



October 29, 2019

First Lady Melania Trump  
The White House  
1600 Pennsylvania Avenue, N.W.  
Washington, DC 20500

Dear Mrs. Trump:

We want to express our sincere appreciation for the leadership you have provided in highlighting the youth e-cigarette epidemic, meeting with youth who have been impacted by this crisis and championing the bold action to reverse the epidemic that was announced by the Administration on September 11, 2019. Our organizations strongly support the Administration's plan to clear the market of all flavored e-cigarettes, including mint and menthol flavors.

This is an issue that confronts every parent. It is not a surprise that moms have been the strongest voices for action. Millions of moms from all political persuasions and from every part of the country echo the concerns you have raised.

This past week, there have been news reports that the major e-cigarette companies have enlisted political allies to undermine these efforts. We are writing to ask you to continue your fight for our children.

We have clear evidence that mint and menthol e-cigarettes are popular with kids. Data from the 2019 National Youth Tobacco Survey show that 63.9% of high school e-cigarette users use mint or menthol flavors, up from 51.2% in 2018 and 42.3% in 2017.

A policy that does not remove all flavored e-cigarettes will not solve the current epidemic of youth e-cigarette use. Youth who now use mint and menthol e-cigarettes will continue to do so, and youth who use flavors that are removed from the market will simply switch to mint and menthol.

A Schoen poll of likely voters conducted in September after the Administration's September 11 announcement indicates by a 73% to 22% margin, support for the Administration's plan to take flavored e-cigarettes off the market, including support from 74% of Republicans and 70% of Independents. These results are similar to the results of a Morning Consult poll, also conducted in mid-September, that found strong, bipartisan support for the Administration's plan.

Mrs. Trump, you have been a strong voice during this crisis. The health of America's kids is at stake. We stand with you in supporting the Administration's proposal to take ALL flavored e-cigarettes off the market because, as you have recognized, they are fueling the youth e-cigarette epidemic.

Sincerely,

Academy of General Dentistry

Action on Smoking & Health

African American Tobacco Control Leadership Council

Allergy & Asthma Network

American Academy of Family Physicians

American Academy of Oral and Maxillofacial Pathology

American Academy of Oral and Maxillofacial Radiology

American Academy of Pediatrics

American Association for Respiratory Care

American Cancer Society Cancer Action Network

American College Health Association

American College of Cardiology

American College of Physicians

American College of Preventive Medicine

American Federation of School Administrators

American Heart Association

American Lung Association

American Medical Association  
American Psychiatric Association  
American Public Health Association  
American Thoracic Society  
Americans for Nonsmokers' Rights  
Association of State and Territorial Health Officials  
Big Cities Health Coalition  
Campaign for Tobacco-Free Kids  
Catholic Health Association of the United States  
Children's Wisconsin  
ClearWay Minnesota  
Community Anti-Drug Coalitions of America  
Counter Tools  
Eta Sigma Gamma – National Health Education Honorary  
GO2 Foundation for Lung Cancer  
International Association for the Study of Lung Cancer  
March of Dimes  
NAACP  
National Association of County and City Health Officials  
National Association of Pediatric Nurse Practitioners  
National Association of School Nurses  
National Association of Secondary School Principals  
National Education Association  
National Hispanic Medical Association  
National Network of Public Health Institutes  
Oncology Nursing Society  
Parents Against Vaping E-Cigarettes (PAVe)  
Prevent Cancer Foundation  
Protect Kids: Fight Flavored E-Cigarettes  
Public Health Law Center  
Public Health Solutions  
Students Against Destructive Decisions  
The Society of State Leaders of Health and Physical Education  
The Society of Thoracic Surgeons  
Trust for America's Health  
Truth Initiative



October 29, 2019

The Honorable Alex M. Azar  
Secretary  
U.S. Department of Health and Human Services  
200 Independence Avenue, SW  
Washington, DC 20201

Dear Secretary Azar,

Our organizations have commended and supported the Administration's plan, announced on September 11, 2019, to clear the market of all non-tobacco-flavored e-cigarettes, including mint and menthol flavors, until they can be reviewed by the Food and Drug Administration. We appreciate your strong leadership in advancing this plan and agree completely with your statement that "we will not stand idly by as these products become an on-ramp to combustible cigarettes or nicotine addiction for a generation of youth."

Today, we write to call on you to stay the course and make sure the proposal is not undermined by exempting mint- and menthol-flavored e-cigarettes.

