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To: Rep. Merwyn R. “Mitch” Greenlick

Dr. Greenlick:

Thank you for accepting my written testimony as part of the public hearing concerning HB 2546. I am a registered nurse with a master’s degree in tobacco use disorder (TUD). This is the term that replaces historical terms such as dependence or abuse. It was thought by the American Psychiatric Association, editor of the new Diagnostic and Statistical Manual of Mental Disorders-5 (2013), that these older terms are shaming, demeaning, and do not capture the gradation of symptom severity across all substance use disorders.

I am recently retired and a neophyte Oregonian. I retired from the VA in Cincinnati, Ohio in 2013 and moved to Portland to become a full-time professional grandmother. I highly recommend it! While at the VA, I was the Coordinator of the Tobacco Treatment Center which received 2000 facility-wide consults annually. At any given time, 500 Veterans were being assessed and treated across 16 ongoing, weekly treatment classes. All FDA-approved medications for TUD were prescribed. We became a flagship example in the Veterans Health Administration of best practice treatment for TUD and were subsequently awarded a four-year grant to disseminate this evidence-based programming to other VA facilities around the nation. I share this with the hope that my education and experience lends credibility to my testimony.

A Cautionary Tale

I applaud the House Health Care Committee for tackling the pesky issue of electronic nicotine delivery systems (ENDS) before these devices become so embedded in our state economy that our leaders lack the moral courage to effect change. Surely, it would be wise to allow the history of tobacco products and our national health to serve as a cautionary tale. Big Tobacco executives knew as early as the 1940’s that tobacco use caused death and disability but, instead of stopping production, their communication was coded to hide this knowledge. “A biological effect” was code for cancer. Adding ammonia to “enhance the experience” was code for adding a chemical to increase the speed with which nicotine reached the pleasure center of the brain, thereby increasing the likelihood of continued use. Menthol cools the heat sensors in the mucous membranes so a smoker is less aware of ill effects when a stick of burning tobacco, on fire at 650°, is held only a few inches from the face.

This is what we were sold…

The medical community was left to discover the science for themselves…and this is what we got...

The first Surgeon General's Report concerning the harmful effects of tobacco use on health was published in 1964. Big Tobacco response to this first Report was to provide a "safer" product by placing a filter on the cigarette. In the years that followed, the medical community began to see significantly more of the rare adenocarcinoma in the upper lung fields, a function of inhaling more deeply to get the same amount of nicotine past the ventilation holes placed in the filter. Big Tobacco offered "low-tar" cigarettes as smoked by a machine. The medical community was unable to find one shred of evidence to suggest reduced risk for humans who smoke differently than machines. Steve Kottack, spokesman for Kentucky-based Brown and Williamson, stated that they produced low-tar products, not because *they* wanted to, but at the request of *government scientists* who thought it would be healthier!

I could go on and on with many more examples of being sold a bill of goods by Big Tobacco. Since 1964, there have been 40 more Surgeon General Reports. Not one of them says, "Oops, we got it wrong…tobacco use is safe and healthy after all!" yet the powerful influence of tobacco money continues to corrupt all it touches. According to the Center for Disease Control (CDC), in 2011, cigarette and smokeless tobacco companies had enough money to spend a combined total of almost $9 billion just on advertising and promotions. That equals $23 million PER DAY spent on advertising for cigarettes alone, or $27 daily for every single man, woman, and child in the United States. And it is all perfectly legal. It is "business." Never mind that tobacco disease burden kills two times more individuals every year than all the other substance use disorders, HIV/AIDS, motor vehicle accidents, homicides, and suicides combined! Additionally, for every person who dies, 20 more are living a disabled life for their last 10-15 years at the cost of tremendous personal suffering and lost productivity.

This is the truth about tobacco that our society has had to find out for itself.

ENDS Advertising

What would the ENDS manufacturers have us believe about their devices? Taken from their own advertising, we are told:

- A great alternative to help stop smoking.
- They are designed to look and feel like the real deal.
- They provide the same delight, physical, and emotional feelings as traditional cigarettes
- The pleasure of smoking without the problems
- The nicotine hit that smokers crave.
- Cheaper than tobacco.
- Wi-fi option applies social networking principles.
- The freedom to smoke everywhere.
- Get in touch with a personal freedom.
- Healthier than cigarettes.
- Produces a harmless water vapor.

