes, smoke free indoor air laws and reimbursement of pharmacotherapies for cessation treatment would remain. But if smokers receive deceptive information about exaggerated NNP harms or that all products are harmful (absolute risk) without direct comparison to the much greater (relative) harms of smoking, then smokers who have switched to NNPs may go back to smoking, or smokers planning to switch may not even try. Bauld (2017) stated: "Although not harmless, the evidence is unequivocal that (e-cigarette) vaping is much safer than smoking. But misinformation and scaremongering could still be putting people off switching."[22] Using the precautionary principle, the principle that a product with unknown long-term effects should be resisted, to withhold accurate information that NNPs are much less harmful than smoking is therefore iatrogenic.[17] Treating all tobacco

or nicotine products as equally harmful and regulating them as such supports the long-term viability and continued sale of cigarettes and the associated deaths [for details, see Royal College of Physicians[23] (2016; pp.187)], Abrams et. al (2018)[24] and Warner (2018)[17].

A harm minimization framework requires a strategic alignment of action by all stakeholders (manufacturers, regulators, policy makers, scientists, advocates, politicians) and clear communication that risk is proportional to the harms of different nicotine products.[17,24] This is an overarching paramount principle that must be adopted without ambivalence and with enthusiasm. The principle of regulation and policy being proportionate to product risk is the cornerstone of the proposed framework going forward.[24,25] This core principle is covered in more detail by Fairchild and colleagues[25] who outline a continuum where various action steps will differ on the degree that each action step supports harm reduction with less or more conviction.

2.2. How harmful are NNPs relative to smoking?

Summarizing the science, FDA's Commissioner and the Director of the Center for Tobacco Products stated:[6] "Nicotine, though not benign, is not directly responsible for the tobacco-caused cancer, lung disease and heart disease that kill hundreds of thousands of Americans each year" (p.1). Systematic reviews concur that NNPs are substantially less harmful than smoking.[7,16,23,24,26–31] This view recognizes that nicotine per se is not a primary cause of cancers, but does contribute to a limited set of cardiovascular disease risks and risks to the unborn fetus.[7,23,31–34] Consistent with the announcement[6] of FDA's nicotine management strategy to provide NNPs with satisfying levels of nicotine to smokers while reducing harmful exposures, Benowitz (July 28th 2017)[9] stated:

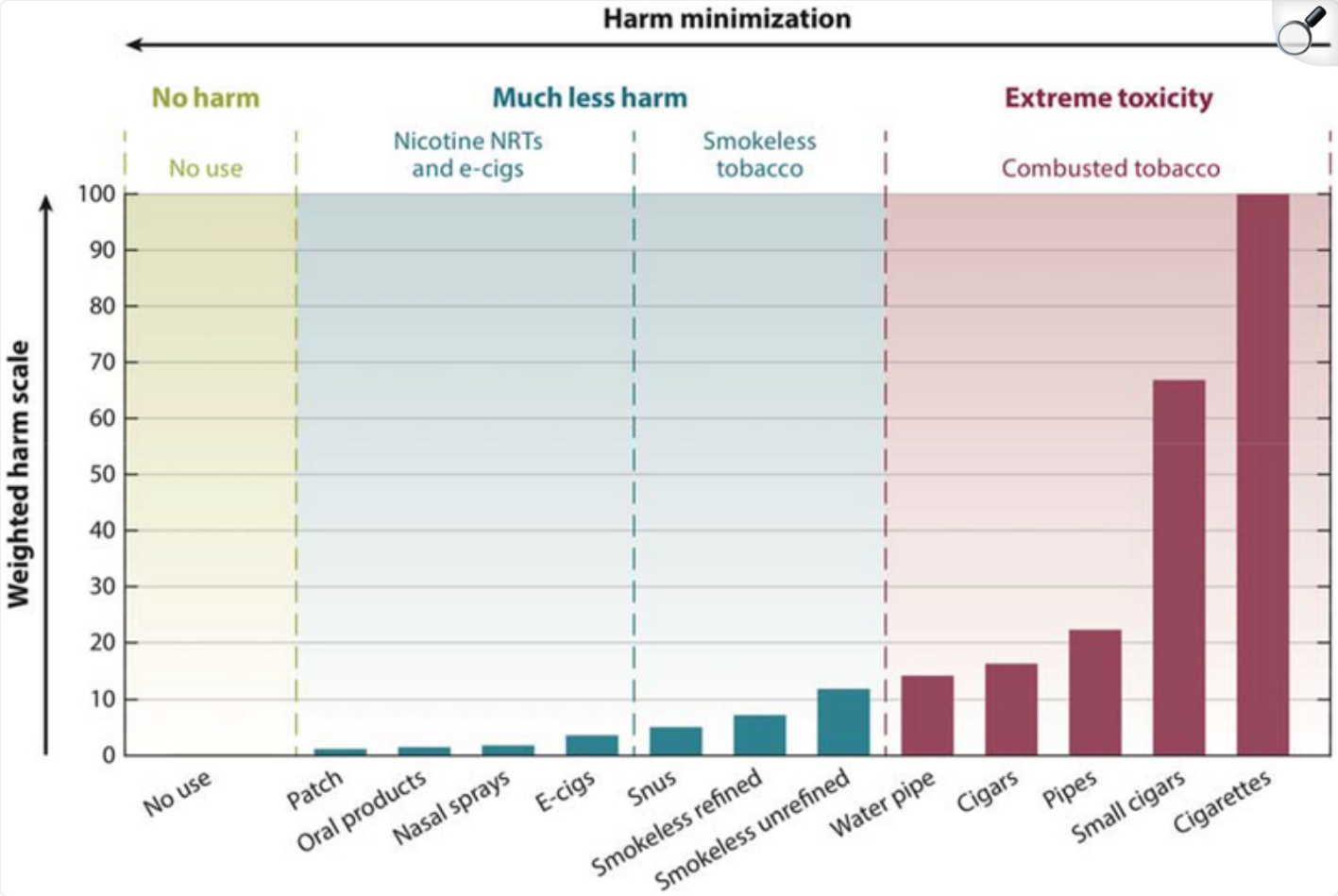
> *"Without question, it is the products of combustion from tobacco that are responsible for most of the harmful effects of tobacco use on health. While nicotine is not harmless, it contributes relatively little to the harmful effects of tobacco use… The risk of using lower nicotine concentration liquids* ***(in e-cigarettes)*** *is that the user must consume many-fold larger amounts of aerosol, often generated at higher temperatures, to achieve desired levels of nicotine…. Larger volumes of aerosol and/or generation of aerosol at higher temperatures would result in the user being exposed to higher levels of aerosol toxicants.* ***It might actually be safer to use e-liquids with high nicotine concentrations compared to lower concentrations.****"*
>
> *[emphasis added]*

NNPs are substantially less harmful than all smoked tobacco products, and they vary in harms within and across specific products. NNPs can be framed as a four-panel supra-ordinate categorical typology

(Figure 1):[24] 1. combusted versus non-combusted products, 2. smokeless tobacco products, 3. nicotine without tobacco products, and 4. No use and thus no exposure. Approximate product harms are depicted by bar graphs adapted from Nutt et al.[35] While combusting tobacco smoke is substantially more toxic than smokeless tobacco, the bar graphs represent a weighted harm scale so the difference is not as large between unrefined smokeless tobacco and the combustible water pipe and premium cigars. The critical point is that differences within the NNPs are relatively small when compared to smoked tobacco. In terms of the harm continuum (Figure 1, explained in more detail in Abrams et al. 2018[24]), we concur with most experts and systematic reviews[15,16,28,36] summarized by West and colleagues who stated with respect to e-cigarette vapor:[37]

> *"Studies that purport to have found concentrations of some toxicants in vapor high or higher than in cigarette smoke, or physiological reactions to vapor similar to or greater than smoking, have either failed to model natural exposure conditions or overstated the clinical significance of physiological changes…. that have little or no relevance to prediction of serious illnesses in e-cigarette users."*

Figure 1.