Mint and menthol e-cigarettes are very popular with youth. Data from the 2019 National Youth Tobacco Survey show that 63.9% of high school e-cigarette users use mint or menthol flavors,

up from 51.2% in 2018 and 42.3% in 2017. Given the prevalence of mint and menthol flavors among youth e-cigarette users and the lack of evidence that these flavors play any role in helping adults quit smoking, there is no public health justification to exempt them from the proposed policy. Both mint and menthol are highly similar flavors that are attractive to kids and are indistinguishable from a public health perspective. Mint and menthol are especially dangerous flavors for teens because they both contain menthol as an ingredient, which has cooling properties that make it easier for teens to tolerate the harsh taste of nicotine.

A policy that does not remove all flavored e-cigarettes will not solve the current epidemic of youth e-cigarette use. Youth who now use mint and menthol e-cigarettes will continue to do so, and youth who use flavors that are removed from the market will simply switch to mint and menthol.

Exempting mint and menthol e-cigarettes from the Administration's policy will leave America's kids at risk. No one will benefit more than Juul and Altria. As reported in the New York Post on the very day the White House announced its new policy, mint now makes up 75% of Juul's revenue.

Protecting America's kids is not only the right thing to do, it is popular. A Schoen poll of likely voters conducted in September after the Administration's September 11 announcement indicates by a 73% to 22% margin, support for the Administration's plan to take flavored e-cigarettes off the market, including support from 74% of Republicans and 70% of Independents. These results are similar to the results of a Morning Consult poll, also conducted in mid-September, that found strong, bipartisan support for the Administration's plan.

Secretary Azar, you have been a strong voice during this crisis. The health of America's kids is at stake. We stand with you in supporting the Administration's proposal to take ALL flavored e-cigarettes off the market because, as you have recognized, they are fueling the youth e-cigarette epidemic.

Sincerely,

Academy of General Dentistry  
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American Association for Dental Research  
American Association for Respiratory Care  
American Cancer Society Cancer Action Network  
American College Health Association  
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American Public Health Association  
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Americans for Nonsmokers' Rights  
Association of State and Territorial Health Officials  
Big Cities Health Coalition  
Campaign for Tobacco-Free Kids  
Catholic Health Association of the United States  
Children's Wisconsin  
ClearWay Minnesota  
Community Anti-Drug Coalitions of America  
Counter Tools  
Eta Sigma Gamma – National Health Education Honorary  
GO2 Foundation for Lung Cancer  
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Public Health Law Center  
Public Health Solutions  
Students Against Destructive Decisions  
The Society of State Leaders of Health and Physical Education  
The Society of Thoracic Surgeons  
Trust for America's Health  
Truth Initiative

CC:

The Honorable Jerome Adams, Surgeon General of the United States  
The Honorable Norman Sharpless, Acting Commissioner of the Food and Drug Administration

# United States Senate

WASHINGTON, DC 20510

October 29, 2019

The Honorable Alex M. Azar II  
Secretary  
U.S. Department of Health and Human Services  
200 Independence Avenue, SW  
Washington, DC 20201

Dear Secretary Azar,

We write with significant concerns about the continued delay by the Trump Administration in issuing a compliance policy to address the terrible epidemic of e-cigarette use among children. After years of delay and inaction, which fueled this epidemic, the Trump Administration announced on September 11, 2019, that the U.S. Food and Drug Administration (FDA) intended to “finalize a compliance policy in the coming weeks that would prioritize the agency’s enforcement of the premarket authorization requirements for non-tobacco flavored e-cigarettes, including mint and menthol, clearing the market of unauthorized, non-tobacco flavored e-cigarette products.”<sup>1</sup> We have long advocated for this action and were encouraged that the Administration had finally decided to act. As of today, however, the FDA has neither finalized nor announced when it will finalize the compliance policy and is reportedly considering significantly weakening this policy by exempting mint and menthol products, which your agency’s own data have demonstrated are incredibly popular among children.<sup>2</sup> While the Administration continues to permit the sale of unauthorized, non-tobacco flavored e-cigarette products, each day more children are becoming e-cigarette users – driven primarily by flavors.<sup>3</sup> We strongly urge the Administration to fulfill its promise to clear the market of all unauthorized, non-tobacco flavored e-cigarettes – including mint and menthol flavors – immediately.

