

## GILCHRIST COUNTY TOBACCO PREVENTION NEWSLETTER

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## Gilchrist S.W.A.T. Youth Reach out to Community through the Holidays!

By Brittany McDaniel, Gilchrist County S.W.A.T Advisor

On the evening of December 11, 2009 the town of Trenton, FL held their yearly "Christmas on Main Street" event. Christmas on Main Street is held once a year in December where different people and organizations can set up booths on Main Street and celebrate the upcoming holidays with the community.

Considering the large crowds in attendance from previous years, the Gilchrist County S.W.A.T. Clubs decided to set up a booth at this year's event. Youth from three different Gilchrist S.W.A.T. Clubs were in attendance that night and were very successful in spreading awareness about the S.W.A.T. cause. With the co-sponsorship of the Tobacco Free Partnership the Gilchrist county S.W.A.T. was able to spread their message to the crowd of 3,000 people who attended Christmas on Main Street.

Throughout the event S.W.A.T. members talked to and informed people about the risks of using tobacco and even related to visitors who had lost loved ones due to tobacco caused illnesses.

The S.W.A.T. youth and advisors were able to help five people who were interested in trying to "kick the habit" by referring them to and informing them about Quitline and AHEC cessation information, those interested in quitting tobacco were also given gum, mints, and information pamphlets.

Gilchrist S.W.A.T. was also able to encourage around 60 people to sign tobacco-free

pledges and handed out pledge bracelets and candy with the S.W.A.T. emblem. The tobacco-free pledge papers were truly outstanding to the visitors along with the ornament decorating activity.

The ornament decorating was an activity that S.W.A.T. provided that night that memorialized those who had been killed by tobacco and went with the theme of the holidays. To every visitor that came to the S.W.A.T. table an opportunity was offered to decorate a scratch off Christmas ornament in memory of a family member or friend who died from tobacco related illness, the decorator could then hang their ornament on the table sized Christmas tree on display or could take the ornament home.

Despite the record breaking cold and slightly rainy conditions of the night, the dedicated youth and advisors of Gilchrist County S.W.A.T. reached out to their community and whole heartedly spread the word about tobacco and its risks.

Trenton's "Christmas on

Main Street" was a good step for the S.W.A.T. outreach and Gilchrist County S.W.A.T. youth look forward to their future of helping the fight against tobacco. The Gilchrist County S.W.A.T. is already making preparations for their upcoming "Kick Butts Day" activity and is once again ready to inform the public about Big Tobacco's deception.

On March 13<sup>th</sup>, 2010 the local quilting guild will be hosting their annual Quilt Fest on Main Street in Trenton. Gilchrist S.W.A.T. plan on using Quilt Fest as an opportunity for their "Kick Butts Day" event because of the large number of people who travel from around the state for the quilt show.

The group plans on having a "Memorial Wall" where people can sign the names of loved ones lost to tobacco and a "Graffiti Wall" where people can write a message to Big Tobacco.

The Gilchrist S.W.A.T. is still making plans towards their "Kick Butts Day" but the event is looking promising.



# Gilchrist County: A Glance at a Namesake

By Thomas J. Harrington, Policy Manager, Quit Doc Research and Education Foundation

Gilchrist County, home to approximately 16,402 people according to the 2005 US Census Bureau estimate, provides a special place for agriculture, land, and certain industries for transportation, equipment, and wholesale merchandise.

Our county in fact derives its namesake from Florida's Governor Albert W. Gilchrist, a former orange grower, militia brigadier general, and Spanish-American War veteran. Serving as governor of Florida between 1909 and 1913, his main focus was actually the health and welfare of the public, as he sponsored legislation to safeguard the public's health by endorsing legislation that sought healthier conditions for the underprivileged and better laws dealing with sanitization. Gilchrist advocated for a sanitarium to fight off tuberculosis, which at the time was a dreadful lung disease, and one that still devastates many poor people in less developed countries around the world today. He also built a hospital for crippled children whose families were too poor to pay for the accommodations.

