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Before the U.S. House of Representatives Committee on Oversight and Reform Subcommittee on Economic and Consumer Policy Don't Vape: Examining the Outbreak of Lung Disease and CDC's Urgent Warning Not to Use E-Cigarettes

September 24, 2019

Mr. Chairman and Members of the Committee:

Thank you for the opportunity to testify. My name is Dr. Albert Rizzo and I am the chief medical officer of the American Lung Association. I am also a practicing pulmonary physician in Delaware. I am privileged to be here and to speak to the dangers of e-cigarette use, especially to the lungs.

For more than a decade, the American Lung Association has been raising the alarm about ecigarettes and their use. The Lung Association will continue to reiterate our recommendation that the public not use any tobacco product, including e-cigarettes. All tobacco products – including ecigarettes – can harm health. The American Lung Association also believes there is no public health benefit to e-cigarettes.

As a pulmonologist, I have seen many patients over the years who present with an acute respiratory illness – similar to what most patients who are afflicted from this pulmonary vaping illness are suffering from. Many patients with acute respiratory illness will need oxygen. Some of them must be intubated. It is particularly distressing and extremely worrisome when due to this vaping illness this is happening in mainly otherwise healthy and relatively young individuals especially when we are without an explanation as to the cause. This is something pulmonary critical care physicians are experiencing across the country right now.

Our nation is currently in the midst of two different e-cigarette crises. One is the ongoing youth ecigarette epidemic and the high prevalence of youth use of e-cigarettes. The second is the outbreak of pulmonary illnesses among both adults and youth attributed to vaping.

Youth E-cigarette Epidemic

The American Lung Association is extremely troubled about the rapid increase of youth using these products. According to the 2019 National Tobacco Youth Survey, 27.5 percent of youth are now using e-cigarettes – up from 20.8 percent in 2018. That is a 32 percent increase from 2018 and a 135 percent increase from 2017.¹

E-cigarettes are the most commonly used tobacco product among youth. According to a 2018 CDC study, the primary reasons teenagers use these products are because the candy and fruit flavors are appealing to them, their friends and family are using them, and they think e-cigarettes are less harmful.²

The high use of flavored e-cigarette among youth is alarming and requires urgent and immediate action. The American Lung Association commends the Trump Administration's announcement that FDA will remove all non-tobacco flavored e-cigarettes from the marketplace. We believe this is a vital and positive step to address the youth e-cigarette epidemic and we urge FDA and the Congress to act to remove all flavored tobacco products from the market, including flavored cigars and menthol cigarettes.

The National Youth Tobacco Survey also reflects how much youth are using e-cigarettes – and just how addicted they are. The survey also asked students if they had vaped on at least 20 days within the last 30 days; 12 percent of 12th graders, seven percent of 10th graders and two percent of 8th graders indicated they vaped that frequently. These numbers are astonishing and underscore the American Lung Association's grave concern that we are at risk of losing another generation to tobacco-caused diseases as the result of e-cigarettes.

There is a great deal of misinformation surrounding the health hazards of e-cigarettes, which have contributed in part to the high e-cigarette use among youth. In January 2018, the National Academies of Science, Engineering and Medicine released a consensus study report that reviewed over 800 different studies.³ That report made clear: using e-cigarettes causes health risks, increases the chance that children and youth will start to use combustible tobacco products and exposes others to dangerous secondhand e-cigarette emissions. They have concluded that there is "substantial evidence" that if a youth or young adult uses an e-cigarette, they are at increased risk of using traditional cigarettes.

This is supported by a study published in the journal *Pediatrics* that found that youth who use ecigarettes were over four times more likely to try a traditional cigarette than youth who did not use e-cigarettes. Youth using e-cigarettes were over three times more likely to become frequent smokers.⁴

Pulmonary Disease Outbreak

The current cluster of pulmonary illnesses is the second public health crisis related to vaping. CDC and state and local health departments are conducting an ongoing investigation of the pulmonary related illnesses due to vaping. As of September 19, there have been seven confirmed vaping-related deaths in six states and 530 reported cases of vaping-related illnesses across 38 states and one territory. No one cause has yet been determined, and the investigation remains ongoing. What we do know is that people – including youth and young adults – are being treated and in a number of cases, hospitalized and intubated with severe lung disease caused by vaping.

Like the youth e-cigarette epidemic, this crisis is also caused by the failure of two different administrations to fully implement the Tobacco Control Act and protect the public health.

What We Don't Know: The Long-Term Health Effects of E-Cigarettes

E-cigarettes are tobacco products. While the FDA now has authority over e-cigarettes, it is only now about to require manufacturers to submit their products for pre-market review. This delay has left unregulated products with unknown chemicals that are being inhaled into the lungs on the market.

