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## Memorandum:

**To:** U.S. Preventive Services Task Force

**From:** Joel L. Nitzkin, MD

**Subject:** **Suggested Modifications to Draft Research Plan: Behavioral Counseling and Pharmacotherapy for Tobacco Cessation in Adults, Including Pregnant Women**

### *Abstract:*

This memo urges USPSTF to expand their consideration of options for smoking cessation to include tobacco harm reduction, alternative health education interventions not involving use of pharmaceuticals, and to address issues raised by e-cigarettes. Available evidence suggests that, for many hard core smokers, THR may be far more effective than currently endorsed smoking cessation protocols. Since the main argument against THR is the assumption that THR cannot be implemented without recruiting large numbers of teen non-smokers to tobacco use, USPSTF is also urged to review the degree to which e-cigarettes, as a THR modality, is attractive to teen non-smokers.

**Rather than continuing to rely on pharmaceutical products as the major intervention for smoking cessation, the USPSTF should play a leadership role in encouraging research and implementation of cessation options that promise to be far more effective.**

### *Introduction:*

I am a public health 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 organizations. In early 2007, while serving as co-chair of the Tobacco Control Task Force of the American Association of Public Health Physicians (AAPHP), I was part of an AAPHP team that subjected the then-proposed FDA Tobacco Law to detailed analysis.

We were shocked by what we saw. Provisions of the law were grossly inconsistent with the art and science of tobacco control. That review, in turn, led to additional literature review to identify the set of tobacco-control policies that would best secure immediate reduction and long-term near-elimination of tobacco-attributable illness, death and addiction in the USA.

Achieving immediate reduction in tobacco-attributable illness and death will require interventions aimed at current smokers. Almost all of the projected eight million tobacco-attributable deaths in the United States over the next twenty years (400,000 deaths per year[1] x 20 years) will be in adult smokers who are now over 35 years of age. Despite our best efforts and our best evidence-based smoking cessation protocols, the estimated numbers of deaths attributable to cigarettes in the United States has remained unchanged for the past fourteen years.[1,2]

Available medical literature suggests that there is another way. Smokers smoke for the nicotine, but it is the other chemical substances in cigarette smoke that cause virtually all of the potentially fatal tobacco-attributable illness.[3] Currently recommended "evidence based" smoking cessation protocols fail about 90% of smokers who use them as directed, even under the best of study conditions.[4] In addition, there are significant numbers of inveterate smokers who feel the need to smoke, just to get through the day. For all of these hard-core smokers, tobacco harm reduction (THR) offers a promising option by which they can secure the nicotine they seek while eliminating almost all of the risk of potentially fatal tobacco-attributable cancer, heart and lung disease.[5]

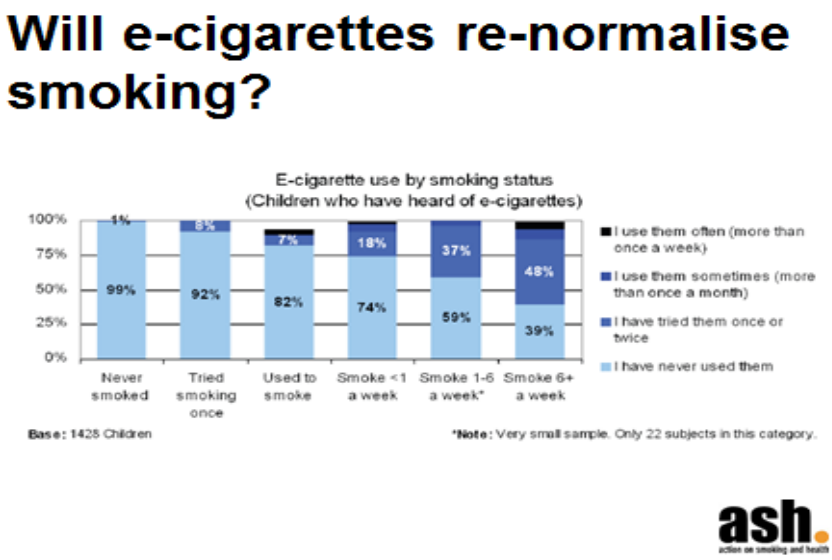
Long term near-elimination of potentially fatal tobacco-attributable illness will require a focus on current teen non-smokers, and interventions to prevent their initiation and use of cigarettes. Given the apparent hazard posed by nicotine to the developing adolescent brain, there is general consensus that the teen interventions should prevent use of any nicotine-containing product.

Herein lies the rub. It seems self-evident, at least to the tobacco control community, that any encouragement of smokers to switch to a lower risk nicotine delivery product would recruit large numbers of teens to initiate tobacco/nicotine use.

