

Food and Drug Administration Center for Tobacco Products  
(Docket No. FDA-2014-N-0189,RIN 0910-AG38)

*Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Regulations on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products*

August 8, 2014

Comments

Executive Summary

The growing mountain of scientific and empirical evidence (detailed in these comments) consistently indicates that electronic cigarettes (e-cigs):

- are 99% (+/-1%) less hazardous than cigarettes,
- are consumed almost exclusively (i.e. >99%) by smokers and exsmokers who quit by switching to e-cigs,
- have helped several million smokers quit and/or sharply reduce cigarette consumption,
- have replaced about 1 Billion packs of cigarettes in the US in the past five years,
- are more effective than FDA approved nicotine gums, lozenges, patches and inhalers for smoking cessation and reducing cigarette consumption,
- pose fewer risks than FDA approved Varenicline (Chantix),
- have not been found to cause any disease or death in users,
- pose no risks to nonusers,
- have further denormalized cigarette smoking,
- have never been found to create nicotine dependence in any nonsmoker, and
- have never been found to precede cigarette smoking in any daily smoker.

Accordingly, the FDA should never issue a Final Rule for its recently proposed Deeming Regulation because it would protect cigarette markets, threaten the lives of millions of vapers and tens of millions of smokers, and give the entrepreneurial e-cig industry to Big Tobacco companies by banning >99% of vapor products now on the market, including all of the products that have proven most effective for smoking cessation and reducing cigarette consumption.

Instead, the Obama administration's FDA (and all other DHHS agencies) should correct, clarify and apologize to vapers, smokers and the public for knowingly and intentionally misrepresenting the scientific and empirical evidence on e-cigs since 2009, for continuously confusing and scaring the public about e-cigs, for unlawfully banning e-cigs in 2009, for funding and encouraging others to demonize and ban vaping, for misrepresenting the public health impact of the Deeming Regulation, and for aggressively campaigning to impose the deadly Deeming Regulation.

According to the US Surgeon General, daily cigarette smoking causes 480,000 deaths annually in the US. In sharp contrast, the scientific and empirical evidence indicate that cigar smoking causes no more than several hundred deaths annually, smokeless tobacco

causes no more than several dozen deaths annually, pipe smoking causes no more than several deaths annually, there's no evidence that e-cigs or dissolvables have ever caused any disease or death.

More than 99% of all tobacco attributable morbidity, mortality and health care costs in the US are caused by daily cigarette smoking, while <1% are caused by the use of smokeless tobacco, cigars, pipe tobacco, e-cigs and dissolvables all COMBINED.

But five years ago, FDA spokesperson Rita Chappelle revealed the agency's unscientific, unethical and inhumane policy to deceive Americans about e-cigs to defend the FDA's unlawful e-cig ban **“We don't want the public to perceive them as a safer alternative to cigarettes.”**

Unfortunately for smokers and public health, this is still an underlying policy of Obama's DHHS, which also has deceitfully and repeatedly claimed that “tobacco use” (instead of “cigarette smoking”) is the nation's leading cause of disease and death. Just as it would be public health malpractice for DHHS to repeatedly claim “insect bites” (instead of “mosquito bites”) are the leading cause of malaria to confuse and scare the public, it is egregious public health malpractice for DHHS (or any other public health agency or official) to falsely claim that “tobacco use” is the leading cause of disease and death.

For nearly thirty years, Congressionally mandated warnings on smokeless tobacco products and the DHHS have deceitfully claimed that smokeless tobacco is NOT a safe alternative to cigarettes despite consistent epidemiologic evidence that smokeless tobacco is 99% less hazardous than cigarettes and despite survey evidence that many smokers have quit smoking by switching to smokeless tobacco.

Obama appointed federal health officials (and their staff and funding recipients) have been maliciously deceiving smokers and the public to believe that all tobacco/nicotine products are as addictive and hazardous as cigarettes (except for the tobacco derived nicotine products marketed by drug companies, which DHHS continues to deceptively tout as most effective for quitting smoking even though gums, lozenges and patches have a 95% failure rate as smoking cessation aids).

Since e-cigs have already helped more than a million cigarette smokers quit smoking and since e-cigs appear to be 99% less hazardous than cigarettes, the only way public health could be negatively impacted by e-cigs is if 100 million nonsmokers begin vaping and no more smokers do so, which isn't going to happen. The same is true for smokeless tobacco products, which the FDA and other DHHS agencies have denied for the past three decades.

Although there is no evidence that public health would benefit if FDA imposes the Deeming Regulation, the FDA and other DHHS agencies (and many of their funding recipients) have falsely claimed otherwise since 2011. To achieve its regulatory agenda, the FDA has been falsely claiming that its regulations are based upon scientific evidence.

The FDA did remove one false statement (after two years of criticism) from one of its many misleading websites stating: "To date, no tobacco products have been scientifically proven to reduce risk of tobacco-related disease, improve safety or cause less harm than other tobacco products." But DHHS has never corrected or clarified its hundreds of other false and misleading claims about e-cigs, smokeless tobacco or cigars.

So what would be the impact of the deeming regulation?

Sections 905(j) and 910 would ban ALL e-cigs (and most cigars, pipe tobacco and dissolvable products) not on the market prior to February 15, 2007 because the manufacturers didn't file Substantial Equivalence (SE) reports with FDA before the May 2011 deadline, and because no e-cig products on the market today are Substantially Equivalent to a product on the market before February 15, 2007.

Under the proposed deeming regulation, ALL e-cig products would be banned two years after the Final Rule is issued unless a manufacturer submits a New Tobacco Product application to the FDA (that would cost millions of dollars for each application), and the FDA approves the application.

While Judge Richard Leon's 2010 ruling overturning the FDA's unlawful 2009 e-cig ban and the largely free market have enabled vapor products to significantly benefit the health of more than a million smokers during the past several years, the FDA Deeming Regulation would not only halt, but would reverse, all that progress because many vapers would return to cigarettes or resort to buying e-cigs from a newly created black market. The Deeming Regulation also would deny tens of millions of cigarette smokers legal access to the most effective smoking cessation products ever invented, and would halt further improvements in e-cig product development.

The FDA has not yet approved any Premarket Tobacco Applications or any MRTP applications for any products currently regulated by Chapter IX of the FSPTCA, and it would cost e-cig manufacturers several million dollars to file each New Tobacco Product application. Recently the FDA announced that it has refused to accept four Premarket Tobacco Applications for currently regulated tobacco products, as well as six MRTP applications, with just one recently submitted MRTP application that is more than 100,000 pages in length.

Meanwhile, the FDA still hasn't taken action on more than 3,000 SE reports filed for products back in 2011, and still hasn't proposed new color graphic warnings for cigarettes packs (after a federal court struck down the agency's previously approved warnings as unconstitutional), which were required by Congress in the FSPTCA.

The TCA requires the FDA to consider the potential impact of black markets before approving new tobacco product regulations. Since FDA's 2009 e-cigarette import ban created a thriving and rapidly growing black market for e-cigarettes, and since black markets have been created by every country that has banned e-cigs, the FDA's proposed Deeming Regulation would almost certainly create a huge black market (perhaps

surpassing \$1 Billion annually) due to explosive sales growth in recent years. While the TCA requires FDA to consider the black market potential of all new regulations, the FDA's proposed Deeming Regulation failed to do so.

Section 911 of the TCA also would ban truthful claims that e-cigs are less hazardous than cigarettes by the several e-cig manufacturers (primarily Big Tobacco companies) whose "cigalike" e-cig products would be approved by the FDA. Meanwhile, unless the FDA extends the current smokeless tobacco exemption in Section 911(b)(2)(C) to e-cigs, those manufacturers could be banned from truthfully claiming that e-cigs are "smokefree" or emit "no smoke".

Since the proposed Deeming Regulation would apply to all of the tens of thousands of different e-liquid products containing nicotine, and to all parts and components of e-cigs, the Deeming Regulation also would authorize the FDA ban all e-cig hardware, cartridges, batteries and rechargers unless and until the FDA approves New Tobacco Product applications for each of those products, which would cost millions of dollars for manufacturers to submit each application.

According to the FDA's estimates, the Deeming Regulation would reduce the number of legal e-cig products from tens of thousands (perhaps 100,000) to less than a half dozen, and would reduce the number of legal e-cig manufacturers from several thousand to fewer than a dozen. In sum, the deeming regulation would decimate the e-cig industry and give it to Altria, Reynolds, Imperial Tobacco, British American Tobacco, Philip Morris International, Japan Tobacco and perhaps one or two of the largest e-cig companies.

Although the cigalike products made by the largest e-cig companies are excellent starter products for smokers, they are far less effective for smoking cessation than are the rapidly expanding billion dollar plus market segment of tanks/mods/premium vaporizers and e-liquid products (all of which would be banned). The proposed Deeming Regulation also would further protect cigarette markets by increasing the price of the several e-cig products that are approved by the FDA.

During the past 20 years, Johnson & Johnson, GlaxoSmithKline, Pfizer and other drug companies have given several hundred million dollars to the Campaign for Tobacco Free Kids, American Cancer Society, American Heart Association, American Lung Association, American Medical Association, American Academy of Pediatrics, Pinney Associates (which employed Mitch Zeller as a lobbyist/consultant for most of the past decade) and others to promote FDA approved drugs as the only effective way to quit smoking, and to demonize and lobby for bans and/or unwarranted regulations on smokeless tobacco products, dissolvables, and e-cigs.

Forty states have now banned the sale of e-cigs to minors, and many more would have done so by now had it not been for opposition lobbying by CTFK, ACS, AHA, ALA, which (after falsely accusing e-cig companies of target marketing to youth) have been hypocritically opposing state bills to ban e-cig sales to minors as a tactic to lobby for the

FDA deeming regulation (so they can continue claiming the Deeming Regulation is necessary since some states still haven't banned e-cig sales to minors).

Please note that the US DOT still hasn't issued a Final Rule on the airline vaping ban it proposed back in 2011, which DOT first attempted to unlawfully impose by fiat.

Cigarette smokers have a human right to truthful health information and legal access to less hazardous alternatives. Consistently, public health officials and agencies have an ethical duty to inform smokers that all smokefree tobacco and nicotine products are far less hazardous alternatives to cigarettes, and to keep all less hazardous alternatives legal and affordable for smokers as long as highly addictive and lethal cigarettes remain on the legal market.

The actions and misleading claims by DHHS on smokeless tobacco and e-cigs are probably the most egregious public health malpractice ever committed by the US government, as the several million vapers and 45 million smokers whose lives DHHS is threatening far exceed the number of victims of the US Public Health Service's infamous Tuskegee syphilis study decades ago.

Instead of issuing a Final Rule for the deeming regulation, the FDA should complete the tasks mandated by Congress in the TCA, and should begin to truthfully informing smokers and the public that all smokefree tobacco and nicotine products are far less hazardous alternatives to cigarettes.

The free market for e-cigs has saved the lives of many smokers and will continue doing so. In sharp contrast, FDA's proposed Deeming Regulation would protect cigarette markets, ban >99% of e-cig products now on the market, give the e-cig industry to Big Tobacco companies, create a huge black market for banned e-cig products, and threaten the lives of vapers, smokers and secondhand smokers.

If the FDA remains misguidedly intent upon imposing regulations on e-cig products, however, the agency should propose far less onerous e-cig regulations similar to those proposed as an option for large premium cigars, which are more hazardous than e-cigs when smoked and inhaled daily.

### Economic Impact of proposed Deeming Regulation

Under the FSPTCA, the only way for a tobacco product (that is regulated by Chapter IX, which will include e-cigs if FDA approves its proposed deeming regulation) can be legally marketed in the US is if the FDA issues a marketing order (for either an SE Report or New Product Application), although companies that submitted SE reports can continue marketing their product until FDA rules on their SE report.

FDA still hasn't taken final action on about 4,000 SE reports for different cigarette, smokeless tobacco and RYO brands. Although FDA hasn't provided any numbers, it appears likely that cigarettes comprise 50%-75% of all SE reports that were submitted to

FDA. While FDA has now approved 46 SE orders for cigarette brands, it is very likely the agency will approve >1,000 more SE orders for cigarette brands within the next several years, as Mitch Zeller has promised to make processing the huge backlog of SE reports a priority.

In sharp contrast, under the FDA's proposed Deeming Regulation, no SE reports would be allowed to be filed for e-cig products, as there were only about a half dozen first generation e-cig products that were sold in the US back in February 2007 (i.e. by NJOY, Ruyan and Crown 7), and those products were not SE substantially equivalent to any of today's far superior cigalike products (which are significantly inferior to more recently developed and marketed tank systems and e-liquids). Thus, it is unlikely that any SE reports would be filed for any e-cig products if a Final Rule is issued for the proposed Deeming Regulation.

The only way e-cig products can receive a marketing order from FDA (under the proposed Deeming Regulation) is if the manufacturer submits a New Tobacco Product application. In its proposed deeming regulation, the FDA estimated that 25 New Product applications for e-cig products would be submitted annually (Table 9), an estimate that appears realistic.

<http://www.regulations.gov/#!documentDetail;D=FDA-2014-N-0189-0001>

FDA's proposed Deeming Regulation also states (on page 179): "We are clarifying here that a PMTA may require one or more types of studies including chemical analysis, nonclinical studies and clinical studies. FDA expects that chemical and design parameter analysis would include the testing of applicable HPHCs and nonclinical analysis would include literature synthesis and, as appropriate, some combination of in vitro or in vivo studies, and computational analyses. For the clinical study component, one or more types of studies may be included to address, as needed, perception, use pattern, or health impact."

FDA also estimated that each Application for Premarket Review of New Tobacco Products for an e-cig product would cost an average applicant just 5,000 staff hours (i.e. 2.5 FTE) (Table 9) and average just \$333,554 (Table 21)

<http://www.fda.gov/downloads/TobaccoProducts/GuidanceComplianceRegulatoryInformation/UCM394914.pdf?>

<http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/UCM394933.pdf>

But in June, 2014, Swedish Match submitted a 100,000+ page MRTP application to the FDA to truthfully market General Snus to smokers as less hazardous alternative to cigarettes.

[http://www.washingtonpost.com/business/apnewsbreak-firm-seeks-to-say-tobacco-cuts-risk/2014/06/10/c22bfe18-f0b6-11e3-85d2-cda8aebfefe0\\_story.html](http://www.washingtonpost.com/business/apnewsbreak-firm-seeks-to-say-tobacco-cuts-risk/2014/06/10/c22bfe18-f0b6-11e3-85d2-cda8aebfefe0_story.html)

<http://www.businesswire.com/news/home/20140611005454/en/Swedish-Match-Submits-Modified-Risk-Tobacco-Product#.U5sD93JdXSI>

Since the FDA's proposed Deeming Regulation would require e-cig companies to conduct most (or more) of the same unwarranted research to submit a New Tobacco

Product application (that the agency's guidance requires for the submission of MRTP applications), the FDA's estimated cost of \$333,554 (utilizing just 2.5 FTEs for one year) for an e-cig company to submit a New Tobacco Product application is significantly lower than the actual cost e-cig companies would have to spend.

Realistically, each Application for Premarket Review of New Tobacco Products submitted by an e-cig company would cost successful applicants at least \$3 million, and perhaps up to \$20 million.

RJ Reynolds, Altria, Imperial, BAT, PMI, Japan Tobacco and perhaps NJOY can afford these costs for their ciglike e-cig products, and they have a professional regulatory staff that is experienced with filing applications to FDA and complying with FDA regs. But almost nobody else would submit a New Tobacco Product application to FDA (that is accepted by the agency) for an e-cigarette product.

A month ago at its Investor Day event, Philip Morris International revealed that the company is relying upon US FDA, UK MHRA and other government regulations to turn PMI's \$2 Billion investment in new THR products into profits.

<http://investors.pmi.com/phoenix.zhtml?c=146476&p=irol-newsArticle&ID=1942860&highlight=>  
<http://www.media-server.com/m/s/get6yg4o/lan/en>  
<https://www.media-server.com/m/instances/8hjnb6wm/items/29n825fv/assets/75ngrwuk/0/file.pdf>

Below are excerpts from PMI's presentation to current and potential stock investors.

“Regulation is the second pillar supporting our RRPs business model.”

“PMI has been seeking RRPs regulation because we see several benefits to rigorous regulatory standards for this new product category. Regulation provides assurance to regulators that RRPs claims are supported by rigorous scientific substantiation. Regulation gives consumers confidence that product information is reliable, and regulation establishes clarity in the marketplace for the industry.”

“We have invested approximately \$2 billion to support our Reduced-Risk Products portfolio by focusing on fundamental research, product development, scientific substantiation and adult smoker understanding.”

“We have hired more than 300 world-class scientists and engineers in key disciplines, including material science, consumer electronics, clinical science and systems toxicology. We have also established a scientific and regulatory affairs group to lead our efforts in the emerging regulation of Reduced-Risk Products.”

“We have a portfolio of over five hundred granted patents worldwide relating to RRPs platforms and a pipeline of around one thousand pending patent applications.”

“Since 2010, we have published over 80 RRPs-related studies in peer-reviewed scientific

journals, such as the American Journal of Physiology, Nature Biotechnology, and Regulatory Toxicology and Pharmacology, and are leading the industry on this key measure of scientific credibility.”

“Regulation is the second pillar supporting our RRP’s business model.”

“PMI has been seeking RRP’s regulation because we see several benefits to rigorous regulatory standards for this new product category. Regulation provides assurance to regulators that RRP’s claims are supported by rigorous scientific substantiation. Regulation gives consumers confidence that product information is reliable, and regulation establishes clarity in the marketplace for the industry.”

“We see RRP’s regulation as an opportunity, although it is, as I said, largely uncharted in most markets today.”

“The growth of the category can be explained by adult smokers’ desire for reduced-risk products, but also by their lower retail selling price compared to combustible cigarettes. This is particularly the case for the so called “e-liquid” products.”

“The e-vapor category as it stands today, can be divided in three different segments: disposable products, rechargeable cartomizers, and e-liquids.

In most cases, the usual entry point in the category is through disposable products. These are single-use cigarette look-alike products which offer no recharging opportunity.

Once adult smokers have tried the disposable products, usually they move to rechargeable e-vapor products, which comprise a rechargeable battery and a pre-filled cartridge containing a nicotine solution that is replaced once it is exhausted. These types of e-vapor products are very popular in markets such as the UK.

Adult smokers also consider e-liquid products mostly for economic reasons but also because they are available in many flavors and nicotine concentration levels, allowing taste customization. These offers are rechargeable e-vapor devices, also called “tanks”, which can be refilled with nicotine-containing liquids. The e-liquid products are growing in several markets and they represent the vast majority of e-vapor sales in France and Italy.

The e-vapor category is not developing at the same speed in every market. We observe a wide range of penetration levels. While these products have generated a high level of interest among adult smokers, their potential seems to be currently limited because they do not satisfy adult smokers.”

“As I said before, the penetration level of e-vapor products among adult smokers varies from market to market. In the most mature e-vapor markets, the category shows sign of



stabilization or even decline. This is the case in the UK, Poland and Italy where the number of adult smokers who used an e-vapor product in the past seven days is relatively stable or declining.”

“If we translate the e-vapor product penetration results into actual numbers of adult smokers, we can observe that, as of April 2014, 3.3 million adult smokers in Italy had tried an e-vapor product in the previous twelve months, 1.5 million purchased an e-vapor product at least once, but only about four hundred thousand adult smokers had used them during the previous week.”

For similarly selfish financial reasons, Altria (the world’s largest cigarette manufacturer) has been urging the FDA to propose and implement the Deeming Regulation since 2010.

In response to FDA’s proposed Deeming Regulation, Lorillard’s press release applauded the proposal.

<http://online.wsj.com/article/PR-CO-20140424-914134.html>

In an article entitled “Why Are Tobacco Companies So Positive About E-Cig Regulation?”, Reynolds American’s Richard Smith was quoted as saying "We believe the F.D.A. will regulate the e-cigarette category based on sound science"

<http://wunc.org/post/why-are-tobacco-companies-so-positive-about-e-cig-regulation>

Several of the largest cigalike manufacturers (which are losing market share to the several thousand companies marketing tanks/premium vapors and e-liquid products, and which can afford the huge expense of submitting New Tobacco Product applications to FDA) also applauded the proposed Deeming Regulation.

<http://www.usnews.com/news/articles/2014/04/24/e-cigarette-advocates-relieved-but-cautious-after-fda-pitches-rules>

<http://www.cnn.com/id/101610895>

<http://time.com/76275/e-cig-execs-are-actually-thrilled-with-new-fda-regulations/>

If 25 New Tobacco Product applications would be submitted to the FDA during the year prior to the Deeming Regulation’s two year deadline following issuance of the Final Rule, it is likely that the FDA would approve 5-10 of those applications, which almost certainly would be for different cigalike e-cig brands (before the FDA sends out Cease and Desist letters to all other e-cig companies ordering them to stop marketing their products in the US).

So the question is about how many Cease and Desist letters will FDA issue, and for how many different e-cig products?

In its proposed Deeming Regulation, the FDA estimated that just 1,675 different e-cigarette products are on the US market (Table 16, page 26) ironically after stating (on page 25): “A single online retailer, myvaporstore.com, claims to sell over 1,000 unique products.”

<http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/UCM394933.pdf>

So even the FDA estimates that its proposed deeming regulation would ban >99% of e-cig products (15/1675=.009) presuming it approves 15 of its estimated 25 new product applications for e-cigs during the second critical year of the Deeming Regulation.

But a recent study found that >34,000 different e-liquid products alone were sold on the Internet (i.e. 7,764 unique brand flavors averaging 4.4 different nicotine levels per brand) not including different PG/VG/water levels or components in 466 identified different e-cig brands.

[http://tobaccocontrol.bmj.com/content/23/suppl\\_3/iii3.full](http://tobaccocontrol.bmj.com/content/23/suppl_3/iii3.full)

[http://tobaccocontrol.bmj.com/content/23/suppl\\_3/iii3/T3.expansion.html](http://tobaccocontrol.bmj.com/content/23/suppl_3/iii3/T3.expansion.html)

[http://tobaccocontrol.bmj.com/content/23/suppl\\_3/iii3/T4.expansion.html](http://tobaccocontrol.bmj.com/content/23/suppl_3/iii3/T4.expansion.html)

CASAA's Carl Phillips has estimated that there >100,000 different e-liquid products on the US market, which appears likely as >5,000 vape shops are now marketing e-liquid products in the US, with many of them mixing (i.e. manufacturing) their own e-liquid products). And the number of e-liquid manufacturers and e-liquid products is likely to continue growing). There are also thousands of different e-cig components on the market, which FDA claims are also subject to the regulation, which would also require those manufacturers to submit new product applications to FDA to keep them on the legal market. **Thus, the FDA's proposed Deeming Regulation would ban >99.9% of all e-cig products now on the market.**

The US Small Business Administration's Office of Advocacy submitted a comment to FDA criticizing its proposed Deeming Regulation at

<http://www.sba.gov/advocacy/816/1086461>

“Advocacy is concerned that the Initial Regulatory Flexibility Analysis (IRFA) contained in the proposed rule lacks essential information required under the Regulatory Flexibility Act (RFA)[3]. Specifically, the IRFA does not discuss the quantitative or qualitative costs of the proposed rule on many potentially affected small entities. Moreover, given the extent of the anticipated costs of this proposal, the IRFA does not adequately consider or explain significant alternatives which accomplish the stated FDA objectives while minimizing the significant economic impact of the proposal on small entities. For this reason, Advocacy recommends that the FDA republish for public comment a Supplemental IRFA before proceeding with this rulemaking.”

US Small Business Administration's Overview of the Regulatory Flexibility Act is at

<http://www.sba.gov/content/rfa-overview-0>

If the FDA issues a Final Rule for its proposed Deeming Regulation, by 2017 it is very likely that the FDA will have approved >1,000 cigarette brands to be legally marketed (via SE reports), while banning >99.9% of e-cig products currently on the market. Instead of improving public health, the FSPTCA, FDA and its proposed Deeming Regulation would protect cigarettes at the expense of e-cigs and public health.

E-cigs are a key reason cigarette consumption has declined sharply in recent years, and Reynolds American reported a 5.5% decline in US cigarette industry shipments in 2Q14.

<http://www.reynoldsamerican.com/releases.cfm?ReleasesType=&Year=>  
[http://files.shareholder.com/downloads/RAI/3345943209x0x771706/d581ea54-beb1-4997-ab94-d68abbd49348/2014-17\\_RAI\\_increases\\_2Q14\\_profitability.pdf](http://files.shareholder.com/downloads/RAI/3345943209x0x771706/d581ea54-beb1-4997-ab94-d68abbd49348/2014-17_RAI_increases_2Q14_profitability.pdf)

The FDA's proposed Deeming Regulation also would create an enormous black market for e-cig products, as that's what has occurred in virtually every country that has banned e-cigs.

For example, despite a sales ban, e-cigs sales increased 1,000% in Australia last year  
<http://au.news.yahoo.com/thewest/lifestyle/a/-/lifestyle/8667633/e-ciggie-a-hot-item-to-beat-smoke-bans/>

Meanwhile, e-cig sales to Canadians have skyrocketed, and Canadian retailers have been selling e-cigs and confronting Health Canada's self proclaimed ban on e-cig sales.  
<http://www.ottawasun.com/2014/04/06/e-cig-retailers-stand-up-to-health-canada>

The FSPTCA requires the FDA to consider the potential of a black market being created by newly proposed tobacco regulations. But the FDA's proposed Deeming Regulation failed to consider the black market that would be created by the Deeming Regulation.

Carl Phillips has projected a huge black market if the Deeming Regulation is approved: "Predicting the black market in e-cigarettes" at  
<http://antithrlies.com/2014/07/04/predicting-the-black-market-in-e-cigarettes/>

A recent (June/July 2014) online survey of 10,000+ vapers found that 79% of e-cig users would turn to black market, 14% would return to cigarettes if their e-cig brand is banned  
<http://www.usnews.com/news/articles/2014/07/17/e-cigarette-users-would-ignore-bans-turn-to-black-market-survey-finds>

### Scientific and Empirical Evidence, and False and Misleading Fear Mongering Claims about E-cigs, Other Tobacco Products and Tobacco Harm Reduction by Obama's FDA and other DHHS Agencies since 2009

Before e-cigs entered the market, dozens of studies and two comprehensive evaluations of epidemiology research confirmed that smokeless tobacco products are exponentially less hazardous than cigarette smoking, and recommended that smokers be provided with truthful information about the comparable health risks of different tobacco products and encouraged to switch to smokefree tobacco alternatives if they cannot or don't want to quit using tobacco.

Tobacco harm reduction: an alternative cessation strategy for inveterate smokers, Brad Rodu and William T Godshall, Harm Reduction Journal 2006, 3:37doi:10.1186/1477-7517-3-37. <http://www.harmreductionjournal.com/content/3/1/37>

More than 80 studies confirming that smokeless tobacco and other noncombustible nicotine products are far less hazardous than cigarettes, and advocating that smokers be

informed of this information (and encouraged to switch to those less hazardous alternatives) were published by Harm Reduction International (formerly IHRA) in 2006 with links to those journal articles at:

<http://www.ihra.net/sub-categories-tobacco-harm-reduction>

Harm reduction in nicotine addiction; Helping people who can't quit, Royal College of Physicians, 2007.

<http://www.tobaccoprogram.org/pdf/4fc74817-64c5-4105-951e-38239b09c5db.pdf>

The 2007 Royal College of Physicians report also suggested that a product resembling the first e-cig products (which the report's authors weren't aware of) could prove to be the most effective product to help smokers quit. Although e-cigs were first marketed in the US in 2006, during 2007 and 2008, the e-cig market began to grow rapidly in the US and in Europe.

In April 2009, Obama's FDA revealed its unscientific, unethical and inhumane policy to deceive Americans about e-cigs and defend the FDA's e-cig ban and nearly 1,000 product seizures by US Customs agents: **“We don't want the public to perceive them as a safer alternative to cigarettes.”**

<http://www.webmd.com/smoking-cessation/features/ecigarettes-under-fire>

On July 22, 2009, Obama appointee FDA Deputy Commissioner Josh Sharfstein (and former Henry Waxman staffer who lobbied Congress to enact the Altria negotiated and endorsed FSPTCA) held a press conference with CDC OSH Matt McKenna, longtime tobacco harm reduction opponent Jonathan Winickoff from Big Pharma funded AAP, and soon to be Chair of FDA TPSAC Jonathan Samet to defend the agency's unlawful and unwarranted e-cig ban from lawsuits by two companies whose products were seized. At that press conference, FDA's e-cig lab findings were misrepresented to scare the public to believe e-cigs are carcinogenic and toxic, e-cig companies were falsely accused of target marketing to youth, and it was alleged (without any evidence provided) that e-cigs are addicting children, can be gateways to cigarettes, can renormalize smoking, and don't help smokers quit.

<http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm173222.htm>

<http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm173401.htm>

<http://www.fda.gov/NewsEvents/PublicHealthFocus/ucm173175.htm>

<http://www.fda.gov/downloads/NewsEvents/Newsroom/MediaTranscripts/UCM173405.pdf>

<http://www.fda.gov/downloads/Drugs/ScienceResearch/UCM173250.pdf>

Those fear mongering claims by FDA (defending the agency's ban on e-cigs, and the confiscation of nearly a thousand e-cig shipments by US Customs Agents) were cited in hundreds (perhaps thousands) of news articles and editorials since 2009, and have been cited by hundreds of state and local health officials, e-cig prohibitionists, and politicians (primarily self proclaimed progressive Democrats) to lobby for state and local laws to ban the sale of e-cigs to adults, ban vaping in workplaces, and restrict marketing of e-cigs to adults.

<http://hamptonroads.com/2011/01/ecigarettes-are-they-safe>

But FDA failed to acknowledge that the trace levels of carcinogens found in e-cig products were nearly identical to levels found in FDA approved nicotine gums and patches, or that the trace level of DEG found in one e-cig sample was at a nontoxic level.

<http://www.ncbi.nlm.nih.gov/pubmed/2272559?>

<http://www.healthnz.co.nz/RuyanCartridgeReport30-Oct-08.pdf>

<http://www.healthnz.co.nz/DublinEcigBenchtopHandout.pdf>

<http://www.starscientific.com/404/stepanov%20tsna%20in.pdf>

The FDA also failed to mention that nitrosamines are present in many FDA regulated foods and drinks.

<http://www.ncbi.nlm.nih.gov/pubmed/7228254>

<http://content.karger.com/ProdukteDB/produkte.asp?Aktion=ShowPDF&ArtikelNr=225438&Ausgabe=245272&ProduktNr=223857&filename=225438.pdf>

The FDA also failed to acknowledge previously published research also found that e-cigs help satisfy the cravings of smokers.

[http://www.healthnz.co.nz/ecig\\_effect-2.pdf](http://www.healthnz.co.nz/ecig_effect-2.pdf)

Meanwhile, another 2009 study found that e-cigarettes emit ZERO smoke and appear to be at least 99% less hazardous alternatives to cigarettes.

<http://www.healthnz.co.nz/ECigsExhaledSmoke.htm>

FDA TPSAC member Neal Benowitz had previously conducted a study on the health risks of vaporizing/smoking marijuana at:

<http://medicalmarijuana.procon.org/view.source.php?sourceID=1379>

"[T]here was virtually no exposure to harmful combustion products using the vaporizing device. Since it replicates smoking's efficiency at producing the desired THC effect using smaller amounts of the active ingredient as opposed to pill forms, this device has great potential for improving the therapeutic utility of THC...

By a significant majority, patients preferred vaporization to smoking, choosing the route of delivery with the fewest side effects and greatest efficiency"

"Smokeless Cannabis Delivery Device Found Efficient and Less Toxic,"

A 2010 study found a first generation Ruyan e-cig reduced cravings among smokers as much as FDA approved nicotine inhaler, was more pleasant than the inhaler, and created less mouth and throat irritation than the inhaler.

Tob Control 2010;19:98-103

C Bullen, H McRobbie, S Thornley, M Glover, R Lin, M Laugesen

<http://tobaccocontrol.bmj.com/content/19/2/98.abstract>

Full text of article available at:

<http://www.healthnz.co.nz/2010%20Bullen%20ECig.pdf>

Another study found nicotine levels absorbed by novice e-cig users were far lower than those from cigarette smoking indicating that e-cigarettes may not contain/emit enough nicotine to create addiction.

<http://www.e-cigarette-forum.com/forum/e-cigarette-news/108228-new-eissenberg-study-vindicates-e-cigarettes.html>

Thankfully for the rule of law, public health, civil liberties, market competition and common sense, all 12 federal appeals court judges upheld Judge Richard Leon's January 15, 2010 ruling striking down FDA's e-cig ban as unlawful.

[https://ecf.dcd.uscourts.gov/cgi-bin/show\\_public\\_doc?2009cv0771-54](https://ecf.dcd.uscourts.gov/cgi-bin/show_public_doc?2009cv0771-54)

[https://ecf.dcd.uscourts.gov/cgi-bin/show\\_public\\_doc?2009cv0771-55](https://ecf.dcd.uscourts.gov/cgi-bin/show_public_doc?2009cv0771-55)

Meanwhile, the Big Pharma funded World Health Organization advisory panel TobReg recommended banning e-cigarettes (while keeping far more hazardous cigarettes on the market) at

[http://whqlibdoc.who.int/publications/2009/9789241209557\\_eng.pdf](http://whqlibdoc.who.int/publications/2009/9789241209557_eng.pdf)

that was appropriately criticized by Murray Laugesen

<http://www.healthnz.co.nz/TobRegCritique.doc>

A subsequent WHO FCTC report contained inaccurate claims about smokeless tobacco and e-cigarettes, and advocated policies that protected cigarettes.

[http://apps.who.int/gb/fctc/PDF/cop4/FCTC\\_COP4\\_12-en.pdf](http://apps.who.int/gb/fctc/PDF/cop4/FCTC_COP4_12-en.pdf)

Inaccurate claims were in 3, 15, 16, 28, 29, and the policies that protected cigarettes were in 16, 20, 26, 29 of that document.

In the US, a Citizens Petition by the American Association of Public Health Physicians (AAPHP) exposed, and urged the FDA to correct and clarify the agency's false and misleading claims about e-cigs made at the FDA's July 22, 2009 press conference, and to truthfully inform the public of existing evidence about the products at

<http://www.regulations.gov/search/Regs/home.html#docketDetail?R=FDA-2010-P-0093>

But the FDA never acted on that Citizens Petition filed by the AAPHP.

Instead, the FDA Filed a Reply Brief in SE/NJOY v FDA to DC Court of Appeals in another attempt to deprive cigarette smokers from legally accessing e-cigs.

<http://vaporsforum.com/showpost.php?p=419437&postcount=147>

Meanwhile, the US DC Court of Appeals accepted amici curiae brief (in SE/NJOY v FDA) filed by Smokefree Pennsylvania, American Council on Science and Health, Consumer Advocates for Smokefree Alternatives Association, National Vapers Club, Midwest Vapers Group, Michael Siegel and Joel Nitzkin in support of Judge Leon's ruling, to reject the FDA's appeal and to keep e-cigs legal.

<http://www.e-cigarette-forum.com/forum/e-cigarette-news/92186-se-njoy-vs-fda-discussion-39.html#post1689042>

brief <http://www.vapersclub.com/Ouramicusbrief.pdf>

A 2010 study by Etter found that e-cigs help smokers quit smoking and reduce cigarette consumption.

<http://www.biomedcentral.com/content/pdf/1471-2458-10-231.pdf>

[http://www.upi.com/Health\\_News/2010/05/04/E-cigarettes-helpful-in-quitting-smoking/UPI-68101272951697/](http://www.upi.com/Health_News/2010/05/04/E-cigarettes-helpful-in-quitting-smoking/UPI-68101272951697/)

A survey of e-cig users found e-cigs help smokers quit and reduce health risks (from Chapter 19 of Tobacco Harm Reduction 2010 Yearbook)

<http://tobaccoharmreduction.org/thr2010yearbook.htm>

Electronic cigarettes (e-cigarettes) as potential tobacco harm reduction products: Results of an online survey of e-cigarette users (by Heavner, Dunworth, Bergen, Nissen and Phillips)

”All respondents previously smoked and 91% had attempted to stop smoking before trying ecigarettes. Most respondents resided in the USA (72%) and 21% were in Europe. About half (55%) were 31-50, while 32% were >50 years old. Most (79%) of the respondents had been using e-cigarettes for <6 months and reported using them as a complete (79%) or partial (17%) replacement for, rather than in addition to (4%), cigarettes. The majority of respondents reported that their general health (91%), smoker’s cough (97%), ability to exercise (84%), and sense of smell (80%) and taste (73%) were better since using e-cigarettes and none reported that these were worse. Although people whose e-cigarette use completely replaced smoking were more likely to experience improvements in health and smoking caused symptoms, most people who substituted e-cigarettes for even some of their cigarettes experienced improvements.”

A 2010 study found that many smokers were willing to substitute smokefree tobacco/nicotine alternatives for cigarettes.

<http://www.harmreductionjournal.com/content/pdf/1477-7517-8-1.pdf>

But in 2010, the FDA appointed its Tobacco Products Scientific Advisory Committee (TPSAC) consisting of no tobacco harm reduction advocates but with three members who had financial conflicts of interests by receiving lots of funding from drug companies.

[http://www.eurekalert.org/pub\\_releases/2010-10/uom-eum100110.php](http://www.eurekalert.org/pub_releases/2010-10/uom-eum100110.php)

<http://tobaccocontrol.bmj.com/content/19/5/e1.abstract>

Meanwhile, federally funded Americans for Nonsmokers Rights misrepresented the scientific evidence on e-cigs and repeated fear mongering claims, while advocating vaping bans (by amending smoking bans to falsely redefine vaping a smokefree e-cig as "smoking").

<http://www.no-smoke.org/learnmore.php?id=645>

That same year, DHHS intensified its ideological campaign to end all tobacco use (instead of reducing cigarette morbidity and mortality), promoted abstinence-only intolerance, opposed effective risk reduction alternatives, perpetuated the lie that all tobacco products are similarly hazardous, and exclusively endorsed ineffective and expensive drug industry products for smoking cessation.

<http://www.hhs.gov/ash/initiatives/tobacco/tobaccostrategicplan2010.pdf>

Ironically, long time drug industry funded promoter of NRT John Hughes acknowledged that NRT products are not very effective for smoking cessation. But instead of recommending smokeless tobacco or e-cigs as low risk alternatives, Hughes recommended using multiple NRT products to try quit smoking.

<http://www.healthcpr.ca/Home/tabid/261/EntryId/19/Should-We-Abandon-Use-of->

[Single-Nicotine-Replacement-Therapy-for-Smoking-Cessation-by-John-Hughes.aspx](#)

At the FDA's 2010 workshop entitled: **Risks and Benefits of Long-Term Use of Nicotine Replacement Therapy (NRT) Products; Public Workshop** at:

<http://www.regulations.gov#!documentDetail;D=FDA-2010-N-0449-0001;oldLink=false>

<http://www.fda.gov/Drugs/NewsEvents/ucm221185.htm>

<http://www.fda.gov/downloads/Drugs/NewsEvents/UCM230910.pdf>

<http://www.fda.gov/downloads/Drugs/NewsEvents/UCM230876.pdf>

many presenters and commenters (including two FDA Tobacco Product Scientific Advisory Committee members) cited the strikingly similar health risk and benefit profiles between Swedish snus and Nicotine Replacement Therapy (NRT) gums and lozenges when recommending FDA approve longterm usage of NRT products (since epidemiology studies on NRT aren't available because the products have only been on the market for several decades).

All twelve public hearing speakers at that workshop revealed that noncombustible nicotine products are far less hazardous than cigarettes, and urged FDA to approve the marketing of NRT for long term usage (as it is currently only recommended for 10 weeks).

