


The **FACTS**
ABOUT

**ELECTRONIC
CIGARETTES**



On behalf of the Electronic Cigarette Association and its members, I am sending you this educational packet. It outlines our position as an industry association and provides information about electronic cigarettes to guide your deliberations about these products. We believe it is important to review the facts about these devices before making any decision that will affect the adult consumers who use these products as an alternative to combustible tobacco cigarettes.

In the following packet you will find a wealth of information and links to resources that will assist you as you address these critical issues. By reviewing this material, we hope you will come to understand the following about electronic cigarettes:

- 1) ECA members do not—according to each state law and as a condition of their membership in the association—market or sell their products to individuals below the legal smoking age of 18.** We understand the sensitivity associated with advertising and marketing campaigns and their potential influence on minors. For this reason, we welcome the opportunity to work with you to put into place safeguards that ensure these products are not sold to minors. Many ECA companies request that retailers place their product out of reach of the general public, generally behind the cash register counter, and request identification from consumers to verify legal age. These companies developed their products for long-term, committed smokers who are, for a variety of reasons, unable or unwilling to quit smoking and want an alternative that will satisfy their need for nicotine but not expose them to the toxic and carcinogenic chemicals found in combustible cigarettes.
- 2) We understand that nicotine is a highly addictive substance.** The position of the Royal College of Physicians in the United Kingdom is informative and instructive as it relates to electronic cigarettes. It makes clear that while nicotine can be addictive, when it is ingested alone, there are no known adverse effects like those that occur through traditional tobacco delivery. It should be clear that, while they provide an alternative to combustible cigarettes, electronic cigarettes are not marketed as smoking cessation products. Companies that join the ECA pledge that they will not make cessation or health claims about their products. These companies readily acknowledge that cigarette smoking is an unhealthy habit and encourage smokers to quit.
- 3) Banning electronic cigarettes and treating them as tobacco products is not fair to the many consumers who use these products legally and for their intended use.** Forcing adults to use electronic cigarettes in designated smoking areas is not only unfair but also unnecessary, as there is no associated threat of secondhand smoke. Many of the more than one million consumers of electronic cigarettes report that they appreciate having a product they can use in public that will neither annoy nor expose others to secondhand smoke. They are also able to use electronic cigarettes in the workplace without decreasing their productivity.

We look forward to working with you to determine how best to approach the sale and use of electronic cigarettes in your jurisdiction. An outright ban of this product is unwarranted and only punishes your constituents who are committed smokers, many of whom are looking for an alternative to a product whose lethal health risks and effects are well-documented.

It is our request and hope that you will hear both sides of this issue and consider the desires of citizens who want to avoid the toxic substances found in cigarettes and have turned to electronic cigarettes as an alternative until they have the desire or willpower to change their unhealthy lifestyle.

I would welcome the opportunity to discuss this with you and answer any questions you might have. You can reach me at 202.587.5593 or msalmon@ecassoc.org.

Sincerely,



Matt Salmon
President
Electronic Cigarette Association



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History and Overview of Electronic Cigarettes

Electronic cigarettes were first introduced in China in 2005. They have since spread to more than 50 countries around the globe and took the U.S. by storm in 2007. Developed as an alternative to traditional tobacco cigarettes, electronic cigarettes—or e-cigarettes—have gained notoriety for their tactical replication of the traditional cigarette, but without the tar and other known harmful ingredients in tobacco. This year, the industry forecasts \$100 million in sales, with more than half a million consumers in the U.S. alone.

The electronic cigarette is a simple device that affords the committed smoker nicotine intake through a battery-operated system. The nicotine (in various labeled doses) is delivered to the consumer through an inhalable cartridge.



Most electronic cigarettes consist of the following items: a rechargeable lithium battery, an atomizer (which heats up the ingredients to create a vapor), and a cartridge.

Standard products contain nicotine, propylene glycol, flavoring (to simulate the tobacco taste), and water.

Experts, non-experts, and organizations have been debating the effects of nicotine long before electronic cigarettes entered the market, and the pharmaceutical answer was to create Nicotine Replacement Therapies (NRTs). However, these products have yet to yield a large decrease in smokers and fail to provide committed smokers a comparable alternative to the daily function they enjoy. Moreover, it is a well-known fact that these cessation products fail 95 percent of the time.

Electronic cigarettes offer another option for the committed smoker who enjoys smoking but who seeks a viable alternative to traditional tobacco smoking. In the five years that electronic cigarettes have been on the market, there have been no known adverse health reactions or complaints. On the other hand, approximately 440,000 people die every year from traditional tobacco smoking.



About the Electronic Cigarette Association (ECA)

The Electronic Cigarette Association (ECA) was formed in May 2009 as a central group of electronic cigarette companies to institute and promote industry-wide standards and a code of conduct, work to maintain sound professional practices, educate the public and policymakers about the industry's activities and potential, and ensure the ethical use of electronic cigarette technologies.

The industry trade group sets forth best practice standards and serves as the guiding body for this unique industry. It seeks to ensure that its products are treated fairly and are able to compete in the marketplace. ECA's mission is to provide the tools and information necessary for policymakers, opinion leaders, the media, and companies worldwide to make informed decisions about the management and use of electronic cigarette technologies, particularly the most recent advances and applications.

All ECA members agree that they will not:

- assert any claims regarding the health or safety of their product,
- make any smoking cessation claims, or
- sell or market their products to those under 18 years of age (all customers must verify their age whether purchasing online or in a retail store).

The member companies of the ECA turned to former Arizona Congressman Matt Salmon to lead the association because of his in-depth knowledge about smoking and public policy. Mr. Salmon was also one of the first federal lawmakers to propose a smoking ban to help protect the general public from the harmful ingredients emitted from combustible tobacco.

Electronic cigarettes have provided committed smokers an alternative to combustible tobacco cigarettes for the past two years in the United States alone. Yet myths and misunderstandings persist about these devices, leading to concerns within state and local governments and confusing and misleading the general public.

