



American Association of Public Health Physicians
The voice of public health physicians, guardians of the public's health
Tobacco Control Task Force
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Tobacco Control Task Force

February 7, 2010

Division of Dockets Management
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, rm. 1061
Rockville, MD 20852

Re: Citizen Petition to Follow-up July 22, 2009 Press Conference on E-cigarettes

Dear FDA:

The undersigned submits this petition under the provisions of the new Tobacco Center legislation for which authority has been delegated to the Commissioner of Food and Drugs under 21 CFR 5.10 to request the Commissioner of Food and drugs to follow-up on its July 22, 2009 press release and press conference with another press release and press conference to amend certain statements on the basis of new information provided in text and as attachments to both of the petitions being submitted today by AAPHP..

This is the second of two petitions I am submitting today on behalf of the Tobacco Control Task Force of the American Association of Public Health Physicians. The other petition is a request to reclassify nicotine vaporizers, also known as “E-cigarettes” or “electronic cigarettes” from “drug-device combinations to “tobacco product.”

We have generated these petitions because reclassification of E-cigarettes to tobacco products could open the door to a new harm reduction component to current tobacco control programming. That new component, in turn, could rapidly and substantially reduce tobacco-related illness and death without increasing the numbers of teens initiating nicotine use. This request for a follow-up press conference is intended to facilitate the proposed reclassification since the tone and content of the initial press conference presented comment that would rule out any consideration of the proposed reclassification.

Neither I nor AAPHP have received or anticipate receipt of any financial support from any electronic cigarette enterprise, any other tobacco-related enterprise, or any pharmaceutical enterprise.

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A. Action requested

AAPHP urges the Food and Drug Administration (FDA) to follow-up the July 22, 2009 press release and press conference with another press release and press conference to amend certain statements on the basis of new information provided as text and attachments to the two AAPHP petitions being submitted today. The tone and content of the initial press conference left the impression that FDA would not consider either reclassification of E-cigarettes from drug-device combination to tobacco product or consider a related harm-reduction initiative. FDA is urged to review the content of the two petitions with consideration of the possibility that the information herein provided will justify a change in the current FDA stance on these issues.

B. Statement of grounds

Impact of FDA July 22, 2009 Press Conference

As a direct result of the FDA July 22, 2009 press conference, (Attachments B5a-c), many have concluded that E-cigarettes are as dangerous or more dangerous as conventional cigarettes and that they are likely to attract large numbers of teens to nicotine use who otherwise would have not initiated nicotine use. This has resulted in public statements, and political action to restrict or ban E-cigarettes. The strongly negative tone of the FDA press conference (Attachment B5B) created a situation in which people were encouraged to draw the incorrect conclusions noted above. One attachment has been added to this petition to document these interpretations (Attachment B4). This is a report from New Jersey GASP that summarizes the actions taken by others, mostly in response to the FDA press conference, as justification for their recommendations regarding E-cigarettes.

The two petitions being submitted today by AAPHP are intended to provide the evidence, data and scientific studies needed for FDA to consider revision of these statements, and, by doing so, consider the proposed reclassification of E-cigarettes from drug-device combinations to tobacco products (as proposed in the other AAPHP petition). In the other petition, FDA is also urged to consider playing a lead role in promoting a new tobacco harm reduction initiative based on honest and direct communication to actual and potential tobacco users of tobacco products to inform them of the differences in risk profiles presented by the various categories of tobacco products. It is our (AAPHP) belief that such an initiative presents the only feasible means by which we, as the American public health community can take the action needed to rapidly and substantially reduce

tobacco-related illness and death in the United States and do so in a way that will not increase teen initiation of tobacco use.