Enter the e-cigarette, and now, a related family of electronic nicotine delivery systems (ENDS). These products are exploding in sales because they satisfy the urge to smoke for many smokers and appear to be far less hazardous than tobacco cigarettes.[6,7] Chemically, they closely resemble the nicotine-only pharmaceutical NRT products, so there is good reason to expect at least as good a reduction in risk as demonstrated by both the NRT products and smokeless tobacco products. They are too new to have had long term study, but available literature strongly suggests that they are helping many smokers quit or sharply reduce their cigarette consumption.[8-15]

Even more remarkable are the data published to date demonstrating a remarkable lack of attractiveness of these devices to teen non-smokers. Every study published to date addressing this issue, including the recently released CDC data show that the remarkable increase in e-cigarette use by teens is almost entirely by teen smokers, with little or no recruitment of teen non-smokers.[5,16,17]

Perhaps the best demonstration of this is in the following slide, from a study done by Action on Smoking and Health in Great Britain, published earlier this year.[5]



The point is this: We have good reason to believe that adding a tobacco harm reduction element to current tobacco control programming could substantially improve our ability to dramatically reduce both immediate and long term tobacco-related illness, death and addiction.

Limiting our consideration of smoking cessation options to the currently available pharmaceutical protocols is preventing our consideration of both non-pharmaceutical smoking cessation protocols and tobacco harm reduction.

The USPSTF can play a leadership role in expanding its consideration of approaches to smoking cessation to include consideration of alternative non-pharmaceutical protocols and tobacco harm reduction.

THR changes our goal from "tobacco cessation" to "smoking cessation." It changes the focus from hatred and distrust of "big tobacco" to science-based eventual near-elimination of tobacco-attributable illness, death and addiction.

Another advantage of changing the goal to "smoking cessation" is to enable us to meet the needs of smokers with depression, bipolar disorder, or schizophrenia, for whom nicotine is very effective in helping them get through the day far fewer disturbing side effects than their prescription medications.

### *Proposed Change in Title*

Public Health and Clinical Interventions for Smoking Cessation to Reduce Tobacco-Attributable Morbidity, Mortality, and Complications of Pregnancy

### *Proposed Realignment of the Analytic Framework*

**The currently proposed analytic framework does not recognize the following critical elements:**

1. As tabulated by CDC, all of the 443,000 tobacco-attributable deaths per year are from a single product – the tobacco cigarette.[1]
2. There are huge differences in in risk of harm, and likely differences in addictive potential, from the different classes of tobacco product
    a. The smoke-free options that have been on the U.S. market since the 1980's pose a risk of potentially fatal tobacco-attributable illness far less than the risk posed by tobacco cigarettes[3] and no risk to non-users of these products.[3]
    b. Being a nicotine-only product, with only the tiniest traces of other toxins, e-cigarettes promise to be even lower in risk than the smoke-free chewing tobacco, snus, other snuff and dissolvable products.
    c. Nicotine-only products are likely to prove less addictive than tobacco cigarettes, and possibly less addictive than the smoke-free whole tobacco products because of the likely presence of additives and attractive and addictive substances in cigarettes.[18]
    d. The pharmaceutical nicotine replacement therapy products (patches, gum, lozenges and inhalers) are all derived from tobacco and all carry traces of other tobacco-related toxins.[19,20] In addition, and despite 30 years of use of these products, there has been no measurable impact on influencing population trends in smoking behavior.[21-23]
    e. Hookahs may prove to be the most acutely hazardous of tobacco products because of carbon monoxide from charcoal fumes.[24] Hookahs could prove to be the most chronically toxic of tobacco products due to exposure to other toxins in charcoal fumes when combined with toxic substances extracted from the tobacco.
3. Self-administered nicotine appears to be beneficial for many mental health patients with depression, bipolar disorder and/or schizophrenia. It helps them get through the day with greater alertness and cognitive skill.[25] Nicotine-dependent individuals known to have a comorbid

psychiatric disorder made up 7.1% of the U.S. population, but consumed 34.2% of all cigarettes smoked in the United States. Nicotine dependent and psychiatrically ill individuals, about 20% of the population, consume about 70% of all cigarettes smoked in the United States.[26] CDC, in a 2013 report on the 2009-2011 National Survey on Drug abuse and Health, reported that reported that an average of 19.9% of adults in the United States had "any mental illness," and that they consumed 30.9% of all cigarettes smoked by adults during that period.[27] In addition, studies have been published demonstrating, at least for schizophrenic patients, cigarettes improve neurocognitive and neuropsychological performance.[28,29] The point is this: banning, or substantially limiting the use of non-pharmaceutical nicotine delivery products, as is current public health policy, may be harmful to about 20% of the U.S. population.. Thus, for at least these individuals, tobacco harm reduction may be a more rational and more beneficial policy.

