

JOSH STEIN
ATTORNEY GENERAL



November 16, 2021

Dr. Robert Califf
c/o U.S. Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20993-0002

Dear Dr. Califf:

Congratulations on your nomination to serve as Commissioner of the Food and Drug Administration. I wish you success throughout the confirmation process.

As you know, one item that is currently high on the FDA's agenda is e-cigarettes. In August of this year, I helped lead a bipartisan coalition of state Attorneys General in urging Acting Commissioner Woodcock to take swift, effective action to protect America's youth from the dangers of e-cigarettes. A copy of that letter is attached. We ask you to review it and act on its recommendations regarding e-cigarette products, including prohibiting non-tobacco flavors (including but not limited to menthol), limiting the amount of nicotine, and restricting marketing to ensure that such products are not attractive to minors.

Since our letter to Acting Commissioner Woodcock, the FDA has announced its first authorizations for marketing of e-cigarette products.¹ Importantly, the FDA has limited the authorizations of flavored products and has denied applications for certain dessert- and fruit-flavored products after determining that they pose a public health threat due to the "well-documented, alarming levels of youth use of such products."²

We appreciate the agency's recognition of the profound risks that e-cigarettes, particularly those with flavors that attract kids, pose to America's youth. For the reasons set forth in our August 18, 2021 letter, we urge the FDA to remain vigilant against those risks, including the risk of products in flavors other than tobacco and those with high nicotine levels that quickly create dependence. I also ask that the FDA act with greater urgency on this issue, given that the health of America's youth is at stake and that the market is saturated with products to appeal to them.

¹ <https://www.fda.gov/news-events/press-announcements/fda-permits-marketing-e-cigarette-products-marking-first-authorization-its-kind-agency>

² <https://www.fda.gov/news-events/press-announcements/fda-denies-marketing-applications-about-55000-flavored-e-cigarette-products-failing-provide-evidence>

Again, good luck with your confirmation. I look forward to working with you with urgency in this effort to protect kids once you have been confirmed Commissioner.

Sincerely,

A handwritten signature in black ink, appearing to read "Josh Stein". The signature is written in a cursive, flowing style.



August 18, 2021

Via E-Mail and U.S. Mail

Hon. Janet Woodcock
Acting Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Dear Commissioner Woodcock:

High-potency nicotine products sold in youth-friendly flavors have swamped the marketplace. These flavored products—from e-cigarettes to oral nicotine pouches—are inherently attractive to youth, a problem compounded when they are marketed in ways that further entice children and teens. Lack of effective national regulation of such products would all but guarantee that a new generation of young people will needlessly become addicted to nicotine. The Food and Drug Administration has the power to regulate these harmful products, and we implore you to take swift, effective measures to protect America's youth.

These products should not be on the market in the first place, as they have not received marketing orders required by Section 910 of the Food, Drug, and Cosmetic Act, as amended by the Family Smoking Prevention and Tobacco Control Act. As the FDA now considers whether to grant Premarket Tobacco Product Applications (PMTAs) for these products and allow them to stay on the market, the undersigned Attorneys General urge you to take the following measures: (1) prohibit all non-tobacco flavors—including menthol, (2) limit the amount of nicotine in these products, and (3) impose marketing restrictions and effective age verification to prevent youth access and appeal.

Although the full scope of the health risks posed by e-cigarettes and the newest generation of oral nicotine products is not yet known—including how their harm compares to that of traditional tobacco products—these products contain nicotine and will serve as a gateway to nicotine addiction for young people. Nicotine has particularly harmful effects on the developing brain, with adolescents being significantly more likely to become addicted than adults.¹ Adolescent nicotine consumption is also associated with numerous adverse physical outcomes such as nicotine poisoning and toxicity, as well as mental health and behavioral problems like major depressive disorder, academic problems,

¹ Menglu Yuan et al., *Nicotine and the adolescent brain*, 593(16) *J. of Physiology*, 3397-3412 (2015).

and addiction to other substances.² Moreover, use of e-cigarettes is associated with higher susceptibility to later use of combustible cigarettes and cigars.³

Our concerns are based on our extensive experience in dealing with the dangers of combustible tobacco products. Manufacturers of such products have a well-documented history of using appealing flavors and marketing tactics to target youth. Manufacturers of new nicotine products have been quick to adopt many of those tried-and-true approaches and have taken full advantage of the relatively few restrictions applicable to their products. As a consequence, these products are still permitted to be sold in a virtually unlimited variety of flavors and are marketed in ways that directly appeal to youth.