Using ENDS as a treatment for TUD has already been disproven so, by law, manufacturers may no longer make this claim. In our experience at the Cincinnati VA TTC, patients who used electronic devices as a substitute tired of it after a month or so and went back to their preferred tobacco product. It just wasn't the same. It was like an alcoholic sitting at the same bar with the same bartender and the same drinking buddies but drinking near-beer. After a while, the drinker gets fed up…everything seems the same but he gets none of the high he wants from the beer in the first place. "Aw, heck, give me a real beer!" ENDS start-up kits cost from $40-200. Cartridges range from $3-20 per day depending on type and amount smoked. Batteries last from 2 hours to 1.5 days. Devices become clogged or the atomizer burns out and needs to be replaced at additional cost of $25 every few months. The freedom ploy is almost comical. Is it really freedom when one HAS to use a product every hour, every day, every year…even if they don't really want to? Even when wanting to stay in bed but instead need to get more batteries from the store? Even when strapped for cash but need to buy more nicotine cartridges to feed the disorder? Even when sick and tired of being sick and tired? This is not freedom. It is called "active substance use disorder." Eighty-five percent of tobacco users want to stop. They just don't know how. Nor is the average medical provider trained in evidence-based TUD treatment in order to help them effectively. Treatment may be hard to find, inconvenient, and uncovered by insurance plans. Ninety-five percent of tobacco users are able to finally tap into their one known resource, their own motivation, but only after they have been terrified by a medical catastrophe, e.g., stroke, heart attack, cancer, or COPD diagnosis (West and Sohal, 2006). It is not surprising that ENDS manufacturers have stepped in to fill the gap. How perfect. Now an individual with TUD can use and not use at the same time!

ENDS Safety and Nicotine

My biggest concern is the claim of safety of these electronic devices. It might seem clear-cut that inhaling "water vapor with a little nicotine" is far safer than inhaling 7000 chemicals from regular tobacco, 69 of which cause cancer and 599 of which are added by the tobacco companies. However, it may surprise you to know that, health-wise, nicotine is actually the least problematic chemical in

tobacco…other than the fact that it is the most addictive drug on the planet, of course, and keeps those afflicted with TUD trotting back for the 6,999 other chemicals! There is a mythical fear of nicotine that, when taken out of context, is totally out of proportion to its real danger. The ads for the tobacco treatment drug, Chantix®, pander to this fear. "Most importantly…Chantix does not contain nicotine…" Patients have asked me, "Why are you putting me on nicotine replacement therapy when I want to get off nicotine?" My answer was, "I don't care about getting you off nicotine…I will get you off nicotine in a few months. Taking medical-grade nicotine products now will help ease withdrawal so you can stop TOBACCO immediately. There is no safe level of tobacco use. It is not the nicotine that kills you. It is the tobacco." Other patients would say, "I don't want to take the patches. I am already on so many other medications." My answer was, "You are already on nicotine from your tobacco. I want to get you off the acetone, acetylene, arsenic, benzene, butane, cadmium, lead, formaldehyde, cyanide, carbon monoxide, ammonia, mercury, phenol, tar, turpentine, and vinyl chloride…just to name a few!"

ENDS manufacturers will not say where they get their nicotine. Indeed, three alkaloids of *tobacco* have been found in some pre-filled cartridge liquids, suggesting they get their nicotine from tobacco. It is not medical-grade nicotine as are pharmaceutical nicotine replacement therapy products. Also, the amount of nicotine in the liquid is not always consistent with the label. Some cartridges were advertised as having no nicotine but, when tested by an outside laboratory, did contain it. Other liquids were labelled has having a certain amount of nicotine but contained none. In other words, there is no quality control. The refill bottle of liquid nicotine containing 1000 mg is downright scary. Putting nicotine into perspective, a pack a day smoker is probably tolerant of about 20 mg of nicotine over 24 hours. A ten stogie cigar per day smoker (I have treated such an individual) may be tolerant of up to 4000 mg of nicotine over 24 hours! Tolerance depends on use and develops over time. Asking how much nicotine is too much for a tolerant individual is like asking, "How high is the sky?" If a tolerant person were to suddenly get a small spike of nicotine, (s)he would become dizzy and/or nauseated for an hour or so then return to a slightly higher level of tolerance than before.

