S.B. 367 Act Concerning Electronic Nicotine Delivery Systems and Vapor Products

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My name is John Martin, Ph.D. I am Professor Emeritus of Psychology and a former Professor of Psychiatry at two major US medical schools. I am a licensed clinical psychologist specializing in addictions and health behavior change. As a clinician who has dedicated a career to smoking cessation and harm reduction, I am writing to express my concern over S.B. 37 a proposed nicotine cap on electronic nicotine delivery systems (ENDS).

As a principal research investigator, I have been awarded more than $4 million dollars in federal and state research grants on smoking assessment and treatment, some of which was cited in the Surgeon General Report on Nicotine Addiction. I have published approximately 70 scholarly articles, 20 book chapters, and two books in the areas of smoking behavior and treatment, alcohol abuse, and health behavior change. I was responsible for the largest clinical treatment program for recovering alcoholic smokers ever conducted, the findings of which were published in flagship psychology and addictions journals. My research group was among the first to address the question of compensation and smoking topography as it relates to treatment. We investigated the "puff topography" of smoking in both laboratories and real-world settings and developed the "brand fading" step-down approach, achieving our goals of both harm reduction and smoking cessation.

Based on my education, training, and experience, it is my opinion that S.B. 367, the proposed cap of nicotine-content for e-liquids to only 3 percent (35 mg/mL), will defeat the harm reduction benefits gained from users of higher nicotine concentration products. Because a large portion of e-cigarette users in Connecticut use products with nicotine concentrations greater than 3%, the potential risk of reversing public health gains is significant. The 3% cap will severely restrict the options available for those wanting to quit or reduce their risk. It will also remove a valuable tool for those of us working with smokers to stop smoking.

Reduction in health risk

I and other professionals who have worked in the "trenches" with some of the most dependent smokers have come to realize that a one-size-fits-all approach to quitting smoking and harm reduction does not work. There are tens of millions of adults who do *not* want to stop smoking. I encounter these smokers on a regular basis. For this population, switching from cigarettes to ENDS could significantly reduce their risk of disease and ultimately lead to complete cessation. There is a growing scientific consensus that e-cigarettes are substantially safer than combustible cigarettes. A recent study published in JAMA Network Open found Participants who switched exclusively to e-cigarettes containing 5% nicotine demonstrated significant reductions from baseline in NNAL (major metabolite of a tobacco specific carcinogen), carbon monoxide, and self-reported respiratory symptoms.[1] A 2021 study conducted by

[1] Pulvers K, Nollen NL, Rice M, Schmid CH, Qu K, Benowitz NL, Ahluwalia JS. Effect of Pod e-Cigarettes vs Cigarettes on Carcinogen Exposure Among African American and Latinx Smokers: A Randomized Clinical Trial. JAMA Netw Open. 2020 Nov 2;3(11):e2026324. doi: 10.1001/jamanetworkopen.2020.26324. PMID: 33206193; PMCID: PMC7675102.

some of the leading public health authorities in the field concluded that vaping reduces health risks, "possibly substantially". [2]

Smoking cessation tool

Smoking cessation can be a very complex and individualized process and we rely on a variety of tools and techniques to assist patients and smokers seeking treatment through our community clinics in quitting. ENDS have proven to be highly effective for harm reduction and is now the best tool for smoking cessation. A recent New England Journal of Medicine article concluded that e-cigarettes outperformed nicotine replacement products by a margin of 2 to 1.[3]

The benefits of electronic cigarettes rest upon their ability to replicate smoking, including the sensory aspects and the reduction of urges to smoke. Products that most closely mimic these qualities have an increased likelihood of being used repeatedly. If current users of higher nicotine products are forced to move to 3% products, they will likely experience urges to smoke and thus may return to smoking. Recent research bears this out. A 2020 abuse liability study showed that users of a 5% nicotine product experienced greater reductions in urge to smoke compared to users of a 3% nicotine product.[4]

Increase in health risk

Lowering nicotine concentration not only increases urge to smoke, it exposes users to greater levels of potential toxins. As demonstrated by 3 major recent randomized controlled studies, higher nicotine concentration products are associated with significant reductions in potential carcinogens compared to lower concentration devices.[5] Users of reduced nicotine products will take more or longer puffs to