The disparity in the way the FDA has treated e-cigarettes and regular cigarettes has allowed an explosion of growth in e-cigarette use and nicotine addiction, especially amongst youth,⁴ to the point that the U.S. Surgeon General called it an epidemic in 2019.⁵ E-cigarette use among high school students increased dramatically, from just 1.5% in 2011 to 11.7% in 2017, and then to 27.5% in 2019.⁶ 2020 data shows that 19.6% of high school students have used an e-cigarette in the past 30 days, with 38.9% of those reporting e-cigarette use on 20 or more days of the past 30 days, and 22.5% reporting daily use. This youth e-cigarette boom was led by JUUL, but countless other companies—including all the major tobacco companies—have also cashed in.

At the same time, new oral nicotine products (like Zyn, On!, and Velo) threaten to become the next JUUL, further intensifying the nation’s underage nicotine binge.⁷ Indeed, nicotine pouches—led by Zyn—are quickly becoming the fastest-growing nicotine category in convenience stores, growing by about 500% during the 24 weeks ending on May 30, 2020.⁸ A fall 2020 survey shows

² Brenda Douglass, Susan Solecki & Theresa Fay-Hillier, *The Harmful Consequences of Vaping: A Public Health Threat*, 31(2) J. Addictions, 79-84 (2020); Shivani M. Gaiha & Bonnie Halpern-Felsher, *Escalating Safety Concerns Are Not Changing Adolescent E-Cigarette Use Patterns: The Possible Role of Adolescent Mental Health*, 66(1) J. Adolescent Health, 3-5 (2020); Shivani M. Gaiha & Bonnie Halpern-Felsher, *Public Health Considerations for Adolescent Initiation of Electronic Cigarettes*, 145(2) Pediatrics, S175-S180 (2020); Olufunmilayo H. Obisesan et al., *Association Between e-Cigarette Use and Depression in the Behavioral Risk Factor Surveillance System, 2016-2017*, 2(12) JAMA Network Open e1916800 (2019).

³ Kaitlyn M. Berry et al., *Association of Electronic Cigarette Use With Subsequent Initiation of Tobacco Cigarettes in US Youths*, 2(2) JAMA Network Open e187794 (2019); Elizabeth C. Hair et al., *A longitudinal analysis of e-cigarette use and cigar, little cigar or cigarillo initiation among youth and youth adults: 2017–2019*, 226 Drug and Alcohol Dependence, Volume 108821 (2021).

⁴ Lavanya Ramanathan, *We killed the cigarette. What we got in return is mango-flavored nicotine in ‘party mode.’*, The Washington Post (Aug. 8, 2018) https://www.washingtonpost.com/lifestyle/style/we-killed-the-cigarette-what-we-got-in-return-is-mango-flavored-nicotine-in-party-mode/2018/08/08/bf4db3a8-8b8a-11e8-8aea-86e88ae760d8_story.html; Kristy Marynak et al., *Exposure to Electronic Cigarette Advertising Among Middle and High School Students — United States, 2014-2016*, 67(10) MMWR Morbidity and Mortality Weekly Report 294-299 (2018).

⁵ *Surgeon General’s Advisory on E-Cigarette Use Among Youth*, Center for Disease Control and Prevention (Apr. 19, 2019) https://www.cdc.gov/tobacco/basic_information/e-cigarettes/surgeon-general-advisory/index.html.

⁶ Karen A. Cullen et al., *e-Cigarette Use Among Youth in the United States, 2019*, 322(21) JAMA 2095-2103 (2019).

⁷ Benjamin Schneider, *Is Zyn the Next Juul?*, SF Weekly (June 3, 2021) <https://www.sfweekly.com/culture/zyn-next-juul/>; *Oral nicotine products entice customers with ‘tobacco free’ claims, falsely implying lower risk*, Truth Initiative (May 7, 2021) <https://truthinitiative.org/research-resources/tobacco-industry-marketing/oral-nicotine-products-entice-customers-tobacco-free>; *What is Zyn and what are oral nicotine pouches?*, Truth Initiative (Feb. 9 2021) <https://truthinitiative.org/research-resources/emerging-tobacco-products/what-zyn-and-what-are-oral-nicotine-pouches>.