Bill Godshall of Smokefree Pennsylvania also testimony is below and posted at:

<http://www.e-cigarette-forum.com/forum/e-cigarette-news/133438-fda-urged-approve-nrt-long-term-usage.html>

"I'm Bill Godshall, founder and executive director of Smokefree Pennsylvania, a nonprofit organization that since 1990 has been advocating local, state and federal policies to reduce indoor tobacco smoke pollution, reduce tobacco marketing to youth, hold cigarette companies accountable for their egregious past actions, preserve civil justice remedies for those injured by cigarettes, increase cigarette tax rates, fund tobacco education and smoking cessation services, and inform smokers that all smokefree tobacco/nicotine products are far less hazardous alternatives to cigarettes.

For disclosure, neither I nor Smokefree Pennsylvania have ever received any direct or indirect funding from any tobacco, drug or electronic cigarette company or trade association.

I'm here to urge the FDA to stop protecting cigarettes from market competition by far less hazardous smokefree nicotine and tobacco products.

More than ninety nine percent of all tobacco attributable mortality and more than ninety nine percent of tobacco attributable health care costs in the US are caused by repeated inhalation of tobacco smoke, while <1% are caused by the use of noncombustible tobacco and nicotine products. Existing evidence also indicates that cigarettes are at least 100 times more hazardous than the smokefree nicotine and tobacco products marketed in the US, including smokeless tobacco products, electronic cigarettes and nicotine products marketed to treat tobacco dependence.



While quitting all tobacco/nicotine use may be the best way for smokers to improve their health, switching to smokefree tobacco/nicotine products reduces smoker's health risks nearly as much as quitting all tobacco/nicotine use. Surveys indicate that more than a million smokers have quit smoking by switching to smokeless tobacco products, and sales reports indicate that nearly a half million smokers have switched to electronic cigarettes in just the past several years. Nonsmokers also benefit when smokers switch to or substitute smokefree alternatives, as they emit NO tobacco smoke.

As currently regulated by the FDA to treat tobacco dependence, nicotine products have had a 95% failure rate. But these products are deceptively promoted by drug companies, public health agencies and drug industry funded anti-tobacco organizations as the most effective way to quit smoking.

Although the FDA has only approved nicotine products for short term (10-12 weeks) usage to treat tobacco dependence, research and sales data indicate that a large percentage (probably a majority) of nicotine gum and lozenges are used for "off label" purposes as either long term or temporary nicotine maintenance alternatives to cigarettes.

But instead of taking actions to reduce current "off label" usage of nicotine products, the FDA should encourage and approve the marketing of nicotine products to smokers as long term and as temporary cigarette alternatives, similar to the way smokeless tobacco and electronic cigarettes are marketed to smokers.

Concurrently, the FDA should eliminate the current warning on nicotine products that urge consumers to discontinue use if they also use a tobacco product, and instead should encourage smokers to continue substituting nicotine products for cigarettes as often as possible.

The FDA also should allow the sale of \$5-\$10 packages of nicotine products, allow sales at all retail stores that sell cigarettes, and allow higher levels of nicotine in the products to satisfy the cravings of most smokers.

If the FDA doesn't take these long overdue actions to protect public health, the most effective way for companies to increase nicotine product usage by smokers would be to market their products as tobacco products under the FSPTCA.

The FDA also should stop trying to ban electronic cigarettes by misclassifying them as drug devices, which Federal Judge Richard Leon has already struck down, and instead the FDA should classify and reasonably regulate e-cigarettes as tobacco products in accordance with the FSPTCA.

Josh Sharstein's misleading fear mongering claims about e-cigarettes at a July 22, 2009 press conference, which have been repeated hundreds of times and have appeared in dozens of news articles, also should be clarified and corrected by the agency. The FDA has an ethical duty to inform smokers that nicotine is addictive, but that all smokefree tobacco and nicotine products are far less hazardous long term and temporary alternatives

to cigarettes.

Smokers have a human right to truthful health information and legal access to far less hazardous alternatives. The FDA should provide for that.”

But less than two weeks after that FDA meeting, the CDC (when releasing 2009 BRFSS tobacco use data in 2010 that found significant declines in cigarettes smoking) chose to grossly mislead the public about the risks of smokeless tobacco products.

[http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5943a2.htm?s\\_cid=mm5943a2\\_e](http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5943a2.htm?s_cid=mm5943a2_e)

Among the CDC’s false claims in that report:

"The health consequences of cigarette smoking and smokeless tobacco use both have been well documented, including increased risk for lung, throat, oral, and other types of cancers (1,2)."

"Research suggests that persons who use multiple tobacco products might have a more difficult time quitting, which might result in longer durations of product use and an increased likelihood of experiencing tobacco-related morbidity and mortality (5,6)."

"Other reports also have found that young men have a high prevalence of cigarette smoking and smokeless tobacco use in the United States and that smokeless tobacco might be a starter product for cigarette smoking among young men (6,7)."

In a press release promoting that report, CDC Director Dr. Tom Frieden claimed "Tobacco use is the leading preventable cause of death in this country and unfortunately smokers are also using smokeless tobacco."

<http://consumer.healthday.com/Article.asp?AID=645458>

The CDC’s Terry Pechacek told WebMD "Using smokeless tobacco can keep the nicotine habit alive, making it even harder to quit than going cold turkey," and "The tobacco companies market smokeless tobacco as a substitute for smokers, but they don’t help people quit smoking."

<http://www.webmd.com/smoking-cessation/news/20101104/smokeless-tobacco-rates-on-the-rise>

Longtime smokeless tobacco opponent Steven Hecht (who has been funded by NIH and was hired by the FDA CTP) also grossly exaggerated the very low disease risks of smokeless tobacco to scare/prevent smokers from switching at:

<http://www.webmd.com/cancer/news/20070810/smokeless-tobacco-not-safe-alternative>

<http://www.sciencedaily.com/releases/2007/08/070809130018.htm>

<http://www.medpagetoday.com/HematologyOncology/OtherCancers/6389>

<http://cebp.aacrjournals.org/content/16/8/1567.abstract>

<http://www.sciencedaily.com/releases/2007/12/071224125651.htm>

The CDC’s 2010 BRFSS found record low daily and overall smoking rates (12.7%, 17.7%), significant declines from 2008-2009 (-5%, -3%), from 2007-2008 (-8%, -7%), and from 2005-2009 (-17%, -14%)

[http://apps.nccd.cdc.gov/brfss/display\\_c.asp?yr\\_c=2009&yr=2008&cat=TU&state=US&](http://apps.nccd.cdc.gov/brfss/display_c.asp?yr_c=2009&yr=2008&cat=TU&state=US&)

[bkey=20080018&qkey=4394&qtype=C&grp=0&SUBMIT2=Compare  
http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5943a2.htm?s\\_cid=mm5943a2\\_e](http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5943a2.htm?s_cid=mm5943a2_e)

#### BRFSS Median % Cigarette Smokers

Year	Everyday	Some days
2005	15.3	5.2
2006	14.7	5.1
2007	14.5	5.2
2008	13.4	4.9
2009	12.7	5.0

But two months prior, CDC claimed there was no decline in the smoking rate from 2008-2009, and no significant decline from 2005-2009.

[http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5935a3.htm?s\\_cid=mm5935a3\\_w](http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5935a3.htm?s_cid=mm5935a3_w)

And the previous year, CDC claimed no significant decline in smoking rate from 2007-2008.

<http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5844a2.htm>

Meanwhile in 2010, a retaliatory lawsuit by California Attorney General Jerry Brown (against SE and NJOY, the two companies that sued the FDA) was settled by NJOY, whereby the company agreed to not do what it never did,

[http://ag.ca.gov/cms\\_attachments/press/pdfs/n2008\\_consent\\_judgment\\_se.pdf](http://ag.ca.gov/cms_attachments/press/pdfs/n2008_consent_judgment_se.pdf)  
[http://ag.ca.gov/cms\\_attachments/press/pdfs/n1965\\_sottera\\_consent\\_judgment.pdf](http://ag.ca.gov/cms_attachments/press/pdfs/n1965_sottera_consent_judgment.pdf)

as CA AG Brown continued to misrepresent the evidence about e-cigarettes and e-cigarette marketing in a press release

<http://caag.state.ca.us/newsalerts/release.php?id=1965&>

Later, CA AG Brown announced a settlement with Smoking Everywhere just days before his election for Governor

<http://sify.com/finance/e-cigarette-maker-accepts-california-marketing-limits-news-debt-kk4dkjehfif.html>

that was nearly identical to one with NJOY with Brown again falsely claiming that e-cigs were marketed to youth in a press release nearly identical to the one for the NJOY settlement

<http://ag.ca.gov/newsalerts/release.php?id=2008&>

In December 2010, a Federal Appeals Court panel upheld Judge Leon's ruling that the FDA could not ban e-cigs

<http://prescriptions.blogs.nytimes.com/2010/12/07/e-cigarettes-win-appeals-ruling/?src=twrhp>

<http://reason.com/blog/2010/12/07/appeals-court-says-fda-may-not>

But the FDA responded by asking for a rehearing and rehearing en banc, and filing a motion asking that the stay be reinstated pending a rehearing (Sottera, Inc NJOY v FDA)

FDA files request for a rehearing/rehearing en banc in e-cigarette lawsuit appeal  
<http://online.wsj.com/article/SB10001424052748703581204576033640017829896.html>  
<http://www.e-cigarette-forum.com/forum/e-cigarette-news/92186-se-njoy-vs-fda-discussion-115.html#post2345950>

In response, NJOY filed an "Opposition to Motion for Stay Pending Disposition of Petition for Rehearing and Rehearing En Banc"  
<http://www.e-cigarette-forum.com/forum/e-cigarette-news/92186-se-njoy-vs-fda-discussion-121.html#post2360957>

Meanwhile, the Big Pharma funded e-cig prohibitionists filed an amicus brief in support of FDA's request for a rehearing/rehearing en banc  
<http://www.e-cigarette-forum.com/forum/e-cigarette-news/92186-se-njoy-vs-fda-discussion-124.html#post2378812>

Also in December 2010, a study was published finding that e-cigs are about 99% less hazardous alternatives to tobacco cigarettes (since they emit no smoke), that e-cigs satisfy the cravings of many smokers, and have helped hundreds of thousands of smokers stop smoking or significantly reduce cigarette consumption.  
<http://www.sciencedaily.com/releases/2010/12/101216102116.htm>  
<http://www.palgrave-journals.com/jphp/journal/v32/n1/full/jphp201041a.html>

Ironically, at the beginning of 2011, Barack Obama wisely stated "But we are also making it our mission to root out regulations that conflict, that are not worth the cost, or that are just plain dumb." In an op/ed in the Wall Street Journal entitled "Toward a 21st-Century Regulatory System".  
[http://online.wsj.com/article/SB10001424052748703396604576088272112103698.html?mod=WSJ\\_hp\\_MIDDLENexttoWhatsNewsTop](http://online.wsj.com/article/SB10001424052748703396604576088272112103698.html?mod=WSJ_hp_MIDDLENexttoWhatsNewsTop)

Meanwhile, FDA Deputy Commissioner Josh Sharfstein's departed from the FDA  
<http://www.washingtonpost.com/wp-dyn/content/article/2011/01/04/AR2011010402572.html>

Shortly thereafter, a Federal Appeals Court upheld Judge Leon's ruling against the FDA's e-cig ban by denying FDA's appeal for rehearing and for reinstating stay of an injunction.  
[http://online.wsj.com/article/SB10001424052748703555804576102462014074174.html?mod=googlenews\\_wsj](http://online.wsj.com/article/SB10001424052748703555804576102462014074174.html?mod=googlenews_wsj)  
<http://vaporsforum.com/showthread.php?t=27195> (full text)

FDA's then director for the Center of Tobacco Products Lawrence Deyton called for a "renewed - and expanded - war on tobacco use", and confused tobacco use with tobacco morbidity and mortality, 99% of which is caused by repeated inhalation of tobacco smoke  
<http://www.publichealthreports.org/archives/issueopen.cfm?articleID=2597>

Meanwhile, another lab report published by FDA researchers found nothing hazardous in e-cigarettes, but the abstract failed to acknowledge that finding, while highlighting that some e-cigs contained slightly different levels of nicotine than stated on the package.

<http://www.tandfonline.com/doi/abs/10.1080/10826076.2011.572213>

During that time, Altria began conducting pharmacology, pharmacokinetic and toxicology studies of propylene glycol aerosol in animals

<http://www.sciencedirect.com/science/article/pii/S0300483X11002095>

Then, the FDA issued a “Strategic Priorities on Tobacco Products” that conflicted with FDA policies as well as its past actions

<http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/ucm246751.htm>

”3.3.1 Develop and implement science-based policy, regulations, enforcement strategies, and compliance programs to protect the public health

3.3.2 Provide the public with accurate, trustworthy, and accessible information about tobacco products”

Instead of reducing cigarette consumption/morbidity/mortality, Obama's National Prevention Strategy "Tobacco Free Lives" promoted abstinence-only intolerance, and protected cigarette and drug industry profits by targeting and misrepresenting the disease risks of less hazardous tobacco products. (Note this weblink is longer available)

<http://www.healthcare.gov/center/councils/nphpphc/strategy/report.pdf>

In response to losing the federal lawsuit filed by e-cig companies, on April 25, 2011 the FDA stated its intent to regulate e-cigarettes as tobacco products by imposing the "deeming" regulation and by imposing additional regulations on e-cigarettes (despite the agency's repeated claims that it bases all of its regulatory policies on scientific evidence).

<http://www.fda.gov/NewsEvents/PublicHealthFocus/ucm252360.htm>

The FDA's announcement meant that e-cigarettes, e-liquid, nicotine gums, lozenges, patches, nasal sprays, skin creams, beverages and at least several dissolvables joined cigars and pipe tobacco as tobacco products that are currently unregulated by the FDA (as long as the manufacturer or importer makes no therapeutic claim).

The FDA stated it "intends to propose a regulation" to extend the many different Chapter IX provisions of the FSPTCA

[http://frwebgate.access.gpo.gov/cgi-](http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=111_cong_public_laws&docid=f:publ031.111.pdf)

[bin/getdoc.cgi?dbname=111\\_cong\\_public\\_laws&docid=f:publ031.111.pdf](http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=111_cong_public_laws&docid=f:publ031.111.pdf) to ALL to all currently unregulated tobacco products, which requires the Secretary of HHS to determine that any new regulation "would be appropriate for the protection of the public health," which would not be achieved by the agency's proposed Deeming Regulation.

But instead of pointing out that the FDA had conceded that e-cigs were now legal and that FDA's e-cig ban was unlawful, most news stories touted how the agency intended to regulate e-cigs as tobacco products.

[http://www.boston.com/business/articles/2011/04/26/tobacco\\_rules\\_apply\\_to\\_electronic\\_smokes/](http://www.boston.com/business/articles/2011/04/26/tobacco_rules_apply_to_electronic_smokes/)

<http://www2.journalnow.com/business/2011/apr/26/wsbiz01-fda-to-regulate-e-cigs-as-tobacco-products-ar-978270/>

<http://uk.reuters.com/article/2011/04/26/health-us-fda-tobacco-idUKTRE73O5KK20110426>

<http://www.news-herald.com/articles/2011/04/27/news/nh3931540.txt?viewmode=default>

Meanwhile, Big Pharma funded WHO TobReg urged the banning of e-cig, and imposing more unsubstantiated regulations for smokeless tobacco

[http://www.who.int/tobacco/global\\_interaction/tobreg/publications/tsr\\_955/en/index.html](http://www.who.int/tobacco/global_interaction/tobreg/publications/tsr_955/en/index.html)

WHO TobReg also misrepresented smokeless tobacco risks, and urged sales bans and unsubstantiated regulations

[http://www.who.int/tobacco/global\\_interaction/tobreg/brisbane\\_2002\\_smokeless/en/index.html](http://www.who.int/tobacco/global_interaction/tobreg/brisbane_2002_smokeless/en/index.html)

WHO TobReg opposed smokeless tobacco as harm reduction alternative for smokers

[http://www.who.int/tobacco/global\\_interaction/tobreg/publications/tsr\\_951/en/index.html](http://www.who.int/tobacco/global_interaction/tobreg/publications/tsr_951/en/index.html)

WHO urged taxing smokeless tobacco at same rate as far more hazardous cigarettes

[http://www.who.int/tobacco/publications/tax\\_administration/en/index.html](http://www.who.int/tobacco/publications/tax_administration/en/index.html)

WHO TobReg urged banning flavored tobacco products, but not flavored NRT products

[http://www.who.int/tobacco/global\\_interaction/tobreg/9789241209458.pdf](http://www.who.int/tobacco/global_interaction/tobreg/9789241209458.pdf)

WHO also falsely claimed that all tobacco products similarly deadly

<http://www.who.int/tobacco/resources/publications/wntd/2006/en/index.html>

About the same time, British American Tobacco created Nicoventures to develop new nicotine products

[http://www.bat.com/group/sites/UK\\_\\_3MNFEN.nsf/vwPagesWebLive/DO8FLL93?opendocument&SKN=1](http://www.bat.com/group/sites/UK__3MNFEN.nsf/vwPagesWebLive/DO8FLL93?opendocument&SKN=1)

[http://www.bat.com/group/sites/uk\\_\\_3mnfen.nsf/vwPagesWebLive/DO8FLL93/\\$FILE/medMD8FNE7K.pdf?openelement](http://www.bat.com/group/sites/uk__3mnfen.nsf/vwPagesWebLive/DO8FLL93/$FILE/medMD8FNE7K.pdf?openelement)

<http://www.industryleadersmagazine.com/british-american-tobacco%E2%80%99s-new-tobacco-free-nicotine-nicoventures/>

<http://www.bloomberg.com/news/2011-04-05/bat-creates-division-to-make-safer-alternative-to-cigarettes.html>

[http://www.acsh.org/factsfears/newsID.2510/news\\_detail.asp](http://www.acsh.org/factsfears/newsID.2510/news_detail.asp)

<http://www.ft.com/intl/cms/s/0/4ceee0e6-8c7a-11e0-883f-00144feab49a.html#axzz1O4TOU5Js>

while Philip Morris International bought the rights to a new nicotine delivery system

<http://www.medicalnewstoday.com/articles/226787.php>

<http://www.dailymail.co.uk/health/article-1391541/Smoking-Marlboro-maker-buys-smoke-free-nicotine-inhaler-tobacco-companies-seek-consumer-acceptable-products.html>

In the US, Andrea Vansickle presented data from two ongoing VCU studies finding e-cigs emit nicotine to consumers, which refuted highly publicized claims by VCU researcher Thomas Eissenberg (and now FDA TPSAC member) the previous year stating that e-cigs emit no nicotine.

[http://www.preventionconnections.org/conferenceslides/Tobacco\\_Harm\\_Reduction.pdf](http://www.preventionconnections.org/conferenceslides/Tobacco_Harm_Reduction.pdf)

[http://www.news.vcu.edu/news/Study\\_reveals\\_a\\_need\\_to\\_evaluate\\_and\\_regulate\\_electronic\\_cigarettes](http://www.news.vcu.edu/news/Study_reveals_a_need_to_evaluate_and_regulate_electronic_cigarettes)

A 2011 study found that no-nicotine e-cigarettes were helpful for smoking cessation among smokers with high behavioral dependence

<http://www.medicalnewstoday.com/releases/224925.php>

<http://erj.ersjournals.com/content/early/2011/05/12/09031936.00109610.abstract?sid=eaf9ad0-c457-41ce-a423-830a9879ef42>

A 2011 study: “Interviews With Vapers: Implications for Future Research With Electronic Cigarettes” found that e-cig users switch from cigarettes with a learning curve, report health benefits, and cite new and different products

<http://ntr.oxfordjournals.org/content/early/2011/05/12/ntr.ntr088.abstract?keytype=ref&ijkey=095WzUwnLNO6Er9> (abstract)

<http://ntr.oxfordjournals.org/content/early/2011/05/12/ntr.ntr088.full.pdf+html> (full text)

<http://vapersforum.com/showthread.php?t=30631>

A 2011 survey of 3,587 e-cigarette consumers finds overwhelming majority said products helped them quit smoking

<http://onlinelibrary.wiley.com/doi/10.1111/j.1360-0443.2011.03505.x/abstract>

<http://ectoh.org/documents/3B.5%20Etter%20Electronic%20cigarettes%20-%20utilization%20satisfaction%20and%20perceived%20efficacy.pdf>

<http://www.scribd.com/doc/61623650/Electronic-Cigarettes%E2%80%9494Users-Profile-Utilization-Satisfaction-and-Perceived-Efficiency> (full text)

ACSH critiqued the new survey findings by Etter/Bullen at

[http://www.acsh.org/factsfears/newsID.2883/news\\_detail.asp](http://www.acsh.org/factsfears/newsID.2883/news_detail.asp)

Beginning in 2011, the FDA and its TPSAC considered two integrally related issues involving far less hazardous smokefree Tobacco Harm Reduction alternatives for smokers: Modified Risk Tobacco Products and Dissolvables.

The FDA contracted with the Institute of Medicine (IOM) to recommend guidelines for MRTP claims (i.e. reduced risk claims for cigarettes and smokeless tobacco products). The IOM announced its committee for Scientific Standards for Studies on Reduced Risk Tobacco Products at:

<http://www8.nationalacademies.org/cp/committeevew.aspx?key=49321>

The IOM announced its Committee on Scientific Standards for Studies on Modified Risk Tobacco Products meeting in DC at

<http://iom.edu/Activities/PublicHealth/ModifiedRiskTobacco/2011-MAY-09/Agenda.aspx>

The FDA contracted IOM Committee invited tobacco manufacturers to present (that mostly focus on so-called modified risk cigarettes), invited anti-tobacco activists to present (who misrepresented the comparable health risks of combustible versus noncombustible tobacco); and invited regulators and researchers to present (who proposed dozens of different studies costing millions of dollars before any smokefree product could be truthfully marketed to smokers as less hazardous alternative). But the IOM committee didn't invite any tobacco harm reduction or consumer health advocates to present.

During the public comments period, eight interested parties testified, with all but one presenter pointing out that all smokeless tobacco products are far less hazardous than all cigarettes. The list of people/organizations that made public comments to the IOM Committee is at:

<http://vapersforum.com/showpost.php?p=565463&postcount=4>

The public statement by William T. Godshall, MPH, Executive Director of Smokefree Pennsylvania at the IOM Committee meeting, which was posted at <http://vapersforum.com/showpost.php?p=565457&postcount=1> is reprinted below.

"I'm Bill Godshall, founder and executive director of Smokefree Pennsylvania, a nonprofit organization that since 1990 has been advocating local, state and federal policies to reduce indoor tobacco smoke pollution, reduce tobacco marketing to youth, hold cigarette companies accountable for past misdeeds, increase cigarette tax rates, fund tobacco education and smoking cessation services, and inform smokers that all smokefree tobacco/nicotine products are far less hazardous alternatives to cigarettes.

For disclosure, neither Smokefree Pennsylvania nor I have ever received any direct or indirect funding from any tobacco, drug or electronic cigarette company or trade association.

There appear to be three different types of modified risk or reduced exposure applications that will be submitted to the FDA via Section 911 of the FSPTCA:

- those comparing a smokefree tobacco product to cigarettes,
- those comparing a cigarette to other cigarettes, and
- those comparing a smokefree product to other smokefree products.

Existing scientific evidence indicates that all cigarettes pose similar morbidity and mortality risks, and that all smokeless tobacco products marketed in the US pose similar morbidity and mortality risks. So additional evidence is needed before one cigarette can be determined to be less hazardous than another, and more evidence is needed before one smokeless tobacco product can be determined to be less hazardous than another.

In sharp contrast, many decades of scientific evidence confirms that daily use of smokefree tobacco products marketed in the US and Sweden pose about 99% fewer mortality risks than cigarette smoking, and that switching to smokefree tobacco products reduces a smoker's mortality risks nearly as much as quitting all tobacco/nicotine. Nonsmokers are also exposed to less tobacco smoke when smokers switch to smokefree alternatives.

Since >99% of all tobacco attributable deaths in the US are caused by the repeated inhalation of tobacco smoke, while <1% are caused by the use of noncombustible tobacco products, it is vitally important for this committee to acknowledge these exponential differences of risk and encourage the FDA to incorporate this into the establishment of criteria for evaluating modified risk and reduced exposure tobacco product applications.



In the absence of reduced risk marketing claims, population surveys confirm that several million smokers have already switched to smokeless tobacco products even though the vast majority of smokers inaccurately believe that smokeless tobacco is just as hazardous as cigarettes. So smokeless tobacco products have already saved more lives (of smokers) than could be offset even if every non-tobacco user in America begins to use smokeless tobacco. Even if many more non-tobacco users begin using smokeless tobacco products, the truthful marketing of smokefree tobacco products as lower risk or reduced exposure alternatives to cigarettes can only further reduce tobacco morbidity and mortality (to a meaningful degree).

Therefore, this committee should encourage the FDA to not require new costly studies for a smokefree tobacco product to claim it is less hazardous than cigarettes. But post-market surveillance would be helpful.

Requiring additional scientific studies before a company can make these types of modified risk or reduced exposure claims would be a “truth tax” for far less hazardous smokefree alternatives, would unfairly protect cigarettes from market competition by lower risk alternatives, and would threaten instead of improve public health.

Once the FDA begins approving truthful modified risk or reduced exposure claims for smokeless tobacco products compared to cigarettes, the agency also will be prompted to evaluate and eliminate the 25 year old intentionally misleading Congressionally mandated warning on smokeless tobacco products and advertisements stating: “This product is not a safe alternative to cigarettes,” which has confused most smokers to believe that smokefree products are just as hazardous as cigarettes.

Please remember that smokers have a human right to accurate and relevant health information and legal access to far less hazardous alternatives. The IOM and FDA should ensure that.”

Scott Ballin's statement to the IOM Committee is at:

<http://vaporsforum.com/showpost.php?p=565462&postcount=3>

Elaine Keller's and CASAA's statement to the IOM Committee is at:

<http://www.casaa.org/news/article.asp?articleID=115&l=a&p=>

Unfortunately, at that same meeting the director for the FDA's Center for Tobacco Products Lawrence Deyton instructed the IOM Committee to NOT consider any differences in risk between different types of tobacco products when making recommendations to the FDA (i.e. don't acknowledge that smokeless tobacco products are less hazardous than cigarettes).

<http://www8.nationalacademies.org/cp...aspx?key=49321>

<http://www8.nationalacademies.org/cp/meetingview.aspx?MeetingID=4923&MeetingNo=1>

By instructing the IOM panel to not consider differences in risk between different types of tobacco products, Deyton basically instructed the committee to consider smokeless tobacco products to be just as hazardous as cigarettes, thus sabotaging any objective scientific evaluation and recommendations by the committee.

The Food Drug and Law Institute published an article on the IOM committee meeting.  
<http://www.fdpi.org/membersonly/tobacco/index.html>

Complying with Deyton's instructions, the Institute of Medicine committee issued a report that failed to acknowledge the huge body of scientific evidence confirming that smokefree tobacco products are far less hazardous than cigarettes, and recommended that smokeless tobacco companies be required to spend millions (or tens of millions) of dollars on unwarranted studies prior to submitting an MRTP application to the FDA to truthfully claim that their smokeless tobacco product is less hazardous than cigarettes. When announcing the IOM Committee report, Committee Chair Jane Henney falsely claimed "Right now there's a shortage of scientific evidence on the health effects of modified risk tobacco products."

<http://www.iom.edu/Reports/2011/Scientific-Standards-for-Studies-on-Modified-Risk-Tobacco-Products.aspx>

<http://www8.nationalacademies.org/onpinews/newsitem.aspx?RecordID=13294>

[http://www.iom.edu/~media/Files/Activity%20Files/PublicHealth/Modified-Risk-Tobacco/modifiedrisktobacco\\_reportbrief.pdf](http://www.iom.edu/~media/Files/Activity%20Files/PublicHealth/Modified-Risk-Tobacco/modifiedrisktobacco_reportbrief.pdf)

Bill Godshall criticized the IOM Committee's refusal to consider the scientific evidence and its report at:

<http://www.snuscentral.org/snus-brad-rodu-bill-godshall-snus-news-snus-reviews/bill-godshall-institute-of-medicine-report-to-fda-on-smokeless-tobacco-an-outrage.html>

Jacob Sullum also criticized the committee's actions at "IOM Report Recommends That the FDA Continue Suppressing Lifesaving Information About Cigarette Alternatives"

<http://www.oncologyreport.com/news/clinical/single-article/iom-calls-for-research-on-e-cigs-tobacco-lozenges/d4272d58f9.html>

Also in 2011, the FDA created a new webpage entitled "Health Fraud" at <http://www.fda.gov/TobaccoProducts/ResourcesforYou/ucm255658.htm> addressing MRTP claims in Section 911 of the FSPTCA that grossly misrepresented the scientific and empirical evidence by stating:

"Claiming less harm or reduced risk of disease from using tobacco products misleads consumers to think that these products are safe to use. FDA considers these kinds of claims to be health fraud. These kinds of claims can only be made after scientific evidence to support them has been submitted to FDA, and FDA has issued an order permitting their marketing use. To date, no tobacco products have been scientifically proven to reduce risk of tobacco-related disease, improve safety or cause less harm than other tobacco products."

On August 25/26 of 2011, the FDA held a MRTP workshop, where the FDA invited and

reimbursed numerous tobacco harm reduction opponents, but only several tobacco harm reduction advocates, to present their recommendations on requirements for submitting an MRTP application to the FDA. Most of the tobacco harm reduction opponents urged the FDA to require dozens of new studies costing many millions of dollars before any smokeless tobacco product manufacturer could submit a MRTP application to the FDA to truthfully inform smokers that smokeless tobacco is a less hazardous alternative to cigarettes.

The archived webcast of August 25/26 FDA MRTP workshop

[http://www.fda.gov/TobaccoProducts/NewsEvents/ucm259201.htm#Archived\\_Webcast](http://www.fda.gov/TobaccoProducts/NewsEvents/ucm259201.htm#Archived_Webcast)  
<http://www.fda.gov/TobaccoProducts/NewsEvents/ucm259201.htm>

During the public comment period at the August 25 FDA meeting, William T. Godshall, MPH, Executive Director of Smokefree Pennsylvania presented the following testimony.

“I’m Bill Godshall, founder and executive director of Smokefree Pennsylvania, a nonprofit organization that since 1990 has been advocating local, state and federal policies to reduce indoor tobacco smoke pollution, reduce tobacco marketing to youth, hold cigarette companies accountable, increase cigarette tax rates, fund tobacco education and smoking cessation services, inform smokers that all smokefree tobacco/nicotine products are far less hazardous alternatives to cigarettes, and in 2007 I convinced Senator Mike Enzi to amend the FSPTCA to require picture warnings on cigarette packs.

For disclosure, neither Smokefree Pennsylvania nor I have ever received any direct or indirect funding from any tobacco, drug or electronic cigarette company or trade association.

It is important to recognize that Section 911 and other provisions of Chapter IX of the FSPTCA only apply to: cigarettes, cigarette tobacco, RYO tobacco and smokeless tobacco products. Although the FDA has stated that it intends to propose a regulation to apply Chapter IX to all currently unregulated tobacco products, Section 911 does not apply to small cigars, large cigars, pipe tobacco, hookah/shisha tobacco, electronic cigarettes, e-liquid, tobacco skin cream, tobacco water and at least two dissolvable tobacco products.

Thus, there appear to be three different types of MRTP applications that tobacco companies might submit to the FDA:

- comparing a smokeless tobacco product to cigarettes,
- comparing a cigarette to other cigarettes, and
- comparing a smokeless product to other smokeless products.

Since there is no scientific evidence indicating that any type of cigarette is less hazardous than other cigarettes, and since there is insufficient evidence indicating that any type of smokeless tobacco product is less hazardous than other smokeless tobacco products used in the US, the FDA should require additional studies for MRTP applications seeking to

claim that one cigarette is less hazardous than another and for those seeking to claim that one smokeless product is less hazardous than another.

In sharp contrast, a growing body of scientific evidence has found that daily use of smokefree tobacco products marketed in the US and Sweden pose about 99% fewer mortality risks than cigarettes, and that switching to a smokefree tobacco product reduces a smoker's mortality risks nearly as much as quitting all tobacco/nicotine. Nonsmokers are also exposed to less tobacco smoke when smokers switch to smokeless tobacco. In fact, NRT and smokeless tobacco products have very similar health risk and benefit profiles.

Since >99% of all tobacco attributable deaths and healthcare costs in the US are caused by the repeated inhalation of tobacco smoke, and that <1% are caused by smokeless tobacco products, it is vitally important for the FDA to publicly acknowledge the exponential differences of risk between cigarettes and smokeless tobacco, and to take this into account when considering criteria for evaluating MRTP applications.

Even in the absence of reduced risk marketing claims, population surveys found that several million smokers have already switched to smokeless tobacco products, despite numerous surveys finding that most smokers inaccurately believe smokeless products are as hazardous as cigarettes. So smokeless tobacco products have already saved more lives (of smokers) than could be offset even if every American non tobacco user begins to use smokeless tobacco. Besides, federal and state laws, and the 1998 MSA, already prohibit the marketing of smokeless tobacco products to youth.

The questions posed by the FDA to presenters of this conference inaccurately presume that there is no evidence that smokeless tobacco products are less hazardous than cigarettes.

If the FDA desires further evidence that the marketing of smokeless tobacco to smokers as less hazardous alternatives won't harm public health, the agency should consider that e-cigarettes have been marketed to smokers as less hazardous alternatives for several years. As a result, smokers who switched now account for virtually all e-cigarette consumers, there is no evidence youth or non tobacco users have begun using e-cigarettes, and surveys of e-cigarette consumers have found that nearly all perceive significant health benefits from switching to e-cigarettes, and that most had previously failed to quit smoking by using FDA approved smoking cessation products.

In sum, there is no justification for FDA to require any new studies for the approval of MRTP applications seeking to claim that a smokeless tobacco product is less hazardous than cigarettes. Any regulation requiring smokeless tobacco companies to conduct additional studies to make that claim is tantamount to a "truth tax".

Just as heroin addicts and the public have a right to be truthfully informed that methadone, clean needles and condoms can reduce risks of transmitting and contracting HIV, hepatitis and other diseases, tobacco consumers (and the public) have a human right

to be truthfully informed that smokeless tobacco products are far less hazardous alternatives to cigarettes.

Just as the US Public Health Service had an ethical duty to inform black syphilis patients in the infamous Tuskegee Study that effective syphilis treatments were available, the FDA and public health agencies have an ethical duty to truthfully inform tobacco consumers that smokeless tobacco is far less hazardous than cigarettes.

But since 1986 when Congress enacted the Comprehensive Smokeless Tobacco Education Act, public health agencies have intentionally mislead the public to believe that smokeless tobacco is just as hazardous as smoking cigarettes, which has discouraged tens of millions of smokers from switching to smokeless, and has encouraged smokeless users to switch to far more hazardous cigarettes.

Despite repeated assertions that the FDA will rely upon scientific evidence, the FDA's webpage about Section 911 that is ironically titled "Health Fraud" falsely states "**To date, no tobacco products have been scientifically proven to reduce risk of tobacco-related disease, improve safety or cause less harm than other tobacco products.**"

Although the FDA has stated that it will comply with Judge Richard Leon's ruling that e-cigarettes are tobacco products, the FDA hasn't clarified or corrected any of Josh Sharfstein's prohibitionist fear mongering propaganda about e-cigarettes. The FDA's website still contains inaccurate and misleading information about the risks and benefits of e-cigarettes, false claims that e-cigarettes are marketed to youth, and false claims that e-cigarettes are unapproved drug devices, which continue to be cited in news stories and by prohibitionists to continue deceiving the public.

The FDA also has invited many abstinence-only tobacco prohibitionists to its staff, its TPSAC and to present at this workshop, while inviting very few, if any, harm reduction advocates or tobacco consumers.

It was wrong for cigarette companies to mislead the public about the health risks of cigarettes for decades. But it is far worse for the FDA, health agencies, organizations and/or professionals to mislead the public about the comparable health risks of cigarettes and noncombustible tobacco products.

As long as the FDA and health agencies continue to misrepresent the health risks of smokefree tobacco products, the public will justifiably continue to distrust the FDA on other critically important public health issues.

Ironically, at the FDA's 2010 scientific workshop titled "Risks and Benefits of Long-Term Use of Nicotine Replacement Therapy (NRT) Products", there appeared to be a consensus that longterm use of NRT poses very few if any health risks because longterm use of Swedish snus poses very few if any health risks. I strongly suggest the FDA review presentations and discussions at that conference."

Following that conference, Godshall submitted the following supplemental written comments to FDA's MRTP docket.

“Legal and Regulatory Scope of Section 911 of the Family Smoking Prevention and Tobacco Control Act (FSPTCA)

Pursuant to Judge Richard Leon's ruling in the *Sottera, Inc v FDA* at [https://ecf.dcd.uscourts.gov/cgi-bin/show\\_public\\_doc?2009cv0771-54](https://ecf.dcd.uscourts.gov/cgi-bin/show_public_doc?2009cv0771-54) and the FDA's April, 25, 2011 statement agreeing to comply with Judge Leon's ruling at <http://www.fda.gov/NewsEvents/PublicHealthFocus/ucm252360.htm>, any product containing nicotine derived from tobacco and intended for human consumption can be marketed as a tobacco product (as long as the manufacturer or importer make no therapeutic claims) as defined in Title I Section 101(rr)(1) of the FSPTCA at [http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=111\\_cong\\_public\\_laws&docid=f:publ031.111.pdf](http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=111_cong_public_laws&docid=f:publ031.111.pdf).

But as stipulated in Section 901(b) of the FSPTCA, Chapter IX (including Section 911) of the FSPTCA now only applies “to all cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco products” although the FDA has the authority to apply some/many/all provisions of Chapter IX to other tobacco products, and the agency has stated its intent to propose a regulation (in the future) to propose a regulation that would apply Chapter IX provisions to all presently unregulated tobacco products <http://www.fda.gov/NewsEvents/PublicHealthFocus/ucm252360.htm>.

So at this time, Chapter IX provisions (including Section 911) of the FSPTCA do not apply to small cigars, large cigars, pipe tobacco, hookah/shisha tobacco, electronic cigarettes (e-cigarettes), e-liquid, tobacco skin cream, tobacco water and at least the two dissolvable tobacco products, with the two latter products exempted per FDA's March, 2011 letter to Star Scientific, Inc. informing the company that Chapter IX didn't apply to Ariva-BDL or to Stonewall-BDL (presumably because they don't meet the definition of a smokeless tobacco product) cited at <http://www2.journalnow.com/news/2011/mar/24/wsbiz01-two-tobacco-products-free-of-fda-oversight-ar-886868/>.

Since Chapter IX doesn't apply to many different types of tobacco products, since Chapter IX may not apply to some/many/most/all other dissolvable tobacco products, since new products that resemble FDA approved Nicotine Replacement Therapy (NRT) products can now be lawfully marketed as tobacco products (without being subject to Chapter IX), and since the FDA has stated its intent to propose a regulation to apply Chapter IX to currently unregulated tobacco products, the FDA would be wise to consider the applicability of ALL tobacco and NRT products that are currently on the market, as well as those that could be potentially developed and marketed in the future when researching, considering and developing criteria for approving different types of potential MRTP applications that may be submitted in future years.

It is critically important that the FDA truthfully inform the public about the provisions in Section 911 of the FSPTCA. Unfortunately, the FDA now posts grossly misleading

information about Sections 911, 902 & 903 of the FSPTCA on its webpage ironically entitled “Heath Fraud” at: <http://www.fda.gov/TobaccoProducts/ResourcesforYou/ucm255658.htm> that confuses readers to believe that these sections of the FSPTCA apply to ALL tobacco products by stating: “Claiming less harm or reduced risk of disease from using tobacco products misleads consumers to think that these products are safe to use. FDA considers these kinds of claims to be health fraud. These kinds of claims can only be made after scientific evidence to support them has been submitted to FDA, and FDA has issued an order permitting their marketing use.”

