

PRELIMINARY TRANSCRIPT

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6 VAPING IN AMERICA: E-CIGARETTE

7 MANUFACTURERS' IMPACT ON PUBLIC HEALTH

8 WEDNESDAY, FEBRUARY 5, 2020

9 House of Representatives,

10 Subcommittee on Oversight and Investigations,

11 Committee on Energy and Commerce,

12 Washington, D.C.

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16 The subcommittee met, pursuant to call, at 10:30 a.m., in  
17 Room 2123, Rayburn House Office Building, Hon. Diana DeGette  
18 [chairwoman of the subcommittee] presiding.

19 Members present: Representatives DeGette, Schakowsky,  
20 Kennedy, Ruiz, Kuster, Castor, Sarbanes, Tonko, Clarke, Pallone  
21 (ex officio), Guthrie, McKinley, Griffith, Brooks, Duncan, and  
22 Walden (ex officio).

23 Also present: Representative Shalala.

24 Staff present: Kevin Barstow, Chief Oversight Counsel;  
25 Jesseca Boyer, Professional Staff Member; Jeff Carroll, Staff

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26 Director; Manmeet Dhindsa, Counsel; Austin Flack, Staff  
27 Assistant; Waverly Gordon, Deputy Chief Counsel; Tiffany  
28 Guarascio, Deputy Staff Director; Judy Harvey, Counsel; Zach  
29 Kahan, Outreach and Member Service Coordinator; Chris Knauer,  
30 Oversight Staff Director; Joe Orlando, Staff Assistant; Kaitlyn  
31 Peel, Digital Director; Peter Rechter, Counsel; Alivia Roberts,  
32 Press Assistant; Tim Robinson, Chief Counsel; Emily Ryan, GAO  
33 Detailee; Benjamin Tabor, Staff Assistant; C.J. Young, Press  
34 Secretary; Jennifer Barblan, Minority Chief Counsel, O&I; Mike  
35 Bloomquist, Minority Staff Director; Diane Cutler, Minority  
36 Detailee, O&I; Jordan Davis, Minority Senior Advisor; Tyler  
37 Greenberg, Minority Staff Assistant; Brittany Havens, Minority  
38 Professional Staff, O&I; Peter Kielty, Minority General Counsel;  
39 Ryan Long, Minority Deputy Staff Director; Zach Roday, Minority  
40 Communications Director; Kristin Seum, Minority Counsel, Health;  
41 Kristen Shatynski, Minority Professional Staff Member, Health;  
42 and Alan Slobodin, Minority Chief Investigative Counsel, O&I.

43 Ms. DeGette. [Presiding.] The Subcommittee on Oversight  
44 and Investigations hearing will now come to order.

45 Today, the Subcommittee on Oversight and Investigations is  
46 holding a hearing entitled, "Vaping in America: E-Cigarette  
47 Manufacturers' Impact on Public Health". The purpose of today's  
48 hearing is to examine the role of manufacturers in the marketing  
49 and use of e-cigarettes in the United States as well as the  
50 associated public health implications.

51 The chair now recognizes herself for the purposes of an  
52 opening statement.

53 Today, we are here again to continue our examination of a  
54 growing public health crisis -- the soaring use of e-cigarettes  
55 by young people. Simply put, our nation faces a youth vaping  
56 epidemic.

57 In September, this panel heard from federal and state health  
58 officials about the skyrocketing use of e-cigarettes throughout  
59 the United States. Last year, more than 5 million young people  
60 reported using e-cigarettes, up from 3.6 million who reported  
61 using them the year before.

62 Just the other day, I met with a group of high school students  
63 in Denver at my alma mater South High School. And while the most  
64 recent national survey found that 1 in 4 high school students  
65 are currently vaping, when I told this to the students, they all  
66 shook their heads and said they believe the actual rate is much,  
67 much higher. In fact, one sophomore I talked to thinks that more

68 than 60 percent of his peers are using e-cigarettes.

69 Now, as I have said before many times, this teen vaping  
70 epidemic is personal to me because in my State of Colorado we  
71 have the highest percentage of teens vaping than anywhere.  
72 According to the Centers for Disease Control and Prevention,  
73 e-cigarettes pose risks to all users, but most particularly to  
74 young people.

75 The vast majority of e-cigarettes contain nicotine, which,  
76 according to the National Institutes of Health, can be as  
77 addictive as heroin or cocaine, a fact which anecdotally was  
78 cemented by the high school students I actually talked to the  
79 other day.

80 Nicotine can harm brain development, affect respiratory  
81 health, and can lead to heart disease. Further, research shows  
82 that youth who use e-cigarettes are more likely to be using  
83 combustible cigarettes, a fact also confirmed to me by the high  
84 school students.

85 E-cigarette manufacturers have been negligent at best or  
86 intentional at worst in attracting young people to their products.

87 Flavor options, concealable designs, highly addictive nicotine  
88 levels, and slick marketing campaigns have all been used to lure  
89 millions of young people into using e-cigarettes.

90 Parents and public officials have been left scrambling to  
91 address this epidemic, and no one -- not parents, not public health  
92 officials, and not the students who vape -- fully understands

93 the health impact of e-cigarettes. What is worse is many of the  
94 young people actually believe that these products are safe or  
95 harmless, also confirmed to me by the South High Rebels I was  
96 talking to. And you know what? This simply is not true.

97 The CDC has stated that all tobacco products, including  
98 e-cigarettes, carry health risks. The only reason e-cigarettes  
99 are available on the market today is because the Food and Drug  
100 Administration gave them a temporary pass by exercising, or  
101 refusing to exercise, its enforcement discretion.

102 No e-cigarette currently being sold in the United States  
103 has been reviewed by the FDA for its impact on public health.

104 Instead, the e-cigarette industry has essentially been allowed  
105 to conduct a public health experiment in real time without knowing  
106 what the consequences of these products may be, and our young  
107 people are paying the price.

108 So, this is why Congress decided to act. In December,  
109 Chairman Pallone, myself, as well as some of my other colleagues  
110 today, took an important first step to raise the nationwide  
111 minimum age to buy any tobacco product, including e-cigarettes,  
112 to 21. Clearly, more needs to be done, such as advancing  
113 legislation that Chairman Pallone, I, and others have introduced  
114 to tackle this public health priority.

115 These efforts are all the more important, given that the  
116 administration recently caved to industry influence. Despite  
117 the FDA's announcement last September that it intended to ban

118 all non-tobacco-flavored e-cigarette products to address the  
119 rising youth use rate, the final policy issued in January includes  
120 exemptions and loopholes. Not only are menthol-flavored  
121 e-cigarettes still allowed under the FDA's new guidelines, so  
122 are the fruity and sweet-flavored e-liquids and disposable  
123 e-cigarette products. These loopholes may lead to young people  
124 shifting to using menthol-flavored products or disposable  
125 e-cigarettes that remain on the market. In fact, there are  
126 reports that the shift is already happening.

127         The kids at South told me that it is harder for them to get  
128 e-cigarettes at the gas station. Good news. The bad news is  
129 people are just going to these vape shops to get these products.

130         While companies claim that the e-cigarettes have the  
131 potential to help adults who smoke combustible cigarettes, it  
132 is important that CDC cautions such as the health benefit would  
133 only apply if the smoker were able to quit completely. We know  
134 that a majority of adult e-cigarette users, however, are dual  
135 users, meaning they both smoke and vape, which could be more  
136 dangerous than using either product alone.

137         So now, the question is, for every adult smoker who may quit  
138 smoking because they are using an e-cigarette, how many young  
139 people will start using those e-cigarettes and develop a lifelong  
140 nicotine addiction? We must ensure that we are not only  
141 attempting to solve one public health problem by creating another  
142 at the expense of young people's health.

143           The responsibility to protect young people from these  
144 dangerous products cannot fall solely on parents, teachers, and  
145 health officials. And I am glad you gentlemen are here because  
146 the industry caused this mess, and the industry needs to be  
147 responsible for cleaning it up.

148           Today, we are going to hear from the companies responsible  
149 for these products. I really do appreciate you coming because  
150 I really do want you to be part of the solution.

151           And so, we are going to have a lot of questions. We are  
152 looking forward to this hearing.

153           I know I went a little overtime, Mr. Guthrie, which I don't  
154 usually do. So, I am happy to give you another minute for your  
155 opening statement.

156           And with that, I am pleased to recognize the ranking member  
157 of the subcommittee, Mr. Guthrie, for 5 minutes -- 6 minutes.

158           Mr. Guthrie. Six minutes. Well, thank you, Chair DeGette.

159           I appreciate the opportunity to be here and appreciate all  
160 of our witnesses here this morning.

161           I thank you for holding this important hearing, and I share  
162 your concern about youth vaping trends that have emerged in the  
163 United States in recent years.

164           The U.S. Surgeon General has called e-cigarette use by youth  
165 an epidemic and warned that it threatens decades of progress  
166 towards ensuring that fewer young people use tobacco. The most  
167 recent data from the National Youth Tobacco Survey showed that

168 27.5 percent of youths -- and, of course, you said that you think  
169 it is higher than that from your sample there -- reported using  
170 these cigarettes compared with 20.8 percent in 2018. We do know  
171 it is more, and the market has increased.

172 The marketing of e-cigarette products to children must stop  
173 and youth access to e-cigarette products must be prevented. This  
174 will require an all-hands-on-deck approach from all parties,  
175 including the federal government, manufacturers, and retail  
176 stores.

177 We have already made strides to curb youth access in tobacco  
178 since we last held a hearing in September. In December, as  
179 mentioned by the chair, Congress passed, and President Trump  
180 signed into law, legislation to raise the legal age to purchase  
181 tobacco products, including e-cigarettes, from 18 to 21.

182 On January the 2nd, 2020, FDA issued guidance, finalizing  
183 its enforcement policy regarding unauthorized flavored  
184 cartridge-based e-cigarettes that appeal to children, including  
185 fruit and mint. Under this policy, as of February the 6th, 2020,  
186 tomorrow, companies must cease manufacturing, distribution, and  
187 sale of unauthorized flavored cartridge-based e-cigarette other  
188 than tobacco or menthol, or risk FDA enforcement action. This  
189 guidance also gives the FDA the ability to pivot its enforcement  
190 priorities as needed. I hope to hear from our witnesses today  
191 whether this enforcement guidance will effectively target youth  
192 access or if there are other or more effective steps the FDA should



193 take, either alone or in conjunction with the industry.

194 Further, according to FDA's new guidelines, manufacturers  
195 like the ones before us today must submit premarket tobacco  
196 product applications to FDA by May 12th, 2020 for deemed tobacco  
197 products, including e-cigarette products, that were on the market  
198 as of August the 8th, 2016. Through their applications,  
199 manufacturers or importers must demonstrate to the FDA, among  
200 other things, that marketing of new tobacco products would be  
201 appropriate for the protection of public health. As part of this  
202 determination, FDA must consider the risk and benefits of the  
203 product to the population as a whole, including users and  
204 non-users of tobacco products. If manufacturers do not submit  
205 their premarket applications by May 12th, any products for which  
206 an application is not submitted must be pulled from the market.

207 These legal and regulatory developments will drastically  
208 change the e-cigarette landscape in the coming months and year.

209 While these actions are aimed at reducing the attraction of  
210 e-cigarettes to youth and protecting broader public health, wide  
211 bans and narrowing of what is legally available in the legitimate  
212 marketplace will almost certainly shift product use for existing  
213 users to other products that are still available.

214 We must be vigilant in responding to this potential shift  
215 in utilization, which may result in an increase of black market  
216 or counterfeit demand for e-cigarette products. We must ensure  
217 that our efforts to protect our youth and the broader public health

218 do not inadvertently create a bigger and more complicated problem.

219           Though not directly related to today's hearing, I continue  
220 to be concerned about the lung injury outbreak associated with  
221 vaping and e-cigarette use. These illnesses have been closely  
222 associated with black market products and THC, a marijuana  
223 derivative. While the number of cases appear to have peaked when  
224 this subcommittee held its first e-cigarette hearing in  
225 September, we have since learned that, according to the Centers  
226 for Disease Control, an illness outbreak was strongly linked to  
227 vitamin E acetate and additive to THC or marijuana e-cigarettes.

228           We need to more clearly understand the cause of these illnesses.

229           It is my understanding that the e-cigarette manufacturers  
230 have taken, and are continuing to take, their own actions to  
231 prevent youth access to their products. This hearing can serve  
232 as a constructive discussion for us to learn more about what these  
233 manufacturers are doing to prevent youth utilization of these  
234 cigarettes.

235           Before I conclude, I would like to make a quick comment and  
236 recognize a subsidiary of Reynolds that is located in my district.

237           It is Kentucky Bioprocessing. Kentucky Bioprocessing was  
238 founded in Owensboro, Kentucky, with a group of visionary local  
239 entrepreneurs who wanted to find ways to use the tobacco plant  
240 that are constructive to public health. And in doing so, they  
241 found that it was a host for growing vaccines for Ebola, a  
242 population that was used in emergency situations in the previous

243 Ebola outbreak, and is now working to address potential vaccines  
244 for the coronavirus. I am glad that KBP is working on alternative  
245 uses for tobacco in order to better America's public health.

246 I thank our witnesses for being here today and being part  
247 of this important discussion.

248 And I yield back.

249 Ms. DeGette. I thank the gentleman. The chair now  
250 recognizes the chair of the full committee, Mr. Pallone, for 5  
251 minutes.

252 The Chairman. Thank you, Madam Chair.

253 I am pleased we are holding this hearing, so we can shed  
254 more light on the youth tobacco epidemic and how we got here.

255 The significant progress that was made to curb tobacco use has  
256 simply vanished. Last year, 6.2 million middle school and high  
257 school students reported using tobacco products, including one  
258 in three high school students and one in eight middle school  
259 students. And these are shocking and concerning numbers.

260 And today, we are here to not only ask how this happened,  
261 but what is going to be done to reverse these dangerous new trends  
262 in tobacco use. While federal regulators share in this blame,  
263 a large portion of culpability rests with the manufacturers of  
264 e-cigarette products. These manufacturers saw an opportunity  
265 to hook a new generation on their products and used every trick  
266 in the book to make their products appeal to kids through sweet  
267 flavors, glossy marketing campaigns, and slick product designs.

268           It is long past time that the Food and Drug Administration  
269           move forward with reviewing the health and safety risks of the  
270           e-cigarette products that are currently on the market. And then,  
271           the FDA must act swiftly to remove any products that are not in  
272           compliance.

273           But it is also time for the manufacturers, including those  
274           before us today, to acknowledge the responsibility they have to  
275           ensure young people are protected from a lifetime of nicotine  
276           addiction. We do not know all of the long-term health  
277           implications of e-cigarette use, but we do know that nicotine  
278           harms the developing brain and that young people who use  
279           e-cigarettes are more likely to try combustible cigarettes as  
280           well.

281           And that is why I am so disappointed that President Trump  
282           chose to side with industry over the nation's public health by  
283           permitting flavored products to remain on the market, like  
284           menthol, disposable e-cigarettes, and open tank systems mixed  
285           in vape shops. The President's announcement last month falls  
286           far short of the promises he made last year to address the youth  
287           tobacco epidemic. And we shouldn't be fooled; a so-called flavor  
288           ban that exempts menthol and vape shops is not a flavor ban at  
289           all. And that is also why it is critical that we continue to  
290           move forward legislatively with a solution, since the Trump  
291           administration will not.

292           And I look forward to bringing my bill, the Reversing the

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293 Youth Tobacco Epidemic Act, to the floor soon. My legislation  
294 not only includes a full flavor ban, it also bans certain  
295 non-face-to-face sales and protects kids from predatory  
296 marketing. It's a comprehensive approach to end this epidemic,  
297 and I hope that it garners the bipartisan support that it deserves  
298 when it comes to the floor.

299 In the meantime, I want to hear more from the manufacturers  
300 and what role they believe their companies have played in the  
301 creation of this epidemic and what they are doing to correct it.

302 It is chilling to sit and watch as we are seeing history repeat  
303 itself. We have been here before, as the tobacco industry  
304 admitted to misleading millions of users on the safety of tobacco  
305 products, and we can't sit idly by as it happens again. For that  
306 reason, I hope the witnesses today are forthcoming and acknowledge  
307 the role they must play in reversing these dangerous and  
308 disturbing trends.

309 And I just wanted to say, a few years ago, I started going  
310 around to some of my middle schools and talking to the students,  
311 and I was amazed at how they didn't think that there was any harmful  
312 aspect of e-cigarettes, that they didn't contain any nicotine,  
313 that they didn't cause any addiction, that they actually were  
314 just bubble gum or cotton candy and that was it.

315 It is the misleading marketing, in my opinion, that has  
316 caused this epidemic and made young people feel that there was  
317 absolutely no problem with vaping. And that is why all the gains

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318 that we made from trying to discourage tobacco use, cigarettes,  
319 putting the warnings, all that has evaporated now because we have  
320 this young generation that, until recently, just thought there  
321 was not a problem.

322 And I am pleased to see that we have some younger people  
323 here in the audience today speaking out against this, not here  
324 necessarily, but outside and getting the public and the media  
325 more aware.

326 Thank you, Madam Chair.

327 Ms. DeGette. I thank the gentleman. The chair now yields  
328 5 minutes to the ranking member of the full committee, Mr. Walden.

329 Mr. Walden. Thank you very much, Madam Chair.

330 And I, too, Mr. Chairman, am glad these young people are  
331 here. When I was a student body president in high school -- I  
332 know it was a long time ago -- I led the effort before the school  
333 board to get smoking out of the bathrooms. It wasn't legal there,  
334 but we actually created a smoking area outside, which was  
335 revolutionary. You had to have parental permission, and all this  
336 other stuff, but we got it out of the bathrooms, because I hated  
337 smoking. I was the only one in my family that didn't smoke.  
338 And my, we have come a long way. So, stay involved in all of  
339 this.

340 And, Mr. Guthrie, I would be curious, too. I am going over  
341 to the coronavirus briefing for the House in a few minutes. So,  
342 I hope we can find out more about the work that is being done

343 with the tobacco plant, because vaccines, and getting to them  
344 quicker, is something that we have all been working toward for  
345 a long time.