In July 2009, the Food and Drug Administration (FDA) issued a press release warning consumers against the use of electronic cigarettes, a statement filled with claims unsupported by facts or sound scientific evidence. This prompted certain localities to pursue legal, legislative, and regulatory action against electronic cigarettes without evaluating the actual and potential benefits of these products. Moreover, these jurisdictions have neglected to consider the motivations of electronic cigarette opponents who could [profit from the prohibition of these products](#).

In every local campaign against electronic cigarettes, the ECA has sought to educate decision-makers about these devices and the reasons why banning the sale of a product much less harmful than conventional—and legal—combustible tobacco cigarettes is a misinformed and misguided choice.

Certain counties and states have responded to the FDA's warning with attempts to ban the sale of electronic cigarettes or prohibit their use indoors. In the case of Suffolk County, New York, ECA President Matt Salmon wrote legislators to open a dialogue about this issue and discuss their concerns. Although the legislators did ban the use of electronic cigarettes in nonsmoking areas, they did not ban the actual sale of the product. They also banned the sale of electronic cigarettes to those under the legal smoking age, an initiative that the ECA fully supports. In another case, Oregon's Attorney General recently issued a ban on the sale of two electronic cigarette brands in three retail locations. The Attorney General's office stated in their [press release](#), "Oregon recently reached legal settlements with three retailers prohibiting them from selling e-cigarettes in the state until they meet state and federal standards." This was based on claims related to marketing materials, not on the legality of the product itself. One brand decided not to participate in a compromise with the Attorney General's office and is now being sued. The second brand, a member company of the ECA, is currently working to provide the testing required by the Oregon Attorney General's office to validate the claims in question.

One recent victory for the ECA, the industry, and consumers was the veto of Senate Bill 400 in California. Governor Schwarzenegger heard the views of thousands of electronic cigarette consumers, the ECA, and others as he considered whether to sign or veto the legislation to ban electronic cigarettes in California. After carefully weighing all the facts and input, Governor Schwarzenegger vetoed SB 400, siding with California consumers by defending their choice and preserving their access to electronic cigarettes.

Aside from the fact that banning electronic cigarettes restricts consumer freedom, the reality of the situation is that electronic cigarettes spare smokers the negative effects of tobacco and the harms from tobacco smoke. At the very least, these devices deserve fair consideration and full and open discussion.

At the core of all this debate is the fact that electronic cigarettes give consumers another option—one that has not killed more than 440,000 Americans, as tobacco has.

Before acting on unsubstantiated speculation or false conceptions, decision-makers need to know the truth about electronic cigarettes.

California Protects Adult Consumers' Access to Electronic Cigarettes

On September 11, 2009, the California Senate passed bill 400, which would have banned "...the sale, distribution, or offering for sale of electronic cigarettes that have not been approved or cleared by the federal Food and Drug Administration."

In response to this action, the ECA actively communicated to Governor Schwarzenegger its members' concerns about the measure and the fact that banning these electronic cigarettes would disenfranchise thousands of California adult smokers who have difficulty quitting but want an alternative to combustible cigarettes without the host of harmful chemicals.

In response, Governor Schwarzenegger vetoed the bill on October 11, 2009 and provided the following statement explaining his decision:

To the Members of the California State Senate:

I am returning Senate Bill 400 without my signature.

While I support restricting access of electronic cigarettes to children under the age of 18, I cannot sign a measure that also declares them a federally regulated drug when the matter is currently being decided through pending litigation.

Items defined as "tobacco products" are legal for anyone over the age of 18. If adults want to purchase and consume these products with an understanding of the associated health risks, they should be able to do so unless and until federal law changes the legal status of these tobacco products.

For this reason, I am unable to sign this bill.

Sincerely,

Arnold Schwarzenegger
Governor of California

Mr. Salmon, president of the Electronic Cigarette Association, credited this legislative victory to the efforts of thousands of consumers and ECA members who appealed directly to Governor Schwarzenegger with the facts about electronic cigarettes.

The veto of SB 400 is both significant and instructive for other states and localities considering a ban on the sale of electronic cigarettes. Clearly, Governor Schwarzenegger understands the importance of allowing access to a viable alternative to combustible tobacco products for informed adult consumers until and unless federal law changes the legal status of electronic cigarettes.

At the same time, while he underscores the importance of protecting adult consumers' access to electronic cigarettes, he also supports prohibiting the sale of these devices to those under the legal smoking age.

The ECA fully affirms these stances on electronic cigarettes. In fact, ECA President Matt Salmon made clear, commenting on SB 400, that the industry trade association "...agree(s) with the original intent of SB 400 to ban sales to those under the legal smoking age. And we support that on a national level as well."

State and local governments would do well to follow the example that Governor Schwarzenegger and the State of California have set in striking a reasonable balance between access for adult consumers and protection for those below the legal smoking age.

The following tobacco statistics were obtained from the [American Cancer Society](#), reports from the [Centers for Disease Control and Prevention](#) last updated in November 2008, [Longwood University](#), [U.S. Department of Labor](#), and the [World Health Organization Report on the Global Tobacco Epidemic, 2008](#) in addition to other sources.

Tobacco Smoking Consumption

- For the first time since 1965, the percentage of U.S. adults who smoke tobacco rose between 2007 and the first half of 2008. There are 45.3 million (20.8 percent) tobacco smokers in the United States.
- There are 1.1 billion tobacco smokers worldwide, and if current trends continue, that number is expected to increase to 1.6 billion by 2025.
- The United States ranks fifth among countries with the highest rate of tobacco smokers. The top 10 countries (China, India, Indonesia, Russian Federation, United States, Japan, Brazil, Bangladesh, Germany, and Turkey) represent two-thirds of the world's smoking population.
- Approximately 10 million cigarettes are purchased per minute worldwide, 15 billion cigarettes are sold each day, and 5 trillion cigarettes are produced and used annually.
- More than 360 billion cigarettes were smoked in the United States in 2007, creating an estimated total of 135,000,000 pounds of discarded butts. Cigarette butts make up 38 percent of litter worldwide and are considered the leading litter problem in the United States.

