House Federal and State Affairs Committee

Kansas State Legislature

Thursday, April 26, 2012

Hearing on HR No. 6026 – Tobacco Harm Reduction

Barriers to Tobacco Harm Reduction

A Statement in Favor of this House Resolution by

Joel L. Nitzkin, MD, MPH, DPA

Principal Consultant, JLN, MD Associates, LLC

4939 Chestnut Street, New Orleans, LA 70115-2941

Phone: 504 899 7893; Fax: 504 899 7557; Email: jln@jln-md.com

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Verbal Presentation

Personal Introduction:

Mr. Chairman and members of the committee, I am Dr. Joel Nitzkin. I am a physician, board certified in Preventive Medicine, as my medical specialty. I have been a local health director, state health director, and President of two national public health associations. Since the mid-1990's I have been in the private practice of public health as a policy consultant.

I have been involved in tobacco control since the 1970's. The story that brings me to this hearing, today began in February of 2007 when the FDA Tobacco bill was introduced into Congress. At that time I was serving as co-chair of the Tobacco Control Task Force of the American Association of Public Health Physicians. In response to what we saw as flaws in that bill, our AAPHP Task Force did extensive networking within the public health community and an independent review of the tobacco control literature. We did this to determine the best possible approach to reducing tobacco-attributable illness, death, and property damage in the USA. It was this networking and review that drew our attention to tobacco harm reduction.

Our research, since that time, led us to the conclusion that **a well-coordinated tobacco harm reduction initiative, added to current tobacco control programming, could save the lives of 4 million of the 8 million current adult American Smokers who will otherwise die of a tobacco related illness over the next twenty years.** The two actions needed to secure this public health benefit are 1) to actively promote cold-turkey quitting and 2) to inform smokers who are unable or unwilling to quit, that they could reduce their future risk of tobacco related illness by 98% or better by switching to one of a number of much-lower-risk smokeless tobacco products or E-cigarettes. **Such a tobacco harm reduction initiative could be done at**

remarkably low cost without decreasing quit rates and without increasing the numbers of teens initiating tobacco use.

Back to Basics: How Tobacco Causes Illness and Death

For a toxin or bacterium to cause illness, three things must be present. The first is the Host – the person at risk of illness. The second is the Agent – the chemical or bacterium capable of causing illness. The third is the Environment that enables the agent to enter the host in a way that will result in illness and possible death.

We have no idea as to which of the toxins, or what combination of toxins in cigarette smoke, cause the cancer and lung disease and much of the heart disease. What we do know is that, in the USA, 400,000 deaths per year in cigarette smokers, and 40,000 deaths in non-smokers are due to exposure to cigarette smoke. We also know **that the risk of potentially fatal illness posed by smoke-free tobacco/nicotine products currently on the American market is less than 2% the risk posed by cigarettes.** This means that the key factor in causing illness is not the chemical profile of the tobacco product, but the means by which the Host is exposed. **Our problem is not "tobacco." Our problem is cigarette smoke.**

Tobacco harm reduction is based on this simple observation. If an American smoker switches to a smoke-free tobacco product, he or she can eventually cut his or her risk of potentially fatal tobacco-attributable illness by more than 98%.

Barriers to Tobacco Harm Reduction in the USA

For more than half a century, the goal of American tobacco control programming has been a "Tobacco Free Society." This goal was based on the erroneous presumption that all tobacco products presented the same high risk of illness and death. This presumption was augmented by the egregiously irresponsible behavior of major cigarette companies in their predatory marketing

of cigarettes to teens while lying about both the addictiveness of nicotine and the risk of illness posed by cigarettes.

This, in turn, has resulted in a mindset in the medical and public health communities that rules out any consideration of non-pharmaceutical tobacco products as part of any public health initiative. In other words, **if you, as a legislator, approach a doctor or public health professional to talk about tobacco harm reduction, you can anticipate a response ranging from skepticism to outright hostility.**

The usual reasons given for objecting to even discussing tobacco harm reduction are lack of proof, the perceived risk of mouth cancer, dual use as an increase in harm, guestimated reductions in quit rates and guestimated increases in the numbers of teens initiating tobacco use. Since this is much more than I can cover in this brief verbal presentation, I have formatted my handout as a resource kit for each of you. **This handout material presents these and other objections in terms of the case why these should not block either discussion or implementation of a tobacco harm reduction initiative. If and when a physician or other public health professional expresses one of these objections, you can request that they respond to the information and bibliographic references in this resource material. In addition, both Dr. Rodu and I stand ready to discuss any and all of these issues with anyone wishing to learn more.**

Conflict of Interest Statement

Neither I, nor AAPHP has ever received any financial support for any of the work we have done in the tobacco control arena. This work has been done on a voluntary basis. I am indebted to the Heartland Institute for the travel funds that have made it possible for me to participate in this legislative hearing. My relationship with the Heartland Institute is that of a Senior Fellow in

Tobacco Control, with no payment for my time and participation, and no input by the Institute relative to my verbal or written presentation.