346 So, Chair, thank you for holding this hearing.

347 Electronic cigarettes or e-cigarettes, the long illnesses  
348 associated with vaping, the youth vaping epidemic, these are major  
349 health concerns for the United States, and particularly, and  
350 sadly, in my home State of Oregon, which, unfortunately, is one  
351 of the 27 states where there was a confirmed death from an  
352 e-cigarette or vaping product use-associated lung injury, EVALI.

353 Since the subcommittee's hearing in September with federal  
354 and state health officials, we have learned more about what causes  
355 these tragic lung illnesses. According to the Centers for  
356 Disease Control and Prevention, laboratory data show that vitamin  
357 E acetate and additive in some THC-containing vaping products  
358 is strongly linked to the EVALI outbreak.

359 While there is still more to learn about the EVALI and what  
360 causes it, we must remain vigilant about a separate, but equally  
361 alarming issue, the troubling statistics regarding e-cigarette  
362 use among youth. As Republican Leader Guthrie noted, the most  
363 recent data from the National Youth Tobacco Survey is alarming.

364 We all share this concern. Twenty-seven and a half percent of  
365 youth reported using e-cigarettes in 2019. That compares to 20.8  
366 percent in 2018. It is a big jump from 11.3 percent just three  
367 years ago.

368           Given these trends, the Trump administration, the states,  
369 manufacturers, all of you before us today in this committee, are  
370 right to look for solutions to curb/stop youth access to  
371 e-cigarettes. I applaud the Trump administration's pursuit of  
372 a solution to address our country's youth vaping epidemic. For  
373 example, in December, President Trump signed legislation to raise  
374 the legal age to purchase tobacco products from 18 to 21.

375           Additionally, the U.S. Food and Drug Administration, FDA,  
376 issued guidance in January finalizing its enforcement policy  
377 regarding unauthorized flavored cartridge-based e-cigarettes  
378 that appeal to children, including fruit and mint. In addition  
379 to these two changes, the May deadline for manufacturers to submit  
380 the premarket tobacco product applications, PMTA, to FDA is  
381 quickly approaching, which will shift the industry's landscape  
382 even further.

383           Now, while these are all promising steps, we remain concerned  
384 about the counterfeit and black market products that current  
385 e-cigarette users, including our youth, may increasingly turn  
386 to, when products they are currently using will no longer be  
387 available in the legal and legitimate marketplace.

388           I am also concerned about the potential shifts of youth usage  
389 to other non-cartridge-based e-cigarettes, and I am interested  
390 in hearing from the companies today their thoughts on how we can  
391 prevent this from occurring.

392           I would also like to note the irony of the Health Subcommittee



393 of this full committee holding a hearing just two weeks ago that  
394 included bills to deschedule and decriminalize marijuana, much  
395 of which is smoke; followed by this hearing where my colleagues  
396 are now denouncing smoking tobacco in all forms. While I have  
397 concerns about the epidemic of youth tobacco usage, I believe  
398 that concern should extend to expanded youth access to marijuana  
399 and marijuana-related products, especially considering the death  
400 in Oregon was likely related to a THC vape pod purchased at a  
401 dispensary. Denouncing smoking tobacco in all forms while  
402 embracing the descheduling or legalization of marijuana is, at  
403 best, inconsistent when considering long-term health outcomes  
404 and a lack of research and data.

405 In addition to the committee's ongoing work, Chair DeGette,  
406 I hope you will invite the FDA to testify again once the PMTA  
407 deadline passes in May. I think we could really benefit --

408 Ms. DeGette. We will.

409 Mr. Walden. Excellent.

410 While we heard from the FDA in September, it is critical  
411 for all of us to continue to hear from the FDA as the issue evolves  
412 and the FDA begins to evaluate manufacturers' PMTAs.

413 We also need a full investigation to counterfeit and black  
414 market products that are likely to fill the void of the products  
415 that are expected to exit the market, whether from the  
416 administration's January guidance or from manufacturers who do  
417 not file PMTAs and, accordingly, remove their products from the

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418 market. We want to make sure the FDA stands ready to address  
419 these issues as they arise to protect current e-cigarette users,  
420 but, most importantly, our youth.

421 So, I want to thank the companies before us for voluntarily  
422 coming here. It is important that we hear from you.

423 And, Madam Chair, I appreciate you holding this hearing.

424 I will have to go over to that coronavirus for the Members, but  
425 we will be back and forth. And I yield back.

426 Ms. DeGette. Take notes over there. Okay?

427 Mr. Walden. Yes, I will.

428 Ms. DeGette. And I just want to say, I don't think there  
429 is anybody on this committee that thinks marijuana should be  
430 legalized for people under 21.

431 Mr. Walden. Here, here.

432 Ms. DeGette. And in addition, I think everybody on this  
433 committee will agree that we need to continue to do the research  
434 on that, too.

435 Mr. Walden. Yes.

436 Ms. DeGette. There has been woefully inadequate research.

437 Mr. Walden. Fully agree.

438 Ms. DeGette. In fact, we are planning to have a hearing  
439 on that sometime in the near future.

440 Mr. Walden. Excellent. Thank you, Madam Chair.

441 Ms. DeGette. The chair would now ask unanimous consent that  
442 the members' written opening statements be made part of the

443 record. Without objection, so ordered.

444 The chair would also like to welcome Representative Shalala  
445 for joining us at the hearing today. Representative Shalala is  
446 not on this committee. And so, under Rule 11 of the House of  
447 Representatives, Members, Delegates, and Residents can  
448 participate in committee hearings, but they are not able to  
449 question witnesses. But I think we could all stipulate that she  
450 probably has more institutional knowledge about health care  
451 policy than anybody in this Congress. So, we are really happy  
452 to have you join us.

453 I would now like to introduce our witnesses for today's  
454 hearing.

455 Mr. K.C. Crosthwaite, CEO of JUUL, welcome.

456 Mr. Ricardo Oberlander, who is the president and CEO of  
457 Reynolds America, Inc., welcome. Glad to have you.

458 Mr. Ryan Nivakoff, CEO of NJOY, LLC.

459 Mr. Antoine Blonde, who is president of Fontem U.S., welcome.

460 Mr. Jerry Loftin, who is the president of Logic Technology  
461 Development, LLC, and welcome to you, too, Mr. Loftin.

462 Thanks to all of our witnesses for appearing today before  
463 the subcommittee.

464 You are aware that the committee is holding an investigative  
465 hearing, and when doing so, has the practice of taking testimony  
466 under oath. Does anyone have any objection to testifying under  
467 oath today?

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468           Let the record reflect that the witnesses have responded  
469 no.

470           The chair, then, advises you that, under the rules of the  
471 House and the rules of the committee, you are entitled to be  
472 accompanied by counsel. Does anyone desire to be accompanied  
473 by counsel today?

474           Let the record reflect, again, that the witnesses have  
475 responded no.

476           If you would, then, please rise and raise your right hand,  
477 so that you may be sworn-in.

478           [Witnesses sworn.]

479           You may be seated.

480           Let the record reflect the witnesses have responded  
481 affirmatively, and all of you are now under oath and subject to  
482 the penalties set forth in Title 18, Section 1001, of the U.S.  
483 Code.

484           The chair will now recognize our witnesses for a 5-minute  
485 summary of their written statements.

486           In front of each of you there is a microphone, a timer, and  
487 a series of lights. The timer will count down your time, and  
488 the red light will turn on when your 5 minutes have come to an  
489 end.

490           And so now, Mr. Crosthwaite, I am delighted to recognize  
491 you for 5 minutes, please.

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492 TESTIMONIES OF K.C. CROSTHWAITE, CEO, JUUL LABS, INC.; RICARDO  
493 OBERLANDER, PRESIDENT AND CEO, REYNOLDS AMERICAN, INC.; RYAN  
494 NIVAKOFF, CEO, NJOY, LLC; ANTOINE BLONDE, PRESIDENT, FONTEM U.S.,  
495 AND JERRY LOFTIN, PRESIDENT, LOGIC TECHNOLOGY DEVELOPMENT, LLC

496

497 TESTIMONY OF K.C. CROSTHWAITE

498 Mr. Crosthwaite. Chair DeGette, Chairman Pallone, Ranking  
499 Members Guthrie and Walden, other distinguished subcommittee  
500 members, my name K.C. Crosthwaite, and I am CEO of JUUL Labs,  
501 a position I assumed when I joined the company about four months  
502 ago.

503 At JUUL Labs, our thousands of U.S. employees are committed  
504 to helping adult smokers transition away from combustible  
505 cigarettes while combating the serious problem of underage use.

506 As we look at the vapor category, it is helpful to begin by noting  
507 the significant changes that have taken place in a relatively  
508 short period of time.

509 At the start of 2019, most Americans lived in states where  
510 the legal age of purchase was just 18. Vapor products were  
511 available in a wide array of flavors. There was low awareness  
512 of black market vapor products, and the deadline for PMTA  
513 submissions to the FDA was uncertain.

514 In contract, today, 21-plus is the law of the land, thanks  
515 to many of you on this committee. Under FDA guidance, pod-based  
516 products are now available in only tobacco and menthol.

517 Congress, the FDA, and the President have raised the alarm on  
518 black market products, and the PMTA deadline of May 2020 is rapidly  
519 approaching.

520 At JUUL Labs, we recognize the importance of these steps.

521 Over the past few years, trust in our company and category has  
522 eroded. We know some of our past actions have contributed to  
523 that erosion and we are committed to taking concrete action to  
524 re-earn that trust.

525 We halted our broadcast, print, and digital product  
526 advertising. We voluntarily restricted the sale of flavors other  
527 than tobacco and menthol, and we restructured our company to focus  
528 on developing technologies to combat underage use and to conduct  
529 research in support of our PMTA submission.

530 Clearly, we still have a long way to go. Underage use rates  
531 remain unacceptably high, but we believe that this challenge can,  
532 and must, be met. It threatens the entire harm reduction  
533 opportunity represented by vapor products. And that opportunity  
534 is too important to lose.

535 Combustible cigarettes remain the leading cause of  
536 preventable death in our country and worldwide. More than 34  
537 million Americans still smoke. Each year, nearly half a million  
538 Americans die from smoking-related diseases. To be clear, anyone  
539 who doesn't use nicotine shouldn't start. Anyone who smokes  
540 should quit. For those who cannot or will not quit, less harmful  
541 alternatives like vapor products should be available.

542           Public health authorities agree that it is not the nicotine,  
543 but the burning of tobacco and smoke that causes disease and death.

544           As the FDA noted in 2017, in quote, "Nicotine, while highly  
545 addictive, is delivered through products that represent a  
546 continuum of risk and is most harmful when delivered through smoke  
547 particles in combustible cigarettes." End of quote.

548           At the same time, the FDA stated its intent to encourage  
549 innovation that could provide adult smokers a less harmful way  
550 to consume nicotine. JUUL products are one example of this type  
551 of innovation. Our products are not risk-free, but research  
552 indicates that vapor products are substantially lower risk than  
553 cigarettes. Research also indicates that many, if not most,  
554 adult smokers who try JUUL products are able to successfully  
555 transition completely off of cigarettes. We will provide all  
556 of this research to the FDA through the PMTA process.

557           That process, which we support, is a science- and  
558 evidence-based review that will evaluate the harm reduction  
559 potential of our products along with the ability to prevent youth  
560 usage. If authorized by the FDA, our products will be marketed  
561 under strict oversight, subject to the comprehensive regulatory  
562 powers invested in the agency by Congress.

563           Chair DeGette, Ranking Member Guthrie, my company is working  
564 hard to listen to our stakeholders, so, together, we can make  
565 progress towards the twin goals of helping more adults switch  
566 away from cigarettes while combating underage use. My hope is

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567 today's panel can be another step along that path.

568 I thank you for the opportunity and I look forward to  
569 answering your questions.

570 [The prepared statement of Mr. Crosthwaite follows:]

571

572 \*\*\*\*\* INSERT 1 \*\*\*\*\*



PRELIMINARY TRANSCRIPT

573 Ms. DeGette. Thank you so much.

574 The chair now recognizes Mr. Oberlander for 5 minutes for  
575 an opening statement.

576 Actually, hold on for 1 minute. We are going to replace  
577 Mr. Crosthwaite's microphone, so you don't have to keep shifting  
578 back and forth all day.

579 Thank you so much.

580 Mr. Oberlander, you are now recognizes for 5 minutes.

581 TESTIMONY OF RICARDO OBERLANDER

582

583 Mr. Oberlander. Chair DeGette, Ranking Member Guthrie, and  
584 members of the subcommittee, Chairman Pallone, Ranking Member  
585 Walden, and distinguished members, my name is Ricardo Oberlander.

586 I am the president of Reynolds American, Inc.

587 I appreciate this opportunity to share information about  
588 our company and to continue this important conversation today.

589 Over a decade ago, Reynolds set a goal to transform the  
590 tobacco market through innovative products that could make  
591 tobacco harm reduction a reality for adult smokers. Doing so  
592 requires us to provide consumer-acceptable products that may  
593 present less risk, including products in the vaping category.

594 In pursuing this goal, we have focused on both innovation  
595 and responsibility, because the two must not be separated. The  
596 way we bring innovative products to market and how we market those  
597 products are as important as the products themselves. Our  
598 marketing is important. It is how we communicate with adult  
599 smokers about alternatives to combustible cigarettes.

600 As detailed in our submissions to the committee, we have  
601 rigorous standards in place to ensure our marketing is accurate  
602 and is responsibly directed to adult smokers 21 and older. We  
603 pose numerous restrictions on the content of our marketing and  
604 limit with whom we communicate.

605 Our vapor brand is VUSE. Our consumer demographics confirm

606 our focus on adults. Ninety-five percent of VUSE consumers are  
607 over 25 and 70 percent are over 35.

608 With respect to youth vaping, when VUSE was the market leader  
609 through 2017, youth vaping rates actually declined. And the most  
610 recent National Youth Tobacco Survey results show that VUSE is  
611 not popular among youth. Thus, we have demonstrated, and  
612 continue to demonstrate, that it is possible to responsibly market  
613 alternative products and manufacture them under rigorous product  
614 stewardship standards.

615 The increasing youth vaping over the past two years and  
616 serious health issues from illicit products are now at the heart  
617 of a national discussion. These issues are being discussed  
618 within families, by educators, and in state and local governments.

619 They are being discussed in law enforcement communities, the  
620 White House, and here today in the United States Congress. We  
621 support action by the administration and Congress to address both  
622 issues. It is important to public health and to adult consumers.

623 Looking forward, FDA's premarket tobacco application  
624 process provides a pathway for vapor products aligned with public  
625 health priorities. We believe vapor products can be manufactured  
626 and marketed responsibly within this framework. In fact, we have  
627 already made extensive PMTA submissions for our VUSE products.

628 There are additional actions we encourage you to consider.

629 First, transparency in the PMTA process is critical. We  
630 suggest FDA disclose which products have been submitted for PMTA

631 approval. This will help retailers and the public know which  
632 vapor products are undergoing PMTA review and are eligible to  
633 remain on the market, and will help FDA and state officials enforce  
634 the law.

635 Second, FDA needs to adopt regulations that expedite  
636 important innovations. For example, we are exploring  
637 technologies that could provide additional measures for reducing  
638 potential youth usage. However, the current PMTA process,  
639 although thorough and welcome, would significantly delay bringing  
640 this type of responsible innovation to market.

641 Third, FDA should consider adopting additional and rotating  
642 warnings for vapor products. These warnings could reinforce that  
643 vaping products are not safe and not for youth. We already  
644 include many such statements in our packaging and brand website.

645 And finally, FDA has a track record of success with its youth  
646 prevention program. We applaud the agency's success and  
647 encourage it to be continued and expanded.

648 In conclusion, we believe a level setting of the vapor market  
649 through the PMTA process will help address these serious issues  
650 facing us today. At the same time, it will foster continued  
651 transformation of the tobacco category and significantly benefit  
652 public health.

653 I thank the committee for the opportunity to share Reynolds'  
654 views about these important issues and reiterate our full  
655 commitment to cooperating with this committee and FDA.

PRELIMINARY TRANSCRIPT

656 [The prepared statement of Mr. Oberlander follows:]

657

658 \*\*\*\*\* INSERT 2 \*\*\*\*\*

PRELIMINARY TRANSCRIPT

659 Ms. DeGette. Thank you so much.

660 Mr. Nivakoff, now you are recognized for 5 minutes, please.

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661 TESTIMONY OF RYAN NIVAKOFF

662

663 Mr. Nivakoff. Good morning, Chair DeGette, Chairman  
664 Pallone, Ranking Member Guthrie, Ranking Member Walden, and  
665 distinguished members of the subcommittee.

666 My name is Ryan Nivakoff, and I am the CEO of NJOY. Thank  
667 you for the opportunity to testify today to discuss with you the  
668 important public health dynamics associated with electronic  
669 cigarettes. I am humbled to be here today to provide NJOY's  
670 insights into this complex and vitally important conversation.

671 By way of background, I joined NJOY for deeply personal  
672 reasons. As I am sure is the case with many of the people in  
673 this room, my family has been victimized by one of the most deadly  
674 articles of commerce ever created, the combustible cigarette.

675 As a boy, I watched as my grandmother perished well before her  
676 time and as my once-virile grandfather, a veteran of the Army  
677 and Marine Corps, and a police officer for over 38 years, spent  
678 the last six years of his life attached feebly to an oxygen tank,  
679 unable to even sit up without losing his breath. It is with these  
680 horrifying memories in mind that I joined NJOY and wrote our  
681 mission statement to make smoking history by helping adults find  
682 an alternative to combustible cigarettes.

683 From day one, it was clear to me that neither we at NJOY  
684 nor other pioneers in harm reduction would be able to advance  
685 that mission if the public health benefits of electronic

686 cigarettes were overshadowed by a surge of youth use. To that  
687 end, NJOY has pursued its mission with the goal of ensuring that  
688 our products do not fall into the hands of America's youth.

