House Energy and Commerce Committee, Oversight and Investigations Subcommittee

Vaping in America: E-Cigarette Manufacturers' Impact on Public Health

February 5, 2020

10:30 AM, 2123 Rayburn House Office Building

Purpose

The purpose of the hearing is to examine the role of manufacturers in the marketing and use of e-cigarettes in the United States and the public health implications.

Members Present

Chairwoman DeGette, Ranking Member Guthrie, Chairman Pallone, Ranking Member Walden, Representatives McKinley, Schakowsky, Duncan, Kennedy, Griffith, Castor, Kuster, Ruiz, Clarke, and Tonko

Witnesses

Mr. Crosthwaite, CEO, JUUL Labs, Inc.
Mr. Oberlander, President & CEO, Reynolds American Inc.
Mr. Nivakoff, CEO, NJOY, LLC
Mr. Blonde, President, Fontem U. S.
Mr. Loftin, President, Logic Technology Development, LLC

Opening Statements

Chairwoman DeGette said our nation faces a youth vaping epidemic. More than 5 million young people reported using e-cigarettes. 1 in 4 high school students are using e-cigarettes but a group of high school students believed it was even more than that. One sophomore thinks that more than 60% of his peers are vaping. According to the CDC, all users are at risk but especially young people. E-cigarette manufacturers have been negligent in marketing tactics. The FDA gave this industry a "temporary pass" which is why these products are even allowed currently. In December, this committee raised the age requirement to 21+ rather than 18+. FDA announced that there would be restrictions yet there are loopholes and it has been ineffective. Majority of adult users are using both – e-cigarettes and combustible cigarettes. The question is for every adult smoker who may quit smoking because they are using an e-cigarette, how many young people are going to start using e-cigarettes and develop lifelong illnesses. Thank you manufacturers for being here.

Ranking Member Guthrie said he shares the concerns Chairwoman just expressed. The most recent data shows that the market has only increased despite the FDA restrictions and conversations. In December, legislation stated that users now had to be 21+. Starting tomorrow, companies must cease the production and distribution of unauthorized flavors of e-cigarette. This guidance gives the FDA to pivot its enforcement parties as needed. He is looking forward to hearing from the witnesses because there may be better solutions. FDA must consider the public health implications of users and non-users as a whole when moving forward. Pre-market applications must be submitted to the FDA by May by manufacturers. According to the CDC, there have been lung illnesses that have been directly

caused by these products. Congress must do more to ensure the safety of our youth and the overall population.

Chairman Pallone said 6.2 million middle school and high school students reported use of these e-cigarette products. Federal regulators are to share the blame with manufacturers. The FDA needs to move forward with reviewing the current products on the market. Manufacturers need to acknowledge the responsibility they have in this. The flavor ban is not a flavor ban at all because there are loopholes. He is proposing legislation called The Reversing Youth Tobacco Epidemic soon – a flavor ban and protects the youth from predatory sale situations. A few years ago, he went around to middle schools and they were unaware of the harms of e-cigarettes. His opinion is that it is the misleading marketing that has led us to this youth use epidemic.

Ranking Member Walden said these are huge concerns in the vaping industry. The CDC has reported that the use rates have been climbing and that there are links between use and death and/or illnesses. He applauds the Trump Administration for taking action by raising the age requirement to 21+ in December. The FDA issues a guidance policy in January. The May deadline for manufacturers is approaching soon and that will shift the market even more. He noted the irony of the HELP Subcommittee holding a hearing on descheduling marijuana – also smoking related. He thinks that consistency with all of these kinds of products will protect the youth of this nation best. He said that Congress would benefit if the FDA was asked to testify after the May deadline for PMTAs. Investigations for black-market products is also necessary. Congress wants to make sure that the FDA is prepared to review these products and do their part in this epidemic.

Testimony

Mr. Crosthwaite said there have been significant changes in the vapor category in the short period of time. The start of 2019, most Americans lived in states where the legal age of purchase was just 18. Vapor products were available in a wide array of flavors. There was low awareness of black-market vapor products. And the deadline for PMTA submissions to the FDA was uncertain. Today, there is a 21+ age requirement. Under FDA guidance, pod-based products are now available in only Tobacco and Menthol, flavors that can be found in currently available cigarettes. Congress, the FDA and the President have raised the alarm on black-market products. And the PMTA deadline of May 2020 is rapidly approaching. A comprehensive review was directed which resulted in a halt in advertisement. Restructure of the company to allocate resources to technologies that targeted the underage usage is a priority. There is still a long way to go - more than 34 million Americans still smoke. Each year, nearly half a million Americans die from smoking-related diseases – 1 person every minute. The economic costs exceed $300 billion. To be clear, people should not start to smoke but those who cannot quit should be able to use less harmful vapor products. His company is working hard to focus on adults who are combatting combustible cigarette use while also protecting the youth.

