



April 1, 2022

The Honorable Robert Califf, M.D.  
Commissioner  
Food and Drug Administration  
10903 New Hampshire Ave  
Silver Spring, MD 20993

Dear Commissioner Califf:

On behalf of the American Academy of Family Physicians (AAFP), representing more than 127,600 family physicians and medical students across the country, I write to congratulate you on your confirmation as Commissioner of the Food and Drug Administration (FDA). The AAFP shares your commitment to protecting the public's health through science-based decision making and we look forward to partnering to advance these shared goals.

Family physicians provide comprehensive, whole-person primary care to patients across the lifespan. This includes providing counseling on preventive care and administering immunizations, as well as prescribing medications to treat acute and chronic conditions and ordering medical devices. The FDA is tasked with ensuring each of these drugs, devices, and other products are safe and effective, and therefore plays a vital role in ensuring patients can fully benefit from primary care. The AAFP has long supported the FDA's efforts to advance public health and we've appreciated the agency's ongoing partnership throughout the COVID-19 pandemic. We look forward to working together to continue executing a data-driven COVID-19 response, reduce tobacco smoking and nicotine addiction, address the opioid epidemic, and improve access to evidence-based reproductive health care.

### COVID-19 Response

The AAFP applauds the FDA's ongoing efforts to ensure the availability of safe and effective COVID-19 vaccines, therapeutics, and tests, as well as high-quality masks to prevent the spread of the virus. These products have been essential to protecting families from contracting COVID-19, severe disease, and death. Family physicians counsel patients about how to protect themselves from COVID-19 and the importance of getting vaccinated, as well as prescribe and refer patients to treatment when they are diagnosed with COVID-19. The AAFP has appreciated the FDA's outreach and educational efforts to ensure frontline physicians have the most up to date information and urge the agency to continue prioritizing this work moving forward.

Looking forward, the AAFP urges FDA focus on preventing and responding to future variants and surges. The AAFP is eagerly awaiting the authorization of a COVID-19 vaccine for children under the age of five, once a review of the available data indicates it is safe and effective. We are also closely tracking developments related to additional boosters. However, family physicians continue to report that monoclonal antibody treatments and antivirals are in short supply. We've [called](#) on Congress to

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provide adequate funding to support these efforts and we look forward to continuing to partner with the FDA to:

- **Ensure safe and effective vaccines and boosters are available to patients of all ages (following the robust review of available data), including updated vaccines or variant-specific boosters that may be required in the future,**
- **Increase the development and availability of monoclonal antibody and antiviral treatments that are effective against new variants, and**
- **Continue to bolster our testing and surveillance capacity through the development of COVID-19 diagnostic tests, including at-home, rapid, and polymerase chain reaction (PCR) tests.**

**The AAFP urges FDA to work with other agencies within HHS to develop and publish a plan to ensure ongoing availability of COVID-19 vaccines, therapeutics, and tests after the national public health emergency ends.** We are pleased that the FDA released guidance for COVID-19 test and other device manufacturers outlining the timeline and process for transitioning from PHE operations to normal operations. We urge FDA to publish clarifying information and guidance regarding the continued availability of vaccines and therapeutics that have not yet been fully approved after the end of the PHE, including the process for how FDA will notify the public about the expiration of emergency use authorizations (EUAs). While the AAFP recognizes that the existing EUAs may not be tied to the PHE, the issuance of clear guidance would promote public trust and reduce confusion among health care professionals and other stakeholders.

#### Tobacco and Nicotine

The AAFP appreciates the FDA's frequent reiteration that there are no safe tobacco products. Cigarette smoking (including secondhand smoke exposure) is the leading cause of death and preventable disease in the United States, accounting for more than 480,000 deaths each year.<sup>i</sup> Cigarette smoking has been causally linked to diseases of nearly all organs of the body, including an increased risk of heart disease, stroke, chronic obstructive pulmonary disease (COPD), diabetes mellitus, and lung cancer.<sup>ii</sup> Lung cancer caused by smoking is the leading cause of lung cancer deaths.<sup>iii</sup> It also causes complications in pregnancy, harms the fetus, and leads to diminished overall health status.<sup>iv</sup> The AAFP provides a number of resources on smoking cessation treatment and can support the administration with developing or sharing additional resources for tobacco use screening and treatment.

Menthol in cigarettes mitigates harshness of tobacco smoke to new smokers making it more appealing to non-smokers and young people.<sup>v</sup> Menthol cigarettes are also more addictive and make it harder to quit smoking. The tobacco industry has targeted marketing for menthol cigarettes towards Black communities which has led to a dramatic increase in prevalence of menthol cigarette use among Black individuals: 5% of Black smokers in the 1950s to 85 percent today, compared to just 29 percent of White smokers.<sup>vi, vii, viii</sup> **The AAFP strongly supports removing all flavored tobacco and nicotine products from the market, including menthol cigarettes and all flavors of cigars.**

The AAFP applauds the FDA's efforts to ban the sale of all flavored [electronic nicotine delivery systems \(ENDS\)](#), also called electronic cigarettes, e-cigarettes, vaping devices, or vape pens. **Young people continue to use ENDS at alarming levels, and many ENDS products contain highly addictive levels of nicotine.** CDC and FDA's most recent National Youth Tobacco Survey showed that more than 2 million middle and high school students reported using e-cigarettes in the first half of this year, even when many schools were closed because of the COVID-19 pandemic. Any non-

tobacco flavored nicotine products are more likely to appeal to young people and increase rates of nicotine and tobacco use. **All flavored nicotine and tobacco products must be cleared from the market, and the AAFP strongly supports the FDA's efforts to do so.**