689         Though hollow as it may sound, this industry has the greatest  
690 incentive, both moral and economic, to ensure that youth use is  
691 eliminated. If that goal is not accomplished, this life-changing  
692 technology may, rightfully and ironically, be relegated to the  
693 ashtray of history. We see today's hearing as an opportunity  
694 for productive dialog to move forward together collectively to  
695 protect the public health.

696         There are approximately 34 million Americans who still smoke  
697 combustible cigarettes and over a billion people worldwide.  
698 Those smokers face a greater than 50 percent chance of premature  
699 death if they continue to smoke. And each year, nearly 500,000  
700 Americans die prematurely from smoking-related disease.

701         Switching adult smokers from combustible cigarettes to  
702 electronic cigarettes has the potential to save millions of lives  
703 and trillions of dollars in preventable health care expenses.

704         These assertions are not mere industry taglines designed to  
705 obfuscate otherwise nefarious or profit-driven motives. Former  
706 FDA Commissioner Scott Gottlieb has stated, "If you can fully  
707 switch every currently addicted adult smoker who is using  
708 combustible tobacco products onto e-cigarettes, you will have  
709 a profound impact on public health."

710         With this in mind, NJOY has recognized from inception that,



711 contrary to popular opinion, addicting a new generation of  
712 nicotine users would not further our moral or financial bottom  
713 lines, but, rather, would be our undoing. We have built our  
714 business in accordance with that ethos, and the data prove that  
715 it is working.

716 According to the National Youth Tobacco Survey, in 2019,  
717 only 1.2 percent of high school students who used electronic  
718 cigarettes within the prior 30 days reported using NJOY products.

719 Indeed, in the most recent National Youth Tobacco Survey, NJOY's  
720 use rate for high-schoolers, despite being one of the top three  
721 national brands, is over nine times lower than the combined use  
722 of two brands that were not even part of the survey, but were  
723 written in by students who used those brands.

724 Further, the FDA's yearly retail inspection violation data  
725 consistently shows that NJOY's products are involved in the fewest  
726 violations of the top four e-cigarette brands. For example, in  
727 the fiscal year beginning October 2017, FDA recorded more than  
728 3,300 violations including electronic cigarettes, of which only  
729 20 involved NJOY products, which is less than 1 percent. The  
730 following fiscal year, FDA recorded over 5,250 violations, only  
731 28 of which involved NJOY products, barely one-half of 1 percent.

732 And in the present fiscal year, NJOY products were involved in  
733 only eight violations of the 839 recorded by FDA thus far, again,  
734 less than 1 percent.

735 While NJOY will strive to continue to reduce this number

736 even farther, NJOY is proud of its track record of success thus  
737 far. To be clear, however, my goal is not to aggrandize NJOY's  
738 track record, nor to draw comparisons against my competition.

739 Rather, I provide this data merely to demonstrate that, with  
740 proper regulation and vigilant self-policing, there is a path  
741 forward for this life-changing technology, a path that can provide  
742 an off-ramp for adults without creating an on-ramp for youth.

743 And I am confident that everyone on this panel shares that very  
744 same dedication to eliminating underage vaping.

745 I welcome the opportunity to share with the subcommittee  
746 more detail about the policies and procedures by which NJOY has  
747 been able to serve its mission to adult smokers while minimizing  
748 access to youth. I look forward to answering your questions,  
749 and thank you again for the opportunity to be here.

750 [The prepared statement of Mr. Nivakoff follows:]

751

752 \*\*\*\*\* INSERT 3 \*\*\*\*\*

PRELIMINARY TRANSCRIPT

753                   Ms. DeGette. Thank you so much.

754                   I now recognize Mr. Blonde for 5 minutes for an opening  
755                   statement.

756 TESTIMONY OF ANTOINE BLONDE

757

758 Mr. Blonde. Chair DeGette, Chairman Pallone, Ranking  
759 Member Guthrie, members of the subcommittee, thank you for the  
760 opportunity to appear today before the House Committee on Energy  
761 and Commerce, Oversight and Investigations Subcommittee, to  
762 discuss the important issues regarding electronic nicotine  
763 delivery systems, ENDS, commonly referred to as e-cigarettes.

764 My name is Antoine Blonde, and I am president of Fontem U.S.  
765 Incorporated. Fontem U.S. markets and sells the blu brands,  
766 which we acquired from another company in June 2015.

767 As you are aware, Fontem has cooperated extensively with  
768 the committee's investigation since it began last August and  
769 provided several hundred pages of material in response to the  
770 committee's request for information.

771 We believe the facts make clear that Fontem is a responsible  
772 actor in the e-cigarette marketplace, and we are committed to  
773 ensuring that our business practices are consistent with our  
774 objective of providing adult consumers only with the highest  
775 quality products and an enjoyable product experience.

776 I would like to briefly address four points.

777 First, Fontem believes without equivocation that youth  
778 should not use any e-cigarette product. We share the  
779 subcommittee's view that preventing youth access to e-cigarettes  
780 is an issue of critical importance. In this regard, Fontem does

781 not, and has never, directed its marketing efforts for  
782 e-cigarettes to youth.

783         Second, Fontem takes extensive steps to ensure that its  
784 e-cigarettes sales channel reflects Fontem's commitment to youth  
785 access prevention. Fontem's e-cigarettes are sold through three  
786 main distribution channels: the traditional brick and mortar  
787 -- the convenience stores, the gas stations -- ecommerce, and  
788 vape shops. In each distribution channel, Fontem takes steps  
789 to ensure that youth do not have access to blu products.

790         Third, Fontem has invested extensively in its product  
791 stewardship program. Fontem is also committed to responsible  
792 product stewardship practices and ensuring product quality is  
793 thoughtfully integrated from product conception to consumer use.

794         Fourth, Fontem's products have not been found by the U.S.  
795 Center of Disease Control to be involved in any of the incidents  
796 of respiratory illness it has investigated. We were deeply  
797 concerned by reports last year linking respiratory illnesses to  
798 the use of vaping products, and we joined calls for the CDC to  
799 investigate these instances as soon as possible.

800         Vitamin E acetate is not, and has never been, an ingredient  
801 in blu products, and we are not aware of any Fontem product being  
802 referenced by the CDC as involving incidences it has investigated.

803         Further, we fully agree with the CDC's advice that consumers  
804 should not buy any vaping product, especially the one containing  
805 THC, from unknown sources or in the black market. Of course,

806 we will continue to monitor these developments very closely.

807           These initiatives are some examples of Fontem's extensive  
808 efforts in the areas of youth access prevention and product  
809 quality. All of us at Fontem are dedicated to ensuring that our  
810 products are of the highest quality and that they are marketed  
811 and sold only to other consumers.

812           I thank you for your time and attention to these important  
813 issues. On behalf of Fontem U.S., we look forward to working  
814 with the Congress and FDA and continue doing so. And I am happy  
815 to answer any question you will have.

816           [The prepared statement of Mr. Blonde follows:]

817

818           \*\*\*\*\* INSERT 4 \*\*\*\*\*

PRELIMINARY TRANSCRIPT

819           Ms. DeGette. Thank you, Mr. Blonde. And I apologize for  
820           mispronouncing your name earlier.

821           Mr. Loftin, you are now recognized for 5 minutes for an  
822           opening statement.

823 TESTIMONY OF JERRY LOFTIN

824

825 Mr. Loftin. Chairman DeGette, Ranking Member Guthrie, and  
826 members of the subcommittee, thank you for inviting me to testify  
827 at this hearing.

828 I am Jay Loftin, president of Logic, and I appreciate the  
829 opportunity to contribute to this very important inquiry.

830 To my knowledge, only one company has all of its ENDS  
831 premarket tobacco applications accepted for substantive review  
832 by the FDA. That is Logic. Logic has consistently acted  
833 responsibly. Since we started, Logic has had numerous measures  
834 to deter youth access to ENDS.

835 We share your concerns regarding unlawful products and those  
836 that intentionally target minors, or are marketed as low-risk  
837 or cessation products without approval. So, as much as I am  
838 grateful for the opportunity to participate today and discuss  
839 the numerous challenges we face, I do not wish to be painted with  
840 the same brush as others because we operate differently.

841 We have made every effort to responsibly market our products  
842 with controls in place aimed at preventing youth appeal and  
843 access. We did this not because it was mandated by law at the  
844 time, or because we were facing lawsuits, or because we generated  
845 bad publicity with our products or marketing. We did this because  
846 it is the right thing to do.

847 We don't suggest that our products are cessation devices.



848       We have not, and do not, use influencers to convince children  
849       or adults to try our products. We are not evangelists claiming  
850       to offer a cure for smoking.

851               Other companies have caused tremendous damage to the  
852       reputation of this category while putting America's youth in  
853       harm's way. Logic has always, and will always, responsibly  
854       market and sell its products to adults only, period.

855               From our first day, Logic's product packaging and website  
856       have carried a warning clearly stating that our products contain  
857       nicotine which is addictive; our products are for adults only,  
858       and underage sale is prohibited. Purchases through our website  
859       have always been restricted to age-verified adults. And even  
860       before the Deeming regulations took effect, we further restricted  
861       sales to those age 21 and above. Perhaps others now have some  
862       of these practices in place, but introducing these when you must,  
863       rather than because it is the right thing to do, is different  
864       altogether.

865               Logic isn't a brand that resonates with youth. Our online  
866       data shows that Logic's typical consumer looks much more like  
867       me than my adult children. This is not by chance. It is the  
868       result of the responsible steps that Logic has taken, such as  
869       only using people who are over the age of 30 in our consumer  
870       marketing materials.

871               Was it difficult to stand by and watch others take a less  
872       responsible approach and see our competitors' business soar?

873 Yes, it was. Their growth came at great cost. It has tarnished  
874 the entire category, caused a serious youth uptake problem, and  
875 created doubt and fear in this country.

876 Rather than treating counterfeit products as an excuse for  
877 the problems at hand, Logic has committed substantial resources  
878 towards eliminating them. For nearly four years, we have worked  
879 with the FDA, Homeland Security, CBP, and law enforcement to stop  
880 thousands of illegitimate sales of our products online and at  
881 retail.

882 We have vocally and consistently called for the FDA to close  
883 the window that it had opened when it pushed the PMTA deadlines  
884 back, and for the FDA to immediately and robustly impose and  
885 enforce premarket regulatory requirements. The FDA has the  
886 authority to rid the market of products that are not appropriate  
887 for the protection of public health and to determine, based on  
888 science and evidence, including the likely impact on the  
889 population as a whole, whether a product should remain on the  
890 market, irrespective of design, irrespective of flavor.

891 Yes, Logic has flavored products. That is because many  
892 adults prefer them to the taste of menthol. The simple existence  
893 of flavors doesn't cause a youth problem. What does is  
894 irresponsible marketing combined with products that are designed  
895 and marketed to appeal to youth. That is why we don't agree with  
896 wholesale bans on flavors. That is why we believe in allowing  
897 the FDA to decide which products should be on the market through

898 the PMTA process.

899 Having never manufactured or marketed our products to appeal  
900 to young people, having acted with responsibility and integrity,  
901 I and everyone at Logic will do what we can to support the committee  
902 with this ongoing work. Thank you for your time.

903 [The prepared statement of Mr. Loftin follows:]

904

905 \*\*\*\*\* INSERT 5 \*\*\*\*\*

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906 Ms. DeGette. Thank you so much, Mr. Loftin.

907 It is now time for the committee to ask questions, and the  
908 chair will recognize herself for 5 minutes.

909 People are confused when it comes to the health and safety  
910 of e-cigarettes, and I heard this the other day over at South  
911 High School. The U.S. Surgeon General has noted that young people  
912 try e-cigarettes assuming that either they are less harmful than  
913 other tobacco products or even that they are not harmful at all.

914 So, I want to clear a couple of things up with this panel.

915 These questions should be able to be answered with a simple  
916 yes-or-no answer.

917 My first question is, isn't it true that nicotine is  
918 addictive? Mr. Crosthwaite?

919 Mr. Crosthwaite. Yes, nicotine is addictive.

920 Ms. DeGette. Mr. Oberlander?

921 Mr. Oberlander. Nicotine is addictive.

922 Ms. DeGette. Mr. Nivakoff?

923 Mr. Nivakoff. Yes.

924 Ms. DeGette. Mr. Blonde?

925 Mr. Blonde. Yes.

926 Ms. DeGette. Mr. Loftin?

927 Mr. Loftin. Yes.

928 Ms. DeGette. And isn't it true, then, that using the  
929 products each of your companies makes which contain nicotine could  
930 lead to nicotine addiction?

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931 Mr. Crosthwaite?

932 Mr. Crosthwaite. Yes, nicotine is addictive.

933 Ms. DeGette. And your products could lead to nicotine  
934 addiction, correct?

935 Mr. Crosthwaite. Yes, they could.

936 Ms. DeGette. Mr. Oberlander?

937 Mr. Oberlander. Any product containing nicotine is  
938 addictive.

939 Ms. DeGette. And your products that people use containing  
940 nicotine could cause people to become addicted, yes?

941 Mr. Oberlander. Yes, they do.

942 Ms. DeGette. Mr. Nivakoff?

943 Mr. Nivakoff. Yes, ma'am.

944 Ms. DeGette. Mr. Blonde?

945 Mr. Blonde. Yes.

946 Ms. DeGette. Mr. Loftin?

947 Mr. Loftin. Yes.

948 Ms. DeGette. And do you agree with the medical studies that  
949 show that nicotine can have negative consequences for respiratory  
950 health and can cause an increase in blood pressure, heart rate,  
951 and lead to heart disease, and also could harm brain development  
952 in young people?

953 Mr. Crosthwaite?

954 Mr. Crosthwaite. As part of our PMTA, we will have all of  
955 our studies submitted to be reviewed by the --

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956 Ms. DeGette. So, have you seen the studies that show that  
957 there are these issues that I just mentioned?

958 Mr. Crosthwaite. I'm not familiar with the one you're  
959 referring to.

960 Ms. DeGette. You don't know? So, do you maintain that  
961 nicotine causes no health consequences in people then?

962 Mr. Crosthwaite. No, nicotine is addictive and --

963 Ms. DeGette. And does it have health consequences?

964 Mr. Crosthwaite. It can cause harm.

965 Ms. DeGette. Yes.

966 Mr. Oberlander, did you hear my question about the studies?

967 What is your view?

968 Mr. Oberlander. Yes, I did. Our scientific team actually  
969 monitors all the literature regarding --

970 Ms. DeGette. So, would you agree that nicotine could cause  
971 respiratory health issues, blood pressure, heart rate, and brain  
972 development issues?

973 Mr. Oberlander. As I said before, nicotine is addictive  
974 and tobacco products can cause harm.

975 Ms. DeGette. Could they cause the harms I just talked about?

976 Mr. Oberlander. I am not familiar with --

977 Ms. DeGette. You don't know?

978 Mr. Nivakoff, what about you?

979 Mr. Nivakoff. I am not in a position to corroborate nor  
980 repudiate --

PRELIMINARY TRANSCRIPT

981 Ms. DeGette. So, you don't know if it could cause those  
982 harms?

983 Mr. Nivakoff. Nicotine can cause health issues. I am just  
984 not --

985 Ms. DeGette. What health issues do you think --

986 Mr. Nivakoff. I am just not in a position to corroborate  
987 --

988 Ms. DeGette. Yes, what health issues do you think they could  
989 cause?

990 Mr. Nivakoff. Nicotine can raise your blood pressure.

991 Ms. DeGette. Okay.

992 Mr. Nivakoff. It can cause headaches.

993 Ms. DeGette. Okay. But you don't really know about any  
994 other things?

995 Mr. Nivakoff. I am not aware of the studies that --

996 Ms. DeGette. Even though you are the CEO of the company?  
997 Okay.

998 Mr. Blonde?

999 Mr. Blonde. Nicotine is addictive and, as such, can cause  
1000 harm.

1001 Ms. DeGette. Okay. The harm, I find it fascinating no one  
1002 really wants to talk about what that harm is. The medical studies  
1003 show that it can cause respiratory health problems, blood  
1004 pressure, heart rate problems, and brain development problems  
1005 in young people. Do you think it could cause any of those harms?

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1006 Mr. Blonde. I have no reason to doubt those studies, but  
1007 I am not aware of them.

1008 Ms. DeGette. Thank you. Thank you very much.

1009 Mr. Loftin?

1010 Mr. Loftin. Nicotine is addictive and we put all the warning  
1011 labels onto our product.

1012 Ms. DeGette. I understand that. Do you think it could  
1013 cause the harms that I am talking about?

1014 Mr. Loftin. We are going to leave that up to the FDA to  
1015 decide through the PMTA process, the specifics of --

1016 Ms. DeGette. So, you are not going to commit to that,  
1017 either? See, when you say nicotine is addictive, I don't think  
1018 that a lot of young people understand what that means in terms  
1019 of health consequences.

1020 Mr. Nivakoff, I was really moved by what you said about,  
1021 I think, your grandmother and your grandfather. My mother died  
1022 of lung cancer at age 54 from smoking, which she started doing  
1023 when she was under 21. And I am sure she knew it was addictive,  
1024 but I don't think she had any idea.

1025 And I think people think that e-cigarettes, sure, they are  
1026 addictive, but they are not going to cause the same harm as  
1027 cigarettes. In fact, we don't really know.

1028 Now I want to ask you another yes-or-no question. Maybe  
1029 you will answer it. Do you agree with the CDC that there is no  
1030 completely safe tobacco product, including e-cigarettes?



PRELIMINARY TRANSCRIPT

1031 Mr. Crosthwaite?

1032 Mr. Crosthwaite. Yes, our products are not without --

1033 Ms. DeGette. Mr. Oberlander?

1034 Mr. Oberlander. No tobacco product is safe.

1035 Ms. DeGette. Including your e-cigarettes?

1036 Mr. Oberlander. Including them.

1037 Ms. DeGette. Mr. Nivakoff?

1038 Mr. Nivakoff. Yes, ma'am, I agree.

1039 Ms. DeGette. Mr. Blonde?

1040 Mr. Blonde. I agree.

1041 Ms. DeGette. And, Mr. Loftin?

1042 Mr. Loftin. All tobacco products carry risk.

1043 Ms. DeGette. Okay. One last question. Do you all agree  
1044 that there is a youth vaping epidemic in this country and that  
1045 people under 21 should not be using e-cigarettes, including your  
1046 products?