Health Impact of Tobacco Smoking

- More than 440,000 people in the United States die of tobacco-related diseases each year (approximately 1,095 deaths per day or 45 deaths per hour), accounting for one in every five deaths and representing the single largest cause of preventable death in the United States.
- With more than 4,000 chemical compounds, 60 of which are known or suspected to cause cancer, tobacco smoking is thought to negatively affect every part of the human body.
- Tobacco kills more Americans than AIDS, drugs, homicides, fires, and auto accidents combined.

- Every year fires started by cigarettes are responsible for more than \$6 billion in U.S. societal costs and direct property damage, about 2,500 injuries, and over 1,000 deaths. One in four forest fires is caused by tobacco cigarettes.
- It takes a person an average of six to eight attempts to successfully quit smoking. Each year 45 percent of smokers will quit for one day; however, the average success rate is less than three percent.

Tobacco Smoking and Cessation Economics

- Tobacco smoking costs the United States more than \$97 billion annually in lost productivity (consumers taking “smoking breaks”) and more than \$96 billion in health care expenses.
- Consumers spent \$3 billion worldwide in 2008 on smoking cessation products. That amount is an increase from \$1.4 billion in 2002. Still, smoking cessation products are known to be about five percent effective, and 80 percent of smoking cessation products are sold to habitual nicotine users.

Tobacco Smoking Consumer Expense

- The average cost of a pack of tobacco cigarettes is \$6 in the United States, a 200 percent increase over the last decade. Since 1998, 44 states have increased cigarette taxes 90 times, and the federal government has increased cigarette taxes multiple times.
- If a person smokes one pack of tobacco cigarettes per day for 50 years (average age of starting tobacco smoking is 13), they will spend \$109,500 on tobacco cigarettes, compared with \$122,220 on groceries during the same period.

Myth: Electronic cigarettes are being sold to kids.

Fact: Electronic cigarettes are intended for committed smokers of the legal age to smoke. The industry advocates proper labeling, encourages retailers to check identification of customers, and insists that electronic cigarette companies in good standing validate age prior to transacting online purchases. The ECA has gone a step further and required proper labeling and identification for all its members to establish and continue their membership. In a recent industry study that included a random sample of U.S. electronic cigarette consumers, the average respondent's age was 44 years old. Further, with an average product price of about \$100, electronic cigarettes can hardly be considered kid-friendly.

Myth: Electronic cigarette cartridges offer many flavors to attract adolescent users.

Fact: All products—which are intended for adult consumers only—offer a variety of flavors. The preference for flavor is universal and not age-specific. Products of all types offer colors, flavors, and other variations to appeal to consumer tastes. To suggest that the cartridge flavors for electronic cigarettes were devised to appeal to kids is patently false and not substantiated by facts. Such an argument is tantamount to suggesting that nicotine-infused smoking cessation gums are available in mint and cinnamon flavors in order to appeal to children. Electronic cigarettes sold by companies in good standing with the ECA are intended for and marketed to long-term, adult smokers.

Myth: Electronic cigarettes make nicotine readily available to non-smokers.

Fact: Electronic cigarettes are marketed to current smokers, not non-smokers. Nicotine is widely available in over-the-counter products, including tobacco cigarettes and smoking cessation gums and lozenges, and no evidence suggests that these products or electronic cigarettes increase the consumption of nicotine by those who do not wish to smoke. In a recent industry study that included a random sample of U.S. electronic cigarette consumers, 96 percent of respondents were smokers purchasing the product for personal use, and 4 percent purchased the product for a friend or relative who smoked.

Myth: The contents of electronic cigarettes are unknown.

Fact: Multiple studies have been conducted and the ingredients are well-known. Numerous studies by different laboratories around the globe have identified that the vapor that is inhaled when using an electronic cigarette, depending on the manufacturer, contains approximately 20 ingredients. These include nicotine, which is regarded as generally safe for human consumption when ingested prudently and in accordance with proper labeling. By contrast, tobacco smoke contains 4,000 ingredients, including arsenic and carbon monoxide, and dozens of cancer-causing ingredients.

The composition of a typical electronic cigarette may be found in any of the following recipes (from Wikipedia):

Substance	Recipe 1	Recipe 2	Recipe 3	Recipe 4
Propylene glycol	85%	80%	90%	80%
Nicotine	6%	4%	2%	0.1%
Glycerol	2%	5%	-	5%
Tobacco essence	-	4%	4.5%	1%
Essence	2%	-	1%	1%
Organic acid	1%	-	-	2%
Anti-oxidation agent	1%	-	-	-
Butyl valerate	-	1%	-	-
Isopentyl hexanoate	-	1%	-	-
Lauryl laurate	-	0.6%	-	-
Benzyl benzoate	-	0.4%	-	-
Methyl octylnicate	-	0-5%	-	-
Ethyl heptylate	-	0.2%	-	-
Hexyl hexanoate	-	0.3%	-	-
Geranyl butyrate	-	2%	-	-
Menthol	-	0.5%	-	-
Citric acid	-	0.5%	2.5%	-
Water	-	-	-	2.9%
Alcohol	-	-	-	8%

Myth: People consume too much nicotine with electronic cigarettes because there is no regulation.

Fact: The amount of nicotine in electronic cigarettes is much less than other over-the-counter products.

Tobacco cigarettes and smoking cessation products, like electronic cigarettes and many other non-smoking-related products, rely on consumers to regulate their consumption and use according to manufacturer labeling. No one can control the misuse of products when directions are not followed.

That said, the intake of nicotine from electronic cigarettes appears to be substantially less than acceptable standards already in the marketplace. For instance, the consumption of a tobacco cigarette delivers about 1-1.5 mg of nicotine. With the average U.S. smoker consuming 13.9 cigarettes per day, they consume 14-21 mg of nicotine daily. Depending on the smoking cessation product, labeling suggests consumption of six to 48 mg of nicotine per day.

By comparison, an electronic cigarette cartridge, depending on manufacturer and cartridge style, produces zero to 16 mgs of nicotine when fully consumed (after approximately 300 puffs). A recent industry study indicates the average electronic cigarette user takes 62.8 puffs per day. This suggests the average electronic cigarette smoker is consuming 3.36 mg of nicotine per day—far less than the amounts for cigarettes or smoking cessation products.

Myth: Electronic cigarettes cannot be legally marketed in the United States.