Also on that same webpage, the FDA’s answer to its own question “What is Tobacco-Related Health Fraud?” deceptively states: “False or misleading claims in the promotion, advertising, distribution or sale of tobacco products, including suggestions that a tobacco product is safer, less harmful, contains a reduced level or is free of a harmful substance, or presents a lower risk of tobacco-related disease compared to other tobacco products.”  
**The FDA should correct those misleading statements.**

#### Smokeless Tobacco Products Pose Very Few Health Risks and are Exponentially Less Hazardous Alternatives to Cigarettes

While cigarettes and smokefree tobacco products are similarly addictive (i.e. creating daily dependence), published epidemiology research finds that daily cigarette smoking imposes about 100 times greater mortality risks than does daily use of smokefree tobacco products marketed in the U.S. and Sweden. On a continuum of tobacco mortality risk from 1 to 100 (whereby Nicotine Replacement Products are 1 and cigarettes are 100), smokefree tobacco products are below 2.

Nearly five years ago, I coauthored the most comprehensive evaluation of epidemiology research on smokeless tobacco products, which found that smokeless tobacco products used in the U.S. and Sweden are exponentially less hazardous than cigarette smoking, and recommended that smokers be provided with truthful information about the comparable health risks of different tobacco products and encouraged to switch to smokefree tobacco alternatives if they cannot or don’t want to quit using tobacco.

*Tobacco harm reduction: an alternative cessation strategy for inveterate smokers, Brad Rodu and William T Godshall, Harm Reduction Journal 2006, 3:37doi:10.1186/1477-7517-3-37. <http://www.harmreductionjournal.com/content/3/1/37>*

In 2007, the Royal College of Physicians published a report on the comparable health risks of smokeless tobacco products and cigarettes, that similarly concluded smokeless tobacco products are far less hazardous than cigarettes, and that smokers who cannot or won’t quit tobacco use should be encouraged to switch to smokeless alternatives.

*Harm reduction in nicotine addiction; Helping people who can't quit, Royal College of Physicians, 2007. <http://bookshop.rcplondon.ac.uk/details.aspx?e=234>  
[http://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(07\)61482-2/fulltext#article\\_upsell](http://www.thelancet.com/journals/lancet/article/PIIS0140-6736(07)61482-2/fulltext#article_upsell)*

A comprehensive evaluation of epidemiological research on Swedish snus published in 2007 at [http://nzhta.chmeds.ac.nz/publications/smokeless\\_tobacco.pdf](http://nzhta.chmeds.ac.nz/publications/smokeless_tobacco.pdf) similarly concluded that Swedish snus poses exponentially fewer health risks than cigarettes.

In 2008, the American Association of Public Health Physicians published a white paper at <http://www.aaphp.org/Resources/Documents/20081026HarmReductionResolutionAsPassedl.pdf> that evaluated the existing epidemiological research, and similarly concluded that smokeless tobacco products are exponentially less hazardous than cigarettes, and that vast public health gains could be achieved simply by eliminating the federally required (since 1986) warning on smokeless tobacco products that misleadingly states “This product is not a safe alternative to cigarettes.”

In 2010, the American Association of Public Health Physicians updated the new scientific evidence published since its 2008 white paper at <http://www.aaphp.org/special/joelstobac/2010/harmredcupdatejuly2010.html>

The Tobacco Harm Reduction 2010 yearbook published by TobaccoHarmReduction.org at <http://tobaccoharmreduction.org/thr2010yearbook.htm> similarly evaluated the published research and concluded that the health risks posed by smokeless tobacco products are exponentially fewer than the health risks posed by cigarettes.

A recently updated report by the American Council on Science and Health and Brad Rodu **The Scientific Foundation for Tobacco Harm Reduction, 2006-2011** at <http://www.harmreductionjournal.com/content/pdf/1477-7517-8-19.pdf> evaluating all published studies (during the past five years) on the health risks of smokeless tobacco products, confirming that they are far less hazardous than cigarettes, and that increasingly more smokers have quit smoking by switching to smokeless tobacco alternatives.

Authors of a recently published meta analysis of North American and European epidemiological cohort and case-control studies relating any form of cancer to smokeless tobacco use (i.e. 62 US and 18 Scandinavian studies) reported the following results: “Random-effects meta-analysis estimates for most sites showed little association. Smoking-adjusted estimates were only significant for oropharyngeal cancer (1.36, CI 1.04–1.77,  $n = 19$ ) and prostate cancer (1.29, 1.07–1.55,  $n = 4$ ). The oropharyngeal association disappeared for estimates published since 1990 (1.00, 0.83–1.20,  $n = 14$ ), for Scandinavia (0.97, 0.68–1.37,  $n = 7$ ), and for alcohol-adjusted estimates (1.07, 0.84–1.37,  $n = 10$ ). Any effect of current US products or Scandinavian snuff seems very limited. The prostate cancer data are inadequate for a clear conclusion.” and “Smokeless tobacco-attributable deaths would be 1,102 (1.1%) if as many used smokeless tobacco as had smoked, and 2,081 (2.0%) if everyone used smokeless tobacco.”

*Systematic review of the relation between smokeless tobacco and cancer in Europe and North America, Peter N Lee and Jan Hamling, BMC Medicine 2009, 7:36doi:10.1186/1741-7015-7-36*  
<http://www.biomedcentral.com/1741-7015/7/36>

Another recently published comprehensive meta analyses of 150 studies on various diseases found no association with snus use and cancer of the oropharynx (meta-analysis RR 0.97, 95% CI 0.68-1.37), oesophagus (1.10, 0.92-1.33), stomach (0.98, 0.82-1.17), pancreas (1.20, 0.66-2.20), lung (0.71, 0.66-0.76) or other sites, or with heart disease (1.01, 0.91-1.12) or stroke (1.05, 0.95-1.15). The author concluded: “Using snus is clearly much safer than smoking. While smoking substantially increases the risk of



cancer and cardiovascular diseases, any increase from snus use is undemonstrated, and if it exists is probably about 1% of that from smoking.”

*Summary of the epidemiological evidence relating snus to health, Peter N Lee, Regul Toxicol Pharmacol 2011, Mar, 59(2):197-214 <http://www.ncbi.nlm.nih.gov/pubmed/21163315>*

A previously published and widely reported meta analysis of 11 studies found that snus use was associated with slightly elevated risk of fatal myocardial infarction and fatal stroke, but wasn't associated with all myocardial infarctions or strokes, casting doubt on its findings about fatal heart attacks and strokes.

*Use of smokeless tobacco and risk of myocardial infarction and stroke: systematic review with meta-analysis, Paulo Boffetta, Kurt Straif, BMJ 2009; 339:b3060*  
<http://www.bmj.com/content/339/bmj.b3060.full>

A study found that Star's Ariva and Stonewall dissolvable tobacco products contained far lower levels of tobacco specific nitrosamines than various American moist snuff products and several Swedish snus products, and that nitrosamine levels in Star's Ariva and Stonewall were just slightly higher than nitrosamine levels in GlaxoSmithKline's Nicorette gum and Nicoderm CQ skin patch.

*Tobacco-specific nitrosamines in new tobacco products, Irina Stepanov, Joni Jensen, Dorothy Hatsukami, Stephen S. Hecht, Nicotine and Tobacco Research Volume 8, Number 2 (April 2006) 309-313.*  
<http://www.starscientific.com/404/stepanov%20tsna%20in.pdf>

Another study evaluating plasma nicotine levels, heart rates, and reduction in cigarette cravings following use of Star's Ariva dissolvable tobacco product were very similar to those following use of GlaxoSmithKline's Commit dissolvable nicotine product.

Meanwhile, participants reported that Star's Ariva tasted better than GSK's Commit.

*Evaluating the Acute Effects of Oral, Non-combustible Potential Reduced Exposure Products Marketed to Smokers, Caroline O Cobb, Michael F Weaver, Thomas Eissenberg, Tob Control*  
*doi:10.1136/tc.2008.028993*

[http://static.mgnetwork.com/rtd/pdfs/20090712\\_toba.pdf](http://static.mgnetwork.com/rtd/pdfs/20090712_toba.pdf)

The daily inhalation of tobacco smoke causes more than 99% of tobacco attributable mortality in the US <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5425a1.htm> and more than 99% of all tobacco attributable healthcare costs. Meanwhile, the evidence indicates that the use of smokefree tobacco/nicotine products causes less than .1% of tobacco attributable mortality and healthcare costs.

On a scale of mortality risk from 1 to 100, on which NRT products are 1 and cigarettes are 100, smokeless tobacco products are between 1 and 2. Smokers who switch to smokefree tobacco/nicotine products reduce their health risks nearly as much as smokers who quit all tobacco/nicotine usage. Besides, usage of smokefree tobacco products poses no known risks for nonusers because they emit ZERO smoke.

In light of this recently published research demonstrating that smokeless tobacco products are far less hazardous than cigarettes and pose far fewer oral cancer risks than cigarettes, **the FDA should propose a regulation to eliminate the currently mandated warning labels on smokeless tobacco products that misleading state “This product is not a safe alternative to cigarettes,” and “This product may cause mouth cancer.”**

A 2008 meta analysis of smokeless tobacco use and periodontal diseases at <http://www.biomedcentral.com/1472-6831/8/13> and another 2011 study at <http://www.ncbi.nlm.nih.gov/pubmed/21762421> found that Swedish snus poses far fewer risks of periodontal disease and tooth loss than are posed by cigarette smoking, and poses risks far more similar to those found in never-tobacco-users.

Therefore, **the FDA should propose a regulation to eliminate the inaccurate but currently mandatory warning on smokeless tobacco products that states: “This product may cause gum disease and tooth loss.”**

Millions of smokers in the US, Sweden and Norway have already switched to smokefree tobacco products

Switching from cigarettes to smokefree tobacco products has been occurring in the U.S. and in Sweden for many decades, and isn't an unproven theory (as some harm reduction opponents claim).

The 1986 nationwide Adult Use of Tobacco Survey (AUTS), conducted by the CDC Office on Smoking and Health, found that 7% (i.e., 1.67 million) of male ex-smokers indicated they had used smokeless tobacco (ST) products to help them quit smoking cigarettes, and 6.4% (i.e., 1.63 million) of males who currently smoked indicated using ST to help them quit smoking. In comparison, just 1.7% of male ex-smokers (i.e., 404,600) and 2.4% of males who currently smoked (i.e., 609,000) indicated using organized programs to help them quit smoking cigarettes.

*Smokeless Tobacco Use in the United States: The Adult Use of Tobacco Surveys, Novotny, Pierce, Fiore & Davis, NCI Monograph 8, 25-29, NIH, U.S. DHHS, 1989.*

A 1984 Philip Morris market research survey of 489 adult male ST product users in Houston, Atlanta, and Florida (who were interviewed outside retail stores after purchasing ST) found that 37% of ST users stated they were former cigarette smokers (including 22% of those under age 35 and 50% of those 35 years or older). The survey also found that, in response to the question, “Did you start using smokeless/chewing tobacco as a replacement for cigarettes, that is, when you stopped smoking cigarettes, or not?” 20% of ST users said YES. These findings were consistent in the three different survey locations. Interestingly, 62% of respondents who used both ST and cigarettes reported that ST was “*more enjoyable*” than cigarettes.

*Smokeless Tobacco Study – Atlanta/Florida, Philip Morris USA Marketing Research Department Report, Miller K, <http://tobaccodocuments.org/pm/2045600026-0045.html>*

The 1991 NHIS found that 33.3% (i.e., 1.75 million) of U.S. adult ST users reported being former cigarette smokers, and the 1998 NHIS found that 31.1% of ST users reported being former cigarette smokers. The 1998 NHIS found that 5.8% of daily snuff users reported quitting smoking cigarettes within the past year, that daily snuff users were 3.2 times more likely to report being former cigarette smokers than were never snuff users who had smoked, and that daily snuff users were 4.2 times more likely to have quit smoking in the past year than were never snuff users who had smoked.

*Use of Smokeless Tobacco Among Adults – United States, 1991, Morbidity and Mortality Weekly Report, Vol 42, No 14, 263-266, April 16, 1993, CDC, U.S. DHHS.*

<http://www.cdc.gov/mmwr/preview/mmwrhtml/00020232.htm>

*Tomar S, Snuff Use and Smoking in US Men: Implications for Harm Reduction, American Journal of Preventive Medicine, 2002, Vol. 23, No. 3, 143-149.*

The 1987 NHIS found that, among 23-to-34 year old U.S. males, those who had smoked cigarettes and then subsequently used snuff were 2.1 times more likely to have quit smoking than were cigarette-only users.

*Most smokeless tobacco use is not a causal gateway to cigarettes: using order of product use to evaluate causation in a national US sample, Kozlowski L, O'Connor, Edwards BQ, Flaherty BP, Addiction, 2003, Vol. 98, 1077-1085. <http://www.blackwell-synergy.com/links/doi/10.1046/j.1360-0443.2003.00460.x/abs>*

A study of 51 female and 59 male ST users (in the Northwestern U.S.), in which 98% of females and 90% of males were either current or former cigarette smokers, found that 52% of females and 59% of males responded affirmatively when asked whether they used ST in place of cigarettes while quitting smoking.

*A comparison of male and female smokeless tobacco use, Cohen-Smith D, Severson H, Nicotine & Tobacco Research, 1999, Vol. 1, 211-218.*

Another study found that 72% of an estimated 359,000 U.S. smokers who switched to ST products on their last smoking cessation attempt successfully quit smoking.

*Switching to smokefree tobacco as a smoking cessation method: evidence from the 2000 National Health Interview Survey, Brad Rodu and Carl V Phillips, Harm Reduction Journal 2008, 5:18doi:10.1186/1477-7517-5-18. <http://www.harmreductionjournal.com/content/pdf/1477-7517-5-18.pdf>*

In Sweden, moist oral snuff is called snus. Unlike moist oral snuff commonly used in the U.S., snus is pasteurized, not fermented, and stored in refrigerators from the time of manufacture until sold at retail. Also in contrast to most ST products commonly sold in the U.S. (except for dissolvable ST products), snus is spitfree, contains fewer nitrosamines, and has not been found to be associated with mouth cancer. In 2003, Foulds et al found that snus posed exponentially fewer health risks than cigarettes, and that many Swedish smokers had quit smoking by switching to snus.

*Effect of smokeless tobacco (snus) on public health in Sweden, Foulds J, Ramstrom L, Burke M, Fagerstrom K, Tobacco Control, 2003, Vol 12, 349-359. <http://tc.bmjournals.com/cgi/content/full/12/4/349>*

When a large national sample of Swedish ex-smokers was asked about how they succeeded in quitting, 50% stated that they had stopped without help, 33% said they used snuff, and 17% said they had used some form of NRT.

*Smokeless Tobacco and Cardiovascular Disease, Asplund, K, Progress in Cardiovascular Diseases, Vol. 45, No 5, (March/April) 2003, 383-394.*

Another survey of more than 6,700 Swedes found that more than 25% of male cigarette smokers indicated they had switched to snus. The survey also found that snus was more effective than NRT products as a smoking cessation aid.

*Role of snus in initiation and cessation of tobacco smoking in Sweden, Ramström and Foulds Tob Control.2006; 15: 210-214. <http://tobaccocontrol.bmj.com/cgi/content/full/15/3/210>*

Largely due to smokers switching to snus, the male cigarette smoking rate in Sweden dropped from 40% in 1976 to just 15% in 2002, while snus use among Swedish men

increased from 10% to 23%. Due to this decline in smoking, male lung cancer rates in Sweden are the lowest in Europe, while Sweden's oral cancer rate has fallen during the last 20 years as snus use sharply increased.

*Effect of smokeless tobacco (snus) on public health in Sweden, Foulds J, Ramstrom L, Burke M, Fagerstrom K, Tobacco Control, 2003, Vol 12, 349-359. <http://tc.bmjournals.com/cgi/content/full/12/4/349>*

An international panel of seven experts, using the Delphi approach, estimated that an additional 10% of cigarette smokers would quit over five years if all smokefree tobacco products in the U.S. were required to be low-nitrosamine products and if those products were accompanied by a warning label that stated: "This product is addictive and may increase your risk of disease. This product is substantially less harmful than cigarettes, but abstaining from tobacco use altogether is the safest course of action."

*The potential impact of a low-nitrosamine smokeless tobacco product on cigarette smoking in the United States: Estimates of a panel of experts, Levy D, Mumford E, Cummings KM, et al. Addictive Behaviors, Nov. 2005. <http://www.ascribe.org/cgi-in/behold.pl?ascribeid=20051114.171444&time=07%2042%20PST&year=2005&public=1>*

Authors of a recent survey of Norwegian men who were either former or current smokers reported: "In a regression model in which education, number of previous attempts to quit smoking, perception of risk, and age were controlled for, the odds ratio (OR) for reporting total abstinence at the time of the survey was significantly higher for those who had used varenicline (OR = 4.95,  $p < .006$ ) and snus (OR = 2.68,  $p < .001$ ) compared with those who had used nicotine chewing gum (reference OR = 1)." and "Compared with medicinal nicotine products, snus and varenicline increased the probability of quitting smoking completely".

*The use of snus for quitting smoking compared with medicinal products, Karl Erik Lund, Ann McNeill, Janne Scheffels, Nicotine Tob Res (2010) doi: 10.1093/ntr/ntq105 <http://ntr.oxfordjournals.org/content/early/2010/07/09/ntr.ntq105.full.pdf+html>*

A 2011 study at <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3118776/?tool=pubmed> similarly confirmed that many Swedish male and female smokers have switched to snus, that very few snus users switched to cigarettes, and that dual usage isn't very prevalent but rather primarily serves as a transition period for smokers as they switch to snus. Amazingly, however, the authors of this study misinterpreted their own data by concluding "The increase in snus use is being paralleled by a slight increase in dual use and the smoking prevalence does not seem to be influenced by snus."

### The Vast Majority of Smokers Inaccurately Believe that Smokeless Tobacco Products are as Hazardous as Cigarettes

While ST products are far less hazardous alternatives to cigarettes, a recent survey of more than 13,000 cigarette smokers in the US, Canada, UK and Australia found that only 13% correctly believed that ST products are less hazardous than cigarettes.

*Smokers' beliefs about the relative safety of other tobacco products: Findings from the ITC Collaboration, Richard J. O'Connor; Ann McNeill; Ron Borland; David Hammond; Bill King; Christian Boudreau; K. Michael Cummings, Nicotine & Tobacco Research, Volume 9, Issue 10 October 2007, pages 1033-1042. <http://www.informaworld.com/smpp/content~content=a783052257~db=all~order=page>*

A 2000 survey of 36,012 young adults entering the U.S. Air Force found that 75% of males and 81% of females incorrectly believed that switching from cigarettes to ST products would not result in any risk reduction, while another 16% of males and 13% of females incorrectly believed that only a small risk reduction would occur. Only 2% of males and 1% of females correctly thought that a large risk reduction would occur by switching from cigarettes to ST.

*Modified Tobacco Use and Lifestyle Change in Risk-Reducing Beliefs About Smoking, Haddock CK, Lando H, Klesges RC, et al, American Journal of Preventive Medicine, 2004 Vol. 27, No. 1, 35-41.*

Another survey found that 89% of college freshmen incorrectly believe that ST is just as or more harmful than cigarettes.

*Harm perception of nicotine products in college freshmen, Smith SY, Curbow B, Stillman FA, Nicotine Tob Res. 2007 Sep;9(9):977-82.*

<http://www.informaworld.com/smpp/content~content=a781712955~db=all~tab=content~order=page>

A survey of more than 2,000 adult U.S. smokers found that only 10.7% correctly agreed that ST products are less hazardous than cigarettes, while 82.9% incorrectly disagreed.

*Smoker Awareness of and Beliefs About Supposedly Less-Harmful Tobacco Products, O'Conner RJ, Hyland A, Giovino G, et al, American Journal of Preventive Medicine, 2005, Vol. 29, No. 2, 85-90.*

In yet another survey, when asked if they believed that chewing tobacco is just as likely to cause cancer as smoking cigarettes, 82% of U.S. smokers incorrectly agreed.

*Informing Consumers about the Relative Health Risks of Different Nicotine Delivery Products, presentation by K. Michael Cummings at the National Conference on Tobacco or Health, New Orleans, LA, November 2001.*

A recently published study in 2011 at <http://www.harmreductionjournal.com/content/pdf/1477-7517-8-21.pdf> similarly found that 5 of 6 smokers in the US inaccurately believe that smokeless tobacco products are just as hazardous as cigarettes.

The reason for this lack of knowledge is largely due to the 1986 Comprehensive Smokeless Tobacco Education Act, which required three rotating warnings on all smokeless tobacco products (i.e. This product is not a safe alternative to cigarettes. This product may cause mouth cancer. This product may cause gum disease and tooth loss.) Since the FSPTCA now requires even larger warnings on smokeless tobacco products and advertisements, **it is critically important for the FDA propose a regulation to eliminate these misleading mandatory warnings on smokeless tobacco products.**

Authors of a study that evaluated 316 English language websites (none of which were tobacco companies) that contained health risk information about cigarettes and smokeless tobacco use concluded: "The risk from ST is widely conflated with the risk from cigarettes on websites that provide health advice and information. Almost every website had statements that played up the health risks from ST without caveat, making it difficult for consumers to recognize the huge contrast with cigarettes. The quantitative claims of health risks from ST were very often beyond a worst-case-scenario interpretation of the scientific literature. A large portion of websites directly stated or implied that the risks from ST and cigarettes are similar."

*You might as well smoke; the misleading and harmful public message about smokeless tobacco, Carl V Phillips, Constance Wang, Brian Guenzel,*

*BMC Public Health* 2005, 5:31doi:10.1186/1471-2458-5-31  
<http://www.biomedcentral.com/1471-2458/5/31>

It is extremely important that FDA truthfully inform all tobacco consumers and the public about the vastly different health risks and benefits of different types of tobacco products. Unfortunately, the FDA, like many other government health agencies, is presently misrepresenting the health risks of different products by falsely claiming:

**“To date, no tobacco products have been scientifically proven to reduce risk of tobacco-related disease, improve safety or cause less harm than other tobacco products.”** at <http://www.fda.gov/TobaccoProducts/ResourcesforYou/ucm255658.htm>, the webpage entitled “Health Fraud”. **The FDA needs to correct that webpage ASAP.**

### Smokers have a Human Right to be Truthfully Informed that Smokeless Tobacco Products are Far Less Hazardous Alternatives to Cigarettes

Just as sexually active individuals have a human right to be informed that condoms can reduce risks of pregnancy and STD transmission, and just as heroin addicts have a right to be informed that clean needles can reduce risks of HIV, hepatitis and other blood borne diseases, cigarette smokers have a human right to be truthfully informed that ST products are far less hazardous alternatives than cigarettes.

*Harm reduction, public health, and human rights: Smokers have a right to be informed of significant harm reduction options, Kozlowski L, Nicotine & Tobacco Research, S55-S60, 2002.*

[http://ash.org.uk/html/regulation/pdfs/hr\\_kozlowski.pdf](http://ash.org.uk/html/regulation/pdfs/hr_kozlowski.pdf)

*First Tell The Truth, A Dialogue on Human Rights, Deception, and the Use of Smokeless Tobacco as a Substitute for Cigarettes, Kozlowski L, Tob Control, 12:34-36, 2003.*

[http://tc.bmjournals.com/cgi/search?andorexactfulltext=and&resourcetype=1&disp\\_type=&sortspec=relavance&author1=&fulltext=&volume=12&firstpage=34](http://tc.bmjournals.com/cgi/search?andorexactfulltext=and&resourcetype=1&disp_type=&sortspec=relavance&author1=&fulltext=&volume=12&firstpage=34)

### Public Health Officials have an Ethical Duty to Truthfully Inform Smokers that Smokeless Tobacco Products are Far Less Hazardous Alternatives

Just as the US Public Health Service had an ethical duty to inform black syphilis sufferers in the notorious Tuskegee Study that there were effective treatments for syphilis, public health officials have an ethical duty to truthfully inform smokers that ST products are less hazardous alternatives to cigarettes. To intentionally deceive smokers and the public about health risks of smokeless tobacco products is public health malpractice.

### No Evidence Smokeless Tobacco is a Gateway to Cigarette Smoking

Authors of a recently published analysis of NSDUH data concluded that: “Smokeless Tobacco (ST) use has played virtually no role in smoking initiation among White men and boys, the demographic groups among which ST use is most prevalent. There is evidence that, compared with cigarette initiators, ST initiators are significantly less likely to smoke.”

*Evidence against a gateway from smokeless tobacco use to smoking, Brad Rodu and Philip Cole, Nicotine Tob Res (2010) 12 (5): 530-534. doi: 10.1093/ntr/ntq033*

<http://ntr.oxfordjournals.org/content/12/5/530.short>

Using most of the same data, a 2009 SAMHSA report found that, among US residents who had used both cigarettes and smokeless tobacco products in their lifetime, 65.5% used cigarettes prior to smokeless tobacco use, and 31.8% used smokeless tobacco prior to cigarette usage.

Substance Abuse and Mental Health Services Administration, Office of Applied Studies. (February 19, 2009). *The NSDUH Report: Smokeless Tobacco Use, Initiation, and Relationship to Cigarette Smoking: 2002 to 2007*. Rockville, MD. <http://www.oas.samhsa.gov/2k9/smokelesstobacco/smokelesstobacco.htm>

### Smokeless Tobacco Products Pose Very Little Risk of Accidental Child Ingestion

A recently published article, which has been widely publicized by abstinence-only advocates who oppose tobacco harm reduction, alleged that dissolvable tobacco products (which the author's repeatedly referred to as candy-like) are potentially toxic to children and that thousands of cases of ingestion of tobacco products has been reported.

*Unintentional Child Poisonings Through Ingestion of Conventional and Novel Tobacco Products*, Gregory N Connolly, Patricia Richter, Alfred Aleguas Jr, Terry Pechacek, Stephen Stanfill, Hilbert Albert, *Pediatrics* 2009-2835.

<http://pediatrics.aappublications.org/content/early/2010/04/19/peds.2009-2835.abstract>

In rebutting the alarmist claims made in the Connolly et al article, Brad Rodu revealed that, according to the 2008 report of the American Association of Poison Control Centers, all types of tobacco products only accounted for 1% of all reported exposures to non-pharmaceutical agents of all kinds in children less than 6 years of age, and that smokeless tobacco products accounted for just 15% of the reported tobacco exposures.

*Poisoning Public Health Issues*, Brad Rodu, *Tobacco Truth*, April 19, 2010

<http://rodutobaccotruth.blogspot.com/2010/04/poisoning-public-health-issues.html>

A recently published study at <http://www.sciencedirect.com/science/article/pii/S0273230011001553> evaluated twenty-seven years of annual reports by American Association of Poison Control Centers (AAPCC) for occurrence and outcomes associated with accidental ingestion events involving tobacco and pharmaceutical nicotine products among young children. In sharp contrast to the alarmist claims by Connolly et al (cited above), the author of this far more comprehensive review concluded: "The rate of major, non-fatal, outcomes was <0.1%. Data from AAPCC reports and other sources indicate the frequency of accidental poisoning events is relatively low for tobacco products compared with other products such as drugs, dietary supplements, cleaning products, and personal care products. These findings, along with those for pharmaceutical nicotine products, are consistent with published case reports and reviews, indicating that the frequency and severity of outcomes associated with accidental ingestion of tobacco products by young children appear to be relatively low. However, adults should keep tobacco products out of the reach of children."

### The Overwhelming Majority of NRT Users Switch Back to Cigarettes

A meta-analysis found that an average of just 7% of those using over-the-counter NRT products remained cigarette free after six months, a 93% relapse rate.

*A meta-analysis of the efficacy of over-the-counter nicotine replacement, Hughes JR, Shiffman S, Callas P, Zhang Z, Tobacco Control, 2003, Vol. 12, 21-27.*  
<http://tc.bmjournals.com/cgi/content/full/12/1/21?ijkey=5.ko5/Oz4yutl>

Another recent meta-analysis also found that 7% of NRT remain cigarette free after six months, and that just 2% remain cigarette free after 20 months (a 98% relapse rate).

*Effectiveness and safety of nicotine replacement therapy assisted reduction to stop smoking: systematic review and meta-analysis, David Moore, Paul Aveyard, Martin Connock, Dechao Wang, Anne Fry-Smith, Pelham Barton, BMJ 2009;338:b1024*  
[http://www.bmj.com/cgi/content/full/338/apr02\\_3/b1024](http://www.bmj.com/cgi/content/full/338/apr02_3/b1024)

A meta analysis of seven placebo controlled randomised controlled trials involving different NRT products found that just 6.75% of those receiving NRT had quit smoking after six months. While this may have been twice the quit rate compared to placebo, it represents a 93.25% failure rate for smoking cessation, and clearly indicates that smokers need additional and alternative methods of reducing the health risk of cigarette smoking.

*Effectiveness and safety of nicotine replacement therapy assisted reduction to stop smoking: systematic review and meta-analysis, David Moore, Paul Aveyard, Martin Connock, Dechao Wang, Ann Fry-Smith, Pelham Burton, BMJ 2009; 338:b1024*  
<http://www.sciencedirect.com/science/article/pii/S0306460311001572>

While supposedly double-blind clinical trials have found that NRT products double the chances of quitting when compared to using a placebo, skepticism has been raised about the accuracy and reliability of these studies, since it is likely that many participants who were assigned to placebos realized they were not getting nicotine.

*The blind spot in the nicotine replacement therapy literature: Assessment of the double-blind in clinical trials, Mooney M, White T, Hatsukami D, Addictive Behaviors, 2004 Vol. 29, 673-684.*  
[http://whyquit.com/studies/NRT\\_Blinding\\_Failures.pdf](http://whyquit.com/studies/NRT_Blinding_Failures.pdf)

*Precessation treatment with nicotine patch significantly increases abstinence rates relative to conventional treatment, Jed E. Rose, Joseph E. Herskovic, Frederique M. Behm and Eric C. Westman, Nicotine & Tobacco Research 2009 11(9):1067-1075; doi:10.1093/ntr/ntp103.*  
<http://ntr.oxfordjournals.org/cgi/content/abstract/ntp103>

Skin patches appear to be ineffective smoking cessation aids for those who fail to quit smoking during their first use of NRT, as two published studies on the use of NRT skin patches to quit smoking after an initial failure with NRT found six-month smoking cessation rates of 0% and 1.4%, respectively.

*Recycling with nicotine patches in smoking cessation. Tonnesen P, Norregaard J, Sawe U, Simonsen K, Addiction. 1993 Apr;88(4):533-9.*  
[http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=pubmed&dopt=Abstract&list\\_uids=8485431&query\\_hl=2](http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=pubmed&dopt=Abstract&list_uids=8485431&query_hl=2)

*Double blind trial of repeated treatment with transdermal nicotine for relapsed smokers. Gourlay SG, Forbes Q, Marriner T, et al. British Medical Journal, 1995, Vol. 311, No 7001 363-366.*

A survey of 500 U.S. smokers found only 16% agreed that NRT helps people quit smoking.

*Attitudes toward nicotine replacement therapy in smokers and ex-smokers in the general public. Etter JF, Perneger TV, Clinical Pharmacol Therapy 2001 Volume 69, 175-83.*



An estimated 36.6% of current nicotine gum users have consumed the product for longer than six months, indicating that long-term nicotine maintenance can occur with NRT gum, just as can occur with smokefree tobacco products.

*Persistent use of nicotine replacement therapy: analysis of actual purchase patterns in a population based sample, Shiffman S, Hughes JR, Pillitteri JL, Burton SL, Tobacco Control, Vol. 12, 310-316, 2003.*  
<http://tc.bmjournals.com/cgi/content/full/12/3/310>

Dissolvable nicotine lozenges marketed by GlaxoSmithKline as smoking cessation aids (formerly called Commit and now called Nicorette) have been available in different flavorings, including cherry, mint and formerly cappuccino.

<http://www.nicorette.com/quit-smoking-products/nicorette-nicotine-lozenge.aspx?showsplash=true>  
<http://www.nicorette.com/quit-smoking-products/nicorette-mini.aspx>

Ironically (or not), critics of flavored tobacco products that receive funding from drug companies have remained silent about strikingly similar flavored NRT products.

This extensive research indicates that the more than 95% of smokers who have used NRT products (to quit smoking) relapse back to cigarettes, that subsequent attempts to quit by using NRT virtually always fail, and that smokers should be provided truthful information about, and legal and affordable access to, other types of smokefree tobacco/nicotine products.

Marketing of tobacco products to minors violates the 1998 Master Settlement Agreement, laws in all 50 states, and the FSPTCA

Although some anti-tobacco activists continue to publicly accuse tobacco companies of target marketing tobacco products to youth (including dissolvable tobacco products), it is critically important to note that marketing tobacco products to minors violates the 1998 Master Settlement Agreement, statutes in all 50 states, and the FSPTCA.

During the Senate HELP Committee markup of the FSPTCA in 2009, Senators Sherrod Brown and Jeff Merkley (when proposing the amendment to require the FDA to study dissolvable tobacco products) repeatedly accused RJ Reynolds of target marketing the company's new dissolvable tobacco products (i.e. Camel Orbs, Strips and Sticks) to minors. But no evidence was provided indicating that Reynolds (or any other tobacco company) was marketing their tobacco products to minors.

Similar unsubstantiated allegations were made against Star back in 2001/2002 when Citizens Petitions urged the FDA to ban Star's Ariva and Stonewall dissolvable tobacco products. In the past decade, no evidence has been provided indicating that youth use Ariva or Stonewall, or that Star markets its products to minors.

All three of the 2001/2002 Citizen Petitions urging the FDA to ban Star's Ariva and Stonewall also repeatedly referred to the products as "candy like" in an attempt to deceive the agency and the public to believe that Star was marketing to youth. A decade later, and the same false "candy like" references to dissolvable tobacco products has been repeated by those who accuse tobacco companies of marketing the products to minors.

Instead of repeating unsubstantiated accusations to the media, anyone who has any evidence that any tobacco products are being illegally marketed to youth should notify the State AG, State Health Department and/or FDA for enforcement or other remedial action.

Referring to any tobacco product as “candy” or “candy-like” can only encourage youth to use these products, which raises serious concerns about the true motives of those who call tobacco products “candy” or “candy-like”. But that’s precisely what many anti tobacco activists have done, including Karla Sneegas from the Indiana Dept. of Health, as well as in an article recently coauthored by FDA’s Lawrence Deyton.

At the July TPSAC meeting, Neal Benowitz repeatedly cited the results of a 2010 junk science push-poll at <http://www.healthyouthva.org/documents/Meltdown.pdf> that showed prearranged photographs of similar looking candy and tobacco products/packages to youth (the latter of which most youth had never heard of or seen before), and then asked the youth if they believed the tobacco products looked like candy and if they might want to try using them. The grossly misleading VA Foundation for Healthy Youth's press release publicizing the manufactured results of this push-poll is at: [http://www.healthyouthva.org/documents/press-releases/Smokeless\\_Tobacco\\_Survey\\_Rel\\_May2010.pdf](http://www.healthyouthva.org/documents/press-releases/Smokeless_Tobacco_Survey_Rel_May2010.pdf) and a subsequent newspaper article (that repeated the push-poll’s unscientific findings) entitled “Many teens mistook smokeless tobacco products for candy” is at: [http://www2.timesdispatch.com/rtd/business/local/article/B-TOBA07\\_20100506-210802/342684/](http://www2.timesdispatch.com/rtd/business/local/article/B-TOBA07_20100506-210802/342684/)

Since Section 906(d)(3)(A)(ii) of the FDA tobacco laws prohibits the FDA from banning tobacco sales to 18 year olds (the vast majority of whom are 12<sup>th</sup> grade high school students), it is doubtful that any amount or type of FDA tobacco regulation can substantially reduce tobacco use among 12<sup>th</sup> graders (or underclass peers/siblings who obtain tobacco from 18 year olds).

Although some surveys indicate that youth usage of smokeless tobacco products has increased slightly during the past several years, it is likely that many new youth smokeless users are also cigarette smokers who desire smokefree alternatives to cigarettes. While many anti tobacco extremists have falsely claimed that smokers who also use smokefree tobacco products increase their risks, dual usage of smokeless tobacco and cigarettes is a necessary prerequisite (that can last several weeks, months or years) for cigarette smokers to switch to less hazardous smokefree alternatives, which sharply reduces their tobacco attributable disease and death risks.

Interestingly, a newly published survey of 14-18 year old adolescents in Finland found that 10% had used NRT products, and that most users were daily smokers. The reasons for NRT use were just try (56%), to quit (33%) and smoking not possible (24%).

*Adolescents’ self-reported reasons for using nicotine replacement therapy products: A population-based study, Susanna Raisamo, David Doku, Arja Rimpela, Addictive Behaviors Volume 36, Issue 9, September 2011, 945-947.*

<http://www.sciencedirect.com/science/article/pii/S0306460311001572>

## Electronic Cigarettes also are Far Less Hazardous Alternatives to Cigarettes, and Have Helped About a Million Smokers Quit Smoking

Although electronic cigarettes (e-cigarettes) are not currently subject to Section 911's MRTP provisions, approximately one million smokers have quit smoking or sharply reduced their cigarette consumption by switching to or substituting smokefree e-cigarettes. To date, there is no evidence that e-cigarette usage has harmed anyone, which is logical since the products emit a tiny amount of vaporized nicotine (similar to nicotine inhalers that are marketed as smoking cessation aids) and water vapor. Of the dozen plus laboratory tests conducted on e-cigarettes, only one (conducted by the FDA in 2009) found a trace (and well below toxic) level of one so-called toxic chemical in just one of eighteen samples tested, and levels of nitrosamines in e-cigarettes are nearly identical to those in nicotine gums and patches. And despite marketing claims by many e-cigarette companies that the products are less hazardous than cigarettes, there is no evidence that e-cigarettes are used by youth or non-tobacco-users.

<http://www.healthnz.co.nz/RuyanCartridgeReport30-Oct-08.pdf>

<http://www.starscientific.com/404/stepanov%20tsna%20in.pdf>

<http://www.casaa.org/resources/lab.asp>

<http://www.hsph.harvard.edu/centers-institutes/population-development/files/article.jphp.pdf>

[http://www.jstage.jst.go.jp/article/seikatsueisei/55/1/55\\_59/article](http://www.jstage.jst.go.jp/article/seikatsueisei/55/1/55_59/article)

<http://erj.ersjournals.com/content/early/2011/05/12/09031936.00109610.abstract?sid=eadf9ad0-c457-41ce-a423-830a9879ef42>

<http://ectoh.org/documents/3B.5%20Etter%20Electronic%20cigarettes%20-%20utilization%20satisfaction%20and%20perceived%20efficacy.pdf>

<http://ntr.oxfordjournals.org/content/early/2011/05/12/ntr.ntr088.abstract?keytype=ref&ijkey=095WzUwnLNO6Er9>

<http://www.thetakeaway.org/2011/may/31/rethinking-quitting-campaigns-world-no-smoke-day/>

<http://www.scribd.com/doc/61623650/Electronic-Cigarettes%E2%80%94Users-Profile-Utilization-Satisfaction-and-Perceived-Efficiency>

<http://www.ncbi.nlm.nih.gov/pubmed/21801287>

<http://www.scirp.org/journal/PaperInformation.aspx?paperID=6134&publishStatus=2>

<http://www.sciencedirect.com/science/article/pii/S0300483X11002095>

<http://www.tandfonline.com/doi/abs/10.1080/10826076.2011.572213>

<http://www.casaa.org/news/article.asp?articleID=197&l=a&p=>

<http://www.cabinetoffice.gov.uk/resource-library/behavioural-insight-team-annual-update>

Former FDA Commissioner David Kessler has also acknowledged the benefits of smokeless tobacco, dissolvables and e-cigarettes as less hazardous alternatives for cigarette smokers at <http://www.westport-news.com/business/article/Q-A-Former-FDA-Commissioner-talks-about-tobacco-1735433.php> by stating "there's no doubt that in terms of risk of death there are some advantages to that substitution."