It is imperative that the Administration promptly finalize the compliance policy. E-cigarette use among children continues to rise at an alarming rate. Approximately 20 percent of high school students reported using e-cigarettes in 2018, which is more than a 75 percent

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<sup>1</sup> “Trump Administration Combating Epidemic of Youth E-Cigarette Use with Plan to Clear Market of Unauthorized, Non-Tobacco-Flavored E-Cigarette Products,” Sept. 11, 2019, <https://www.hhs.gov/about/news/2019/09/11/trump-administration-combating-epidemic-youth-ecigarette-use-plan-clear-market.html>.

<sup>2</sup> “Trump Administration Combating Epidemic of Youth E-Cigarette Use with Plan to Clear Market of Unauthorized, Non-Tobacco-Flavored E-Cigarette Products,” Sept. 11, 2019, <https://www.hhs.gov/about/news/2019/09/11/trump-administration-combating-epidemic-youth-ecigarette-use-plan-clear-market.html>.

<sup>3</sup> “Quick Facts on the Risks of E-cigarettes for Kids, Teens, and Young Adults,” *Centers for Disease Control and Prevention*, March 11, 2019, [https://www.cdc.gov/tobacco/basic\\_information/e-cigarettes/Quick-Facts-on-the-Risks-of-E-cigarettes-for-Kids-Teens-and-Young-Adults.html](https://www.cdc.gov/tobacco/basic_information/e-cigarettes/Quick-Facts-on-the-Risks-of-E-cigarettes-for-Kids-Teens-and-Young-Adults.html).

of the compliance policy will be an important step in ongoing work to ensure e-cigarettes are not marketed to, sold to, or used by kids.”<sup>11</sup>

With each day, more children continue to be lured to e-cigarettes by flavors such as fruit, candy, and mint or menthol. We are therefore deeply troubled that there is no final compliance policy more than six weeks after the Oval Office announcement. Instead, the FDA provides assurances that the agency is working “as quickly as possible” to finalize a compliance policy.<sup>12</sup> It is increasingly unclear what the FDA’s final compliance policy will look like.

The Trump Administration is reportedly considering allowing mint and menthol flavors to remain on the market even if and when the FDA does finalize a compliance policy, despite nearly two-thirds of kids who use e-cigarettes using mint and menthol flavored products.<sup>13</sup> This is unacceptable. The Administration has already delayed action for far too long to address this public health crisis.

Further fueling our concerns, on October 25, 2019, news reports indicated that this reconsideration follows warnings from President Trump’s campaign manager, Brad Parscale, that a policy removing flavored e-cigarettes from the market “could backfire in the 2020 election” and that “Trump supporters who use e-cigarettes could abandon the president if he follows through on a ban.”<sup>14</sup> We are outraged that the President appears to be playing politics with children’s health.

Because of the ever-increasing epidemic of youth e-cigarette use that has been fueled by flavors that include mint and menthol, we implore the Administration to finalize a compliance policy removing all unauthorized, non-tobacco flavored e-cigarettes from the market immediately. It must not bow to industry or political pressure at the expense of the public health. If you have any questions regarding this letter, please contact Andi Lipstein Fristedt with the HELP Committee Staff at (202) 224-7675.

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<sup>11</sup> “Trump Administration Combating Epidemic of Youth E-Cigarette Use with Plan to Clear Market of Unauthorized, Non-Tobacco-Flavored E-Cigarette Products,” Sept. 11, 2019, <https://www.hhs.gov/about/news/2019/09/11/trump-administration-combating-epidemic-youth-ecigarette-use-plan-clear-market.html>.

<sup>12</sup> “FDA working ‘as quickly as possible’ on e-cigarette flavor ban,” *The Hill*, Oct. 25, 2019, <https://thehill.com/policy/healthcare/467469-fda-working-as-quickly-as-possible-on-e-cigarette-flavor-ban>.

<sup>13</sup> *Id.*; “Trump Considers Retreat From Ban of Mint and Menthol Vaping Flavors,” *Bloomberg*, Oct. 25, 2019, <https://www.bloomberg.com/news/articles/2019-10-25/trump-considers-retreat-from-ban-of-mint-menthol-vaping-flavors>; “Trump Administration Combating Epidemic of Youth E-Cigarette Use with Plan to Clear Market of Unauthorized, Non-Tobacco-Flavored E-Cigarette Products,” Sept. 11, 2019, <https://www.hhs.gov/about/news/2019/09/11/trump-administration-combating-epidemic-youth-ecigarette-use-plan-clear-market.html>.