Resource Material

Differences in Risk, Comparing Smoke-Free Tobacco Products to Cigarettes

The evidence that smoke-free products pose substantially less risk of death than cigarettes is based on studies done in the United States and Scandinavia. American risk data relative to smoke-free tobacco products, dating from the mid-1980's, reflect risks posed by **chewing tobacco and moist snuff**, with Scandinavian data mainly based on **Swedish snus**.[1-11]

Dissolvables (sticks, strips, orbs and lozenges) and E-cigarettes have only been on the market a few years, so there are no long-term epidemiologic studies documenting their impact on tobacco-attributable illness or death. These are included as low-risk alternatives to cigarettes because of their physical and chemical similarities to snus and the NRT products.

Smoke-free products that are low-risk alternatives to cigarettes also include **pharmaceutical nicotine replacement therapy (NRT) products** (gum, lozenges, patches etc) when used on a long term basis. It is important to note that none of the NRT products have been approved by FDA for long term use.

Relatively little data on long term risk are available for **pipes, cigars, hookahs** and other combustible products. Given that they all involve inhalation of products of combustion; they are not recommended for tobacco harm reduction (THR) because they are expected to confer risks substantially higher than the smoke-free options. In hookahs, also known as shishas or water pipes, charcoal is burned, with the hot smoke being drawn through flavored tobacco and water. Charcoal fumes have excessive carbon monoxide and a wide range of carcinogens and other toxins.

Many still believe that smokeless products currently on the American and Scandinavian markets present a risk of **oropharyngeal cancer** far in excess of the risk posed by cigarettes. This belief is incorrect. This issue was dealt with in a definitive manner in a review of 62 US and 18 Scandinavian studies by Lee and Hamling in 2009.[5] A minimally elevated risk of oropharyngeal cancer was evident in American epidemiologic studies prior to 1990, but not in more recent American or any Scandinavian studies. Smoking and alcohol consumption are the major risk factors for oropharyngeal cancer. More recent studies with better control for these confounders have concluded that the risk of oropharyngeal cancer posed by smokeless products is minimal to nonexistent.

The question of the **cardiovascular risk** posed by smokeless tobacco products was explored in a 2009 review by Piano et al.[9] This review found that smokeless tobacco users experience little or no excess cardiovascular mortality when compared to non-tobacco users.

Older reviews estimated that the risk posed by smokeless tobacco products is less than 10% of the risk posed by cigarettes, and possibly, less than 1%.[1-4] More recent reviews[5-11] provide relative risks for cancer and cardiovascular diseases that are in the extreme lower end of this range. **While smokeless tobacco products pose unacceptable cancer risk according to toxicological assessments.[12] such risk has not been borne out in epidemiologic studies.**

Thus, in both absolute and relative terms, smoke-free tobacco/nicotine products in the United States and Scandinavia present a remarkably small risk of cancer and cardiovascular disease, no perceptible risk of lung cancer or other lung disease, and no risk to non-users.

Risk Posed by Smokeless Tobacco Products in the USA

While much lower in risk than cigarettes, no tobacco or nicotine product is risk free. Thus, the term "harm reduction." If the current 46 million American smokers had been using smoke-free tobacco products instead of cigarettes, we would likely be seeing **between 800 and 8,000 tobacco-attributable deaths per year** among tobacco users, **instead of the current 440,000.** Eight hundred to 8,000 preventable deaths per year are much better than 440,000; but they would still constitute a significant public health problem. The smoke-free products that presented a significant risk of mouth cancer in the USA, prior to the 1980's are no longer on the market.

Risk Posed by Smokeless Tobacco Products in Asia

International data showing a high risk of mouth cancer from smoke-free tobacco products are based on highly contaminated and crudely made tobacco products widely used in Asia, Selected smokeless tobacco products, popular in Asia, pose high risks of oropharyngeal cancer. This risk is probably related to high concentration of contaminants or to ingredients other than the tobacco.[13] Since these products are not generally available in the United States, the risks they pose are not considered in this study.

