Nicotine & Tobacco Research Advance Access published April 19, 2016

Title: What Drives Tobacco Control Policy?

Author:
Joel L. Nitzkin, MD
Principal Consultant
JLN, MD Associates, LLC
4039 Chestnut Street
New Orleans, LA 70115-2941
Phone: 504 899 7893
Fax: 504 899 7557
jlnitzkin@gmail.com

Dr. Nitzkin is the sole author and corresponding author

Accepted Manuscript

Downloaded from http://ntr.oxfordjournals.org/ by guest on April 20, 2016

© The Author 2016. Published by Oxford University Press on behalf of the Society for Research on Nicotine and Tobacco.
This is an Open Access article distributed under the terms of the Creative Commons Attribution-NonCommercial-NoDerivs licence (http://creativecommons.org/licenses/by-nc-nd/3.0/), which permits non-commercial reproduction and distribution of the work, in any medium, provided the original work is not altered or transformed in any way, and that the work is properly cited. For commercial re-use, please contact journals.permissions@oup.com

This is a follow-up to the presentation by Dr. David Ashley of the FDA's Center for Tobacco Products (CTP) at the March 2016 meeting of the Society for Research on Nicotine and Tobacco (SRNT). He shared serious doubts about whether Swedish Match should be granted Modified Risk Tobacco Product (MRTP) status for eight snus products.[1]

As published in *Nicotine and Tobacco Research* (NTR),[2] and re-emphasized at the SRNT meeting, the FDA claims to be committed to a science-based regulatory agenda, rather than one based on political or special-interest concerns.

Some question this FDA claim.

It makes little sense to impose little or no regulatory burden on cigarettes currently on the market while attempting to remove far-lower-risk and less-addictive e-cigarettes and related vapor devices (e-cigs) from the market, and hesitating to grant Swedish Match's snus products MRTP status. It makes even less sense to deal with pharmaceutical nicotine products (patches, gums, etc.) as if they have no nicotine.

A major problem with the FDA Tobacco Law relates to the requirement that the manufacturer of a new or reduced risk product document that it will not harm non-users of the product (i.e. will not recruit non-users to nicotine addiction). Unfortunately, FDA's interpretation of this wording imposes a cost burden so substantial that, if unchanged, it will eliminate all of the smaller companies and all of the customizable products from the e-cig marketplace.[3]

Accepted Manuscript

Downloaded from http://ntr.oxfordjournals.org/ by guest on April 20, 2016

One might expect that advertising a product as lower-risk than cigarettes might recruit non-smoking teens to nicotine addiction. Recent experience with e-cigs in both the United Kingdom and the United States provides convincing evidence that such advertising, while it may recruit some to product experimentation, will recruit very few to continuing use, while attracting large numbers of teen smokers away from cigarettes.[4-6] Allowing e-cig manufacturers to reference this class-of product experience to satisfy the harm-to-non-users provision of the law would eliminate a currently proposed unbearable cost burden.

If FDA determines it does not have the administrative flexibility to re-interpret this provision of the law, public health authorities could urge congressional action to amend it.

The cigarette is the most addictive and hazardous tobacco product, and the dominant nicotine-delivery product in the United States. All of the commonly quoted American data on tobacco-related illness and death relate to this one product.[7] Despite public statements to the contrary, snus and the other smokeless products that have been widely available on the American market for a very long time show no measurable increase in risk of any potentially fatal tobacco-attributable illness.[8,9]

Thus, a good case can be made for serious consideration of adding a tobacco harm reduction (THR) component to current tobacco-control programming. Such an initiative would publicly compare the risks of e-cigs and other smokeless products to cigarettes. This would encourage smokers who are unable or unwilling to quit to switch to a lower-risk product. As seen by this author, THR would likely yield reductions in tobacco-

Accepted Manuscript

Downloaded from http://ntr.oxfordjournals.org/ by guest on April 20, 2016

related illness and death not otherwise achievable, and do so while continuing to reduce teen recruitment to nicotine addiction.