⁸ Hannah Prokop, *Nicotine Pouches: Tobacco’s Fast-Growing Subcategory*, CSP Daily News (Oct. 16, 2020) <https://www.cspdailynews.com/tobacco/nicotine-pouches-tobaccos-fast-growing-subcategory>.

that 13% of 15-24 year olds used nicotine pouches in the past 30 days.⁹ Critically, sale of these products has not been authorized by the FDA, much less approved for cessation purposes. The FDA should act quickly to rein in these products before a full-blown youth crisis emerges—as we are still experiencing with e-cigarettes—and countless additional youth become addicted to nicotine.

Newer oral nicotine products are designed to be much more discreet and attractive than previous generations of products. For instance, a nicotine pouch, which is small and sits unnoticeably between the lips and gums, does not contain actual tobacco leaves and does not require the user to spit.¹⁰ These products can be consumed anytime, anywhere—including in schools—without any visible indication they’re being used. Unsurprisingly, manufacturers are vigorously marketing these nicotine products by touting users’ ability to consume them in any setting. In fact, a recent study shows that of 38 million pieces of oral nicotine direct mail sent to US consumers, 84% featured claims that the product could be used anywhere.¹¹

In weighing whether e-cigarettes and oral nicotine products should be allowed to remain on the market, the FDA should protect children by eliminating youth-appealing flavors, limiting nicotine levels, and restricting marketing.

Prohibit Non-Tobacco Flavors

The common denominator with all of these youth-appealing nicotine products is clear: flavors. Instead of tobacco flavor, these products come in a staggering variety of flavors, including in the broad categories of fruit, dessert, and mint/menthol. Allowing such flavors to remain on the market poses a serious risk to the health of America’s youth.

It has been well documented that flavored combustible and e-cigarettes (including menthol) attract youth at alarming rates, and we have every reason to expect that the same will be true for the newest generation of oral nicotine products. Young people are more likely to report interest in trying an e-cigarette if it is flavored, with e-cigarette “taste” being one of the top reasons why teens start using e-cigarettes.¹² More than 80% of adolescents using e-cigarettes choose non-tobacco-flavors, and the most popular flavors are fruit, mint, and menthol.¹³

⁹ *What is Zyn and what are oral nicotine pouches?*, Truth Initiative (Feb. 9 2021) <https://truthinitiative.org/research-resources/emerging-tobacco-products/what-zyn-and-what-are-oral-nicotine-pouches>.

¹⁰ While the newer products do not contain actual tobacco leaves, the nicotine in them is often still derived from the tobacco leaf. But the nicotine can also be produced synthetically. For instance, a number of products, such as Puff Bar disposable e-cigarettes (popular among youth and coming in flavors like Blueberry Ice, Mango, and Watermelon) and Rush nicotine pouches (sold on Amazon with no apparent age verification and in flavors like Cinnabuzz, Mintsanity, and Citrus) purport to use nicotine not derived from tobacco. To the extent the FDA does not regulate such synthetic nicotine products through its Center for Tobacco Products, it should act swiftly to regulate them under the Food Drug and Cosmetic Act through its Center for Drug Evaluation and Research. To let these synthetic nicotine products fall through the regulatory cracks and remain on the market would be unconscionable.

¹¹ Lauren Czaplicki et al., *Oral nicotine marketing claims in direct-mail advertising*, *Tobacco Control* 1-4 (2021).

¹² Brian A. King, *Flavors Are a Major Driver of the Youth E-Cigarette Epidemic*, 110(6) *Am. J. of Pub. Health* 773-774 (2020).

¹³ Bridget K. Ambrose et al., *Flavored Tobacco Product Use Among US Youth Aged 12-17 Years, 2013-2014*, 314(17) *JAMA* 1871-1873 (2019); Brian A. King, *Flavors Are a Major Driver of the Youth E-Cigarette Epidemic*, 110(6) *Am. J. of Pub. Health* 773-774 (2020).

The concern over flavors is not new. On August 8, 2014, twenty-nine Attorneys General submitted comments in support of the FDA’s Notice of Proposed Rule, 79 Fed. Reg. 23142 (April 25, 2014), deeming all tobacco products, including e-cigarettes, to be under its jurisdiction. Those comments supported the FDA’s rule, but also urged it to restrict e-cigarette flavors in the same manner in which cigarette flavors were restricted because of the risk flavored e-cigarettes pose to young people. The FDA declined to take that step, however, partly out of hope that flavored e-cigarettes would help transition current smokers to a potentially less harmful product.¹⁴ Seven years later, there is still no definitive evidence that e-cigarette use is associated with smoking cessation, much less that flavored e-cigarettes contribute to smoking cessation. However, as shown by the data cited above, there is overwhelming evidence that flavored e-cigarettes are hooking a new generation on nicotine.