E-cigarettes also have been found to contain/emit similar or lower levels of nicotine than nicotine gums and lozenges

<http://www.healthnz.co.nz/2010%20Bullen%20ECig.pdf>

<http://www.e-cigarette-forum.com/forum/e-cigarette-news/108228-new-eissenberg-study-vindicates-e-cigarettes.html>

This indicates that e-cigarettes emit enough nicotine to satisfy the cravings of smokers, but may not emit enough nicotine to addict nonsmokers. Several published surveys have confirmed that e-cigarettes satisfy the cravings of smokers, and provide many health benefits to users who switched from cigarettes.

<http://ntr.oxfordjournals.org/content/early/2011/05/12/ntr.ntr088.full.pdf+html>  
<http://www.biomedcentral.com/content/pdf/1471-2458-10-231.pdf>  
<http://tobaccoharmreduction.org/thr2010yearbook.htm> (see chapter 9)

Other public health organizations that have extensively studied e-cigarettes have also endorsed their use by smokers, including The American Association of Public Health Physicians at <http://www.regulations.gov/search/Regs/home.html#docketDetail?R=FDA-2010-P-0093> and the American Council on Science and Health at [http://www.acsh.org/factsfears/newsID.2849/news\\_detail.asp](http://www.acsh.org/factsfears/newsID.2849/news_detail.asp).

Unfortunately, after stating it would comply with Judge Richard Leon's court ruling at <http://www.fda.gov/NewsEvents/PublicHealthFocus/ucm252360.htm>, FDA webpages continue to falsely claim that e-cigarettes are unapproved drug devices, continue to misrepresent the health risks and benefits, and continue to falsely claim that e-cigarettes are marketed to children via legally defective 2009/2010 agency documents, including former FDA Deputy Commissioner Josh Sharfstein's July 22, 2009 press conference materials and the agency's gross misrepresentation of its own laboratory report findings on SE & NJOY e-cigarettes products <http://www.fda.gov/NewsEvents/PublicHealthFocus/ucm172906.htm>.

**The FDA should take corrective action to eliminate all of the agency's inaccurate and misleading claims about e-cigarettes, and issue a correction/clarification to the public."**

During that same summer (2011), the FDA TPSAC held a meeting to discuss Dissolvable Tobacco Products (as mandated by the FSPTCA). Prior to that meeting, however, TPSAC member Greg Connolly, CDC's Terry Pechacek, and AAP's Jonathan Winickoff falsely claimed (in an article published by AAP's Pediatrics) that dissolvables poison children and are target marketed to youth. While the data they cited found that cigarettes accounted for 77% of 13,705 reported childhood tobacco ingestions compared to just one (.00007%) ingestion of a Camel Orb, the article was entitled "Unintended Child Poisonings Through Ingestion of Conventional and Novel Tobacco Products", contained a picture of Camel Orbs (but not cigarettes) and claimed that Camel Orbs are "toxic" and "poisonous".

A NY Times article with the headline "Flavored Tobacco Pellets Are Denounced as a Lure to Young Users" interviewed the authors of that so-called study, who further demonized dissolvable tobacco products at:

<http://www.nytimes.com/2010/04/19/business/19smoke.html?src=busln>

Commenting on the study to further vilify dissolvable tobacco products, CTFK's Matt Myer's was quoted as saying "Some of these products look like candy, are flavored like candy and have colorful packaging like candy."

<http://www.cnn.com/2010/OPINION/06/29/myers.big.tobacco/>

Then, GlaxoSmithKline urged the FDA to stop RJR test-market sales of smokefree tobacco products

<http://www2.journalnow.com/business/2010/oct/04/drug-maker-asks-fda-to-stop-rjr-test-market-sales-ar-434417/>

In preparation for the July 21/22 FDA TPSAC meeting at

<http://www.fda.gov/AdvisoryCommittees/Calendar/ucm257684.htm>

FDA's David Ashley instructed the TPSAC to focus on potential and hypothetical risks posed by dissolvables, but didn't ask the TPSAC to consider any potential benefits of the products.

"Questions to TPSAC

1) In response to the information you have been provided for this meeting, discuss the possible public health impact relating to:

- a) marketing of dissolvable tobacco products
- b) perception and use of dissolvable tobacco products by children and adults
- c) abuse liability of dissolvable tobacco products
- d) health risks of dissolvable tobacco products
- e) risk of accidental ingestion of dissolvable tobacco products
- f) features of dissolvable tobacco products that may contribute to tobacco initiation
- g) features of dissolvable tobacco products that may lead tobacco users to singular or dual-use of dissolvable tobacco products instead of quitting"

During that July 21/22 meeting, TPSAC member Neal Benowitz repeatedly cited findings of a junk science push-poll (that FDA invited the authors to present at the meeting) in which youths were deceived to believe three new smokefree tobacco products (which most youths hadn't previously seen or heard of) were candy products (by showing them intentionally deceptive look-alike photos), and then asked the youths if they believed the tobacco products looked like candy, and if they might try using them.

<http://www.healthyouthva.org/documents/Meltdown.pdf>

In sharp contrast, William T. Godshall and Smokefree Pennsylvania submitted lengthy written comments similar to those submitted to the FDA on MRTP (including the following excerpts) to FDA TPSAC for its July 2011 meeting and its forthcoming study and report on dissolvable tobacco products.

#### “Legal and Regulatory Scope of Dissolvable Tobacco Products

Pursuant to Judge Richard Leon's ruling in the Sottera, Inc v FDA at

[https://ecf.dcd.uscourts.gov/cgi-bin/show\\_public\\_doc?2009cv0771-54](https://ecf.dcd.uscourts.gov/cgi-bin/show_public_doc?2009cv0771-54) and the FDA's April, 25, 2011 statement agreeing to comply with Judge Leon's ruling at

<http://www.fda.gov/NewsEvents/PublicHealthFocus/ucm252360.htm> any product containing nicotine that is intended for human consumption can be marketed as a tobacco product as long as the manufacturer or importer makes no therapeutic claim.

Therefore, the TPSAC should consider ALL dissolvable tobacco and nicotine products, including Nicotine Replacement Therapy (NRT) products, in its forthcoming study and report on dissolvable tobacco products.

Since the FDA notified Star Scientific, Inc. in March, 2011 that Chapter IX of the Family Smoking Prevention and Tobacco Control Act (FSPTCA) [http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=111\\_cong\\_public\\_laws&docid=f:publ031.111.pdf](http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=111_cong_public_laws&docid=f:publ031.111.pdf) doesn't apply to two of the company's dissolvable tobacco products [Ariva-BDL and Stonewall-BDL] (presumably because they don't meet the definition of a smokeless tobacco product) <http://www2.journalnow.com/news/2011/mar/24/wsbiz01-two-tobacco-products-free-of-fda-oversight-ar-886868/>, since dissolvable nicotine products also probably don't meet the definition of a smokeless tobacco product, and because other dissolvable tobacco products may not meet the definition of a smokeless tobacco product, it would be wise for the TPSAC to realize that Chapter IX of the FSPTCA may not apply to some/many/most/all dissolvable tobacco products.

### Dissolvable Tobacco Products are Similar to Dissolvable NRT Products

At the FDA's 2010 workshop entitled: Risks and Benefits of Long-Term Use of Nicotine Replacement Therapy (NRT) Products; Public Workshop <http://www.regulations.gov/#!documentDetail;D=FDA-2010-N-0449-0001;oldLink=false>

many presenters and commenters (including two TPSAC members) cited the similarities between Swedish snus and NRT products in suggesting that Swedish snus studies be considered for evaluating the long term risks and benefits of NRT usage (since longterm studies on NRT aren't available because the products have only been on the market for several decades).

Since dissolvable tobacco products have been on the market for the past decade, and since these products also closely resemble Swedish snus, the TPSAC should also consider research on Swedish snus in evaluating dissolvable tobacco products.

A study evaluating plasma nicotine levels, heart rates, and reduction in cigarette cravings following use of Star's Ariva dissolvable tobacco product were very similar to those following use of GlaxoSmithKline's Commit dissolvable nicotine product. Meanwhile, participants reported that Star's Ariva tasted better than GSK's Commit.

*Evaluating the Acute Effects of Oral, Non-combustible Potential Reduced Exposure Products Marketed to Smokers, Caroline O Cobb, Michael F Weaver, Thomas Eissenberg, Tob Control*  
doi:10.1136/tc.2008.028993

[http://static.mgnetwork.com/rtd/pdfs/20090712\\_toba.pdf](http://static.mgnetwork.com/rtd/pdfs/20090712_toba.pdf)

Another study found that Star's Ariva and Stonewall dissolvable tobacco products contained far lower levels of tobacco specific nitrosamines than various American moist snuff products and several Swedish snus products, and that nitrosamine levels in Star's Ariva and Stonewall were just slightly higher than nitrosamine levels in GlaxoSmithKline's Nicorette gum and Nicoderm CQ skin patch.

*Tobacco-specific nitrosamines in new tobacco products, Irina Stepanov, Joni Jensen, Dorothy Hatsukami, Stephen S. Hecht, Nicotine and Tobacco Research Volume 8, Number 2 (April 2006) 309-313.*

<http://www.starscientific.com/404/stepanov%20tsna%20in.pdf>

Dissolvable tobacco products appear to be even more similar to dissolvable NRT lozenges than they are to Swedish Snus. In their 2001 Citizen Petition urging the FDA declare and regulate Star's Ariva as a drug (instead of as a tobacco product), the National Center for Tobacco Free Kids (CTFK), American Cancer Society (ACS), American Heart Association (AHA), American Legacy Foundation (ALF) and others argued that Star's Ariva was strikingly similar to NRT products that are approved by the FDA to be marketed as smoking cessation aids.

ALL smokefree tobacco products marketed in the U.S. and Sweden are far less hazardous alternatives to cigarettes

While cigarettes and smokefree tobacco products are similarly addictive (i.e. creating daily dependence), published epidemiology research finds that daily cigarette smoking imposes about 100 times greater mortality risks than does daily use of smokefree tobacco products marketed in the U.S. and Sweden. On a continuum of tobacco mortality risk from 1 to 100 (whereby NRT products are 1 and cigarettes are 100), smokefree tobacco products are below 2.”

“Flavored dissolvable tobacco products are similar to flavored NRT

Sugars and other flavorings have been used the manufacture of cigars and smokefree tobacco products for hundreds of years, and there is no credible evidence indicating that youth are more likely to begin using these products compared to other tobacco products.

Dissolvable nicotine lozenges marketed by GlaxoSmithKline as smoking cessation aids (formerly called Commit and now called Nicorette) have been available in different flavorings, including cherry, mint and formerly cappuccino.

<http://www.nicorette.com/quit-smoking-products/nicorette-nicotine-lozenge.aspx?showsplash=true>

<http://www.nicorette.com/quit-smoking-products/nicorette-mini.aspx>

Ironically (or not), critics of flavored tobacco products that receive funding from drug companies have remained silent about strikingly similar flavored NRT products.

Marketing of tobacco to minors violates the 1998 Master Settlement Agreement, laws in all 50 states, and the FSPTCA

Although some anti-tobacco activists continue to publicly accuse tobacco companies of target marketing tobacco products to youth (including dissolvable tobacco products), it is critically important to note that marketing tobacco products to minors violates the 1998 Master Settlement Agreement, statutes in all 50 states, and the FSPTCA.

During the Senate HELP Committee markup of the FSPTCA in 2009, Senators Sherrod Brown and Jeff Merkley (when proposing the amendment to require the FDA to study dissolvable tobacco products) repeatedly accused RJ Reynolds of target marketing the company's new dissolvable tobacco products (i.e. Camel Orbs, Strips and Sticks) to minors. But no evidence was provided indicating that Reynolds (or any other tobacco company) was marketing their tobacco products to minors.

Similar unsubstantiated allegations were made against Star back in 2001/2002 when Citizens Petitions urged the FDA to ban Star's Ariva and Stonewall dissolvable tobacco products. In the past decade, no evidence has been provided indicating that youth use Ariva or Stonewall, or that Star markets its products to minors.

All three of the 2001/2002 Citizen Petitions urging the FDA to ban Star's Ariva and Stonewall also repeatedly referred to the products as "candy like" in an attempt to deceive the agency and the public to believe that Star was marketing to youth. A decade later, and the same false "candy like" references to dissolvable tobacco products has been repeated by those who accuse tobacco companies of marketing the products to minors.

Instead of repeating unsubstantiated accusations to the media, anyone who has any evidence that any tobacco products are being illegally marketed to youth should notify the State AG, State Health Department and/or FDA for enforcement or other remedial action.

Referring to any tobacco product as "candy" or "candy-like" can only encourage youth to use these products, which raises serious concerns about the true motives of those who call tobacco products "candy" or "candy-like".

Also, since Section 906(d)(3)(A)(ii) of the FDA tobacco laws prohibits the FDA from banning tobacco sales to 18 year olds (the vast majority of whom are 12<sup>th</sup> grade high school students), it is doubtful that any amount or type of FDA tobacco regulation can substantially reduce tobacco use among 12<sup>th</sup> graders (or underclass peers/siblings who obtain tobacco from 18 year olds).

Although youth usage of smokeless tobacco products has increased slightly during the past several years, it is likely that many of the new smokeless users are cigarette smokers just as most new adult smokeless tobacco users are cigarette smokers. Dual usage of smokefree tobacco products is a prerequisite for switching to them, which sharply reduces tobacco attributable disease and death risks.

A newly published survey of 14-18 year old adolescents in Finland found that 10% had used NRT products, and that most users were daily smokers. The reasons for NRT use were just try (56%), to quit (33%) and smoking not possible (24%). *Adolescents' self-reported reasons for using nicotine replacement therapy products: A population-based study*, Susanna Raisamo, David Doku, Arja Rimpela, *Addictive Behaviors* Volume 36, Issue 9, September 2011, 945-947. <http://www.sciencedirect.com/science/article/pii/S0306460311001572>

But anti-tobacco activists who demonize dissolvable tobacco products and/or advocate banning them aren't demonizing NRT products or advocating banning NRT products, probably because many of them are receiving drug industry funding to demonize and advocate bans on tobacco very similar tobacco products.

Financial Conflict of Interest of TPSAC member Jack Henningfield



Although TPSAC member Jack Henningfield has extensive knowledge and expertise on tobacco and nicotine products, he should be recused from serving on TPSAC as it considers Dissolvable Tobacco Products due to financial conflicts of interest since he has repeatedly criticized and opposed the use of smokeless tobacco products while promoting NRT products during the past decade with funding from GSK and other drug companies (that correctly perceive dissolvable tobacco products as competitors of their NRT products) and since dissolvable nicotine products can now be marketed as dissolvable tobacco products. GSK also submitted a Citizen Petition to the FDA in 2002 that unsuccessfully urged the FDA to remove Star's Ariva from the market.

#### National Center for Public Policy Research

Jeff Stier, Director of the Risk Analysis Division of the National Center for Public Policy Research, has asked me to cite his organization's endorsement (in this submission) urging the FDA TPSAC to support smokefree tobacco harm reduction products and policies in its forthcoming report on dissolvable tobacco products and other activities.

#### Disclosure

Since 1990, Smokefree Pennsylvania has advocated policies to reduce tobacco smoke pollution indoors, increase cigarette taxes, reduce tobacco marketing to youth, preserve civil justice remedies for those injured by cigarettes, expand smoking cessation services, and inform smokers that smokefree tobacco/nicotine products are far less hazardous alternatives to cigarettes. Neither William Godshall nor Smokefree Pennsylvania have ever received any funding from a tobacco, drug, e-cigarette or any other company that markets tobacco or nicotine products.”

Arguing that the current text of the warning label is “misleading,” RJ Reynolds Tobacco Company and American Snuff Company filed a Citizen Petition on July 28, 2011 requesting the FDA to initiate a rulemaking procedure to adjust the smokeless tobacco (ST) product warning label statement from “WARNING: This product is not a safe alternative to cigarettes” to “WARNING: No tobacco product is safe, but this product presents substantially lower risks to health than cigarettes.” In the petition, Reynolds stated the adjusted wording would make the statement non-misleading and would promote greater public understanding of the risks associated with ST use.  
<http://www.regulations.gov/#!documentDetail;D=FDA-2011-P-0573-0001>

But the FDA has never acted upon Reynold's petition, which is a key reason most Americans still inaccurately believe that smokeless tobacco is as hazardous as cigarettes.

Also in 2011, a study was published finding smokers found Camel Snus, Marlboro Snus, Star Ariva and Star Stonewall (both dissolvables) were similar for cigarette withdrawal and craving relief.  
<http://www.sciencedirect.com/science/article/pii/S0376871611001529>

Another study found Star Ariva and Camel Orbs, Strips & Sticks (all dissolvables) contained significantly lower nitrosamine levels than Copenhagen and Skoal long cut straight.

<http://ntr.oxfordjournals.org/content/14/3/274.abstract>  
<http://ntr.oxfordjournals.org/content/14/3/274.full.pdf+html>

That same year, UCSF's Stan Glantz (who has been awarded funding by the FDA to study and recommend tobacco policies, and who vehemently opposes smokers switching to any lower risk tobacco/nicotine alternatives) falsely claimed that tobacco morbidity/mortality doesn't decline (and may increase) when smokers switch to smokeless tobacco or when smokers are informed that smokeless is far less hazardous. Glantz also grossly misrepresented the scientific and empirical evidence on smokeless tobacco and e-cigs, and criticized researchers studying the products.

<http://tobacco.ucsf.edu/two-high-profile-uncritical-media-stories-industry-supported-harm-reduction>

Meanwhile, a meta analysis confirmed that youth smoking is highly correlated with parental and sibling smoking (in sharp contrast to claims that youth smoking is caused by tobacco industry marketing).

<http://thorax.bmj.com/content/early/2011/02/15/thx.2010.153379.abstract>

Another study similarly found adolescent smoking correlated to parental smoking

<http://www.sciencedirect.com/science/article/pii/S0376871612000464>

Another study found children of smokers are far more likely to become smokers (23%-29%) than children of nonsmokers (8%), older sibling smoking also highly correlated; refutes claims that FDA regulation "protects children" and that the leading causes of youth smoking are target marketing by industry, advertising, flavored cigarettes, nicotine manipulation, retail displays, packaging, movies with smoking scenes, e-cigs etc.

<http://pediatrics.aappublications.org/content/early/2013/07/31/peds.2013-0067.abstract>  
<http://www.medpagetoday.com/PrimaryCare/Smoking/40829>

And another study found that children of smoking parents are three times more likely to smoke (than children of nonsmokers), and that children with older siblings who smoke are six times more likely to smoke (than children with nonsmoking siblings).

<http://pediatrics.aappublications.org/content/early/2013/07/31/peds.2013-0067.full.pdf+html>  
<http://wamc.org/post/dr-michael-vuolo-purdue-university-smoking-and-familial-influence>

A study found Canadian youth in single parent households were 1.78 times more likely to smoke than those in two parent households.

<http://onlinelibrary.wiley.com/doi/10.1111/j.1525-1446.2011.00979.x/abstract>

A study by the American Heart Association (which has been heavily funded by Big Pharma companies, and is now being funded by the FDA after it urged the agency to ban e-cigs in 2009) found sudden cardiac death risk linked to cigarette consumption level, with 1-14 cigarettes/day posing a 1.8 RR, 15-24 cigarettes/day posing a 2.6 RR, and more than 25 cigarettes/day posing a 3.4 RR (as compared to never smokers). But instead of pointing out that smokers can significantly reduce risks by reducing cigarette

consumption, the study was negatively titled "Even light smoking increases women's risk of sudden cardiac death."

<http://newsroom.heart.org/pr/aha/smoking-tip-sheet-nov-14-2011-217833.aspx> (Abstract 15980)

Another study found smoking prevalence of pack or more per day in US declined from 22.9% in 1965 to 7.2% in 2007, and smoking prevalence of 10-19 cigarettes per day declined from 10.5% to 5.4%.

<http://jama.ama-assn.org/content/305/11/1106.short>  
<http://www.medicalnewstoday.com/articles/219085.php>

A CDC survey data found sharp declines in cigarette consumption and smoking rates among US high school students from 1991-2009 (including a record low 5.3% daily smoking rate), but CDC misrepresented the data in an article at

<http://www.cfah.org/hbns/archives/viewSupportDoc.cfm?supportingDocID=1034>

and in a press release at

<http://www.ajpmonline.org/webfiles/images/journals/amepre/AJPM%20Embargoed%20for%20Aug%202-%20High%20School.pdf>

to falsely allege and criticize a nonexistent increase in "light smoking" (whose actual prevalence declined) and to claim smaller (than actual) declines in heavy and moderate smoking (by using different denominators for 1991 and 2009 calculations instead of comparing actual prevalence rates). CDC further under-reported the actual decline in cigarette consumption and smoking prevalence by comparing 2009 data to 1991 data instead of higher prevalence data in 1993, 1995, 1997, 1999 or 2001.

[http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5926a1.htm?s\\_cid=mm5926a1\\_e](http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5926a1.htm?s_cid=mm5926a1_e).

The actual "current frequent smoking" rate (i.e. smoked >19 days in past 30 days) among US high school students declined from 16.8% in 1999 to 7.3% in 2009.

While it appears that CDC has wisely created three new categories of smokers (heavy, moderate, light) using YRBS data and provided selective data for these new categories for 1991 and 2009 (see rates below), the two Figures of data provided and repeatedly cited by CDC (in its new article) for heavy, moderate and light smokers from 1991 to 2009 are intentionally deceptive (as any reductions in the percentage of heavy and moderate smokers automatically increases the percentage of light smokers, as now defined by CDC). Since 1.3% of students reported smoking 1-5 cigarettes per day in 2009 (a rate that also declined sharply from 1991, which CDC hasn't acknowledged), and since 14.2% of students reported being non-daily (occasional) smokers in 2009, the CDC has obscured sharp declines in the light daily smoking rate and the overall daily smoking rate by including non-daily smokers in its definition of "light smokers". The CDC should instead create a separate category for non-daily youth smokers (as the NHIS has done for adult smokers for decades), who accounted for 73.3% of "current smokers" in high school in 2009.

Below are Actual Cigarette Smoking Rates among US High School Students (YRBS)

1991 2009

4.95% 1.5% (Heavy Smokers = >10 cigarettes/day)

4.15% 2.5% (Moderate Smokers = 6-10 cigarettes/day)  
18.4% 15.5% (Light Smokers = <1-5 cigarettes/day)  
27.5% 19.5% (Current Smokers = Heavy+Moderate+Light Smokers = smoked at least once during past 30 days)  
12.7% 7.3% (Current Frequent Smokers = smoked >19 days during past 30 days)

Reuters repeated CDC misrepresentations of 1991-2009 changes in smoking among high school students at

<http://www.reuters.com/article/2011/08/04/us-smoking-teens-idUSTRE7736IU20110804>

Meanwhile, a 2011 study found accidental ingestion of tobacco by youth poses very low health/safety risks

<http://www.sciencedirect.com/science/article/pii/S0273230011001553>

<http://www.ncbi.nlm.nih.gov/pubmed/21821089>

A study presented at the 2011 AAP conference found that many youths and teachers confused drugs with candy. But none of those who urged the FDA to ban dissolvable tobacco products has urged the FDA to ban all drugs that might be confused with candy.

[http://www.ivanhoe.com/channels/p\\_channelstory.cfm?storyid=28265](http://www.ivanhoe.com/channels/p_channelstory.cfm?storyid=28265)

And a 2012 study found that medications are the leading cause of accidental poisoning deaths among children. Interestingly, the study didn't even mention tobacco/nicotine products due to their extremely low poisoning risk.

<http://www.multivu.com/mnr/55155-safe-kids-worldwide-medication-safety-campaign-research-report>

<http://www.safekids.org/assets/docs/safety-basics/safety-tips-by-risk-area/medicine-safety-study-2012.pdf>

In preparation for FDA TPSAC's January 18-20, 2012 followup meeting on Dissolvables at <https://collaboration.fda.gov/p49817128/>

the minutes from which are at

<http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/TobaccoProductsScientificAdvisoryCommittee/UCM292441.pdf>

William Godshall and Smokefree Pennsylvania submitted similar written comments on dissolvables that he submitted in 2011 at:

<http://www.e-cigarette-forum.com/forum/legislation-news/251011-next-fda-tpsac-meeting-3.html>

and Godshall presented similar oral testimony to the FDA TPSAC at its January 19 meeting, which are posted at:

<http://www.e-cigarette-forum.com/forum/legislation-news/251011-next-fda-tpsac-meeting-6.html#post5080514>

CASAA's Carl Phillips also presented oral testimony to FDA TPSAC on dissolvables, pointing out that they are far less hazardous alternatives to cigarettes and more closely resemble NRT products, which is posted at:

<http://ep-ology.blogspot.com/2012/01/my-testimony-at-todays-fda-tobacco.html>

After 14 other tobacco harm reduction advocates urged FDA TPSAC to consider all of the scientific evidence (see Thursday recording beginning at 5:20), TPSAC decided to

focus its dissolvables report (due March 23) on nonexistent and miniscule product risks, and to ignore tobacco harm reduction evidence (see Friday afternoon recording).

Archived recordings of the TPSAC meeting webcasts are at.

Wednesday, January 18: <https://collaboration.fda.gov/p24943709/>

Thursday, January 19: <https://collaboration.fda.gov/p49817128/>

Friday, January 20: <https://collaboration.fda.gov/p36812959/>

To meet the deadline for its report on dissolvables, TPSAC held another meeting on March 1, 2012

<https://collaboration.fda.gov/p30903822/>

<http://www.fda.gov/AdvisoryCommittees/Calendar/ucm291512.htm?source=govdelivery>

Smokefree Pennsylvania's Bill Godshall presented oral testimony to the FDA TPSAC at its March meeting, which is posted at

<http://www.e-cigarette-forum.com/forum/legislation-news/261037-tobacco-harm-reduction-advocates-casaa-confront-fda-its-tpsac-about-risks-different-tobacco-nicotine-products-5.html#post5458449>

Several weeks later, FDA's TPSAC issued its report on dissolvables that truthfully acknowledged that the products posed fewer disease risks than cigarettes, and could reduce disease risks for smokers who switched to dissolvables.

<http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/TobaccoProductsScientificAdvisoryCommittee/UCM295842.pdf>

<http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/TobaccoProductsScientificAdvisoryCommittee/UCM295994.pdf>

The TPSCA report on dissolvables generate the following news articles

[http://www.boston.com/lifestyle/health/articles/2012/03/22/fda\\_panel\\_dissolvable\\_tobacco\\_could\\_reduce\\_risks/](http://www.boston.com/lifestyle/health/articles/2012/03/22/fda_panel_dissolvable_tobacco_could_reduce_risks/)

<http://www2.journalnow.com/business/2012/mar/22/2/report-dissolvable-tobacco-products-safer-ar-2076717/>

<http://www.allvoices.com/contributed-news/11775248-victory-for-tobacco-harm-reduction>

[http://www.acsh.org/factsfears/newsID.3488/news\\_detail.asp](http://www.acsh.org/factsfears/newsID.3488/news_detail.asp)

<http://www.conservativeblog.org/amyridenour/2012/3/22/fda-science-panel-dissolvable-tobacco-could-reduce-disease.html>

But one week after its TPSAC truthfully reported that dissolvables are less hazardous than cigarettes, the FDA once again falsely insisted that all smokeless tobacco products are just as hazardous as cigarettes in announcing and issuing its Modified Risk Tobacco Product (MRTP) applications Draft Guidance and in its establishment of a list of Hazardous and Potentially Hazardous Constituents (HPHC) in tobacco smoke and smokeless tobacco.

<http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm297925.htm>

In the FDA's press release, DHHS Secretary Sebelius incorrectly claimed the MRTP application draft guidance and HPHC list would provide "Americans with the facts about the dangers of tobacco use" and that DHHS "will continue to do everything we can to help smokers quit and prevent kids from starting." FDA Commissioner Margaret

Hamburg inaccurately claimed "We are forging new territory to ensure that tobacco companies provide accurate information and do not mislead American consumers."

FDA's announced draft guidance for MRTP applications failed to acknowledge that cigarettes are far more hazardous than smokeless tobacco, or that it would cost millions of dollars for any smokeless tobacco company to truthfully inform consumers that smokeless tobacco is less hazardous than cigarettes

<http://www.gpo.gov/fdsys/pkg/FR-2012-04-03/pdf/2012-7908.pdf>

<http://www.fda.gov/downloads/TobaccoProducts/GuidanceComplianceRegulatoryInformation/UCM297751.pdf>

<http://www.regulations.gov/?source=govdelivery#!documentDetail;D=FDA-2012-D-0071-0001>

ACSH cited the FDA's actions with the headline "The FDA says no to harm reduction"  
[http://www.acsh.org/factsfears/newsID.3512/news\\_detail.asp](http://www.acsh.org/factsfears/newsID.3512/news_detail.asp)

Mike Siegel similarly critiqued the FDA's MRTP draft guidance "FDA Guidance on Modified Risk Tobacco Products Puts Nearly Insurmountable Barrier in Front of the Development of Reduced Risk Products"

<http://tobaccoanalysis.blogspot.com/2012/04/fda-guidance-on-modified-risk-tobacco.html>

In response, Smokefree Pennsylvania submitted comments to the FDA on its Draft Guidance for MRTP Applications, which reiterated previous testimony and comments to the FDA's IOM Committee and the FDA's TPSAC, which are posted at

<http://www.e-cigarette-forum.com/forum/legislation-news/282911-fda-draft-guidance-modified-risk-tobacco-4.html#post6308560>

CASAA also submitted comments on FDA Draft Guidance for MRTP Applications criticizing the agency's proposal to deny tobacco and nicotine consumers of truthful information about smokefree alternatives, which are posted at:

<http://blog.casaa.org/2012/06/casaas-comment-on-fda-draft-guidance.html>

Meanwhile, Philip Morris International praised and supported the FDA's draft guidance for MRTP for requiring many different expensive studies

<http://www.regulations.gov#!documentDetail;D=FDA-2011-N-0443-0057>

In June, 2014, Swedish Match submitted a 100,000+ page MRTP application to the FDA to truthfully market General Snus to smokers as less hazardous alternative to cigarettes

[http://www.washingtonpost.com/business/apnewsbreak-firm-seeks-to-say-tobacco-cuts-risk/2014/06/10/c22bfe18-f0b6-11e3-85d2-cda8aebfefe0\\_story.html](http://www.washingtonpost.com/business/apnewsbreak-firm-seeks-to-say-tobacco-cuts-risk/2014/06/10/c22bfe18-f0b6-11e3-85d2-cda8aebfefe0_story.html)

<http://www.businesswire.com/news/home/20140611005454/en/Swedish-Match-Submits-Modified-Risk-Tobacco-Product#.U5sD93JdXSI>

The cost incurred by Swedish Match to research and submit its 100,000+ page MRTP application to the FDA verified previous oral and written testimony by Bill Godshall and others to the FDA's IOM Committee, FDA's TPSAC and to the FDA that it would cost a smokeless tobacco manufacturer millions (and perhaps tens of millions) of dollars to submit an MRTP application to the FDA if the agency required submitter to conduct dozens of studies just to verify the scientific consensus that smokeless tobacco products are less hazardous than cigarettes.

As previously stated, since the FDA's proposed Deeming Regulation would require e-cig companies to conduct most (or more) of the same unwarranted research to submit a New Tobacco Product application (that the agency's guidance requires for the submission of MRTP applications), the FDA's estimated cost of \$333,554 (using just 2.5 FTEs for one year) for an e-cig company to submit a New Tobacco Product application is significantly lower than the cost e-cig companies would have to actually spend, probably by at least ten fold.

Brad Rodu revealed that Swedish Match's MRTP application also requested the FDA to exempt the company from including the currently mandated false and misleading fear mongering warnings that were required since 1986.

<http://rodutobaccotruth.blogspot.com/2014/06/swedish-match-files-to-change-smokeless.html>

ACSH – Swedish Match's snus: the first FDA application as "modified risk." Good luck!

<http://acsh.org/2014/06/swedish-matches-snus-first-fda-application-modified-risk-good-luck/>

Back to 2011

But tobacco harm reduction opponents continued protecting cigarette markets by misrepresenting scientific evidence, risks, benefits and marketing of smokefree tobacco/nicotine products

[http://journals.lww.com/oncology-times/Fulltext/2011/07100/Cigarette\\_Alternatives\\_Threatening\\_Anti\\_Smoking.1.aspx](http://journals.lww.com/oncology-times/Fulltext/2011/07100/Cigarette_Alternatives_Threatening_Anti_Smoking.1.aspx)

Meanwhile, the US Dept of Veterans Affairs falsely claimed the 2009 FDA lab analysis <http://www.fda.gov/downloads/TobaccoProducts/NewsEvents/UCM266138.pdf> found that e-cigarettes "expose users to harmful chemical ingredients, including many of the same toxic and carcinogenic compounds found in conventional cigarettes," grossly exaggerated unsubstantiated hypothetical risks, denied well documented health benefits to smokers who switched to e-cigs, urged healthcare providers to discourage smokers from switching to e-cigs, urged healthcare providers to discourage smokers from switching to e-cigs, and advocated banning e-cigs use where smoking is banned despite no smoke and zero evidence of harm.

[http://www.va.gov/vhapublications/ViewPublication.asp?pub\\_ID=243](http://www.va.gov/vhapublications/ViewPublication.asp?pub_ID=243)

A 2011 CDC five year "Million Hearts" initiative correctly cited reducing "smoking" as important for reducing heart attacks and strokes, but reducing "tobacco use" was cited in program's stated principles, interventions and forthcoming grants to communities.

<http://www.nejm.org/doi/full/10.1056/NEJMp1110421>

A CDC Vital Signs article on 2010 cigarette smoking survey findings misled readers to believe that all tobacco products are as hazardous as cigarettes, that reducing cigarette

consumption won't reduce smoker's health risks, that tobacco/nicotine abstinence is only way for smokers to reduce health risks, and that drug industry products, healthcare service providers and state funded tobacco control programs are the most effective ways to reduce smoking; encouraged employers to ban use of all tobacco products on property by anyone at any time despite no evidence of public health benefits.

<http://www.cdc.gov/VitalSigns/adultsmoking/index.html>

Meanwhile, a ten page NEJM article by drug industry funded researchers/consultants promoted abstinence-only tobacco policies and drug treatment for all tobacco consumers.

[http://www.nejm.org/doi/full/10.1056/NEJMcp1101512?query=featured\\_home](http://www.nejm.org/doi/full/10.1056/NEJMcp1101512?query=featured_home)

The CDC released its 2020 Health Goals that appropriately included "Reduce illness, disability, and death related to tobacco use and secondhand smoke exposure," but deceptively (20 times) attributed problems caused by cigarette smoking as being caused by "tobacco use", failed to acknowledge that smokers sharply reduce risks by switching to far less hazardous smokefree alternatives, exaggerated the risks of smokeless tobacco and cigar use, and promoted abstinence-only policies and programs instead of those to reduce cigarette consumption and diseases.

<http://www.healthypeople.gov/2020/topicsobjectives2020/overview.aspx?topicid=41>

[http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6042a7.htm?s\\_cid=mm6042a7\\_e&source=govdelivery](http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6042a7.htm?s_cid=mm6042a7_e&source=govdelivery)

The CDC also gave a \$24 million grant to University of Wisconsin to "promote tobacco-free living" (among other things)

<http://www.jsonline.com:80/blogs/news/130661768.html>

FDA and NIH announced a joint study on tobacco use and risk perceptions, but FDA's press release falsely attributed health risks of cigarettes to other tobacco products by stating "While smoking rates have dropped significantly since their peak in the 1960s, nearly 70 million Americans ages 12 and older were current users of tobacco products in 2010. As a result, death and disease caused by tobacco use is still a tremendous public health burden. Tobacco use is the leading preventable cause of disease, disability, and death in the United States."

<http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm274626.htm>

A new report by ACSH/Rodu: The Scientific Foundation for Tobacco Harm Reduction, 2006-2011 comprehensively reviewed the scientific evidence of different risks and benefits of different tobacco and nicotine products, revealing that smokefree products are exponentially less hazardous than cigarettes.

<http://www.harmreductionjournal.com/content/8/1/19/abstract>

<http://www.harmreductionjournal.com/content/pdf/1477-7517-8-19.pdf> (full text)

A 2011 study by Foulds revealed the results of interview with many e-cig users, finding the products were very effective for smoking cessation, reducing cigarette consumption, and perceived health benefits



<http://www.ncbi.nlm.nih.gov/pubmed/21801287>

“Smoking Cessation with E-Cigarettes in Smokers with a Documented History of Depression and Recurring Relapses” delineated a case report of heavy smokers with depression who quit smoking with e-cigarettes after failing previous attempts using NRT, bupropion and counseling).

<http://www.scirp.org/journal/PaperInformation.aspx?paperID=6134&publishStatus=2>

Another study found that smokers who relapsed after use of approved smoking cessation therapies subsequently quit smoking with e-cigs

<http://www.jmedicalcasereports.com/content/pdf/1752-1947-5-585.pdf>

In 2011, the first clinical trial on e-cigs (using a first generation product that is no longer on the market) found they were far more effective than NRT for smoking cessation and reducing daily cigarette consumption. Among forty participants who didn't want to quit smoking, overall daily cigarette consumption declined 80% after 24 weeks, with 22.5% remaining totally smokefree, 12.5% reducing daily cigarette consumption by at least 80%, and another 20% reducing daily cigarette consumption by at least 50%.

<http://www.biomedcentral.com/1471-2458/11/786> (abstract)

<http://www.biomedcentral.com/content/pdf/1471-2458-11-786.pdf> (full text)

In contrast to the unwarranted vilification of nicotine, another study found that nicotine may act as treatment for some symptoms of schizophrenia

<http://www.news-medical.net/news/20110111/Nicotine-may-act-as-treatment-for-some-symptoms-of-schizophrenia.aspx>

And a clinical trial found that snus was more effective than placebo for smoking cessation

<http://ntr.oxfordjournals.org/cgi/content/abstract/ntr214v1>

Meanwhile, a survey found that about 11.1 million adult Americans had used snus, 4 million had used e-cigarettes, and 1.4 million had used dissolvable tobacco products. Current smokers were 22 times more likely to have used e-cigarettes than never smokers, 7 times more likely to have used dissolvables, and 4 times more likely to have used snus (indicating that smokers were far more likely than nonsmokers to use these new smokefree alternatives).

<http://surveillance.mstobaccodata.org/wp-content/uploads/2010/06/2011-APHA-Presentation.pdf>

But in 2011, in response to a request by Sen. Frank Lautenberg, Obama appointed US DOT Secretary LaHood proposed banning e-cig use on airlines, with a 60 day public comment period

<http://www.dot.gov/affairs/2011/dot11911.html> (DOT press release)

<http://www.scribd.com/doc/65089872/DOT-OST-2011-0044-0003> (proposed regulation)

<http://www.regulations.gov/#!docketDetail;dct=FR%252BPR%252BN%252BO%252BSR;rpp=10;po=0;D=DOT-OST-2011-0044>

News stories touted the DOT proposed e-cig ban on airlines as if it were a done deal.

<http://ori.msnbc.msn.com/id/44518729/ns/travel-news/>

<http://www.bloomberg.com/news/2011-09-14/electronic-cigarette-ban-sought-by-u-s-on-commercial-flights.html>

<http://aviationblog.dallasnews.com/archives/2011/09/government-shocks-electronic-c.html>

<http://www.cnn.com/2011/09/15/travel/electronic-cigarettes-ban/index.html>

[http://blogs.star-telegram.com/sky\\_talk/2011/09/dot-proposes-ban-on-electronic-cigarettes-on-flights.html](http://blogs.star-telegram.com/sky_talk/2011/09/dot-proposes-ban-on-electronic-cigarettes-on-flights.html)

In response, Smokefree Pennsylvania urged the US DOT to reject its proposed e-cigarette usage ban on air flights, and to extend the current smoking ban (on scheduled flights) to include chartered flights.