1047 Mr. Crosthwaite?

1048 Mr. Crosthwaite. I completely agree.

1049 Ms. DeGette. Mr. Oberlander?

1050 Mr. Oberlander. Chair DeGette, one --

1051 Ms. DeGette. Mr. Nivakoff?

1052 Mr. Nivakoff. Yes, ma'am, I agree.

1053 Ms. DeGette. Mr. Blonde?

1054 Mr. Blonde. Absolutely.

1055 Ms. DeGette. Mr. Loftin?

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1056 Mr. Loftin. I agree.

1057 Ms. DeGette. What did you want to say?

1058 Mr. Oberlander. One youth vaping is too many.

1059 Ms. DeGette. Thank you. Thank you very much. I  
1060 appreciate all of you.

1061 And now, I recognize Mr. Guthrie for 5 minutes.

1062 Mr. Guthrie. Good to see you all here. Thank you for being  
1063 here.

1064 And I want to begin by asking, actually, I want to begin  
1065 by understanding the FDA's authorities. So, concerns have been  
1066 raised about disposable products still being on the market and,  
1067 therefore, potentially available to youth, including newer  
1068 flavored products such as Puff Bars or POSH.

1069 And this is directed to Mr. Blonde and Mr. Nivakoff. I want  
1070 to make sure we all understand FDA's authorities. Is it correct  
1071 that, under the Deeming Rule, FDA can currently remove products  
1072 that enter the market after August the 8th, 2016?

1073 Mr. Nivakoff. Yes, sir, that is correct.

1074 Mr. Guthrie. It is correct?

1075 Mr. Blonde. It is correct.

1076 Mr. Guthrie. In fact, the FDA has used the authority,  
1077 removing nearly 100 flavored products by EonSmoke from the market  
1078 in October of 2019. So, to Mr. Blonde and Mr. Nivakoff, under  
1079 the January enforcement guidance, what actions can FDA take  
1080 against manufacturers of non-cartridge-based products, such as

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1081 disposable products, if the FDA finds the manufacturers fail to  
1082 keep them away from minors?

1083 Mr. Nivakoff. Who would you like to go first, sir?

1084 Mr. Guthrie. You can go first, yes.

1085 Mr. Nivakoff. I think what is sometimes lost in the FDA  
1086 guidance is that there were three prongs of the FDA's guidance  
1087 document that allowed FDA to take action against products,  
1088 products that included flavors, and products that are targeted  
1089 towards minors, or manufactured or marketed in a way that make  
1090 them attractive to youth.

1091 So, the products that you refer to, while I can't comment  
1092 on their genesis, I can say that, to the extent that they create  
1093 an increased level of youth use, the FDA has sweeping authority  
1094 to remove them from the market summarily.

1095 Mr. Guthrie. So, since you answered that, I will ask Mr.  
1096 Blonde to answer this second. You first and, then, second. So,  
1097 what has your company -- because they have disposable products  
1098 where the others don't -- what have you done to prevent disposable  
1099 products from being unavailable to youth?

1100 Mr. Nivakoff. Historically, our disposable products have  
1101 not contributed to really any statistically-meaningful level of  
1102 youth use. Our historical practice to avoid youth use across  
1103 the spectrum of our products has been avoiding, and in our case  
1104 eliminating, all advertising activity that occurs outside of the  
1105 confines of the physical premises of a licensed tobacco retailer.

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1106 We have eliminated the social media presence.

1107 And then, specifically with respect to I think the inference  
1108 regarding flavored disposables, a week ago, we made the decision  
1109 to voluntarily remove our flavored products, flavored disposable  
1110 products, from stores; albeit, not because those products have  
1111 created increased access to youth use. We did so because we felt  
1112 it was consistent with the spirit of the FDA guidance that the  
1113 large businesses use the PMTA process to adjudicate whether or  
1114 not flavors are appropriate for the protection of public health.

1115 Mr. Guthrie. Okay. Mr. Blonde, I have another question  
1116 to get to. Your company, to keep disposable products out of the  
1117 hands of youth, what is your company doing?

1118 Mr. Blonde. As for all of our products, we keep all of our  
1119 products outside of the hands of youth through a very robust youth  
1120 access prevention program. And this is through our marketing  
1121 practices. The use of all the means that we put in marketing  
1122 are only related to adult consumers, and we are being very careful  
1123 about that.

1124 We are using very strict labeling rules as well to make sure  
1125 that our products are informative and appropriate for consumption  
1126 for adult smokers only. And we engage very actively with our  
1127 retailers/partners to make sure that not any product is being  
1128 sold to a youth.

1129 Mr. Guthrie. Thank you.

1130 And some of the others, since you all answered, I just want

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1131 to get to. What actions as your company, recent actions have  
1132 your companies taken to curb youth access to the products? And  
1133 do you monitor access and how do you make sure youth aren't using  
1134 them?

1135 And then, I think Mr. Loftin used the term they have controls  
1136 in place. So, if you want to talk about what controls in place  
1137 each of you, the other two can kind of answer that question, to  
1138 keep youth from having access to your product.

1139 Mr. Crosthwaite. When I joined the organization, it was  
1140 obvious to me that youth use levels were unacceptable. And we  
1141 took immediate action when I joined and we pulled back and stopped  
1142 all of our product, our digital and broadcast/print advertising.

1143 When I saw the access that youth were getting to certain flavors,  
1144 including the bars, we stopped shipping them in November of last  
1145 year.

1146 We are also focused at preventing access in the retail  
1147 channel and working on technology solutions with retailers to  
1148 ensure that identifications are scanned and bulk limit purchases  
1149 are in place, so that transactions are only happening with adults  
1150 in retail stores. It is an effort that we are focused on, and  
1151 we know we must combat the underage access to e-vapor.

1152 Mr. Guthrie. Can I jump to Mr. Oberlander? And then, we  
1153 will get to Mr. Loftin, hopefully.

1154 Mr. Oberlander. First of all, our communication has been  
1155 directed to adult consumers 21-plus since the very beginning.

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1156 Second, most of our engagement is one-to-one mission-based.  
1157 Third, we are early supporters of Tobacco 21+. Fourth, we have  
1158 age-gated protocols in process for all our online interactions;  
1159 we have state-of-the-art stage-gating for online purchases.  
1160 Fifth, we have enhanced our contractual policies and penalties  
1161 --

1162 Mr. Guthrie. Okay, I am out of time. But, with the  
1163 indulgence of the chairman, Mr. Loftin, you said you have controls  
1164 in place? So, you are going to give me a few seconds.

1165 Mr. Loftin. Yes, sir. We always have a health warning.  
1166 Online, we have strict age verification. We have no marketing  
1167 flavors that we specifically go after minors. Consumer  
1168 marketing, all our models are above 30 years old, and we use no  
1169 social influencers.

1170 Mr. Guthrie. Thank you very much.

1171 I yield back.

1172 Ms. DeGette. The chair now recognizes the chairman of the  
1173 full committee for 5 minutes, Mr. Pallone.

1174 The Chairman. Thank you, Madam Chair.

1175 I just wanted to say a little disclaimer here. I heard all  
1176 of you over and over again say you were responsible men, men of  
1177 integrity. That is not true. People who have integrity and are  
1178 responsible don't sell products which, after listening to Ms.  
1179 DeGette's questions, you admit make people sick, probably kill  
1180 people. If you wanted to be men of integrity and responsible

1181 men, you would not be selling this product. You would do  
1182 something else. So, I just want you to understand I am very upset  
1183 by hearing this constant reference to your integrity and  
1184 responsibility. It is just false.

1185 But I wanted to get to the bottom of this. I don't believe  
1186 for one minute that any of you did not purposely target young  
1187 people, but you are not going to admit that. So, let me get to  
1188 my questions.

1189 I continue to be alarmed by the rapid increase in the number  
1190 of young people who are using your product, youth interest and  
1191 curiosity in e-cigarettes. That stems not only from availability  
1192 and kid-friendly flavors, but also from the persuasive and  
1193 targeted marketing tactics. And these tactics are not dissimilar  
1194 to those used by Big Tobacco decades ago. Instead of Joe Camel,  
1195 e-cigarette companies have used social media to convince  
1196 consumers these products will make you cool.

1197 A Stanford study found that in the years following the launch  
1198 of its product, JUUL's advertising was, and I quote, "widely  
1199 distributed on social media channels frequented by youth, was  
1200 amplified by hashtag extensions, and catalyzed by compensated  
1201 influencers and affiliates."

1202 So, my questions are all of you, Mr. Crosthwaite. I could  
1203 ask the others, but I don't have enough time.

1204 Mr. Crosthwaite, at the time that JUUL used these tactics,  
1205 were any controls in place to prevent the advertising and

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1206 marketing activities from reaching young people? Briefly, if  
1207 you could answer? Were there any controls or any effort to  
1208 prevent the advertising and marketing from reaching young people?

1209 Mr. Crosthwaite. Just to be clear, we do not do any of the  
1210 social media programs today. They are not in place.

1211 The Chairman. No, I am talking about when you started doing  
1212 it.

1213 Mr. Crosthwaite. Yes, so, from my recollection, looking  
1214 back in time, this company never had any intention to market to  
1215 youth.

1216 The Chairman. I know you are going to say you had no  
1217 intention. I don't think anybody here is going to admit their  
1218 intent was to market to youth. But what I am asking you, at the  
1219 time that you were doing this, were any controls in place to  
1220 prevent the advertising and marketing activities from reaching  
1221 young people? If the answer is no, you can say no.

1222 Mr. Crosthwaite. It was before my time at the company and  
1223 --

1224 The Chairman. Okay, it was before your time.

1225 Mr. Crosthwaite. -- we are not in social media.

1226 The Chairman. JUUL has acknowledged that it was not able  
1227 to prevent young people from engaging with its product on social  
1228 media. So, I am not going to ask you that.

1229 But, in the November 2018 release announcing your action  
1230 plan to address underage use of e-cigarettes, JUUL's stated, and



1231 I quote it, "User-generated social media posts involving JUUL  
1232 products or our brand are proliferating across platforms and must  
1233 be swiftly addressed." Unquote.

1234 So, Mr. Crosthwaite, what was the tipping point that led  
1235 JUUL to decide that it's marketing practices were a problem that  
1236 needed to be addressed? I know you are going to say you didn't  
1237 target young people, but your action plans state that at some  
1238 point you realized that the social media was causing that. So,  
1239 what was the tipping point that led JUUL to decide that these  
1240 marketing practices were a problem that you should address? At  
1241 what point?

1242 Mr. Crosthwaite. Well, the company in the past has taken  
1243 actions when youth data became available, and I believe it was  
1244 in, my best recollection, 2018 the company stopped being on social  
1245 media.

1246 The Chairman. Okay. Now you have disabled Facebook and  
1247 Instagram accounts, but hashtags involving your products continue  
1248 to be shared across these social platforms. Despite your efforts  
1249 to end your social media presence, it is clear that your influence  
1250 continues to be active through user-generated content. As you  
1251 indicated, again in this action plan, and I quote, "There is no  
1252 question that this user-generated social media content is linked  
1253 to the appeal of vaping to underage users."

1254 So, Mr. Crosthwaite, after years of marketing practices to  
1255 attract young people, is it reasonable to say that JUUL's actions

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1256 were too little too late? I mean, hasn't the train already left  
1257 the station? Because now, you know, the social media is being  
1258 used by the people themselves, not by yours. So, don't you think  
1259 that taking this off the market or all social media was a little  
1260 too late? Yes or no?

1261 Mr. Crosthwaite. Mr. Chairman, when I joined the  
1262 organization, I knew more needed to be done. And that is why  
1263 I took the steps that I took to combat this issue that we are  
1264 facing.

1265 The Chairman. Okay. Last question, because I only have  
1266 got a few minutes. Do you agree that kids who cannot legally  
1267 purchase tobacco products should never be the target of tobacco  
1268 product advertising, including e-cigarette advertising and  
1269 marketing? Yes or no?

1270 Mr. Crosthwaite. No, the products should never be intended  
1271 to be marketed to youth, and that is not the company's intentions.

1272 The Chairman. All right. Thank you.

1273 Thank you, Madam Chair.

1274 Ms. DeGette. The chair now recognizes Mr. McKinley for 5  
1275 minutes.

1276 Mr. McKinley. Thank you, Madam Chair.

1277 I want to go back to, there are numbers of studies that were  
1278 done by the National Academies of Sciences, Engineering, and  
1279 Medicine. As a result of all those studies, they have come to  
1280 a conclusion that said that, included in the vaping products are

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1281 heavy metals, ultrafine particles, and toxic and carcinogen  
1282 materials, ingredients. Do any of you deny that there are  
1283 ultrafine particles? Let's just focus on the ultrafine  
1284 particles, the particles in the fluids. Do any of you deny that  
1285 these particles are there, despite the reports?

1286 Mr. Crosthwaite?

1287 Mr. Crosthwaite. Sorry, I am not familiar with the specific  
1288 report that you are referring to, but I will tell you, for our  
1289 --

1290 Mr. McKinley. It is just a conclusion. Really,  
1291 specifically to your product, do you have ultrafine particles  
1292 in your product?

1293 Mr. Crosthwaite. I am not familiar with the ultrafine  
1294 particles that --

1295 Mr. McKinley. Ultrafine particles are defined as 1 micron,  
1296 1 micron of materials. In a hearing earlier, they indicated that  
1297 1 micron exists in almost all, if not all, and maybe even larger.

1298 But the concern for young people -- well, maybe for anyone --  
1299 is 1 micron getting in someone's lungs can have some long-term,  
1300 very deleterious effect. And if we are allowing 1 micron to be  
1301 in these fluids, it is going to be introduced to people's lungs  
1302 in young people, old. Anyone that uses this product is going  
1303 to have a health risk, a health problem with it. And they are  
1304 saying that.

1305 So, you don't. Any of the rest of you acknowledge that,

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1306 yes, maybe it is in there? Mr. Oberlander?

1307 Mr. Oberlander. If I can, I understand your concern, sir.

1308 Mr. McKinley. Use your microphone, please.

1309 Mr. Oberlander. Sorry. Can you hear me now?

1310 Ms. DeGette. Yes.

1311 Mr. Oberlander. Okay, sorry.

1312 I understand your concern, sir, but we do believe that,  
1313 actually, through the PMTA applications, we can actually provide  
1314 the FDA with all the evidence in order to understand what is the  
1315 level of exposure of chemicals that you have mentioned and other  
1316 substances, in order for the FDA to make a decision about the  
1317 impact on public health.

1318 Mr. McKinley. Okay. Apparently, I am not going to get  
1319 quite the answer I am looking for -- or just an answer. Just  
1320 for people to understand, 1 micro, the science of a micron most  
1321 people wouldn't understand that, but 50 microns is below the naked  
1322 eye. We are talking about 1/50th of a micron is going to be in  
1323 your lungs; we are going to be introducing it. It is a millionth  
1324 of a meter. We are talking about something extremely small.  
1325 And at 1 micron getting into your lungs, you are going to have  
1326 some long-term problems.

1327 When we have been debating the Clean Air Act and the issues  
1328 on that, we allow up to two and a half. That is the limit we  
1329 think that we can tolerate, the two and a half. But we are  
1330 allowing this product to be down to 1 micron, significantly

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1331 causing long-term health care risks.

1332 And so, I guess my concern is, not only are we allowing these  
1333 small microns to get into our lungs, but we are also allowing  
1334 people to introduce other cancerous materials that are in THC,  
1335 the acetate. Is that something that we should be paying more  
1336 attention to, how to prevent people from aftermarket introducing  
1337 a product into their device? And how do we make it so that it  
1338 is not tamper-resistant, but tamper-proof? So that people can't  
1339 play with this and cause even more health concerns.

1340 CDC has come out with quite a study about all this, the THC  
1341 additive that we were talking about, the vitamin E acetate, how  
1342 that is being put into aftermarket utilization. Are any of you  
1343 doing anything to prevent the aftermarket introduction of THC  
1344 and this vitamin E acetate? Any of you?

1345 Mr. Loftin. Congressman --

1346 Mr. McKinley. Mr. Loftin, please.

1347 Mr. Loftin. Yes, Congressman, we have pre-filled, sealed  
1348 cartridges that they can't get in at this point.

1349 Mr. McKinley. Okay. So, we have got one of you that has  
1350 got a preventive.

1351 I have run out of time. I yield back. Thank you.

1352 Ms. DeGette. I thank the gentleman. The chair now  
1353 recognizes Ms. Schakowsky for 5 minutes.

1354 Ms. Schakowsky. Last September, President Trump promised  
1355 to take action to take all of the non-tobacco-flavored products

1356 from the marketplace in response to the youth vaping epidemic.  
1357 But he didn't. That is not true. Incredibly, the Trump  
1358 administration caved to special interests and created exemptions  
1359 for disposable e-cigarettes in every imaginable flavor and  
1360 menthol-flavored e-cigarettes.

1361 So, Mr. Blonde, this carveout will allow, it is my  
1362 understanding, that Fontem "Vivid Vanilla" and "Cherry Blast"  
1363 -- these are disposable products, clearly not aimed at adults  
1364 -- to remain on the market. We will get back to that later.

1365 We already have reports of young people shifting to these  
1366 fruit- and dessert-flavored disposable products. There was a  
1367 headline in The New York Times last week that says, "Teens Find  
1368 a Big Loophole in the New Flavored Vaping Ban".

1369 So, you all say your products were created to help adults  
1370 to stop smoking tobacco, but, thanks to your products, this is  
1371 an entire generation of young people that are now addicted to  
1372 nicotine. And we have heard discussion about what that problem  
1373 can be and the microns. And I thank Mr. McKinley for that.