Misleading Warnings Mandated for Smokeless Tobacco Products in the USA

The perception that smokeless products present the same risk as cigarettes is amplified by the misleading warnings currently mandated for smokeless tobacco products. These four warnings date from the early 1980's, and were written into the 2009 FDA tobacco law.

1. "not a safe alternative to cigarettes:" This warning has left more than 80% of smokers with the erroneous impression that smokeless products present the same risk of potentially fatal illness as cigarettes.
2. "mouth cancer" – risk is so low as to be barely detectable.
3. "tooth and gum disease" – risk is for relatively minor abnormalities, much of which will resolve after discontinuing use of the tobacco product.
4. "addictive" – this is the only accurate warning.

Thus, if one is to promote smoke-free tobacco products as an alternative to smoking – one must point out the misleading nature of three of the four mandated warnings on smokeless tobacco products.

Dual Use

Many opponents of tobacco harm reduction oppose THR on the basis that smokers will simply add smokeless tobacco use to their current cigarette use, and not reduce their use of cigarettes. This, in turn, is based on the marketing of smokeless products that encourages their use in places where smoking is prohibited. Data available to date suggest that dual use is a natural transition state between cigarette smoking and abstinence from cigarettes. The one reasonably comprehensive study to explore this issue showed that dual users smoke fewer cigarettes than exclusive smokers.[14]

Reduced Quit Rates:

Getting current smokers to quit has been a mainstay of tobacco control programming in the United States for more than a half-century. Results have been disappointing. Annual quit rates hover around 3% per year. Available pharmaceutical therapies only increase these rates to about 7%, when abstinence is measured six to twelve months after completion of therapy.[15] In other words, currently available cessation therapies fail 93% of smokers who use them as directed.

Rodu and Phillips,[16] utilized American 2000 National Health Interview Survey data to compare smokeless tobacco to NRT products as an aide to quitting cigarettes. They found that smokeless tobacco had the highest proportion of success (73%), compared to 0% to 35% for the various NRT products.

Using a one-year follow-up to the American 2002 Tobacco Use Supplement to the Current Population Survey, Zhu et al[17] found that "men quit smokeless tobacco at three times the rate of quitting cigarettes (38.8% vs. 11.6%; $p<0.001$)." These findings are not unexpected, given the perception that, addiction to cigarettes is substantially enhanced by habituation to the cigarette-handling ritual.[18-20] and the emotional appeal of advertising themes.

Thus, THR could substantially increase cigarette quit rates without adversely impacting overall tobacco/nicotine quit rates.

Increased Numbers of Teens Initiating tobacco/nicotine use

Critics of THR believe that it will lead to increased teenage smokeless tobacco use, which will function as a "gateway" to smoking.[21] However, there is no evidence for this in Sweden, where smokeless tobacco use has been high for many decades. A 2008 study of 3,000 adolescents from the Stockholm area by Galanti et al. found that "the majority of tobacco users (70%) started by smoking cigarettes" and "the proportion of adolescent smoking prevalence attributable to a potential induction effect of snus is likely small."[22] That same year the European Commission's Scientific Committee on Emerging and Newly Identified Health Risks concluded that "The Swedish data...do not support the hypothesis that...snus is a gateway to future smoking."[23]

In the U.S. teenagers who use smokeless tobacco are more likely than non-users to subsequently smoke.[24,25] However, other American studies have concluded that smokeless tobacco is not a gateway to smoking among teenagers.[26-28] O'Connor et al. commented that "Continued evasion of the [harm reduction] issue based on claims that smokeless tobacco can cause smoking seems, to us, to be an unethical violation of the human right to honest, health-relevant information."[27]

The major benefits of smoking, as seen by teens, include a rite of passage to adulthood – a way to "be grown up," a way to be popular, glamorous, sexy, charming, tough, independent, and strong; and a way to feel at ease in a group or crowd.[29] These themes are unlikely to apply to smoke-free products which are less visible to others while in use. They also seem unlikely to apply to the e-cigarettes which teens are likely to see as imitation cigarettes.

Thus a well-managed THR initiative is not likely to attract teens or others who would not have initiated tobacco use.