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Products along the harm minimization continuum. Adapted from Nutt et al., 2014[35] and reproduced from Abrams et al., 2018[24] The figure depicts four panels representing classes of products ranging from exceptionally low harm to exceptionally high harm. Panel 1 (*left*) depicts no use and thus no exposure. Panel 2 (*left middle*) depicts the class of nicotine delivery products without any tobacco (e-cigs/e-vapor products and nicotine replacement therapies - NRTs). Products containing tobacco are depicted as noncombusted or smokeless (panel 3, *right middle*) and combusted or smoked (panel 4, *right*). Panels 2 and 3 constitute the broader supra-ordinate category of non-combusted nicotine products (NNPs).

Some scientists and advocates have expressed concerns regarding potential cardiovascular and respiratory risks of e-vapor in certain cell preparation and acute physiological exposure studies.[28,38]

Extrapolation from many of these studies appears to be questionable when the studies imply direct causal links to long-term human harms equal to or greater than smoking or make no direct comparison with smoking so relative harms can be compared. Although nicotine use poses some risk for smokers with existing cardiovascular disease, risk is small relative to the risk posed by smoking cigarettes.[7,31,34,36,39,40]

There is less controversy about cancer risk, but there has been exaggeration of harms when NNPs are not explicitly compared with deadly smoking.[38] A recent review of cancer risk[41] suggests that e-cigarette emissions under normal use have about 1% of the cancer potency of tobacco smoke, even less than the Royal College of Physicians estimate of about 5%.[23,41] This conclusion is consistent with others[42] and puts in perspective circumstances (i.e., excessive power generated to the atomizer coil) under which some toxicants (e.g., formaldehyde, acrolein) can be produced.[42–44]

We suggest some of the divisiveness that paralyzes policymaking and confuses the public can be mitigated by paying closer attention to the strongest evolving scientific syntheses and not relying on select, isolated studies that exaggerate claims of harms and/or omit direct comparisons of harms relative to smoking. Strong assertions that go beyond the science (e.g., conflating correlation with causation, cherry picking results to highlight a particular viewpoint) are troubling trends that lead to greater confusion than is warranted.[45–50] Adhering to good research practices (e.g., research integrity, ethics and professional standards, honesty and transparency, openness and accountability, complete expression of study limitations) is also necessary to reduce these apparent conflicts.[24,51,52]

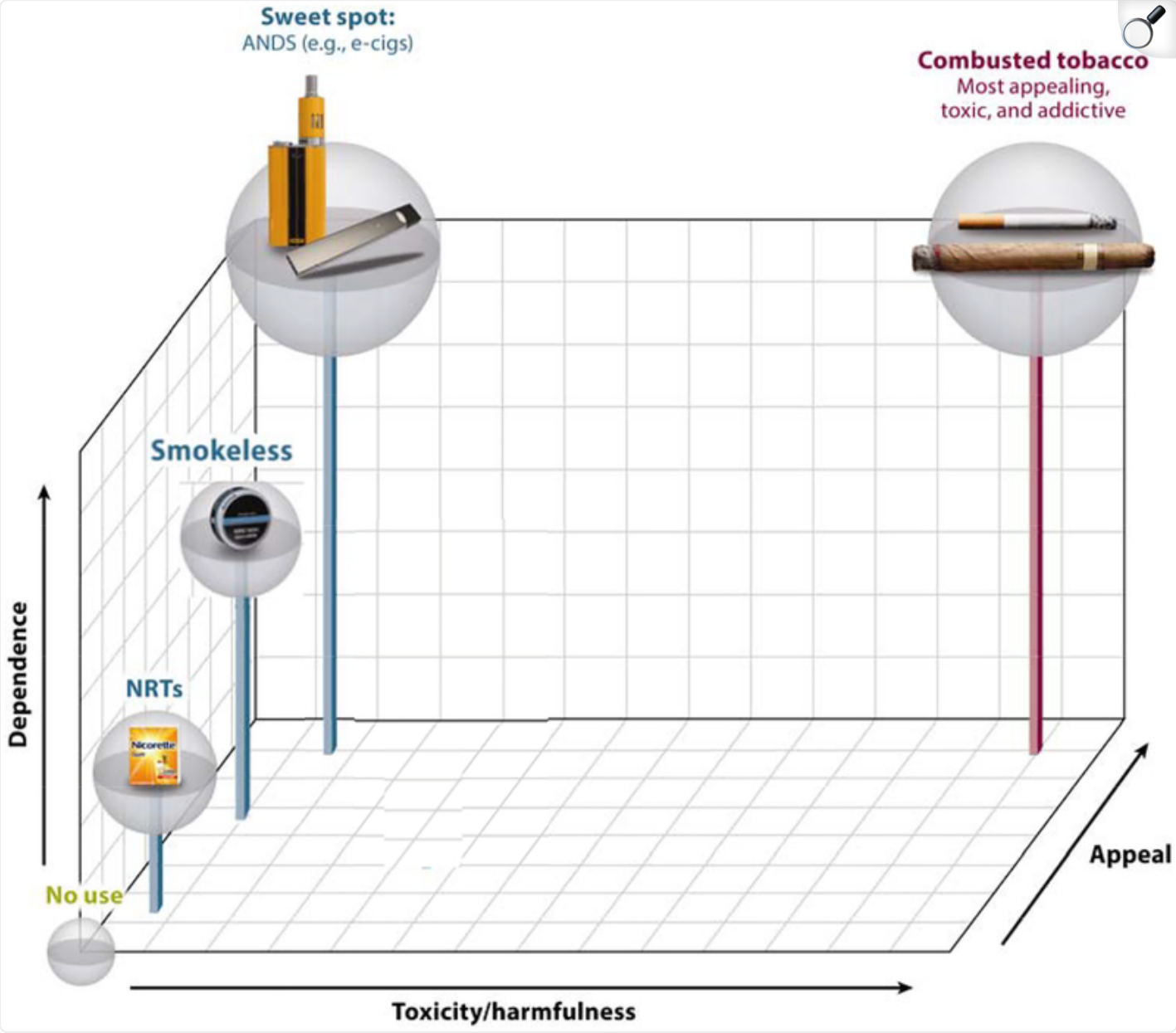
The bottom line is that product standards are widely used by FDA to provide specific criteria to be met for a class of products without burdensome and expensive pre-market approval. Prudent product standards can readily eliminate or minimize many of the unnecessary potential risks of NNPs (e.g., temperature controls) and ensure quality control over devices, and purity of liquids (e.g., nicotine, propylene glycol, vegetable glycerin, flavorings) while retaining their ability to appeal to and satisfy smokers and protecting children such as with child resistant packaging.[40]