<http://www.e-cigarette-forum.com/forum/legislation-news/235094-need-comments-us-plane-ban-nov-14-a-6.html#post4563461>

Consumer Advocates for Smokefree Alternatives Association (CASAA) and Competitive Enterprise Institute (CEI) also urged US DOT to reject its proposed e-cigarette usage ban on air flights

<http://www.scribd.com/doc/72749757/Comments-of-the-Consumer-Advocates-for-Smoke-free-Alternatives-Association-and-The-Competitive-Enterprise-Institute-to-the-U-S-Department-of-Transportation>

<http://cei.org/news-releases/government-plan-ban-e-cigarettes-airplanes-opposed-public-interest-groups>

Nearly three years after proposed its airline e-cig usage ban, the US DOT still hasn't issued a Final Rule, probably because it likely would be overturned in litigation.

Meanwhile, the UK government Cabinet office 'nudge unit' wisely encouraged smokers to try using e-cigs to reduce smoking-related deaths

<http://www.guardian.co.uk:80/society/2011/sep/14/smokeless-nicotine-cigarettes-government>

<http://www.dailymail.co.uk/health/article-2037616/Fancy-lighting-smoke-Puff-smokeless-nicotine-cigarette-says-government.html#ixzz1Y5IaNQoa>

<http://www.ecigarettdirect.co.uk/ashtray-blog/2011/09/nudge-safe-nicotine-use.html>

Behavioral Insight Team annual update (see pages 3, 6, 7, 8 at

<http://www.cabinetoffice.gov.uk/resource-library/behavioural-insight-team-annual-update>

In contrast, California e-cig opponent Prue Talbot criticized e-cigs for being slightly different, complained about quality control of first generation e-cigs, and misrepresented the health/safety risks/benefits of e-cigs.

<http://ntr.oxfordjournals.org/content/early/2011/10/11/ntr.ntr164.abstract>

Back in DC, US Senate Democrats Blumenthal, Lautenberg & Brown urged the FDA to "swiftly" expand tobacco regulations, falsely accused industry of undermining the

FSPTCA, urged the agency to apply Chapter IX to all cigars, pipe tobacco, hookah/shisha, dissolvables, e-cigarettes and other tobacco products, criticized companies for marketing exponentially less hazardous smokefree alternatives to smokers, and grossly misrepresented the health risks/benefits and marketing of smokefree alternatives to cigarettes.

<http://www.cspdigitals.com/tobaccoenews/tom-letter.pdf>

<http://www.cspnet.com/news/tobacco/articles/senators-send-letter-fda-other-tobacco-products>

By 2011, approximately one million smokers had quit smoking or sharply reduced their cigarette consumption by switching to or substituting smokefree e-cigs. There was no evidence that e-cig use had harmed anyone. All of the dozen plus laboratory tests conducted on e-cigarettes found that e-cigarettes emitted no hazardous levels of any constituents, and that levels of nitrosamines in e-cigarettes are nearly identical (i.e. very little if any) to those in nicotine gums and patches.

<http://www.healthnz.co.nz/RuyanCartr...t30-Oct-08.pdf>

<http://www.starscientific.com/404/st...0tsna%20in.pdf>

<http://www.healthnz.co.nz/DublinEcigBenchtopHandout.pdf>

[http://www.casaa.org/files/Study\\_TSN...NJOY\\_Vapor.pdf](http://www.casaa.org/files/Study_TSN...NJOY_Vapor.pdf)

[Lab Reports / E Liquid Facts / E Cigarette and E Liquid from Totally Wicked](#)

[http://cdn.johnsoncreeksmokejuice.co...CMS\\_Report.pdf](http://cdn.johnsoncreeksmokejuice.co...CMS_Report.pdf)

<http://www.libertystix.com/LibertySt...ysis072309.pdf>

<http://truthaboutecigs.com/science/8.pdf>

<http://www.casaa.org/files/Exponent%...DA-Summary.pdf>

<http://www.hsph.harvard.edu/centers-...ticle.jphp.pdf>

[Taylor & Francis Online :: ANALYSIS OF ELECTRONIC CIGARETTE CARTRIDGES, REFILL SOLUTIONS, AND SMOKE FOR NICOTINE AND NICOTINE RELATED IMPURITIES - Journal of Liquid Chromatography & Related Technologies - Volume 34, Issue 14](#)

A Literature Review for Glycerol and Glycols for Entertainment Services & Technology Association had also found no health risks to humans from inhaling propylene glycol

[http://tsp.plasa.org/tsp/working\\_groups/FS/docs/HSE.pdf](http://tsp.plasa.org/tsp/working_groups/FS/docs/HSE.pdf)

And by 2011, many published surveys had confirmed that e-cigarettes satisfied the cravings of smokers, helped many smokers quit and/or sharply reduce cigarette consumption, and provided perceived health benefits to users who switched from cigarettes.

[Sign In](#)

<http://www.biomedcentral.com/content...458-10-231.pdf>

[THR2010. \(tobaccoharmreduction.org\) \(see chapter 9\)](#)

<http://ectoh.org/documents/3B.5%20Et...20efficacy.pdf>

<http://www.ajpmonline.org/webfiles/i...AMEPRE3013.pdf>

[Electronic cigarettes \(e-cigs\): views of af... \[Int J Clin Pract. 2011\] - PubMed - NCBI Interviews With Electronic Cigarettes](#)

A Japanese study similarly found e-cigarettes to be effective for decreasing cigarette

consumption at SEIKATSUEISEI : Vol. 55 (2011) , No. 1 p.59-64, while a recently published case study found e-cigarettes effective for smoking cessation among depressed patients <http://www.scirp.org/journal/PaperIn...ublishStatus=2>.

Also in 2011, former FDA Commissioner David Kessler has also acknowledged the benefits of smokeless tobacco, dissolvables and e-cigarettes as less hazardous alternatives for cigarette smokers at Q&A: Former FDA Commissioner talks about tobacco - Westport News by stating "there's no doubt that in terms of risk of death there are some advantages to that substitution."

A 2011 CDC published survey found that 1.2% (2.5 million) of US adults reported past-month use of an e-cig in 2010, ever-use of e-cigarettes quadrupled from .6% in 2009 to 2.7% in 2010, awareness of products doubled from 16.4% in 2009 to 32.2% in 2010. But the CDC authors repeatedly criticized e-cigs <http://tobaccocontrol.bmj.com/content/early/2011/10/27/tobaccocontrol-2011-050044.abstract>

Another 2011 CDC survey on smoking cessation inquired only about government approved drugs and counseling (while failing to ask about cold turkey, smokeless tobacco or e-cigs), and then touted government approved drugs and counseling as only effective ways to quit smoking. [http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6044a2.htm?s\\_cid=mm6044a2\\_w](http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6044a2.htm?s_cid=mm6044a2_w)

In a 2011 NY Times column, John Tierney revealed the benefits of e-cigs. E-cigarettes help smokers quit, but they have some unlikely critics [http://www.nytimes.com/2011/11/08/science/e-cigarettes-help-smokers-quit-but-they-have-some-unlikely-critics.html?\\_r=1&ref=science](http://www.nytimes.com/2011/11/08/science/e-cigarettes-help-smokers-quit-but-they-have-some-unlikely-critics.html?_r=1&ref=science)

A Legacy survey of current and former smokers aged 18-49 in 8 US metropolitan areas found that 5.3% (but just .9% of blacks) had tried using an e-cigarette. Among respondents who had heard of e-cigarettes, 63% (but only 35% of blacks) correctly believed e-cigs are less hazardous than cigarettes, 10% incorrectly believed e-cigs posed similar risks as cigarettes, 2% incorrectly believed e-cigs are more hazardous than cigarettes, and 25% said they didn't know. But the survey didn't inquire if former smokers quit by switching to e-cigarettes, or if current smokers reduced cigarette consumption by substituting e-cigarettes. <http://www.legacyforhealth.org/Ecigs.pdf>

At the end of 2011, the FDA urged tobacco users to quit ALL tobacco use for the New Year and falsely attributed cigarette smoking risks to all tobacco use by stating "Tobacco use remains the single largest preventable cause of disease, disability, and premature death in the United States" <http://www.fda.gov/TobaccoProducts/NewsEvents/ucm285236.htm?source=govdelivery>

At that same time, more than 5,000 people signed a Petition to the White House to "Recognize electronic cigarettes as an effective alternative to smoking and support job creation in this new industry"

[https://www.whitehouse.gov/petitions/%21/petition/recognize-electronic-cigarettes-effective-alternative-smoking-and-support-job-creation-new-industry/57vtB0QK?utm\\_source=wh.gov&utm\\_medium=shorturl&utm\\_campaign=shorturl](https://www.whitehouse.gov/petitions/%21/petition/recognize-electronic-cigarettes-effective-alternative-smoking-and-support-job-creation-new-industry/57vtB0QK?utm_source=wh.gov&utm_medium=shorturl&utm_campaign=shorturl)  
<http://www.e-cigarette-forum.com/forum/law-e-cigarette/250506-my-response-white-gov-post.html>

But in response to the 2011 White House Petition, FDA's then Director of the Center for Tobacco Products Lawrence Deyton unscientifically, dishonestly and misleadingly wrote: *"E-cigarettes may contain ingredients that are known to be toxic to humans or otherwise harm public health – for example, if they are attractive to young people and lead kids to try other tobacco products, including conventional cigarettes, which are known to cause disease and lead to premature death. Because clinical studies of these products have not been submitted to the Food and Drug Administration (FDA), consumers currently have no way of knowing what types or concentrations of potentially harmful chemical are found in these products, or how much nicotine people inhale when they use these products. . . . However, in light of the lack of validated scientific data, including a lack of reliable indicators of nicotine and harmful chemical content, FDA cannot at this time conclude that electronic cigarettes are an effective alternative to smoking.*

A 2012 study by Vardavas et al found that inhalation of e-cig vapor has no acute effect on pulmonary function (as measured by spirometry testing), but the article's title and abstract mislead readers about study's findings, while its authors (including past FDA TPSAC member Greg Connolly) urged FDA to once again regulate (i.e. ban) e-cigs.  
<http://chestjournal.chestpubs.org/content/early/2011/12/21/chest.11-2443.abstract>  
<http://uk.reuters.com/article/2012/01/05/us-e-cigarettes-idUKTRE8041WB20120105>  
<http://medicalxpress.com/news/2012-01-e-cigarettes-affect-users-airways.html>  
<http://www.lungenaerzte-im-netz.de/lin/linaktuell/psfile/pdf/97/Originalar4f0ed30c6b30d.pdf>

Mike Siegel revealed that the Vardavas et al study confirmed e-cigarettes are far less hazardous than cigarettes  
<http://tobaccoanalysis.blogspot.com/2012/01/new-study-shows-that-in-contrast-to.html>

Meanwhile, the American Council on Science and Health critiqued the rhetoric in the Vardavas et al study "E-Cigarette study is just amateur propaganda"  
[http://www.acsh.org/factsfears/newsID.3305/news\\_detail.asp](http://www.acsh.org/factsfears/newsID.3305/news_detail.asp)

Meanwhile, two published study found that e-cigs deliver as much nicotine as cigarettes, in contrast to previous claims by one study's coauthor Tom Eissenberg.  
<http://www.newswire.ca/en/story/869239/electronic-cigarettes-deliver-as-much-nicotine-as-tobacco-cigarettes>  
<http://erj.ersjournals.com/content/38/5/1219.extract>  
<http://onlinelibrary.wiley.com/doi/10.1111/j.1360-0443.2012.03791.x/abstract>

As FDA continued to misrepresent the scientific evidence by falsely claiming all tobacco products are as harmful as cigarettes at <http://www.fda.gov/TobaccoProducts/ResourcesforYou/ucm255658.htm> and by posting false and misleading claims about e-cigarettes at <http://www.fda.gov/NewsEvents/PublicHealthFocus/ucm172906.htm> <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/2009/ucm173222.htm> and <http://www.fda.gov/downloads/NewsEvents/Newsroom/MediaTranscripts/UCM173405.pdf>, the Washington Post published a puff piece claiming FDA relies upon scientific evidence for all tobacco regulatory actions. [http://www.washingtonpost.com/politics/putting-the-science-behind-fdas-tobacco-regulation/2012/04/29/gIQAHorgpT\\_story.html](http://www.washingtonpost.com/politics/putting-the-science-behind-fdas-tobacco-regulation/2012/04/29/gIQAHorgpT_story.html)

Mike Siegel criticized the FDA's actions: FDA Warns Smokers Against Using Electronic Cigarettes Because Unlike Tobacco Cigarettes, Their Risks are Not Precisely Known <http://tobaccoanalysis.blogspot.com/2012/05/fda-warns-smokers-against-using.html> and Further Analysis of FDA Warning on Electronic Cigarettes: What is the Agency Saying to Smokers Who Have Quit Using E-Cigs and Tried NRT Unsuccessfully in the Past? <http://tobaccoanalysis.blogspot.com/2012/05/further-analysis-of-fda-warning-on.html>

Brad Rodu similarly criticized the agency for misrepresenting the health risks of different tobacco products: Health Fraud at FDA.gov - criticizes FDA for falsely claiming "To date, no tobacco products have been scientifically proven to reduce risk of tobacco-related disease, improve safety or cause less harm than other tobacco products." <http://rodutobaccotruth.blogspot.com/2012/07/health-fraud-at-fdagov.html>

Instead of correcting its misinformation about e-cigs, the FDA continued its witch hunt against e-cigs by sending a letter to e-cig companies requesting information on adverse event reports (but not on beneficial health effects). <http://www.e-cigarette-forum.com/forum/legislation-news/277925-fda-sends-letter-e-cigarette-company-ies-requesting-info-adverse-events.html>

In 2012, a WHO report acknowledged "**People have a right to accurate information about the harms of tobacco use,**" but deceptively attributed cigarette diseases/deaths/costs to use of other tobacco products, misleadingly referred to "cigarettes" as "tobacco" and "smoking" as "tobacco use" dozens of times (including twice in title) to confuse readers to believe all tobacco products pose similar health risks, claims WHO's goal is a "tobacco-free world" instead of reducing disease. <http://www.who.int/tobacco/en/> [http://whqlibdoc.who.int/publications/2011/9789240687813\\_eng.pdf](http://whqlibdoc.who.int/publications/2011/9789240687813_eng.pdf) (full text)

Meanwhile, the theme of the 2012 World Conference on Tobacco OR Health (which was heavily funded by Big Pharma companies) "Towards a Tobacco-Free World" promoted abstinence-only anti-tobacco extremism instead of reducing morbidity/mortality <http://www.wctoh2012.org/edm/edm3-a1.html>

The FDA celebrated WHO's "World No Tobacco Day" by repeating false WHO claim

that tobacco (not just cigarettes) kills up to half of users

<http://www.fda.gov/TobaccoProducts/NewsEvents/ucm256546.htm>

US DHHS' Koh celebrated the WHO's "World No Tobacco Day" by deceptively claiming that tobacco use (not cigarette smoking) is the major preventable cause of disease and death worldwide

<http://www.medilexicon.com/medicalnews.php?newsid=227010>

Similarly, the CDC deceptively claimed "tobacco use" instead of "cigarette smoking" is the leading preventable cause of death worldwide in promoting WHO's 2012 World No Tobacco Day.

[http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6120a1.htm?s\\_cid=mm6120a1\\_e](http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6120a1.htm?s_cid=mm6120a1_e)

As Obama's FDA continued denying and misrepresenting scientific evidence in 2012 by falsely claiming "To date, no tobacco products have been scientifically proven to reduce risk of tobacco-related disease, improve safety or cause less harm than other tobacco products," the agency announced a partnership with NIH and issued RFAs to fund scientific research to advance FDA's abstinence-only regulatory agenda.

<http://grants.nih.gov/grants/guide/rfa-files/RFA-DA-13-003.html>

<http://grants.nih.gov/grants/guide/rfa-files/RFA-FD-12-002.html>

<http://www.fda.gov/TobaccoProducts/ResourcesforYou/ucm255658.htm>

After misrepresenting risks of e-cigarettes and urging the filing of adverse event reports since 2009 (but not for tobacco products, NRT or high risk smoking cessation drugs), FDA issued a misleading report on adverse event reports for e-cigs to further confuse, scare and push FDA's unwarranted Deeming Regulation.

<http://www.e-cigarette-forum.com/forum/media-general-news/321820-fda-tobacco-program-office-issues-misleading-report-adverse-events.html>

<http://ntr.oxfordjournals.org/content/early/2012/07/11/ntr.nts145.extract>

In 2012, Obama's DHHS created and touted a new abstinence-only website "Be Tobacco Free" that repeated false and misleading claims about e-cigs, smokeless tobacco, nicotine and FDA approved smoking cessation drugs, and falsely claimed its new website is the "best and most up-to-date tobacco-related information from across its agencies."

<http://betobaccofree.hhs.gov/?source=govdelivery>

<http://www.fda.gov/TobaccoProducts/NewsEvents/ucm328124.htm>

<http://ohsonline.com/articles/2012/11/19/hhs-launches-betobaccofree.aspx?>

DHHS' webpage on e-cigs repeated FDA's false and misleading fear mongering claims.

<http://betobaccofree.hhs.gov/about-tobacco/Electronic-Cigarettes/index.html>

DHHS' webpage repeated misleading claims about tobacco and nicotine.

<http://betobaccofree.hhs.gov/about-tobacco/tobacco-and-nicotine/index.html>

DHHS' webpage on Smoked Tobacco Products falsely listed e-cigarettes as a smoked tobacco product.

<http://betobaccofree.hhs.gov/about-tobacco/Smoked-Tobacco-Products/index.html>

The ACSH appropriately criticized the new DHHS website for demonizing e-cigs

<http://www.acsh.org/new-us-website-wrongly-demonizes-e-cigs/>

At the 2012 SRNT meeting, the keynote presentation by DHHS Assistant Secretary Howard Koh deceptively entitled "Ending the Tobacco Epidemic: A Federal Plan" (even though smoking causes 99% of tobacco attributable morbidity and mortality) to further promote abstinence-only tobacco intolerance and prohibition.

[http://srnt.org/conferences/2012/pdf/2012\\_SRNT\\_Preliminary\\_Program\\_G.pdf](http://srnt.org/conferences/2012/pdf/2012_SRNT_Preliminary_Program_G.pdf)

<http://ntr.oxfordjournals.org/content/14/9/1006.extract>

Meanwhile, a study found a 40% decline in mean daily cigarette consumption (from 14.7 to 8.8) among 43 first time e-cigarette users who weren't interested in quitting smoking. But the authors inaccurately claimed tobacco toxicant exposure was NOT lowered, that "e-cigs may provide no public health benefit", and that their findings supported FDA regulation of e-cigarettes.

[http://www.srnt.org/conferences/2012/pdf/2012\\_Abstacts\\_H.pdf](http://www.srnt.org/conferences/2012/pdf/2012_Abstacts_H.pdf) (POS3-107 on page 121)

In 2012, the US Army falsely claimed "Smokeless tobacco is as harmful as smoking tobacco." and "Tobacco jeopardizes the military by reducing the overall performance of the Soldier" in promoting abstinence-only for smokeless tobacco.

<http://phc.amedd.army.mil/topics/healthyliving/tc/Pages/GreatAmericanSpitOut2011.aspx>

The 2012 SG Report misrepresented the rapidly declining record-low youth smoking rates, falsely claimed that "tobacco" (instead of "cigarette smoking") is leading cause of preventable death, criticized the tobacco industry, and hypocritically cited smoking among 12th graders while failing to recommend banning cigarette sales to 12th graders.

<http://www.hhs.gov/news/press/2012pres/03/20120308a.html>

<http://www.surgeongeneral.gov/library/preventing-youth-tobacco-use/index.html>

In a press release promoting the US SG report, FDA Commissioner Margaret Hamburg falsely claimed "tobacco use" (instead of "cigarette smoking") is the leading cause of preventable death.

<http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm295369.htm?source=govdelivery>

Meanwhile, Fagerstrom & Eissenberg called for tobacco product specific research and policy development "Dependence on Tobacco and Nicotine Products: A Case for Product-Specific Assessment".

<http://www.ncbi.nlm.nih.gov/pubmed/22459798>

The previous year Karl Fagerstrom first recommended changing the name of the Fagerstrom Test for Nicotine Dependence to the Fagerstrom Test for Cigarette Dependence (since cigarettes are far more harmful than other tobacco/nicotine products).

<http://ntr.oxfordjournals.org/content/early/2011/10/20/ntr.ntr137.extract>

A 2012 study found that a Fact Sheet on the comparable risks of cigarettes, smokeless tobacco and NRT increased the knowledge and desire to use smokeless tobacco among smokers.

<http://www.harmreductionjournal.com/content/pdf/1477-7517-9-19.pdf>

<http://www.harmreductionjournal.com/imedia/3427676527443503/supp1.doc>



Brad Rodu highlighted the importance of this study - What a Difference the Truth Makes: Researchers Say Government Needs to Get Smokers Facts about Smokeless Tobacco  
<http://rodutobaccotruth.blogspot.com/2012/09/what-difference-truth-makes-researchers.html>

In 2012, FDA Commissioner Margaret Hamburg also falsely claimed that the agency is "working to make sure all Americans, young and old, understand the true dangers of tobacco use", while greatly exaggerating the negligible public health impact of the FSPTCA and the agency's actions to reduce tobacco attributable diseases.  
<http://in.reuters.com/article/2012/07/11/column-hamburg-idINL2E8IBBRE20120711>  
<http://www.fda.gov/TobaccoProducts/ResourcesforYou/ucm255658.htm>

Meanwhile, the FDA created a webpage to promote abstinence-only no-tobacco-use.  
<http://www.fda.gov/TobaccoProducts/NewsEvents/ucm311315.htm?source=govdelivery>

To further lobby for the FDA Deeming Regulation in 2012, the CDC exaggerated the hazards of hookah smoking by claiming hookah smoke "is at least as toxic as cigarette smoke", that "hookah smokers may absorb higher concentrations of the toxins found in cigarette smoke", and that "A typical 1-hour-long hookah smoking session involves inhaling 100–200 times the volume of smoke inhaled from a single cigarette."  
[http://www.cdc.gov/tobacco/data\\_statistics/fact\\_sheets/tobacco\\_industry/hookahs/](http://www.cdc.gov/tobacco/data_statistics/fact_sheets/tobacco_industry/hookahs/)  
<http://www.click2houston.com/news/CDC-warns-hookah-not-safer-than-cigarettes/-/1735978/7644406/-/k2pvr/-/index.html>  
<http://www.courier-journal.com/article/20120101/NEWS01/301010042/1003/rsslink>

And yet, University of Pittsburgh researcher Brian Primack found a 25% decline in hookah use by US college students since 2008, but repeated the false claim that smoke inhaled from one hookah session is equivalent to smoking 100 cigarettes.  
<http://triblive.com/news/allegheeny/1960896-74/hookah-students-tobacco-primack-percent-smoke-think-college-hookahs-lierley>

An FIU researcher also falsely claimed hookah smokers inhale 100 times more smoke than a cigarette smoker inhales from a cigarette  
<http://www.nbcmiami.com/news/local/Hookah-Smokers-Putting-Health-in-Jeopardy-FIU-Researcher-Says-160330735.html>

In response, Carl Phillips detailed the mathematical impossibility of inhaling smoke from 100 cigarettes during a single hookah session  
<http://ep-ology.blogspot.com/2012/03/unhealthy-news-206-does-journalism.html>

Also in 2012, a Clearstream Air Study found nothing hazardous in exhaled e-cig vapor  
<http://www.utahvapers.com/resources/Clearstream-air-lab-results.pdf>  
<http://www.utahvapers.com/clearstream.html>

Another study found that emissions of volatile organic compounds from e-cig vapor are much lower than found in cigarette smoke  
<http://onlinelibrary.wiley.com/doi/10.1111/j.1600-0668.2012.00792.x/abstract;jsessionid=33855B65D8E691F5D7D3BE1E9818DFC3.d02t04>

Mike Siegel delineated the findings of this new study at  
<http://tobaccoanalysis.blogspot.com/2012/06/new-study-shows-that-emission-of.html>

Another 2012 study found that acute active and passive e-cigarette vapor exposure does not influence complete blood count (CBC) indices in smokers and never smokers, respectively. In contrast, acute active and passive tobacco cigarette smoking increase the secondary proteins of acute inflammatory loadwhite blood cell, lymphocyte and granulocyte counts for at least one hour.

<http://www.sciencedirect.com/science/article/pii/S0278691512005030?v=s5>

Meanwhile, another study found that nicotine improves memory in people with mild cognitive impairment

<http://www.neurology.org/content/78/2/91.short>

Brad Rodu critiqued that study of nicotine's benefits (something DHHS refuses to acknowledge) at: Nicotine Improves Cognitive Performance

<http://rodutobaccotruth.blogspot.com/2012/02/nicotine-improves-cognitive-performance.html>

Meanwhile, it was announced that a Birmingham court would oversee 1,200 lawsuits filed against Pfizer after adverse reactions to Chantix (which FDA has approved for treating tobacco dependence)

<http://apnews1.iwon.com//article/20110104/D9KHQPCO0.html>

A study also revealed reports of violence by 428 varenicline users, most for any prescription drug

<http://www.plosone.org/article/info%3Adoi%2F10.1371%2Fjournal.pone.0015337>

A lawsuit filed against Pfizer claimed Chantix caused a murder and suicide

<http://www.wtae.com/r/27837994/detail.html>

The FDA stated that Chantix' side effects were not reported properly

<http://www.newsinferno.com/pharmaceuticals/chantix-side-effects-not-reported-properly-fda-says/>

FDA also issued a cardiovascular disease warning for Chantix

<http://www.fda.gov/Drugs/DrugSafety/ucm259161.htm>

[http://www.medpagetoday.com/PrimaryCare/Smoking/27711?utm\\_content=&utm\\_medium=email&utm\\_campaign=DailyHeadlines&utm\\_source=WC&userid=220600](http://www.medpagetoday.com/PrimaryCare/Smoking/27711?utm_content=&utm_medium=email&utm_campaign=DailyHeadlines&utm_source=WC&userid=220600)

Meanwhile, France stopped paying for Chantix due to concerns about adverse side effects.

<http://www.theday.com/article/20110601/BIZ02/306019907/-1/BIZ>

<http://fr.canoe.ca/infos/international/archives/2011/05/20110531-113949.html>

A post marketing surveillance study on Verenicline (Chantix/Champix) in New Zealand from 2007-2011 identified 171 adverse events, including 48 reports of myocardial ischaemia (including 12 reports of MI and 8 reports of angina), 50 reports of

hypotensive events, 27 reports of dysrhythmia events, including two unexplained sudden deaths.

<http://adisonline.com/drugsafety/pages/articleviewer.aspx?year=2012&issue=35010&article=00004&type=abstract>

A Tasmanian coroner warned about Champix (Chantix) after a suicide occurred.

<http://www.abc.net.au/news/stories/2011/05/26/3227734.htm>

A meta analysis of studies found that varenicline (Chantix) significantly increased risk of serious adverse cardiovascular events

<http://www.cmaj.ca/content/early/2011/07/04/cmaj.110218.full.pdf>

[http://www.nytimes.com/2011/07/05/business/05smoke.html?\\_r=1](http://www.nytimes.com/2011/07/05/business/05smoke.html?_r=1)

<http://www.cbc.ca/news/health/story/2011/07/04/smoking-cessation-heart-champix.html>

FDA issued a Drug Safety Communication for Chantix (varenicline)

<http://www.fda.gov/Drugs/DrugSafety/ucm276737.htm>

<http://finance.yahoo.com/news/FDA-studies-do-not-tie-apf-2046540568.html?x=0&.v=4>

A study found that varenicline (Chantix/Champix) substantially increased risk of reported depression and suicide/self injurious behavior, sharply conflicting with FDA's study.

<http://www.plosone.org/article/info%3Adoi%2F10.1371%2Fjournal.pone.0027016>

<http://www.foxnews.com/health/2011/11/03/new-study-contradicts-fda-says-chantix-raises-suicide-risks/>

<http://www.dailymail.co.uk/news/article-2056892/Anti-smoking-drug-greatly-raises-suicide-risk-used-resort.html?ito=feeds-newsxml>

<http://medicalxpress.com/news/2011-11-chantix-unsuitable-first-line-cessation.html>

[http://www.acsh.org/factsfears/newsID.3142/news\\_detail.asp](http://www.acsh.org/factsfears/newsID.3142/news_detail.asp)

A study of 371 patients found that NRT and varenicline had a 7% success rate (i.e. 93% failure rate) for smoking cessation.

<http://www.ncbi.nlm.nih.gov/pubmed/22726377>

Facing more than 2,600 lawsuits, Pfizer tried to delay the first product liability trial for Chantix.

<http://www.nasdaq.com/article/pfizer-seeks-delay-of-chantix-case-and-cites-new-safety-data-20121016-01043#.UH29wI7aFWQ>

Then Pfizer settled 80% of Chantix lawsuits for \$273 million

[http://newsandinsight.thomsonreuters.com/Legal/News/2013/03 - March/Pfizer settles suits over anti-smoking drug for \\$273 mln/](http://newsandinsight.thomsonreuters.com/Legal/News/2013/03 - March/Pfizer settles suits over anti-smoking drug for $273 mln/)

But the FDA, Pfizer and Pfizer funded health and medical groups continue to recommend Chantix as a safe and effective way to quit smoking.

Meanwhile, a study found that FDA approved NRT products aren't as effective for smoking cessation as touted

<http://ntr.oxfordjournals.org/content/early/2011/04/06/ntr.ntr055.abstract>

A study found that most NRT users in England used the products for smoking reduction, not for smoking cessation

<http://onlinelibrary.wiley.com/doi/10.1111/j.1360-0443.2010.03215.x/abstract>

And another study found that 10% of 14-18 year olds in Finland have used NRT products, and that far more youth used to "just try" than "to quit" smoking

<http://www.sciencedirect.com/science/article/pii/S0306460311001572>

Simon Chapman study criticizes health agencies and organizations for claiming drug industry products are only effective ways to quit smoking.

Tar Wars over Smoking Cessation

<http://www.bmj.com/content/343/bmj.d5008.full?keytype=ref&ijkey=7GXlbpq39uvfd1Q>

Ross MacKenzie similarly wrote "Smokers don't need a broken crutch to quit" that critiques varenicline and drug company funding of smoking cessation drug promoters.

<http://theconversation.edu.au/smokers-dont-need-a-broken-crutch-to-quit-4216>

Another study confirmed past research findings that NRT products are ineffective for smoking cessation and nicotine cessation, with coauthor Greg Connolly calls for FDA to ban NRT and to ban cigarettes (by mandating sharp declines in nicotine levels)

<http://www.hsph.harvard.edu/news/press-releases/2011-releases/nicotine-replacement-therapies.html>

<http://www.nytimes.com/2012/01/10/health/study-finds-nicotine-gum-and-patches-dont-help-smokers-quit.html>

<http://www.guardian.co.uk/science/2012/jan/09/nicotine-replacement-quitting-smoking?INTCMP=SRCH>

<http://healthland.time.com/2012/01/09/nicotine-gum-and-patch-dont-help-smokers-quit-long-term/>

<http://www.businessweek.com/news/2012-01-10/nicotine-patches-gums-fail-to-help-smokers-quit-for-good.html>

[http://www.cbsnews.com/8301-504763\\_162-57355421-10391704/nicotine-patches-gum-wont-help-smokers-quit-for-good-study/](http://www.cbsnews.com/8301-504763_162-57355421-10391704/nicotine-patches-gum-wont-help-smokers-quit-for-good-study/)

<http://www.dailymail.co.uk/health/article-2084237/Nicotine-patches-branded-waste-time-study-finds-dont-help-smokers-quit-long-term.html>

In response, GSK defended NRT's 95+% failure rate, while falsely claiming that smoking cessation requires quitting all tobacco/nicotine: "GlaxoSmithKline Consumer Healthcare understands successfully quitting smoking requires breaking the body's addiction to nicotine."

<http://www.hsph.harvard.edu/news/press-releases/2011-releases/nicotine-replacement-therapies.html>

Another study found that drug industry NRT products haven't enhanced, but rather have hindered, smoking cessation efforts.

<http://www.annualreviews.org/doi/abs/10.1146/annurev-publhealth-031811-124624>

RTI's Douglas Kamerow defended NRT's abysmal smoking cessation failure rate, while falsely claiming "tobacco use" instead of "cigarette smoking" is leading cause of death in US, while failing to reports RTI's many financial conflicts of interest.

<http://www.bmj.com/content/344/bmj.e450>

In response, Mike Siegel criticized Douglas Kamerow's defense of NRT for failing to disclose conflicts of interest, exposed RTI's receipt of funds from 13 drug companies.  
<http://tobaccoanalysis.blogspot.com/2012/01/chief-scientist-of-rti-attacks-alpert.html>

Another study found continued use of NRT patch after/during relapse to cigarettes improves cessation rate to just 9.6% at 10th week.  
<http://onlinelibrary.wiley.com:80/doi/10.1111/j.1360-0443.2012.03801.x/abstract>  
<http://uk.reuters.com/article/2012/02/09/us-nicotine-patch-idUKTRE8182DD20120209>

Another study found NRT is not very effective for smoking cessation, and may reduce smoking cessation rates.  
<http://tobaccocontrol.bmj.com/content/21/2/110.full.pdf+html>

A study found that nicotine patches ineffective for smoking cessation among pregnant women  
<http://www.medpagetoday.com/PrimaryCare/Smoking/31421>  
<http://www.nejm.org/doi/full/10.1056/NEJMoa1109582>

And yet another study found that FDA approved "tobacco dependence" drug treatments are ineffective for 90% of smokers.  
<http://www.healthcanal.com/genetics-birth-defects/44008-gene-influences-success-of-nicotine-replacement-therapy-in-smokers.html>

Meanwhile, a study found that the NHS helpline (in the UK) and government subsidized nicotine patches don't help smokers quit  
[http://www.bmj.com/highwire/filestream/575382/field\\_highwire\\_article\\_pdf/0.pdf](http://www.bmj.com/highwire/filestream/575382/field_highwire_article_pdf/0.pdf)  
<http://www.dailymail.co.uk/health/article-2119094/Giving-smokers-free-nicotine-patches-intensive-NHS-helpline-counselling-does-help-quit.html?ito=feeds-newsxml>  
<http://health.usnews.com/health-news/news/articles/2012/03/23/helpline-free-nicotine-patches-dont-help-smokers-quit-study>

In sharp contrast, a study by Italian e-cig researchers highlighted the benefits for smokers who switch to e-cigs, and concluded:  
"Electronic cigarettes may prove to be the most promising solution for the reduction in the use of traditional cigarettes and their associated risk, with the positive features of these products clearly outweighing the negative features."  
<http://www.ncbi.nlm.nih.gov/pubmed/22283580>

Another study found a 40% decline in mean daily cigarette consumption (from 14.7 to 8.8) among 43 first time e-cigarette users who weren't interested in quitting smoking. But the authors inaccurately claimed tobacco toxicant exposure was NOT lowered, that "e-cigs may provide no public health benefit", and that their findings support FDA regulation of e-cigarettes.  
[http://www.srnt.org/conferences/2012/pdf/2012\\_Abstracts\\_H.pdf](http://www.srnt.org/conferences/2012/pdf/2012_Abstracts_H.pdf) (POS3-107 on page 121)

A study of 16 different brands found that e-cigs deliver less nicotine per inhale than cigarettes via machine testing, found effective nicotine vaporization, and differences among brands.

<http://ntr.oxfordjournals.org/content/early/2012/04/21/ntr.nts103.abstract?sid=57d8a432-1091-4f8e-ac41-aa7e1131b1ca>  
<http://www.ncbi.nlm.nih.gov/pubmed/22529223>

ACSH released a new publication “Helping Smokers Quit: The Science Behind Tobacco Harm Reduction” that delineated the health benefits of smoker switching to noncombustible tobacco/nicotine products.

[http://acsh.org/docLib/20120214\\_HelpingSmokersQuitFINAL.pdf](http://acsh.org/docLib/20120214_HelpingSmokersQuitFINAL.pdf)

A survey conducted in 2010 found 5.1% (12.1 million) adults in US had ever tried snus, 1.8% (4.2 million) tried e-cigarettes, and .6% (1.4 million) tried dissolvable tobacco products. Smokers were far more likely than never smokers to indicate use of these far less hazardous smokefree alternatives to cigarettes.

<http://www.hindawi.com:80/journals/jeph/2012/989474/>  
<http://www.hindawi.com/journals/jeph/2012/989474/tab2/>

A Legacy Foundation survey (conducted January-April, 2010) found that 3.4% of American adults (about 8 million) reported ever using an e-cigarette, that cigarette smokers were 22.8 times more likely to have used an e-cigarette than never smokers (11.4% vs .5%), that 2% of former smokers had used an e-cigarette (including some/many/most who may have quit smoking with e-cigarettes) and that e-cigarette users self-reported better health status. The online survey also found that 1.22% (about 2.9 million) of respondents indicated using an e-cigarette in the past 30 days, including 4.1% of cigarette smokers, .5% of former smokers and .3% of never smokers. The survey also found that 40% of American adults had heard of e-cigarettes (including 57% of smokers and 32.5% of never smokers), and that 70% (of those who had heard of e-cigarettes) believed them to be less harmful than cigarettes.

<http://ajph.aphapublications.org/doi/abs/10.2105/AJPH.2011.300526>

But Legacy survey authors again called for FDA to ban e-cigarette sales until the agency approves them for "safety and effectiveness" required for drugs and drug devices, which Judge Leon and the DC Court of Appeals struck down as unlawful.

Legacy’s press release omitted and misrepresented its key survey findings about e-cigs, repeated false and misleading fear mongering claims, and urged smokers to not use e-cigarettes, and recommended FDA ban e-cigs.

<http://www.legacyforhealth.org/5118.aspx>

Mike Siegel critiqued the Legacy e-cig survey and press release: New Article Calls for Removal of Electronic Cigarettes from Market With No Data to Substantiate Benefits of their Removal and Without Disclosure of Conflict of Interest of Study Author

<http://tobaccoanalysis.blogspot.com/2012/07/new-article-calls-for-removal-of.html>

ACSH similarly critiqued the study “Legacy Foundation’s results on e-cig: It’s working, so don’t use it”

[http://www.acsh.org/factsfears/newsID.3798/news\\_detail.asp](http://www.acsh.org/factsfears/newsID.3798/news_detail.asp)

Another study found that one third of Czech smokers had tried using e-cigarettes; Centre for Tobacco Addiction's Eva Kvalikova said smokefree alternatives pose "almost zero risk", said banning indoor use "doesn't make sense".

<http://www.radio.cz/en/section/curraffrs/the-e-cigarette-phenomenon-study-finds-a-third-of-czech-smokers-have-tried-the-new-safe-cigarettes>  
<http://onlinelibrary.wiley.com/doi/10.1111/j.1360-0443.2012.03916.x/full>

Meanwhile, a 2012 study found that nicotine may slow down Parkinson's disease

[http://www.shanghaidaily.com/article/article\\_xinhua.asp?id=90234](http://www.shanghaidaily.com/article/article_xinhua.asp?id=90234)  
[http://www.prd-journal.com/article/S1353-8020\(12\)00290-8/abstract](http://www.prd-journal.com/article/S1353-8020(12)00290-8/abstract)

And yet another study revealed schizophrenic smokers can benefit from smokefree harm reduction alternatives.

[http://www.schres-journal.com/article/S0920-9964\(12\)00177-6/abstract](http://www.schres-journal.com/article/S0920-9964(12)00177-6/abstract)  
<http://www.clinicalpsychiatrynews.com/news/adult-psychiatry/single-article/watch-for-heavy-smoking-in-schizophrenia/8977c8d47d57bc9e5ff46ba73f139d6e.html>

There have been several dozen reports worldwide (primarily in 2011 and 2012) that e-cig batteries have caught fire or exploded, with most involving home-made e-cig devices that weren't properly vented, or due to consumers using batteries or rechargers that weren't made for that e-cig model. There have been far more reports of battery fires and explosions in laptop computers, cigarette lighters, cell phones, and even flashlights.