Beliefs that underlie the FDA's refusal to consider tobacco harm reduction appear to include the following:

1. Non-pharmaceutical nicotine products are considered to have harms, but no benefits. Thus, evidence that self-administered nicotine offers cognitive/behavioral benefits for persons with schizophrenia, depression and bipolar disorder has not been considered. With no consideration of potential benefits, endorsement of low-risk products as substitutes for cigarettes is not on the tobacco-policy table for discussion.
2. Tobacco use is considered a disease, not a behavior. Study designs appropriate to address long-term behavioral change are not considered. This, too, rules out consideration of low-risk products as substitutes for cigarettes.
3. The primary determinant of risk is considered to be the chemical composition of the product. This belief contradicts the fact that it is the class of tobacco product, whether combusted or smoke-free, that determines both its addictiveness and its risk of potentially fatal tobacco-attributable illness. This belief imposes requirements for unnecessarily detailed product-specific chemical analyses and population studies if a manufacturer is to seek approval for a new product or request MRTP status. These are regulatory burdens not placed on the major cigarette brands.
4. Pharmaceutical nicotine-delivery products (patches, gums, etc.) are treated by the FDA as if they have no nicotine. These are the nicotine products most accessible to minors. They are sold on open shelves in a variety of candy and fruit flavors without enforcement of age restrictions. They are approved for unlimited use as to dose and

Accepted Manuscript

Downloaded from http://ntr.oxfordjournals.org/ by guest on April 20, 2016

duration, for simultaneous use of multiple products and for use by those who continue to smoke. They are advertised on television. Tobacco-related surveillance systems do not track use of these products.

Despite the absence of combustion and tar, the low concentration of the other toxins in cigarette smoke, and e-cigs' failure to recruit non-smoking teens to continuing nicotine use, proposed deeming regulations address e-cigs as if they are as hazardous and addictive as tobacco cigarettes. Despite evidence to the contrary,[4,11] public-health authorities continue to allege that these products increase teen cigarette use.[6]

A science-based regulatory agenda would not remove low-risk products from the market by imposing unbearable regulatory costs. It would seriously consider and fund research into possible benefits of low risk products, consider feasible approaches to tobacco harm reduction, and refrain from misleading public statements.

References

1. Ashley DL. How science informs FDA's regulatory decisions: Deeming, PMTA and MRTPA. In: *Special Symposium*. Chicago, Ill. 2/March; 2016. Society for Research on Nicotine and Tobacco, 2016 Program.
2. Ashley DL, Backinger CL, van Bemmel DM, Neveleff DJ. Tobacco regulatory science: Research to inform regulatory action at the Food and Drug Administration's Center for Tobacco Products. *Nicotine Tob Res*. 2014;16(8) (August):1045-1049.
3. Mickle T. FDA Cloud Hangs Over Vape Shops. *The Wall St J*. 2015 7 July.
4. Centers for Disease Control and Prevention. National Youth Tobacco Survey; 2015. November 11, 2015.
5. McNeill A, Brose L, Calder R, Hitchman S. *E-cigarettes: An Evidence Update Plus Policy Implications*. *A report commissioned by Public Health England.* London, England. August; 2015. Public Health England. 19 August 2015.
6. Sandman PM. A promising candidate for most dangerously dishonest public health news release of the year. The Peter Sandman Risk Communication Website; 2015. 13 August 2015.

Accepted Manuscript

Downloaded from http://ntr.oxfordjournals.org/ by guest on April 20, 2016

7. Office of the Surgeon General U. *The Health Consequences of Smoking - 50 Years of Progress*; 2014.
8. Rodu B. The Scientific Foundation for Tobacco Harm Reduction, 2006-2011. *Harm Reduct J*. 2011;8(19):8-19.
9. Lee P. Epidemiologic Evidence relating snus to health - an updated review based on recent publications. *Harm Reduc J*. 2013;10(36) (6/Dec).
10. Fucito L.M., Bars M, Forray A et al. Writing Committee for the SRNT Policy and Treatment Networks. Addressing the evidence for FDA nicotine replacement therapy label changes: a policy statement of the Association for the Treatment of Tobacco use and Dependence and the Society for Research on Nicotine and Tobacco. *Nicotine Tob Res*. 2014;7 (16, Jul):909-14.
11. Johnston LO PM, Bachman J, Schulenberg J. Teen smoking continues to decline in 2013. In: *Monitoring the Future*. http://monitoringthefuture.org/pressreleases/13cigpr_complete.pdf University of Michigan. 17 Jan 2014.

Accepted Manuscript

Downloaded from http://ntr.oxfordjournals.org/ by guest on April 20, 2016