2.3. A Three-Dimensional Nicotine Management Framework

Nicotine and tobacco products can fit into a three-dimensional conceptual space [Figure 2 and in Abrams et al. (2018)[24]] that is not necessarily to scale: (1) harmfulness (x-axis), (2) appeal (z-axis) and (3) dependence (y-axis).[24] All three dimensions must be simultaneously considered to determine how new NNP products will impact on net population health. NNPs differ substantially from smoking in their toxicity (x-axis). NNP's appeal relates to their ability to displace smoking (z-axis), which contributes to the likelihood that the product will be adopted and its use sustained at a scale large enough to affect

population health improvement (i.e., reach or market penetration).[53] Appeal is complex and encompasses attractiveness of the product, sensory characteristics, and subjective satisfaction as well as cost, accessibility, and marketing practices.[40,54–56] A product with minimal appeal will not be adopted or used extensively (e.g., over-the-counter NRT[57,58]). NNPs must be sufficiently appealing to encourage a larger portion of smokers to switch from the high- to the low-harm products.[54] Dependence (y-axis) refers to the potential for the product to provide satisfaction and induce a degree of addiction, which is a function both of its pharmacological and its subjective rewarding and sensory properties. Dependence can reflect a response to withdrawal and to enjoying, liking or needing nicotine's well-documented desirable effects, like improved alertness, concentration, mood and memory.[59,60] Some degree of dependence upon less harmful NNPs may have to be acceptable to society to speed the demise of smoking and its attendant massive harms by ensuring NNPs are sufficiently enjoyable and effective at providing the experience smokers want including the beneficial effects of nicotine on cognition and memory.[59,60]

Figure 2.



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Multidimensional framework for nicotine containing products, considering (1) harmfulness, (2) appeal, and (3) dependence. Reproduced from Abrams et al., 2018[24] The top, back, right corner depicts the most popular (appealing), highly satisfying (dependence), and toxic space (combusted products), whereas no use at all is zero on all three axes. The bottom, front, left space depicts products that have low toxicity but little appeal or satisfaction (e.g., nicotine replacement therapies - NRTs). Minimizing risk while making a net population health impact requires products to successfully compete with and replace smoking. Thus, the sweet spot,

where ANDS or NNP's products might fall, is depicted by high appeal and satisfaction but low toxicity along with products such as Swedish-type snus, which has successfully displaced cigarettes in Sweden.

The three dimensional space depicted in Figure 2 can be helpful in locating what may be the "sweet spot" of an ideal NNP. Availability of safe, appealing flavors, efficient nicotine delivery, and lower cost than cigarettes all play an important role in improving the overall appeal on a large-scale basis.[55,56] Some e-cigarettes appear to be able to occupy the "sweet spot" because some smokers have found an e-cigarette to sustain use and replace smoking.[28,55,56,61–64] E-cigarettes are used by more smokers than NRT in quit attempts in both the US and the UK.[23,65] Evidence also suggests they can be effective in helping smokers to quit smoking.[46] The more appealing and satisfying the NNP product is the greater the likelihood of switching away from smoking.

A tradeoff is raised between concerns for youth uptake among non-users who otherwise would not have smoked if NNPs did not exist and helping smokers and potential smokers to switch (including youth who would have smoked anyway). The risk to youth non-users will increase as products evolve and become better at finding that sweet spot (appeal and satisfaction) to replace smoked tobacco (e.g., better smoking cessation medication, JUUL's use of benzoic acid salts, modern tank or modular e-cigarette devices, heat-not-burn or smokeless tobacco products). While higher nicotine dependence liability is likely for some users, this risk must be considered in the overall calculus of a harm reduction benefit for smokers and potential smokers when the nicotine is decoupled from toxic smoke.

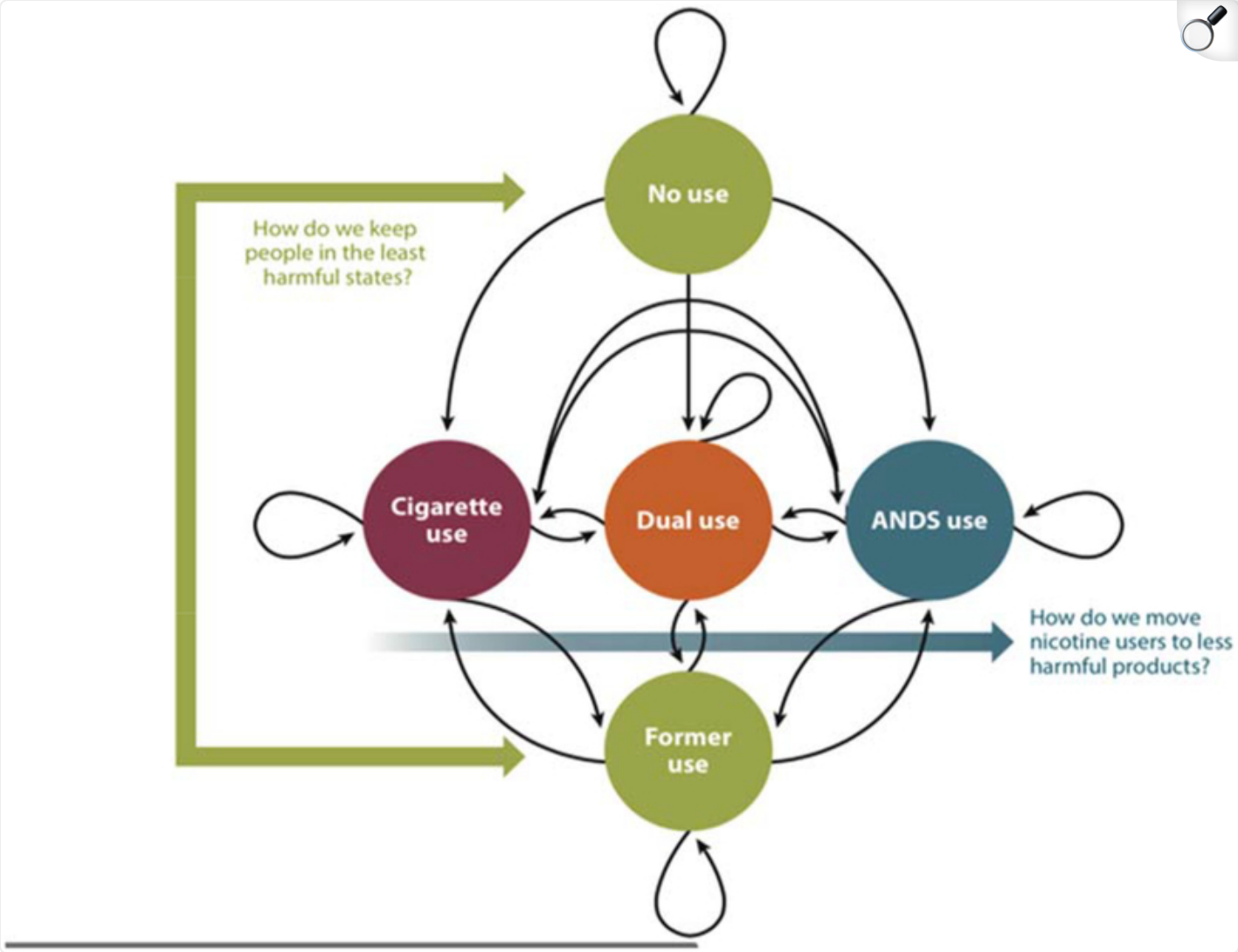
Different products can be ordered in this space, compared to one another and evaluated on their ability to minimize net harm and maximize net benefits (finding the "sweet spot"). If NNPs can compete with and ultimately replace smoking,[10] the net population toxicant exposure can be substantially reduced as has been shown in the Swedish experienced with snus use among males.[66] Holding all three dimensions in consideration at the same time is critical for an overarching new framework for guiding planned action steps and provides a conceptual and visual road map to speed the demise of using deadly smoked tobacco as the preferred way to enjoy nicotine.