Amended FDA Stance Proposed for Follow-up Press Conference

The relative safety of E-cigarettes compared to other tobacco products and compared to FDA approved pharmaceutical smoking cessation products currently on the market should not be an issue for the following reasons:

1. If regulated by FDA as tobacco products, FDA could require standards for chemical composition and quality of manufacture similar to those imposed on pharmaceutical products.
2. The limited studies done to date by FDA on E-cigarette liquid, and publicly announced July 22, 2009 (Attachments B5a-c) prove that the products tested have levels of carcinogenic contaminants similar to the concentrations of these same contaminants in nicotine replacement products already approved by FDA (Attachments B5d-i). These levels are several orders of magnitude less than conventional cigarette smoke. Both within this petition, and as a separate petition to FDA, AAPHP is requesting a follow-up to the July 22, 2009 press release to address the following:
 - a. How the risk posed by E-cigarettes, based on chemical composition, compares to the risk posed by pharmaceutical nicotine replacement products and conventional cigarettes,
 - b. The issue of “drug-device combination” vs. “tobacco product.”
 - c. The possible role E-cigarettes and other low-risk tobacco products might play relative to reducing future tobacco-related illness and death among current smokers.
 - d. What is currently known about the attractiveness of E-cigarettes, compared to low-exposure conventional cigarettes and NRT products to teens and whether there is evidence that such products play a significant role in attracting teens to nicotine use.
3. With over three years of experience with E-cigarettes in the United States, we are not aware of any reports of illness directly attributable to their use. It is important to note that there were E-cigarette products on the American market prior to the February, 2007 date specified in the new FDA/Tobacco law relative to introduction of new products to the marketplace.
4. E-cigarettes use the same nicotine, with about the same level of trace contaminants as FDA approved NRT products. There are a large number of studies and reviews that demonstrate the safety of E-cigarettes in comparison with pharmaceutical NRT products and conventional cigarettes (Attachments B6a-j).
5. Propylene glycol and the other major ingredients in E-cigarettes are generally recognized as safe (Attachment B6i).
6. Judge Leon, in his January 14, 2010 opinion, stated the following: “Together, both Smoking Everywhere and NJOY have already sold hundreds of thousands of electronic cigarettes, yet FDA cites no evidence that those electronic cigarettes are any more an immediate threat to public health and safety than traditional cigarettes, which are readily available to the public” (Attachment B3).

Please note that a more detailed discussion of the major problems with the FDA July 22, 2009 press conference, and the urgent need for FDA to address these issues was the subject of correspondence forwarded to FDA by AAPHP August 29, 2009 (Attachment B5f).

Annotated index to attached reference materials

Please note that the attachments to this petition are identical in numbering, scope and content to the attachments to other AAPHP petition – the one requesting reclassification of E-cigarettes from drug-device combinations to tobacco products.

Attachment A: Harm Reduction References

1. **AAPHP Resolution and White Paper: The Case for Harm Reduction for control of tobacco-related illness and death**, October 26, 2008 (from www.aaphp.org web site). This well documented 37 page report does not directly address E-cigarettes, but makes the case for a harm reduction initiative based on commercially available tobacco products to achieve substantial personal and public health benefits not otherwise obtainable.
2. Rodu B; Phillips CV: **Switching to smokeless tobacco as a smoking cessation method: evidence from the 2000 National Health Interview Survey**. Harm Reduction Journal 5:18 (2008)
3. Philips CV: **Debunking the claim that abstinence is usually healthier for smokers than switching to a low-risk alternative, and other observations about anti-tobacco-harm-reduction arguments**. Harm Reduction Journal 6:29 doi 10-1186/1477-7517-6-29 2009
4. Nitzkin: J: **Promoting Snus Will Save Lives in the USA** – an article posted on the Tobacco Issues Page of the www.aaphp.org web site in response to the paper by Zhu et al, Tobacco Control, 2008 “**Quitting cigarettes completely or switching to smokeless tobacco: do U.S. Data replicate the Swedish Results**” This paper is remarkable in that the data show considerable potential benefit to switching to smokeless tobacco, but the abstract declares this point to be “unproven” on the basis that it has not been subjected to a controlled clinical trial. February 6, 2009 (from www.aaphp.org web site)
5. Fagerstrom K: **The nicotine market: An attempt to estimate the nicotine intake from various sources and the total nicotine consumption in some countries**. Nicotine & Tobacco Research, 7:3, pp 343-350, June 2005. In this paper Fagerstrom presents an approach to determining the amount of nicotine consumed by the population by type of tobacco product – from cigars to cigarettes, smokeless tobacco products and NRTs. He then provides estimates for a number of European countries based on this approach.
6. Godshall E-mail 12/29/09 5:12PM Godshall used the formula and data from the Fagerstrom paper to estimate the percentages of nicotine intake in the USA from cigarettes, smokeless and NRT products.
7. Rodu B, Godshall WT: **Tobacco harm reduction: an alternative cessation strategy for inveterate smokers**. Harm Reduction Journal 3:37 (2006). This literature review describes the traditional and modern smokeless products, their prevalence and use in the United States and Sweden and the epidemiologic evidence for their low health risks, both in absolute terms