Nicotine poisoning does exist, however. My greatest fear of the 1000 mg refill bottle of nicotine, is for non-tolerant individuals, especially young children and pets. According to the CDC, Poison Control centers around the country are seeing a significant rise in calls concerning exposure to both nicotine from cartridges and refill bottles. Pet Poison Control centers are also showing an increase in veterinary emergencies related to nicotine poisoning. Nicotine poisoning has a rapid onset of symptoms – generally within 15 to 60 minutes following ingestion or exposure. Symptoms include vomiting, diarrhea, agitation, elevations in heart and respiration rates, tremors, ataxia, weakness, seizures, cyanosis, coma,

cardiac arrest, and death. A fatal dose for a toddler or small pet is **1-2 mg**. A child could succumb with **10 mg**. A non-tolerant adolescent or adult may die after exposure to **30-60 mg**. This refill bottle contains 1000 mg…with no safety lid…no warning labels…and often smells like candy!




Other ENDS Liquid Constituents

So what about the other ingredients in ENDS liquid besides nicotine? This liquid has been shown to contain up to 20 other chemical ingredients that may, or may not, be declared on the label. These include:

- Rimonabant- a weight loss drug that is banned in the U.S.
- Amino-tadalafil- the Chinese form of Cialis.
- Vitamin C
- Lobeline- also known as "puke-weed," causes dry mouth, increased heart rate, confusions, seizures, coma, and death.
- Anabasine-a tobacco alkaloid that can block nerve transmission and cause death by asystole (heart stops).
- Myosmine- a tobacco alkaloid that contributes to esophageal cancer.
- B-nicotyrine- a tobacco alkaloid that inhibits CYP2A6 enzymatic system through which many medications for mental health disorders are also metabolized.
- Acrolein-a pulmonary irritant. Was used as a chemical weapon in WWI that caused lung cancer, bleeding from the bladder, and is implicated in multiple sclerosis.
- Formaldehyde- known to be carcinogenic.
- Nitrosamines- known to be carcinogenic.
- Di-ethylene glycol- a solvent/humectant in tobacco that is also used in brake fluid and wallpaper stripper. Has caused 1,823 known death across the world since it was discovered to be fatal. Caused 84 deaths in infants and children in Nigeria.
- Flavorings- chocolate, mint, strawberry daiquiri, biscotti, peach, cherry, coffee, apple, almond, bubblegum, cola, Boston cream pie, gummy bear, cotton candy and last but not least…tobacco!

Let me say here that the only reason that I can purchase even a Pepto-Bismol over-the-counter is because the FDA has already received copious amounts of data and research from Procter and Gamble about its every ingredient, efficacy, side effects, quality control, age restrictions, and whether little ol' me will be able to safely self-administer it without a professional prescriber. Even so, Pepto-Bismol is sold with a lengthy list of warnings…just to be on the safe side.

On the other hand, the FDA has written extensively about the complete lack of studies by ENDS manufacturers concerning:

- E-liquid composition, vapor composition, product quality, infectivity, carcinogenicity
- Pharmacodynamics, pharmacokinetics, toxicokinetics
- Safety of long-term inhalation of other drugs or flavorings
- Addictive potential, addictive liability, risks of possessing bottles of large quantities of liquid nicotine in the home
- Puff topography, dosage, dosing regiment
- Effect on nicotine withdrawal, adverse effects
- Efficacy for treatment of TUD and comparison to FDA-approved medications
- Efficacy of administration of other drugs in e-liquid
- Surveillance, pharmacovigilance
- Safety of exposure to exhaled vapor
- Safety of consumer to use without an expert intermediary
- Safety of selling without age restriction
- Safety of selling without either nicotine warnings or tobacco warnings

Make no mistake, ENDS deliver a psychoactive drug without FDA regulation. Additionally, it provides other ingredients that have pharmacological effects on the human body without any information for the consumer regarding pharmacokinetic delivery or safety.

Constituents of E-Vapor

For this section of my testimony, let me first include a diagram of the inner anatomy of an electronic cigarette. Other ENDS devices contain some configuration of the same basic components.

In 2013, Williams, Villarreal, Bozhilov, Lin, and Talbot published an article titled "Metal and Silicate Particles Including Nanoparticles Are Present in Electronic Cigarette Cartomizer Fluid and Aerosol." (PLoS ONE 8 (3): e57987. Doi: 10.1371/journal.pone.0057987).