3. Making a Population Impact: Modeling State Transitions to Characterize Benefits over Harms

As stated previously, the core principle for the alignment of stakeholders is that regulatory, other strategies and tactics and communications are made proportional to the relative harms of each class of

products and every NNP product is always compared with deadly smoking. The FDA's Center for Tobacco Products' public health standard implies an integrated consideration of product benefits and harms at the individual and population levels (including likelihoods of initiation and cessation). Population net toxicant exposure depends on the patterns and prevalence of product use that vary along the continuum of harm (Figures 1 and 2). Figure 3 presents a model using the example of cigarettes and NNPs (e-cigarettes) to illustrate the possible states and pathways that must be considered to optimize the framework for smoking control.[24,67] Briefly, directed arrows represent transitions; looped arrows at each state represent maintenance of that state.

Figure 3.



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Markov state transition model of cigarette and non-combusted nicotine products (NNPs), or alternative nicotine delivery systems (ANDS) use. Adapted from Cobb et al., 2015[67] and reproduced from Abrams et al., 2018[24] Directed arrows represent transitions, whereas looped arrows at each state represent maintenance of that state. Traditional youth prevention and smoking cessation strategies reinforce the states of noncurrent and former use depicted by green circles, and complementary new harm minimization strategies facilitate movement away from deadly combusted tobacco smoking to substantially less harmful alternative NNP/ANDS products (*blue arrow*).

Each strategy influences the flow from one state to another. The FDA two-part strategy[6] includes policy and regulation (a) to keep non-users and former users in the no use states at the top and bottom of Figure 3; and (b) harm minimization strategies that facilitate movement away from smoking (depicted by the arrow from smoking to exclusive e-cigarette use either via dual use or directly switching and thus skipping dual use). It should be noted that one could remain in dual use with no reduction in cigarette smoking, resulting in no change in harm but no known increased harm in terms of biomarker evidence to date.[68] Outcomes can be determined empirically using population prevalence rates in states and transition rates between states. Simulation modeling of policy and regulation effects on transition rates can indicate tipping points for benefits and harms, given different scenarios of product use, harmful exposure and smoking prevalence.[69] Examples of these approaches could be to impose a differential tax on nicotine-containing products proportional to their degree of harm (less harmful, lower tax),[70] ensure efficient nicotine delivery and appeal in NNPs,[8,71] and simultaneously reduce the appeal of smoking by banning menthol or flavored cigars and reducing nicotine yields in smoked products but not in NNPs.[55,56,72,73] Making combusted tobacco more expensive and less appealing and NNPs less expensive and more appealing will heighten the contrast between less and more harmful products and help steer smokers at any age away from smoking. This can be achieved through not only regulating products, but also through policies and communications that differentially incentivize those manufacturers willing to responsibly make and market much less harmful NNPs to adult consumers and phase out smoked products.

3.1. Do E-Cigarettes Attract Youth and Lead More to Smoking Over and Above the Counterfactual (the Absence of E-Cigarettes)?

Studies show that current e-cigarette use by youth consists largely of experimentation, not long-term use.[24,74,75] Longitudinal studies, a meta-analysis[76] (with a later correction of errors that reduced the effect size[77]), and a systematic review[16] show as expected that some youth ever e-cigarette users will use cigarettes during a short follow-up period,[78–87] raising concern about so-called “gateway” effects (i.e., e-cigarette use leading directly and causally to regular daily smoking).[47] The authors duly note that finding such an association, even in longitudinal studies, does not imply causality.[76] Confounding influences, such as shared vulnerability factors that predispose youth to try alcohol, marijuana, other drugs and risky experiences,[50,74,75,88] cannot be easily ruled out.[17] Moreover, the proportion of early users who progress beyond experimentation (e.g., use on < 5 of the past 30 days) to later daily or lifetime use has not been established. The proportion who progress to long term daily use has been extrapolated from cross-sectional studies with a wide range from about 25% to over 60 % of ever smokers possibly becoming daily users.[89–91] One combined prospective and retrospective longitudinal study by Colby et al (2012)[91] reported on lifetime smoking trajectories up to age approximately 40 years and found that 34% of those who ever tried a cigarette did not progress to daily smoking and an

additional 27% were former smokers prior to age 40. A recent study of youth and young adults (age 15 to 24 years) in a large nationally representative sample (n = 15,275) prospectively examined product use transitions over a period of 2.5 years and showed that short-term transitions (≤1 year) between use of any product to subsequent use of any other product were equally likely, but affected only a small proportion of the population who were already product users.[92] After 2.5 years, the strongest transition probabilities were from initial use of cigarettes to continuing to smoke cigarettes, and from use of any other products including e-cigarettes to no current use.[92]

Taken together the studies reviewed to date suggest extreme caution be exercised when attempting to make predictions from ever use or even from any past 30-day use to daily use, let alone to the likelihood of a future lifetime of smoking cigarettes. To have a net public health harm, the progression to lifetime use must be over and above those who would have smoked anyway. Moreover, even if there was a gateway effect from ever tried an e-cigarette to a lifetime of smoking, we concur with Kozlowski and Warner (2017) and others[24] who conclude that overall youth smoking prevalence has dropped at faster rate during the steepest rise in e-cigarette use: while society must be vigilant, fears of hypothesized harms[93] due to gateway effects among youth are unlikely to undermine the much larger benefits of discouraging smoking behavior in the whole population.[47]

Finally, simulation modeling with sensitivity analyses shows that the purported gateway effect (if it exists at all) would have to be implausibly large to increase the net public health harm over benefits.[67,69] Both Levy et. al[69] and Warner and Mendez[94] independently concluded that e-cigarettes have substantial potential to improve net public health consistent with the majority of other published simulation studies including the 2018 National Academies of Science, Engineering and Medicine (NASEM), even under very conservative consumptions.[16,69,95–98] The public health benefit does diminish in the models when it is assumed there is a very high relative risk of vaping compared to smoking (e.g., 50% risk) coupled with a high assumed (direct causal) gateway effect for non-using youth and/or with a low adult cessation rate. One outlier simulation model concluded that there would be a net public health harm under almost all assumptions, but this model assumed vaping would have almost no effect on current smokers as well as a very large gateway effect on youth (for every one case of cessation there would be about eight new lifetime smokers).[99] The strongest scientific evidence is not consistent with these extreme assumptions.[17,47,76,94] The outlier model is also based on a misleading negative correlation between e-cigarettes and smoking cessation from a meta-analysis[100] of studies, many of which did not even address the cessation hypothesis. The meta-analysis has been debunked.[46]