Lack of Proof

The final major reason that opponents of THR refuse to even consider a THR initiative that would promote use of non-pharmaceutical smokeless tobacco products is lack of proof that such an initiative would yield substantial public health benefits and could be done in a way that would not decrease quit rates or increase teen initiation rates. In this context, "proof" is taken to mean demonstration of safety and efficacy by means of a **randomized placebo-controlled clinical trial**. The problem here is that such a trial would be **ethically impermissible** and would be **physically impossible** to conduct. First, it would be ethically impermissible to require that those randomized to the "control" arm of the study smoke cigarettes. This is because we know that such smoking will cause serious illness and death in that cohort. Second, placebo control will be impossible because the subjects and investigators will know the arm of the study for each subject. Third, the study-assigned behaviors would have to be maintained for 15-20 years, the "incubation period" for onset of the potentially fatal cancer heart and lung diseases that would be the objective of this study. Finally, prevention of decreasing quit rates or increasing teen initiation rates would require participation by both governmental authorities and voluntary health organizations to control vendor advertising and to provide supplemental health education messages.

This last point requires further discussion. Advertising a tobacco product as 98% less hazardous than cigarettes would likely tobacco quit rates and increase teen initiation rates, in the absence of countervailing measures. This is where participation by both governmental authorities and voluntary health organizations comes in. The countervailing health education and strict control of advertising content cannot reasonably be done by the tobacco companies. Effective health education relating to the harms of nicotine addiction and the residual cancer and heart disease should be able to prevent the unwanted changes in quit and initiation rates.

In other words, for THR to be implemented as a public health initiative, federal authorities will have to reconsider what they will or will not accept as "proof," and public health authorities will have to actively participate in the program.

Next Steps

Next steps seem clear.

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1. First, we need public health authorities to become familiar with the literature on THR, as reviewed herein, so that a decision can be made as to whether the potential benefits of THR warrant serious consideration as a potential public health initiative.
2. Then we will need to consider the respective roles of public and private sectors in such an initiative and how we can best work together to improve the health of the American people.

Bibliographic References

The literature reviews that lead Dr. Nitzkin to the conclusions noted above are posted on the Tobacco page of the AAPHP web site at www.aaphp.org/tobacco. This page is open to the public, without fee or registration.

1. Royal College of Physicians of London, 2002, *Protecting Smokers, Saving Lives* <<http://www.rcplondon.ac.uk/pubs/books/protsmokers/index.asp> London> (Accessed 6 January 2009).
2. Levy D, Mumford E, Cummings K, et al. The relative risks of a low-nitrosamine smokeless tobacco product compared with smoking cigarettes; estimates of a panel of experts. Cancer Epidemiol Biomarkers Prev 2004;13:2035-42.
3. Phillips C, Sargent C, Rabiu D, Rodu B. Calculating the comparative mortality risk from smokeless tobacco vs. smoking. Am J Epidemiol 2006;163(S189).
4. Nitzkin JL, Rodu B, 2008, 26 October, *AAPHP Resolution and White Paper: The Case for Harm Reduction for Control of Tobacco-Related Illness and Death*, in AAPHP Tobacco Issues <http://www.aaphp.org/special/joelstobac/20081026HarmReductionResolutionAsPassed1.pdf> (Accessed 3 August 2010).
5. Lee PN, Hamlin J, 2009, 29 July, *Systematic Review of the Relation Between Smokeless Tobacco and Cancer in Europe and North America*. BioMed Center Medicine;7(36), literature review <http://www.biomedcentral.com/1741-7015/7/36/abstract> (Accessed 17 August 2010).
6. Lee P. Circulatory disease and smokeless tobacco in Western populations: A review of the evidence. Int J Epidemiol 2007;36:789-804.
7. Boffetta P, Straif K. Use of smokeless tobacco and risk of myocardial infarction and stroke. Br Med J 2009 18 August;339(doi: 10.1136/bmj.b3060):3060.
8. Lee P, Hamling J. The relation between smokeless tobacco and cancer in Northern Europe and North America. A commentary on differences between the conclusions reached by two recent reviews. BioMed Center Cancer 2009;9:256.
9. Piano MR, Benowitz NL, FitzGerald GA, Corbridge S, Heath J, Hahn E et al., 2010, 14 September, *Impact of Smokeless Tobacco Products on Cardiovascular Disease: Implications for Policy, Prevention, and Treatment*. Circulation;122, A Policy Statement from the American Heart Association

<<http://circ.ahajournals.org/cgi/content/abstract/CIR.0b013e3181f432c3v1>> (Accessed 14 September 2010).

10. Rodu B, Nitzkin JL, 2010, 28 June, *Update on the Scientific Status of Tobacco Harm Reduction, 2008-2010 Prepared for the American Association of Public Health Physicians*, in Tobacco Issues Page on Http://Www.Aaphp.Org Web Site, Update to October 2008 AAPHP White Paper on Tobacco Harm Reduction <http://www.aaphp.org/special/joelstobac/2010/harmredcnupdatejuly2010.html> (Accessed 8 July 2010).