and in comparison with smoking. This review does not consider E-cigarettes or tobacco-extracts. It covers smokeless tobacco products.

8. <http://www.harmreduction.org> This web site, developed and maintained by Dr. Carl Philips of the University of Alberta and Dr. Brad Rodu of the University of Louisville promotes itself as “The leading source of information of safer alternatives for smokers who cannot or do not wish to quit using nicotine. Attachment A8 is a print out of the home page as it appeared 11/10/2009.
9. Rodu B, Cole P: **Nicotine Maintenance for inveterate smokers**. Technology, Vol 6, pp 17-21, 1999. This paper makes the case for encouraging inveterate smokers to switch to less harmful nicotine delivery products.
10. Petition by the NY state health commissioner to FDA requesting that NRT products be made more readily available and at lower cost. Downloaded from <http://www.regulations.gov/search/Regs/home.html#docketDetail?R=FDA-2008-P-0116>
11. O’Connor RJ, Hyland A, Giovino G, Fong GT, Cummings KM. **Smoker awareness of and beliefs about supposedly less harmful tobacco products**. Am J Prev Med 2005; 29: 85-90
Abstract only
http://www.ncbi.nlm.nih.gov/pubmed/16005803?itool=EntrezSystem2.PEntrez.Pubmed.Pubmed_ResultsPanel.Pubmed_RVDocSum&ordinalpos=6
12. Cummings KM. **Informing Consumers about the Relative Health Risks of Different Nicotine Delivery Products**, presented at the National Conference on Tobacco or Health, New Orleans, LA, 2001.
13. O’Connor RJ, MCNEILL A, BORLAND R, et al. **Smokers’ beliefs about the relative safety of other tobacco products: findings from the ITC Collaboration**. Nic & Tob Res 2007; 9: 1033-42. Abstract only
http://www.ncbi.nlm.nih.gov/pubmed/17943619?itool=EntrezSystem2.PEntrez.Pubmed.Pubmed_ResultsPanel.Pubmed_RVDocSum&ordinalpos=2
14. Altria comment to FDA Dockets Management 12/22/2009 requesting that FDA recognize that smokeless tobacco products are less hazardous than cigarettes
15. Gartner CE, Hall WD, Vos T, Bertram MY, Wallace AL, Limm SS: **Assessment of Swedish snus for tobacco harm reduction: an epidemiological modeling study**. Lancet 369(9578) 2010-4, 2007. There was little difference in health-adjusted life expectancy between smokers who quit all tobacco and those who switched to snus. Current smokers who switch to snus rather than continuing to smoke can realize substantial health benefits. Abstract only
16. Ramstrom LM, Foulds J: **Role of snus in initiation and cessation of tobacco smoking in Sweden**. Tobacco Control 15:210-214 2006. Use of snus in Sweden is associated with a reduced risk of becoming a daily smoker and an increased likelihood of stopping smoking.
17. **Smoking-attributable mortality, Years of Potential Lief Lost and Productivity Losses – United States, 200-2004**. MMWR Weekly November 14, 2008 57(45); 1226-1228
<http://www.cdc.gov/mmwr/preview/mmwrhtm/mm5745a3.htm> “During 2000-2004, an estimated 443,000 persons in the United States died prematurely each year as a result of moking or exposure to secondhand smoke. This figure is higher than the average annual estimate of approximately 438,000 deaths during 1997-2001.”