In conclusion, we concur with Warner's (2018)[17] overall synthesis of the evidence that uptake of cigarettes among adolescents is declining at an unprecedented rate, and even if vaping caused some never smoking adolescents to try smoking and even if some of those triers progress to daily and then to a

lifetime of smoking, then even a moderate rate of smoking cessation (see section on cessation below) still makes e-cigarettes a net public health benefit.[17]

3.2. Do E-Cigarettes Help Smoking Cessation or Reduction?

Randomized controlled trials (RCTs) and well-designed observational studies show that e-cigarettes can help some adult smokers to quit smoking[15,28,46,101–106] at rates similar to or higher than NRT.[107] Despite the increasingly positive evidence, a questionable meta-analysis[100] (including observational studies, with loosely-defined measures of exposure and outcomes, inability or failure to control for potential confounders or lacking use of adequate comparison groups), reported that use of e-cigarettes was associated with no change or negative correlations with smoking cessation. But the Cochrane Handbook cautions: "meta-analysis of studies that are at risk of bias may be seriously misleading. If bias is present in each (or some) of the individual studies, meta-analysis will simply compound the errors, and produce a 'wrong' result that may be interpreted as having more credibility"[108] (p. 247). In sharp contrast to this problematic meta-analysis, studies that take into account how and why e-cigarettes were used (e.g., frequency and duration of use, type of device, use specifically for cessation) suggest that daily vaping can facilitate quit attempts and cessation.[61–64] Newer tank, mod and pod systems that are more satisfying (sweet spot) may improve outcome efficacy.[109] Recent studies using large national US samples as well as the conclusions from Warner (2018) and the NASEM report[15–17,110] indicate that use of e-cigarettes is associated with smoking cessation and with a greater number of quit attempts than NRT.[65,111–114] Warner and Mendez (2018)[94] reported that in the UK,[115,116] e-cigarettes increased smoking cessation by at least 8% and in the US by at least 12% based on studies done by Zhu et. al (2017) and others.[46,111–113] The recent and more methodologically sound studies (see Villanti et. al for details)[46] seriously challenge and debunk the conclusions of the meta-analysis of Kalkhoran and Glantz (2016)[100] and the updated meta-analysis of Glantz and Bareham (2018).[117]

Concerns have been raised about persistent dual use (no smoking reduction or cessation, but continued use of both products) undermining cessation in those who might otherwise have quit.[100] The counterfactual case (what would the cessation rate among dual users have been if e-cigarettes had not existed) is impossible to directly determine, but many considerations mitigate concerns. Dual use even without appreciable reduction in smoking does not appear to increase biological markers of harm.[26,27] Surveys of e-cigarette users indicate that quitting cigarettes is their primary reason for use,[28] even among youth.[118]

In the years when e-cigarette use increased the most, quit attempts also increased.[119–122] Studies from the UK converge with US studies indicating e-cigarettes have increased quitting smoking over and above what would have otherwise been expected.[17,94,113,116,123] Some patterns of infrequent e-cigarette use or

even past use measured at one point in time may be (mistakenly) called “dual use” leading to overestimates of chronic dual use.[124] While “some-day” use of e-cigarettes is most common among smokers, the highest prevalence of daily e-cigarette use is seen among recent (<3 years) former smokers.[125]

Public Health England[15] provides details about heat-not-burn NNPs, compares systematic reviews and meta-analyses, and estimates an additional 20,000 smokers’ quitting is attributed to e-cigarettes. Other reasons for e-cigarettes and smoking cessation success include that: (a) dual use was common with some users switching almost immediately while others took months to years before switching completely; (b) people are trying various products (tank models) and different nicotine strengths – perhaps to find their individual “sweet spot” (Figure 2); and (c) over time, the use of e-cigarette flavors (fruit/beverage, dessert/pastry and candy/chocolate/sweets) are favored instead of their initial use of tobacco or menthol/mint flavors.[15,110,126]

As is the case with using FDA-approved NRTs while still smoking (as a reduce to quit strategy), dual use of e-cigarettes either for a short period or perhaps even for a longer period of several years duration may be necessary along with finding devices, nicotine delivery levels and satisfying flavors (the sweet spot) that help vapers along the path to complete smoking cessation and possibly prevents relapse.[127] There is a need to more precisely define and measure the frequency, intensity and duration of co-use at frequent time intervals[128] within the same individuals to understand different types of co-use behavior and avoid the generic and confusing term “dual use”. Differences between persistent dual users and eventual switchers are not fully understood. Longitudinal studies over several years of all possible product use states, including dual use and switching (Figure 3) are needed and assumptions of negative effects of dual use on public health are premature.[24,92]

In summary, the accumulating evidence does not support the contention that e-cigarettes either inhibit cessation or are undermining historical “tobacco control” cessation efforts. Rather, the stronger studies suggest e-cigarettes are increasing cessation rates and quit attempts over and above the historical rates by reaching a larger proportion of smokers.[15,112,113] Simulation models already reviewed above are consistent in showing that under all but the most implausible scenarios switching to safer NNPs results in net population benefits.[24,46,48,67,94,129]

4. Proactively Communicating Accurate, Evidence-based Information to the Public

Public education must ensure consumers of nicotine containing products are accurately informed about differential harms compared to deadly smoking (relative risk) and not simply compared to no use

(absolute risk).[24] A related need is to sharpen the language describing similarities and differences between combustible and noncombustible tobacco and NNPs along the harm continuum. Because nicotine is primarily derived from the tobacco plant, legal definitions of tobacco products in the US include all forms of tobacco-derived nicotine and conflate their harms. Legal contortions permit tobacco-derived nicotine in the form of nicotine replacement products to be classified as therapeutics while nicotine delivery products with similar, negligible risks are classified as consumer products, resulting in regulatory confusion. In the end, tobacco and nicotine product consumers are the most important victims of this lack of clarity.[48,49,130–133] The potential positive impact of e-cigarettes may have therefore been slowed by overstated claims of their harms.[47,48] Only 5.3% of Americans correctly believe e-cigarettes are "much less harmful" than cigarettes, 37% believe they are the same or worse than smoking, and 34% don't know.[134,135] Misperceptions of harms have increased in recent years.[48,135–137] Misinformation deprives individuals of the opportunity to take health-protective action and is deceptive to consumers.[48,131] Accurate public education is needed to communicate the importance of smoking cessation and nicotine's relative safety when de-coupled from smoke.[6]