In this research study from University of California (Riverside) Department of Cell Biology and Neuroscience, it was found that each puff of inhaled electronic cigarette aerosol vapor contained 4,000,000 particles/cm^3 of 22 different elements that were between 10-1000 nanometers (nm) in size. (nm =1 billionth meter.) These ultra-microscopic particles are entirely capable of reaching the deepest level of the alveolar air sacs in the lungs, being absorbed into the bloodstream, and distributed throughout the body. The particles were derived from the battery, fiberglass wick, silver-coated copper

wire, and tin solder joint components. Exposure was facilitated by the functions of heating the liquid and high airflow rate required to operate the device. If one were to use the device ten times in a day for 100 puffs, this would result in exposure to 10^8 particles less than 1000 nm in size, some of which would be heavy metals.

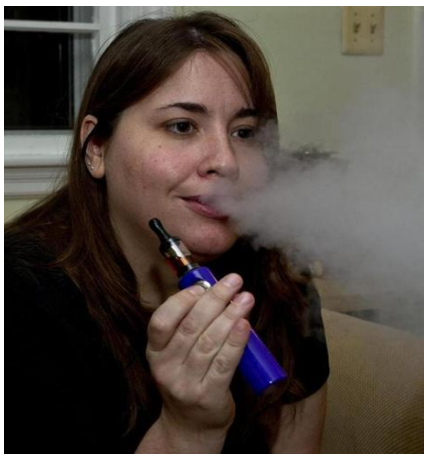
Indeed, particulate concentrations inhaled from e-vapor aerosol was even higher than conventional tobacco smoke for sodium, iron, aluminum, and nickel. Equal concentrations were found for copper, magnesium, lead, chromium, and manganese. Only levels of zinc were less. Also concerning, e-vapor aerosol was found to contain ten additional kinds of particles that are not found in tobacco smoke, i.e., boron, silicon, calcium, sulfur, tin, barium, zirconium, strontium, titanium, and lithium.

Exposure to the 22 different elements that have been found in e-vapor have been associated in the scientific literature with the following medical conditions:

- Bronchitis and pneumonia
- Shortness of breath and coughing
- Pulmonary siderosis (deposits of iron in the lungs)
- Pulmonary fibrosis (hardening of the lungs)
- Asthma and wheezing
- Decreased lung function
- Interstitial pulmonary lesions (Vineyard sprayer's lung from copper)
- Metal fume fever (inhalation of dust/fumes of zinc, magnesium, silver, chromium, cadmium)
- Stannosis (tin pneumoconiosis)
- Lung cancer
- Kidney damage
- Reproductive and developmental toxicity
- Leukemia
- Anaphylaxsis (allergic shock)

Exposure to Secondhand E-Vapor

The Williams et al. study also examined the particulate matter of the room air containing ENDS smoke. They found calcium, potassium, sodium, silicon, and aluminum. These elements have been correlated with coughing, wheezing, shortness of breath, bronchitis, impaired lung function and asthma.



The real question before us is not: Are ENDS safer than traditional tobacco products? The question is: **Are ENDS safe?** Clearly, based on this one study by Wiliams et al., the science shows they are not! Callahan-Lyon published a literature review of 44 studies concerning the human health effects of e-cigarettes (*Tobacco Control*, 2014; 23: ii36-ii40). The author concludes that the scientific evidence is either limited, lacking, or inconclusive. So does the scientific community embark upon research to see who gets sick and how? What is the long-term effect of inhaling gummy bear flavoring anyway? How much tin is safe and healthy to inhale? Or perhaps we should rely on the ENDS manufacturers to inform us about the safety of their products, like Brown and Williamson did so many years ago…

TUD: A Pediatric Illness

In my graduate studies, I was surprised to learn that TUD is actually a pediatric illness since, on the average, 90% of those who first experiment with tobacco are regular users by the time they are 20 years old. Tolerance to nicotine develops rapidly, often within the first 2-10 cigarettes. Those first cigarettes usually come from a parent's pack…smoked after school while unsupervised. Unlike other substance use disorders, tolerant individuals do not use nicotine to feel high, but to ward of the discomfort of physical withdrawal. The half-life of nicotine is short, about one hour. For individuals with a high tolerance, they can be in nicotine withdrawal only ten minutes after their last cigarette. The old recovery adage, "One is too many and 1000 are never enough" is particularly true in TUD. The predominant symptoms of nicotine withdrawal are restlessness, irritability, anxiety, stress, and craving. Within seven seconds of nicotine inhalation, neurotransmitters of pleasure are released in the mesolimbic reward pathway of the brain. Ahhhhh…withdrawal is relieved.