Fact: The FDA has not issued any formal guidance on electronic cigarettes. While it is true that some manufacturers had the importation of their products stopped or delayed earlier in 2009, it is also true that the FDA has only provided informal comments about electronic cigarettes through its spokespeople and has not issued any formal guidance on the topic. The FDA currently only has jurisdiction to regulate drugs and medical devices, and electronic cigarettes fall under neither of these categories.

Myth: You can stop people from smoking.

Fact: Tobacco smoking increased in the United States in 2008 for the first time since 1965. After a 30-year decline in tobacco smoking in the United States, the percentage of American adults who smoke tobacco increased in 2008 and for the first time since 1965—this despite decades of dedicated legislative and educational efforts. It is clear that some people will choose to smoke and that further improvement in public health requires accepting this reality and embracing innovative new products that are less hazardous than tobacco cigarettes and more effective than abstinence.

Myth: Smoking cessation products work.

Fact: Only three to seven percent of people who use these products are able to quit for at least six months. While abstaining from tobacco smoking is a good goal, cessation products on the market have been proven in multiple studies to have a failure rate of around 95 percent. Pharmaceutical companies receive billions from the sales of these products while being well aware of their products' lack of success and that the majority of sales are to people seeking alternative forms of nicotine delivery rather than a smoking cessation solution. Electronic cigarettes offer an alternative to traditional cigarettes and are not used for smoking cessation.

Myth: Nicotine is bad for you.

Fact: The long-term use of nicotine is significantly safer than tobacco smoking. Nicotine suffers from guilt by association with tobacco. The carcinogenic properties of nicotine in a stand-alone form, separated from tobacco smoke, indicate that nicotine on its own does not promote the development of cancer in healthy tissue and has no mutagenic properties. The Royal College of Physicians, as well as a [study](#) by the National Institutes of Health, [indicates](#) that there are no grounds to suspect appreciable long-term adverse effects on health from the long-term use of nicotine.

“This is about as idiotic and irrational an approach as I have ever seen in my 22 years in tobacco control and public health. A public policy maker who touts himself as being a champion of the public's health as well as some of the leading national health advocacy organizations is demanding that we ban what is clearly a much safer cigarette than those on the market, but that we allow, protect, approve and institutionalize the really toxic ones.”

- Michael Siegel, a physician, researcher and professor at the Boston University School of Public Health, in response to Senator Frank Lautenberg's (D-New Jersey) letter to the FDA suggesting the ban of electronic cigarettes

“We have every reason to believe the hazard posed by electronic cigarettes would be much lower than 1 percent of that posed by (tobacco) cigarettes. The testing guidelines in the current tobacco act (circulating through Congress) would represent a ban on electronic cigarettes, (yet) if we get all tobacco smokers to switch from regular cigarettes (to electronic cigarettes), we would eventually reduce the U.S. death toll from more than 400,000 a year to less than 4,000, maybe as low as 400.”

- Joel Nitzkin, MD, MPH, DPA, FACPM, Chair, Tobacco Control Task Force, American Association of Public Health Physicians

“The vast majority of the harm caused by smoking is from the method of nicotine delivery rather than from the nicotine itself. There would be a parallel problem if people got caffeine from smoking tea leaves rather than making an infusion of these leaves in hot water. It is clear to far-sighted researchers that there are huge gains to be made from dealing with the delivery system.”

- David Sweanor, BA, JD, Adjunct Professor, Faculty of Law, University of Ottawa

“Nicotine is probably the second most used drug after caffeine. Amazingly, no one thinks of caffeine as a harmful drug. Nor should they. The possible dangers of nicotine are dwarfed by the dangers associated with tobacco. Pure nicotine has not been associated with the risk of cancer.”

- The International Harm Reduction Association

“The standard for lower-risk products for use by current smokers should be the hazard posed by (tobacco) cigarettes, not a pharmaceutical safety standard.”

- Joel Nitzkin, MD, MPH, DPA, FACPM, Chair, Tobacco Control Task Force, American Association of Public Health Physicians

“Telling smokers they may not use electronic cigarettes until they're approved by the FDA is like telling a floundering swimmer not to climb aboard a raft because it might have a leak.”

- *Jacob Sullum, senior editor at Reason magazine, nationally syndicated columnist and author of the critically-acclaimed book For Your Own Good: The Anti-Smoking Crusade and the Tyranny of Public Health (Free Press, 1998)*

“If the FDA would act within its own historical context it should recognize that when faced with an epidemic it should be focusing on the greatest possible reduction in deaths rather than looking at alternatives to cigarettes as if cigarettes themselves did not exist. Had the FDA acted like this in 1938 we'd likely still not have antibiotics, and had they acted this way during the various vaccination campaigns smallpox would likely still be around.”

- *David Sweanor, BA, JD, Adjunct Professor, Faculty of Law, University of Ottawa*

“Huge disparities and inconsistencies exist between the tobacco and nicotine product regulations. Combustible tobacco products are the least regulated and nicotine products are the most highly regulated. Given the huge differences in the proven or likely hazards of these products to individual and public health, this represents a substantial and illogical regulatory imbalance. The regulation of nicotine products needs to be radically overhauled to encourage the use of less harmful products.”

- *Royal College of Physicians*

“If one could entertain the unrealistic assumption that all tobacco users would switch to clean nicotine tomorrow, we would see an immediate effect (for the better) on cardiovascular disorders, and a delayed effect on respiratory and cancer disease.”

- *The International Harm Reduction Association*

“Smokefree Pennsylvania strongly urges the FDA to consider the enormous public health disaster the agency would create by banning electronic cigarettes. Denying 45 million (tobacco) cigarette smokers access to this exponentially less hazardous alternative would result in millions of preventable deaths among smokers and millions of non-smokers continuing to be exposed to tobacco smoke pollution. It is absurd to even contemplate protecting the deadliest nicotine products (tobacco cigarettes) from market competition by these less hazardous nicotine products.”