5. Conclusions: Reaffirming Harm Minimization and Smoking Control as the New Tobacco Control

Charting a new course in tobacco control via harm reduction must be seriously considered. Innovations in technology and accelerating adoption of NNPs have taken the "tobacco control" community, policymakers and cigarette companies by storm and surprise.[10,24] In many other areas, technological advances transform behaviors at the population level. New products consistently, although not always predictably, make old ones obsolete. In light of NNPs, which themselves are undergoing transformation and evolution to minimize toxic exposures, the logic of smoking harm minimization is simple and compelling. As Michael Russell, a pioneering tobacco control scientist, put it, "People smoke for nicotine but they die from the tar."[138] The safest course is to stop smoking or, better, never to start. But a harm minimization framework recognizes that demanding the unrealistic and unrealized utopian dream (i.e., elimination of any and all consumer nicotine or tobacco products regardless of their relative harms and the related destruction of the entire tobacco and nicotine consumer product industry) actually undercuts the realistic benefits of pragmatism. When a harmful behavior cannot be eliminated, it is necessary to reduce its adverse health consequences to the greatest extent possible among any users of nicotine or tobacco containing consumer products.[10,23,30,130,139]

As stated several times, a critical organizing harm minimization principle is that policy, regulation, science and advocacy should be evidence-based and aligned proportional to the degree of product harm. The two-part regulatory scheme proposed for FDA should in spirit and in action place priority on ensuring accurate communication about the appeal, safety and quality for less harmful NNPs and speed

their approval with prudent but not overly burdensome product standards and approve their ability to make truthful claims that their products are substantially less harmful than inhaled smoke from combusting tobacco.[6]

The status quo, unfortunately, is now upside down. Staying the course now risks perpetuation of smoked tobacco, prolongs unnecessary excessive deaths and slows adoption of much less harmful NNPs. Harm minimization strategies have the potential to realign market forces and economic incentives for consumers and those manufacturers willing to responsibly make and market much less harmful NNPs to adult consumers.[10,53,70,140–142] Even if the minimal risk of harm to some youth who otherwise would not have smoked is marginally increased, such risks must be weighed against the substantial and immediate benefits of displacing smoking with safer nicotine products among both mostly those youth who will use tobacco anyway and any already smoking adults.[10,23,24,30,32,47,53,70,130,143]

The FDA's new comprehensive nicotine framework[6,24,144] acknowledges that there are now satisfying and enjoyable nicotine-containing products that are acceptable alternatives for adult smokers that these products could displace smoking.[10] Within a nicotine management reframing of strategy,[24] all industries that make and market different forms of nicotine products (e.g., pharmaceutical, e-cigarette, smokeless tobacco, and even the combusted tobacco makers –the so called "Big Tobacco" industry) can be politically and economically aligned with regulators, public health advocates, scientists and health care practice to speedily phase out smoked tobacco products.[24,145,146] Current and future smokers' lives are at stake.

A laser-like focus on making smoked tobacco products obsolete suggests the overall framework for the future is to focus policy, regulation, communication and practice ***on smoking control*** rather than on general tobacco control while discouraging use of any products by underage youth as much as possible.[10,24] The three-dimensional framework provides a road map to find the "sweet spot" to maximize the replacement of smoked tobacco with NNPs. The model of all the stocks and flows coupled with survey data and simulation modeling provides a basis for post market tracking of the impact of NNPs on the population. Harm minimization can complement traditional tobacco control strategies that are effective. Given tectonic changes in the product landscape, some of these strategies may remain effective, but others may now be more harmful than helpful to public health because by opposing harm reduction alternatives to deadly smoked tobacco one is inadvertently helping to perpetuate smoking rather than speeding the replacement of smoking with NNPs.[130] Opposing harm reduction in effect slows the speedy demise of using deadly smoked tobacco products. Going forward, both old and new strategies need to be carefully aligned using the paramount principle of having regulation, policy, advocacy and communications be proportional to the risk ratio of each class of tobacco or nicotine product. If most

smokers in the US switched within the next 10 years to NNPs, it is estimated that over 6 million premature deaths and 86 million lost life years would be averted.[24,147]

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Footnotes

DISCLOSURE STATEMENT

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The Relative Risks of Tobacco Products

On this page:

Significant progress has been made in reducing cigarette smoking in the United States through comprehensive, population-level strategies. However, more than 30 million U.S. adults still smoke cigarettes, and smoking remains the leading cause of premature disease and death nationwide.

FDA's Center for Tobacco Products (CTP) is committed to protecting the health of all people in the United States through a comprehensive approach to reduce the burden of tobacco use. This includes timely and evidence-based public health education that complements the agency's regulatory actions.

In addition to preventing youth initiation and promoting cessation among people who use tobacco products, CTP is working to educate adults who smoke about the relative risks of tobacco products.

What Is Meant by "Relative Risks" of Tobacco Products?

No tobacco product is safe. However, the health risks for different tobacco products exist on a spectrum, which is sometimes referred to as a "continuum of risk." Combusted, or smoked, tobacco products—such as cigarettes—are the most harmful type of tobacco product. Non-

combusted products—such as e-cigarettes and other smokeless tobacco products—generally have lower health risks than cigarettes and other combustible tobacco products.

Before introducing a new tobacco product (/tobacco-products/products-guidance-regulations/market-and-distribute-tobacco-product) to the U.S. market, a company must submit a marketing application to the FDA and receive authorization. FDA scientists evaluate these applications to determine whether the product meets the applicable statutory standards. Tobacco products that may be legally marketed in the United States are listed in FDA's Searchable Tobacco Products Database (https://www.accessdata.fda.gov/scripts/searchtobacco/).

Additionally, to market a tobacco product as a modified risk tobacco product (/tobacco-products/advertising-and-promotion/modified-risk-tobacco-products) (MRTP), a MRTP application must be submitted to the FDA. An MRTP order applies only to specific products, not an entire class of tobacco products. An MRTP application generally must demonstrate that the product will significantly reduce harm and the risk of tobacco-related disease to individual tobacco users and benefit the health of the population as a whole.

Are E-Cigarettes a Lower-Risk Alternative to Cigarettes?

While e-cigarettes can generally be a lower-risk alternative for adults who smoke cigarettes, the use of e-cigarettes is not risk-free. These products deliver harmful chemicals and contain nicotine, which is highly addictive. Moreover, given the harmful chemicals found in e-cigarettes, further high-quality research on both short- and long-term health outcomes is needed.

Given that there is no safe tobacco product, youth and adults who do not use tobacco products should not start using e-cigarettes.

For adults who smoke, switching completely from cigarettes to e-cigarettes may reduce exposure to many harmful chemicals (https://nap.nationalacademies.org/catalog/24952/public-health-consequences-of-e-cigarettes) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) found in cigarettes. However, it is important that they switch completely from cigarettes to e-cigarettes to get the full health benefit. Long periods of dual use of cigarettes and e-cigarettes can result in harms to health similar to, or in addition to, the harms from exclusive use of cigarettes.

To date, FDA has authorized 34 tobacco- and menthol-flavored e-cigarette products and devices (https://digitalmedia.hhs.gov/tobacco/print_materials/CTP-250?locale=en). These products have undergone rigorous scientific review, including toxicologic assessments, and have been found

by FDA to meet the statutory public health standard.

Are Nicotine Pouches a Lower-Risk Alternative to Cigarettes?

While nicotine pouches can generally be a lower-risk alternative for adults who smoke cigarettes, the use of nicotine pouches is not risk free. Nicotine pouches contain nicotine, which is highly addictive, and can deliver harmful chemicals.