If Governor Gilchrist were alive today he no doubt would continue fighting for a healthier society for all people, especially for our children. He most likely would be appalled to learn that the rate of young people using tobacco products in Gilchrist County is over twice the amount of young people in the state. According to 2008 data, the exposure to tobacco prevention use education in Gilchrist County in fact is about 5 times less



*Gilchrist County Courthouse, Trenton, Florida*

than exposure to the same education across the state for middle school students, a very vulnerable group to the tobacco companies' incessant onslaught of new marketing tactics and flavored smokeless products. When it comes to exposure, a much higher percentage of these same students in our county compared to the rest of the state are exposed to secondhand smoke. Many usually seem to mistake the effects of secondhand smoke from having to endure long-term exposure yet the 2006 U.S. Surgeon General's Report clearly states that secondhand smoke can cause immediate harm to the bystander person who unintentionally inhales it.

In comparison with the rest of the state, if one were to categorize different areas of age and tobacco use in-

stances into quartiles, our county would find itself in the most unfavorable quartile for several critical areas. This includes the percentage of high school and middle school students who have smoked a cigarette in the last 30 days, the percentage of adults who are current cigarette smokers, and those who die from coronary heart disease (age-adjusted). In the final analysis, it's not just a matter of one's health but it becomes a matter of life and death as a clear correlation exists between heart disease and tobacco use according to the American Heart Association.

Governor Gilchrist might even be more appalled to read that the percent of mothers who smoke when pregnant in his own home county is more than three times that of the entire state

(24.7% versus 7.1%). He may have wondered how this could have happened in a county named after someone who focused so intently on bettering the community's health, specifically the most vulnerable as many might deem the child in the womb. What it boils down to is lack of awareness and the need for better communication about how tobacco can cause all kinds of lasting health problems as well as being the most preventable cause of death in the United States. Clearly there is more work to be done in terms of educating the public about the health hazards of tobacco use, whether it is the single mom who finds herself pregnant or the teenager who is bombarded by peer pressure or the kid who walks into a store where all the tobacco ads are placed at that child's

## Albert W. Gilchrist, Continued

height, suggesting that the normal way of life for being a grownup is to use tobacco as if it were candy or gum. Governor Gilchrist would probably take some form of public action but what can a group of concerned citizens and elected officials do?

We can do something collectively as a county seeing that no current policies that concern tobacco-free public areas exist. Other counties such as Sarasota (not far from where Governor Gilchrist settled in Punta Gorda) have implemented ordinances allowing for designated smoking areas at places for public recreation such as parks and beaches. We have the same opportunity to establish healthy smoke-free environments in our places of public recreation as well. The idea is

certainly not having non-smokers being against smokers but to allow smoke-free passageways for the health of others, particularly those who are most susceptible to secondhand smoke: children, the elderly, and the infirm. These were the same groups of people that Governor Gilchrist cared for the most in protecting and preserving the public health for generations to come. When we can start changing the standards on a public scale like Governor Gilchrist sought to accomplish, we'll see fewer health problems with younger people, fewer hospitalizations for chronic obstructive pulmonary disease, and healthier adults leading longer and happier lives.



Governor Albert W. Gilchrist

## Secondhand Smoke – Not Just an Annoyance

By Kirk G. Voelker M.D., Co Founder of the Quit Doc Research and Education Foundation

Let's say you are at McArthur Park with your daughter at your side, watching your son's baseball game. The guy next to you lights up a cigarette. You give him a quick glance. He looks straight ahead, not making eye contact. He thinks to himself, "So what! I'm allowed to enjoy a cigarette? It's a free country; if I want to smoke I can smoke. Besides I'm not hurting anyone else but myself. And I don't even think I'm doing that! So don't get so uppity with that 'you shouldn't be smoking here' look."

Of course, you don't say anything and neither does he. Well here are the reasons why he is wrong...