- *William T. Godshall, MPH, Executive Director, Smokefree Pennsylvania*

“It would be wrong to characterize those on a moral quest as being public health advocates, and this is true whether looking at abstinence-only campaigns on sex, on alcohol, on illicit drugs, or on nicotine. Campaigns based on making better people rather than making people better are driven by moral concerns rather than public health concerns.”

- David Sweanor, BA, JD, Adjunct Professor, Faculty of Law, University of Ottawa

“There are no grounds to suspect appreciable long-term adverse effects on health from the long-term use of NRT (nicotine replacement therapy). The use of NRT is many orders of magnitude safer than (tobacco) smoking.

“Although stopping tobacco use is the ideal outcome for individual and public health, this is difficult to achieve. Harm reduction approaches in public health are sometimes criticized for condoning the activity they are trying to make safer. The Royal College of Physicians takes no position on the morality of smoking. However, since smoking (tobacco) is dangerous to health, and is hard to give up, the College wants to see a range of effective methods to smokers quit or to reduce the harm they sustain.”

- Royal College of Physicians

“Oddly, though there has been much focus on issues such as where the product could be used, how it was taxed, limits on advertising, controls on places of sale, packaging requirements...there has been little to nothing being done about the product itself.”

“If we recognize that the needs of smokers can be met in a way that does not necessarily result in the untimely death of roughly half of long-term users, maybe we can move society conceptually to the point that nicotine delivery can go through the same metamorphosis as we’ve seen with auto safety, telecommunications, sanitation, pharmaceuticals, food preparation standards, alcoholic beverages and a myriad of other goods and services. The market could be transformed through a virtuous circle of increasing consumer awareness and ever-less-hazardous alternatives to cigarettes.”

- David Sweanor, BA, JD, Adjunct Professor, Faculty of Law, University of Ottawa

In July 2009, the FDA held a press conference warning people of the purported potential health risks and side effects of electronic cigarette use. The ECA questioned the FDA study because it lacked scientific backing and drew upon untested assumptions; it condemned electronic cigarettes without any peer-reviewed data or solid scientific reasoning to explain its conclusions.

In contrast, numerous studies conducted by separate international laboratories have tested the benefits of electronic cigarettes over traditional combustible tobacco. They have found that the inhaled vapor from an electronic cigarette—depending on the manufacturer—contains approximately 20 ingredients, including nicotine, all considered generally safe for human intake when consumed prudently and in accordance with correct labeling. Tobacco smoke, on the other hand, contains 4,000 ingredients, including arsenic and carbon monoxide, in addition to dozens of cancer-causing ingredients.

A summary of the FDA's study is below, followed by the conclusions from two response studies that refute the FDA's position, with sound evidence and scientific data, in demonstrating that electronic cigarettes are just as safe as—and more likely safer than—their tobacco product counterparts.

FDA Study: Evaluation of Electronic Cigarettes

Despite the fact that electronic cigarettes don't fall under its jurisdiction, the FDA performed a study on two electronic cigarette products: the NJOY e-cigarette and the Smoking Everywhere electronic cigarette. Using a 10mg-cartridge Nicotrol Inhaler as a control for a few test methods, the FDA concluded that nicotine was present in both products. The report also issues a warning against the vapor from e-cigarettes with the conjecture that it “may also provide other potentially harmful volatile components,” an assumption based on unfounded concerns by the FDA's Center for Drug Evaluation and Research.

Though these results in context appear to be conclusive, the FDA failed to follow basic scientific protocols and came to presumptive conclusions based on a sampling of only two products on the market. The FDA's conclusions, from a public health perspective, are shortsighted at best.

Technical Review and Analysis of FDA Report: Evaluation of Electronic Cigarettes

Completed on July 30, 2009, the Technical Review and Analysis of FDA Report: Evaluation of Electronic Cigarettes was designed to examine the FDA's conclusions, under the direction of Janci Chunn Lindsay, Ph.D. of Exponent Health Sciences, Toxicology and Mechanistic Biology Division.

Sottera, Inc., the Scottsdale-based distributor of NJOY electronic cigarette products, hired Exponent Health Science to review and analyze the FDA's scientific methods and findings. The goal was to evaluate whether the FDA accurately compared NJOY products to FDA-approved nicotine-delivery products such as the Nicotrol inhaler and Nicorette gum.

Exponent found the following inaccuracies in the FDA report:

- “The report failed to present standard protocols for proper study design with regards to the testing of the referenced control device, documenting the number of samples tested either within or across tests, or presenting statistical analyses . . . when quantifiable results were obtained.
- “The chemical content of similar nicotine-containing FDA-approved products was not completely described with respect to the presence of tobacco-specific nitrosamines (TSNAs) and other tobacco-associated impurities that have also been found in nicotine replacement therapy (NRT) devices at similar, if not higher, levels.
- “In the lots that were tested by the FDA, none of the key chemicals of concern in this study—such as TSNAs and tobacco-associated impurities—could be quantifiably measured in the liquid of NJOY’s cartridges because they were all below the limits of quantification (LOQ).
- “All of the tobacco-associated impurities found in the NJOY products were ‘present but at less than the level of the Nicotrol inhaler [manufacturer] specification,’ according to the FDA report.
- “There is no indication in the published scientific literature that cotinine or β -nicotyrine are carcinogenic or have toxicity ratings of concern. These were the only tobacco-associated impurities found in trace levels in the vapor phase of (some of) NJOY’s products.
- “The report does not reflect the actual dose of nicotine delivered to the user from the “control” Nicotrol inhaler device when used as recommended by the manufacturer (6–16 cartridges/day or 24–64 mg of nicotine, 50 mcg/100 mL puff). By comparison, NJOY devices delivered 46 mcg/100 mL in the highest-strength cartridge tested, according to the FDA report.
- “Data presented in the report does not adequately support the opinion that users of NJOY products would actually be exposed to TSNAs and tobacco-specific impurities in the vapor phase during normal device use; and if exposed, that those levels would be a health concern as compared to other FDA-approved products.”

Accordingly, the FDA report fails to support its own allegations against NJOY electronic cigarette products. In fact, NJOY products have been shown to possess only a trace amount of the noxious chemicals found in standard cigarettes and less than or similar amounts to that of FDA-approved nicotine-containing products. Furthermore, these same approved NRTs have not been required by the FDA to include toxicity information in their own product warnings. The FDA’s concern for users’ health, then, is not valid, as consistent regulations would be in place for all smoking alternatives.