A 2006 CPSC Cigarette Lighters Status Report documented dozens of explosions, hundreds of fires, and thousands of emergency room treated injuries caused by cigarette lighters.

<http://www.cpsc.gov/library/foia/foia07/brief/cigarettelighters.pdf>

Mike Siegel has pointed out the compared risks of injuries caused by e-cigs versus cigarette lighters at: "Defective Electronic Cigarette Battery Injures One Person; Defective but Legal Cigarette Lighters Injure 1000 Per Year"

<http://tobaccoanalysis.blogspot.com/2012/05/defective-electronic-cigarette-battery.html>

A man's death was reportedly caused by an exploding cigarette lighter

<http://www.digtriad.com/news/national/article/227128/175/Exploding-Cigarette-Lighter-Could-Be-Cause-Of-Mans-Death->

Considering the sharply increasing number of e-cigs on the market during the past several years, and the reduced frequency of reported exploding e-cig batteries, the risk of an e-cig battery exploding is well below one in a million, and rapidly declining.

But if the FDA issues a Final Rule for the proposed Deeming Regulation, and if the FDA strictly regulates (i.e. bans) "components" of e-cigs, the number of exploding e-cigs and e-cig batteries will sharply increase as more consumers will make home-made devices with no quality control.

A prospective clinical trial presented at SRNT-Europe conference found the use of 7.2mg, 4.8mg, and No Nicotine e-cigarettes resulted in smoking abstinence for 11%, 17% and 4% respectively after three months (among cigarette smokers who didn't even want

to quit), and for 13%, 9% and 4% respectively after twelve months. A 50% reduction in cigarette consumption occurred for an additional 21%, 16% and 19% of participants after three months, and for 9%, 8% and 10% after twelve months. These results indicate that e-cigarettes are far superior to NRT products for smoking cessation and for reducing cigarette consumption.

<http://www.srn-teurope.org/assets/Abstract-Book-Final.pdf> (See P54 on Page 87)

Another study found e-cigs the most promising products for inhalation of nicotine

<http://ntr.oxfordjournals.org/content/14/10/1127.abstract>

Meanwhile, a survey of 1,000 UK smokers finds 47% don't expect to quit in next year, more than half were interested in trying e-cigarettes, 18% had used e-cigarette, and 11% regularly used e-cigs.

<http://www.sourcewire.com/news/74438/majority-of-smokers-are-ignoring-stoptober-says-survey>

A survey of 179 Polish e-cig users found 66% of users no longer smoked any cigarettes and 25% smoked fewer than 5 cigarettes per day, 41% primarily used e-cigs to quit smoking, 41% primarily used e-cigs to reduce harm associated with smoking, and 82% believed e-cigs to be less hazardous than cigarette smoking.

<http://onlinelibrary.wiley.com:80/doi/10.1111/j.1465-3362.2012.00512.x/abstract>

2010/2011 survey data of 20-28 year old Midwestern adults found 70% were aware of e-cigarettes, 7% had ever used an e-cigarette, 1.2% had used in past 30 days. Among those aware of e-cigarettes, 45% agreed that e-cigarettes can help people quit smoking, 53% agreed that e-cigarettes are less hazardous than cigarettes.

<http://ajph.aphapublications.org/doi/abs/10.2105/AJPH.2012.300947>

Meanwhile, after misrepresenting the risks of e-cigarettes and urging the filing of adverse event reports since 2009, the FDA issued a misleading report on adverse event reports for e-cigs to further confuse, scare and push FDA's unwarranted deeming regulation.

<http://www.e-cigarette-forum.com/forum/media-general-news/321820-fda-tobacco-program-office-issues-misleading-report-adverse-events.html>

<http://ntr.oxfordjournals.org/content/early/2012/07/11/ntr.nts145.extract>

At the 2012 European Society of Cardiology conference, Dr. Konstantinos Farsalinos cited his research in a presentation entitled: Electronic cigarettes do not damage the heart

<http://www.trust.org/alertnet/news/greek-study-finds-e-cigarettes-no-threat-to-heart/>

<http://www.businessweek.com/news/2012-08-25/e-cigarettes-pose-no-risk-of-heart-disease-study-finds>

<http://www.youtube.com/watch?v=poOP9skjaxM> (5/17/12 interview/presentation by Dr.

Konstantinos Farsalinos)

The VPLive Vape Team replayed Dr. Konstantinos Farsalinos' e-cigarette heart study presentation at European Society of Cardiology, and interviewed him at

[http://www.youtube.com/watch?feature=player\\_embedded&v=e2rqYp-yPPA](http://www.youtube.com/watch?feature=player_embedded&v=e2rqYp-yPPA) (begins at 24 minutes)



An abstract presented at 2012 European Respiratory Society (ERS) conference confirmed previous study findings that e-cigarettes slightly reduce airway resistance for ten minutes.  
[https://www.ersnetsecure.org/public/prg\\_congres.abstract?ww\\_i\\_presentation=59718](https://www.ersnetsecure.org/public/prg_congres.abstract?ww_i_presentation=59718)

But abstract author Christina Gratiou, Chair of the ERS Tobacco Control Committee, issued a press release misrepresenting her own abstract's findings by claiming: "Experts warn that e-cigarettes can damage the lungs"  
[http://www.eurekaalert.org/pub\\_releases/2012-09/elf-ewt083112.php](http://www.eurekaalert.org/pub_releases/2012-09/elf-ewt083112.php)

Mike Siegel revealed this discrepancy and the Gratiou's conflicts of interest: Electronic Cigarette Opponents Fail to Disclose Relevant Conflicts of Interest to the Public  
<http://tobaccoanalysis.blogspot.com/2012/08/electronic-cigarette-opponents-fail-to.html>  
and at: More Conflicts of Interest Being Hid by Electronic Cigarette Opponents: Funding of their Organization by Big Pharma Not Disclosed  
<http://tobaccoanalysis.blogspot.com/2012/08/more-conflicts-of-interest-being-hid-by.html>

Another 2012 study found that e-cig vapor contains exponentially less particulate matter (PM) than secondhand cigarette smoke  
<http://www.ncbi.nlm.nih.gov/pubmed/22913171#>

And another e-cig study found no risk from environmental vapor exposure when comparing the effects of e-cigarette vapor and cigarette smoke on indoor air quality  
<http://informahealthcare.com/doi/abs/10.3109/08958378.2012.724728>  
<http://www.prnewswire.com/news-releases/new-e-cigarette-study-shows-no-risk-from-environmental-vapor-exposure-172645481.html>

Mike Siegel evaluated and commented on this new study:  
New Study Provides Much More Evidence that Vaping is Much Safer than Smoking  
<http://tobaccoanalysis.blogspot.com/2012/10/new-study-provides-more-evidence-that.html>

As did ACSH: Vape away -- e-cigs produce far fewer toxins than cigarette smoke  
<http://www.acsh.org/vape-away-e-cigs-produce-far-fewer-toxins-than-cigarette-smoke/>

A study found dual users of snus and cigarettes consumed significantly fewer cigarettes (mean 56.6/week) than smokers who quit snus use (mean 79.6/week) and exclusive smokers (mean 80.2/week) among Norwegian males; 73% of dual users reported using cigarettes first and 24% reported using snus first; 39.5% of daily snus users reported being a former smoker, 21.6% reported being an occasional smoker, and 9.8% reported being a daily smoker. The exclusive smoking rate among Norwegian men declined from about half in 1985 to below 20% in 2010, while the exclusive snus usage rate increased from 3% in 1985 to 12% in 2010.  
<http://ntr.oxfordjournals.org/content/early/2012/09/12/ntr.nts185.full.pdf+html>

More Smokers in Iceland Switch to Loose Tobacco  
[http://www.icelandreview.com/icelandreview/daily\\_news/More\\_Smokers\\_in\\_Iceland\\_Switch\\_to\\_Loose\\_Tobacco\\_0\\_394205.news.aspx](http://www.icelandreview.com/icelandreview/daily_news/More_Smokers_in_Iceland_Switch_to_Loose_Tobacco_0_394205.news.aspx)

A survey found 81% of Swedish males and 79% of Swedish females who reported using snus to quit smoking have successfully quit smoking compared to 50%-60% who used

pharmaceutical nicotine and counseling, found snus was the most common smoking cessation aid used by men (22%).

[http://7thspace.com/headlines/427305/population\\_based\\_survey\\_of\\_cessation\\_aids\\_used\\_by\\_swedish\\_smokers.html](http://7thspace.com/headlines/427305/population_based_survey_of_cessation_aids_used_by_swedish_smokers.html)

<http://www.harmreductionjournal.com/content/9/1/38/abstract>

<http://www.harmreductionjournal.com/content/pdf/1477-7517-9-38.pdf>

Meanwhile, Philip Morris International published a series of studies on its newly developed heat-not-burn tobacco products.

PMI series- Reduced exposure evaluation of an Electrically Heated Cigarette Smoking System. Part 1: Non-clinical and clinical insights

<http://www.sciencedirect.com/science/article/pii/S0273230012001651>

PMI series - Reduced exposure evaluation of an Electrically Heated Cigarette Smoking System. Part 2: Smoke chemistry and in vitro toxicological evaluation using smoking regimens reflecting human puffing behavior

<http://www.sciencedirect.com/science/article/pii/S0273230012001614>

PMI series - Reduced exposure evaluation of an electrically heated cigarette smoking system. Part 3: Eight-day randomized clinical trial in the UK

<http://www.sciencedirect.com/science/article/pii/S0273230012001675>

PMI series - Reduced exposure evaluation of an Electrically Heated Cigarette Smoking System. Part 4: Eight-day randomized clinical trial in Korea

<http://www.sciencedirect.com/science/article/pii/S0273230012001705>

PMI Series - Reduced exposure evaluation of an electrically heated cigarette smoking system. Part 5: 8-Day randomized clinical trial in Japan

<http://www.sciencedirect.com/science/article/pii/S0273230012001602>

PMI series - Reduced exposure evaluation of an electrically heated cigarette smoking system. Part 6: 6-day randomized clinical trial of a menthol cigarette in Japan

<http://www.sciencedirect.com/science/article/pii/S027323001200164X>

PMI Series - Reduced exposure evaluation of an Electrically Heated Cigarette Smoking System. Part 7: A one-month, randomized, ambulatory, controlled clinical study in Poland

<http://www.sciencedirect.com/science/article/pii/S0273230012001638>

PMI Series - Reduced exposure evaluation of an Electrically Heated Cigarette Smoking System. Part 8: Nicotine Bridging - estimating smoke constituent exposure by their relationships to both nicotine levels in mainstream cigarette smoke and in smokers

<http://www.sciencedirect.com/science/article/pii/S0273230012001626>

Tobacco Control also published a 2012 study confirming e-cigarettes contain nonhazardous levels of propylene glycol, glyceryl and nicotine. Unfortunately, the study's authors misrepresented and contradicted their own findings, existing evidence and public health goals by concluding: "While the current attention on traditional tobacco products is important, it is also necessary to focus on novelty products

like ENDS, which may encourage maintenance of tobacco usage behaviour and slow down the impact of national smoking control programmes."

<http://tobaccocontrol.bmj.com/content/early/2012/11/30/tobaccocontrol-2012-050483.abstract>

Also in 2012, CDC reported a 40.7% decline in US adult per capita cigarette consumption from 2000-2011 and a 36% decline in adult per capita consumption of combustible tobacco products. But the accompanying editorial falsely claimed "morbidity and mortality effects of other forms of combustible tobacco are similar to those of cigarettes" (as cigars are less hazardous because most cigar and pipe smokers don't inhale smoke and don't smoke daily), misleadingly claimed "The data suggest that certain smokers have switched from cigarettes to other combustible tobacco products" (as there is no evidence that a significant number of cigarette smokers have switched to cigars, although some have switched to RYO), and advocated the FDA "Deeming" regulation and tax increases for cigars and smoking tobacco.

[http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6130a1.htm?s\\_cid=mm6130a1\\_e](http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6130a1.htm?s_cid=mm6130a1_e)

To further advocate unwarranted FDA "Deeming" regulation and tax hikes, Obama's CDC and drug industry funded anti-tobacco extremists downplayed the huge decline in cigarette smoking, grossly exaggerated cigar disease risks, youth usage and rate of switching by cigarette smokers. The news media repeated those false and misleading claims without checking the facts or interviewing objective experts.

<http://www.prnewswire.com/news-releases/drop-in-cigarette-consumption-offset-by-increases-in-other-forms-of-smoked-tobacco-164753946.html>

[http://www.tobaccofreekids.org/press\\_releases/post/2012\\_08\\_02\\_cdc](http://www.tobaccofreekids.org/press_releases/post/2012_08_02_cdc)

<http://www.usatoday.com/news/health/story/2012-08-02/tobacco-cigarettes-cigars/56702480/1>

<http://www.reuters.com/article/2012/08/02/us-usa-health-tobacco-idUSBRE87117L20120802>

<http://www.nytimes.com/2012/08/03/health/more-smokers-switch-to-less-taxed-loose-tobacco-or-cigars-cdc-finds.html?>

<http://www.businessweek.com/news/2012-08-02/smokers-in-u-dot-s-dot-switch-to-pipes-cigars-from-cigarettes>

<http://health.usnews.com/health-news/news/articles/2012/08/02/smokers-drop-pricey-cigarettes-for-cheaper-alternatives-cdc>

Then CDC issued a second report and press release that same week again pushing the FDA Deeming regulation and higher taxes for OTP, and more funding for government anti tobacco programs. But CDC data showed huge declines from 2000-2011 in past-month teen use (that agency misleadingly calls "current use") of cigarettes, combustible tobacco and all tobacco. The first sentence of CDC's report falsely attributed cigarette diseases to use of other tobacco products, while the agency's editorial and press release unjustifiably attacked cigars and greatly exaggerated their disease risks, and failed to acknowledge that Tobacco Control Act prohibits FDA from banning tobacco sales to 12th grade students.

[http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6131a1.htm?s\\_cid=mm6131a1\\_e](http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6131a1.htm?s_cid=mm6131a1_e)

[http://www.cdc.gov/media/releases/2012/p0809\\_youth\\_tobacco.html](http://www.cdc.gov/media/releases/2012/p0809_youth_tobacco.html)

Reuters and Time repeated CDC's anti-cigar propaganda, downplayed the huge declines in youth smoking during past decade, failed to acknowledge that cigarettes are far more hazardous than cigars and OTP, and failed to acknowledge that the Tobacco Control Act prohibits FDA from banning tobacco sales to high school seniors.

<http://www.chicagotribune.com/health/sns-rt-us-usa-health-tobaccobre87813r-20120809,0,6286804.story>  
<http://healthland.time.com/2012/08/09/teens-and-tobacco-use-why-declines-in-middle-and-high-school-students-stalled/>

In response, Sen. Frank Lautenberg (D-NJ) cited CDC's anti-cigar propaganda to once again urge FDA to issue the Deeming Regulation and to ban flavored cigars.  
<http://www.lautenberg.senate.gov/newsroom/record.cfm?id=337453&>

Meanwhile, Sen. Richard Blumenthal (D-CT) also repeated CDC's anti-cigar propaganda.  
<http://www.blumenthal.senate.gov/newsroom/press/release/-blumenthal-statement-on-cdcs-new-report-about-youth-smoking>

Also in response, Brad Rodu highlighted the scientific evidence on cigar risks.  
<http://rodutobaccotruth.blogspot.com/2012/08/the-health-risks-of-cigar-smoking.html>

A Cigar Manufacturer also responded: CDC Tobacco Report Lacks Evidence Sales data doesn't support allegation that cigarette smokers are switching to cigars.  
<http://www.cspnet.com/news/tobacco/articles/cigar-manufacturer-cdc-tobacco-report-lacks-evidence>

A meta analysis confirmed the very large lung cancer risk from cigarette smoking, but found lower risks for cigar and pipe only smokers.  
[http://7thspace.com/headlines/420492/systematic\\_review\\_with\\_meta\\_analysis\\_of\\_the\\_epidemiological\\_evidence\\_in\\_the\\_1900s\\_relating\\_smoking\\_to\\_lung\\_cancer.html](http://7thspace.com/headlines/420492/systematic_review_with_meta_analysis_of_the_epidemiological_evidence_in_the_1900s_relating_smoking_to_lung_cancer.html)

Brad Rodu also highlighted the scientific evidence in: Pipe Smoking and Health  
<http://rodutobaccotruth.blogspot.com/2012/08/pipe-smoking-and-health.html>

Ironically, in July 2014, the CDC issued a MMWR with NATS data finding daily cigar smoking by just 3.3% of premium cigar smokers, 13.3% of cigarillo smokers, and 36% of little filtered cigar smokers, confirming that cigars are far less addictive and harmful than cigarettes (but didn't correct or clarify any past claims by the agency about cigars).  
[http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6330a2.htm?s\\_cid=mm6330a2\\_e](http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6330a2.htm?s_cid=mm6330a2_e)

In 2012, SAMHSA issued its 2011 survey data on Americans 12 years and older finding that cigarette smoking, cigar smoking, smokeless tobacco use and all tobacco use had declined from 2010.  
<http://consumer.healthday.com/Article.asp?AID=670848>  
<http://www.samhsa.gov/data/NSDUH/2k11Results/NSDUHresults2011.htm#Ch4>

At the MTF press conference in 2012 exposing record low youth cigarette smoking rates in US, DHHS' Howard Koh falsely claimed "tobacco" is leading cause of preventable death (its cigarette smoking), accused (but provided no evidence indicating) tobacco companies marketed candy flavored cigars and smokeless tobacco to children, while exaggerating the disease risks of Other Tobacco Products (OTP).  
<http://www.c-span.org/Events/Survey-of-Teen-Drug-Use-Released/10737436717/> (beginning at 10 minutes into webcast)

During 2011 and 2012, it was revealed that CDC was unlawfully funding many state and local health agencies to lobby for changes in tobacco laws (including e-cig usage and sales bans).

Federal stimulus funds were used by King County/Seattle to misrepresent the health risks of smokefree tobacco/nicotine products and to lobby for banning outdoor usage of ALL tobacco products (including e-cigarettes) at ALL parks, beaches, aquatic areas, walking and hiking trails, parking areas, recreational sites (pages 36-39)  
<http://www.ci.kirkland.wa.us/Assets/Parks/Parks+PDFs/ParkBoard/0+KIRKLAND+PAR+K+BOARD+PACKET+Mar+9+11+web2.pdf>

Jeff Stier revealed this illegal activity in a National Review article “The truth about The War on E-Cigarettes: The CDC should stop funding harmful campaigns” at  
<http://www.nationalreview.com:80/articles/277484/war-e-cigarettes-jeff-stier>

CDC gives federal funds to groups that lobby for laws not based on health science  
<http://thehill.com/blogs/congress-blog/healthcare/153625-obamacares-big-bucks>

Jeff Stier on federal health funds spent lobbying for e-cig usage bans  
[http://www.talk1200.com/cc-common/podcast/single\\_page.html?podcast=interviews&selected\\_podcast=060611jeffStierWEB.mp3](http://www.talk1200.com/cc-common/podcast/single_page.html?podcast=interviews&selected_podcast=060611jeffStierWEB.mp3)

Jeff Stier: The CDC is subsidizing left-wing activist groups  
<http://dailycaller.com/2011/06/01/the-cdc-is-subsidizing-left-wing-activist-groups/>

Jeff Stier & Gregory Conley - The War on E-Cigarettes: The CDC should stop funding harmful campaigns  
<http://www.nationalreview.com/articles/277484/war-e-cigarettes-jeff-stier>

DHHS Inspector General: Health grants could have illegally funded lobbying  
<http://thehill.com/blogs/healthwatch/lobbying/237015-hhs-inspector-general-says-grants-may-have-illegally-funded-lobbying>

The US House Energy and Commerce Committee sent a letter to DHHS Secretary Sebelius investigating unlawful spending of CDC CPPW and CTG grants for lobbying purposes.  
[http://www.cspnet.com/sites/default/files/Energy%20and%20Commerce%20Committee%20Letter%20to%20Secretary%20Sebelius%20\(August%2013,%202012\).pdf](http://www.cspnet.com/sites/default/files/Energy%20and%20Commerce%20Committee%20Letter%20to%20Secretary%20Sebelius%20(August%2013,%202012).pdf)

"No part of the money appropriated by any enactment of Congress shall, in the absence of express authorization by Congress, be used directly or indirectly to pay for any personal service, advertisement, telegram, telephone, letter, printed or written matter, or other device, intended or designed to influence in any manner a Member of Congress, a jurisdiction, or an official of any government, to favor, adopt, or oppose, by vote or otherwise, any legislation, law, ratifications, policy, or appropriation, whether before or after the introduction of any bill, measure, or resolution proposing such legislation, law ratifications, policy or appropriation." (18 U.S.C. Section 1919)

Congress Raises Serious Questions About Use of Federal Funds for Lobbying  
<http://www.cspnet.com/news/tobacco/articles/congress-raises-serious-questions-about-use-federal-funds-lobbying>

Stimulus Grants Used to Lobby for Tobacco Taxes? NATO calls for an explanation, and for practice to stop  
<http://www.cspnet.com/news/tobacco/articles/stimulus-grants-used-lobby-tobacco-taxes>

George Will: Why government needs a diet  
[http://www.washingtonpost.com:80/opinions/george-will-why-government-needs-a-diet/2012/08/22/9704da34-ebcc-11e1-9ddc-340d5efb1e9c\\_story.html](http://www.washingtonpost.com:80/opinions/george-will-why-government-needs-a-diet/2012/08/22/9704da34-ebcc-11e1-9ddc-340d5efb1e9c_story.html)

The Hill - HHS Inspector General: Health grants could have Illegally funded lobbying  
<http://thehill.com/blogs/healthwatch/lobbying/237015-hhs-inspector-general-says-grants-may-have-illegally-funded-lobbying>

Jeff Stier - Oversight of CDC Grants Is Necessary  
<http://www.jeffstier.org/12059/oversight-of-cdc-grants-is-necessary>

Nanny of the Month: CDC lobbying grants  
<http://reason.com/reasontv/2012/08/31/nanny-of-the-month-august-2012-stimulus>

Jeff Stier exposes Obama CDC stimulous grants funding state/local lobbying campaigns (including e-cigarette sales/use bans, dissolvable sales/use bans, indoor/outdoor tobacco usage bans) on 8/1 Late Nights with Jim Bohannon  
<http://www.jimbotalk.net/programhighlights> (click on August 1)

Jeff Stier: Oversight of CDC grants is necessary  
<http://www.jeffstier.org:80/12059/oversight-of-cdc-grants-is-necessary>

A review of CDC Community Transformation Grants (CTG) States and Communities  
<http://www.cdc.gov/communitytransformation/funds/index.htm>  
<http://www.cdc.gov/communitytransformation/funds/programs.htm>  
reveals that many CDC CPPW grants appear to have been spent since 2010 to lobby for tobacco tax increases, dissolvable and flavored tobacco sales bans, e-cigarette use and smoking bans in workplaces and public housing, tobacco and e-cigarette use bans on government property. Below are excerpts from some DHHS grants and quarterly reports.

Mississippi State Department of Health  
<http://www.recovery.gov/Transparency/RecoveryData/Pages/RecipientProjectSummary508.aspx?AwardIDSUR=88831&qtr=2012Q2>

“The Mississippi State Department of Health (MSDH) Office of Tobacco Control (OTC) will utilize funding to engage in a two-year campaign that will result in the passage and implementation of a comprehensive, statewide smoke-free air law.”

North Carolina Department of Health and Human Services  
<http://www.recovery.gov/Transparency/RecoveryData/Pages/RecipientProjectSummary508.aspx?AwardIDSUR=98785&qtr=2012Q1>

“North Carolina, with the leadership of the Tobacco Prevention and Control Branch (TPCB) in NC DPH, will build support for comprehensive statewide policies for smoke-

free workplaces and public places by January 2012. TPCB will serve as a resource for both seasoned and new partners to build public, media, and legislative support for a comprehensive smoke-free law.

In addition, North Carolina will work for successful implementation and evaluation of the new smoke-free restaurant and bars law in North Carolina and will assist local governments that wish to use their expanded authority to create stronger smoke-free ordinances to cover government-owned grounds and public places. New, successful smoke-free laws will build support and momentum for more comprehensive smoke-free legislation.”

Idaho Department of Health and Welfare

<http://www.recovery.gov/Transparency/RecoveryData/Pages/RecipientProjectSummary508.aspx?AwardIDSUR=88763&qtr=2012Q2>

“Project Filter continues to work with the local public health districts to implement smoke-free initiatives in parks, tot-lots and playgrounds.

Project Filter has contracted with the seven local public health districts to work with cities to adopt smoke-free parks.”

University of Kentucky

<http://www.recovery.gov/Transparency/RecoveryData/Pages/RecipientProjectSummary508.aspx?AwardIDSUR=88831&qtr=2012Q2>

“The long-term goal is to develop a best practices framework for disseminating scientific knowledge about the effects of secondhand smoke and smoke-free laws and implementing effective community policy change and maintenance strategies in rural underserved communities.”

New York City Department of Health

<http://www.recovery.gov/Transparency/RecoveryData/Pages/RecipientProjectSummary508.aspx?AwardIDSUR=93025&qtr=2010Q4>

“Vendor is responsible for education and advocacy activities with community members and policy makers to expand smoke free outdoor areas; reduce the number of tobacco retailers; and increase the price of tobacco products.”

King County, Washington

<http://www.recovery.gov/Transparency/RecoveryData/Pages/RecipientProjectSummary508.aspx?AwardIDSUR=90028&qtr=2010Q2>

“Staff have also met with the King County Board of Health Tobacco Policy Committee in May and in June to develop county-wide tobacco policies to be implemented later in 2010. A package of policies will be brought to the Board of Health for a vote in fall of 2010.”

Respiratory Health Association of Metropolitan Chicago

<http://www.recovery.gov/Transparency/RecoveryData/Pages/RecipientProjectSummary508.aspx?AwardIDSUR=91116&qtr=2011Q4>

“We continued to work with officials from the Park District and Chicago Public Schools on pending policy changes, expected to be enacted in spring 2012. Population-based strategies include public education and policies to prohibit vending and restrict tobacco advertising in retail outlets and in the community.”

Jefferson County, Alabama

<http://www.recovery.gov/Transparency/RecoveryData/Pages/RecipientProjectSummary508.aspx?AwardIDSUR=97634&qtr=2011Q4>

“Smoke-free policy presentations given to the Bessemer, Birmingham and Midfield City Councils and the Jefferson County Mayors Association; the City of Midfield adopted a comprehensive smoke-free policy.”

Los Angeles Health Department

<http://www.recovery.gov/Transparency/RecoveryData/Pages/RecipientProjectSummary508.aspx?AwardIDSUR=90812&qtr=2011Q2>

“Implement a coordinated community action plan comprised seven interventions, including multi-faceted public education campaign, and the implementation of a variety of evidence-based interventions at the city and county-level including comprehensive smoke free outdoor air policies, smoke free multi-unit housing policies, point of purchase marketing restrictions, cigarette butt litter free policies, a policy and smoking cessation initiative targeting schools, and smoking cessation initiatives targeting social service agencies.

TRUST had smoke-free outdoor area efforts underway in 10 cities and smoke-free multi-unit housing efforts in 8. The Carson and Hermosa Beach City Councils took first step in adopting a comprehensive outdoor policy. The Huntington Park and Santa Monica City Councils took initial actions towards smoke-free housing policies that include smoke-free units.”

Santa Clara Dept of Health

<http://www.recovery.gov/Transparency/RecoveryData/Pages/RecipientProjectSummary508.aspx?AwardIDSUR=90471&qtr=2012Q2>

“The CPPW Tobacco Prevention and Control Program will utilize media and marketing to counter pro-tobacco influences, establish local tobacco retail licensing requirements, limit tobacco advertising near schools, advocate effectively for increasing the price of tobacco through evidence-based pricing strategies, and build significantly greater capacity for smoking cessation services.

San Jose City Council voted unanimously to adopt smoke-free areas in outdoor dining establishments, service lines, and outdoor common areas of multi-family residences. Impacts > 945,000 residents. ? Sunnyvale City Council adopted ordinance that makes all parks, trails, and other recreation areas smoke-free. Impacts > 140,000. ? Milpitas City Council approved smoke-free parks ban; moves forward with smoke-free worksites discussion. Impacts > 66,000. ? Morgan Hill City Council adopted comprehensive outdoor smoke-free policy with exemptions.”

Meanwhile Mike Siegel revealed: Groups that Opposed Electronic Cigarettes Accepted \$2.8 Million From Pfizer Alone in 2011-2012 (CTFK, ACS, AHA, ALA, AMA, AAP, Legacy, ASH urged FDA to ban e-cigarettes)

<http://tobaccoanalysis.blogspot.com/2012/09/anti-smoking-groups-that-opposed.html>

[http://www.pfizer.com/responsibility/grants\\_contributions/transparency\\_in\\_grants.jsp](http://www.pfizer.com/responsibility/grants_contributions/transparency_in_grants.jsp)

Mike Siegel also revealed: Groups that urged FDA to ban e-cigarettes received \$1.4 Million from GlaxoSmithKline, in addition to \$2.8 Million from Pfizer, but failed to disclose when calling for FDA to ban products.



<http://tobaccoanalysis.blogspot.com/2012/10/anti-smoking-groups-that-oppose.html>

Mike Siegel also pointed out that, since 2009, Pfizer gave \$2.75 million and GSK gave \$1.35 million to groups that have lobbied to ban e-cigarettes and new smokeless tobacco products, that have made false claims about e-cigarettes and smokeless tobacco products, and that have falsely touted drug industry products as most effective and safest way to quit smoking.

<http://tobaccoanalysis.blogspot.com/2012/11/despite-best-efforts-of-anti-smoking.html>

Washington Post exclusive: As drug industry influence over research grows, so does the potential for bias

[http://www.washingtonpost.com/business/economy/as-drug-industrys-influence-over-research-grows-so-does-the-potential-for-bias/2012/11/24/bb64d596-1264-11e2-be82-c3411b7680a9\\_story.html](http://www.washingtonpost.com/business/economy/as-drug-industrys-influence-over-research-grows-so-does-the-potential-for-bias/2012/11/24/bb64d596-1264-11e2-be82-c3411b7680a9_story.html)

A study found that reducing daily cigarette consumption significantly reduces smoker's mortality risks.

<http://www.jpost.com:80/Health/Article.aspx?id=293443>

<http://aje.oxfordjournals.org/content/175/10/1006.abstract>

But CDC OSH Director Tim McAfee falsely claimed that reducing cigarette consumption won't reduce disease risks for smokers.

<http://health.usnews.com/health-news/news/articles/2012/11/08/anti-smoking-progress-stalls-among-us-adults-report>

Smoking fewer cigarettes is only a benefit if it's a step to stopping smoking altogether, McAfee said. "Smoking fewer cigarettes is not a substitute for quitting," he said.

On December 17, 2012, more than a dozen e-cig consumers and supporters testified at a FDA public hearing (on Section 918 of the FSPTCA) about the many benefits of e-cigs, and how FDA approved drugs didn't help them quit smoking

<http://www.fda.gov/Drugs/NewsEvents/ucm324938.htm>

<https://collaboration.fda.gov/p98191651/?launcher=false&fcsContent=true&pbMode=normal>

<https://collaboration.fda.gov/p95861884/?launcher=false&fcsContent=true&pbMode=normal>

<https://collaboration.fda.gov/p36279658/?launcher=false&fcsContent=true&pbMode=normal>

<https://collaboration.fda.gov/p20988129/?launcher=false&fcsContent=true&pbMode=normal>

Agenda: FDA Public Hearing, December 17, 2012 where 15 of the 23 scheduled testifiers were tobacco harm reduction advocates, and 8 are drug industry funded/affiliated NRT promoters

<http://www.fda.gov/downloads/Drugs/NewsEvents/UCM331857.pdf>

Smokefree Pennsylvania / Bill Godshall's testimony to FDA on Section 918

<http://www.e-cigarette-forum.com/forum/legislation-news/354422-fda-hold-public-hearing-dec-17-nrt-regulation-5.html#post8013502>

Carl Phillips' testimony to FDA on Section 918

<http://www.e-cigarette-forum.com/forum/legislation-news/354422-fda-hold-public-hearing-dec-17-nrt-regulation-5.html#post8012707>

CASAA / Elaine Keller's testimony to FDA on Section 918

<http://www.e-cigarette-forum.com/forum/legislation-news/354422-fda-hold-public-hearing-dec-17-nrt-regulation-5.html#post8013541>

Greg Conley's testimony to FDA on Section 918

<http://www.e-cigarette-forum.com/forum/legislation-news/354422-fda-hold-public-hearing-dec-17-nrt-regulation-5.html#post8005516>

Scott Ballin's testimony to FDA on Section 918

<http://www.e-cigarette-forum.com/forum/legislation-news/354422-fda-hold-public-hearing-dec-17-nrt-regulation-6.html#post8020926>

Then Smokefree Pennsylvania submitted to FDA's docket for Section 918 vast quantities of scientific and empirical evidence documenting that e-cigs and other noncombustible tobacco/nicotine products are far less hazardous than cigarettes and have helped many smokers quit smoking and reduce cigarette consumption, and that FDA approved nicotine gums, lozenges and patches have very low success rates for smoking cessation.

<http://www.e-cigarette-forum.com/forum/legislation-news/364397-casaa-call-action-submit-written-comments-sec-918-tobacco-act-6.html#post8403639>

<http://www.e-cigarette-forum.com/forum/legislation-news/364397-casaa-call-action-submit-written-comments-sec-918-tobacco-act-7.html#post8403683> and

<http://www.e-cigarette-forum.com/forum/legislation-news/364397-casaa-call-action-submit-written-comments-sec-918-tobacco-act-7.html#post8403705>

CASAA also submitted additional comments to FDA on Section 918

<http://blog.casaa.org/2013/01/casaa-submits-comments-to-fda.html>

E-cig consumers submitted at least an additional 5,200 comments to the FDA's Docket on Section 918 (accounting for >99% of docket submissions) informing the agency of the benefits of e-cigs, and urging the agency to not ban or unjustifiably regulate the products.

**But the FDA has only made 99 of these comments available to the public.**

<http://www.regulations.gov#!docketDetail;D=FDA-2012-N-1148>

Then in April 2013, the FDA sent a Report to Congress on Section 918 of FSPTCA that contradicted and misrepresented the evidence provided to the agency on the health benefits of smokers switching to e-cigarettes or smokefree tobacco products, and on NRT's dismal success rate for smoking and nicotine cessation at the 12/17/12 Section 918 public hearing, in >5,200 public comments submitted to agency's dockets, at a 2/3/11 IOM MRTP meeting, at a 8/25/11 FDA MRTP meeting, at many FDA TPSAC meetings, and in 2012 comments submitted to FDA on its MRTP Draft Guidance.

<http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/UCM348930.pdf>

<http://www.fda.gov/Drugs/NewsEvents/ucm324938.htm>

<http://www.fda.gov/TobaccoProducts/NewsEvents/ucm259201.htm>

<http://www.e-cigarette-forum.com/forum/legislation-news/159016-iom-committee-scientific-standards-studies-reduced-risk-tobacco-products.html>

In February 2013, more than 25,000 people submitted a Petition to White House to "Prevent the FDA from regulating or banning the sale and use of electronic cigarettes, accessories and associated liquids", but the White House still hasn't responded.

<https://petitions.whitehouse.gov/petition/prevent-fda-regulating-or-banning-sale-and-use-electronic-cigarettes-accessories-and-associated/RQLBYRsd>

After fourteen months, FDA's Mitch Zeller responded our Petition to White House to "Prevent the FDA from regulating or banning the sale and use of electronic cigarettes, accessories and associated liquids" on the same day the deeming regulation was proposed by falsely claiming "the proposed regulation would not ban them." In fact, the deeming reg would ban ALL e-cig products that FDA doesn't explicitly approve (which would include >99% of the ten thousand plus e-cig products, including all mods and e-liquid).

<https://petitions.whitehouse.gov/petition/prevent-fda-regulating-or-banning-sale-and-use-electronic-cigarettes-accessories-and-associated/RQLBYRsd>

Godshall presentation on FDA Deeming Regulation at 4/23/13 FDLI conference

<http://www.e-cigarette-forum.com/forum/legislation-news/409895-godshall-presentation-fda-deeming-regulation-food-drug-law-institute-conference-dc.html>

Brad Rodu delineated the scientific evidence on nicotine at "Misperceiving nicotine health risks"

<http://rodutobaccotruth.blogspot.com/2013/04/misperceiving-nicotine-health-risks.html>

According to another study, Nicotine in Peppers, Other Plants Linked With Lower Parkinson's Risk: Study

[http://www.huffingtonpost.com/2013/05/09/nicotine-peppers-parkinsons-disease-risk\\_n\\_3246499.html?](http://www.huffingtonpost.com/2013/05/09/nicotine-peppers-parkinsons-disease-risk_n_3246499.html?)

<http://onlinelibrary.wiley.com/doi/10.1002/ana.23884/abstract;jsessionid=42A4BACDC638101D0596690ACCBC1B7F.d01t01>

[http://www.eurekalert.org/pub\\_releases/2013-05/w-cep050713.php](http://www.eurekalert.org/pub_releases/2013-05/w-cep050713.php)

A toxicological review concluded "propylene glycols present a very low risk to human health."

<http://informahealthcare.com/doi/abs/10.3109/10408444.2013.792328>

A study found the cytotoxicology of e-cig vapor significantly lower than cigarette smoke

<http://informahealthcare.com/doi/abs/10.3109/08958378.2013.793439>

Another study found that e-cigarettes expose consumers to exponentially fewer hazardous contaminants than cigarette smoke

<http://tobaccocontrol.bmj.com/content/early/2013/03/05/tobaccocontrol-2012-050859.abstract>

<http://tobaccoanalysis.blogspot.fi/2013/03/new-study-of-electronic-cigarette-vapor.html>

<http://www.acsh.org/new-data-on-safety-of-e-cigarettes/>

Meanwhile, SAMHSA reported finding more adolescents now begin using alcohol, illegal drugs and marijuana than cigarettes (and that far more begin smoking cigarettes than using e-cigs).

<http://www.samhsa.gov/newsroom/advisories/1308285320.aspx>

<http://www.sciencedaily.com/releases/2013/08/130829112815.htm>

<http://consumer.healthday.com/general-health-information-16/misc-alcohol-news-13/hundreds-of-thousands-of-teens-use-marijuana-alcohol-each-day-report-679721.html>

SAMHSA's report stated that on an average day:

- 7,639 kids aged 12 to 17 drink alcohol for the first time,
- 4,594 use an illicit drug for the first time,
- 4,000 use marijuana for the first time,
- 3,701 smoke cigarettes for the first time,
- 2,151 misuse prescription pain relievers for the first time.

A study presented to the European Society of Cardiology found e-cig use has no immediate adverse effects on coronary circulation (blood and oxygen supply to the heart). Study found significant elevations in HbCO and CVRI and decrease in CFVR after smoking two cigarettes, while no difference was found for those parameters after electronic cigarette use by smokers and ex-smokers.

<http://spo.escardio.org/SessionDetails.aspx?eevtid=60&sessId=11188&subSessId=0#.UiYJgdKOTQ1>

<http://ecigarette-research.com/web/index.php/research/127-no-adverse-effects>

<http://www.youtube.com/watch?v=ztrGafEg4>

<http://www.theheart.org/article/1575989.do>

Another study found that regular use of e-cigs by nonsmoking youth is extremely low. The survey found just 0.1% in 2/2010, 0.3% in 10/2010, and 0.4% in 6/2011 of nonsmoking high school students had used an e-cig in past-30-days, consistent with 0.5% found in the 2011 NTYS survey that CDC's Tom Frieden misrepresented to confuse, scare and lobby for unwarranted and counterproductive FDA Deeming Regulation.