Mr. Oberlander said Reynolds set a goal to transform the tobacco market through innovative products that could make tobacco harm reduction a reality for adult smokers.

Doing so, requires them to provide consumer-acceptable products that may present less risk, including products in the vapor category. They have focused on both innovation and responsibility, because the two must not be separated. The way Reynolds brings innovative products to market, and how they market those products, are as important as the products themselves. Their vapor brand is VUSE. And their consumer demographics confirm our focus on adults: 95% of VUSE consumers are over 25, and 70% are over 35. The increase in youth vaping over the past two years, and serious health issues from illicit products, are now at the heart of a national discussion. Products can be manufactures and marketed responsibly. Some important components that need to be considered are as follows. Transparency in the PMTA process is critical. FDA needs to adopt regulations that expedite innovations. FDA should consider adopting more warnings. And continuing the youth prevention program. They believe that the PMTA process will be beneficial.

Mr. Nivakoff said that the combustible cigarette has personally affected him because of the loss of family members. His focus is to help smoking adults find an alternative. NJOY has made it a mission to ensure that their products to not fall into the hands of America's youth. There are approximately 34 million Americans who still smoke combustible cigarettes, and over a billion people worldwide. These smokers face a greater than 50% chance of premature death if they continue to smoke—and each year nearly 500,000 Americans die prematurely from smoking-related disease. Switching adult smokers from combustible cigarettes to electronic cigarettes has the potential to save millions of lives and trillions of dollars in preventable healthcare expenses. He provided statistics on how NJOY has not played a major role in the youth use that was previously discussed. But he does recognize the public health issue and is willing to work towards a solution.

Mr. Blonde said Fontem has cooperated extensively with the Committee's investigation since it began last August and provided materials in response to the Committee's request. He believes Fontem is a responsible actor in the e-cigarette marketplace. Fontem has invested significant resources to ensure that its products are designed for and responsibly advertised to adult consumers only. They use industry-standard online age-gating and age-verification mechanisms to prevent youth access to its products online. They are also committed to youth access prevention. Investment in the product stewardship program has been extensive. Fontem's products have not been found by the CDC to be involved in any of the incidences for respiratory illness it has investigated.

Mr. Loftin said Logic believes that youth should never have access to any tobacco products or Electronic Nicotine Delivery Systems (ENDS). The business practices of some have caused tremendous damage to the reputation of this important category. Logic believes that a proper balance can be struck between offering adult smokers suitable options and restricting youth access. The FDA should enforce premarket authorizations for all ENDS products and take actions against companies that do not comply for those regulations. He said that flavor bans are not the solution but reframing marketing techniques is. This is an ongoing process but flavor bans would be counterproductive when getting adults to switch to e-cigarettes.

Questions and Answers

Chairwoman DeGette asked if it was true that nicotine is addictive and if their products could lead to addiction. **Mr. Crosthwaite, Mr. Oberlander, Mr. Nivakoff, Mr. Blonde** and **Mr. Loftin** said yes. **Chairwoman DeGette** asked if the witnesses agree with the medical studies that state that nicotine use can have negative consequences on respiratory health and brain development. **Mr. Crosthwaite** said that the research will be submitted during the PMTA process. **Chairwoman DeGette** asked if the witnesses agree with the CDC when they stated that there is no completely safe tobacco products including e-cigarettes. **Mr. Crosthwaite, Mr. Oberlander, Mr. Nivakoff, Mr. Blonde** and **Mr. Loftin** said yes. **Chairwoman DeGette** asked if they agreed that individuals under the age of 21 should not be using these products, including their companies' products. **Mr. Crosthwaite, Mr. Oberlander, Mr. Nivakoff, Mr. Blonde** and **Mr. Loftin** said yes.

Ranking Member Guthrie asked if it is correct that the FDA can currently remove products that enter the market after August 8th. **Mr. Nivakoff** and **Mr. Blonde** said yes. **Ranking Member Guthrie** asked under the January enforcement guidance, what actions the FDA can take if the manufacturers fail to keep disposable away products from minors. **Mr. Nivakoff** said that there are three prongs in the guidance and that the FDA can sweep the market of these. **Mr. Blonde** said his company uses a youth access prevention program. **Ranking Member Guthrie** asked how their companies monitor the youth accessibility issue. **Mr. Crosthwaite** said his company halted marketing tactics that were appealing to the youth population. **Mr. Loftin** said the controls his company has in place reflect the fact that the marketing is not intended for the youth.