The 2014 national, government-sponsored *Monitoring the Future Survey* on adolescent drug use was recently published by Johnston, O'Malley, Miech, Bachman, & Schulenberg from the University of Michigan Institute for Social Research. One of the key findings is an alarming increase in e-cigarette use at the 8th, 10th, and 12th grade levels as compared to tobacco cigarette use. E-cigarette use was TWICE the level of tobacco cigarette use in the 8th and 10th grades! Specifically, the Survey found:

- Among 8th graders, 8.7 percent reported using an e-cigarette in the past 30 days, while only 4 percent reported using a traditional cigarette.
- Among 10th graders, 16.2 percent reported using an e-cigarette and 7.2 percent reported using a traditional cigarette.
- Among 12th graders, 17.1 percent reported e-cigarette use and 13.6 percent reported use of a traditional cigarette.

These data reflect an ever-decreasing level of tobacco cigarette use due to the implementation of evidence-based tobacco control strategies. In general, these strategies include higher taxes on tobacco products, strong state and local tobacco control laws, well-funded tobacco prevention and treatment programming at the CDC-recommended levels for that state, and effective mass media campaigns that expose the true harm of tobacco use. Sadly, these data also reflect what happens when ENDS manufacturers are legally permitted to target our youth with the same tactics long used to market regular tobacco to children to include celebrity endorsements, slick TV and magazine ads, and sponsorship of race cars and concerts. Most egregious is the use of 100's of flavorings as mentioned elsewhere in this testimony. *Monitoring the Future Survey* results also show that fewer students

associate “great risk” with use of the e-cigarette as compared to a tobacco cigarette. It is not yet known if e-cigarette use will serve as a gateway drug to regular tobacco use. In the Survey, four to seven percent of students used the e-cigarette only, but it is not yet known what will happen as they age, becoming ever more tolerant of nicotine. What will happen if they are in withdrawal and have no nicotine e-cartridges? Dual use of cigarettes and smokeless tobacco is now so common place that a best-practice assessment question is, “What do you do when you cannot smoke?” In other words, how will one get a dose of nicotine to stave off withdrawal when one cannot use the preferred form?

Treatment of TUD in the Pediatric Population

There is a plethora of published literature concerning the protective factors against initiation, experimentation, and regular tobacco use. These protective factors include:

- Strong affiliation in a faith community
- Clear parental rules
- Strong parental disciplinary practices
- Active parental teaching not to use tobacco
- Lower rates of maternal tobacco/other drug use
- High quality of parent-child interactions
- Strong anti-tobacco community norms

There is also a great deal of literature concerning the following treatment strategies that have been shown to reduce tobacco use, In general, these strategies are:

- Serial assessment of susceptibility, starting in late grade school with targeted interventions for children found to be susceptible to use in the near future
- Health educational messages that focus on the immediate risk of addiction, effect on oral health, decreased ability to participate in sports, and decreased attractiveness to the opposite sex...NOT distant adverse health effects
- Therapies to reduce general impulsivity which has been correlated with increased likelihood to initiate and experiment with tobacco
- Training in problem-solving skills, especially concerning how to talk to tobacco-using parents
- Enhancement of self-confidence and refusal skills

Parents, schools, clinicians, and the legislative community all have a role to play in helping children avoid tobacco. For parents, recommendations are:

- Quit oneself, share own quit struggle with child to demonstrate how difficult it can be to stop. Children routinely underestimate how hard that can be.
- Talk to child about the unacceptability of tobacco use
- Establish a tobacco-free home
- Monitor tobacco use behavior
- Establish/implement negative consequences for tobacco use
- Educate child about adverse effects
- Discuss actual prevalence rates which are far lower than perceived rates
- Encourage involvement in community activities

- Discuss manipulative tobacco ads
- Ban use of promotional items with logos since this increases the likelihood a child will use tobacco in the near future
- Delay/restrict PG-13/R-rated movies since these expose children to depictions of tobacco use, especially by romantic characters
- Maintain overall positive home environment