1374 Mr. Crosthwaite, JUUL cannot deny the role of its legacy  
1375 in the epidemic. JUUL is literally a common verb now; "JUULing"  
1376 is now what people are talking about. And each of you must accept  
1377 responsibility for the role that you have played in reviving the  
1378 youth tobacco epidemic or youth vaping epidemic.

1379 Mr. Loftin, yes or no, do you believe the administration's  
1380 exemption for any disposable product will leave many mint, fruity,

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1381 and other sweet cigarette products easily accessible to young  
1382 people?

1383 Mr. Loftin. We were disappointed in the guidance. We  
1384 thought it should have gone further and all companies and all  
1385 products should have been a part of the PMTA process.

1386 Ms. Schakowsky. Mr. Nivakoff, NJOY recently decided to  
1387 voluntarily stop selling all flavored disposable products, and  
1388 that they are not available to youth. Do you believe there is  
1389 a risk that they will simply turn to using the disposable flavored  
1390 products?

1391 Mr. Nivakoff. As the data has demonstrated, NJOY hasn't  
1392 contributed statistically to youth use historically. So, the  
1393 notion that youth would switch from our flavored disposable  
1394 product to another flavored disposable product is factually  
1395 inaccurate because they haven't been using it to begin with.

1396 Ms. Schakowsky. So, disposable e-cigarettes are attractive  
1397 to youth because they cost less, can be easily hidden, and have  
1398 an enticing range of flavors. Mr. Blonde, given what you have  
1399 heard here today, will you join NJOY and commit to voluntarily  
1400 suspending the sales of your disposable "Vivid Vanilla" and  
1401 "Cherry Crush" products?

1402 Mr. Blonde. Our disposable products have been on the market  
1403 for about 10 years, and as for other disposable products, these  
1404 are widely obtained by very older consumers. We are not aware  
1405 of any issue, current issue, caused by our disposable flavored.

1406           And the fact that the FDA excluded the disposables from the  
1407 guidance, we will comply on completely, but on disposables, we  
1408 do have 9 million vaporers in the U.S., more or less adult smokers,  
1409 that are currently using our products which look like a cigarette.

1410           It has been designed like that and didn't change the design in  
1411 the last 10 years.

1412           I am aware --

1413           Ms. Schakowsky. And you are not concerned that those are  
1414 also used by kids, that they may be attracted by those names?

1415           Mr. Blonde. We don't have any issue.

1416           Ms. Schakowsky. No, you --

1417           Mr. Blonde. We don't have an issue right now on historical,  
1418 and we are monitoring that very carefully.

1419           I have a concern, though. I have seen The New York Times  
1420 articles recently about new disposables coming into the market  
1421 that probably don't have a youth access prevention program that  
1422 would be robust enough, and as well, apparently, will be in some  
1423 foam factors that will be very appealing to these --

1424           Ms. Schakowsky. My time has expired.

1425           I hear a lot of you relying on the Food and Drug  
1426 Administration, and it seems to me that, as much as we want to  
1427 have the data, that you ought to know -- I was just shocked that  
1428 you did not know about the reports about the content of your vaping  
1429 products.

1430           And I will yield back.



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1431 Ms. DeGette. I thank the gentlelady. The chair now  
1432 recognizes Mr. Duncan for 5 minutes.

1433 Mr. Duncan. Thank you, Madam Chair.

1434 And thank you all for being here today.

1435 You know, e-cigarette products have been in use at least  
1436 since the early 2000s, I believe. And I know that we can all  
1437 agree that the youth vaping epidemic is a serious problem. But  
1438 this has been a recent development. So, you have to stop and  
1439 ask yourself, if the products have been out there for that long,  
1440 you have to ask yourself, why is this a recent occurrence? I  
1441 say "recent"; within the last few years.

1442 E-cigarettes were developed as an alternative to tobacco  
1443 products, tobacco products which can contain tar and other things  
1444 that are damaging to the body. But you also have to ask yourself,  
1445 if e-products are used, e-cigarette products are used in Europe  
1446 and other places in the world, why they aren't seeing the uptick  
1447 in health-related problems that we are seeing and the deaths that  
1448 we are seeing here in the United States. These are rhetorical  
1449 questions that we have to ask ourselves.

1450 And I want to reference, Madam Chair, a Politico article  
1451 dated October of 2019 and submit it for the record.

1452 Ms. DeGette. Without objection.

1453 [The information follows:]

1454

1455 \*\*\*\*\* COMMITTEE INSERT \*\*\*\*\*

1456           Mr. Duncan. In that article, it also references that the  
1457 Trump administration is urging people to avoid buying unregulated  
1458 vape products. And I think we can point to the unregulated vape  
1459 products, the black market products, and the tampered-with  
1460 products as the leading cause for the health problems. They are  
1461 not seeing that in Europe.

1462           In fact, Constantine Vardavas, a European Respiratory  
1463 Society Scientific Regulations Director within the EU says this,  
1464 "We have not seen anything like what we are seeing in the U.S.  
1465 recently in Europe, to my knowledge as a scientist, and I'm pretty  
1466 aware of the field."

1467           Clive Bates, former Chief of the UK charity Action on Smoking  
1468 and Health said this, "You're terrifying people who are  
1469 benefitting from vaping by not smoking." I think that was the  
1470 ultimate reason the e-cigarette products were created in the first  
1471 place.

1472           So, the question I have is, are youth being pushed to black  
1473 market where they are finding THC pods and other counterfeit  
1474 products? The lung illnesses that have been reported over the  
1475 last several months are almost directly linked to the black market  
1476 products, not the commercially-produced products by the companies  
1477 represented here today.

1478           So, I think it is extremely important that we have an ongoing  
1479 conversation about how your companies are working to minimize  
1480 the number of black market products and what we in Congress can

1481 do. Instead of attacking you for developing an alternative  
1482 cigarette use, we ought to talk about how we can work together  
1483 to help this industry because it is an alternative to smoking.

1484 I personally believe that much more could be done to assist  
1485 the Customs and Border Protection with identifying, and  
1486 Immigration and Customs Enforcement, which seems to get the ire  
1487 of the left, but there are Customs Enforcement officers that are  
1488 actually enforcing our customs laws. Okay? We need to help them  
1489 to identify and intercept black market e-cigarettes.

1490 So, my first question for all the witnesses is, can you speak  
1491 to the relationships your companies have with CBP agents and how  
1492 you are working alongside them to combat the influx of black market  
1493 e-cigarettes? And I will start with Mr. Crosthwaite.

1494 Mr. Crosthwaite. Thank you.

1495 And first, our hearts go out to anyone who was hurt and  
1496 impacted by the unfortunate EVALI situation, and we were fully  
1497 supportive when that investigation was going on. And we do not  
1498 sell any THC products or products that contain vitamin E.

1499 But you are right to call out the amount of illicit products  
1500 that exist in the United States market.

1501 Mr. Duncan. Is it difficult for the CBP officers to detect  
1502 a counterfeit product versus a legitimate product, if it is  
1503 manufactured overseas?

1504 Mr. Crosthwaite. Yes. So, we have a brand protection  
1505 organization within our company who works with law enforcement,

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1506 Border Patrol, other regulatory agencies, on education,  
1507 awareness, and helping combat this issue.

1508 Mr. Duncan. Mr. Oberlander? Put your microphone on.

1509 Mr. Oberlander. Mr. Congressman, first of all, this is a  
1510 very serious issue and I understand your concern. When the EVALI  
1511 crisis broke out, we were very concerned about, I mean very sorry  
1512 for the pain that actually the families of victims were going  
1513 through. And then, we immediately contacted the FDA and the CDC  
1514 offering our help. We had, to my knowledge, no confirmed cases  
1515 associated with our VUSE products. I mean associated with the  
1516 victims of the EVALI crisis.

1517 Ms. DeGette. Can you move the microphone back up again?

1518 It is okay.

1519 Mr. Duncan. And in the essence of time, I am running out  
1520 here.

1521 Mr. Oberlander. Okay. And then, definitely, we have  
1522 worked with enforcement agencies in order to curb illicit trade,  
1523 which is a serious problem for this country.

1524 Mr. Duncan. Yes. I am out of time, guys. Let me just  
1525 reiterate, we need to work with the Customs and Border Patrol  
1526 and Immigration and Customs Enforcement agencies, and this  
1527 committee needs to work with them as well, even though we don't  
1528 have necessarily jurisdiction, to figure out how we can stop the  
1529 counterfeit products from coming into this country and address  
1530 the real problem. And that is tampering with the legitimate

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1531 products and the counterfeit products that people are using in  
1532 this country, because, apparently, it is not a problem in Europe.

1533 And with that, I yield back.

1534 Ms. DeGette. The gentleman yields back. The chair now  
1535 recognizes Mr. Kennedy for 5 minutes.

1536 Mr. Kennedy. Thank you, Madam Chair, for holding this  
1537 hearing.

1538 Thank you to our witnesses for being here.

1539 We have heard consistent testimony from all of you this  
1540 morning saying these products were designed to help people  
1541 transition off cigarettes, that they were not designed to market  
1542 to children or youth, and that if you are not a smoker, you should  
1543 not start.

1544 To echo some of the skepticism from my colleagues, some of  
1545 these products are marketed for 99 cents. It seems pretty easy  
1546 to get started.

1547 I had a youth council of high school students from my district  
1548 over the course of the past several years. It was probably about  
1549 four years ago where a high school student asked me if Congress  
1550 was going to step in and regulate e-cigarettes because everyone  
1551 in their school was smoking.

1552 It is a bit difficult for us, I think, to hear your concern  
1553 for youth when there was systemic and systematic and strategic  
1554 social media campaigns to get products in front of kids. It is  
1555 very difficult for me to understand -- and I am certain that all

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1556 of you have followed this information -- I can't imagine that  
1557 your companies don't. I can't imagine that you would be a CEO  
1558 if you didn't.

1559 But when Johns Hopkins says, from 2016 to 2018, the adult  
1560 non-smokers that are now using e-cigarette products has doubled,  
1561 that there are now 6 million people that you claim were not the  
1562 targeted market audience for your products, but there are 6  
1563 million more customers that have come in that weren't the folks  
1564 that supposedly, at least outwardly, people were marketing to.

1565 In a 2019 Youth Tobacco Survey, a quarter of high school students  
1566 had vaped in the last 30 days. And yet, we are saying we are  
1567 not marketing to them. I think it is pretty hard to say that  
1568 the consequence of the products that you have injected, and the  
1569 ways in which you have gone about your businesses, haven't  
1570 marketed to kids.

1571 Mr. Crosthwaite, I understand that you are newly at the  
1572 position. I understand that the previous executives might not  
1573 have done things the way that you would have wanted and your  
1574 company would have wanted, and certainly I would have wanted.

1575 So, we have seen a change there.

1576 But, respectfully, what are you going to do to fix it? You  
1577 can stop advertising now. You can stop putting up some of these  
1578 bars. And I appreciate that, but we have now created an epidemic  
1579 that is going to be touching today a quarter of all high school  
1580 students; that the bars that you put up -- I disagree a bit with

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1581 Mr. Duncan's formulation of this, but he is not wrong. We now  
1582 step in to regulate; you create incentives for a black market.

1583 Kids are going to go someplace else. Your company now is old  
1584 news, and they are off to the next one, because of an industry  
1585 that you helped create. And there are quotes in The New York  
1586 Times from people in your company that have said that that was,  
1587 in fact, never really the objective. And now, you are before  
1588 us saying, "Yes, we are open for regulation." What are we going  
1589 to do to stop this? What do I do?

1590 And if the concern is a black market and an evolution of  
1591 new products that will come out that don't have the robust  
1592 protections that you all are now putting in place, would you pledge  
1593 at this moment not to purchase one of those companies or acquire  
1594 one of those companies or engage in those product sales?

1595 Mr. Crosthwaite?

1596 Mr. Crosthwaite. We do not sell any of the --

1597 Mr. Kennedy. Will you not sell? Will you not? Will you  
1598 pledge not to acquire a company that is engaged? You have put  
1599 up bars, but there are new products out there from new companies  
1600 that don't face that regulation. Would you pledge not to acquire  
1601 such a company that engages in those practices?

1602 Mr. Crosthwaite. What we are focused on is submitting our  
1603 PMTA. We have no plans at this time to --

1604 Mr. Kennedy. So, no plan?

1605 Mr. Oberlander?

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1606 Mr. Oberlander. Could you repeat your question, please?

1607 Mr. Kennedy. Will you pledge not to acquire a company that  
1608 does not currently abide by the practices that you say you abide  
1609 by, as they increase their own market share?

1610 Mr. Oberlander. We are not focused on that --

1611 Mr. Kennedy. So, a second non-answer.

1612 Mr. Nivakoff?

1613 Mr. Nivakoff. I would fully pledge.

1614 Mr. Kennedy. Fully pledge?

1615 Mr. Blonde?

1616 Mr. Blonde. We don't have any intent to purchase any  
1617 company.

1618 Mr. Kennedy. Mr. Loftin?

1619 Mr. Loftin. We have no intent, but we will honor that we  
1620 will always market responsibly.

1621 Mr. Kennedy. And so, given that we have now created this  
1622 industry that has a younger generation that is now addicted, what  
1623 do you want us to do about it?

1624 Mr. Crosthwaite?

1625 Mr. Crosthwaite. Congressman, I fully recognize that the  
1626 opportunity for the millions of adult smokers who still use  
1627 combustible cigarettes to have an alternative is at risk if we  
1628 don't address this issue. And we are focused on combating  
1629 underage access because I know it puts it all at risk if we don't  
1630 make progress here.



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1631 Mr. Kennedy. So, how do I trust what you say?

1632 Mr. Crosthwaite. My actions so far since I have joined  
1633 support our recognition that more needed to be done. So, we have  
1634 taken action and we recognize more needs to be done to turn this  
1635 issue around. We have been successful converting millions of  
1636 adults away from the most harmful form of tobacco use, and also  
1637 recognize that that is at risk if we don't continue to make  
1638 progress.

1639 Mr. Kennedy. I yield back.

1640 Ms. DeGette. The chair now recognizes Mr. Griffith for 5  
1641 minutes.

1642 Mr. Griffith. Thank you very much, Madam Chair. I  
1643 appreciate it.

1644 We heard testimony earlier from Dr. Nora Volkow -- this was  
1645 at a previous hearing -- that in December the number of youth  
1646 who were using the vaping products, there were more youth using  
1647 THC vaping products than nicotine vaping products. The youth  
1648 vaping epidemic is a separate health concern from the e-cigarette,  
1649 vaping-association lung injury, EVALI outbreak. The use of  
1650 vitamin E acetate in THC has been strongly linked to those lung  
1651 illnesses. Is vitamin E acetate used in any of your brands'  
1652 cartridges? We will start with you Mr. Crosthwaite.

1653 Mr. Crosthwaite. No, Congressman.

1654 Mr. Oberlander. No.

1655 Mr. Nivakoff. No, sir.

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1656 Mr. Blonde. No, sir.

1657 Mr. Loftin. No, sir.

1658 Mr. Griffith. So, none of your companies sell anything that  
1659 contains THC or is specifically designed to be used with THC  
1660 products? Can I assume that to be correct?

1661 Mr. Crosthwaite. Correct, we do not.

1662 Mr. Oberlander. No, sir.

1663 Mr. Nivakoff. No, sir.

1664 Mr. Blonde. No, sir.

1665 Mr. Loftin. No, sir.

1666 Mr. Griffith. Now can your products be adulterated so they  
1667 can be used with THC products, modified or changed? Do you know?

1668 Mr. Crosthwaite. Our products are not designed to be  
1669 changed or modified. They are tamper-resistant.

1670 Mr. Oberlander. Our products are also designed to be  
1671 tamper-resistant.

1672 Mr. Nivakoff. The same answer, sir.

1673 Mr. Blonde. Same answer, sir.

1674 Mr. Loftin. Our products are presealed cartridges. They  
1675 can't get in them.

1676 Mr. Griffith. And what steps do you have, or plan to take,  
1677 to prevent somebody using your device with some kind of a knockoff  
1678 product that could be used with one of your devices?

1679 Mr. Crosthwaite. So, we take steps, when we see in the  
1680 market illegal products that come on, to work to get them removed

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1681 from the market. There are pods out there that are not intended  
1682 to be used with our device. When we see it, we try to get them  
1683 off the market.

1684 Mr. Oberlander. To my knowledge, at this point in time,  
1685 we don't have any counterfeit or illicit products actually for  
1686 our VUSE products.

1687 Mr. Griffith. Does anybody have a different answer?

1688 Mr. Oberlander. We closely monitor the market.

1689 Mr. Griffith. Thank you.

1690 Does anybody have a different answer? Okay.

1691 It is interesting because I had some folks who own vape shops  
1692 come in to see me recently, and what they said was, "Look, we  
1693 want people to come in and inspect us. We want them to see that  
1694 we're using the right products, that we're not selling anything  
1695 that's contraband or has been smuggled into the country, or that  
1696 has THC when it's not supposed to be there. We don't sell those  
1697 products."

1698 Would you all agree that it is important that we have  
1699 regulations, but that we also make it possible for there to be  
1700 outlets for adults to go to vape shops instead of being bought  
1701 on the street corner from some renegade company?

1702 Mr. Crosthwaite. Congressman, we completely support the  
1703 FDA process and believe it is the most appropriate body to provide  
1704 oversight for this industry and, in fact, to preserve the chance  
1705 for adults to have access to alternatives to combustible

1706 cigarettes.

1707 Mr. Griffith. And does anybody else have a different answer  
1708 or something they would like to add to that? Mr. Loftin?

1709 Mr. Loftin. At Logic, we don't believe it has gone far  
1710 enough. We think all products and all companies should go through  
1711 the same process.

1712 Mr. Griffith. All right. I appreciate that.

1713 And I also understand that some of you make a zero-nicotine  
1714 product. Can you explain why and for what purpose a nicotine-free  
1715 EVP might serve us? That would be a vaping product, for those  
1716 who are watching at home. No nicotine?