Chairman Pallone asked if at the time JUUL used marketing tactics that were used on social media platforms, if controls were used to prevent targeting youth. **Mr. Crosthwaite** said it was before his time. **Chairman Pallone** asked what the tipping point that led JUUL to believe that their marketing tactics were targeting youth. **Mr. Crosthwaite** said that the company stopped sharing social media marketing in 2018. **Chairman Pallone** asked if JUUL's actions were too late. **Mr. Crosthwaite** said he has been proactive since he joined the company and cannot speak to the history of the company.

Rep. McKinley asked about the particles in the fluids that has been reported in this products. **Mr. Crosthwaite** said he is not familiar. **Rep. McKinley** asked if any of the companies are preventing the after-market production tampering. **Mr. Loftin** said that his companies has sealed products.

Rep. Schakowsky asked if the Trump Administration's exemption of certain disposable products will allow these products to be easily accessible. **Mr. Loftin** said that his company was disappointed by the Administration's decisions and that all products should go through the PMTA approval process. **Rep. Schakowsky** asked if NJOY's decision to stop selling all flavored, disposable products would introduce risk for youth to get it from elsewhere. **Mr. Nivakoff** said their data does not reflect high rates of youth use to begin with.

Rep. Duncan asked how the companies are working with CBP agents to combat the distribution of black-market products. **Mr. Crosthwaite** said there are a lot of illicit drugs. And that his company has a brand protection program to help with this.

Rep. Kennedy asked if these witnesses can pledge not to acquire a company that does not abide by the practices that these companies say they abide by. **Mr. Crosthwaite, Mr. Oberlander, Mr. Nivakoff, Mr. Blonde** and **Mr. Loftin** said yes. **Rep. Kennedy** asked what these witness want Congress to do because there is a younger generation that is already addicted. **Mr. Crosthwaite** said to continue to do what has been done.

Rep. Griffith asked if Vitamin E is used in any of the cartridges currently. **Mr. Crosthwaite, Mr. Oberlander, Mr. Nivakoff, Mr. Blonde** and **Mr. Loftin** said no. **Rep. Griffith** asked their products are designed to be tampered with. **Mr. Crosthwaite, Mr. Oberlander, Mr. Nivakoff, Mr. Blonde** and **Mr. Loftin** said no. **Rep. Griffith** asked about the zero nicotine products. **Mr. Blonde** said that it is merely for smokers who are laying off of the smoking and using it to adapt.

Rep. Castor asked why Fontem actively uses social media influencers which directly affects the youth. **Mr. Blonde** said that they have currently stopped producing any content. **Rep. Castor** asked all other witnesses if their companies use social influencers. **Mr. Crosthwaite, Mr. Oberlander, Mr. Nivakoff,** and **Mr. Loftin** said no.

Rep. Kuster asked Mr. Crosthwaite was aware of reports stating that youth were turning to combustible cigarettes to end their e-cigarette addiction. **Mr. Crosthwaite** said that his company took action.

Ranking Member Walden asked what concerns each of these witnesses have about counterfeit products. **Mr. Crosthwaite** and **Mr. Loftin** said that they have recognized counterfeit products. **Mr. Oberlander, Mr. Nivakoff,** and **Mr. Blonde** said they have not seen the counterfeit products of their specific companies. **Ranking Member Walden** asked what kind of transparency needs to be provided to retail store owners about what products are permitted versus not. **Mr. Crosthwaite** said that they are willing to comply with the steps that are outlined PMTA. **Mr. Oberlander** said that the FDA should make this publically available after the PMTA process so that everyone is on the same page.

Rep. Ruiz asked about the marketing tactics that are driving youth sales. **Mr. Loftin** said that it's all about the atmosphere about having fun and the irresponsibility of marketing from companies. **Rep. Ruiz** asked about Fontem's flash sale on the specific flavors that the FDA banned. **Mr. Blonde** said that this sale was directed to other consumers.

Rep. Clarke asked if youth e-cigarette use is a national health threat. **Mr. Nivakoff** said yes. **Rep. Clarke** asked which products intentionally target young people. **Mr. Loftin** said he will not speak about other companies, but again irresponsibility of marketing. **Rep. Clarke** asked why so many young people are drawn to JUUL products. **Mr. Crosthwaite** said that it

was an unintended consequences of helping the older population to switch from combustible cigarettes.

Rep. Tonko asked the rate of youth being affected America is willing to tolerate. **Mr. Crosthwaite** said that the rates are currently unacceptable. **Rep. Tonko** asked if the increasing youth use was the reason he removed mint flavor from his company. **Mr. Crosthwaite** said yes. **Rep. Tonko** asked if menthol will become the new mint. **Mr. Crosthwaite** said that the FDA and JUUL are going to monitor this.

Rep. Guthrie asked if it would be helpful if the FDA finalizes their regulations before May, and what setback it would cause if not. **Mr. Crosthwaite** said that a final regulation would be helpful. **Mr. Oberlander** said that it would be helpful. **Mr. Nivakoff** said the current regulations are sufficient.