Given that there is no safe tobacco product, youth and adults who do not use tobacco products should not start using nicotine pouches.

For adults who smoke, switching completely from cigarettes to nicotine pouches may reduce exposure to many harmful chemicals found in cigarettes. However, it is important that they switch completely from cigarettes to nicotine pouches to get the full health benefit.

To date, FDA has authorized 20 nicotine pouch products (/news-events/press-announcements/fda-authorizes-marketing-20-zyn-nicotine-pouch-products-after-extensive-scientific-review). These products have undergone rigorous scientific review, including toxicologic assessments, and have been found by FDA to meet the statutory public health standard.

What Options Are Available to Adults Who Smoke Cigarettes and Are Looking to Quit?

For adults who currently smoke cigarettes, fully quitting the use of all forms of tobacco products would most benefit their health. Evidence-based, FDA-approved medications (/consumers/consumer-updates/want-quit-smoking-fda-approved-and-fda-cleared-cessation-products-can-help)—including nicotine replacement therapy (NRT), bupropion, and varenicline—have been proven to be safe and effective. These approved medications, along with behavioral counseling, should be the first line of therapeutic treatment for adults seeking to quit smoking. Behavioral counseling and medication are independently effective and combining them increases the likelihood of cessation.

As part of its efforts to encourage quitting among adults, CTP has developed cessation education materials (https://digitalmedia.hhs.gov/tobacco/?locale=en) for a wide range of audiences. CTP also partners with the National Cancer Institute's smokefree.gov (https://smokefree.gov/), which provides quitting support to people who use tobacco products.

For adults who smoke and choose to switch to another tobacco product that isn't as harmful as a cigarette, it is important that they switch completely from cigarettes to get the full health benefit. Since there is no safe tobacco product, eventual abstinence from all tobacco products should be the end goal.

Why Is It Important for Adults Who Smoke to Understand the Relative Risks of Tobacco Products?

Many people who use tobacco products have misperceptions about the varying risks of tobacco products, which may prevent them from switching to a lower-risk alternative. Adults who smoke who fully switch from cigarettes to a lower-risk alternative can generally reduce their health risk and exposure to toxic and cancer-causing chemicals.

What Is CTP Doing to Educate Adults Who Smoke About the Relative Risks of Tobacco Products?

The concept of relative risk is complex, and it is important to ensure efforts to educate adults who smoke on this topic are evidence-based and likely to achieve desired outcomes, while also minimizing impact on unintended audiences, including youth.

CTP is continuing to build scientific knowledge through research to inform the development of educational strategies and approaches, including potential messaging. A priority of this research is identifying effective ways to reach intended audiences while minimizing the impact of any potential consequences on unintended audiences.

Studies are planned on messages related to the relative risks of tobacco products that include participation by adults who smoke, as well as research among health care providers in primary care settings who may play a key role in the delivery of potential messaging. For example, on August 21, 2024, NIH's National Cancer Institute (NCI) awarded a grant to Johns Hopkins University and University of Pennsylvania to support research for four FYs (2024-2027) (/tobacco-products/ctp-newsroom/funding-awarded-study-messaging-about-continuum-risk-tobacco-products). This research will investigate the effects of continuum of risk messaging on tobacco use behavior and other relevant outcomes among audiences for whom messaging could be potentially useful (i.e., adults who use combustible products) and on those for whom the messaging could have negative consequences (e.g., youth).

LOCAL NEWS

Undercover Study: Half Of California Tobacco And Vape Shops Don't ID Teens

CBS NEWS BAY AREA

June 24, 2019 / 9:56 AM PDT / CBS San Francisco

STANFORD (CBS SF / CNN) -- An undercover operation in California found that half of tobacco and vape shops failed to check IDs for teens purchasing e-cigarettes and other nicotine products, despite a state ...oducts to 21.

...stores without ID, instructing them to tell the truth about ... purchase vape products -- e-cigarettes or e-liquids with ...tore asked for ID and made a sale.

...d nicotine-containing products to the teens, according to ...urnal JAMA Pediatrics. Liquor stores, supermarkets and

pharmacies were significantly more likely to check for ID and less likely to make the illegal sales.

The research team, consisting of scientists from the California Department of Public Health and Stanford University, also found that vape and tobacco shops were more likely to sell teenagers vape products than traditional cigarettes.

• **ALSO READ:** San Francisco Moves Closer To Banning All E-Cigarette Sales Citywide

It's unclear why that's the case, but "one possibility may be that vape products cost more and they might have a higher profit margin for retailers, so the temptation is greater to sell," said Lisa Henriksen, a co-author of the study and a senior research scientist at the Stanford Prevention Research Center.

'Raising the age is not enough'

Anti-tobacco advocates say the research raises questions over recent efforts to raise the legal age for purchasing tobacco to 21, most recently championed by Senate Majority Leader Mitch McConnell.

The president of the Campaign for Tobacco-Free Kids, Matthew L. Myers, said the study "underscores the serious shortcomings of claims" from vape manufacturers that "the only solution needed for the youth e-[illegible]"

[illegible]cent years, with nearly 40% of 12th graders now saying [illegible]d last year. "Raising the age is not enough and won't work [illegible]g IDs of young purchasers," said Myers.

George Conley, president of the American Vaping Association, said that "due to California's recently enacted law raising the age to purchase tobacco and vaping products to 21, it is probable that those under 18 are less likely to successfully purchase than in the past, but retailers are still mistakenly selling products to adults between the ages of 18 and 21."

In June 2016, California raised its age limit for tobacco products to 21, and more than 98% of retailers were aware of the new age restriction seven months after it went into effect, according to a survey conducted by researchers at the California Department of Public Health.

Conley added that "no youth sales should ever be permitted" and said his group supports mandatory ID scanners at points of sale. The country's leading vape manufacturer, Juul Labs, has also advocated for "Tobacco 21" laws in digital, print and radio ads.

In a statement last week, after Connecticut raised the purchase age for tobacco and vape products to 21, Juul said the laws "fight one of the largest contributors to this problem: sharing by legal-age peers." The company also said it has its own secret-shopper program, targeting 2,000 stores a month to ensure age verification.

But Myers, whose group has long advocated for raising the legal age to purchase tobacco, says recent laws that do that -- such as those passed in Texas and Illinois -- don't go far enough. "It's critical to prohibit the flavored products that are enticing and addicting kids," he said.

Preventing teen access

Juul has considered opening private retail stores that would check customers' IDs at the door. The move came amid heightened scrutiny of the company, including a lawsuit from North Carolina's attorney general accusing the manufacturer of marketing products to children.

In September, the FDA announced that a "blitz" on retailers resulted in more than 1,300 warning letters and fines related to sales of Juuls and other e-cigarettes to minors. In November, the agency proposed a plan to limit flavored vape products to age-restricted, adult-only stores, such as vape shops.

"We need to commend the FDA for trying to solve the epidemic of youth vaping by restricting the retail environment for these products," said Henriksen, who co-authored the new study on IDs.

"What we're worried about," she said, "is concentrating sales in stores with the worst record [of age verification and illegal sales] without stepping up enforcement significantly."