18. Smoking continues gradual decline among U.S. teens, smokeless tobacco threatens a comeback. Press release December 14, 2009 from the Monitoring the Future program at the University of Michigan. <http://www.monitoringthefuture.org/pressreleases/09cigpr.pdf>
Annual reductions in the percentage of teens initiating smoking have slowed in recent years.
19. Murrelle L et al: **Hypotheses and fundamental study design characteristics for evaluating potential reduced-risk tobacco products. Part I: Heuristic.** Regulatory Toxicology and Pharmacology (2009), doi:10.1016/j.yrph.2009.12.002. In this paper, the authors explore the numbers of participants and numbers of years of observation needed to explore possible benefit from reduced risk tobacco products in reducing the risk of lung cancer. Depending on the product and end points being sought, duration of study ranged from five to more than fifteen years. Documenting the risk-reducing effect of a potential reduced-risk tobacco product by means of a long-term prospective study of smokers, switchers and quitters, could, depending on the expected level of risk reduction from the reduced risk tobacco product, require observations on 8,000 to more than 100,000. subjects. The authors of this study did not comment on the ethics, feasibility, or practicality of multi-year studies with such large numbers of participants.
20. Pankow JF, Watanabe KH, Tocalino PL, Luo W; Austin DF: **Calculated Cancer Risks for Conventional and “Potentially Reduced Exposure Product” Cigarettes.** Cancer Epidemiol Biomarkers Prev 16(3) pages 584-592 (2007). This paper makes the case that since the major carcinogens in cigarette smoke only account for less than 2% of the lung cancer caused by cigarettes, reducing their concentration in cigarette smoke will be unlikely to reduce this cancer risk by any noticeable amount.
21. The home page of the Tobacco Control Research Branch of the National Cancer Institute has, as its opening line, “The vision of the TCRB is a world free of tobacco use and related cancer and suffering.” <http://www.cancercontrol.cancer.gov/tcrb/about.html>. This item is included as an attachment to this petition to document the commitment of federal agencies and others to the concept of a tobacco free society. This commitment has been commonly interpreted as ruling out any consideration of use of any commercially available non-pharmaceutical tobacco product in a harm reduction mode.

Attachment B: Electronic Cigarette References

1. Ben Thomas Group LLC: **Study to Determine the Presence of TSNA in NJOY Vapor.** A report to Scottera, Inc, dba NJOY December 9, 2009. Ben Thomas Group, LLC, 11200 Westheimer Rd, Suite 900, Houston TX 77042. This paper affirms the safety of the NJOY product.
2. **Experiences of Electronic Cigarette Users Suggests that These Could Be Life-Saving Devices and that They are Effective for Smoking Cessation.** Commentary on Dr. Siegel’s tobacco policy blog, at: <http://tobaccoanalysis.blogspot.com/2009/08/experiences-of-electronic-cigarette.html>. Rcd as E-mail Message from M Siegel, 8/7/2009 9:38AM; with introduction edited by J. L. Nitzkin 2/27/2010 to adapt to FDA petition guidelines. The passionate testimonials of of electronic cigarette users suggest that these devices are effective in helping smokers to quit and stay off cigarettes. These are all the comments from electronic cigarette users in response to Dr. Whelan’s *Washington Times* [op-ed piece](#). They are taken from the *Washington Times* [site](#) as well as the *Digg* [site](#) for this article. Dr Siegel has not omitted any comments from electronic cigarette users, which is remarkable because there is not a single

comment from a user who has not found these devices to be satisfactory as a substitute for conventional cigarettes.