Former CDC Director Thomas Frieden said, "Tobacco products are guilty until proven innocent."⁵ Unfortunately, for too long, the lack of oversight and regulation under the guise that e-cigarettes were a cessation product has left us with two different public health crises. Moreover, we do not know the mid-to long-term consequences that may be caused by the use of e-cigarettes. However, there are several questions that must be asked:

- 1. Do e-cigarettes cause cancer? Some of the chemicals found in some e-cigarettes are carcinogenic. Will use of e-cigarettes cause cancer?
- 2. Will the inhalation of the chemicals in e-cigarettes cause chronic obstructive pulmonary disease (COPD) or another lung disease in users?
- 3. How do e-cigarettes impact people with asthma?
- 4. And the latest question that we are just beginning to consider is what, if any, will be the long-term health consequences to those who have been hospitalized as a result of pulmonary vaping outbreak?

There is so much that remains to be determined about the lasting health consequences of ecigarettes. In 1964, the Surgeon General released the first report on the health hazards of smoking, concluding that smoking cigarettes caused lung cancer. Fifty years later, the Surgeon General's report in 2014 concluded that smoking was a causal factor in liver and colorectal cancers, as well as that smoking causes diabetes mellitus, rheumatoid arthritis and immune system weakness, increased risk for tuberculosis disease and death, ectopic (tubal) pregnancy and impaired fertility, cleft lip and cleft palates in babies of women who smoke during early pregnancy, erectile dysfunction, and age-related macular degeneration.⁶ It is hard to predict the possible health consequences we will see in 50 years as the result of e-cigarettes but what I can say right now is that we are very troubled by what we see so far.

What We Do Know: E-Cigarettes Contain Dangerous Chemicals

No e-cigarette has currently undergone a premarket review. FDA has also not issued any product standards for e-cigarettes, which means e-cigarette composition and effects vary. As a result of the lack of FDA oversight, we do not know what is in each individual product – including the levels of nicotine.

Almost all e-cigarettes contain nicotine.⁷ Nicotine is not benign: in addition to it being extremely addictive it can cause an increase in blood pressure, heart rate and blood flow, and may also lead to the hardening of arterial walls.⁸ According to CDC, nicotine use among youth and young adults can alter brain development and cause memory and learning problems.⁹ In addition, it may prime the brain for addictions to other drugs including cocaine and methamphetamines.¹⁰

The inhalation of these harmful chemicals can cause irreversible lung damage and lung diseases, as well as cardiovascular disease. A study from the University of North Carolina found that even in small doses, inhaling the two primary ingredients found in e-cigarettes – propylene glycol and vegetable glycerin – is likely to expose users to a high level of toxins, and that the more ingredients a user is inhaling, the greater the toxicity.¹¹

Research also shows that e-cigarettes may contain dangerous chemicals including diacetyl (which can cause a dangerous lung disease often referred to as "popcorn lung"), acrolein (which causes irreversible lung disease) and formaldehyde, a carcinogen or substance known to cause cancer.¹²

Flavors in E-Cigarettes Contain Chemicals

The American Lung Association has long advocated for the removal of flavored tobacco products from the market, as flavors have been shown to initiate kids to tobacco use and a lifetime of addiction and tobacco-related death and disease. According to a 2015 study published in the

Journal of the American Medical Association, 81 percent of youth who have ever used tobacco products initiated with a flavored product.¹³ Fruit and mint and menthol are the most popular flavors among high school students using e-cigarettes, with 65.9 percent of kids using fruit-flavored e-cigarettes and 63.9 percent using mint or menthol e-cigarette flavors.¹⁴

Flavors in e-cigarettes are created through the combination of chemicals that pose a risk for severe lung damage. A 2015 study conducted at the Harvard T.H. Chan School of Public Health published in Environmental Health Perspective tested 51 different flavored e-cigarettes – including many flavors researchers believed would appeal to kids, such as cotton candy, bubble gum and cupcake. They found at least one chemical associated with respiratory disease was found in 47 of those 51 flavors tested. The chemicals they found included diacetyl, acetoin and 2,3-pentanedione.¹⁵

E-Cigarettes Are Not a Cessation Product

The American Lung Association believes <u>every smoker can quit</u> all tobacco products – including ecigarettes. The Lung Association does <u>not</u> accept the idea that a certain percentage of tobacco users can't quit – only that access to those evidence-based and proven-effective treatments, including a combination of behavior modification counseling plus pharmacotherapy, have not reached underserved individuals nor have they been implemented in repeated manners, since we know many smokers may take up to 10-11 quit attempts before being successful.

Switching is Not Quitting

It is important to note that switching to e-cigarettes does not mean quitting. Quitting means ending your addiction to nicotine, which can be very difficult. I have had several patients who have switched to e-cigarettes believing they had quit. I have had to have tough conversations with them explaining that they had neither actually quit but instead have switched to another harmful product.