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[2] Balfour DJK, Benowitz NL, Colby SM, et al. Balancing consideration of the risks and benefits of e-cigarettes. Am J Public Health. Published online ahead of print August 19, 2021: e1–e12 Acceptance Date: May 15, 2021. DOI: https://doi.org/10.2105/AJPH.2021.306416

[3] Hajek P, Phillips-Waller A, Przulj D, Pesola F, Myers Smith K, Bisal N, Li J, Parrott S, Sasieni P, Dawkins L, Ross L, Goniewicz M, Wu Q, McRobbie HJ. A Randomized Trial of E-Cigarettes versus Nicotine-Replacement Therapy. N Engl J Med. 2019 Feb 14;380(7):629-637. doi: 10.1056/NEJMoa1808779. Epub 2019 Jan 30. PMID: 30699054.

[4] Goldenson, N. et. al. Abuse Liability Assessment of JL Electronic Nicotine Delivery System (ENDS) in Two Nicotine Concentrations Compared to Usual Brand Cigarette, Nicotine Gum and a Comparator ENDS Late Breaking Oral Presentation at the 82nd Annual Scientific Meeting of the College on Problems of Drug Dependence June 22, 2020Late Breaking Oral Presentation at the 82nd Annual Scientific Meeting of the College on Problems of Drug Dependence.

[5] Cobb CO, Foulds J, Yen MS, Veldheer S, Lopez AA, Yingst JM, Bullen C, Kang L, Eissenberg T; Randomised Control Trial Methods Workgroup of the Center for the Study of Tobacco Products. Effect of an electronic nicotine delivery system with 0, 8, or 36 mg/mL liquid nicotine versus a cigarette substitute on tobacco-related toxicant exposure: a four-arm, parallel-group, randomised, controlled trial. Lancet Respir Med. 2021 Apr 12:S2213-2600(21)00022-9. doi: 10.1016/S2213-2600(21)00022-9. Epub ahead of print. PMID: 33857436.

Kosmider L, Cox S, Zaciera M, Kurek J, Goniewicz ML, McRobbie H, Kimber C, Dawkins L. Daily exposure to formaldehyde and acetaldehyde and potential health risk associated with use of high and low nicotine e-liquid concentrations. Sci Rep. 2020 Apr 16;10(1):6546. doi: 10.1038/s41598-020-63292-1. PMID: 32300142; PMCID: PMC7162853.

achieve their desired level of nicotine thus defeating the harm reduction benefits of e-cigarettes. As concluded in one of those studies, published in Lancet, "[f]uture ENDS trials should involve products with well characterised nicotine delivery, including those with nicotine delivery approaching that of a cigarette."[6] That same study found that those using the higher nicotine product smoked fewer cigarettes per day compared to users of the lower nicotine product.[7]

Reactance effect

As an addiction specialist who has conducted research and clinical interventions with alcoholics as well as smokers, I am also concerned that there may be an effect from this legislation that will run counter to its intended purpose. Most people, including smokers, may likely experience an opposite reaction, including resentment at being denied their own free choice regarding whether or which ENDS products they are permitted to use. For example, a large body of research from the fields of addiction and health behavior change demonstrates that prohibitions, threats and fear communications produce negative effects.[8] Confrontation leads to equal or greater levels of resistance. Two major meta-

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Risa J. Robinson & Edward C. Hensel (2019) Behavior-based yield for electronic cigarette users of different strength eliquids based on natural environment topography, Inhalation Toxicology, 31:13-14, 484-491, DOI: 10.1080/08958378.2020.1718804

[6] Cobb CO, Foulds J, Yen MS, Veldheer S, Lopez AA, Yingst JM, Bullen C, Kang L, Eissenberg T; Randomised Control Trial Methods Workgroup of the Center for the Study of Tobacco Products. Effect of an electronic nicotine delivery system with 0, 8, or 36 mg/mL liquid nicotine versus a cigarette substitute on tobacco-related toxicant exposure: a four-arm, parallel-group, randomised, controlled trial. Lancet Respir Med. 2021 Apr 12:S2213-2600(21)00022-9. doi: 10.1016/S2213-2600(21)00022-9. Epub ahead of print. PMID: 33857436.