3. Judge Leon's 1/14/2010 opinion ordering FDA to allow importation of Smoking Everywhere and NJOY E-cigarette products as downloaded from https://ecf.dcd.uscourts.gov/cgi-bin/show_public_doc?2009cv0771-54. The Reuters description of this opinion reads, in part, as follows:

A U.S. judge on Thursday granted a preliminary injunction barring the Obama administration from trying to regulate electronic cigarettes (*as drug-device combinations*) and prevent them from being imported into the United States.

In a sharply worded decision, U.S. District Judge Richard Leon scolded the Food and Drug Administration for trying to assert jurisdiction over the cigarettes, which are battery-powered or rechargeable devices that vaporize a liquid nicotine solution.

"This case appears to be yet another example of FDA's aggressive efforts to regulate recreational tobacco products as drugs or devices," he said in granting an injunction barring the FDA from regulating the cigarettes as a drug-device combination.

4. **New Jersey GASP report on Electronic Cigarettes (E-Cigarettes)**
<http://www.njgasp.org/E-Cigs%20White%Paper.pdf> -- This nine page report erroneously is dated January 11, 2009 (should be January 11, 2010) (as downloaded 2/4/2010). This report is included to show the impact the July 22, 2009 FDA press conference had on many tobacco-related organizations who then, based on this severely flawed FDA report concluded that E-cigarettes are extremely harmful, should be banned; and even present significant hazard to non-smokers. On page 6 it cites calls for E-cigarettes to be banned. These calls were issued by the American Lung Association, American Cancer Society, American Heart Association and Campaign for Tobacco Free Kids – all on the basis of the FDA press conference. On page 6, based on the FDA report, it states as a fact that “E-cigarettes appeal to youth.” Later in the report it cites multiple localities and even foreign countries taking action against E-cigarettes. Other sources of information showed that each of these that were subsequent to the FDA July 22, 2009 press conference were as a result of the press conference.
5. **FDA Analysis and Responses to FDA Press Release**
 - a. News Events links to July 22, 2009 Press “to discuss potential health risks associated with electronic cigarettes.”
 - b. July 22, 2009 press release transcript – verbatim transcript condemning E-cigarettes as contaminated with carcinogens and being marketed to minors
 - c. FDA E-cigarette laboratory analysis serving as basis for July 22 press conference – very limited study for contaminants of a few Smoking Everywhere and Njoy E-cigarette fluid and headspace vapor, with no comparisons to NRT products or cigarette smoke.
<http://www.fda.gov/downloads/Drugs/ScienceResearch/UCM173250.pdf>
 - d. **Scientific Review of FDA Report-** evaluation of FDA study prepared for NJOY by Exponent Health Services pointing out major deficiencies in FDA study design and

interpretation of data.

http://www.njoythefreedom.com/contactcommerce/images/press_releases/Response%20to%20the%20FDA%20Summary.pdf