1. His secondhand smoke is harming your daughter by increasing her risk of bronchitis and asthma. Over time, it leads to an increased chance of lung cancer in your daughter.
2. His secondhand smoke is harming you – there is an increase in risk of heart attacks and stroke to those who are exposed to secondhand smoke. In fact secondhand smoke is responsible for up to 47,000 deaths in the United States each year. In cities who outlaw smoking in public places, there is a significant decrease in heart attacks within a year after starting the ban. Secondhand smoke levels in outdoor public places can reach levels as high as those found in indoor facilities. According to the 2006 Surgeon Gen-

eral's report there is no risk-free level of exposure to secondhand smoke.

3. His secondhand smoke is annoying- for we non smokers, sitting next to a person who is smoking is as annoying as sitting in a car next to someone with gaseous digestive problems.
4. His smoking is teaching your children that this poisonous addiction, that robs an average of 14 years from each smoker's life, is socially acceptable. Even in this area designed to promote healthy outdoor activities, smoking is condoned. If grownups can do it why can't kids?
5. It reinforces the link between the tobacco industry and sports. For years the tobacco industry has sponsored and advertised at sporting events, misleading young people's perception of tobacco use. The tobacco industry knows that if they can get kids hooked on tobacco, they will have addicts for life.
6. Cigarette butts are the most common litter in the world and yes, someone has to pick them up.

So what can you do? Join The Free Partnership of Gilchrist County and start saving lives!

Agree or disagree, we want to hear from you. For more information, contact Tracy DeCubeliis, Tobacco Prevention Specialist of Gilchrist County, at 352-463-7006, or by email at [tracyd@quitdoc.com](mailto:tracyd@quitdoc.com)

## Thirdhand Smoke: Cancer-Causing Residue That Lasts!

By Barry Hummel Jr., MD

In January 2009, researchers coined the term "thirdhand smoke" to describe the heavy chemicals in smoke that linger on furniture, clothes, carpets, and other surfaces long after the smoker has left the room. Now, another group of researchers has found in a recent study that those chemicals may react with other indoor air chemicals to form potential cancer-causing substances.

After exposing a piece of paper to smoke, researchers at Lawrence Berkeley National Laboratory in Berkeley, California, found that the sheet had levels of newly formed carcinogens that were 10 times higher after three hours in the presence of an indoor air chemical called nitrous acid. Nitrous acid is commonly emitted by household appliances, making it possible that people may face an increased risk from indoor tobacco smoke in a way that has not been recognized in the past.

Previous research has demonstrated that secondhand smoke, which is inhaled by non-smokers exposed to fumes from cigarettes and other tobacco products, raises the risk of cancer and heart disease. Overall, tobacco use causes 20 percent of all cancer deaths, according to the study published in February, 2010, in the journal *Proceedings of the National Academy of Sciences*. More research is needed to identify the potential health hazards of thirdhand smoke, reported Lara Gundel, one of the study's authors.

"We have considered that nicotine on surfaces has been pretty benign up to this point. It turns out we shouldn't say that now," said Gundel, a staff scientist, in a Feb. 5 interview. "People can be exposed to toxins in tobacco smoke in a way that's never been recognized before."

The study found that when the residue from tobacco smoke settles on indoor surfaces, it mixes with indoor air pollutants to form tobacco-specific nitrosamines (TSNAs) which are potent cancer-causing substances found in tobacco smoke, as well as unburned tobacco.

The researchers checked for nitrosamine levels by exposing paper to tobacco smoke and then to nitrous acid. Nitrous acid is produced by gas ovens and burners that aren't properly vented and also by cars. They also tested the surfaces on the inside of a truck of a heavy smoker.

In both cases, researchers found that the reaction between the nicotine in thirdhand smoke and the nitrous acid produced two known and potent nitrosamines. They also found a tobacco-specific nitrosamine that is absent in freshly emitted tobacco smoke.