New Zealand Safety Report on the Ruyan e-cigarette Cartridge and Inhaled Aerosol

Health New Zealand, Ltd., in conjunction with various government, university, and commercial laboratories, conducted a series of tests on the Ruyan electronic cigarette's nicotine refill cartridge.

Author Murray Laugesen, responsible for over 30 reports on smoking and the testing of cigarettes and cigarette alternatives, aimed to assess the safety of the Ruyan electronic cigarette and its cartridges, as well as any possible risks and benefits.

Upon the conclusion of his study, Dr. Laugesen found the Ruyan electronic cigarette to be a safe substitute for traditional tobacco smoking. The electronic cigarette is also safe on all tested measurements and performs exactly as it is designed to do. Using micro-electronics, the Ruyan electronic cigarette releases a slight amount of nicotine, which is dissolved in propylene glycol (PG)—two small and extremely safe molecules—into a thin vapor, that contains no more than half the nicotine of a tobacco cigarette.

Dr. Laugesen's tests also provided these conclusions, emphasizing the safety of electronic cigarettes over tobacco products:

- “On a daily dose basis, TSNAs in the 16 mg nicotine e-cartridge are 1,200 times less than in the tobacco of 20 manufactured cigarettes, and 3,000 times less than the daily dose in a can of Swedish moist snuff. Therefore, the Ruyan® e-cigarette cartridge does not contain carcinogenic levels of TSNAs, in that no product containing these trace levels has been shown to cause cancer.”
- “The Ruyan E-cigarette cartridge liquid does not behave like a tobacco extract. The absence of a monoamine oxidase (MAO) inhibitor effect means the e-cigarette has no detectable addictive potential beyond that of nicotine.”
- “The e-cigarette shows no increase in expired CO. The absence of any such effect from the e-cigarette shows that combustion does not occur—as confirmed by the lack of flame or smoke. As nicotine has a low vapor pressure, the piezoelectric ceramic element in the e-cigarette is needed to cause vaporization of the nicotine-propylene glycol solution. Cigarette smoke is produced by combustion at temperatures of up to 1,000 degrees Centigrade, which is highly destructive, breaking up tobacco into free radicals and many small harmful gas molecules such as carbon monoxide, butadiene, and benzene. Thus, mist from the e-cigarette is created by vaporizing a liquid, whereas smoke is created by incinerating plant.”

- “Through an analysis of published data on nicotine absorption, informal comments of bystanders, and the observation of e-cigarette smoking indoors, it was found that the e-cigarette generates no sidestream smoke from its (artificially lit) tip, as opposed to cigarette smoke, which is a mixture of sidestream smoke and exhaled mainstream smoke. In e-cigarettes, any exhaled PG mist visibly dissipates to vapor within seconds. Non-smoking bystanders do not find the mist unpleasant. The mist is odorless, and those close by quickly realize it does not have the odor of smoke or the irritating quality of tobacco cigarette smoke.”

In contrast to the inhaled nicotine in cigarette smoke, the e-cigarette’s exhaled PG mist most likely contains little to no nicotine and absolutely no carbon monoxide. It is therefore not harmful to bystanders because it does not have a lit flame or produce combustion of tobacco smoke.

If the e-cigarette is used as intended, it would indeed be permitted under New Zealand’s Smoke-free Environments Act 1990.³³

The following international resources assembled for easier access to information on public policy, public health, science, and legal aspects of the electronic cigarettes topic.

Harm Reduction in Nicotine Addiction: Helping People Who Can't Quit

Royal College of Physicians

This 252-page report from the Tobacco Advisory Group of the Royal College concludes that tobacco cigarettes are freely available and medicinal nicotine products are available, but regulations restrict availability and effectiveness and the combination limits gains in public health by denying smokers the right to choose safer nicotine products.

Interview of Joel Nitzkin, MD, MPH, DPA, FACPM

Chair, Tobacco Control Task Force
American Association of Public Health Physicians

“We have every reason to believe the hazard posed by electronic cigarettes would be much lower than one percent of that posed by (tobacco) cigarettes,” says Dr. Nitzkin in this online interview. “The testing guidelines in the current tobacco act (circulating through Congress) would represent a ban on electronic cigarettes, (yet) if we get all tobacco smokers to switch from regular cigarettes (to electronic cigarettes), we would reduce the U.S. death toll from 400,000 a year to less than 4,000, maybe as low as 400.”

Stories from Electronic Cigarette Users

Care2 Petition Site

The debates and discussions conducted on the validity of electronic cigarettes often fail to include the voice of consumers who value having an alternative to combustible cigarettes. This site offers the accounts of thousands of electronic cigarette users who express their thoughts about these innovative products.

Tobacco Harm Reduction Project

University of Alberta, School of Public Health

Suggesting that smokers have options other than quitting entirely is controversial, but it should not be. Almost all of public health is devoted to reducing risks and harms, not eliminating them altogether. A good analogy is seatbelts. Instead of telling people that they should just quit driving, we try to make cars and roads as safe as possible. Similarly, we do not tell people to quit playing hockey or bicycling, but we try to get them to wear helmets. This site offers research, essays, and insightful links.

Interview of David Sweanor, BA, JD

Adjunct Professor, Faculty of Law, University of Ottawa
Global Harm Reduction Strategist and Expert

“The vast majority of the harm caused by smoking is from the method of nicotine delivery rather than from the nicotine itself. There would be a parallel problem if people got caffeine from smoking tea leaves rather than making an infusion of these leaves in hot water,” says Sweanor in this online interview. “Everything has risks, so simply pointing out that something is ‘not safe’ shows a person to be either ignorant or disingenuous (because) anyone who believes (tobacco) cigarettes are no more hazardous than electronic cigarettes (needs) a remedial course in basic sciences.”

Tobacco Harm Reduction: The Best Hope for Averting Deaths

Global Health and Innovation Summit at Yale
Carl V. Phillips, MPP, Ph.D. and Karyn Heavner, Ph.D.