- e. **Prominent Doctors Specializing in Tobacco Harm Reduction Question FDA Study- report** by inLife summarizing criticisms of FDA report by prominent researchers and public health physicians.
<http://www.standardnewsire.com/news/162574365.html>
 - f. AAPHP letter to Dr. Deyton urging correction of misleading information in July 22 press conference.
 - g. Siegel M (Blog post 7/22/2009): **Tobacco-Specific Carcinogens Found in Nicotine Replacement Products; Will Anti-Smoking Groups Call for Removal of these Products from the Market? Despite Laboratory Finding of Carcinogens in Nicotine Replacement Medications, FDA Fails to Hold Press Conference to Express Concern About Potential Dangers of Nicotine Replacement Products.** This Blog entry criticizes FDA for condemning E-cigarettes on basis of trace carcinogens without also condemning NRT products for similar contamination.
<http://tobaccoanalysis.blogspot.com/>
 - h. Siegel M (Blog post 7/30/2009): **Comparison of Carcinogen Levels Shows that Electronic Cigarettes are Much Safer than Conventional Ones.** This Blog entry shows TSN levels in selected electronic cigarettes, NRTs, snus, smokeless tobacco and cigarettes. <http://tobaccoanalysis.blogspot.com/2009/07/comparison.html>.
 - i. Siegel M (from Blog): **List of Identified, Known Carcinogens in Electronic Cigarettes vs. Conventional Cigarettes.** This Blog entry shows no carcinogens in electronic cigarettes beyond trace quantities, and 57 in conventional cigarettes.
<http://tobaccoanalysis.blogspot.com/2009/07/list-of-identified-known-carcinogens-in.html>.
6. Liquid and Vapor Analyses
- a. **Safety Report on the Ruyan E-cigarette Cartridge and Inhaled Aerosol**
Study shows TSNA levels in vaporized nicotine liquid is below what would be considered carcinogenic. Report includes both laboratory analyses and literature review. Report done by Health New Zealand Ltd.
<http://www.healthnz.co.nz/RuyanCartr...t30-Oct-08.pdf>
 - b. **e-cigs.co.uk** – study of one bottle of “e-juice XX High 36mg/ml rated Nicotine Solution provided by Hertfordshire Training Standards showing concentrations of major ingredients by GC MS. The liquid conformed to manufacturing specs. Considered hazardous due to nicotine content, authors urged warning labels regarding ingestion, skin contact, and to keep out of reach of children.
<http://www.e-cigs.co.uk/docs/E249A.pdf>. Bulk E-cigarette liquid is commonly used by vapers (E-cigarette users) to refill the cigarette cartridges. This is easily done and is considerably less expensive than buying more cartridges.
 - c. **InLife** (Alliance Technologies) – two studies of Regal Cartridge Liquid by GCMS; first for major ingredients, second for TSNA and TSIs
<http://truthaboutecigs.com/science/8.pdf>
<http://truthaboutecigs.com/science/9.pdf>
 - d. **esmoke.net** – Precision Testing Labs studies of eSmoke LLC liquid – 3 certificates showing no detectable diethylene glycol and one sheet showing no detectable

contamination by a long list of semivolatile organics.

<http://www.esmoke.net/batch/090124/PGDrumGCFID.pdf> (PG Raw Material)

<http://www.esmoke.net/batch/090124/GLDrumGCFID.pdf> (Glycerin Raw Material)

<http://www.esmoke.net/batch/090124/090124-GCFID.pdf> (GC/FID)

<http://www.esmoke.net/batch/090124/090124-GCMS.pdf> (GC/MS)

- e. **Totally Wicked/TECC** – due diligence GC-MS analysis of 3 nicotine cartridges to confirm major constituents and their relative concentrations
http://www.theelectroniccigarette.co...ogy_report.pdf
- f. **Gamucci** – due diligence GC-MS analysis of 4 nicotine cartridges to confirm major constituents and their relative concentrations
<http://www.ecigaretteschoice.com/GamucciLabStudy.pdf>
- g. **Instead** – due diligence GC-MS analysis of 2 nicotine cartridges and vapor to confirm major constituents and their relative concentrations
<http://www.e-cig.org/pdfs/Instead-ELiquid-Report.pdf>
- h. **SuperSmoker** – lab analysis of the vapor from 20 SuperSmoker cigarettes, cigars and cartridges to document compliance with German and FDA GRAS standards of major ingredients. Attachment is summary report.
<http://www.supersmokerjp.com/images/...anslatiion.pdf>
- i. **Propylene Glycol Studies** – a Vapers Club review of the literature and EPA assessments of the safety of Propylene Glycol, in response to the FDA condemnation of E-cigarettes as untested and of unknown safety. Vapers Club is a group of E-cigarette users organized to try to keep E-cigarettes on the American Market. They are not associated with any manufacturer or vendor.
<http://www.vapersclub.com/pg.html>
- j. Siegel M (from Blog): **No tobacco-specific nitrosamines or diethylene glycol detected in inLife electronic cigarettes: Do anti-smoking groups still want ex-smokers to return to the real thing?** – This Blog entry sees the scare instilled into the American public by the FDA July 22 press release as damaging to the health of the public. : <http://tobaccoanalysis.blogspot.com/2010/01/no-tobacco-specific-nitrosamines-or.html>.