Another problem with switching to e-cigarettes that I have seen and that studies have found is that many people become dual users. More than half of all adult e-cigarette users continue to use traditional cigarettes.¹⁶ This is troublesome because it suggests that e-cigarette use is not replacing smoking, as e-cigarette companies claim, but instead supplementing smoking. Dual use is not an effective way to safeguard your health. Smoking even a few cigarettes a day can be dangerous so quitting smoking is the single best step a smoker can take to improve the length and quality of their life.¹⁷

Unfortunately, unproven health claims made by e-cigarette manufacturers and their supporters from the time these products were first introduced to the market in 2009 led many smokers who are desperate to end their addiction attempt to use e-cigarettes to quit smoking. This was deliberate: several e-cigarette companies, including JUUL, have made unsubstantiated cessation claims.¹⁸ However, no e-cigarette has been found by the FDA's Center for Drug Evaluation and Research to be safe and effective in helping smokers quit.

Instead, the data shows that smokers who try to use e-cigarettes either continue to smoke cigarettes, switch to using e-cigarettes or both. None of those is quitting. Indeed, a study published in the Annals of Internal Medicine found that smokers who used e-cigarettes to help them quit smoking were less likely to quit than those who did not use e-cigarettes. Only 10.1 percent of the smokers who used e-cigarettes had quit smoking after six months compared to 26.6 percent of smokers who did not use e-cigarettes.¹⁹

The New England Journal of Medicine published a study in January 2019 that compared e-cigarettes to NRT gum in terms of efficacy for smoking cessation. In this study, over 90 percent of smokers prescribed nicotine replacement therapy (NRT) **quit smoking** – ending their nicotine addiction entirely. In contrast, 80 percent of the smokers given e-cigarettes did not quit but switched and instead became addicted to e-cigarettes. This puts them at potential risk for other serious health harms, continued addiction and return to conventional cigarettes.²⁰

The American Lung Association believes everyone who uses tobacco products can quit using methods that are proven safe and effective by the FDA, including the seven FDA-approved medications and individual, phone, and group counseling.

Conclusion

In conclusion, e-cigarettes are not safe. They are responsible for the possible loss of another generation of American youth to tobacco use, death and disease. In addition to the high youth prevalence, we do not know the cause of the current outbreak that threatens the health and lives of hundreds and possibly thousands of Americans. The American Lung Association supports President Trump's call to "clear the markets" of flavored e-cigarettes.

E-cigarettes are not a tobacco cessation product. No e-cigarette has been found by the Food and Drug Administration to help smokers quit and end their addiction to nicotine.

It is my profound hope that another generation is not lost to tobacco use and that we do not see even more death and disease caused by vaping and e-cigarette use.

Thank you for the opportunity to testify today and I'm happy to take any questions.

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² Tsai, James, Kimp Walton, Blair N Coleman, Saida R Sharapova, Sarah E Johnson, Sara M Kennedy, and Ralph S Caraballo. "Reasons for Electronic Cigarette Use Among Middle and High School Students - National Youth Tobacco Survey, United States, 2016." *Morbidity and Mortality Weekly Report*. Centers for Disease Control and Prevention, February 16, 2018.

³ The National Academies of Sciences, Engineering, and Medicine "Public Health Consequences of E-Cigarettes – Conclusions by Level of Evidence." The National Academies of Sciences, Engineering, and Medicine, January, 2018 ⁴ Barrington-Timis, Jessica L, Grace Kong, Adam M. Leventhal, Feifei Liu, Margaret Mayer, Tess Boley Cruz, Suchitra Krishnan-Sarin, et al. "E-cigarette Use and Subsequent Smoking Frequency Among Adolescents." *Pediatrics* 142, no. 6 (December 2018).

⁵ "Smoking to kill 5.6 million US kids if not stubbed out: report." www.reuters.com, January 17, 2014. <u>https://www.reuters.com/article/us-usa-smoking-report/smoking-to-kill-5-6-million-us-kids-if-not-stubbed-out-report-idUSBREA0G07C20140117</u>

⁶ U.S. Department of Health and Human Services. "Health Consequences of Smoking, Surgeon General fact sheet." HHS.gov. U.S. Department of Health and Human Services, January 14, 2014

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⁸ "How Smoking and Nicotine Damage Your Body." www.heart.org, February 17, 2015.

https://www.heart.org/en/healthy-living/healthy-lifestyle/quit-smoking-tobacco/how-smoking-and-nicotine-damage-your-body.

⁹ U.S. Department of Health and Human Services. "E-Cigarette Use Among Youth and Young Adults." HHS.gov. U.S. Department of Health and Human Services, January 1, 2017

¹⁰ U.S. Department of Health and Human Services. "E-Cigarette Use Among Youth and Young Adults." HHS.gov. U.S. Department of Health and Human Services, January 1, 2017

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 ¹² Sleiman, Mohamad, Jennifer M Logue, V Nahuel Montesinos, Marion L Russell, Marta I Litter, Lara A Gundel, and Hugo Destaillats. "Emissions from Electronic Cigarettes: Key Parameters Affecting the Release of Harmful Chemicals." *Environmental Science & Technology* 50, no. 17 (September 6, 2016): 9644-51. <u>https://doi.org/10.1021/acs.est.6b01741</u>.
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