This presentation explains that anti-tobacco efforts in the Western World have struggled to reduce tobacco use by more than half and in the process have vilified nicotine, misinformed the public about its risk, and established mindsets that resist a solution that will improve public health.

Does Big Pharma Have Links to Anti-Electronic Cigarette Campaign?

Associated Content, James Dunworth

In this short article, Dunworth enumerates the campaign donations made by pharmaceutical companies to Senator Frank Lautenberg, whose letter asked the FDA to ban electronic cigarettes. Lautenberg hails from the home state of Big Pharma, which generates more than \$3 billion in smoking cessation product sales, the very products whose market share may be threatened by electronic cigarettes.

Smoking Cessation Gum Fails 95% of the Time

American Journal of Preventive Medicine

This study of 3,297 people who were interested in quitting smoking found that only 9.3 percent of those who used 2 mg or 4 mg nicotine-infused smoking cessation gums stopped tobacco smoking for six months, while 3.5 percent of those using a placebo accomplished the same. This suggests an approximately 95 percent product failure rate.

Smoking and Tobacco Use in the United States

U.S. Department of Human and Health Services, Centers for Disease Control and Prevention (CDC)

This area on the CDC Web site provides tables, charts, and statistics about the consumption, economics and health effects of tobacco cigarettes in the United States.

The Tobacco Atlas

World Health Organization (WHO), Tobacco Free Initiative

The Tobacco Atlas maps the history and predictions for the future of the tobacco epidemic. It also illustrates how tobacco influences economics, big business, politics, trade, and crimes such as smuggling, litigation, and deceit. Further, it provides insight into the importance of a multifaceted approach to reduce tobacco use to save and improve the lives of the millions of smokers worldwide.



Interview Sources and Biographies

The following nationally and globally recognized individuals are third-party experts in the harm reduction and medical fields and are making themselves available to the media for discussion on the topic of electronic cigarettes. To arrange interviews contact:

Matt Salmon

President, Electronic Cigarette Association

Matt Salmon is a former member of the U.S. House of Representatives from Arizona (1995-2001). Today, he is president of the Electronic Cigarette Association (ECA), following on a path of life's work in the public health arena that has included pushing through a law in the state of Arizona that was among the first public smoking bans, and later being named Congressman of the Year by the American Cancer Society.

Prior to his current position, Salmon was President of the Competitive Telecommunications Association, another Washington, D.C.-based trade association. Salmon began his public service as a member of the Arizona legislature in 1991 and served as assistant majority leader of the Arizona State Senate (1993-95) before being elected to the first of five terms in Congress in the fall of 1995. While he was a Congressman, term limits were a high profile issue, and he was one of the few to honor a campaign pledge to not run for re-election after three terms.

Salmon was instrumental in the release of U.S.-based academic researcher Song Yongyi from a China detention center in 2000. He left Congress in 2001 and began a successful second career as a public policy leader in Washington, D.C. Salmon's role in the ECA is influenced by watching a family member battle emphysema and cancer after a lifetime's use of tobacco products. He received an undergraduate degree from Arizona State University in 1981 and a master's in public administration from Brigham Young University in 1986.

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David Sweanor BA, JD

Adjunct Professor, Faculty of Law, University of Ottawa

Special Lecturer, Division of Epidemiology and Public Health, University of Nottingham

David Sweanor is an attorney and a crusader in the non-smoking movement in Canada. He has played a key role in Canadian efforts regarding tobacco taxation, advertising restrictions, package labeling, environmental tobacco smoke, smoking cessation, and product regulation. Since 1983, he has worked on public health efforts, specializing in tobacco issues and focusing on how legal measures can greatly impact population health.

His active involvement includes successfully advocating for public policy changes in Canada. Per capita cigarette consumption in Canada has declined by roughly 60 percent, much of which can be directly tied to policy interventions. The organization where he did most of his Canadian work in his capacity as counsel, the Non-Smokers' Rights Association, received significant international recognition for many groundbreaking public health advances. He has worked with the International Union Against Cancer, World Health Organization, World Bank, Pan American Health Organization and numerous governments, foundations, law firms, companies making smoking cessation products and health agencies.

David has been widely published in peer-reviewed scientific journals as well as having authored work for major national and international health and social service organizations. He has spoken at conferences in numerous cities around the world and has been a frequent guest on major media in Canada and other countries. He has testified before parliamentary committees in Canada and elsewhere in the world, including both Senate and House committees in the United States. Various awards for his work include a "Public Health Hero" lifetime achievement award from the Pan-American Health Organization.

Sweanor received an undergraduate degree from the University of Western Ontario in 1978 and a law degree from the University of Toronto in 1981 and was called to the bar of the Law Society of Upper Canada in 1983. He is currently an Adjunct Professor, Faculty of Law, at the University of Ottawa and a Special Lecturer, Division of Epidemiology and Public Health, at the University of Nottingham.

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Interview Sources and Biographies (cont.)

Joel L. Nitzkin, MD, MPH, DPA, FACPM

**Chair, Tobacco Control Task Force
American Association of Public Health Physicians**

Dr. Nitzkin is a public health physician, board-certified in public health/general preventive medicine. Nitzkin holds a doctorate in public administration and operates a consultancy firm based on the use of medical, public health, policy, and management skills to address causation, prevention and quality of service issues.

He has been actively involved in tobacco control since the late 1970s, has been part of the Tobacco Control Task Force—and current chairman—of the [American Association of Public Health Physicians](#) and has authored many letters and participated in a variety of interviews about the public policy of tobacco and electronic cigarettes.

Nitzkin has served as the director of an urban health department in Rochester, NY, and was appointed to the Louisiana State Health Office as Director in 1989, where he led the public health agency. He has been an active member on boards of directors in health insurance, hospital, long-term care, and mental health entities and taken on a number of assignments dealing with correctional health, leprosy, healthcare quality, telemedicine, home care, and community outreach. In 1997, Nitzkin incorporated JLN, MD Associates, LLC, his consultancy.

