

Senate Committee on Health, Education, Labor and Pensions

Examining the Response to Lung Illnesses and Rising Youth Electronic Cigarette Use

10:00 am, 430 Dirksen Senate Office Building

Purpose

The purpose of this hearing is to shine a spotlight on steps taken by the FDA and CDC to respond to the youth vaping epidemic, and identify areas for improvement.

Members Present

Chairman Alexander, Ranking member Murray, Senator Paul, Enzi, Hassan, Burr, Baldwin, Kaine, Collins, Smith, Murkowski, Rosen, Cassidy, Romney

Witnesses

Mitch Zeller., Director, Center for Tobacco Products, US Food and Drug Administration

Anne Schuchat, MD., Principal Deputy Director, Centers for Disease Control and Prevention

Opening Statements

Chairman Alexander said that as many as 1 in 4 high school students nationwide use e-cigarettes. Furthermore, most of these students are purchasing the product illegally. It is expected that when consumers purchase aspirin, the FDA has approved the item. It is also expected that when consumers purchase an e-cigarette, the FD has also approved that product, however that is not true. Not a single e-cigarette has been reviewed and approved for sale by the FDA. There have been far too many vaping related injuries and deaths over the last six months. It also remains true that a large portion of these injuries are associated with vaping THC products rather than nicotine products. It is crucial that the FDA creates and finalizes rules for the manufacturing of e-cigarettes.

Ranking member Murray said that so many people across the nation are concerned with youth vaping and vaping related illnesses. These problems were created by large tobacco companies who use predatory marketing tactics to appeal to youth consumers. While the rest of the nation is treating this like a public health crisis, tobacco companies are treating it like a business. They are purposefully misleading consumers and avoiding all accountability. It remains true that this administration is putting tobacco companies' profits ahead children's health. The lack of oversight has allowed this unregulated market to grow and effect more individuals every day. It is time to get serious about lowering the rate of nicotine consumption among the nation's youth.

Testimony

Mr. Zeller said that the FDA takes this epidemic very seriously. FDAs initial attempt to regulate e-cigarettes dates back to before the current epidemic. However, FDAs actions were challenged and overturned in court. Since then the FDA has continued to educate the public on the harms of nicotine addiction and exercise any oversight authority possible. It is important to recognize that no e-cigarette product is on the market legally because none of them have obtained a marketing authorization from the FDA. The FDA is committed to doing everything that it can to prevent youth tobacco usage. Furthermore, the FDA is

especially concerned with the increase of lung injuries associated with vaping. FDA labs are currently analyzing samples of vaping products linked to lung injuries. A number of these products have similar ingredients that may be contributing to injury.

Dr. Schuchat said that the CDC has been working tirelessly to get to the bottom of the vaping epidemic. They rely on public health data to understand the scope of the problem and analyze trends in overall usage. However, the data collection method needs to be updated with modern technology and run by a trained full time staff. Currently the CDC recommends that consumers immediately stop vaping products with THC and consider stopping vaping entirely. While it is true that there is some commonality among vaping products associated with lung injuries, it is also true that there is no one ingredient found in all of them that can be identified as a the source of injuries. A report from the CDC found that most youth e-cigarette users obtain the product from a friend or a class mate. It is also true that children are far more likely than adults to use e-cigarettes. The CDC is working hard to trace back products purchased on the black market.

Questions and Answer

Chairman Alexander asked if CDCs advice is to refrain from using e-cigarette products. **Dr. Schuchat** said that CDCs official recommendation is to immediately stop vaping THC products and to consider stopping vaping all together. **Chairman Alexander** asked if consumers should listen to the CDC or the FDA. **Mr. Zeller** said that the FDAs recommendations are consistent with the CDC. **Chairman Alexander** asked how much of the 5 billion dollars collected from tobacco companies in prior years have gone towards addressing youth vaping. **Mr. Zeller** said about 150 million dollars.

Ranking member Murray asked why Mr. Zeller made no mention of the proposed rule to ban all flavors other than tobacco from the market. **Mr. Zeller** said that that question should be directed to the White House. **Ranking member Murray** asked if Mr. Zeller supports the ban on all flavors. **Mr. Zeller** said he can only comment on the ongoing process by the FDA. **Sen. Murray** asked if bans on flavors should include mint and menthol flavors. **Dr. Schuchat** said yes. But CDC also expects consumers to switch to whatever flavor is left. **Ranking member Murray** asked if the current epidemic could have been avoided if the FDA required premarket authorization. **Mr. Zeller** said that that is a more complicated question than it seems. These products would have likely stayed on the market.

Sen. Enzi asked if MR. Zeller can commit to issuing a new report by FDA as soon as possible. **Mr. Zeller** said yes. **Sen. Enzi** asked why the FDA is trying to highlight the association between smoking and less known health outcomes. **Mr. Zeller** said that the FDA took previous legal outcomes into consideration and published a final rule to help educate the public on the lesser known health outcomes associated with smoking. These outcomes are very serious and the public has a right to this information.