People are most likely to be exposed to these carcinogens by either inhaling dust or by skin contact, the authors said. Infants and toddlers are most susceptible because they are more likely to come in contact with the materials that absorb these chemicals; they are also more likely to ingest such chemicals because they frequently interact with their environment by "mouthing" objects.

Using fans or opening a window doesn't help eliminate the hazards because most of the nicotine and other substances from burning cigarettes aren't found in the air, but are absorbed by these materials and surfaces.

"Buildings, rooms, public places should be 100 percent smoke free," Gundel added. "Replace nicotine-laden furniture, carpets and curtains. Nicotine absorbs into these materials. The stuff that's imbedded can continue to come to the surface."

The researchers are now trying to determine how long these tobacco-specific nitrosamines may last, especially those created as a result of the interaction of thirdhand smoke and the indoor air pollutant, nitrous acid.

## Smokers With Cancer Could Quit and Double Survival Rate

By Barry Hummel, Jr., MD

Until now, there has been little proof that quitting smoking makes any difference to survival. According to a new study, however, people with early lung cancer who quit smoking could actually double their chances of surviving.

The research was published in January, 2010 in the *BMJ*, formerly known as the *British Medical Journal*. British researchers compiled and analyzed previous data from 10 smaller studies that examined the survival rates of smokers after being diagnosed with lung cancer. The study was funded by the British Heart Foundation, Cancer Research U.K. and other British governmental agencies.

The researchers found that people with lung cancer who continued smoking had a 29 to 33 percent chance of surviving five years. However, lung cancer patients who gave up smoking increased their chances of surviving for five years to 63 to 70 percent, almost double the survival rate among patients who continued smoking.

Lung cancer is the top cancer worldwide, and the prognosis is usually poor. Only about 7 percent of patients make it to five years, though about 20 percent of patients are diagnosed early enough to be treated.

"The message is you should never give up on giving up (smoking)," said Amanda Parsons, of the U.K. Centre for Tobacco Control Studies at the

University of Birmingham, who led the study. "Even at the stage where you have been diagnosed with early stage lung cancer ... if you give up smoking, your body can still partially recover and your risk is reduced," she said.

Most - but not all - doctors recommend lung cancer patients quit smoking. Some medical professionals "think it is inhuman to dwell on the matter - that it adds to feelings of guilt and takes away a lifelong comfort from the dying patient," wrote Tom Treasure of University College London and Janet Treasure of King's College London in an accompanying editorial in the *BMJ*. Treasure and King went on to write that patients and their families should now be told about the study results, "because the potential benefit is great."

The research might also provide some clues on how smoking causes cancer. Scientists aren't sure if tobacco smoke or nicotine affects lung cancer once it has developed, though there is some evidence that continued exposure to such harmful chemicals may speed up the disease. This research implies that this is the case, given that discontinuing tobacco use improves survival rates. Further research into this would also be helpful, since establishing this connection and knowing precisely how smoking tobacco impacts cancer could potentially lead to new treatments.

They are also looking to develop ways to track exposure to nitrosamines.

"We know that these residual levels of nicotine may build up over time after several smoking cycles, and we know that through the process of aging, thirdhand smoke can become more toxic over time. Our work highlights the importance of thirdhand smoke reactions at indoor interfaces, particularly the

production of nitrosamines with potential health impacts," said study co-author Hugo Destailats, in a statement. Destailats is a chemist with the Indoor Environment Department of the Berkeley national lab's Environmental Energy Technologies Division.

The study was sponsored by the University of California's Tobacco-Related Disease Research Program.

# FDA Probes Candy-like Tobacco Products

By Barry Hummel, Jr., MD

U.S. health officials at the Food and Drug Administration (FDA) are asking for more information about new, flavored dissolvable tobacco products. Regulators are particularly concerned that the products and packaging look too much like candy, making it easier to entice children to start using tobacco.

The products that are most concerning are made by Reynolds American Inc's R.J. Reynolds Tobacco Company as part of the Camel brand. In addition, the FDA is also looking into products manufactured by Star Scientific Inc., which contain powdered "smokeless" tobacco but are brightly colored, coffee- or mint-flavored lozenges.