<http://tobaccoanalysis.blogspot.com/2013/09/new-study-shows-that-regular-use-of.html>

<http://www.sciencedirect.com/science/article/pii/S0306460313002736>

Debunking more than a century of false claims about nicotine toxicity, another study found evidence indicating that more than 500mg of nicotine is required to kill an adult, (in sharp contrast to the 60mg as has been repeatedly claimed by public health agencies and others)

“How much nicotine kills a human? Tracing back the generally accepted lethal dose to dubious self-experiments in the nineteenth century”

<http://link.springer.com/article/10.1007%2Fs00204-013-1127-0/fulltext.html>

Meanwhile, a study by e-cig opponents concluded: “from our review of the literature and bearing in mind the long experience with theatrical mists, the short-term toxicity can be considered to be very low - except for some individuals with reactive airways - and the long-term toxicity depends on the additives and contaminants in PG [propylene glycol] and/or glycerol.”

<http://www.karger.com/Article/FullText/353253>

Another study found nicotine, propylene glycol and most flavorings used in e-cigs are nontoxic to cells, just one of 20 tested flavorings found marginally cytotoxic (but far less than cigarette smoke).

<http://www.mdpi.com/1660-4601/10/10/5146>

<http://www.ecigarette-research.com/web/index.php/research/135-evaluation-of-the-cytotoxic#comment-623>

A pre clinical study of inhaled propylene glycol found no adverse respiratory effects.

<http://www.ncbi.nlm.nih.gov/pubmed/18158714>

<http://tobaccoanalysis.blogspot.com/2013/10/pre-clinical-study-of-inhaled-propylene.html>

Another study found exhaled e-cig vapor contains nonhazardous trace levels of nicotine (averaging 2.5  $\mu\text{g}/\text{m}^3$ ) and none of the many toxicants in 2<sup>nd</sup> hand smoke.

<http://ntr.oxfordjournals.org/content/early/2013/12/10/ntr.ntt203.abstract.html>

A study found that in contrast to cigarette smoking, e-cig use not associated with elastic properties of ascending aorta.

<http://www.ecigarette-research.com/EUROECHO2013-ecigs.pdf>

Another study found asthmatic smokers who switched to e-cigs (including exclusive vapers and dual use vapers who reduced cigarette consumption) had significant improvements in spirometry data, asthma control and airway hyper-responsiveness (AHR).

<http://www.mdpi.com/1660-4601/11/5/4965>

Konstantinos Farsalinos: First study to demonstrate improvements in smoking asthma patients after switching to e-cigarette use

<http://www.ecigarette-research.com/web/index.php/2013-04-07-09-50-07/2014/163-ecigs-asthma>

Mike Siegel: New study shows improvement in asthma among smokers who switch to electronic cigarettes, including dual users

<http://tobaccoanalysis.blogspot.com/2014/05/new-study-shows-improvement-in-asthma.html>

Konstantinos Farsalinos: Effects of e-cigarette use on exhaled nitric oxide

<http://www.ecigarette-research.com/web/index.php/2013-04-07-09-50-07/2014/167-no-ecigs>

Mike Siegel: CDC Study Shows that Electronic Cigarette Use is Growing Among Smokers and Helping Some Smokers Quit, But Without any Increasing Appeal to Nonsmokers

[http://tobaccoanalysis.blogspot.com/2013/03/cdc-study-shows-that-electronic.html#disqus\\_thread](http://tobaccoanalysis.blogspot.com/2013/03/cdc-study-shows-that-electronic.html#disqus_thread)

Study of schizophrenic smokers (who didn't want to quit) found that 14% quit smoking and 50% cut cigarette consumption in half fifty two weeks after trying e-cigs.

<http://www.mdpi.com/1660-4601/10/2/446>

Another study documented the effectiveness of e-cigs for smoking cessation among 1,000 ex-smokers

<http://onlinelibrary.wiley.com/doi/10.1111/add.12150/abstract>

<http://tobaccoanalysis.blogspot.com/2013/04/new-study-documents-effectiveness-of.html>

<http://www.reuters.com/article/2013/04/04/us-e-cigarettes-tobacco-idUSBRE93313B20130404>

Electronic cigarette: a possible substitute for cigarette dependence

(Comprehensive review of research on e-cigarettes that found many benefits and negligible risks of e-cigs)

<http://archest.fsm.it/pne/pdf/79/01/pne79-1-04-caponnetto-polosa.pdf>

A clinical trial found e-cigs more effective for smoking cessation and sharply reducing cigarette consumption among smokers who don't want to quit than NRT has been for smokers who want to quit. After being given e-cigs for 12 weeks, the study found 11% and 13% cigarette abstinence rate among group given 7.2mg nicotine e-cigs after week-12 and week-52 respectively, and that 22.3% and 10.3% of participants who didn't quit smoking (including group given no nicotine e-cigs) reduced daily cigarette consumption by at least 50% after weeks 12 and 52 respectively.

<http://www.plosone.org/article/info%3Adoi%2F10.1371%2Fjournal.pone.0066317>

<http://www.plosone.org/article/fetchObject.action?uri=info%3Adoi%2F10.1371%2Fjournal.pone.0066317&representation=PDF>

In Italy, E-Cigarettes Helped Smokers Quit Nicotine Entirely, Even When They Didn't Want To

<http://www.medicaldaily.com/articles/16822/20130624/electronic-cigarettes-quit-smoking-nicotine-italy-study.htm>

A 2010-2012 survey found 13% of smokers in Hawaii used e-cigs to quit, that many of these e-cig users had already unsuccessfully used FDA approved drugs to try quitting (i.e. 45% nicotine patch, 44% gum, 13% varenicline/Chantix, 12% bupropion), and that e-cig users were far more likely than other smokers to have previously tried quitting with nicotine gum (3.7 times), patch (2.5 times), Chantix (2.9 times), bupropion (2.3 times). But authors absurdly conclude (based upon no evidence presented in study).

<http://ajph.aphapublications.org/doi/abs/10.2105/AJPH.2013.301453>

<http://www.medicalnewstoday.com/releases/263500.php>

A Czech study of 1,738 cigarette smokers finds that half have used an e-cig at least once, 9% reported regular use of e-cigs, and 7% reported daily use of e-cigs. Among smokers who reported regular use of e-cigs, 60% reported reduced cigarette consumption.

<http://journal.publications.chestnet.org/article.aspx?articleid=1714565>

A study of smokers (who didn't want to quit smoking) found that (after 24 months) 12.5% quit smoking with e-cigs, and another 27.5% reduced cigarette consumption from a median of 24 cigs/day to just 4 cigs/day

<http://link.springer.com/article/10.1007/s11739-013-0977-z>

A Gallup Poll found 48% of former smokers in US reported quitting "cold turkey", 5% with nicotine patch, 3% with e-cigs, 2% with prescription drugs, 1% with nicotine gum.

<http://www.gallup.com/poll/163763/smokers-quit-tried-multiple-times.aspx?>

[http://www.huffingtonpost.com/2013/08/04/quit-smoking-cigarettes\\_n\\_3684381.html](http://www.huffingtonpost.com/2013/08/04/quit-smoking-cigarettes_n_3684381.html)

NJOY says soon-to-be-published study found that among 25 smokers not interested in quitting who were given NJOY Kings, 89% reduced cigarette consumption by an average of 39% after one week, 32% reduced consumption by 50% or more, 16% quit smoking.

<http://www.businesswire.com/news/home/20130812005267/en/Pilot-Study-Finds-NJOY-E-Cigarette-Leads-Short-Term>

A study of 111 smokers who quit smoking by switching to e-cigs found that 20% quit smoking on first day of e-cig use, 42% quit smoking during first month of e-cig use, 74% began using e-cigs containing more than 15mg/ml of nicotine, and 65% subsequently used lower nicotine e-cigs. Also among participants, 82% reported improved olfactory and gustatory senses after beginning e-cigarette use, 77% reported improved exercise capacity and 59% reported less morning cough, while 71% reported weight gain.  
<http://www.la-press.com/evaluating-nicotine-levels-selection-and-patterns-of-electronic-cigare-article-a3858>

A randomized controlled trial of 673 smokers wanting to quit finds smoking cessation rate of 23.2% after 1 month, 13.1% after 3 months and 7.3% after 6 months for users of old 16mg/ml nicotine e-cigs (in a country where e-cigs are banned and demonized) compared to 16.9%, 9.2% and 5.8% respectively for 21mg nicotine patch users.  
[http://download.thelancet.com/flatcontentassets/pdfs/PIIS0140-6736\(13\)61842-5.pdf](http://download.thelancet.com/flatcontentassets/pdfs/PIIS0140-6736(13)61842-5.pdf)  
<http://press.thelancet.com/ecigarettescomment.pdf> (comment by study's coauthor Peter Hajek)

Another comprehensive review of the scientific evidence found many health benefits and negligible risks of e-cigs.

“A fresh look at tobacco harm reduction: the case for the electronic cigarette”  
<http://www.harmreductionjournal.com/content/pdf/1477-7517-10-19.pdf>

A study found smokers (who had never used an e-cig and weren't interested in quitting) reduced their cigarette consumption by 44% and increased readiness and confidence to quit smoking after one week of e-cig experimentation and ad libitum use  
<http://ntr.oxfordjournals.org/content/early/2013/10/22/ntr.ntt138.abstract>

Another study found 22% of daily vapers who also smoked (dual users) quit smoking after one month, and 46% quit smoking after one year. Among daily vapers, 98% of still vaped daily after one month, 89% after one year. Among daily vapers who had quit smoking, 6% relapsed to cigarettes after one month, remaining at 6% after one year.  
<http://www.sciencedirect.com/science/article/pii/S0306460313003304>  
<http://www.healthnewsline.net/can-e-cigs-actually-help-smokers-kick-the-butt/2531086/>  
<http://www.reuters.com/article/2013/11/06/us-ecigarettes-smoking-idUSBRE9A519420131106>  
<http://americanlivewire.com/new-e-cig-study-research-vaping-electronic-cigarette-quit-smoking-cessation-2013-10/>

Brad Rodu: The Scientific Evidence for E-Cigarettes

<http://rodutobaccotruth.blogspot.com/2013/10/the-scientific-evidence-for-e-cigarettes.html>  
<http://blog.heartland.org/2013/11/the-scientific-evidence-for-e-cigarettes/>

A study found that switching from cigarettes to e-cigs for two weeks sharply reduced arterial COHb, venous COHb and cotinine levels (indicating that switching to e-cigs reduces nicotine consumption by smokers), increased oxygen saturation and perceived improvements in health and lifestyle parameters.  
<http://www.samj.org.za/index.php/samj/article/view/6887/5480>

An Internet survey of 4,616 vapers found that 69% initially vaped with “tobacco flavored” e-cigs, but that 69% of vapers who quit smoking (and 58% of vapers who still smoked) switched between different flavored e-cig products on a daily basis, and that

70% of vapers who quit smoking (and 56% of vapers who still smoked) would find vaping less enjoyable if flavorings were limited.

<http://www.mdpi.com/1660-4601/10/12/7272>

Analysis of rodent toxicology studies finds nicotine poses negligible oral or dermal toxic risk for humans, finds e-liquid containing <.025% nicotine not classified by EU CLP, e-liquid with .025%-.05% nicotine classified as Category 4 (the lowest category) for dermal toxicity, e-liquid with .025%-.166% nicotine classified as Category 4 for oral toxicity.

[http://ecita.org.uk/docs/EU\\_Classification\\_of\\_nicotine\\_mixtures\\_acute\\_oral\\_and\\_dermal\\_toxicity.pdf](http://ecita.org.uk/docs/EU_Classification_of_nicotine_mixtures_acute_oral_and_dermal_toxicity.pdf)

In June 2013, Clive Bates posted an excellent analysis of the data refuting the widely publicized false claims that e-cigs were a gateway to cigarettes for children at:

We need to talk about the children – the gateway effect examined

<http://www.clivebates.com/?p=1262>

But citing the Obama administration's tobacco abstinence policy goal, the US Air Force restricted outdoor tobacco use (including smokeless tobacco and e-cigarettes) at bases worldwide to only "designated tobacco areas" that must be at least 50 feet from sidewalks, parking lots and building entrance ways, at least 100 feet from playgrounds, and at least 200 feet from medical facilities.

<http://www.afrc.af.mil/news/story.asp?id=123330815>

<http://www.stripes.com/news/air-force-expanding-smoking-restrictions-1.200832>

Meanwhile, the NCI awarded \$2.3 million to tobacco harm reduction opponents to study young adults use of tobacco harm reduction products

<http://www.sciencedaily.com/releases/2013/02/130207150842.htm>

In September 2013, the US Centers for Disease Control (CDC) issued a MMWR stating that NYTS survey data found "past-30-day" use of an e-cigarette among 6-12 graders increased from 1.1% in 2011 (.8% by current smokers and .3% by nonsmokers) to 2.1% in 2012 (1.6% by current smokers and .5% by nonsmokers). The MMWR also reported that "ever use" of an e-cigarette increased from 3.3% in 2011 to 6.8% in 2012 (including 6.2% by "ever smokers" and .6% by never smokers"). The CDC, however, didn't release corresponding NYTS data on cigarette smoking necessary for objective data analysis.

[http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6235a6.htm?s\\_cid=mm6235a6\\_w](http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6235a6.htm?s_cid=mm6235a6_w)

But despite no evidence that e-cigs have ever created daily dependence in any nonsmoker (youth or adult), despite no evidence e-cig use has preceded cigarette use in any smoker, and despite no evidence of daily e-cig use among teens, an accompanying CDC press release promoting FDA e-cig regulations (issued with a two day embargo to increase news coverage) quoted CDC Director Tom Frieden and CDC Office of Smoking and Health Director Tim McAfee claiming that e-cigs have addicted many youth and are gateways to cigarette smoking. And despite lots of evidence that e-cigs have helped many smokers quit smoking, CDC's press release misleadingly stated "there is no conclusive scientific evidence that e-cigarettes promote successful long-term quitting."

<http://www.cdc.gov/media/releases/2013/p0905-ecigarette-use.html>



CDC's Frieden and McAfee repeated these same false fear mongering claims about e-cigs to many different news media, generated lots of news coverage at.

<http://www.nbcnews.com/video/nightly-news/52932213/#52932213>

<http://www.cbsnews.com/video/watch?id=50154438n>

[http://video.foxnews.com/v/2655099711001/e-cigarette-use-on-the-rise-slippery-slope-for-teens/?playlist\\_id=930909749001](http://video.foxnews.com/v/2655099711001/e-cigarette-use-on-the-rise-slippery-slope-for-teens/?playlist_id=930909749001)

<http://health.usnews.com/health-news/health-wellness/articles/2013/09/05/e-cigarette-use-doubles-among-young-people>

Many other news outlets reported CDC's fear mongering claims about nicotine and e-cigarettes as if they were factual, with very little or no objective analysis.

[http://www.nytimes.com/2013/09/06/health/e-cigarette-use-doubles-among-students-survey-shows.html?hp&\\_r=0](http://www.nytimes.com/2013/09/06/health/e-cigarette-use-doubles-among-students-survey-shows.html?hp&_r=0)

<http://online.wsj.com/article/SB10001424127887323893004579057080653155754.html>

[http://www.washingtonpost.com/national/health-science/e-cigarette-use-among-middle-and-high-school-students-skyrockets-cdc-data-show/2013/09/05/77d1839c-1632-11e3-a2ec-b47e45e6f8ef\\_story.html](http://www.washingtonpost.com/national/health-science/e-cigarette-use-among-middle-and-high-school-students-skyrockets-cdc-data-show/2013/09/05/77d1839c-1632-11e3-a2ec-b47e45e6f8ef_story.html)

<http://abcnews.go.com/WNT/video/teen-electronic-cigarettes-rise-20173228>

<http://www.npr.org/blogs/health/2013/09/04/219097263/kids-use-of-electronic-cigarettes-doubles>

[http://www.latimes.com/science/sciencenow/la-sci-sn-electronic-cigarettes-students-20130905,0,3435331\\_story](http://www.latimes.com/science/sciencenow/la-sci-sn-electronic-cigarettes-students-20130905,0,3435331_story)

<http://uk.reuters.com/article/2013/09/05/us-usa-health-e-cigarettes-idUKBRE9840X820130905>

<http://nypost.com/2013/09/05/more-children-smoking-electronic-cigarettes-study/>

<http://www.ktiv.com/story/23350405/study-childrens-use-of-e-cigarettes-increasing>

A week later, Congressman Henry Waxman and other House Democrats repeated CDC's claims about e-cigs in letters to FDA's Margaret Hamburg (urging her to propose the "deeming" regulation and other e-cig regs).

<http://democrats.energycommerce.house.gov/sites/default/files/documents/Hamburg-Adolescent-Use-of-E-Cigarette-2013-9-16.pdf>

<http://thehill.com/blogs/regwatch/pending-regs/322519-house-dems-call-for-cigar-e-cigarette-regulations>

The following week, 37 State Attorneys General repeated CDC's claims about e-cigs in a letter urging FDA's Margaret Hamburg to propose e-cig regs by the end of October.

<http://naag.org/ags-urge-fda-to-regulate-sale-and-advertising-of-e-cigarettes.php>

[http://www.naag.org/assets/files/pdf/E%20Cigarette%20Final%20Letter%20\(5\)\(1\).pdf](http://www.naag.org/assets/files/pdf/E%20Cigarette%20Final%20Letter%20(5)(1).pdf)

But the most important findings of 2011/2012 NYTS survey data on tobacco use were that:

- teen smokers were >20 times more likely than nonsmokers to have reported "ever use" and "past-30-day-use" of e-cigs in both 2011 and 2012,
- among high school students, 7.6% of smokers and .36% of nonsmokers reported "past 30 day" e-cig use in 2011, increasing to 15.7% of smokers and .7% of nonsmokers in 2012.
- among high school students, exclusive use of cigarettes plummeted from 14.6% in 2011 to just 11.8% in 2012 (a record low),
- among junior high students, 7% of smokers and .3% of nonsmokers reported "past 30 day" e-cig use in 2011, increasing to 20% of smokers and .4% of nonsmokers in 2012,
- among junior high students, exclusive cigarette smoking plummeted from 4% in 2011 to 2.8% in 2012 (a record low), and thus
- e-cigs are a gateway away from (not towards) cigarette smoking.

CDC's intentional misrepresentation of the scientific evidence and its own survey data was unethical public health malpractice.

Mike Siegel criticized the false and misleading claims by CDC on his blog: New study shows that regular use of electronic cigarettes by nonsmoking youth is extremely low, survey finds just 0.1% in 2/2010, 0.3% in 10/2010, and 0.4% in 6/2011 of nonsmoking high school students had used an e-cig in past-30-days, consistent with 0.5% found in the 2011 NTYS survey that CDC's Tom Frieden misrepresented to confuse, scare and lobby for unwarranted and counterproductive FDA regulation/ban.

<http://tobaccoanalysis.blogspot.com/2013/09/new-study-shows-that-regular-use-of.html>  
<http://www.sciencedirect.com/science/article/pii/S0306460313002736>

2012 NSDUH and MTF surveys found that pack/day, half pack/day, daily, past month, past year initiation, and lifetime cigarette smoking rates ALL sharply declined among teens.

2012 NSDUH: Pack/day smoking rates among daily smokers by age group

<http://www.samhsa.gov/data/NSDUH/2012SummNatFindDetTables/NationalFindings/NSDUHresults2012.htm#fig4.6>

2012 MTF: Half pack/day, daily, past 30 day and lifetime teen cigarette smoking rates

[http://www.monitoringthefuture.org/data/12data/pr12cig\\_1.pdf](http://www.monitoringthefuture.org/data/12data/pr12cig_1.pdf)

2012 NSDUH: Past month cigarette smoking by teens

<http://www.samhsa.gov/data/NSDUH/2012SummNatFindDetTables/NationalFindings/NSDUHresults2012.htm#fig4.4>

2012 NSDUH: Past month use of different tobacco products by teens

<http://www.samhsa.gov/data/NSDUH/2012SummNatFindDetTables/NationalFindings/NSDUHresults2012.htm#fig4.2>

2012 NSDUH: Past year cigarette initiation by teens

<http://www.samhsa.gov/data/NSDUH/2012SummNatFindDetTables/NationalFindings/NSDUHresults2012.htm#fig5.8>

2012 NSDUH: Past year cigarette initiation by age of first use

<http://www.samhsa.gov/data/NSDUH/2012SummNatFindDetTables/NationalFindings/NSDUHresults2012.htm#fig5.7>

Refuting CDC's claim that e-cigs are gateway to cigarettes for young people, the CDC NHIS found the percentage of 18-24 year olds who have never smoked a cigarette continues to grow.

<http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6239a5.htm?>

Another study found that e-cigs are not a gateway to cigarettes, as just one of 43 college students who said their first tobacco use was an e-cig went on to report past month cigarette smoking

<http://consumer.healthday.com/cancer-information-5/tobacco-and-kids-health-news-662/e-cigarettes-may-not-be-gateway-to-smoking-study-681597.html>

Another 2012 US survey of 10,000+ found current smokers were 156 times more likely than never smokers (6.3% vs .04%) to report past 30 day e-cig use, once again confirming that e-cigs are a gateway away from (not towards) cigarette smoking. Smokers also were 37 times more likely than long-term former smokers (6.3% vs .17%)

to report past 30 day e-cig use, indicating very little use by long-term former smokers. But authors fail to cite these extremely important findings in study abstract. Survey also asked about snus.

<http://www.plosone.org/article/info%3Adoi%2F10.1371%2Fjournal.pone.0079332>

An article revealed CDC's NYTS found significant decline in use of "cigarettes or e-cigs" by middle and high school students from 2011 to 2012, which CDC's Tom Frieden falsely claimed found that e-cigs were addicting children and were gateways to cigarettes

<http://fivethirtyeight.com/features/what-do-we-really-know-about-the-safety-of-e-cigarettes/>

Pepper et al 2011 phone survey of 258 US males ages 11-19 found current smoker were infinitely more likely than nonsmokers to report ever use of an e-cigs (9.5% vs 0%)

<http://ntr.oxfordjournals.org/content/early/2013/02/20/ntr.ntt013.abstract>

Camenga et al 2/2010 survey of 1,719 NY and CT high school students finds cigarette smokers were 56 times more likely than nonsmokers to report past 30 day e-cig use (7% vs .1%).

Camenga et al 10/2010 survey of 1,702 NY and CT high school students finds cigarette smokers were 56 times more likely than nonsmokers to report past 30 day e-cig use (13.1% vs .3%).

Camenga et al 6/2011 survey of 1,345 NY and CT high school students finds cigarette smokers were 56 times more likely than nonsmokers to report past 30 day e-cig use (14.2% vs .4%)

<http://www.sciencedirect.com/science/article/pii/S0306460313002736>

Glantz et al 2011 survey of 75,643 Korean teens (grades 7 –12) found ever smokers were 16 times more likely than never smokers to report ever use of an e-cig (30.4% vs 1.9%), while current smokers were 20 times more likely than never smokers to report past 30 day e-cig use (29.5% vs 1.5%).

<http://www.sciencedirect.com/science/article/pii/S1054139X13007489>

Adult surveys also have found that smokers are far more likely than nonsmokers to have reported e-cig use.

CDC's 2010 HealthStyles mail survey of 4,184 US adults found current smokers were 6 times more likely than never smokers to report ever use of an e-cig (6.8% vs 1.2%).

<http://www.pubfacts.com/detail/23449421/Awareness-and-ever-use-of-electronic-cigarettes-among-U.S.-adults-2010-2011>

CDC's 2010 HealthStyles web survey of 2,505 US adults found current smokers were 8 times more likely than never smokers to report ever use of an e-cig (9.8% vs 1.3%).

<http://www.pubfacts.com/detail/23449421/Awareness-and-ever-use-of-electronic-cigarettes-among-U.S.-adults-2010-2011>.

CDC's 2011 HealthStyles web survey of 4,050 US adults found current smokers were 16 times more likely than never smokers to report ever use of an e-cig (21.2% vs 1.3%).

<http://www.pubfacts.com/detail/23449421/Awareness-and-ever-use-of-electronic-cigarettes-among-U.S.-adults-2010-2011>.

E-cig opponent Robert McMillan's 2010 phone survey of 3,158 US adults found daily smokers were 21 times more likely than never smoker to report ever use of an e-cig (6.2% vs .3%), and non daily smokers were 27 times more likely (8.2% vs .3%). Past month use of e-cigs was reported by fewer than 1% of survey participants.

<http://www.hindawi.com/journals/jeph/2012/989474/>

Zhu et al 2102 phone survey of 10,041 US adults found current smokers were 156 times more likely than never smokers to report past 30 day e-cig use (6.3% vs .04%).

<http://www.plosone.org/article/info%3Adoi%2F10.1371%2Fjournal.pone.0079332>

In November 2013, CDC released more 2011/2012 NYTS data confirming that:

- teen smokers were >20 times more likely than nonsmokers to report e-cig use,
- <1% of nonsmoking teens reported past use of an e-cig,
- teen cigarette smoking declined from 2011 to 2012 as e-cig use increased,
- e-cigs appear to be gateways away from (not towards) cigarettes for teens, and
- CDC has been lying about e-cigs, nicotine and youth to lobby for FDA ban/regs.

[http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6245a2.htm?s\\_cid=mm6245a2\\_e](http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6245a2.htm?s_cid=mm6245a2_e)

In November 2013, CDC issued more press releases that grossly misrepresented NYTS data to lobby for FDA deeming and other regs for e-cigs, cigars, hookah and OTP

<http://www.cdc.gov/media/releases/2013/p1114-emerging-tobacco-products.html>

<http://www.cdc.gov/media/releases/2013/p0905-ecigarette-use.html>

<http://www.cdc.gov/media/releases/2013/p1022-flavored-cigarettes.html>

In response, Brad Rodu posted two analyses delineating CDC's misrepresentations:

The CDC abuses facts about e-cigarettes (Part 1)

<http://rodutobaccotruth.blogspot.com/2013/12/the-cdc-abuses-facts-about-e-cigarettes.html>

Brad Rodu: The CDC abuses facts about e-cigarettes (Part II)

[http://rodutobaccotruth.blogspot.com/2013/12/the-cdc-abuses-facts-about-e-cigarettes\\_11.html](http://rodutobaccotruth.blogspot.com/2013/12/the-cdc-abuses-facts-about-e-cigarettes_11.html)

The NIDA funded MTF 2013 survey found record low rates and significant declines since 2010 for daily, past-30-day, and lifetime cigarette smoking among 8<sup>th</sup>, 10<sup>th</sup>, and 12<sup>th</sup> graders, refuting CDC's false claims that e-cigs are gateways to cigarettes for teens.

<http://www.monitoringthefuture.org/data/13data/13tobtbl1.pdf>

<http://www.monitoringthefuture.org/data/13data/13tobfig1.pdf>

MTF found, that since 1996, daily cigarette smoking rates have declined by 83% among 8<sup>th</sup> graders (10.4% to 1.8%), by 76% among 10<sup>th</sup> graders (18.3% to 4.4%), and by 62% among 12<sup>th</sup> graders (22.2% to 8.5%).

In October 2013, a CDC study was published citing additional 2011 NYTS data at

<http://www.sciencedirect.com/science/article/pii/S1054139X13004151> finding that 9.2% of 6<sup>th</sup>-12<sup>th</sup> graders had reported cigar use in the "past 30 days" (including 3.3% who reported flavored cigar use) and that 11.9% reported cigarette use in the "past 30 days" (including

4.2% who reported flavored cigarette use), and concluded that “Efforts are needed to reduce flavored tobacco product use among youth.”

That same day, CDC issued a press release in which CDC Director Tom Frieden misrepresented “past-30-day” cigar use as “daily use” (just as occurred in CDC’s press release on e-cigs), falsely claimed “The so-called small cigars look like cigarettes, addict as much as cigarettes and they kill like cigarettes,” falsely claimed flavored cigars “are more likely to result in get kids getting addicted,” and falsely accused tobacco companies and retailers of illegally target marketing tobacco to youth.

<http://www.cdc.gov/media/releases/2013/p1022-flavored-cigarettes.html>

Many news headlines and stories repeated Frieden’s false claims about cigars and flavorings, including:

<http://www.nbcnews.com/health/too-many-american-teens-are-smoking-little-cigars-report-says-8C11433058>

<http://www.usatoday.com/story/news/nation/2013/10/22/youth-smokers-flavored-cigarettes-little-cigars/3151593/>

[http://hosted.ap.org/dynamic/stories/U/US\\_MED\\_KIDS\\_FLAVORED\\_CIGARS?](http://hosted.ap.org/dynamic/stories/U/US_MED_KIDS_FLAVORED_CIGARS?)

<http://www.cnn.com/2013/10/24/health/kids-flavored-tobacco/>

<http://www.foxnews.com/health/2013/10/22/cdc-flavored-tobacco-products-luring-underage-smokers/>

<http://www.medicaldaily.com/more-us-teens-smoking-flavored-little-cigars-are-cheaper-just-deadly-cigarettes-260563>

Although cigars aren’t effective tobacco harm reduction alternatives for cigarette smokers (because the few cigarette smokers who switch to cigars tend to smoke them the same way they smoked cigarettes), the evidence consistently indicates that cigars are far less addictive and far less hazardous than cigarettes (since most cigar smokers don’t smoke daily, and since most don’t inhale the smoke). There is no evidence that flavored cigars are more addictive than nonflavored cigars, it’s been illegal to sell cigarettes and cigars to minors in all 50 states for decades, and the MSA prohibits companies from target marketing any tobacco product to youth.

Further, according to 2012 NSDUH, “past month” cigar use among 12-17 year olds declined from 4.8% in 2004 to 3.4% in 2011, and then declined to a record low 2.6% in 2012, for a 46% decline since 2004.

<http://www.samhsa.gov/data/NSDUH/2012SummNatFindDetTables/NationalFindings/NSDUHresults2012.htm#fig4.2>

The CDC’s Youth Risk Behavior Survey YRBS similarly found that “past-30-day” cigar use by 9<sup>th</sup>-12<sup>th</sup> graders declined by 40% from 1997 to 2011.

[http://www.cdc.gov/healthyouth/yrbs/pdf/us\\_tobacco\\_trend\\_yrbs.pdf](http://www.cdc.gov/healthyouth/yrbs/pdf/us_tobacco_trend_yrbs.pdf)

So while the CDC claimed that use of flavored cigars and cigarettes is increasing, the CDC cited 2011 NYTS data instead of 2012 data (which the agency hasn’t released), and all other DHHS survey data found that cigar use among teens has declined significantly.

Regarding e-cigs, a 2013 study found exhaled e-cig vapor contains nonhazardous trace levels of nicotine (averaging 2.5 µg/m<sup>3</sup>) and none of the many toxicants in 2nd hand smoke.

<http://ntr.oxfordjournals.org/content/early/2013/12/10/ntr.ntt203.abstract.html>

Another 2013 study found that in contrast to cigarette smoking, e-cig use not associated with elastic properties of ascending aorta

<http://www.ecigarette-research.com/EUROECHO2013-ecigs.pdf>

Another study revealed the characterization of chemicals released to the environment by electronic cigarettes use (ClearStream-AIR project), indicating that e-cigs pose no risks to nonusers

[http://clearstream.flavourart.it/site/wp-content/uploads/2012/09/CSA\\_ItaEng.pdf](http://clearstream.flavourart.it/site/wp-content/uploads/2012/09/CSA_ItaEng.pdf)

The most comprehensive scientific review (of all previously published studies and dozens of unpublished lab reports) found no evidence that e-cig vapor poses harm or risks to users or nonusers.

Igor Burstyn: Peering through the mist: systematic review of what the chemistry of contaminants in electronic cigarettes tells us about health risks

<http://www.biomedcentral.com/content/pdf/1471-2458-14-18.pdf>

<http://www.biomedcentral.com/1471-2458/14/18/abstract>

<http://www.ncbi.nlm.nih.gov/pubmed/24406205#>

Besides, all of the following products and activities emit far greater levels of indoor air pollution than does an e-cig, but none of those who have lobbied to ban e-cig use indoors haven advocated banning any of them.

- every exhale by every smoker for an hour after smoking every cigarette
- smokers' clothes and hair
- plywood and other building materials
- glues
- paint
- carpeting
- furniture
- appliances
- cooking
- a cup of coffee
- printers
- photocopiers
- cleaning products
- dry cleaned clothes
- hair sprays
- perfumes
- nail polish and remover
- air fresheners

An Internet survey of 4,616 vapers found that 69% initially vaped with “tobacco flavored” e-cigs, but that 69% of vapers who quit smoking (and 58% of vapers who still smoked) switched between different flavored e-cig products on a daily basis, and that

70% of vapers who quit smoking (and 56% of vapers who still smoked) would find vaping less enjoyable if flavorings were limited.

<http://www.mdpi.com/1660-4601/10/12/7272>

Another study found that e-cigs are effective substitutes for cigarette smokers.

“Safety evaluation and risk assessment of electronic cigarettes as tobacco cigarette substitutes: a systemic review”

<http://taw.sagepub.com/content/5/2/67>

Another study found that nicotine is safe, and helps Alzheimer’s and Parkinson’s sufferers

<http://www.tampabay.com/news/health/study-finds-nicotine-safe-helps-in-alzheimers-parkinsons/2175396>

Several months ago, the Royal College of Physicians endorsed e-cigs to help smokers quit smoking

<http://www.rcplondon.ac.uk/commentary/what-you-need-know-about-electronic-cigarettes>

14 Electronic Cigarette studies that shame the critics

<http://www.churnmag.com/features/14-electronic-cigarette-studies-that-shame-the-critics/>

An international expert panel convened by the Independent Scientific Committee on Drugs found that smokeless tobacco, e-cigarettes, nasal sprays, gums, lozenges and patches are ALL exponentially less harmful than cigarettes

<http://www.karger.com/Article/FullText/360220>

Survey data reported by ASH UK “Use of electronic cigarettes in Great Britain” found:

- 2.1 million adults in UK currently use e-cig products, increasing from 700,000 in 2012
- 17.7% of adult smokers are current vapers,
- 4.7% of exsmokers (who switched to vaping) are current vapers,
- .1% of never smokers are current vapers,
- 47% of vapers now use prefilled cartridges and 52% began using prefilled cartridges,
- 41% of vapers now use tanks and e-liquid and 24% began using tanks and e-liquid,
- 8% of vapers now use disposable e-cigs, and 20% began using disposables,
- current vaping by minors is rare and confined almost entirely to smokers and exsmokers

[http://www.ash.org.uk/files/documents/ASH\\_891.pdf](http://www.ash.org.uk/files/documents/ASH_891.pdf)

And an international survey of more than 19,000 e-cig vapers found that:

- 81% completely quitting smoking by switching to vaping,
- 5.8% reported “occasional smoking”,
- 13% reported “daily smoking”, with cigarette consumption declining from a median of 20/day at onset of vaping to just 4/day at time of survey,
- participants vaped for a median of 10 months, with 97.1% reporting daily vaping,
- participants reduced levels of nicotine consumed by 33% from a median of 18mg/ml at onset of vaping to a median of 12 mg/ml at time of survey,

- 21.5% used vapor products containing more than 20mg/ml nicotine,
  - 3.5% used vapor products containing NO nicotine,
  - vast majority used second (eGo-type) and newer generation (Mods) vaporizers,
  - just 3.7% used “cigalike” e-cig products,
  - 99.5% were cigarette smokers when at onset of vaping,
  - none of the .5% who were nonsmokers at onset of vaping became a smoker afterward, and most of them used NO nicotine vapor products, and
  - participants average age was 39, with 74.7% from Europe and 20.7% from America.
- <http://www.ecigarette-research.com/web/index.php/research/2014/161-survey-ecig>  
<http://www.mdpi.com/1660-4601/11/4/4356>

Meanwhile, the CDC deceptively labeled/rated State policies for Tobacco Use (not cigarettes) on cigarette tax, state spending and misleading smoking ban criteria, while once again equating all tobacco use with truly hazardous cigarette smoking

[http://www.cdc.gov/stltpublichealth/psr/docs/PSR-2013-National\\_Summary.pdf](http://www.cdc.gov/stltpublichealth/psr/docs/PSR-2013-National_Summary.pdf)  
[http://www.cdc.gov/stltpublichealth/psr/state\\_reports.html](http://www.cdc.gov/stltpublichealth/psr/state_reports.html)

The NY Times (which has repeatedly editorialized in support of the FDA’s proposed Deeming Regulation) ran a front page headline/article touting two unpublished studies, demonized e-liquid and premium vaporizers, failed to acknowledge that a cup of coffee emits far more carcinogens and toxins than premium vaporizers using e-liquid, which are far more effective than cigalike e-cigs for smoking cessation.

<http://www.nytimes.com/2014/05/04/business/some-e-cigarettes-deliver-a-puff-of-carcinogens.html?>

Konstantinos Farsalinos, who was a peer reviewed of one of the unpublished studies touted by the NY Times, revealed details of what the study actually found “Formaldehyde release in e-cigarette vapor: The New York Times story explained in detail”

<http://www.ecigarette-research.com/web/index.php/2013-04-07-09-50-07/2014/162-nyt-formald>

But despite no evidence that nicotine ingestion has ever killed any human, the NY Times deceitfully claimed (on a front page article) nicotine e-liquid is poisoning children to shock readers and lobby for FDA’s proposed Deeming Regulation.

[http://www.nytimes.com/2014/03/24/business/selling-a-poison-by-the-barrel-liquid-nicotine-for-e-cigarettes.html?emc=edit\\_th\\_20140324&nl=todaysheadlines&nid=12253159&\\_r=1](http://www.nytimes.com/2014/03/24/business/selling-a-poison-by-the-barrel-liquid-nicotine-for-e-cigarettes.html?emc=edit_th_20140324&nl=todaysheadlines&nid=12253159&_r=1)

In response, objective and honest public health advocates appropriately confronted and repudiated the false and misleading fear mongering claims made by the NY Times.

Carl Phillips: New York Times goes “more at 11:00” with story on e-cigs and poisoning  
<http://antithrllies.com/2014/03/24/new-york-times-goes-more-at-1100-with-story-on-ecigs-and-poisoning/>

ACSH: Tons of toxic nicotine out there – care in handling is required. Meanwhile, keep on vaping  
<http://acsh.org/2014/03/tons-toxic-nicotine-care-handling-required-meanwhile-keep-vaping/>



Jacob Sullum: NY Times warns that drinking e-cigarette fluid could become a fatal fad among toddlers

<http://reason.com/blog/2014/03/24/new-york-times-warns-that-drinking-e-cig>

Amy Fairchild and Ronald Bayer: Liquid Death from E-Cigarettes? You've got a long way to go, baby

[http://www.huffingtonpost.com/dr-amy-fairchild/liquid-death-from-ecigare\\_b\\_5044145.html?](http://www.huffingtonpost.com/dr-amy-fairchild/liquid-death-from-ecigare_b_5044145.html?)

E-cig industry being unfairly targeted?

<http://video.foxbusiness.com/v/3395321281001/e-cig-industry-being-unfairly-targeted/#sp=show-clips>

E-cig overdose: How much liquid nicotine would it take to kill you?

<http://www.kpbs.org/news/2014/mar/28/e-cigarette-overdose-how-much-liquid-nicotine-woul/>

Clive Bates on toxic claims about e-cigs

<http://www.clivebates.com/?p=2053#comment-17043>

But one week later, the CDC claimed there were 2,405 (among nearly 8 million total) e-cig exposures reported to Poison Control Centers since 2010, an increased number of calls/month for e-cig exposures (now .1% of all calls to Poison Control Centers), no admissions to critical care or noncritical care units (compared to >500,000 admissions for other substances), and that “The most common adverse health effects in e-cigarette exposure calls were vomiting, nausea, and eye irritation.”