<sup>14</sup> “Trump campaign urges White House to soften proposed flavored vape ban,” *The Washington Post*, Oct. 25, 2019, [https://www.washingtonpost.com/politics/trump-campaign-urges-white-house-to-soften-proposed-flavored-vape-ban/2019/10/25/5d39dbae-f733-11e9-a285-882a8e386a96\\_story.html](https://www.washingtonpost.com/politics/trump-campaign-urges-white-house-to-soften-proposed-flavored-vape-ban/2019/10/25/5d39dbae-f733-11e9-a285-882a8e386a96_story.html).



Sincerely,



Patty Murray  
United States Senator



Richard J. Durbin  
United States Senator



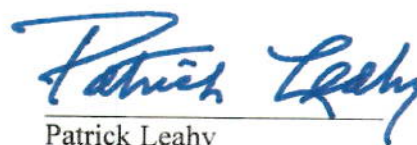
Charles E. Schumer  
United States Senator



Sheldon Whitehouse  
United States Senator



Margaret Wood Hassan  
United States Senator



Patrick Leahy  
United States Senator



Sherrod Brown  
United States Senator



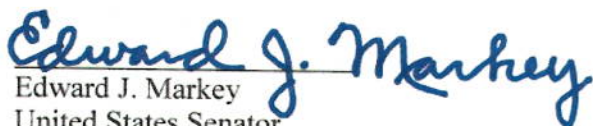
Jack Reed  
United States Senator



Richard Blumenthal  
United States Senator



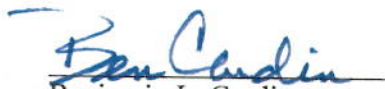
Jeanne Shaheen  
United States Senator



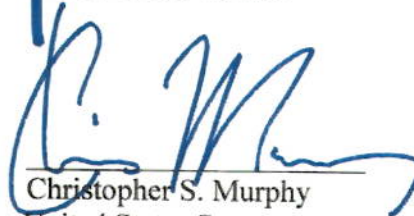
Edward J. Markey  
United States Senator




Elizabeth Warren  
United States Senator



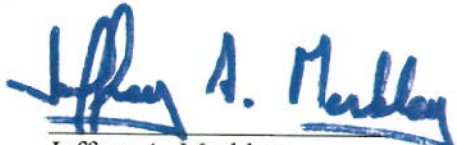
Benjamin L. Cardin  
United States Senator