Both companies have argued that the dissolvable products have been created for adults who must deal with smoking bans in public places such as restaurants and airplanes. The companies claim that such products allow consumers a smoke-free alternative for those times in which they are not allowed to smoke. The companies have also claimed that such products may be used as smoking cessation aids, though none of these dissolvable products has undergone the rigorous FDA testing required to make such a claim.

In response, the FDA sent letters to Reynolds and Star Scientific in early February in which regulators expressed concerns that the products could draw in children and teenagers. Because these products contain an unreported amount of nicotine, there is growing concern that the use of such products by children could lead to nicotine addiction.

There are also concerns regarding the ingestion of too much nicotine, especially since these products are meant to be swallowed. As a rule, smokeless products that are not meant to be swallowed are

associated with increased risks of esophageal and stomach cancer, and it is anticipated that these risks would increase among products that are meant to be ingested.

While laws vary among the U.S. states, most limit tobacco purchases to those 18 and older. As a result, the current FDA regulations of tobacco include provisions to restrict tobacco product advertising and marketing campaigns that might be appealing to children. The FDA is "...concerned that children and adolescents may find dissolvable tobacco products particularly appealing, given the brightly colored packaging, candy-like appearance and easily concealable size of many of these products," wrote Lawrence Deyton, head of the FDA's Center for Tobacco Products.

The letters to Reynolds American and Star Scientific were released as the FDA prepares to hold its first public meeting on tobacco issues later this year. Officials from the FDA's Center for Tobacco Products have quickly moved to establish their new role in the oversight of tobacco products after a new law granted them the power in July, 2009.

Any move by the FDA to further regulate or remove dissolvable tobacco products from the U.S. market would be a huge blow to Star Scientific. The one-time cigarette manufacturer has shifted its focus to making these dissolvable products, claiming that such products expose consumers to lower levels of toxins, and are therefore safer.

Sara Troy Machir, a spokeswoman for Star Scientific, said the company was not surprised by the letter and would cooperate fully. "We're happy to share information with them," Machir said, adding that Star's smokeless products – Ariva and Stonewall – have been on the market for 10 years.

R.J. Reynolds is test-



**Examples of current edible nicotine products. Stonewall and Ariva brands are both manufactured by Star Scientific. Camel brand products are manufactured by Reynolds America.**

marketing three types of products under its Camel brand. These products deliver dissolvable nicotine in tablet, mouth strip and small toothpick-shaped forms.

Since the launch of the Camel products in the spring of 2009, Reynolds American and Star Scientific have been embroiled in a patent dispute over some of the technology behind

the dissolvable products.

The two companies were given two months to respond to the letters from the FDA. Despite acknowledging that the products are currently marketed to adults, FDA regulators requested extensive information on research and marketing practices for these new products.

# New Products Exploit Loophole in Florida Tobacco Excise Tax

By Barry Hummel Jr., MD

During the 2009 legislative session, the Florida Legislature passed increases in the tobacco excise taxes. While most of the attention focused on the \$1.00 per pack increase in the cigarettes excise tax, the tax was also raised on many other products, including pipe tobacco and smokeless tobacco.

However, there was no substantial increase in the tax on cigars. This was due in large part because of the lobbying efforts of cigar manufacturers in the Tampa Bay area. Fearful of the economic impact, the Florida Legislature essentially gave the cigar industry a free pass.

Sadly, the tobacco industry never misses an opportunity.

As a result of this loophole on the taxation of cigars in Florida, the tobacco industry has created a new product to bypass the increased excise tax on cigarettes: "filtered cigars".

What exactly are *filtered cigars*?

To understand the answer, let's first look at the definition of *cigars*. Cigars are "a com-

pact roll of tobacco leaves prepared for smoking". In other words, cigars are made up entirely of rolled tobacco leaves. Unlike cigarettes, they are not wrapped in paper. Some cigars may have a plastic tip, but there are no traditional cigars that include a filter.