Indeed, the FDA has repeatedly acknowledged the role flavors play in addicting youth to tobacco products. In January 2020, the FDA announced that it would prioritize its enforcement against flavored cartridge-based e-cigarettes (except menthol and tobacco flavors) because of their appeal to youth.¹⁵ In response, on February 27, 2020, twenty-seven Attorneys General wrote a letter appealing to the FDA to include menthol flavors in its enforcement priorities for ENDS and to expand its enforcement priorities of ENDS products beyond cartridge based systems to include popular products such as sealed disposables like Puff Bar.

Following menthol’s exception from the FDA’s restriction on flavors, there has been a surge in popularity among youth of e-cigarette products with menthol flavoring. Menthol-flavored e-cigarette sales jumped 54.5% in market share over the four weeks following the FDA 2020 guidance, and 82.8% over eight weeks.¹⁶ Despite industry arguments, it is clear that menthol appeals to youth, just like all other non-tobacco flavors.

The FDA has long known that menthol flavoring in combustible cigarettes appeals to youth and increases the number of teens who become regular smokers.¹⁷ The FDA acknowledged the insidious history of menthol marketing and youth appeal in April of this year when it announced its plan to ban menthol-flavored cigarettes along with all flavors of little cigars. In banning menthol in combustible tobacco products, the FDA took a substantial step in reducing youth initiation. However, the appeal of menthol flavoring to youth does not go away because it is consumed through an e-cigarette or oral product rather than combustible tobacco. The FDA should work toward the same goal it has announced for combustible tobacco and ban menthol, along with all other flavors, for any nicotine product that has not been approved as a cessation product. The FDA can immediately effectuate this goal by denying all PMTAs for products containing menthol or other flavors.

¹⁴ Food and Drug Administration, HHS, 81 Fed. Reg. 28974, at 29055 (2016). On July 19, 2018, a coalition of states continued to raise concerns about flavors, submitting comments in response to the FDA’s Advance Notice of Proposed Rulemaking titled “Regulation of Flavors in Tobacco Products,” again calling upon the FDA to ban the use of flavors, including menthol, in all tobacco products. The comments described how tobacco companies use flavors to mask the harshness of tobacco and nicotine, thereby making it easier for new and younger users to become addicted.

¹⁵ *FDA finalizes enforcement policy on unauthorized flavored cartridge-based e-cigarettes that appeal to children, including fruit and mint*, Food and Drug Administration (Jan. 2, 2020) <https://www.fda.gov/news-events/press-announcements/fda-finalizes-enforcement-policy-unauthorized-flavored-cartridge-based-e-cigarettes-appeal-children>.

¹⁶ Megan C. Diaz et al., *Menthol e-cigarette sales rise following 2020 FDA guidance*, Tobacco Control (2020) (online ahead of print); Fatma Romeh M. Ali et al., *E-cigarette Unit Sales, by Product and Flavor Type — United States, 2014-2020*, 69(37) MMWR Morbidity and Mortality Weekly Report 1313-1318 (2020).

¹⁷ *Preliminary Scientific Evaluation of the Possible Public Health Effects of Menthol versus Nonmenthol Cigarettes*, Food and Drug Administration (2013).

Limit Nicotine Amount

In addition to prohibiting flavored products, the FDA should limit the amount of nicotine in e-cigarette and oral nicotine products.

Unsurprisingly, research shows that higher amounts of nicotine are related to greater likelihood of the user becoming addicted and dependent.¹⁸ With the advent of JUUL’s 5% nicotine salt formula, a “nicotine arms race” ensued that resulted in extremely powerful and addictive e-cigarette products flooding the market and quickly addicting young people, many of whom had never used—and likely would never have used—a tobacco product before.¹⁹

The same concern exists in the woefully under-regulated market for oral nicotine products, where the FDA has also not imposed any rules on acceptable levels of nicotine and companies offer a wide variety of nicotine strengths.²⁰ A recent study of nicotine content in popular nicotine pouch brands, which revealed a wide range in nicotine levels, observed that “nicotine pouch products with high free nicotine may lead to greater nicotine dependency.”²¹ This is especially concerning given prior research showing that young people are often unable to ascertain whether certain tobacco products contain comparably low or high amounts of nicotine—or whether they even contain nicotine at all.²²

Other countries have tackled this problem by imposing limits on the amount of nicotine in products. For instance, the United Kingdom and the European Union allow only 20mg/mL nicotine in e-cigarettes; by contrast, in the United States, JUUL’s 5% product delivers a staggering 59mg/mL nicotine.