4. Since the delay between onset of smoking and onset of a significant incidence of potentially fatal heart or lung disease or cancer is in the range of 10-20 years, and since the delay in measurable reduction in cardiovascular mortality is in the range of 2-5 years,[30-32] with reductions in cancer mortality about 15 years out,[33] it will be exceedingly difficult to demonstrate reductions in morbidity and mortality from randomized clinical trials of smoking cessation interventions.
5. Ethical and liability issues militate against clinical trials of pharmaceutical or THR products for smoking cessation in pregnancy. Research on smoking cessation in pregnancy should focus on counseling and health-education interventions.
6. **The pharmaceutical-based smoking cessation protocols that now dominate the USPSTF recommendations and clinical practice are spectacularly ineffective. They fail about 90% of smokers who use them as directed, even under the best of study conditions, when results are measured six months or more post-intervention.[4] Even worse, more than 30+ years after these products first came into common use, there have had no population-level impacts.[21-23] Rather than continuing to rely on pharmaceutical products as the major intervention for smoking cessation, the USPSTF should play a leadership role in encouraging research and implementation of cessation options that promise to be far more effective:**
    a. Tobacco Harm Reduction (THR) can be defined as advising smokers who are unable or unwilling to quit that they could substantially reduce their risk of potentially fatal tobacco-attributable illness and death by switching to a far lower risk nicotine delivery product. THR products include a wide range of smokeless tobacco products, e-cigarettes and pharmaceutical NRT products, when used on a long term basis, in a harm reduction mode.
    b. There are health education and counseling protocols that appear to be far more effective than those now in common use. The protocol with the best published evidence is the Allen Carr method.[34,35] The Moshammer study[34] showed a 51.4% abstinence rate three years after the intervention. This success was likely due to the totally positive approach to smoking cessation along with the provision of a book and audio CDs to each participant for self-reinforcement whenever the urge to smoke returned. This, and similar protocols, are worthy of consideration for both additional research and trial implementation.
    c. Most users of e-cigarettes report that e-cigarettes help them quit or reduce smoking.[8-15]
7. The major objection by public health authorities to any consideration a THR initiative for smoking cessation is the unsubstantiated belief that such an initiative will necessarily attract large numbers of non-smoking adults and teens to tobacco/nicotine use. Dr. Jonathan Winickoff is Chairman of the American Academy of Pediatrics' Tobacco Consortium. In an article posted online in the Journal of Environmental and Public Health, Dr. Winickoff co-authored a report of a national survey of 3,240 adults (age 18 and above), including 1,802 non-smokers. They were only able to find 6(six) nonsmokers who had ever used e-cigarettes.[36,37] In a second study, Action on Smoking and Health (ASH-UK) was unable to find a single nonsmoker in Great Britain - either youth or

adult - who regularly uses electronic cigarettes. ASH-UK surveyed 12,171 adults and 2,178 children ages 11-18 in February and March of this year. Despite widespread awareness of electronic cigarettes among youth and adults, the survey failed to find a single adult or youth never smoker who regularly uses electronic cigarettes. "among young people who have never smoked ... 0% report continued e-cigarette use and 0% expect to try an e-cigarette soon." The study reports that: "Among adults, electronic cigarette current use ... remains at 0% among those who have never smoked.[5] Despite pronouncements by federal authorities that e-cigarettes were recruiting non-smoking teens to tobacco/nicotine use,[38] The CDC data actually shows that almost all of the teen e-cigarette users are smokers switching to e-cigarettes, not non-smoking teens[39-42] in addition, there are a number of other references supporting the proposition that e-cigarettes can be promoted to smokers without attracting teen or other non-smokers.[8-15] To my knowledge, there are no references documenting e-cigarettes habituating non-smokers to nicotine or as a gateway to smoking.

**Proposed Alternative Analytic Framework:**

I therefore recommend that the currently proposed analytic framework be replaced with the following Proposed Key Questions to be Systematically Reviewed