11. Bertuccio P, La Vecchia C, Silverman D, Petersen G, Bracci P, et al. Cigar and pipe smoking, smokeless tobacco use and pancreatic cancer: An analysis from the International Pancreatic Cancer Case-Control Consortium (PanC4). Ann Oncol 2011 18 January.

12. Yusuf O, Connolly G. Applying toxicological risk assessment principles to constituents of smokeless tobacco products; implications for product regulation. Tob Control 2010 5/October.

13. Gupta P, Ray C. Smokeless tobacco and health in India and South Asia. Respirology 2003 December;8(4):419-31.

14. Frost-Pineda K, Appleton S, Fisher M, Fox K, Gaworski CL, 2010, 16 September, *Does Dual Use Jeopardize the Potential Role of Smokeless Tobacco in Harm Reduction?* Nicotine & Tobacco Research;doi: 10.1093/ntr/ntq147, published on line in advance of print publication <http://ntr.oxfordjournals.org/content/early/2010/09/16/ntr.ntq147.full> (Accessed 16 September 2010).

15. Moore D, Aveyard P, Connock M, Wang D, Fry-smith A, Barton P, 2009, 2 April, *Effectiveness and Safety of Nicotine Replacement Therapy Assisted Reduction to Stop Smoking: Systematic Review and Meta-Analysis*. Br Med J;338 <http://www.bmj.com/cgi/content/full/338/apr02_3/b1024> (Accessed 24 September 2009).

16. Rodu B, Phillips C. Switching to smokeless tobacco as a smoking cessation method: Evidence from the 2000 National Health Interview Survey. Harm Reduction Journal 2008 May;5(18).

17. Zhu SH, Wang JB, Hartman A, Zhuang Y, Gamst A, Gibson JT et al. Quitting cigarettes completely or switching to smokeless tobacco: Do US data replicate the Swedish results? Tob Control 2009 April;18(2):82-7.

18. Frenk H, Dar R. If the data contradict the theory, throw out the data: Nicotine addiction in the 2010 report of the Surgeon General. Harm Reduction Journal 2011 May;8(12).

19. Barrett S. The effects of nicotine, denicotinized tobacco, and nicotine-containing tobacco on cigarette craving, withdrawal, and self-administration in male and female smokers. Behav Pharmacol 2010;21(20):144-52.

20. Dar R, Rosen-Korakin N, Shapira O, Gottlieb Y, Frenk H. The craving to smoke in flight attendants: Relations with smoking deprivation, anticipation of smoking, and actual smoking. J Abnormal Psychol 2010;119(1):248-53.

6-10

21. Tomar S, Fox B, Severson H. Is smokeless tobacco use an appropriate public health strategy for reducing societal harm from cigarette smoking? Int J Environ Res Public Health 2009;6:10-24.

22. Galanti M, Rosendahl I, Wickholm S. The development of tobacco use in adolescence among "snus users" and "cigarette starters": An analysis of the Swedish "BROMS" cohort. Nicotine & Tobacco Research 2008;10:315-23.

23. Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR), 2008, 6/February <http://ec.europa.eu/health/ph_risk/committees/04_scenihr-o-013.pdf> (Accessed 16/June 2011).

24. Tomar S. Is use of smokeless tobacco a risk factor for cigarette smoking? Nicotine & Tobacco Research 2003;5:561-9.

25. Severson H, Forrester K, Biglan A. Use of smokeless tobacco is a risk factor for cigarette smoking. Nicotine & Tobacco Research 2007;9:1331-7.

26. Timberlake D, Huh J, Lakon C. Use of propensity score matching in evaluating smokeless tobacco as a gateway to smoking. Nicotine & Tobacco Research 2009;11:455-62.

27. O'Connor R, Kozlowski L, Flaherty B, Edwards B. Most smokeless tobacco use does not cause cigarette smoking: Results from the 2000 National Household Suirvey on Drug Abuse. Addict Behav 2005;30:325-36.

28. Rodu B, Cole P. Evidence against a gateway from smokeless tobacco use to smoking. Nicotine & Tobacco Research 2010;12:530-4.

29. Centers for Disease Control and Prevention, 1998, *MediaSharp*, Print guide with DVDs and related materials <http://www.cdc.gov/tobacco/publications/dvds_videos/mediasharp/guide_modules/index.htm Atlanta, GA> (Accessed 10 August 2011).