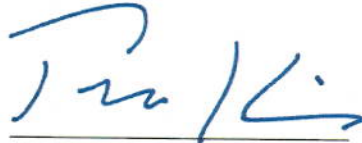



Christopher S. Murphy  
United States Senator

  
Kamala D. Harris  
United States Senator

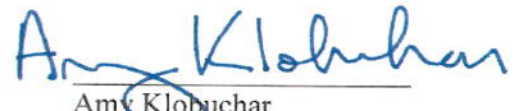
  
Tammy Duckworth  
United States Senator

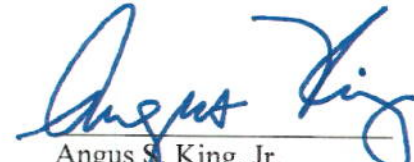
  
Jeffrey A. Merkley  
United States Senator


  
Tim Kaine  
United States Senator

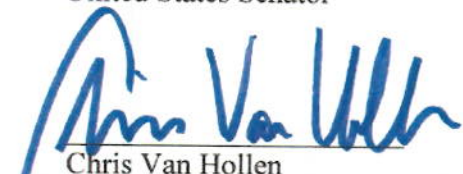
  
Cory A. Booker  
United States Senator

  
Robert Menendez  
United States Senator

  
Amy Klobuchar  
United States Senator

  
Angus S. King, Jr.  
United States Senator

  
Robert P. Casey, Jr.  
United States Senator

  
Chris Van Hollen  
United States Senator

  
Ron Wyden  
United States Senator

  
Mazie K. Hirono  
United States Senator

CC: Norman E. Sharpless, MD  
Acting Commissioner  
Food and Drug Administration



## THE ADMINISTRATION'S PLAN TO REMOVE E-CIGARETTE FLAVORS MUST INCLUDE MENTHOL TO PROTECT KIDS

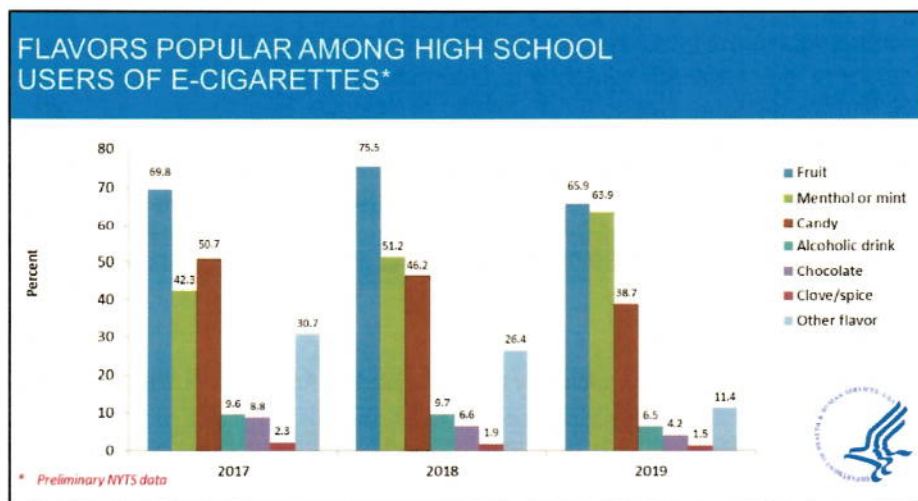
Given the prevalence of menthol (and mint) flavors among youth e-cigarette users, and the lack of evidence that these flavors play any role in helping adults stop smoking, there is no public health justification to exempt them from any policy proposal. If the goal is to remove the e-cigarettes that are most attractive to youth, any proposal that ignores menthol falls short and leaves America's kids at risk.

### Youth E-Cigarette Use in the United States is a Public Health Crisis

- Youth e-cigarette use in the United States has skyrocketed to what the U.S. Surgeon General and the FDA have called "epidemic" levels.<sup>1</sup> It is a public health crisis and *it is getting worse*. E-cigarette use among high school students more than doubled from 2017 to 2019, to more than 1 in 4 high schoolers.<sup>2</sup> Altogether, 5 million middle and high school students used e-cigarettes in 2019 – an increase of nearly 3 million users in two years.<sup>3</sup>

### Flavored products are fueling the youth epidemic. Data strongly establish that menthol (and mint) flavored products are very popular among youth.

- Data from the 2019 National Youth Tobacco Survey show that nearly two-thirds (63.9%) of youth e-cigarette users use mint or menthol flavored e-cigarettes.<sup>4</sup> This is an increase from 42.3 percent in 2017 and 51.2% in 2018.<sup>5</sup> Mint and menthol flavors are now about as popular as fruit flavors among youth.
- The evidence from cigarettes establishes that menthol has unique appeal for youth. Menthol cools and numbs the throat, reducing the harsh taste and irritation from nicotine, making it easier to start smoking, particularly for youth.<sup>6</sup> The FDA has concluded that menthol increases the number of teens who start smoking and who become regular smokers.<sup>7</sup>
- Half (50.1%) of youth who have ever tried smoking initiated with menthol flavored cigarettes.<sup>8</sup> Over half (54 percent) of current youth smokers ages 12-17 smoke menthol cigarettes, compared to less than one-third of smokers ages 35 and older.<sup>9</sup>



### Leaving menthol e-cigarettes on the market will not solve the epidemic of youth e-cigarette use. Youth e-cigarette users will simply shift from one flavor to another.

- Making mint, fruit and candy flavors more difficult to obtain, but leaving menthol e-cigarettes as accessible to young people as they are now, will simply shift youth e-cigarette users from one flavor to another, rather than meaningfully reducing the rate of use. That's what happened when, in November 2018, Juul removed all of its flavors—except tobacco, mint and menthol - from brick-and-mortar retailers but kept mint and menthol flavors on the shelves – youth shifted to mint and



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Centers for Disease Control and Prevention (CDC), "Use of Electronic Cigarettes and Any Tobacco Product Among Middle and High School Students—United States, 2011-2018," *Morbidity and Mortality Weekly Report (MMWR)*, 67(45): 1276-1277.

[https://www.cdc.gov/mmwr/volumes/67/wr/mm6745a5.htm?s\\_cid=mm6745a5\\_w](https://www.cdc.gov/mmwr/volumes/67/wr/mm6745a5.htm?s_cid=mm6745a5_w). Current use defined as any use in the past month.