The AAFP recently joined other stakeholders in [calling on Congress](#) to clarify FDA authority to regulate synthetic nicotine. As you know, there has been an alarming rise in ENDS manufacturers using a loophole in the Family Smoking Prevention and Tobacco Control Act to evade FDA regulation and oversight. The AAFP applauded Congress's swift action to pass legislation closing this loophole. **We urge FDA to use its authority to swiftly implement regulations applying existing federal regulations for traditional tobacco products to all synthetic nicotine products.**

**However, the AAFP remains concerned at delays in implementing regulations to require color graphics depicting the negative health consequences of smoking to accompany new textual warning statements on cigarettes.** The AAFP opposes the use of all forms of nicotine and the advertisement of nicotine delivery products. Any sale of these products should be accompanied by graphic warning labels. While we recognize the FDA is limited in their ability to enforce this rule pending legal challenges, we appreciate the opportunity to continue engaging with your office to ensure this final rule is [implemented as intended](#).

#### Opioid Prescribing and Substance Use Disorder (SUD) Treatment

The AAFP is committed to addressing the dual public health crises of undertreated pain and opioid misuse at the national and local levels. Through its efforts with other physician and medical organizations, as well as governmental entities, the AAFP promotes the advancement of safe pain management and opioid prescribing, and is working to address the growing burden of opioid dependence. **While the AAFP strongly supports prescriber education programs to address over prescribing concerns, the Academy recently shared [concerns](#) about implementing a mandatory training requirement for prescribers.** Physicians have improved prescribing practices through optional trainings over the last six years and are seeking training to improve screening, diagnosis, and treatment of SUD involving opioids and other legal or illicit drugs. Additionally, private and public organizations, medical schools, and residencies have increased training on appropriate prescribing and pain management. Adding mandatory requirements for training would be burdensome to physicians, many of whom have already sought additional training on pain management practices.

These added burdens, such as the mandatory education requirement for physicians to obtain the X-waiver to provide SUD treatment, have been shown to worsen access to evidence-based, appropriate care.<sup>ix</sup> More accessible SUD treatment is critically important to reducing the overdose death rates. The Academy continues to [advocate](#) for Congress to eliminate the X-waiver. We urge FDA to partner with Congress and other agencies to remove unnecessary regulatory barriers and further expand access to MAT.

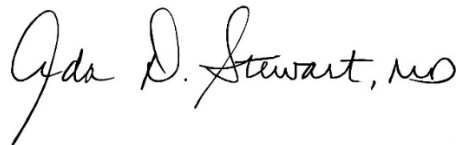
#### Reproductive Health

The AAFP is pleased that the FDA permanently removed the Risk Evaluation and Mitigation Strategy (REMS) in-person dispensing requirement for mifepristone. The [medical community](#) has long called for the [removal](#) of the in-person dispensing requirement since evidence indicates it is unnecessary for ensuring patient safety and instead creates barriers to comprehensive, evidence-based care. Mifepristone is a safe and effective medication when used to terminate a pregnancy or as part of

miscarriage management. We applaud the FDA for modifying its regulatory requirements in response to scientific evidence.

Again, congratulations on your confirmation as FDA Commissioner. We look forward to partnering with you and would appreciate the opportunity to meet with you to discuss our shared goals. To set up a meeting please contact Stephanie Quinn, Senior Vice President of Advocacy, Practice Advancement and Policy, at [squinn@aafp.org](mailto:squinn@aafp.org).

Sincerely,



Ada D. Stewart, MD, FAAFP  
Board Chair, American Academy of Family Physicians

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<sup>i</sup> U.S. Department of Health and Human Services. Smoking cessation. A report of the surgeon general. U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health; 2020. Accessed October 15, 2020. <https://www.hhs.gov/sites/default/files/2020-cessation-sgr-full-report.pdf>

<sup>ii</sup> U.S. Department of Health and Human Services. Smoking cessation. A report of the surgeon general. U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health; 2020. Accessed October 15, 2020. <https://www.hhs.gov/sites/default/files/2020-cessation-sgr-full-report.pdf>

<sup>iii</sup> Ibid

<sup>iv</sup> Ibid.

<sup>v</sup> Wang, TW, et al., "Tobacco Product Use and Associated Factors Among Middle and High School Students—United States, 2019," *MMWR* 68(12), December 6, 2019, <https://www.cdc.gov/mmwr/volumes/68/ss/pdfs/ss6812a1-H.pdf>.

<sup>vi</sup> Gardiner, PS, "The African Americanization of menthol cigarette use in the United States," *Nicotine & Tobacco Research*, 6(S1): S55-S65, 2004.

<sup>vii</sup> Lee, JGL, et al., "A Systematic Review of Neighborhood Disparities in Point-of-Sale Tobacco Marketing," *American Journal of Public Health*, published online ahead of print July 16, 2015.

<sup>viii</sup> Delnevo, CD, et al., "Banning Menthol Cigarettes: A Social Justice Issue Long Overdue," *Nicotine & Tobacco Research*, 22(10): 1673-1675, 2020.

<sup>ix</sup> Kleinman, R. A., & Morris, N. P. (2020). Federal Barriers to Addressing the Opioid Epidemic. *Journal of General Internal Medicine* 2020 35:4, 35(4), 1304–1306. <https://doi.org/10.1007/S11606-020-05721-5>