Attachment C: NRT Product References

JLN Note: The following references are provided in the context of this petition to document both the long term safety of nicotine replacement or inhalation and the relative ineffectiveness of Nicotine Replacement Therapy (NRT) re ultimate cessation of nicotine use. Attachments E6 and E7 address serious problems with some of the initial studies leading to the FDA approval of NRT products. Taken together, this set of attachments supports our impression that NRT therapy cannot stand as a cornerstone of a tobacco harm reduction initiative that could be expected to reduce overall illness and death rates from cigarettes.

1. Moore D, Aveyard P, Connock M, Wang D, Fry-Smith A, Barton P: **Effectiveness and safety of nicotine replacement therapy assisted reduction to stop smoking: systematic review and meta-analysis.** BMJ 338:b1024 2009. This paper documents the dismal track record of pharmaceutical NRT products in securing long-lasting cessation of cigarette smoking. The abstract cites a 93.25% failure rate of NRT products after 6 months (phrased as a 6.25% success rate). The 98.4% failure rate at 20 months is cited in the study, but not mentioned in the abstract

2. Waldum HL et al: **Long term effects of inhaled nicotine**. Life Sci. 58(16) 1339-46 1966. Study on long term (2 year) inhalation of nicotine by rats showing no ill effect. <http://www.ncbi.nlm.nih.gov/pubmed/8614291>
3. Murray RP, Connett, JE, Zapawa M: **Does nicotine replacement therapy cause cancer? Evidence from Lung Health Study** – abstract only – smoking predicts cancer, NRT use does not <http://ntr.oxfordjournals.org/cgi/content/abstract/11/9/1076>
4. Ossip DJ et al: **Adverse effects with use of nicotine replacement therapy among quitline clients** – abstract only; adverse effects mild, few quit due to adverse effects; distribution of over the counter nicotine through quitlines declared safe. <http://ntr.oxfordjournals.org/cgi/content/abstract/11//408>
5. Sumner II W: **Estimating the health consequences of replacing cigarettes with nicotine inhalers** – abstract only; spreadsheet projection of health consequences assuming nicotine accounts for 1/3 of tobacco related illness and death shows substantial health benefit (JLN note: other research indicates nicotine accounts for less than 2% of tobacco relate illness and death – so expected public health benefit much more substantial than estimated in this study) <http://tobaccocontrol.bmj.com/content/12/2/124.abstract>
6. Siegel M (from Blog): **New study shows that at least two-thirds of patients receiving placebo in “double blind” NRT trials know that they are receiving placebo**. This blog entry casts doubt on conclusions regarding effectiveness of nicotine replacement therapy. <http://tobaccoanalysis.blogspot.com/2009/07/new-study-shows-that-at-least-two.html>
7. Siegel M (from Blog): **Effectiveness of nicotine replacement therapy needs to be re-examined**. This Blog entry lists ten problems, including but not limited to conflicts of interest, bias and blinding failures that permeate much of the literature in favor of NRT therapy. <http://tobaccoanalysis.blogspot.com/2009/07/in-my-view-effectiveness-of-nicotine.html>

C. Environmental impact

In accordance with the provision of CFR Title 21, Subpart C (Categorical Exclusions) Section 25.30 (General) paragraph (i) – I (Joel L. Nitzkin, MD – signatory to this petition) claim exclusion for need for environmental impact statement on basis that what we are requesting is limited to “corrections and technical changes in regulations.”

D. Economic Impact

(CFR Title 21 specifies that an economic impact statement is required only when requested by the Commissioner following review of the petition.)

E. Certification

The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition and attachments include all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are favorable to the petition.