[http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6313a4.htm?s\\_cid=mm6313a4\\_e](http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6313a4.htm?s_cid=mm6313a4_e)

[https://aapcc.s3.amazonaws.com/pdfs/annual\\_reports/2012\\_NPDS\\_Annual\\_Report.pdf](https://aapcc.s3.amazonaws.com/pdfs/annual_reports/2012_NPDS_Annual_Report.pdf)

[https://aapcc.s3.amazonaws.com/pdfs/annual\\_reports/2011\\_NPDS\\_Annual\\_Report\\_Final.pdf](https://aapcc.s3.amazonaws.com/pdfs/annual_reports/2011_NPDS_Annual_Report_Final.pdf)

[https://aapcc.s3.amazonaws.com/pdfs/annual\\_reports/2010\\_NPDS\\_Annual\\_Report\\_1.pdf](https://aapcc.s3.amazonaws.com/pdfs/annual_reports/2010_NPDS_Annual_Report_1.pdf)

Then CDC Director Tom Frieden grossly misrepresented Poison Control Center data to create a public panic to lobby for FDA's proposed Deeming Regulation.

<http://content.govdelivery.com/accounts/USCDC/bulletins/ae691>

Tom Frieden “Use of these products is skyrocketing and these poisonings will continue.”

While several news media did some fact checking about e-cig calls to Poison Control Centers

<http://www.sltrib.com/sltrib/news/57770988-78/cigarette-poisonings-calls-poison.html.csp>

[www.cnn.com/2014/04/03/health/ecigs-nicotine-poisoning/index.html?hpt=hp\\_t4](http://www.cnn.com/2014/04/03/health/ecigs-nicotine-poisoning/index.html?hpt=hp_t4)

<http://www.cbsnews.com/videos/e-cigarette-debate-smolders-over-health-claims/>

<http://www.examiner.com/article/electronic-cigarette-poisonings-not-a-problem-some-parts-of-the-country>

many irresponsible news outlets repeated Tom Frieden's false fear mongering claims about e-cig safety without any fact checking.

<http://touch.latimes.com/#section/-1/article/p2p-79811515/>

<http://www.nbcnews.com/health/health-news/e-cigarette-poisonings-skyrocket-mostly-kids-n70961>

<http://www.consumeraffairs.com/news/e-cigs-linked-to-spike-in-calls-to-poison-centers-040414.html>

<http://www.wach.com/news/story.aspx?id=1026088#.U0WwGIVdXSI>

<http://www.muskogeephoenix.com/opinion/x493453294/Ban-e-cig-use-in-public-spaces>

[http://www.sentinel-source.com/report-complaints-of-e-cigarette-poisonings-on-the-rise/article\\_d12c3c82-77af-570d-9d01-da3adb54a160.html](http://www.sentinel-source.com/report-complaints-of-e-cigarette-poisonings-on-the-rise/article_d12c3c82-77af-570d-9d01-da3adb54a160.html)

ACSH: “The sky is falling”, warns CDC about largely-imaginary nicotine “poisonings”  
<http://acsh.org/2014/04/sky-falling-warns-cdc-largely-imaginary-nicotine-poisonings/>

But according to National Poison Data System, e-cigs account for just .1% of exposures reported to Poison Control Centers (about 200/194,500 calls/month)  
[http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6313a4.htm?s\\_cid=mm6313a4\\_e](http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6313a4.htm?s_cid=mm6313a4_e)  
[https://aapcc.s3.amazonaws.com/pdfs/annual\\_reports/2012\\_NPDS\\_Annual\\_Report.pdf](https://aapcc.s3.amazonaws.com/pdfs/annual_reports/2012_NPDS_Annual_Report.pdf)

The NY Times also published a fear mongering editorial that grossly exaggerated nicotine safety risks and youth exposure on tobacco farms, while failing to acknowledge that wearing long shirts, pants and gloves when harvesting tobacco prevents/reduces nicotine exposure to skin.

[http://www.nytimes.com/2014/05/18/opinion/sunday/children-dont-belong-in-tobacco-fields.html?emc=edit\\_tnt\\_20140517&nlid=121516&tnemail0=y&r=0](http://www.nytimes.com/2014/05/18/opinion/sunday/children-dont-belong-in-tobacco-fields.html?emc=edit_tnt_20140517&nlid=121516&tnemail0=y&r=0)

Mike Siegel: New study shows that e-cigarettes, unlike real ones, do not adversely affect acute heart function

<http://tobaccoanalysis.blogspot.com/2014/06/new-study-shows-that-e-cigarettes.html>

Another comprehensive scientific review found that e-cigs provide many health benefits and negligible risks.

Cancer Prevention: The case for or against e-cigarettes: What the scientific research says  
[http://www.nycancerprevention.org/features/case\\_for\\_or\\_against\\_e-cigarettes.html](http://www.nycancerprevention.org/features/case_for_or_against_e-cigarettes.html)

Meanwhile, FDA and Big Pharma funded American Heart Association (which urged FDA to ban e-cigs in 2009) published junk science propaganda by FDA funded UCSF e-cig prohibitionists that grossly misrepresented the scientific and empirical evidence on e-cigs for smoking cessation and cigarette consumption declines to confuse, scare and lobby for FDA’s proposed Deeming Regulation.

<http://circ.ahajournals.org/content/129/19/1972.full>

News outlets touted FDA funded AHA’s propaganda (disguised as science) by FDA funded UCSF e-cig prohibitionists by falsely claiming e-cigs don’t help smokers quit

[http://www.huffingtonpost.com/2014/05/14/e-cigarette-studies\\_n\\_5319225.html](http://www.huffingtonpost.com/2014/05/14/e-cigarette-studies_n_5319225.html)

<http://www.sfgate.com/health/article/E-cigarette-study-Health-benefits-lacking-5472738.php>

<http://dailydigestnews.com/2014/05/study-e-cigarettes-dont-help-people-quit-smoking/>

<http://indianexpress.com/article/lifestyle/health/e-cigarettes-not-healthy-alternative-to-smoking/>

In response, Mike Siegel criticized the AHA published propaganda by UCSF e-cig opponents “Glantz review article is little more than an unscientific hatchet job on e-cigs”

<http://tobaccoanalysis.blogspot.com/2014/05/glantz-review-article-is-little-more.html>

Mike Siegel followed up with another critique “In My View: Why the Glantz scientific review of e-cigarettes is not only unscientific, but dishonest”

<http://tobaccoanalysis.blogspot.com/2014/05/in-my-view-why-glantz-scientific-review.html>

Meanwhile, FDA Commissioner Hamburg falsely claimed “We are a science-based, data-driven public-health agency” in describing the proposed Deeming Regulation (that FDA has advocated since 2011 despite no scientific or public health justification) that would ban >99% of e-cigs, give e-cig industry to Big Tobacco, and threaten the lives of ALL vapers and smokers

<http://www.businessweek.com/articles/2014-05-19/fda-commissioner-hamburg-on-drug-approvals-and-saying-no#p2>

The CDC recently began to unethically recruit and offer to pay e-cig users who were diagnosed with a “serious health condition” (even though their disease wasn’t caused by e-cig use) to appear in CDC television advertisements to mislead and scare the public about e-cigs.

<http://www.plowsharegroup.com/TipsAdRecruitment/>

CDC’s Tim McAfee and FDA’s Mitch Zeller misrepresented much of the evidence on e-cigs at a recent US Senate hearing to demonize the products and lobby for FDA’s proposed Deeming Regulation.

<http://www.help.senate.gov/hearings/hearing/?id=a0a14829-5056-a032-526d-3bc1bfd96586>

<http://www.c-span.org/video/?319401-1/fda-regulation-ecigarettes>

Mike Siegel criticized McAfee’s testimony “In Senate Testimony, CDC Lies in Order to Obscure the Issues Surrounding Electronic Cigarettes”

<http://tobaccoanalysis.blogspot.com/2014/05/in-senate-testimony-cdc-lies-in-order.html>

FDA Commissioner Hamburg’s letter to NY Times deceptively touted the agency’s recently proposed Deeming Regulation as benefiting public health, and falsely claimed “The F.D.A. is committed to the science-based regulation of these products to better protect public health.”

[http://www.nytimes.com/2014/05/13/opinion/regulating-e-cigarettes-the-view-from-the-fda.html?\\_r=0](http://www.nytimes.com/2014/05/13/opinion/regulating-e-cigarettes-the-view-from-the-fda.html?_r=0)

Carl Phillips: Hamburg letter helps clarify FDA’s naivety regarding e-cigarettes

<http://antithrives.com/2014/05/14/hamburg-letter-helps-clarify-fdas-naivety-regarding-e-cigarettes/>

One week after the FDA proposed the Deeming Regulations, in a LA Times article entitled “CDC director explains what he hates about electronic cigarettes”, CDC Director Tom Frieden once again grossly misrepresented the scientific and empirical evidence on e-cigs and public health to confuse, scare and lobby for the Deeming Regulation.

<http://www.latimes.com/science/sciencenow/la-sci-sn-why-tom-frieden-hates-electronic-cigarettes-cdc-20140429,0,4147326.story>

Frieden was quoted as saying:

“If they get another generation of kids more hooked on nicotine and more likely to smoke cigarettes, that’s more harm than good,”

“If they get smokers who would have quit to keep smoking instead of quitting, more harm than good.”

“If they get ex-smokers who have been off nicotine to go back on nicotine and then back to cigarettes, more harm than good.”

“If they get people who want to quit smoking and would have taken medicines to think e-cigarettes are going to help, but they don’t, more harm than good.”

“If they re-glamorize smoking, it’s more harm than good.” and

The FDA “tried to regulate e-cigarettes earlier, and they lost to the tobacco industry.”

Carl Phillips responded with a blog posting “CDC Director Tom Frieden explains that he hates e-cigs because he is clueless”

<http://antithrlies.com/2014/04/29/cdc-director-frieden-explains-that-he-hates-ecigs-because-he-is-clueless/>

Mike Siegel responded with a blog posting “CDC continues to spread unsupported propaganda and misinformation about electronic cigarettes”

<http://tobaccoanalysis.blogspot.com/2014/05/cdc-continues-to-spread-unsupported.html>

A recent Finish survey found that teens who smoke daily were 120 times more likely than never smokers to report ever using an e-cig, fails to disclose critically important differences for those who reported using e-cigs >20 times (presumably because all were daily smokers), finds 17.4% of teens reported ever use of an e-cig, but 12.6% reported e-cig use only once or twice, while just 2% reported using >20 times; authors demonize e-cigs despite their study’s findings.

<http://tobaccocontrol.bmj.com/content/early/2014/05/14/tobaccocontrol-2013-051512.full>

<http://tobaccocontrol.bmj.com/content/early/2014/05/14/tobaccocontrol-2013-051512/T5.expansion.html>

A recent study found asthmatic smokers who switched to e-cigs (including exclusive vapers and dual use vapers who reduced cigarette consumption) had significant improvements in spirometry data, asthma control and airway hyper-responsiveness (AHR).

<http://www.mdpi.com/1660-4601/11/5/4965>

Konstantinos Farsalinos revealed the details of the study: “First study to demonstrate improvements in smoking asthma patients after switching to e-cigarette use”

<http://www.ecigarette-research.com/web/index.php/2013-04-07-09-50-07/2014/163-ecigs-asthma>

Brad Rodu recently revealed that the US government has refused to release important survey data from 2011 on e-cig use “Federal e-cigarette data AWOL”

<http://rodutobaccotruth.blogspot.com/2014/04/federal-e-cigarette-data-awol.html>

US government suppresses 2011 Current Population Survey data on e-cigarette use

“An emerging tobacco product section that was initiated in 2003, asked about use of dissolvables (2010-2011 main survey), and E-cigarettes during the May 2011 follow-up survey.” (see page 13)

<http://www.census.gov/prod/techdoc/cps/cpsjan11.pdf>

A recent UK study found that smokers who used e-cigs to quit smoking were 2.23 times more likely (i.e. 60% more likely) to quit smoking than those who used nicotine gums,

lozenges and/or patches, and were 38% more likely to quit than smokers who used no cessation aid. “Real-world effectiveness of e-cigarettes when used to aid smoking cessation: a cross sectional population study”

<http://onlinelibrary.wiley.com/doi/10.1111/add.12623/abstract>

<http://onlinelibrary.wiley.com/doi/10.1111/add.12623/pdf>

<http://www.addictionjournal.org/press-releases/e-cigarette-use-for-quitting-smoking-is-associated-with-improved-success-rates->

Carl Phillips delineated details of the UK study finding e-cigs more effective than MHRA (and FDA) approved drugs for smoking cessation

“Understanding the new West et al. paper on e-cigarettes and smoking cessation”

<http://ep-ology.com/2014/05/20/understanding-the-new-west-et-al-paper-on-e-cigarettes-and-smoking-cessation/>

Clive Bates : People using e-cigarettes to quit smoking 60 percent more likely to succeed than those using NRT sold over the counter

<http://www.clivebates.com/?p=2163>

Public Health England’s recent report on Electronic Cigarettes reviewed the scientific and empirical evidence on the products’ many health benefits and negligible risks at

[https://www.gov.uk/government/uploads/system/uploads/attachment\\_data/file/311887/E-cigarettes\\_report.pdf](https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/311887/E-cigarettes_report.pdf)

Clive Bates commented “Public Health England goes positive on e-cigarettes”

<http://www.clivebates.com/?p=2172>

53 international nicotine and public health specialists from 15 countries sent a letter to WHO Director-General Margaret Chan stating “Tobacco harm reduction is part of the solution, not part of the problem,” and that e-cigarette and other noncombustible tobacco/nicotine products “could be among the most significant health innovations of the 21st Century—perhaps saving hundreds of millions of lives,” urged Chan, WHO and the FCTC to begin basing their statements and policy recommendations on scientific evidence.

<http://www.nicotinepolicy.net/documents/letters/MargaretChan.pdf>

<http://nicotinepolicy.net/n-s-p/1753-who-needs-to-see-ecigs-as-part-of-a-solution>

<http://www.nicotinepolicy.net/documents/media/WHO-COP-6-E-Cig-letter-Media-Release.pdf>

53 international experts on nicotine science and public health policy sent a 2nd letter to WHO critiquing FDA funded Stan Glantz’s false and misleading claims about the scientific evidence on e-cigs, reiterating their previously expressed support for tobacco harm reduction and e-cigs.

<http://nicotinepolicy.net/documents/letters/response-to-glantz-et-al-letter-to-who.pdf>

<http://nicotinepolicy.net/n-s-p/2003-glantz-letter-to-who-the-importance-of-dispassionate-presentation-and-interpretation-of-evidence>

Mike Siegel: New study shows that e-cigarettes, unlike real ones, do not adversely affect acute heart function

<http://tobaccoanalysis.blogspot.com/2014/06/new-study-shows-that-e-cigarettes.html>

A June 2013 US survey of smokers and former smokers (who quit in past five years) found “ever use” of e-cigs by 46.8%, “past 30 day use” (which DHHS calls “current use”) by 16.1%, and “established use” (defined by authors as using >50 times) by 3.8%. Former smokers (who almost certainly quit by switching to e-cigs) were 3.24 times more likely than daily cigarette smokers (8.3% vs 2.8%) to be “established users” of e-cigs, and 26% of former smokers who “ever used” an e-cig were “established users” (8.3%/38.3%).

[http://www.ajpmonline.org/article/S0749-3797\(14\)00174-3/abstract](http://www.ajpmonline.org/article/S0749-3797(14)00174-3/abstract)

<http://www.newswise.com/articles/improved-methods-to-identify-frequent-e-cigarette-users-needed?>

<http://www.cfah.org/hbns/2014/smokers-slow-to-embrace-routine-use-of-electronic-cigarettes>

The survey also found “cigalikes” were regular brand of 72.1% of “past 30 day users” and 57.9% of “established users”, and “disposable cigalikes” were typically used by 28.2% of “past 30 day users” and 3.6% of “established users”. “Vaporizers” were regular brand of 34.8% of “established users” and 19.9% of “past 30 day users”, and e-cigs were bought Online by 46.2% of “established users” and 24.7% of “past 30 day users”.

Importantly, the authors suggested future e-cig surveys include new category for “established users” (although “daily use” would capture all “established users” while excluding occasional users who have used >50 times, which can occur by using just one e-cig).

Another study found that smokers (who used cigalike e-cigs and FDA approved nicotine inhaler for three days each) rated cigalike e-cigs significantly more satisfying, more helpful, more acceptable, and cooler than an FDA approved nicotine inhaler. 76% of participants reported they would use e-cigs to quit smoking, compared to 24% for FDA approved inhaler, while 18% of participants quit smoking for 3 days using e-cigs and 10% quit smoking for 3 days using FDA approved inhaler. But lead author Michael Steinberg (who has opposed and made false claims about e-cigs) told the news media the study’s findings were attributable to e-cig marketing and advertising (which wasn’t even studied) to make e-cigs appear “cooler”.

<http://link.springer.com/article/10.1007/s11606-014-2889-7>

<http://www.springer.com/about+springer/media/springer+select?SGWID=0-11001-6-1466467-0>

[http://www.newsroomamerica.com/story/425090/cool\\_factor\\_separates\\_e-cigarettes\\_from\\_nicotine\\_inhalers.html](http://www.newsroomamerica.com/story/425090/cool_factor_separates_e-cigarettes_from_nicotine_inhalers.html)

<http://www.livescience.com/46137-electronic-cigs-are-just-cooler.html>

A recent Wall St. Journal article revealed that ‘Vaporizers’ are the new draw in e-cigarettes, and that refillable contraptions are cheaper, more potent than ‘Cigalikes’

<http://online.wsj.com/articles/vaporizers-are-the-new-draw-in-e-cigarettes-1401378596>

Cigalike e-cig sales revenue at convenience stores declined in April/May as more vapers switch to premium vaporizers and e-liquid, and to e-cig kits

<http://www.cspnet.com/category-management-news-data/tobacco-news-data/articles/nielsen-electronic-cigarette-dollar-sales>

A recent study found that increased duration of e-cig use was associated with reduced cigarette consumption

<http://ntr.oxfordjournals.org/content/early/2014/05/13/ntr.ntu061.abstract>

A 2013 survey found that just 65% of US smokers correctly believe that e-cigs are safer than cigarettes, indicating the false and misleading fear mongering claims by FDA and other DHHS agencies, Big Pharma funded promoters of NRT and Chantix, and other e-cig opponents has confused and mislead nearly 15 million smokers in the US about the comparable risks of e-cigs and cigarettes.

<http://www.ajpmonline.org/article/S0749-3797%2814%2900107-X/abstract>

<http://medicalxpress.com/news/2014-05-e-cigarette-awareness-apparently-skepticism.html>

[http://www.huffingtonpost.com/2014/05/20/ecigarette-health-claims\\_n\\_5354740.html](http://www.huffingtonpost.com/2014/05/20/ecigarette-health-claims_n_5354740.html)

FDA's Mitch Zeller made more false claims about e-cigs to push the agency's proposed Deeming Regulation by claiming: "We don't know what's in the products, we don't know who is using them, how they're being used -- although there are alarming reports of large numbers of kids initiating e-cigarette use,"

<http://www.kfbk.com/articles/kfbk-news-461777/federal-government-looking-at-regulations-for-12382843/#ixzz32Zag5Is8>

CDC's Community Preventive Services Task Force (appointed by Tom Frieden) falsely equated highly addictive and lethal cigarettes with ALL Other Tobacco Products (which would include e-cigs if FDA imposes the Deeming Regulation), cited the health benefits of cigarette price hikes to falsely claim OTP price hikes would yield similar public health benefits, and recommended price/tax hikes for all OTP.

<http://www.thecommunityguide.org/tobacco/RRincreasingunitprice.html>

<http://www.thecommunityguide.org/tobacco/increasingunitprice.html>

[http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6321a6.htm?s\\_cid=mm6321a6\\_e](http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6321a6.htm?s_cid=mm6321a6_e)

<http://content.govdelivery.com/accounts/USCDC/bulletins/bab6ec>

CDC's Community Preventive Services Task Force (appointed by Tom Frieden) falsely insinuated that the purpose/impact of smokefree policies was/is to reduce all "tobacco use", falsely cited studies on cigarette use/consumption/morbidity/mortality as studies on tobacco use/consumption/morbidity/mortality, conflated all tobacco use with very hazardous cigarette smoking.

<http://www.thecommunityguide.org/tobacco/RRsmokefreepolicies.html>

<http://www.thecommunityguide.org/tobacco/smokefreepolicies.html>

[http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6321a6.htm?s\\_cid=mm6321a6\\_e](http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6321a6.htm?s_cid=mm6321a6_e)

<http://content.govdelivery.com/accounts/USCDC/bulletins/bab6ec>

Clive Bates: Arguing about e-cigs – a Q&A (excellent analysis and graphics comparing the scientific evidence on e-cigs with the false fear mongering claims by THR opponents)

<http://www.clivebates.com/?p=2197>

A recently published Harvard survey of >26,000 found e-cigs are not a gateway to cigarette smoking, found 20.3% of smokers, 4.7% of exsmokers, and just 1.2% of never smokers had ever used an e-cig.

<https://uk.news.yahoo.com/harvard-study-e-cigarettes-not-gateway-smoking-110418386.html#IRnHTKR>  
<http://tobaccocontrol.bmj.com/content/early/2014/04/30/tobaccocontrol-2013-051394>  
<http://www.medicalnewstoday.com/articles/278313.php>

Mike Siegel: Gateway hypothesis for electronic cigarettes all but destroyed: Data show youth smoking at all-time low

<http://tobaccoanalysis.blogspot.com/2014/06/gateway-hypothesis-for-electronic.html>

But the CDC released cherry picked NATS survey data on use of different tobacco products (and e-cigs) to further lobby for proposed FDA deeming regulation, compared cigarettes with far less hazardous OTP and e-cigs, combined daily use with rare and occasional use data to confuse, and created incomparable “established thresholds” denominators

[http://www.cdc.gov/mmwr/preview/mmwrhtml/mm63e0624a1.htm?s\\_cid=mm63e0624a1\\_e](http://www.cdc.gov/mmwr/preview/mmwrhtml/mm63e0624a1.htm?s_cid=mm63e0624a1_e)

NIDA Director Nora Volkow misrepresented the scientific evidence and scared public about third hand nicotine from e-cig vapor “Chronic e-cigarette use would be expected to produce even higher levels of third hand nicotine exposure, and it’s unclear how such exposure could impact the health of close family members, friends, and coworkers who are regularly exposed to these environments.”

<http://www.drugabuse.gov/news-events/news-releases/2014/05/study-third-hand-nicotine-e-cigarette-exposure-wins-top-nih-addiction-science-award>

DHHS Secretary Sebelius and FDA Commissioner Margaret Hamburg repeated false and misleading fear mongering claims about e-cigs to confuse, scare and lobby for FDA’s newly proposed e-cig Deeming Regulation (which would ban >99% of e-cigs), while NBC News falsely claimed “public health experts” support the FDA Deeming Regulation (as ethical public health experts support smokers switching to far less hazardous e-cigs).

<http://www.nbcnews.com/health/health-news/first-e-cigarette-rules-proposed-fda-n87916>

The FDA is spending \$270 million on studies to promote its extreme regulatory agenda instead of measuring the health impact e-cigs and smokeless tobacco have had on millions of smokers who switched, with most FDA/NIH funding being given to THR opponents and FDA cheerleaders.

<http://www.foxnews.com/health/2014/07/07/e-cigarette-researchers-count-puffs-scour-facebook-to-assess-risks/>

<https://prevention.nih.gov/tobacco-regulatory-science-program/research-portfolio/centers>

<https://prevention.nih.gov/tobacco-regulatory-science-program/research-portfolio>

Surveys by ASH Wales and ASH Scotland find teen nonsmokers far less likely than smokers to report e-cig use, no evidence e-cigs addict nonsmokers, are gateways to cigarettes or renormalize smoking (consistent with findings of all other e-cig surveys).

[http://www.ashwales.org.uk/creo\\_files/upload/downloads/young\\_people\\_and\\_e-cigarettes\\_in\\_wales\\_final\\_march\\_2014.pdf](http://www.ashwales.org.uk/creo_files/upload/downloads/young_people_and_e-cigarettes_in_wales_final_march_2014.pdf)

<http://www.ashscotland.org.uk/media/6155/e%20cig%20Final%20report%2007.14.pdf>



ASH Wales survey (March 2014) finds:

[http://www.ashwales.org.uk/creo\\_files/upload/downloads/young\\_people\\_and\\_e-cigarettes\\_in\\_wales\\_final\\_march\\_2014.pdf](http://www.ashwales.org.uk/creo_files/upload/downloads/young_people_and_e-cigarettes_in_wales_final_march_2014.pdf)

- 14% of teens (13-18 years) currently smoke cigarettes,
- 4.6% of teens uses an e-cig more than once per week,
- 33.7% of teen smokers currently use e-cigs
- 5.6% of teen exsmokers currently use e-cigs
- .3% of teens who never smoked currently use e-cigs
- 1.5% of teens currently use e-cigs and have quit smoking cigarettes,
- 2% of teens currently use e-cigs and have reduced their cigarette consumption,
- 56.1% of teen smokers ever used an e-cig,
- 3.8% of teens who never smoked ever used an e-cig,

ASH Scotland survey (July 2014) finds:

<http://www.ashscotland.org.uk/media/6155/e%20cig%20Final%20report%2007.14.pdf>

- 22% of teens (13-18 years) smoked one or more cigarettes per week,
- 15% of teen smokers used an e-cig one or more times per week,
- 2% of teen nonsmokers used an e-cig one or more times per week,
- 39% of teens reported ever use of an e-cig,
- among teen smokers who used e-cigs, 29% did so to quit smoking, 23% to reduce cigarette consumption,
- 53% of teens agreed that e-cigs are less harmful than cigarettes, while 12% disagreed,
- 12% of teens thought cigarette smoking was cool, and 12% thought e-cig use was cool,

Tamara Tabo – Smoke Signals: The misinformation behind FDA’s proposed regulation of e-cigarettes

<http://abovethelaw.com/2014/05/smoke-signals-the-misinformation-behind-fdas-proposed-regulation-of-e-cigarettes/>

The first sentence on FDA’s new Deeming Regulation webpage falsely claims “tobacco use” is “leading cause of preventable disease and death in the United States” (it’s cigarette smoking) to confuse, scare and lobby for agency’s proposed Deeming Regulation

<http://www.fda.gov/TobaccoProducts/Labeling/ucm388395.htm?>

On recently posted webpage, FDA falsely claimed the “annual death toll from tobacco-attributable disease has risen to more than 480,000” (as cigarette-attributable mortality is 480,000) to falsely claim its proposed Deeming Regulation is “so important for public health”; misrepresented the proposal’s impact on public health; and falsely insinuated e-cigs are marketed to youth, are gateways to cigarettes, and prevent smokers from quitting.

<http://www.fda.gov/downloads/TobaccoProducts/NewsEvents/UCM397724.pdf?>

The first sentence on a new FDA Tobacco Product webpage falsely claimed “Tobacco use is the single largest preventable cause of disease and death in the United States” (it’s daily cigarette smoking), while the webpage falsely portrayed OTP (and e-cigs) as more addictive and harmful than cigarettes, and target marketed to youth.

<http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm392735.htm?>

A recent FDA funded supplement in AJPM misrepresented the 2012 NYTS data to exaggerate youth use of OTP (and e-cigs) and grossly exaggerate the risks of OTP (and e-cigs) to further confuse, scare and to lobby for proposed FDA Deeming Regulation  
<http://www.fda.gov/TobaccoProducts/ProtectingKidsfromTobacco/ucm405173.htm?>  
<http://www.ajpmonline.org/issue/S0749-3797%2814%29X0014-0>

New FDA webpage on Youth Tobacco Use touting 2012 NYTS and FDA funded propaganda in AJPM fails to cite survey's key findings (i.e. teen cigarette smoking sharply declined to record lows, and teens smokers were 20 times more likely than nonsmokers to report e-cig use), while exaggerating teen use of OTP (and e-cigs) to lobby for deeming regulation  
<http://www.fda.gov/TobaccoProducts/ProtectingKidsfromTobacco/ucm405173.htm?>

CDC misrepresented the scientific evidence by falsely claiming “there is not yet any conclusive scientific evidence that e-cigarettes can work as a cessation aid.”  
<http://www.elementsbehavioralhealth.com/behavioral-health-news/new-anti-smoking-shock-campaign-unveiled-by-cdc/>

SAMHSA recently repeated false and misleading fear monger claims about e-cigs to lobby for FDA's proposed Deeming Regulation and to prevent smokers from switching  
[http://beta.samhsa.gov/samhsaNewsLetter/Volume\\_22\\_Number\\_3/e\\_cigarettes/](http://beta.samhsa.gov/samhsaNewsLetter/Volume_22_Number_3/e_cigarettes/)

A recent survey found teen smoking in UK dropped sharply to record lows as more smokers switch to e-cigs (disproving false claims that e-cigs are gateways to and renormalize smoking)  
<http://www.hscic.gov.uk/catalogue/PUB14579>  
<http://www.bbc.com/news/health-28461530>

A recent NCI funded study found that vapers (like cigarette smokers) are more likely to suffer mental health disorders than non vapers, which is consistent with the evidence that virtually all vapers were/are cigarette smokers. But the study's authors repeated false claims that e-cigs don't help smokers quit.  
<http://tobaccocontrol.bmj.com/content/early/2014/05/12/tobaccocontrol-2013-051511.full>  
[http://ucsdnews.ucsd.edu/pressrelease/e\\_cigarettes\\_and\\_mental\\_health](http://ucsdnews.ucsd.edu/pressrelease/e_cigarettes_and_mental_health)  
<http://time.com/97414/the-weird-link-between-e-cigarettes-and-mental-health-disorders/>  
<http://www.medicaldaily.com/e-cigarettes-and-mental-health-e-cigs-may-replace-regular-ones-those-mental-illness-they-believe>

Despite the negligible impact of snus use on life expectancy in Sweden (and the many health benefits snus has provided to smokers who switched)  
<http://www.clivebates.com/?p=434>

and despite no association between snus use and heart disease or heart attacks, FDA and Big Pharma funded American Heart Association recently published and touted cherry picked data on Swedish snus users who had heart attacks, while failing to disclose AHA's financial conflicts of interest.  
<http://newsroom.heart.org/news/quitting-smokeless-tobacco-after-heart-attack-may-extend-life-expectancy>  
<http://circ.ahajournals.org/content/early/2014/05/30/CIRCULATIONAHA.113.007252.abstract>

An AHA spokesperson further misrepresented AHA propaganda on snus to demonize e-cigs and nicotine (but not nicotine products sold by AHA funders at Big Pharma)  
<http://time.com/2912989/snuff-and-e-cigs-are-not-harmless-say-scientists/>

Brad Rodu – Swedish Study: After a Heart Attack, Quitting Tobacco Better Than No Tobacco  
<http://rodutobaccotruth.blogspot.com/2014/06/swedish-study-after-heart-attack.html>

Carl Phillips: New study shows that if you have an MI, you should hope you use tobacco  
<http://antithrlies.com/2014/06/30/new-study-shows-that-if-you-have-an-mi-you-should-hope-you-use-tobacco/>

A newly published study identified 365 documents and 2,227 citations on e-cigarettes published in 162 peer reviewed journals; US FDA, Universita degli Studi di Catania in Italy, and UCSF produced the most documents.

<http://www.biomedcentral.com/content/pdf/1471-2458-14-667.pdf>  
<http://www.biomedcentral.com/1471-2458/14/667>

Unfortunately, most of the studies by FDA and UCSF misrepresented the scientific and empirical evidence on e-cigs.

New online survey of 10,000+ vapers (conducted June/July 2014) finds 79% of e-cig users would turn to black market, 14% would return to cigarettes if their e-cig brand is banned (e.g. by FDA, MHRA or other government regulations)

<http://www.usnews.com/news/articles/2014/07/17/e-cigarette-users-would-ignore-bans-turn-to-black-market-survey-finds>

Survey shows adults who use e-cigs to quit smoking prefer supposedly juvenile flavors  
<http://www.forbes.com/sites/jacobsullum/2014/07/17/survey-shows-adults-who-use-e-cigarettes-to-quit-smoking-prefer-allegedly-juvenile-flavors/>

ECF survey of 10,000+ vapers (conducted June/July 2014) finds:

- 7% of vapers who use Mechanical mods still smoke cigarettes,
- 8% of vapers who use Large/APV devices still smoke cigarettes,
- 17% of vapers who use Mid-sized devices still smoke cigarettes,
- 29% of vapers who use Rechargeable mini devices still smoke cigarettes,
- 49% of vapers who use Disposable e-cigs still smoke cigarettes,
- 92% of vapers worry government regulations would ban vaping products they use,
- 71% of vapers would NOT knowingly buy an e-cig sold by a tobacco company,
- 54% of dual users would NOT knowingly buy an e-cig sold by a tobacco company,
- 34% of vapers (who vaped for 0-3 months) bought first e-cig from a vape shop,
- 9% of vapers (who vaped 2 years or more) bought first e-cig from a vape shop,
- 26% of vapers (who vaped for 0-3 months) bought first e-cig from online vendor,
- 62% of vapers (who vaped 2 years or more) bought first e-cig from online vendor

<http://vaping.com/data/vaping-survey-2014-initial-findings>

ECF survey of 10,000+ vapers (conducted June/July 2014) finds:

- 65.5% of exsmoker vapers consider flavors important in helping them quit smoking,

- 31% of e-liquid users mostly use Fruit flavors,
- 22% of e-liquid users mostly use Tobacco flavor,
- 18% of e-liquid users mostly use Bakery/Dessert flavors,
- 9% of e-liquid users mostly use Menthol flavor,
- 2% of e-liquid users consume 0-1 ml per day,
- 13% of e-liquid users consume 1-2 ml per day,
- 21% of e-liquid users consume 2-3 ml per day,
- 23% of e-liquid users consume 4-5 ml per day,
- 16% of e-liquid users consume 5-6 ml per day,
- 11% of e-liquid users consume 6-7 ml per day,
- 5% of e-liquid users consume 7-8 ml per day,
- 4% of e-liquid users consume 8-9 ml per day,
- 3% of e-liquid users consume 9-10 ml per day,
- 3% of e-liquid users consume >10 ml per day,
- e-liquid users reported using lower nicotine strength e-liquid in 2014 than in 2013

<http://vaping.com/data/big-survey-2014-initial-findings-eliqum>

ECF survey of 10,000+ vapers (conducted June/July 2014) finds:

- 35% use Mid-sized (ego/equivalent) device,
- 32% use Large/APV,
- 26% use Mechanical Mod,
- 4% use Rechargeable mini,
- 1% use Disposable e-cigs
- 2% use Other devices,
- 43% use Generation 2 tank (atomizer head)
- 37% use Re-buildable tank
- 10% use Re-filled cartomizer,
- 6% use Generation 1 tank cartomizer,
- 2% use Disposable atomizer,
- 2% use Pre-filled cartomizer,
- Use of tanks increased from 66% of vapers in 2013 to 86% in 2014,
- Use of Re-filled cartomizers declined from 30% of vapers in 2013 to 10% in 2014

<http://vaping.com/data/big-survey-2014-initial-findings-hardware>

The findings of this new online survey confirm that premium vaporizers and e-liquid (especially flavored e-liquid) are more effective than disposables and other cigalike e-cigs for smoking cessation). Unfortunately, the FDA's proposed Deeming Regulation would ban all premium vaporizers and e-liquid products, while allowing the well funded Big Tobacco companies to submit New Tobacco Applications for inferior disposables and other cigalike e-cigs.

A newly published survey finds teen smoking in UK dropped dramatically to record lows as more smokers switch to e-cigs, disproving the chronically repeated claims (by FDA, CDC and other e-cig opponents) that e-cigs are gateways to cigarettes and renormalize smoking.

<http://www.hscic.gov.uk/catalogue/PUB14579>

<http://www.bbc.com/news/health-28461530>

A newly published survey of 128 NC doctors found that 67% think e-cigs helpful for smoking cessation, and that 35% recommend them to patients who smoke. But study's authors oppose smokers reducing their disease risks by switching to e-cigs.

<http://www.plosone.org/article/info%3Adoi%2F10.1371%2Fjournal.pone.0103462#close>  
<http://www.bizjournals.com/charlotte/blog/health-care/2014/08/studyn-c-docs-recommend-e-cigs-to-stop-smoking.html>

New comprehensive scientific review of e-cigs by Hajek, Etter, Benowitz, Eissenberg, McRobbie concludes: “Regulating EC as strictly as cigarettes, or even more strictly as some regulators propose, is not warranted on current evidence. Health professionals may consider advising smokers unable or unwilling to quit through other routes to switch to EC as a safer alternative to smoking and a possible pathway to complete cessation of nicotine use.” Electronic cigarettes: review of use, content, safety, effects on smokers and potential for harm and benefit

<http://onlinelibrary.wiley.com/doi/10.1111/add.12659/abstract>

<http://www.addictionjournal.org/press-releases/new-scientific-review-says-current-evidence-suggests-potential-benefits-of-e-cig>

<http://onlinelibrary.wiley.com/enhanced/doi/10.1111/add.12659/> (full text)

Among the study's findings:

- Long-term use of EC, compared to smoking, is likely to be much less, if at all, harmful to users or bystanders
- EC use is associate with smoking reduction and there is little evidence that it deters smokers interested in stopping smoking tobacco cigarettes from doing so.
- Regular use of EC by non-smokers is rare and no migration from EC to smoking has been documented...The advent of EC has been accompanied by a decrease rather than increase in smoking uptake by children.
- There are no signs that the advance of EC is increasing the popularity of smoking or sales of cigarettes.

Farsalinos and Pelosa delineated Glantz' and Dutra's misrepresentation of their own survey data on e-cig use in JAMA Pediatrics.

<http://archpedi.jamanetwork.com/article.aspx?articleid=1890731>

<http://www.liaf-onlus.org/docs/eng-polosa-farsalinos-us-adolescents.pdf>

A new National Review op/ed by Michael Hufford and Gilbert Ross delineates the deadly impact of the Deeming Regulation “Let the free market kill the combustible cigarette”

<http://www.nationalreview.com/article/384447/let-free-market-kill-combustible-cigarette-michael-r-hufford-gilbert-ross>

<http://nicotinepolicy.com/gilbert-ross/2256-extinguishing-the-last-combustible-cigarette>

In a Wall St. Journal op/ed, Mike Siegel delineated The E-Cigarette Gateway Myth

<http://online.wsj.com/articles/michael-b-siegel-the-e-cigarette-gateway-myth-1407283557>

## Conclusion

The scientific and empirical evidence has consistently found that e-cigs (and smokeless tobacco) provide significant health benefits for smokers and for public health, with negligible risks for users, no risks for nonusers. E-cigs have not addicting nonsmokers (youth or adults), are not gateways to cigarette smoking, and do not renormalize smoking.

The evidence also consistently demonstrates that, since 2009, the FDA and other DHHS agencies, along with many recipients of Big Pharma funding, have been knowingly and intentionally misrepresenting the scientific and empirical evidence on nicotine, e-cigs, smokeless tobacco, dissolvables, OTP and tobacco harm reduction to confuse and scare the public to achieve their regulatory and policy goals of banning and/or severely restricting the manufacture, marketing and use of e-cigs and other THR products.

The evidence also consistently confirms that the FDA's proposed Deeming Regulation would protect cigarette markets, threaten the lives of millions of vapers and 45 million smokers, and give the e-cig industry to Big Tobacco companies by banning >99% of all e-cig products, including all of the most effective e-cig products for smoking cessation.

Therefore, the FDA should NEVER issue a Final Rule for the Deeming Regulation. Instead, the agency should complete the tasks mandated by Congress in the TCA (including proposing new color graphic warnings for cigarette packs), should correct and clarify its many false and misleading fear mongering claims about e-cigs, OTP and tobacco harm reduction, and should apologize for conspiring to ban e-cigs and mislead the public.

If the FDA remains misguidedly intent upon imposing regulations on e-cig products, however, the agency should propose far less onerous e-cig regulations similar to those proposed as an option for large premium cigars, which are more hazardous than e-cigs when smoked and inhaled daily.