The new products... the so-called *filtered cigars*... look exactly like cigarettes. They are wrapped in paper. They have a filter tip. They are even sold in packs of twenty - exactly like cigarettes.

There is one subtle difference. *Filtered cigars* are wrapped in brown paper. This paper is either stained with tobacco juice or infused with bits of tobacco. By doing this, the makers can claim that the product is a cigar, not a cigarette.

It is a unilateral claim. The manufacturers created, packaged, and distributed these products as cigars without bothering to ask the FDA or state lawmakers to make a determination as to the definition of the products. The manufacturers determined that they were cigars. The manufacturers determined that they did not qualify for the cigarette excise tax. The manufacturers determined that the FDA rules did not apply to the products.

This false distinction is very important for a number of reasons.

As a result of the recent tax increase in Florida, a pack of cigarettes now costs close to \$6.00 per pack. The increased price has resulted in a 22% reduction in cigarette sales in the state. This high cost is also associated with a disproportionate drop in youth cigarette purchases.

However, the price of a pack of *filtered cigars* ranges from \$0.99 to \$1.59. This means you can purchase 4-6 packs of *filtered cigars* for \$6.00 instead of just one pack of cigarettes! These low prices promote smoking, particularly among youth.

Another issue is that fla-

vored cigarettes (with the exception of menthol) were banned in September 2009. This ban was the first restriction to take effect as a result of the Food and Drug Administration's (FDA's) new regulatory authority over tobacco. To date, flavored cigars have not been addressed by the FDA.

Of course, *filtered cigars* are sold in a variety of flavors, including peach and grape, again flaunting the regulations. This is simply another way to get flavored, cigarette-like products into convenience stores... and into the hands of teenagers.

Just who is responsible for this deception?

Santa Fe brand *filtered cigars* are made by Swisher International, Inc. Swisher International is a cigar manufacturer best known for Swisher Sweets. The company has a manufacturing plant in Jacksonville, Florida.

Clipper brand *filtered cigars* are distributed by Global Tobacco, LLC, located in Dal-

las, Texas.

Cheyenne brand *filtered cigars* are distributed by Cheyenne International, LLC, located in Grover, North Carolina.

Wrangler brand *filtered cigars* are distributed by General Tobacco, located in Mayodan, North Carolina.

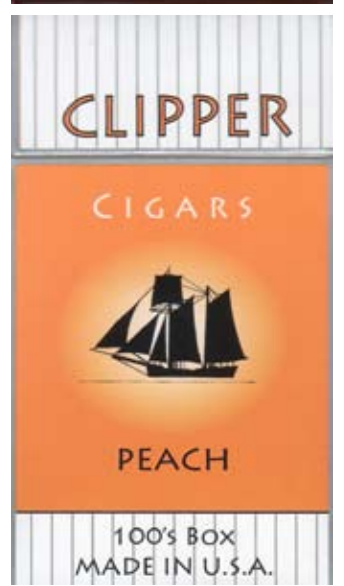
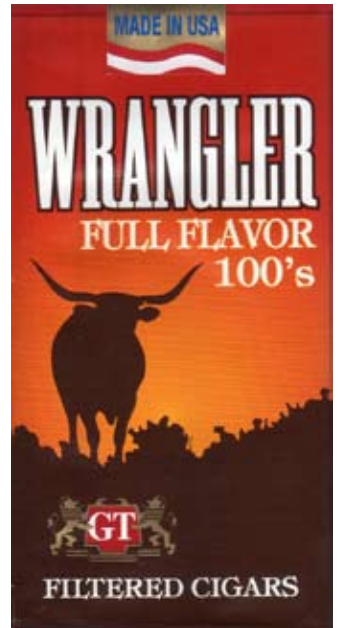
The Quit Doc Research and Education Foundation is currently trying to determine when and how these companies were started to see who is ultimately responsible for this new method of bypassing the rules to target teenagers.