1717 Mr. Crosthwaite. We do not make that product.

1718 Mr. Griffith. You don't make that product? Do you all make  
1719 that? Does anybody else make that product?

1720 Mr. Oberlander. At this point in time, we don't have it.  
1721 We are considering it.

1722 Mr. Nivakoff. No, sir.

1723 Mr. Griffith. Okay.

1724 Mr. Blonde. Yes, we do.

1725 Mr. Griffith. Tell me about it.

1726 Mr. Blonde. In some cases, some smokers have evolved their  
1727 way of taking nicotine. And at blu, we want to offer a full range  
1728 of nicotine.

1729 Mr. Griffith. And they still want to have the feel of having  
1730 something in their mouth or something that they are breathing

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1731 in? What causes that?

1732 Mr. Blonde. Yes, as in my opening statement, I mean, some  
1733 of our adult consumers decide to keep their pleasurable experience  
1734 with our products, but without nicotine.

1735 Mr. Griffith. Right.

1736 Mr. Loftin, do you all have a product like that?

1737 Mr. Loftin. No, sir.

1738 Mr. Griffith. Okay. Well, very good. My time is just  
1739 about up, but I appreciate you --

1740 Ms. DeGette. Will the gentleman yield, please, the rest  
1741 of his time?

1742 Mr. Griffith. I will yield you my 37 seconds, yes, ma'am.

1743 Ms. DeGette. Mr. Blonde, what percentage of your sales are  
1744 the no-nicotine e-cigarettes?

1745 Mr. Blonde. I don't have a precise number, but it is quite  
1746 low.

1747 Ms. DeGette. Quite low? Could you supplement your answers  
1748 with the exact number?

1749 Mr. Blonde. I would be happy to.

1750 Ms. DeGette. Thank you so much.

1751 Thank you. I yield back.

1752 Mr. Griffith. I yield back.

1753 Ms. DeGette. The chair now recognizes Ms. Castor for 5  
1754 minutes.

1755 Ms. Castor. Thank you, Madam Chair, for calling this

1756 important hearing today. It has really highlighted how  
1757 e-cigarettes and vape manufacturers have enticed young people  
1758 to their products.

1759 And I am particularly concerned about companies marketing  
1760 through social media to target -- it is an insidious use of social  
1761 media to target young people. And it has continued to happen  
1762 even after the harm has become clear to young people, the addictive  
1763 nature, the impact on the developing brain, among other health  
1764 impacts.

1765 Mr. Crosthwaite, prior to reforming your social media  
1766 marketing efforts in November of 2018, a large number of the JUUL  
1767 social media followers were young people. In fact, according  
1768 to the Journal of American Medical Association Pediatrics, almost  
1769 half of your Twitter followers were age 13 to 17. You testified  
1770 here today that JUUL should never be marketed to youth, but they  
1771 were extensively marketing to youth in the past. I assumed that  
1772 JUUL addressed its social media presence because it was concerned  
1773 about how its social media activities did impact youth. Is that  
1774 correct?

1775 Mr. Crosthwaite. Yes, it was before I joined the  
1776 organization when the company stopped in social media activity.

1777 And what we are actually focused on today with social media is  
1778 getting posts off. So, we look for posts that we think are  
1779 inappropriate. We ask them to be taken down, so that the access  
1780 to this type of information is not available.

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1781           Ms. Castor.    So, Mr. Blonde, you just heard Mr. Crosthwaite  
1782           state that they have a strategy, a social media strategy, but  
1783           he acknowledged that social media does impact youth use of the  
1784           vapes.   As a major player in the industry, Fontem continues to  
1785           use social media as a marketing tool.   On one hand, you have said  
1786           here today, boy, you have an access program, you are trying to  
1787           do everything you can to discourage, but, on the other hand, you  
1788           continue to actively market to youth through social media.   Why  
1789           do you do that?

1790           Mr. Blonde.   We don't market to youth in any shape or form.

1791           Ms. Castor.   Well, one aspect of Fontem's social media  
1792           activity I am concerned about is the use of the social media  
1793           influencers.   Underage youth who may be blocked from your social  
1794           media accounts still can go to YouTube and see your posts that  
1795           promote your product.   The influencers' promotion of these  
1796           products is especially harmful because the popularity of the  
1797           influencers, the individuals, can sway young people into  
1798           believing that the products are attractive and they are trendy.

1799           Will you commit here today to end your use of influencers to  
1800           market the vapes to young people?

1801           Mr. Blonde.   We have currently stopped producing any content  
1802           from those influencers.

1803           Ms. Castor.   What have you done to actively, then, end the  
1804           influencers' use, the use on YouTube, of all of those videos?

1805           Mr. Blonde.   We have very strict measures as far as it

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1806 pertains to social media. We believe social media is an accepted  
1807 platform of communication for our adult smokers.

1808 Ms. Castor. I mean, what social media is and the use of  
1809 the influencers now, it makes it very difficult to control the  
1810 dissemination of the marketing information.

1811 Mr. Crosthwaite, do you think that the e-cigarette industry  
1812 as a whole should end its use of social media as a marketing tool,  
1813 given the difficulty in preventing youth from being exposed to  
1814 this material, influencers included?

1815 Mr. Crosthwaite. What I have been focused on as CEO, since  
1816 I have joined, is taking every step I believe I can to minimize  
1817 youth getting access to --

1818 Ms. Castor. Was that a yes or --

1819 Mr. Crosthwaite. We are not on social media. I stopped,  
1820 actually, all of our advertising --

1821 Ms. Castor. You are the market leader now. What would you  
1822 say to these other CEOs who are not going down the same path?

1823 Mr. Crosthwaite. I can just share what I have been focused  
1824 on, which is addressing youth getting any really access to  
1825 information that they should not. And that is why I have taken  
1826 the steps I have as CEO.

1827 Ms. Castor. Mr. Loftin, do you use influencers?

1828 Mr. Loftin. We do not use influencers.

1829 Ms. Castor. Mr. Nivakoff?

1830 Mr. Nivakoff. No, ma'am, we do not use influencers.



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1831 Ms. Castor. Mr. Oberlander?

1832 Mr. Oberlander. We do not use social influencers.

1833 Ms. Castor. So, Mr. Blonde, you are the odd man out here.

1834 Mr. Blonde. Again, I mean, the use of influencers, as I  
1835 was going to say, the choice of influencers is making sure that  
1836 all people that we are interacting to are above 25 and look above  
1837 25.

1838 Ms. Castor. Well, that is not good enough in today's age  
1839 of social media. You have got to be proactive and you have got  
1840 to control. If you are say, on the one hand, "I am not going  
1841 to market to youth," and then, on the other hand, you are allowing  
1842 the dissemination of videos and influencers on those platforms,  
1843 you are really being hypocritical and it needs to be brought under  
1844 control. We understand how harmful these products are. You have  
1845 a responsibility, especially with the growing harm, the growing  
1846 evidence of the health impacts to young people, not to market  
1847 to them.

1848 I yield back my time.

1849 Ms. DeGette. The gentlelady from New Hampshire, Ms. Kuster,  
1850 is recognized for 5 minutes.

1851 Ms. Kuster. Thank you, Chairwoman DeGette, and thank you  
1852 for holding this very, very important hearing.

1853 Let me just start by saying, as a mother of two sons, I spent  
1854 the last 30 years trying to keep them from smoking cigarettes.

1855 And instead, you have come into our life with nicotine that is

1856 highly addictive.

1857           So, I want to just say, based on the data, that we are on  
1858 the precipice of minimizing tobacco's hold on our nation's youth,  
1859 but confronting alarming rates of youth nicotine use. As a  
1860 result, e-cigarettes are now the most commonly-used tobacco  
1861 product among youth, surpassing the rate of youth use of  
1862 conventional cigarettes five years ago. In fact, e-cigarette  
1863 use among youth doubled again from 2017 to 2019, demonstrating  
1864 that this problem is only getting worse.

1865           And in my home State of New Hampshire, the Department of  
1866 Health and Human Services estimates that at least a quarter of  
1867 high-schoolers are using vaping products, and those numbers are  
1868 on the rise. Now Dr. Sue Tanski, who was before this committee  
1869 recently, a pediatrician from Dartmouth-Hitchcock, has helped  
1870 us to understand this very issue. Based upon her testimony, sworn  
1871 under oath, we know that biologically the brain is more  
1872 susceptible to nicotine addiction during adolescence. Late  
1873 adolescence begins around 18 and, for most, lasts well into the  
1874 twenties. A brain that is not exposed to psychotropic drugs such  
1875 as nicotine during adolescence is less likely to develop  
1876 addiction.

1877           My State is in the throes of the worst opioid epidemic in  
1878 our lifetime that began with misleading marketing and lack of  
1879 regulatory oversight. And my fear is that we are repeating those  
1880 same mistakes and making way for a new generation grappling with

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1881 addiction that we all fought to avoid.

1882           So, I just want to say, 26 years ago, we had tobacco company  
1883 CEOs sitting in this room testifying before this committee that  
1884 they did not believe that nicotine in their cigarette products  
1885 was addictive. Four years later, the CEOs were forced to admit  
1886 to the risk of nicotine in another hearing before this committee.

1887           Today's schools around the country warn students about the harms  
1888 of nicotine, particularly on developing brains.

1889           Mr. Crosthwaite, JUUL offers a 5 percent nicotine content  
1890 pod which the company claims releases an amount of nicotine  
1891 similar to a pack of 20 cigarettes. Some young users report going  
1892 through a single JUUL pod in three hours. To try to reduce their  
1893 nicotine intake, these young people are now turning to combustible  
1894 cigarettes -- to reduce their nicotine intake.

1895           Are you aware of reports of e-cigarette users so highly  
1896 addicted to your products that they feel the need to switch back  
1897 to regular cigarettes? And if so, do these reports concern you?

1898           Mr. Crosthwaite. Congresswoman, I share your concern about  
1899 the amount of youth getting access to e-vapor. It is unacceptable  
1900 and we must work to combat it.

1901           Ms. Kuster. What is it that you are doing about it today?

1902           Mr. Crosthwaite. So, since I have joined the company, about  
1903 four months ago, we took action to address this issue. So, we  
1904 stopped shipping, when I became CEO in November, our mint product,  
1905 which at the time we got the data that youth were getting access

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1906 to mint, and that was 70 percent of our company at that timeframe.

1907 Ms. Kuster. Seventy percent going to youth for nicotine  
1908 addiction?

1909 Mr. Crosthwaite. No, no. No, 70 --

1910 Ms. Kuster. Seventy percent of your profits were from this  
1911 product that youth were using? Is that the number you are trying  
1912 to explain to us?

1913 Mr. Crosthwaite. No, just to clarify, when we stopped  
1914 shipping mint in November, at that time, of all of our sales,  
1915 that product was 70 percent of our business.

1916 Ms. Kuster. That is what I am trying to say. I mean, for  
1917 the American people, 70 percent of your product was going to youth  
1918 in our country. And four months ago, you stopped that practice?

1919 Mr. Crosthwaite. So, in November, when I saw that youth  
1920 were getting access to mint flavors and found it appealing, I  
1921 took it off the market for our company.

1922 Ms. Kuster. What about the other flavors that are currently  
1923 on the market?

1924 Mr. Crosthwaite. So, today, we sell tobacco and menthol  
1925 in the company.

1926 Ms. Kuster. Menthol e-cigarette?

1927 Mr. Crosthwaite. Yes, in the U.S. market.

1928 Ms. Kuster. And do you think that is getting access to  
1929 youth?

1930 Mr. Crosthwaite. Well, we have paid very close attention

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1931 to the data when we made the decision on mint.

1932 Ms. Kuster. Is there any reason not to take that off the  
1933 market?

1934 Mr. Crosthwaite. Well, today, there are over 10 million  
1935 Americans who use menthol combustible cigarettes.

1936 Ms. Kuster. How many youth?

1937 Mr. Crosthwaite. When we saw the data, menthol was not one  
1938 of the leading flavors that youth were getting access to. The  
1939 number was quite small.

1940 Ms. Kuster. How many youth?

1941 Mr. Crosthwaite. My recollection is I believe the number  
1942 was a few percentage points, but I will have to refer back to  
1943 the report specifically.

1944 Ms. Kuster. My time is up. I just want you to know mothers  
1945 and fathers across this country are watching this hearing very  
1946 carefully.

1947 Thank you.

1948 Ms. DeGette. The chair now recognizes the ranking member  
1949 of the full committee, Mr. Walden, for 5 minutes.

1950 Mr. Walden. Thank you again, Madam Chair, for having this  
1951 hearing.

1952 As I mentioned in my opening statement, I am concerned about  
1953 the counterfeit products, among other things, and the safety  
1954 issues they present in the e-cigarette space. There are plenty  
1955 of news articles about seizures of counterfeit JUUL products,

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1956 in particular. I understand the FDA's Office of Criminal  
1957 Investigations has several ongoing criminal investigations  
1958 related to counterfeit JUUL products that are unrelated to the  
1959 lung injury investigation.

1960 So, for each of you, and pretty quickly, what concerns do  
1961 you each have about counterfeiting of your product?

1962 Mr. Crosthwaite. Counterfeit products are an issue. It  
1963 is something we have been very focused on in the United States  
1964 market, getting them off of the marketplace.

1965 Mr. Walden. All right. Mr. Oberlander?

1966 Mr. Oberlander. Mr. Congressman, at this point in time,  
1967 we haven't seen any counterfeits of VUSE products, but we  
1968 constantly monitor the markets, to my knowledge.

1969 Mr. Walden. All right.

1970 Mr. Nivakoff. We have not seen any reports of counterfeits  
1971 for our product.

1972 Mr. Blonde. We don't see any counterfeit product.

1973 Mr. Loftin. We are very concerned about counterfeit and,  
1974 in fact, I would love to share some of our results by working  
1975 with FDA, Homeland Security, CBP, and local law enforcement, if  
1976 you don't mind.

1977 Mr. Walden. All right. Yes, if you want, real quick.

1978 Mr. Loftin. Through the help of everyone that I just  
1979 mentioned, and all the outside agencies, we closed a factory in  
1980 China shipping in. We also had eight seizures last year just

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1981 in the U.S. in 2019; \$1.5 million dollars worth of product  
1982 confiscated in Nassau County in New York; 681 cease and desist;  
1983 1859 unauthorized online sellers.

1984 Mr. Walden. Okay. All right. If I could get that from  
1985 you? I have got a couple of other questions I want to get to.

1986 I appreciate you have answered the question well, but I would  
1987 like to get the full dataset from you.

1988 Mr. Loftin. Absolutely.

1989 Mr. Walden. Mr. Crosthwaite, I want to go back to you to  
1990 make sure I understood your answer to Ms. Kuster. Did you say  
1991 70 percent of JUUL's profits come from youth mint use? I don't  
1992 think that is what you were saying, right?

1993 Mr. Crosthwaite. No. No, Congressman. What I was saying  
1994 is, when we saw the youth data that came out and that youth were  
1995 getting access to mint, we stopped shipping that in the United  
1996 States. And when we stopped shipping mint in the United States,  
1997 at that time it was 70 percent of what the company sold in the  
1998 United States.

1999 Mr. Walden. To all users, not just youth?

2000 Mr. Crosthwaite. Correct.

2001 Mr. Walden. Okay. All right. In just a few months, the  
2002 entire industry is going to undergo yet another shift when the  
2003 PMTA filing deadline passes after May 12th. Only products for  
2004 which a PMTA has been submitted can remain on the market.

2005 So, the question I have is, how will a consumer retail store

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2006 owner know which products are allowed on the market after this  
2007 date and which ones should be removed? What kind of transparency  
2008 should we be thinking of? Do we need to do something here, once  
2009 that process is completed?

2010 Mr. Crosthwaite, or anybody, want to take that? Yes, go  
2011 ahead.

2012 Mr. Crosthwaite. So, we look forward to submitting our PMTA  
2013 in May and to be in that process, which we think is a very important  
2014 step for the industry to go through, for the FDA to review these  
2015 products.

2016 Mr. Walden. Right.

2017 Mr. Crosthwaite. And, of course, whatever way we need to  
2018 be communicating about our status in that process, we will do  
2019 so.

2020 Mr. Walden. But to the retailers and to consumers --

2021 Mr. Crosthwaite. Right.

2022 Mr. Walden. -- how will they know things are left behind?

2023 Mr. Oberlander. Mr. Congressman, as I mentioned in my oral  
2024 statement, it is paramount that actually the FDA gives full  
2025 transparency of all products that have submitted PMTAs. So, that  
2026 retailers, enforcement agencies, and the FDA actually have full  
2027 visibility about which products are eligible to remain in the  
2028 market or not.

2029 Mr. Walden. Okay. Gentlemen?

2030 Mr. Nivakoff. Sir, I can't speak to my competitors.



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2031 However, our products are almost exclusively sold in highly  
2032 compliant Tier 1 channels with corporate counterparties that have  
2033 fairly robust compliance groups within their stores. And as a  
2034 result, with respect to our products, I don't think there will  
2035 be any confusion.

2036 Mr. Walden. Got it.

2037 Mr. Blonde. We strongly encourage the what you call the  
2038 PMTA process. We intend to submit our PMTA to the FDA by May.

2039 And I agree that we strongly support the fact of full transparency  
2040 to make sure only reliable actors stay in the market.

2041 Mr. Walden. All right. Mr. Loftin

2042 Mr. Loftin. We strongly agree with the PMTA process. In  
2043 fact, we are in standard review and working with them right now.

2044 Mr. Walden. All right. Perfect.

2045 Now this issue with cannabis, THC, whatever, vitamin E, what  
2046 is the best thing we can do here to put a stop to that? Because  
2047 that is some of where the lung injuries are occurring. In a state  
2048 like Oregon that has legalized everything, we are seeing this.

2049 Any of you want to weigh-in on what the best course of action  
2050 for Congress to do to deal with that issue?

2051 Mr. Loftin. I think you add all products and all companies  
2052 involved in that under the PMTA process as well.

2053 Mr. Walden. Okay. Will that get at it?

2054 Mr. Oberlander. I believe the FDA has discretionary power,  
2055 an enforcement power actually, to understand the root cause of

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2056 the situation and actually go after the culprits in this crisis.