The FDA should act now to curb ever-higher levels of nicotine by limiting the nicotine strengths of all products. The FDA can immediately effectuate this goal by denying all PMTAs for products containing high levels of nicotine.

Restrict Marketing

Finally, the FDA should use its authority under Sections 906 and 910 of the Food, Drug, and Cosmetic Act to ensure that nicotine products—whether e-cigarettes, pouches, gum, or lozenges—are not marketed to youth.

¹⁸ Nicholas I. Goldenson et al., *Associations of E-Cigarette Nicotine Concentration and Subsequent Cigarette Smoking and Vaping Levels in Adolescents*, 171(12) *JAMA Pediatrics* 1192-1199 (2017).

¹⁹ See Robert K. Jackler & Divya Ramamurthi, *Nicotine arms race: JUUL and the high-nicotine product market*, 28(6) *Tobacco Control* 623-628 (2019).

²⁰ Stephen Stanfill et al., *Characterization of Total and Unprotonated (Free) Nicotine Content of Nicotine Pouch Products*, *Nicotine & Tobacco Research* 1-7 (2021).

²¹ *Id.*

²² See, e.g., Jeffrey G. Willett et al., *Recognition, use and perceptions of JUUL among youth and young adults*, 28(1) *Tobacco Control* 115-116 (2018); Meghan E. Morean et al., *Adolescents’ awareness of the nicotine strength and e-cigarette status of JUUL e-cigarettes*, 204 *Drug and alcohol dependence* 107512 (2019); Neil McKeganey, Christopher Russell & Farhana Haseen, *Awareness of the presence of nicotine in the JUUL Brand of e-cigarette among adolescents, young adults, and older adults in the United States*, 27(6) *Drugs: Education, Prevention and Policy* 451-461 (2020).

Research shows that marketing influences decision-making by young people and is a significant reason why young people use e-cigarettes.²³ Adolescents are particularly susceptible to marketing and advertising, and exposure to e-cigarette marketing is associated with lower perceptions of risks, including risk of addiction.²⁴ Manufacturers' use of the Internet and social media to market their nicotine products heightens the susceptibility of youth as it greatly increases manufacturers' opportunity to reach and interact with young consumers.²⁵ Moreover, the tobacco industry's use of social media "influencers" can be especially pernicious for youth, given that tobacco marketing messages are more effective when they appear to come from peers rather than corporations.²⁶

E-cigarette companies regularly engage in activities from which their combustible counterparts are barred. In its first few years, JUUL took several pages out of big tobacco's playbook, including the use of company-sponsored parties, billboards with youthful imagery, advertising in magazines read by youth, celebrity endorsements, and emphasis on youthful themes like rebellion, irreverence, popularity, and attractiveness.²⁷ While JUUL has been subjected to scrutiny by the FDA and States for its role in the vaping epidemic and has experienced a decline in market share, other e-cigarette companies have stepped in to vie for that market share. For instance, in November 2020, VUSE, in conjunction with Rolling Stone magazine, promoted its e-cigarette products through a multi-day concert featuring a number of celebrities.²⁸ Unfortunately, these marketing tactics successfully appeal to youth and increase the likelihood that young people will begin vaping.²⁹

Accordingly, the FDA should impose restrictions in any marketing orders it issues that ensure marketing tactics and materials are not attractive to youth and that youth are not bombarded with messages encouraging them to use these products. In addition to imposing the more traditional marketing restrictions that already apply to combustible tobacco products, the FDA should closely examine the digital marketing landscape, including website advertising and the use of social media platforms popular with young people, such as Instagram, Snapchat, and TikTok. As part of that effort, the FDA should require effective age-verification for access to promotional material on the Internet and on social media sites.