[7] *Ibid.*

[8] Leventhal, H. Findings and Theory in the Study of Fear Communications[1]Advances in Experimental Social Psychology Volume 5, 1970, Pages 119-186; Keller PA., Lehmann DR Designing Effective Health Communications: A Meta-Analysis Jr of public policy and marketing, vol 27 (2) fall, 2008 117-130; Patterson GR., Forgatch MS (1985). Therapist behavior as a determinant for client noncompliance: A paradox for the behavior modifier. *Journal of Consulting and Clinical Psychology, 53*(6), 846-851; Glynn, L. H., & Moyers, T. B. (2010). Chasing change talk: The clinician's role in evoking client language about change. *Journal of Substance Abuse Treatment, 39*(1), 65-70; Leffingwell T.R., Neumann C, Leedy M.J., Babitzke A.C. Defensively biased responding to risk information among alcohol-using college students, *Addictive Behaviors 32* (2007) 158 – 165; Neto A, Understanding Motivational Interviewing: An Evolutionary Perspective Evolutionary Psychological Science, 2017; Steindl, C., Jonas, E., Sittenthaler, S., Traut-Mattausch, E., & Greenberg, J. (2015) Understanding psychological reactance: New developments and findings *Zeitschrift für Psychologie, 223*, 205-214; Peters G.J.Y., Ruiter R.A.C, Kok G Threatening communication: a critical re-analysis and a revised meta-analytic test of fear appeal theory Health Psychology Review, 2013 Vol. 7, Supplement 1, S8ÁS31, http://dx.doi.org/10.1080/17437199.2012.703527; Rains, S. A. (2013). The nature of psychological reactance revisited: A meta-analytic review. *Human Communication Research, 39*(1), 47-73; Rains, S. A. (2013). The nature of psychological reactance revisited: A meta-analytic review. *Human Communication Research, 39*(1), 47-73; Karno, M. P., & Longabaugh, R. (2005) An examination of how therapist directiveness interacts with patient anger and reactance to predict alcohol use. *Journal of Studies on Alcohol, 66*, 825-832; Miller, W.R. (2017) Taking the Lower Place: Motivational Interviewing and Social Dominance, the Malahide forum.

analyses (White & Allen, 2000) found that confrontational approaches to behavior change produced a negative reactance effect not only cognitively (dissonance), and emotionally (anger) but also, and especially behaviorally (oppositional behavior).[9] In alcohol abuse treatment, for one, it was found that the more adversarial and controlling the clinician was with their clients, the less likely the clients would change in their drinking behavior (Miller et al., 1993)[10] – a reaction that would be expected with smokers denied or restricted in their e-cigarette choices and preferences.

FDA currently evaluating

Finally, it should also be noted that the FDA is already reviewing all vapor products and will evaluate whether products at differing nicotine levels are appropriate for public health. FDA is in the best position to create efficient regulatory pathways for noncombustible tobacco products that pose substantially less risk to individual users. Respectfully, it is my opinion that this legislation may undermine that process of achieving tobacco harm reduction.

Harming harm reduction

Ultimately, and most probably, the proposed nicotine cap will result in "harming harm reduction" - in the attempts my colleagues and I include in our treatment of smokers - through decreased switching from combustible cigarettes to the safer ENDS products. By doing so, it is my opinion that capping nicotine will ultimately reverse the strong gains made in tobacco harm reduction. The question must be asked: by capping nicotine concentrations, will we be unintentionally violating the "do no harm" oath that physicians (and by proxy healthcare providers overall) adhere to?

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[9] Witte K, Allen M A Meta-Analysis of Fear Appeals: Implications for Effective Public Health Campaigns *Health Educ Behav* 2000; 27; 591

[10] Miller, W.R.; Benefield, R.G.; Tonigan, J.S. Enhancing motivation for change in problem drinking: A controlled comparison of two therapist styles. Journal of Consulting and Clinical Psychology 61(3):455–461, 1993.