## *Proposed Issues to be Systematically Reviewed*

1. What is the risk of potentially fatal tobacco-attributable illness posed by the following classes of tobacco/nicotine products?
    a. Tobacco Cigarettes
    b. Other Combustible tobacco products (pipes and cigars)
    c. Hookahs – that burn charcoal and draw the fumes through flavored tobacco
    d. Smokeless whole-tobacco products on the American Market for more than 20 years – chewing tobacco, snus, other snuff products
    e. Pharmaceutical nicotine replacement therapy products (patches, gum, lozenges, inhalers)
    f. Likely risk posed by newly introduced products, and the means by which these risk estimates can be confirmed:
        i. Dissolvables (sticks, strips and orbs)
        ii. E-cigarettes and other Electronic Nicotine Delivery Systems
        *iii. JLN Note: All this presumes that the interest of the USPSTF is limited to the United States. If this is not the case, then the health-related aspects of use of Gutkha and Pan Masala should also be addressed. These are in common use in India and elsewhere in Asia. These products carry an inordinate risk of mouth cancer.*
        *iv. JLN Note: The purpose of USPSTF review of risk by class of tobacco product is to identify which products should be considered as tobacco harm reduction modalities.*
2. **USPSTF literature review should be limited to smoking cessation protocols that promise to show abstinence rates from smoking of 30 percent or more at six months or more after initiation of the protocol**
    *a. JLN Editorial Note: my personal impression is that, for inveterate smokers, short term interventions are unlikely to ever achieve continuing abstinence rates of 30 percent or more six months or more after initiation of the intervention. Success is likely, however, with long-term interventions in a harm reduction mode that allow the smoker to continue use of the harm reduction product as long as he or she feels the need to do so. Success is*

*also likely for health-education interventions where the participant is left with means for self-reinforcement whenever the urge to smoke returns.*

3. USPSTF should review evidence, pro and con, that a THR initiative could be added to current tobacco control programming in a way that would not increase and might decrease teen initiation of tobacco/nicotine use.
4. USPSTF should consider the needs of mental health patients who appear to benefit from self-administered nicotine. USPSTF should help determine how the medical and public health communities could work with them to achieve maximal benefit with minimal risk of tobacco-attributable illness, death and other harms.

## *Regarding Proposed Contextual Question Currently Rejected for Consideration by the USPSTF*

The popularity of electronic cigarettes and related ENDS products has exploded in the marketplace.[6,7] This growth in usage has largely come from smokers who have been unable or unwilling to quit, many of whom have tried and failed to give up smoking using the available pharmaceutical products.[43,44] This family of products appears to be a paradigm-changing technological innovation that could, and possibly should, transform our tobacco control programming by offering a product that simultaneously reduces risk among smokers and does not attract teens to tobacco/nicotine use.

There are three generations of ENDS products currently on the market, with each generation being more effective and more attractive for long term use than the generation before. The first generation consists of devices that are made to look like tobacco cigarettes, some of which are disposable, and some of which utilize refillable cartridges and rechargeable batteries. The second generation consists of more sophisticated tube-like devices that no longer resemble cigarettes. The third generation, referred to in the vapor community as "mods" look more like pipes or miniature tea pots, with rechargeable batteries and user-selected e-cigarette fluids.[45] Thus, ENDS devices are continuing to evolve in ways that will better satisfy users, more effectively serve as THR modalities, but in ways that will complicate consideration of this family of products by the USPSTF and regulators.

Given their potential as THR modalities, it would be inappropriate for the USPSTF to dismiss or exclude these products from consideration.

The literature considering ENDS devices from a public health perspective has recently been reviewed in a series of well-referenced fact sheets by Action on Smoking and Health of Great Britain.[5,46,47] USPSTF reviewers are urged to review these documents.

## *Proposed Research Approach*

1. Studies that do not show a 30 percent or better abstinence at 6 months or more after initiation of the intervention should be summarily dismissed.
2. The aim of "tobacco cessation" should be replaced with the aim of "smoking cessation."
3. The Condition parameter in the USPSTF research approach table should be amended to include ENDS products and pharmaceutical nicotine replacement therapy products when used long term.
4. Interventions should specifically include Tobacco Harm Reduction.
5. All settings should be included, as primary care physicians can refer patients to community and workplace programs for types of services they cannot provide within their office.
6. Comparators and Outcome Assessments should include population data, as appropriate to ecological studies.
7. Outcomes should include both cessation and reduction in cigarette use.
8. Publication dates since 1985 should be considered for topics new to USPSTF.

### *Disclaimer*

Given my current role as a self-employed policy consultant in the private practice of public health, I have explored the available options to enable me to spend a significant part of my time in pursuit of these tobacco-related policy issues. In doing so, it quickly became obvious that none of the federally funded tobacco control programs and none of the major voluntaries or academic centers would be interested in supporting exploration of policy issues at odds with current federal policy and/or potentially against the interests of their drug company supporters. I therefore arranged a working relationship the R Street Institute to provide a modicum of personal and staff support and an infrastructure to facilitate travel and communication. R Street funding is primarily from indemnity and liability insurance enterprises, with a small amount of their support from tobacco companies, but none from e-cigarette enterprises, the pharmaceutical industry or government. The views I articulate are my own. The support from R Street is based on their perception that the work I am doing is supportive of their goal of markets free of undo governmental interference. They adopted tobacco harm reduction as one of their priority issues when the FDA attempted to eliminate e-cigarettes from the American market by trying to declare them to be unlicensed drug-device combinations.

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