Cigars or Cigarettes? You be the judge!



Samples of new "filtered cigars" currently available in Florida retail outlets.



# Study: "Electronic Cigarettes" Don't Deliver

By Barry Hummel, Jr., MD

*E-cigarettes*, electronic devices that retailers claim allow consumers to inhale vaporized nicotine instead of harmful tobacco smoke, do not appear to live up to the hype, according to research conducted at Virginia Commonwealth University.

"They are as effective at nicotine delivery as puffing on an unlit cigarette," said Dr. Thomas Eissenberg, at the school's Institute for Drug and Alcohol Studies.

His study, funded by the National Cancer Institute, is the first by U.S. researchers to check the function of e-cigarettes. The units are shaped like a cigarette and contain a rechargeable lithium battery. The devices use a filament designed to heat and vaporize liquid nicotine stored in a refillable cartridge. Some users have even nicknamed what they're doing as "vaping" instead of smoking, to reflect the vapor produced by the heating element.

E-cigarettes are typically sold in kiosks in local malls, and their sale and use are currently unregulated in the United States. The devices are marketed as an alternative to smoking, but retailers avoid making claims about health or safety.

Smokers buy the devices primarily to get around no-smoking restrictions. However some retailers are marketing e-cigarettes as method to quit conventional cigarettes.

This latest clinical study suggests that users are not getting the same level of nicotine that they get from smoking tobacco. "These e-cigs do not deliver nicotine," Dr. Eissenberg said of the findings of his study, which he expects to publish in an upcoming issue of *Tobacco Control*, a publication of the British Medical Journal Group.

This past summer, Eissenberg recruited smokers without prior experience using e-cigarettes to volunteer to use two popular brands e-cigarettes. 16 subjects were regularly measured in a clinical setting for the presence of nicotine in their bodies, withdraw symptoms, and



other physiological effects.

"Ten puffs from either of these electronic cigarettes with a 16 mg nicotine cartridge delivered little to no nicotine," the study found.

Meanwhile, the Food and Drug Administration (FDA) is looking to regulate e-cigarettes as a medical device in response to marketing claims that the devices may be used to help smokers quit tobacco. Initial reports also suggest that the units may deliver hazardous chemicals. For example, preliminary checks by federal regulators found diethylene glycol, a chemical used in antifreeze that is toxic to humans. The preliminary FDA analyses also detected known carcinogens, including nitrosamines.

As a result of these findings the FDA imposed a ban on the

importation of these devices in March 2009, pending further regulatory review for any additional health risks. When announcing the ban on e-cigarettes, the government's statement noted there are no health warnings on the products despite the presence of several dangerous chemicals.

The original notice of the import ban also stated that "the product appears to be a combination drug-device," that "requires pre-approval, registration and listing with the FDA" in order to be marketed in the United States.

After the import ban was announced, *Smoking Everywhere*, one of the U.S. companies that imports e-cigarettes, challenged the ban in federal court. In court documents, *Smoking Everywhere* claimed to have sold

600,000 of the devices in the preceding 12 months through a network of 120 distributors in the United States.

As a result of the ban "we are on the verge of going out of business, which is why we are suing the FDA in U.S. District Court," said Washington-based attorney Kip Schwartz, representing *Smoking Everywhere*.

The lawsuit questioned the FDA's authority to block shipments of a non-tobacco product, and says the agency has violated its statutory process for product review. The lawsuit also claims that liquid nicotine is available on the open market through pharmaceutical houses as well as vendors who sell e-cigarettes. However, the FDA was recently granted regulatory authority over tobacco and nicotine in June 2009, and the agency continues to assert this new authority to regulate e-cigarettes.

On January 14, 2010, the District Court judge ruled in favor of *Smoking Everywhere*, stating that the FDA does not have such regulatory authority.

The FDA has taken the matter to the U.S. Court of Appeals, which has yet to decide the case. The appeals panel issued a stay against the judge's ruling until it can rule on the FDA's appeal.