2057 Mr. Walden. All right.

2058 Mr. Crosthwaite. And the benefit of a PMTA process is you  
2059 have preclinical, clinical, behavioral research. For us, for  
2060 example, we will have a hundred scientific studies submitted,  
2061 so the FDA can fully evaluate a product and determine if it is  
2062 appropriate for the protection of public health.

2063 Mr. Walden. All right. My time had expired. Thank you,  
2064 Madam Chair.

2065 Thank you to all of you for your testimony.

2066 Ms. DeGette. I thank the gentleman. The chair now  
2067 recognizes Mr. Ruiz for 5 minutes.

2068 Mr. Ruiz. Thank you very much. Thank you all for being  
2069 here.

2070 Everyone here agrees that youth should not be using vaping  
2071 products, but it is still happening at disturbing rates. That  
2072 is why this committee accepted my bill, the No VAPE Act, when  
2073 we marked up the Reversing the Youth Tobacco Epidemic Act. The  
2074 No VAPE Act would increase penalties on retailers who sell vape  
2075 products to underage teens.

2076 I am also working on legislation to require manufacturers  
2077 to label the vaping products, not just the packaging, to make  
2078 it clear that nicotine in vaping is addictive and harmful to health  
2079 -- I am a doctor; I know that -- and to make it clear for parents  
2080 and teachers to identify vaping products.

2081           It would also prohibit the sales of products that are clearly  
2082 being used to attract teens with the ability to easily conceal  
2083 their use like this sweatshirt. The thread in the hood is the  
2084 vaping product. Or these vaping products disguised as juice  
2085 boxes -- juice boxes. Who else are products like these marketed  
2086 toward but underage youth? These are egregious tactics that  
2087 companies have employed to attract and addict youth to their  
2088 products, and we must stop it.

2089           Mr. Loftin, in your testimony you link the dramatic increase  
2090 in youth usage of e-cigarettes to the combination of, quote,  
2091 "irresponsible marketing and product characteristics" of other  
2092 e-cigarettes. Can you describe the marketing tactics and product  
2093 characteristics you think are driving youth use, including the  
2094 companies that are, or were, engaging in these practices?

2095           Mr. Loftin. Sir, I am not here to talk about the other  
2096 companies, but I will tell you it is based on irresponsible  
2097 marketing --

2098           Mr. Ruiz. Like what?

2099           Mr. Loftin. -- exciting colors --

2100           Mr. Ruiz. You don't have to name companies, but give me  
2101 examples of irresponsible marketing.

2102           Mr. Loftin. Exciting colors, exciting shapes, exciting  
2103 names, parties, all kinds of different things without warning  
2104 labels. It is all about the atmosphere of having fun, and it  
2105 shouldn't be marketed to youth.

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2106 Mr. Ruiz. So, despite companies' attempts to address public  
2107 concerns about their marketing, we know that youth continue to  
2108 be targeted. In guidance published just last month, the FDA  
2109 stated that e-cigarettes, quote, "continue to be marketed to  
2110 minors through a wide variety of media and technology".

2111 Mr. Crosthwaite, in your testimony you state that JUUL has,  
2112 quote, "halted our broadcast, print, and digital product  
2113 advertising". Do you believe that the e-cigarette industry  
2114 should be subject to the same advertising restrictions as  
2115 combustible cigarettes? If not, why not?

2116 Mr. Crosthwaite. Congressman. I share your concern about  
2117 youth getting access to e-vapor --

2118 Mr. Ruiz. Should they be held under the same standards as  
2119 cigarettes?

2120 Mr. Crosthwaite. I took the steps in the company because  
2121 I felt it was critical to limit any sort of awareness to tools  
2122 like we were using.

2123 Mr. Ruiz. They are addictive products. Should they be held  
2124 to the same standards as smoking cigarettes?

2125 Mr. Crosthwaite. I think the FDA is going to have complete  
2126 oversight over marketing practices.

2127 Mr. Ruiz. Okay.

2128 Mr. Crosthwaite. I chose to take the steps we did because  
2129 I felt significant action needed to happen to address this issue.

2130 Mr. Ruiz. All right. So, we know that e-cigarette

2131 manufacturers have also marketed their products through various  
2132 promotions, such as highlighting the affordability and various  
2133 flavors of their products. Certain promotions caught our eye.

2134 After the FDA announced its recent guidance, Reynolds and Fontem  
2135 began online promotions to sell flavors affected by the new  
2136 policy.

2137 Reynolds' website banner promotion, for instance, stated,  
2138 quote, "Last chance to buy vapor flavor packs". "Last chance  
2139 to get your flavored packs." And the home page of Fontem's  
2140 website for its blu products features a promotion for a, quote,  
2141 "Last chance flavor blowout" to, quote, "stock up on selected  
2142 liquid pods flavors before they're gone," end quote. "Buy 10  
2143 products, get 15 free."

2144 It is very obvious that those who sell this product have  
2145 their profit in mind when they are marketing to the public, not  
2146 the public's health. Notably, both promotions excluded menthol  
2147 and tobacco flavors, the two flavors excluded by FDA's flavor  
2148 guidance.

2149 Mr. Blonde, it seems quite unabashed in its interest to cash  
2150 in on flavors that FDA has been urging to take off the market.

2151 Don't you think it is irresponsible of your company to offload  
2152 your remaining stock of flavors in a fire sale at the same time  
2153 FDA is sounding the alarm on the appeal of these products to youth?

2154 Mr. Blonde. The sales on our website are very strictly  
2155 controlled and only accessible to 21-plus adults.

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2156           Mr. Ruiz. So, you are saying it wasn't your decision? You  
2157 are not taking accountability for the fact that, while the FDA  
2158 says let's remove flavors, you are trying to sell your flavors  
2159 and market these flavors that Mr. Loftin said would be considered  
2160 as an irresponsible act of marketing and characteristics of a  
2161 product?

2162           Mr. Blonde. We have several promotions on our website, and  
2163 this one was dedicated to our other consumers currently enjoying  
2164 those flavors and making sure that they could stock them before  
2165 they would be off the market.

2166           Mr. Ruiz. Clearly, flavors have been a target for youth.  
2167 So, you can say the adults, but, clearly, it has been a cause  
2168 for the youth epidemic.

2169           I yield back.

2170           Ms. DeGette. The gentleman yields back. The gentleman  
2171 from Maryland, Mr. Sarbanes, is recognized for 5 minutes.

2172           Mr. Sarbanes. Thank you, Madam Chair.

2173           Thank you to the panel.

2174           So, I understand that the premise of the product that you  
2175 keep pointing to largely is to cure cigarette addiction and move  
2176 people off of cigarette addiction. But when you look at the  
2177 societal impact, it seems to me that the cure here may be worse  
2178 than the disease because we have now created the next great public  
2179 health crisis, really of scandalous proportions.

2180           It is implausible that your companies didn't pick up pretty

2181 quickly that youth vaping was contributing significantly to the  
2182 profitability of the bottom line. I don't know what the various  
2183 cases out there have turned up yet, but I know that in years to  
2184 come we will see emails and memos and other things from the sales  
2185 force going back and forth to headquarters, et cetera, talking  
2186 about the great opportunities to boost the numbers from certain  
2187 kinds of sales. You knew it was happening. And it wasn't until  
2188 this got to crisis proportions and there was a public outcry that  
2189 the accountability kicked in. So, that is something that your  
2190 industry is going to have to live with. And unfortunately, it  
2191 is something our youth are living with and will be with them into  
2192 the future.

2193 I wanted to talk a little bit about the FDA's decision  
2194 because, originally, you know, FDA announced that it would ban  
2195 all flavored e-cigarette products. Hooray. And public health  
2196 experts were encouraged by that, and children's advocates and  
2197 medical. In a way, we couldn't believe it, that the President  
2198 was moving there; he was going to push on the FDA to do it. It  
2199 sounded almost too good to be true as a really forceful response  
2200 to the crisis. And then, of course, it turned out it was too  
2201 good to be true, because when the policy ultimately came down,  
2202 it was significantly weakened with exempting multiple e-cigarette  
2203 products.

2204 So, the question I keep asking myself is, what happened?  
2205 Why would the FDA, the agency that is tasked with regulating

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2206 tobacco, and has as one of their key areas of focus protecting  
2207 America's youth and ensuring a healthier life for every family  
2208 -- this is mission-oriented stuff -- why would they walk back  
2209 their decision? And I just feel like it has got something to  
2210 do with how money moves in Washington.

2211 So, there is a report from the American Public Media that  
2212 talks about the multimillion dollar campaign that JUUL launched  
2213 to push back on the government's efforts to restrict vaping.  
2214 JUUL hired an army of lobbyists, spending almost \$3 million on  
2215 lobbying the federal government, more than doubling its lobbying  
2216 expenses from 2017 and 2018 combined. The Political Action  
2217 Committee reported spending \$200,000 for candidates and  
2218 committees, and JUUL dramatically increased its spending in  
2219 states to combat state-level efforts to restrict their products;  
2220 reported 142 lobbyists registered in 48 states.

2221 Then, when the Citizens United case opened the floodgates  
2222 on how dark money comes into our politics and into the policymaking  
2223 apparatus up here, we saw companies like Reynolds American and  
2224 JUUL invest -- I think 35 percent owner of Altria -- using their  
2225 deep pockets to influence the regulations. Reynolds American  
2226 donated millions of dollars to dark money groups like Americans  
2227 for Tax Reform, Americans for Prosperity. Altria spent \$295  
2228 million on lobbying since 1998, more than ExxonMobil spent in  
2229 the same time period.

2230 So, the problem here is that this culture of responding to



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2231 legitimate scrutiny around a public health crisis, responding  
2232 by turning up your lobbying and money influence on the Hill, means  
2233 that the priorities that the public wants to see are continuing  
2234 to be frustrating because there is an inside game. And I just  
2235 want to speak to that.

2236 I didn't give anybody any opportunity to respond and I have  
2237 now used my time. But I think it is a real concern and it is  
2238 something that we need to shine a light on because the American  
2239 public is, frankly, tired of it.

2240 And I yield back.

2241 Ms. DeGette. The gentlelady from New York is recognized  
2242 for 5 minutes, Ms. Clarke.

2243 Ms. Clarke. I thank you, Madam Chair.

2244 Gentlemen, over the past decade, our public health agencies  
2245 have become increasingly concerned about the youth vaping rates,  
2246 as have all of us. In 2013, the Centers for Disease Control and  
2247 Prevention first sounded the alarm on the increasing use of  
2248 e-cigarettes among youth. And in 2018, the Food and Drug  
2249 Administration declared youth vaping an epidemic. Yet, the  
2250 number of young people using e-cigarettes has continued to grow.

2251 Today, more than 5 million young people use e-cigarettes.

2252 Mr. Nivakoff, is e-cigarette use among youth a national  
2253 public health threat?

2254 Mr. Nivakoff. Yes, ma'am.

2255 Ms. Clarke. The nation's leading public health officials

2256 point to the attractiveness of fruity and sweet flavors, targeted  
2257 marketing tactics, stealth design, and low cost in explaining  
2258 the appeal of e-cigarettes to youth.

2259 Mr. Loftin, your testimony attributes the rise in youth use  
2260 primarily to, quote, "youth appeal of certain products that seem  
2261 to intentionally target minors". End quote. Mr. Loftin, which  
2262 products do you believe intentionally target young people?

2263 Mr. Loftin. Congresswoman, I am not here to talk about the  
2264 other companies, but I know it is irresponsible marketing with  
2265 exciting flavors and colors and shapes and sizes that appeal to  
2266 minors. And if they are doing that, they should stop.

2267 Ms. Clarke. Well, you are a part of an industry, sir. So,  
2268 I don't know how much you all interact with each other outside  
2269 of being called here to testify before us, but the whole industry  
2270 is basically under scrutiny right now. And if you feel as though  
2271 you have colleagues that are unscrupulous in their practices,  
2272 it would seem to me that the industry would have that conversation.

2273 Mr. Crosthwaite, according to national survey data, nearly  
2274 60 percent of high-schoolers and over half of middle-schoolers  
2275 who vape report JUUL as their usual brand. Mr. Crosthwaite, why  
2276 are so many young people drawn to your products?

2277 Mr. Crosthwaite. JUUL has had great success converting  
2278 millions of adults who were using combustible cigarettes, and  
2279 otherwise wouldn't have quit --

2280 Ms. Clarke. Hold on one moment. My question is, why are

2281 so many young people drawn to your product?

2282 Mr. Crosthwaite. And with that success with adults, and  
2283 that social sourcing plays a role in how youths get access to  
2284 e-vapor products. An unintended consequence of our success was  
2285 youth getting access to JUUL.

2286 Ms. Clarke. So, how many young people do you estimate were  
2287 drawn into this because of the adult population that you are  
2288 quoting?

2289 Mr. Crosthwaite. So, when we saw the youth data that came  
2290 out, clearly, those numbers are unacceptable and too high.

2291 Ms. Clarke. But what were those numbers?

2292 Mr. Crosthwaite. They are publicly available numbers that  
2293 the government has --

2294 Ms. Clarke. You don't know what the numbers are, sir?

2295 Mr. Crosthwaite. The studies that came out were the  
2296 Monitoring the Future Study that showed that youth were getting  
2297 access to mint-flavored --

2298 Ms. Clarke. Yes, but do you know what the numbers are?

2299 What did your study indicate, sir?

2300 Mr. Crosthwaite. They all indicated that the youth use was  
2301 just too high.

2302 Ms. Clarke. Mr. Oberlander, beyond pointing to the specific  
2303 product, how did we get here? What caused more than 5 million  
2304 youth to start vaping?

2305 Mr. Oberlander. Madam Clarke, first of all, I share your

2306 concern. And the most important point I would like to remind  
2307 you --

2308 Ms. Clarke. Can you pull the microphone closer, sir?

2309 Mr. Oberlander. When VUSE was the market leader between  
2310 2015-2017, youth vaping rates declined. In the National Youth  
2311 Tobacco Survey from last year, it actually showed that less than  
2312 5 percent of the respondents claimed to have used VUSE.

2313 Additionally, our consumer demographics for our VUSE products  
2314 indicate that 95 percent of our consumers of VUSE actually are  
2315 25 and older, and 70 percent of them are 35 and older.

2316 Ms. Clarke. So, are you saying you just have no idea how  
2317 these 5 million youths starting vaping, sir?

2318 Mr. Oberlander. Frankly, we don't research youth. We  
2319 research --

2320 Ms. Clarke. You have no idea?

2321 Mr. Oberlander. Excuse me. We have only researched  
2322 21-and-plus individuals.

2323 Ms. Clarke. Turning back to you, Mr. Crosthwaite, in your  
2324 testimony you mentioned that JUUL is, quote, "combating the  
2325 serious problem of underage use". Yet, as discussed, youth use  
2326 continues to increase and young people are still using your  
2327 products in high numbers. You came to JUUL from big tobacco,  
2328 which has not always been a stalwart of promoting public health.

2329 Why should we take your word for it when you say that JUUL is  
2330 serious about combating youth use of e-cigarettes?

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2331           Mr. Crosthwaite. I joined the company because I believe  
2332 in the historic opportunity for adults to have another option  
2333 to combustible cigarettes who otherwise wouldn't quit. I also  
2334 recognized that is at risk if we don't solve this problem. The  
2335 youth use situation is unacceptable. And when I joined, I took  
2336 action, and we are prepared to do more over time.

2337           Ms. Clarke. So, as those responsible for perpetuating the  
2338 practices that have so enticed young people to your products,  
2339 I believe that your industry must be willing to take ownership  
2340 over your actions that have contributed to our nation's youth  
2341 vaping epidemic. Each of you, though you tried to differentiate  
2342 what your companies are doing, are all collaborating in an  
2343 industry that has drawn in, and will continue to draw in, young  
2344 people unless you take affirmative actions or unless we do so.

2345           I yield back, Madam Chair.

2346           Ms. DeGette. The gentleman from New York, Mr. Tonko, is  
2347 recognized for 5 minutes.

2348           Mr. Tonko. Thank you, Madam Chair.

2349           Mr. Crosthwaite, for every person that gets off of a  
2350 combustible cigarette, how many will get hooked or start using  
2351 an e-cigarette? In other words, the addiction that might come  
2352 to e-cigarettes for young people, how many are we willing to  
2353 tolerate?

2354           Mr. Crosthwaite. The youth rates are unacceptable. And  
2355 this whole opportunity for adults we recognize is at risk if we

2356 don't address this issue.

2357 Mr. Tonko. I think there is that tipping point. I think  
2358 we really need to take that into consideration. We do not want  
2359 our young people to be the victims that will be addicted, become  
2360 addicted.

2361 Common sense and research show that flavored products are  
2362 an on-ramp to youth e-cigarette use. According to an NIH and  
2363 FDA national survey, nearly 80 percent of youth used the tobacco  
2364 product because, and I quote, "It comes in flavors I like."  
2365 Industry claims that flavored e-cigarettes are important to help  
2366 some adult smokers quit, though whether these flavors are  
2367 necessary to help a person quit smoking is yet unproven.

2368 So, Mr. Crosthwaite, between November of 2018 and November  
2369 of 2019, JUUL voluntarily removed all of its flavored products  
2370 except tobacco and menthol from the U.S. market. Was the  
2371 increasing youth use of non-tobacco flavored products a factor  
2372 in this decision?

2373 Mr. Crosthwaite. So, when I joined the organization, and  
2374 when we saw the data that youth were getting access to mint, it  
2375 is that data that drove the decision I made, which was to take  
2376 mint off the market for the company in November.

2377 Mr. Tonko. And at our subcommittee hearing last fall,  
2378 then-Acting FDA Commissioner Sharpless stated that the research  
2379 is, and I quote, "very strong that flavors draw a child to use".

2380 Mr. Nivakoff, do you agree with FDA that fruity and minty

2381 flavors play a role in attracting our youth to e-cigarettes?

2382 Mr. Nivakoff. I think that NJOY's data overwhelmingly  
2383 demonstrates that flavors did not drive youth to our products.