More from CBS News

Man who died in Sonoma County after being swept by wave identified

6 rescued from San Francisco Bay after multiple sailboats capsize

Golden Gate Bridge tour introduces middle-school students to engineering

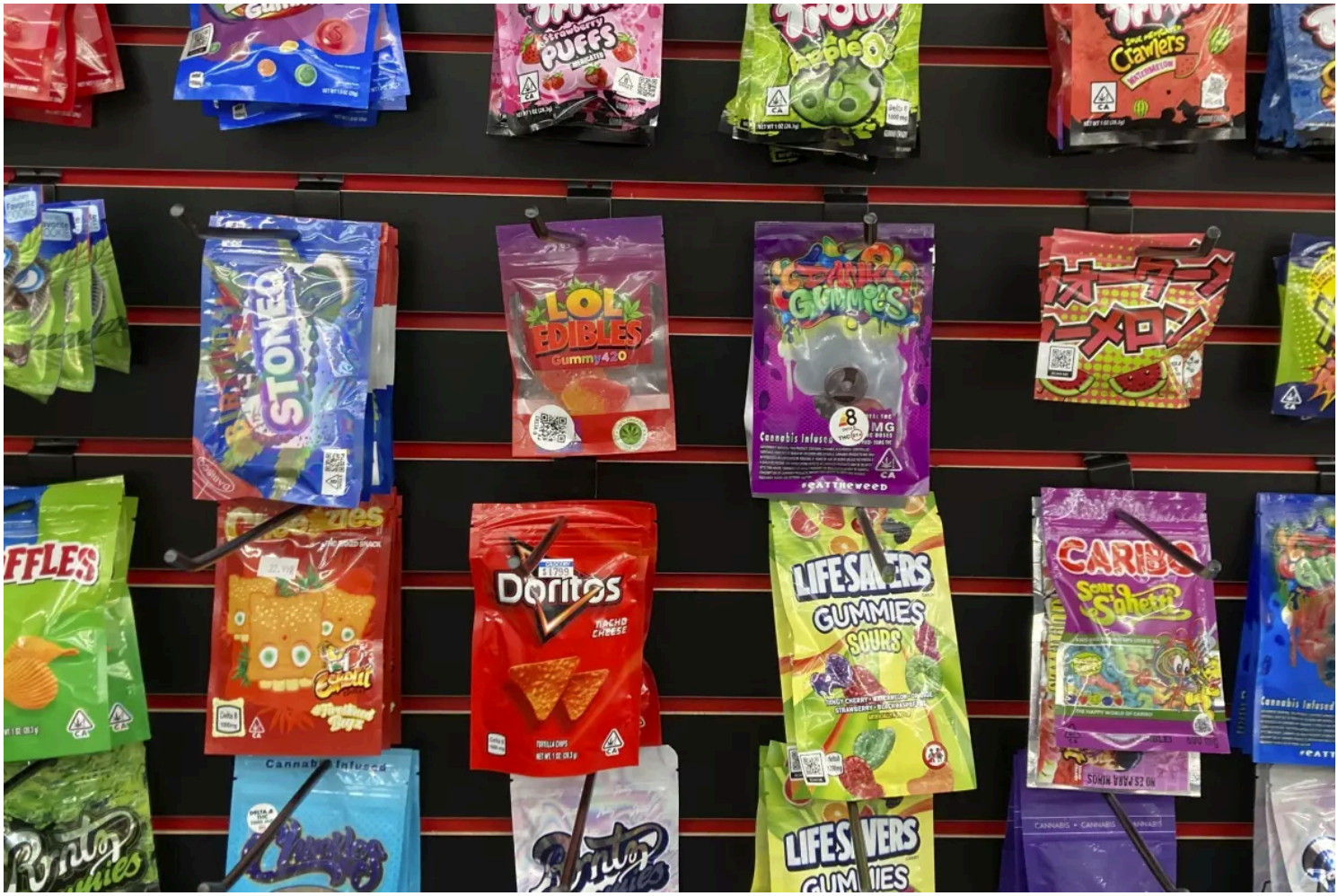
San Francisco leaders explore options as pharmacies struggle to stay open

In: E-Cigarettes

Los Angeles Times

BUSINESS

What to know about delta-8 and other common vape shop drugs



Products advertised as containing synthetically derived delta-8 THC are offered for sale at a smoke shop in north Seattle on Feb. 25, 2022. (Gene Johnson / Associated Press)

By Devi Shastri

Sept. 8, 2024 3 AM PT

They're sold in gas stations, vape shops, online and in other stores around the country in seemingly countless enticing forms: gummies, chocolate bars, chips. Their packaging lists things like delta-8 THC, micro- and macrodoses of "psychedelics" and "nootropics."

These substances are often sold through legal loopholes, despite concerns about potential health risks and a lack of oversight of how they're produced. And in the absence of federal rules, many states have banned or have tried to ban delta-8 THC.

Legal but underregulated drugs are easy to come by, but experts say there are still a lot of uncertainties. Here's what to know.

How are these substances legal?

Drug laws are often specific to the substance, so federal and state regulators are left chasing the newest chemical concoction.

Delta-8 THC exploded in popularity under the Agriculture Improvement Act of 2018, more commonly known as the Farm Bill. Under that law, hemp products and the cannabinoids that could be made from them were classified as distinct from marijuana.

Delta-8 has just a slight chemical tweak from the psychoactive delta-9 compound found in marijuana, but it can still get you high.

It remains in a legally ambiguous area with restrictions that vary state by state, said Robert Mikos, a marijuana policy and law expert at Vanderbilt University. Substances like cannabinoids are also easy to change into new but similar versions of drugs that may come under scrutiny.

"There's been all sorts of things that [have] cycled through popularity over time," he said. "And government enforcement is always one step behind what the chemists can come up with."

If it's on a store shelf though, it's safe, right?

Not necessarily.

Because of a lack of oversight of manufacturing processes and a lack of uniform labeling requirements, it's hard to know what exactly is in a particular product.

For example, the U.S. Food and Drug Administration began investigating illnesses earlier this year caused by recalled Diamond Shruumz products, which in addition to containing muscimol, a legal psychoactive compound from the Amanita muscaria mushroom, were found to contain other unlisted ingredients, including psilocin, a controlled substance.

It's hard to even know basic information about the potency of the drug in many of these products, said Dr. Ginger Nicol, who leads the psychedelics research program at Washington University in St. Louis.

And the concern isn't just limited to the drugs themselves: It extends to other things that could be introduced in the manufacturing process, said Dr. Igor Grant, director of UC San Diego's Center for Medicinal Cannabis Research.

He pointed to how delta-8 is made from CBD.

The chemical process to make delta-8 uses strong acids and more, Grant said, and if some of those other trace chemicals are left behind, they can pose health risks in addition to those already posed by delta-8 itself.

"If this was done by the Food and Drug Administration's standards where they have strong regulations about purity and all that, it'd probably be fine," he said. "But that's not how it's made."

What should you do?

Nicol suggested that people talk to their doctor before taking anything, especially if it's an unregulated drug.

That's in part because of the lack of rigorous research that could improve understanding of the drugs' effects, side effects and safety — and in part because there is so little oversight.

"You can get a bad batch," she said. "Nobody is necessarily testing it for purity or contamination."

Shastri writes for the Associated Press.

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March 3, 2025

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