Sen. Hassan asked if MR. Zeller was aware of any policy related discussions between JUUL and FDA. **Mr. Zeller** said no. **Sen. Hassan** asked how the FDA can make sure that tobacco

companies do not exploit loopholes to sell mint and menthol flavors under a different name. **Mr. Zeller** said that it is hard to get into a policy discussion while the FDA is still in the drafting process of such policies. **Sen. Hassan** asked if FDA will require JUUL to submit their user data inclusive of youth users as opposed to simple purchaser data. **Mr. Zeller** said FDA has an ongoing investigation of JUUL and those results will be available soon.

Sen. Burr asked what additional information CDC needs to make a determination of the cause of lung illnesses. **Dr. Schuchat** said that the CDC has found some common links but there could be many other contaminants causing issues as well. **Sen. Burr** asked if the FDA has investigated vape shops. **Mr. Zeller** said yes.

Sen. Baldwin asked what is currently known about the long term impact of lung injuries associated with vaping. **Dr. Schuchat** said that some individuals will have very long term damages but the extent of the damages is unknown. **Sen. Baldwin** asked why the FDA failed to issue specific marketing guidance to E-cigarette manufacturers when they first entered the market. **Mr. Zeller** said that at the time, FDA did not have the authority to do so.

Sen. Kaine asked if it is still the Trump administrations intent to clear the market of flavored e-cigarette products. **Mr. Zeller** said he cannot answer this questions. **Sen. Kaine** asked is Mr. Zeller knew the answer to his question. **Mr. Zeller** said there is no final answer. **Sen. Kaine** asked if raising the minimum purchasing age for all tobacco products would have a positive public health impact. **Dr. Schuchat** said yes.

Sen. Collins asked if it is true that teens who use e-cigarettes are more likely to smoke cigarettes compared to those who do not. **Mr. Zeller** said yes. This problem is a public health balancing act. **Sen. Collins** asked why the FDA is exercising discretion in allowing these products to be on the market. **Mr. Zeller** said that when there is a final policy, the FDA will use its enforcement discretion that is in line with the policy. **Sen. Collins** asked if banning refillable e-cigarettes would help. **Mr. Zeller** said that may be something the FDA does soon but for now they are not focused on that.

Sen. Smith asked what tools the FDA and CDC have to help teen users quite. **Dr. Schuchat** said there is currently no approved smoking cessation therapy or device for youth users. The best course forward is to focus aggressively on prevention. **Mr. Zeller** said the FDA is spending a lot of money on paid advertisement to spread the word on how dangerous vaping is. Additionally, more needs to be done to develop techniques to help teens quit using nicotine. **Sen. Smith** asked why teens think vaping is safe. **Mr. Zeller** said it is a mind set and word of mouth. **Dr. Schuchat** said there has been a lot of under the radar marketing techniques used.

Sen. Murkowski asked if ultimately research indicates that nicotine is not directly related to the lung injuries associated with vaping, should restrictions on e-cigarette products continue to be pursued. **Dr. Schuchat** said yes. **Mr. Zeller** said yes. Lung injuries and nicotine addiction are two separate issues. **Sen. Murkowski** asked if the CDC is providing

information to state regulatory bodies for testing compounds of concern. **Dr. Schuchat** said yes.

Sen. Rosen asked if second hand vaping is a problem. **Dr. Schuchat** said that there are many carcinogenic materials in vaping products. There is a lot more that needs to be learned about second hand vaping. **Sen. Rosen** asked if it is possible to extrapolate results from cigarette second hand smoke studies. **Dr. Schuchat** said that some aspects can be extrapolated but they are very different. **Mr. Zeller** said that this is a large area of research for the FDA.

Sen. Cassidy asked if it is necessary to do research to tell people that heating up oil and smoking it is dangerous. **Dr. Schuchat** said that yes, only because it could help to understand other unanswered questions. **Sen. Cassidy** asked if it is beneficial if a user switches to an e-cigarette and reduces but does not stop smoking traditional cigarettes. **Mr. Zeller** said that the FDA's official recommendation is to make the complete switch.

Sen. Kaine asked if research suggests that e-cigarettes encourage cessation. **Dr. Schuchat** said that the research is mixed and incomplete. **Sen. Kaine** asked if nicotine salts make products more attractive to consumers. **Dr. Schuchat** said yes. **Sen. Kaine** asked why better public health data is crucial to combatting this problem. **Dr. Schuchat** said that it allows public health officials to be more streamlined, efficient and accurate.

Sen. Romney asked how we got to where we are. **Mr. Zeller** said it is a mix of industry behavior, lack of oversight authority, and the belief that these products are harmless. **Dr. Schuchat** said that we got here due to advertising, flavors and the evolution of nicotine.

Sen. Baldwin asked what percentage of youth users will become addicted to vaping nicotine. **Dr. Schuchat** said it is unknown. **Mr. Zeller** said it is clear that these users are on the path to addiction.