2384 NJOY has the lowest rate of youth use amongst the four major  
2385 brands and has overwhelmingly, by a multiple of greater than 30,  
2386 the lowest rate of violations with FDA retail inspections, despite  
2387 the overwhelming majority of our revenue previously being derived  
2388 from flavors; albeit, all flavors will be off the market as of  
2389 tomorrow.

2390 Mr. Tonko. Well, at the listening session that the White  
2391 House held this past November, you told the President, and I quote,  
2392 "Flavors are an issue. They are attractive to youth." So, how  
2393 does that coordinate or respond to the answer you just gave now?

2394 Mr. Nivakoff. Can you repeat that quote? I don't recall  
2395 saying that, sir.

2396 Mr. Tonko. The quote from the White House listening session  
2397 was, and I quote, "Flavors are an issue. They are attractive  
2398 to our youth."

2399 Mr. Nivakoff. Are you certain that came from me? I might  
2400 have been speaking colloquially about the industry, but I think  
2401 the data clearly demonstrates that flavors with respect to NJOY's  
2402 distribution, which is the only thing over which I exercise  
2403 control, have not been a driver of youth use, as we are  
2404 overwhelmingly the industry leader in avoiding youth use.

2405 Mr. Tonko. Yes, I have a document here that has the

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2406 transcript of the listening session that was held on November  
2407 22nd. And so, that was a direct lift from that transcript.

2408 Mr. Nivakoff. Perhaps you could share the context because,  
2409 out of context, I don't fully understand what the comment is.

2410 But, again, NJOY is the overwhelming market leader. Despite  
2411 having the overwhelming majority of our revenue derived from  
2412 flavors, we have the lowest rate of youth use by any measurable  
2413 benchmark afforded by the federal government.

2414 Mr. Tonko. Again, the context was whether or not flavors  
2415 are a driving force.

2416 So, we will move on. A recent study of e-cigarette use among  
2417 U.S. youth found the use of mint and menthol flavored e-cigarettes  
2418 increased sharply over the past three years. For JUUL, it was  
2419 reported that its mint products contributed 70 percent to its  
2420 overall sales after it restricted the availability of its fruit  
2421 flavors. I am concerned that FDA's action to temporarily  
2422 restrict certain flavored e-cigarettes does not go far enough  
2423 because it exempts menthol products. FDA's website describes  
2424 menthol as, and I quote, "a flavor additive with a minty taste  
2425 and aroma".

2426 So, Mr. Crosthwaite, given the similarities between mint  
2427 and menthol, do you believe it is possible that youth using mint  
2428 e-cigarette products may just switch to those menthol products?

2429 Mr. Crosthwaite. I think it is important the note the  
2430 differences today. We now have Tobacco 21 as the law of the land.



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2431 And our menthol product is actually very different than our mint  
2432 product. It is a tobacco-based formulation that exists.

2433 Mr. Tonko. But do you think it is possible that youth using  
2434 mint will switch to the menthol product?

2435 Mr. Crosthwaite. We know that the FDA is certainly going  
2436 to track it. We are going to do the same.

2437 Mr. Tonko. And, Mr. Oberlander, the same question to you.  
2438 Are you convinced that menthol won't just become the new mint  
2439 in terms of popularity among youth?

2440 Mr. Oberlander. Tobacco and menthol flavors have been not  
2441 perceived by the FDA -- there is no research -- to be popular  
2442 amongst youth. However, we will continue to monitor the market,  
2443 and we encourage the FDA to do the same.

2444 Mr. Tonko. Well, I am disturbed by what we know of youth  
2445 behavior and their likelihood to merely shift from using fruity  
2446 and mint-flavored e-cigarettes to menthol products.  
2447 Unfortunately, I have not heard anything this morning to convince  
2448 me this won't be the case.

2449 And with that, Madam Chair, I yield back.

2450 Ms. DeGette. I thank the gentleman. The ranking member  
2451 and I will now each ask one last round of questions, and I will  
2452 recognize the ranking member, Mr. Guthrie, for 5 minutes.

2453 Mr. Guthrie. Thank you for that.

2454 And again, thank you for being here.

2455 No doubt, e-cigarettes must get out of the hands of our youth.

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2456 And I want to ask each of you just to verify, before we break  
2457 today, are you committed to stopping all youth access, and will  
2458 you commit to keep the committee updated as you take actions to  
2459 stop usage of these cigarettes?

2460 Mr. Crosthwaite?

2461 Mr. Crosthwaite. We are committed to combating access for  
2462 youth getting to e-vapor and we are happy to keep you up-to-speed  
2463 on all of our actions.

2464 Mr. Guthrie. Thank you.

2465 Mr. Oberlander?

2466 Mr. Oberlander. Yes, we are committed.

2467 Mr. Guthrie. Mr. Nivakoff?

2468 Mr. Nivakoff. Yes, sir.

2469 Mr. Guthrie. Mr. Blonde?

2470 Mr. Blonde. Absolutely, sir.

2471 Mr. Guthrie. Mr. Loftin?

2472 Mr. Loftin. We are committed and helping in any way.

2473 Mr. Guthrie. And then, one final question. You have all  
2474 submitted PMTAs or indicated you plan to submit PMTAs. And that  
2475 is important because, in order to stay in the market, you have  
2476 to submit PMTAs, and there seems to be a lot of products that  
2477 aren't, that are on the market that aren't going down that  
2478 direction. But, currently, there is no final regulation from  
2479 FDA on the PMTA process, including what information should be  
2480 submitted and in what format. Do you think it would helpful for

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2481 the FDA to finalize its regulation before May 6th? And if it  
2482 doesn't do it sooner rather than later, what setback will that  
2483 cause your process?

2484 Mr. Crosthwaite? We can just go down the aisle.

2485 Mr. Crosthwaite. We are preparing to submit our FDAs. We  
2486 have opportunities to engage with our regulator and get feedback  
2487 on the process.

2488 Mr. Guthrie. Even without the final regulation? You are  
2489 getting feedback to what you need to do without a final reg in  
2490 place?

2491 Mr. Crosthwaite. We have our regulatory science  
2492 organization that does engage with the FDA and to seek the  
2493 appropriate information to make our filing.

2494 Mr. Guthrie. But would a final regulation be helpful?

2495 Mr. Crosthwaite. Sure. Any clarity is always helpful, but  
2496 we are confident that we are going to submit a fulsome application.

2497 Mr. Guthrie. Mr. Oberlander?

2498 Mr. Oberlander. We have submitted the first set of PMTA  
2499 applications of VUSE products, and we will actually comply with  
2500 the May 12th deadline to submit all others.

2501 Mr. Guthrie. But without a final regulation in place, do  
2502 you feel confident that you are able to --

2503 Mr. Oberlander. Continuous clarity/clarification about  
2504 the process would be helpful for sure.

2505 Mr. Guthrie. Thank you.

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2506 Mr. Nivakoff?

2507 Mr. Nivakoff. We think the current guidance is sufficient.

2508 Mr. Guthrie. So, are you going to submit without a final  
2509 reg?

2510 Mr. Nivakoff. We do plan to submit before a final regulation  
2511 is promulgated. Certainly, we would welcome any additional  
2512 clarity, but we don't think it is a prerequisite.

2513 Mr. Guthrie. Okay. Mr. Blonde?

2514 Mr. Blonde. We agree that we are in the process of  
2515 finalizing our PMTA and submitting in date, and we encourage  
2516 everybody and all the actors in the market should do so.

2517 Mr. Guthrie. Okay. Mr. Loftin?

2518 Mr. Loftin. We have already submitted our PMTAs. We are  
2519 in standard review. We are working with them right now. We will  
2520 work with them if any new regulations come up.

2521 Mr. Guthrie. Thank you.

2522 But my point is, I knew you had to move forward because there  
2523 is not enough time, if you are not moving forward, to go from  
2524 where we are today to have it by May the 6th. But I am sure,  
2525 as the oversight committee of FDA, we would like to see that they  
2526 have a final regulation as you are moving for approval. We think  
2527 that is the way the process should work. But we certainly  
2528 understand you can't wait for that to happen, but clarity is always  
2529 important. And following the process the way it should be  
2530 followed is important to us as well.

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2531 Thank you for being here. As I said, we absolutely must  
2532 get e-cigarettes out of the hands of our youth, and we would like  
2533 for you to update us as you put new controls in place, as Mr.  
2534 Loftin said. You shared with us what you do, but, as you move  
2535 forward, we would like to see that as well. Thank you.

2536 And I yield back.

2537 Ms. DeGette. Thank you. I thank the gentleman.

2538 I just have a couple of quick questions. One of the things  
2539 that the kids at my roundtable earlier this week said is that  
2540 people are just getting e-cigarettes online, now that the age  
2541 has gone up to 21. Mr. Loftin, you said that you have very strict  
2542 online protections before you will send them out, is that right?

2543 Mr. Loftin. Yes, ma'am, we have.

2544 Ms. DeGette. Could you submit we could see?

2545 Mr. Loftin. We have already sent that to the committee  
2546 staff.

2547 Ms. DeGette. Okay.

2548 Mr. Loftin. But I would be glad to do it again as well.

2549 Ms. DeGette. Okay. Great. Thank you.

2550 And do the rest of you all have very strict online  
2551 protections? Mr. Blonde, you are nodding yes.

2552 Mr. Nivakoff?

2553 Mr. Nivakoff. Yes, we do.

2554 Ms. DeGette. Mr. Oberlander?

2555 Mr. Oberlander. Yes, we do.

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2556 Ms. DeGette. And, Mr. Crosthwaite?

2557 Mr. Crosthwaite. Yes.

2558 Ms. DeGette. Okay. Thank you.

2559 The second question that I had was, e-cigarettes are being  
2560 marketed as a smoking cessation tool, but, partly because we  
2561 haven't had a final guidance from the FDA, e-cigarettes are not  
2562 approved by the FDA as a smoking cessation tool. Isn't that  
2563 correct, Mr. Crosthwaite?

2564 Mr. Crosthwaite. Correct. We do not market today as a  
2565 smoking cessation tool.

2566 Ms. DeGette. Okay. But they are not approved by the FDA,  
2567 is that right?

2568 Mr. Crosthwaite. Correct.

2569 Ms. DeGette. Okay. The next question I have -- and I want  
2570 to commend all of you for now realizing the extent of the problem,  
2571 5 million youth vaping. And I want to commend you all for trying  
2572 to remove the marketing. But have you also tried to figure out  
2573 ways that you can help contribute to smoking cessation programs  
2574 or other programs to help kids get off of this highly-addictive  
2575 substance? It is one thing just to say, "We are not going to  
2576 market to you anymore," but we already have millions of underage  
2577 kids who have gotten addicted. What are we going to do about  
2578 that?

2579 Mr. Oberlander, you seem to be nodding.

2580 Mr. Oberlander. Thank you. Chair DeGette, I think this

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2581 is an important issue.

2582 Ms. DeGette. Yes.

2583 Mr. Oberlander. And at Reynolds American, we have a youth  
2584 tobacco prevention program called "Right Decisions Right Now".

2585 We have put a significant amount of money behind it. And only  
2586 last year, we had 800 employees actually contacting schools, I  
2587 mean talking about the dangers, including vapor.

2588 Ms. DeGette. And so, you actually are trying to help kids  
2589 get off of nicotine?

2590 Would that be accurate for JUUL as well, Mr. Crosthwaite?

2591 Mr. Crosthwaite. We are trying to make sure they don't get  
2592 it in the first place, access prevention.

2593 Ms. DeGette. I understand.

2594 Mr. Crosthwaite. And the question you are raising is an  
2595 important one, and we would be happy to engage --

2596 Ms. DeGette. So, you are not doing it? You don't have  
2597 programs right now to try to help people get off of it?

2598 Mr. Crosthwaite. We are not doing programs, right.

2599 Ms. DeGette. Thank you.

2600 What about you, Mr. Nivakoff?

2601 Mr. Nivakoff. Ma'am, we would support any recommendations  
2602 that the committee has.

2603 Ms. DeGette. Right, but you are not aware of any program  
2604 you all have now?

2605 Mr. Nivakoff. No, ma'am. We don't think it is --

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2606 Ms. DeGette. What about you, Mr. Blonde?

2607 Mr. Blonde. No, we don't currently have programs and we  
2608 don't address these --

2609 Ms. DeGette. Would you be willing to consider something  
2610 like that?

2611 Mr. Blonde. We are happy to collaborate with the committee  
2612 and talking to --

2613 Ms. DeGette. Okay. Mr. Loftin?

2614 Mr. Loftin. We are very open to working through that as  
2615 well with the committee.

2616 Ms. DeGette. You don't have any programs right now?

2617 Mr. Loftin. Nothing specific.

2618 Ms. DeGette. Okay. I am going to be honest. I was pleased  
2619 that all of you admitted under oath that nicotine is addictive,  
2620 but I was extremely dismayed when I asked you about the health  
2621 problems with nicotine, that you all were extremely vague in your  
2622 answers and seemed to say, well, you are doing studies right now.

2623 Because it has actually been established that nicotine itself  
2624 has severe health risks.

2625 I have got two reports that I had the staff go get me while  
2626 we were sitting here, and they are surveys of the  
2627 medical research. And the Surgeon General says, "Nicotine  
2628 exposure during adolescence can cause addiction and harm the  
2629 developing brain." So, these kids get addicted; then, they are  
2630 addicted. But, then, it says, "Nicotine can cross the placenta



2631 and has known effects on fetal and postnatal development.  
2632 Therefore, nicotine delivered by e-cigarettes during pregnancy  
2633 can result in multiple adverse consequences, including Sudden  
2634 Infant Death Syndrome, and could result in altered corpus  
2635 callosum, deficits in auditory processing, and obesity."

2636 It goes on to say, "E-cigarettes can expose users to several  
2637 chemicals, including nicotine, carbonyl compounds, and volatile  
2638 organic compounds known to have adverse health effects. The  
2639 health effects in potentially harmful doses of heated and  
2640 aerosolized constituents of e-cigarette liquids, including  
2641 solvents, flavorants, and toxicants, are not completely  
2642 understood." And it goes on to say, "E-cigarette aerosol is not  
2643 harmless water vapor, although it generally contains fewer  
2644 toxicants than combustible tobacco products."

2645 The Indian Journal of Medical and Paediatric Oncology, which  
2646 was in 2015 -- so, that was five years ago, when we already knew  
2647 this stuff -- says, "Nicotine poses several health hazards,  
2648 cardiovascular, respiratory, gastrointestinal disorders,  
2649 decreased immune response, and ill impacts on reproductive  
2650 health, cell proliferation, oxidative stress, apoptosis, DNA  
2651 mutation," et cetera.

2652 I am going to put these studies in the record.

2653 But I also asked the staff to make a copy to give to each  
2654 of you, because I think you need to be aware that, once these  
2655 kids get addicted, then the nicotine is also going to have lifelong

2656 impacts, as long as they stay addicted.

2657 I have one last question for you, Mr. Crosthwaite, and I  
2658 appreciate that you have said that JUUL needs to get it right.

2659 And I appreciate the turning the page, looking forward. You  
2660 said, for example, when you saw the youth data on the mint, you  
2661 quit shipping the mint because it was an unacceptable level.

2662 So, here is my question to you: let's say the 2020 National Youth  
2663 Tobacco Survey does not show a decline in the rate of youth use  
2664 of e-cigarettes, despite all of the efforts that you and the other  
2665 companies, and Congress and the administration, in raising the  
2666 age to 21, have taken. Would you, then, consider suspending the  
2667 sales of all of your products until health officials can figure  
2668 out how we can stop this youth vaping epidemic?

2669 Mr. Crosthwaite. In just a few short months, we are going  
2670 to have our PMTA in with the FDA, who will have all of the  
2671 information to make the determination if, in fact, our product  
2672 is appropriate for the protection of public health. And that  
2673 is the process we think is best to make that determination.

2674 Ms. DeGette. Well, I am glad you are going through that  
2675 process. I am glad everybody is going through that process, but  
2676 my question is: if the number of youth vaping doesn't go down,  
2677 despite all of this, with the effort you have taken already, would  
2678 you stop marketing your e-cigarettes until we figure out how to  
2679 solve this epidemic?

2680 Mr. Crosthwaite. Well, I have stopped all of our broadcast,

2681 print, and digital marketing already.

2682 Ms. DeGette. Okay. So, you are not prepared to go as far  
2683 as what I am suggesting? Wouldn't that be fair to say?

2684 Mr. Crosthwaite. We have taken serious actions to address  
2685 this issue, and we are prepared to do more as we go on.

2686 Ms. DeGette. Okay, but stopping sales altogether until we  
2687 figure it out, that is not what you are thinking about?

2688 Mr. Crosthwaite. We are trying to preserve this opportunity  
2689 for the millions of adults while combating the underage issue  
2690 that exists. And ultimately, we are going to make that filing  
2691 --

2692 Ms. DeGette. I got you. You don't want to answer it. I  
2693 got you.

2694 But I do really want to thank you for coming, and I want  
2695 to thank all of the witnesses for their participation in this  
2696 hearing.

2697 We have a number of documents that we want to put into the  
2698 record. We already put Representative Duncan's article into the  
2699 record.

2700 We have the 2015 study from the Indian Journal of Medical  
2701 and Paediatric Oncology I just referred to.

2702 We have the letter to the committee from the National  
2703 Association of County and City Health Officials.

2704 We have The New York Times article that Congresswoman  
2705 Schakowsky referred to, and the 2016 Surgeon General report on

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2706 the dangers of nicotine.

2707 I would ask unanimous consent that all of those be put in

2708 the record. So ordered.

2709 [The information follows:]

2710 \*\*\*\*\* COMMITTEE INSERT \*\*\*\*\*

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2711           Ms. DeGette. I also want to remind members that, pursuant  
2712 to the committee rules, they have 10 business days to submit  
2713 additional questions for the record, to be answered by the  
2714 witnesses. And if the witnesses could answer those questions,  
2715 we would very much appreciate it. Ms. DeGette. And with that,  
2716 the subcommittee is adjourned.

2717           [Whereupon, at 12:56 p.m., the subcommittee was adjourned.]