Meanwhile, based on the judge's initial ruling, lawyers for the importers have filed a request to compel the FDA to lift its import ban, saying the agency is not likely to win its appeal. The filing says "although e-cigarettes have been sold since 2007, FDA has not identified a single instance, either in this Court or below, of an adverse health effect from e-cigarettes."

Despite the new study that the devices may not deliver nicotine as promised, and despite the import ban currently in place, sales of e-cigarettes continue at shopping mall kiosks and small storefront retailers, apparently drawing from stock imported before the FDA began to block shipments from overseas suppliers.

## Federal Court Deals Blow to Public Health in Ruling FDA Cannot Regulate E-Cigarettes As Drugs or Medical Devices

*Statement of Matthew L. Myers, President, Campaign for Tobacco-Free Kids, January 14, 2010*

Washington, D.C. - In ruling today that the U.S. Food and Drug Administration may not regulate electronic cigarettes as drugs or medical devices, U.S. District Judge Richard Leon has ignored decades of precedent and put America's consumers at unnecessary risk. If upheld, Judge Leon's decision opens a gaping loophole in the protection FDA has provided against the sale and distribution of non-tobacco products that a manufacturer laces with unregulated quantities of nicotine. For years, the FDA has stringently regulated all products containing nicotine when sold to consumers in any form other than a traditional tobacco product because of nicotine's dangerous and addictive impact.

Judge Leon's decision also ignores the common sense distinction that FDA has long drawn between traditional tobacco products that contain nicotine, such as cigarettes, smokeless tobacco, cigars and pipes, and a host of non-tobacco products, ranging from toothpaste to lollipops to water, in which manufacturers have added nicotine, a highly addictive substance.

We urge the government to appeal this ruling in order to protect public health. It is important to note that even if today's ruling is upheld, this ruling leaves open the possibility that the FDA can regulate electronic cigarettes under the new law granting the agency the power to regulate

tobacco products. Like other consumer products, electronic cigarettes should be regulated to protect public health before they are permitted to be sold to consumers.

Judge Leon's decision came in response to a lawsuit filed by two e-cigarette manufacturers that challenged the FDA's jurisdiction over these products and the agency's attempt to prohibit their importation under the Federal Food, Drug and Cosmetic Act. Electronic cigarettes have not been tested for safety or approved by any government agency for sale in the United States, yet manufacturers have been marketing and selling these products in stores and shopping mall kiosks throughout the U.S., as well as on the Internet.

Electronic cigarettes, which are manufactured primarily in China, pose several serious potential risks to public health. First, there is no credible scientific evidence that these products are safe for human consumption or that they are effective at helping smokers or other tobacco users quit, as some manufacturers have claimed. In contrast to tobacco cessation products that have been approved by the FDA, there are no controls on the amount or potency of the nicotine or other substances in electronic cigarettes. Last year, the FDA announced that a laboratory analysis of electronic cigarette samples found that they contain carcinogens and toxic chemicals

such as diethylene glycol, an ingredient used in antifreeze.

Second, these products risk deterring current smokers from quitting by providing an alternative source of nicotine in places where smoking is not allowed. They also provide an unproven and unapproved alternative to smoking cessation therapies that have been approved by the FDA as safe and effective. Smokers concerned about their health should utilize approved smoking cessation medications and counseling rather than unapproved products. As the World Health Organization has concluded, until electronic cigarette manufacturers have conducted the necessary scientific studies and gone through the appropriate regulatory process, "WHO does not consider it to be a legitimate therapy for smokers trying to quit."

Third, these products could serve as a pathway to nicotine addiction for children, leading them to smoke cigarettes and use other tobacco products. Electronic cigarettes have been marketed in youth-friendly candy and fruit flavors including bubblegum, cookies and cream, and cola. These products are also readily accessible to youth because they are widely sold in shopping malls and over the Internet and, because they are not traditional tobacco products, they are not subject to age verification laws.



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