²³ Kristy Marynak et al., *Exposure to Electronic Cigarette Advertising Among Middle and High School Students — United States, 2014-2016*, 67(10) MMWR Morbidity and Mortality Weekly Report 294-299 (2018).

²⁴ Lauren Collins et al., *E-Cigarette Marketing and Communication: How E-Cigarette Companies Market E-Cigarettes and the Public Engages with E-Cigarette Information*, 21(1) Nicotine Tobacco Rsch. 14-24 (2019); Pallav Pokhrel et al., *Receptivity to E-cigarette Marketing, Harm Perceptions, and E-Cigarette Use*, 39(1) Am. J. Health Behav. 121-131 (2016); Karma McKelvey et al., *Youth say ads for flavored e-liquids are for them*, 91 Addict Behav. 164-170 (2019); Erin A. Vogel et al., *Effects of Social Media on Adolescents' Willingness and Intention to Use E-Cigarettes: An Experimental Investigation*, 23(4) Nicotine Tobacco Rsch. 694-701 (published online 2020).

²⁵ Robert K. Jackler et al., *Promotion of tobacco products on Facebook: policy versus practice*, 28(1) Tobacco Control 67-73 (2019).

²⁶ Edward Sepe, Pamela M. Ling & Stanton A. Glantz, *Smooth Moves: Bar and Nightclub Tobacco Promotions That Target Young Adults*, 92(3) Am. J. Pub. Health 414-419 (2002).

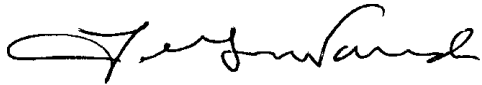
²⁷ Robert K. Jackler et al., *JUUL Advertising Over its First Three Years*, Stanford University School of Medicine (Jan. 31, 2019) https://tobacco-img.stanford.edu/wp-content/uploads/2021/07/21231836/JUUL_Marketing_Stanford.pdf.

²⁸ Noah Manskar, *E-cigarette maker critics fume over concert series aimed at young people*, N.Y. Post (Dec. 6, 2020) <https://nypost.com/2020/12/06/e-cig-maker-accused-of-marketing-to-under-21-crowd-with-concerts/>.

²⁹ Kristy Marynak et al., *Exposure to Electronic Cigarette Advertising Among Middle and High School Students — United States, 2014-2016*, 67(10) MMWR Morbidity and Mortality Weekly Report 294-299 (2018).

As the FDA reviews pending Premarket Tobacco Product Applications, the undersigned Attorneys General urge it to deny applications that will exacerbate America's youth nicotine epidemic and jeopardize our children's health. In addition to addressing the explosion of high-nicotine, flavored e-cigarette products popular among youth, the FDA should be proactive—not reactive—in its approach to newer nicotine products, such as pouches, gums, and lozenges, to ensure they do not add to that epidemic. Now is the time to take decisive action to rein in all youth-appealing products before irreversible damage is done to the public health.

Sincerely,



Lawrence Wasden
Idaho Attorney General



Kwame Raoul
Illinois Attorney General



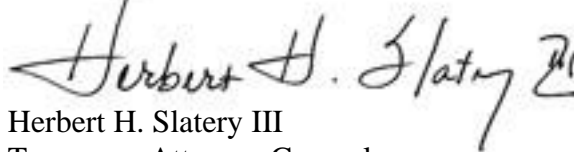
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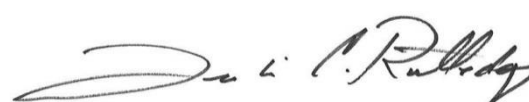
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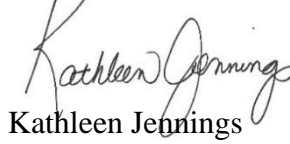
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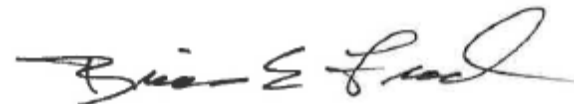
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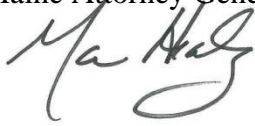
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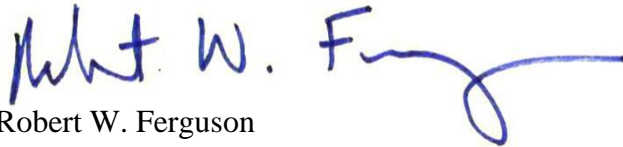
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