Nitzkin has been president of two national public health organizations—the National Association of County and City Health Officials (1988-89) and the American Association of Public Health Physicians (1996-1998)—as well as multiple national advisory committees and commissions since the mid 1980s. His additional professional associations include the American College of Preventive Medicine, American Medical Association, American Public Health Association, and American Society for Public Administration.

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Bill Godshall

Executive Director, SmokeFree Pennsylvania

Bill Godshall is founder and executive director of Smokefree Pennsylvania.

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 cigarette victims, expand smoking cessation services, and inform smokers that smoke-free tobacco/nicotine products are far less hazardous alternatives to cigarettes.

Mr. Godshall has also served as public health educator for the Allegheny County Health Department, director of education for the American Cancer Society in Pittsburgh, and government affairs chair for Stop Teenage Addiction to Tobacco. Godshall earned a Bachelor of Science from Penn State University in 1980 and a Masters of Public Health from the University of Pittsburgh in 1985.

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David Baron, MD

President, Primary Caring of Malibu Medical Group

Fellow, Santa Monica-UCLA Medical Center

Dr. Baron is the president, founder, and family physician of Primary Caring of Malibu Medical Group. Currently the Chief of Staff at Santa Monica-UCLA Medical Center & Orthopaedic Hospital, Dr. Baron has worked in family medicine since 1991 and has been a member of the UCLA medical community since 1997. His professional memberships include vice-chief attending medical staff and executive medical board member at Santa Monica-UCLA Medical Center (2001-2005); fellow at the American Academy of Family Physicians; and member of the California Academy of Family Physicians, American Medical Association, and the California Medical Association.

Dr. Baron received an undergraduate degree and graduated summa cum laude from Amherst College and received his doctorate from University of Pennsylvania School of Medicine. He serves on the board for SmokeStix, an electronic cigarette company.

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Interview Sources and Biographies (cont.)

Michael Siegel, MD, MPH

Boston University School of Public Health

Dr. Michael Siegel is a Professor in the Social and Behavioral Sciences Department at the Boston University School of Public Health. He has conducted tobacco control research for the past 23 years, focusing on secondhand smoke health effects and policies, tobacco industry advertising and marketing practices, and evaluation of tobacco control interventions. After finishing medical school, he completed a preventive medicine residency at the University of California, Berkeley, where he studied the effects of secondhand smoke exposure on bar and restaurant workers. He then completed an epidemiology fellowship at CDC in the Office on Smoking and Health. His present work at Boston University focuses on evaluating national, state, and community-level tobacco control policies.

Dr. Siegel also maintains a tobacco policy blog entitled: [“The Rest of the Story: Tobacco News Analysis and Commentary.”](#)

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Interview Sources and Biographies (cont.)

Brad Rodu

Professor of Medicine

Endowed Chair, Tobacco Harm Reduction Research

University of Louisville

A Professor of Medicine at the University of Louisville, Dr. Rodu holds an endowed chair in tobacco harm reduction research and is a member of the James Graham Brown Cancer Center at U of L.

For the past 15 years, he has been involved in research and policy development regarding tobacco harm reduction (THR). THR acknowledges that millions of smokers are unable or unwilling to quit with conventional cessation methods involving tobacco and nicotine abstinence and encourages them to use cigarette substitutes that are far safer.

Dr. Rodu's research has appeared in a broad range of medical and scientific journals. He has authored commentaries in the general press, as well as the book, *For Smokers Only: How Smokeless Tobacco Can Save Your Life*. In 2003, he served as an expert witness at a congressional hearing on tobacco harm reduction. He has spoken at numerous international forums, including one held in London at the British Houses of Parliament.

His research is supported by unrestricted grants from tobacco manufacturers to the University of Louisville and by the Kentucky Research Challenge Trust Fund.

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The Following are articles concerning the electronic cigarette industry, its consumers, and opponents of these devices:

- “**FDA Miscalculates Real Danger to Smokers.**” *Associated Press*. October 19, 2009
- “**Council Votes to Boost Butts.**” *New York Post*. October 16, 2009.
- “**E-cigarettes Offer Nicotine Without Tobacco, But Are They Safe?**” *Daily Herald*. October 12, 2009.
- “**What Are Electronic Cigarettes?**” *Action on Smoking and Health UK*. October 2009.
- “**FDA’s Drug and E-cigarette Warnings Counterproductive.**” *The Hill*. September 14, 2009.
- “**No Smoke, No Fire, Lots of Heat.**” *The Birmingham News*. September 3, 2009.
- “**E-cigarette Seller Fires Back at U.S. Claims of Impurities.**” *Scottsdale Republic*. August 7, 2009.
- “**FDA Smoke Screen on E-cigarettes.**” *The Washington Times*. August 6, 2009.
- “**Consumer Alert: Health Groups Warn Against E-cigarettes.**” *Consumer Digest*. August 2009.
- “**Electronic Cigarettes Puff Like the Real Thing.**” *The News & Advance*. July 6, 2009.
- “**E-cigarette An Option for Staten Island’s Smokers.**” *silive.com*. July 5, 2009.
- “**E-cigarettes: Nicotine Without Smoke Draws FDA Interest.**” *The Times News*. June 16, 2009.
- “**Smoking Debate Has Become Nicotine-Delivery Debate.**” *Richmond Times-Dispatch*. June 6, 2009.
- “**Blowing Smoke With Legislation.**” *The Miami Herald*. June 5, 2009.
- “**E-cigarette: No Smoke, No Tar, No Regulation.**” *Kentucky.com*. June 3, 2009.
- “**Cigarettes With No Smoke, or, for Now, U.S. Assent.**” *AARP Bulletin Today*. June 2, 2009.
- “**Controversy Swirls Around E-Cigarettes.**” *The Wall Street Journal*. June 2, 2009.
- “**E-cigarette Sales Soar as Regulators Fume.**” *ArcaMax Publishing*. June 2, 2009.
- “**Electronic Cigarette Burning Into U.S. Market.**” *NBC DFW*. June 2, 2009.
- “**Time to Quit? Tax Gives Residents Incentive to Stop Smoking.**” *The Daily Reporter*. May 31, 2009.
- “**Electronic Smoking Device Fires Up a Debate on Its Health Value.**” *The Ledger*. May 30, 2009.