<sup>5</sup> CDC, "Use of Electronic Cigarettes and Any Tobacco Product Among Middle and High School Students—United States, 2011-2018," *MMWR*, 67(45): 1276-1277. [https://www.cdc.gov/mmwr/volumes/67/wr/mm6745a5.htm?s\\_cid=mm6745a5\\_w](https://www.cdc.gov/mmwr/volumes/67/wr/mm6745a5.htm?s_cid=mm6745a5_w).

<sup>6</sup> TPSAC, FDA, "Menthol Cigarettes and Public Health: Review of the Scientific Evidence and Recommendations, 2011,

[https://wayback.archive-](https://wayback.archive-it.org/7993/20170405201731/https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/TobaccoProductsScientificAdvisoryCommittee/UCM269697.pdf)

[it.org/7993/20170405201731/https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/TobaccoProductsScientificAdvisoryCommittee/UCM269697.pdf](https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/TobaccoProductsScientificAdvisoryCommittee/UCM269697.pdf). FDA. *Preliminary Scientific Evaluation of the Possible Public Health Effects of Menthol versus Nonmenthol Cigarettes* (2013).

<sup>7</sup> FDA. *Preliminary Scientific Evaluation of the Possible Public Health Effects of Menthol versus Nonmenthol Cigarettes* (2013).

<sup>8</sup> Ambrose, BK, et al., "Flavored Tobacco Product Use Among US Youth Aged 12-17 Years, 2013-2014," *Journal of the American Medical Association*, published online October 26, 2015.

<sup>9</sup> Villanti, A., et al., "Changes in the prevalence and correlates of menthol cigarette use in the USA, 2004-2014," *Tobacco Control*, published online October 20, 2016

<sup>10</sup> *Breja v. Juul Labs*, No. 3:19-cv-07148, Compl. at 9 (N. D. Cal. Filed Oct. 29, 2019).

<sup>11</sup> Kaplan, S, et al., "Juul Replaces its CEO with a Tobacco executive," *New York Times*, September 25, 2019

<https://www.nytimes.com/2019/09/25/health/juul-vaping.html>

<sup>12</sup> Maloney J. "Juul Debates Pushing Back on E-Cigarette Ban," *Wall Street Journal*, September 12, 2019, <https://www.wsj.com/articles/juul-debates-pushing-back-on-e-cigarette-ban-11568327978?mod=djemwhatsnews>.

<sup>13</sup> King, BA, et al., "Awareness and Ever Use of Electronic Cigarettes Among U.S. Adults, 2010-2011," *Nicotine & Tobacco Research*, 15(9):1623-7, 2013. See also, King, BA, et al., "Trends in Awareness and Use of Electronic Cigarettes among U.S. Adults, 2010-2013," *Nicotine & Tobacco Research*, first published online September 19, 2014; U.S. Preventive Services Task Force, *Final Recommendation Statement: Tobacco Smoking Cessation in Adults, Including Pregnant Women: Behavioral and Pharmacotherapy Interventions*, May 2019, <https://www.uspreventiveservicestaskforce.org/Page/Document/RecommendationStatementFinal/tobacco-use-in-adults-and-pregnant-women-counseling-and-interventions1>;

<sup>14</sup> National Academies of Sciences, Engineering, and Medicine (NASEM), *Public Health Consequences of E-Cigarettes*, Washington, DC: The National Academies Press, 2018, <http://nationalacademies.org/hmd/Reports/2018/public-health-consequences-of-e-cigarettes.aspx> NASEM, *Public Health Consequences of E-Cigarettes*, 2018.

<sup>15</sup> Dai, H & Levanthal, A.M, *Prevalence of e-Cigarette Use Among Adults in the United States, 2014-2018*, *JAMA*, September 16, 2019.

<sup>16</sup> CDC, "Quick Stats: Cigarette Smoking Status Among Current Adult E-Cigarette Users, by Age Group—National Health Interview Survey, United States, 2015," *MMWR* 65(42):1177,

[http://www.cdc.gov/mmwr/volumes/65/wr/mm6542a7.htm?s\\_cid=mm6542a7\\_w](http://www.cdc.gov/mmwr/volumes/65/wr/mm6542a7.htm?s_cid=mm6542a7_w). Mirbolouk, M, et al., "Prevalence and Distribution of E-Cigarette Use Among U.S. Adults: Behavioral Risk Factor Surveillance System, 2016," *Annals of Internal Medicine*, published online August 28, 2018.