Children are more likely to use tobacco if there is a higher rate of tobacco use by students at their school, the most popular students use tobacco, or if the child's best friends use tobacco. For schools, recommendations are:

- Maintain anti-tobacco norm/attitude
- Enforce strict tobacco ban
- Enhance students' self-esteem
- Encourage organized sports
- Teach students that the majority do not use tobacco
- Provide training for teachers

Studies show the vast majority of pediatricians never assess for tobacco use disorder despite the fact that TUD has a pediatric onset. For clinicians, recommendations are:

- Assess for susceptibility to start use, past/present use, motivation to quit beginning around 8-9 years of age
- Advise abstinence for child
- Assist in formulation of personal quit strategy to include nicotine replacement
- Provide follow-up services
- Advise abstinence for parents and refer to treatment if they are tobacco users. If parents refuse to stop, advise they never use in front of the child and do not carry tobacco products visibly.

Last but not least, the legislative community is crucial for support of the parent, school, and clinician. This support should include laws that:

- Ban tobacco advertising on TV and in magazines that are popular with minors
- Pass/enforce laws that penalize retailers who sell to minors, display tobacco next to candy at eye level of a child
- Pass/enforce laws that ban free samples and promotional items
- Most importantly, form a **"Tobacco Court"** as a consequence for illegal possession of tobacco by a minor. This would provide treatment to children afflicted with TUD and avoid criminalizing them. Studies have shown that unscrupulous retailers are more than willing to sell to known minors who are then arrested, carrying a criminal record to perpetuity.

My above testimony concerned the cautionary tale of tobacco products, information about the components of ENDS, liquid constituents, safety issues, basic information about the illness of tobacco use disorder, and recommendations for various segments of society to help our children with this often crippling and fatal disorder. I believe that our society will be judged especially by how we protect and care for those who cannot protect and care for themselves.

HB 2546

Concerning HB 2546 specifically, I have the following suggestions. Some relate to language and may be easy changes to make. Other suggestions are philosophical, political, clinical, or economic and may prove more difficult. All suggestions are offered in the spirit of creating a stronger bill that protects/treats minors while increasing consequences for enablers of legal age. It is my sincere hope that HB 2546 does not founder and is eventually passed.

1) Throughout: Change "inhalant delivery systems" to "electronic nicotine delivery systems (ENDS)." This is becoming the most common term in the medical literature. Page 2, Lines 7-10 could then be eliminated since the pharmaceutical nicotine inhaler is a not an electronic device.
2) Page 2, Line 37: Change "To sell or allow to be sold cigarettes…" to "To sell or allow to be sold tobacco products…"
3) Page 3, Line 12-13: Change …not less than $250 or more than $1000" to "$1000 for each violation. The retailer's license will be revoked after the third violation." Why not have a monetary consequence with some bite? Tobacco companies pay fines for retailers. With $3.5 billion in annual sales, it would not surprise me if ENDS manufacturers followed suit.
4) Page 4, Line 37: Freebasing is one word.
5) Page 5, Lines23-25. DELETE! If it is illegal for a parent to supply/allow alcohol to a minor, it should be illegal for a parent to supply/allow tobacco. Why should parents get off the hook by supplying a deadly drug to their own children? These parents should be remanded to a Tobacco Court along with the minor to learn more about responsible parenting.
6) Page 5, Lines 28-34. DELETE. Substitute "…the minor and parents will be ordered to Tobacco Court for treatment and adjudication concerning the violation. Further violations will continue to be adjudicated by Tobacco Court, to include penalties for either the minor or the parents as the Court sees fit." Education-only programs are ineffective against substance use disorders. Scare tactics about end-of-life medical horrors to not phase children who perceive themselves as invincible. Hopefully, a Tobacco Court would have treatment services that specialize in children, especially the use of treatment medications in the pediatric population.
7) Page 6, Line 2: Change "adult" to "law enforcement or Oregon Liquor Control Commission agent."
8) Page 7, Line 27: Delete. Change to "Employs only family members." Non-family members who need a job should not be coerced by contracts then exposed to potentially smoke.
9) Page 8, Line 19 and page 12, Line 15: Change "10 feet" to "35 feet." Smoke can travel ten feet in an instant, endangering those who are coming and going, especially those on oxygen and with asthma.

Thank you very much for your time and consideration of my testimony.

Respectfully submitted,

Susan E. Myre, RN, MS