AMERICAN DENTAL HYGIENISTS' ASSOCIATION™

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American Dental Hygienists' Association Comments prepared in response to the public meeting titled, "Use of Orally Ingestible Unapproved Prescription Drug Products Containing Fluoride in the Pediatric Population."

Docket No. FDA-2025-N-1557

Comment Category: Health Care Association – D0022

The American Dental Hygienists' Association (ADHA) appreciates the opportunity to comment on the Food and Drug Administration's (FDA) review of orally ingestible, unapproved prescription drug products containing fluoride for pediatric use. As the largest national organization representing licensed dental hygienists—frontline oral health professionals dedicated to disease prevention and health promotion—we offer a person-centered, science-based perspective on fluoride's critical role in dental care.

We commend the FDA's commitment to public health and transparency throughout this review. Our comments respond to the FDA's public meeting titled, "Use of Orally Ingestible Unapproved Prescription Drug Products Containing Fluoride in the Pediatric Population," as announced in the Federal Register (Docket No. FDA-2025-N-1557). We focus on key issues outlined in this document, including clinical use, safety concerns, exposure considerations, and the potential consequences of removing these products from the market.

For decades, fluoride has been one of the most effective, evidence-based tools for preventing caries disease—commonly known as cavities or tooth decay—a disease that disproportionately impacts children in underserved communities and those with low or no water fluoridation.[i] ADHA stands ready to support policies that balance safety with continued access to these proven preventive therapies.

Additionally, ADHA officially supports community water fluoridation as a safe, effective, and cost-efficient method to reduce dental caries disease across the lifespan. We are committed to promoting education about the preventive and therapeutic benefits and safety of community water fluoridation, alongside the advantages of all preventive and therapeutic fluoride products. ADHA also firmly supports dental hygienists' authority to prescribe, administer, and dispense all evidence-based fluoride treatments to ensure optimal oral health outcomes.[ii]

Clinical Use and Prescribing Considerations for Pediatric Tooth Decay Prevention

ADHA strongly supports the clinical use of orally ingestible prescription fluoride products for pediatric patients at high risk of caries disease, especially in communities with limited access to fluoridated water or professional dental care.[iii] Fluoride has been a cornerstone of tooth decay prevention for over 70 years[iv] and remains a critical element in pediatric dental care strategies endorsed by leading organizations such as the Centers for Disease Control and Prevention (CDC)[v], the American

Dental Association (ADA)[vi], and the American Academy of Pediatrics[vii]. These organizations consistently recognize fluoride as a safe, effective, and evidence-based method to prevent caries disease in children, improve oral health, and reduce cavities nationwide.

The authority to prescribe fluoride supplements is essential to ensuring timely, targeted, and equitable prevention for children who might otherwise fall through the cracks. Unlike over-the-counter toothpaste, fluoride supplements must be carefully tailored based on a child's total fluoride exposure[viii]—requiring clinical judgment and professional oversight. When dental professionals are empowered to prescribe and administer these therapies—especially in schools, Head Start programs, and public health clinics—it enables immediate intervention before tooth decay progresses.

As more children grow up in non-fluoridated communities or areas with limited dental access, prescription fluoride becomes not just helpful—but essential. Nationally, over one-third of Americans live in non-fluoridated areas[ix], and in many underserved regions, a dental hygienist may be the only oral health provider a child regularly sees. Preventing dental disease in these communities depends on maintaining access to these long-standing, evidence-based prescription tools.

Safety Concerns

ADHA shares the FDA's commitment to safeguarding pediatric health and appreciates the Agency's continued evaluation of safety concerns surrounding prescription fluoride drug products. Fluoride is a naturally occurring mineral found in nearly all sources of water and is supported by scientific and peer-reviewed research as a safe and effective treatment for preventing caries disease in pediatric patients.[x] According to 2023 data from the Centers for Disease Control and Prevention, fluoride reduces dental caries by approximately 25% in children.[xi]

While concerns have emerged in recent years linking systemic fluoride exposure to neurodevelopmental or endocrine effects, it is critical to distinguish between high-dose, uncontrolled environmental exposure and the carefully calibrated, clinically prescribed fluoride doses used in oral health practice.[xii] Many of these referenced studies that raise safety questions stem from regions or practices with fluoride levels far exceeding U.S. prescription standards or involve methodological flaws that limit their applicability to clinical settings.

In contrast, prescription fluoride supplements in the U.S. are administered in low, age-adjusted doses based on a child's total fluoride exposure, including drinking water, diet, and toothpaste use.[xiii] These products are not used indiscriminately—they require clinical judgment, dosing discipline, and adherence to evidence-based protocols. When used as intended, the available literature supports their safety and efficacy as a preventive tool in pediatric oral health.

We encourage the FDA to continue reviewing the most rigorous and contextually relevant research—and to distinguish between speculative findings from high-exposure populations and the long-standing, science-based use of low-dose fluoride in clinical pediatric care. Prematurely limiting

access to these products may have unintended public health consequences, especially for children in fluoride-poor and underserved areas who rely on these medications to avoid preventable dental disease.[xiv]

Appropriateness of Pediatric Use Considering Additional Sources of Exposure

While fluoride is available from multiple sources—including drinking water and toothpaste—ADHA emphasizes that these alone are not always sufficient to ensure optimal protection, particularly for pediatric patients.[xv] Fluoride levels in U.S. drinking water vary widely[xvi], and many communities fall below the threshold needed to effectively prevent tooth decay.[xvii] Relying solely on naturally occurring fluoride or toothpaste use leaves significant gaps[xviii], especially for children in non-fluoridated areas or those with limited access to dental products or regular oral health care.

Ingestible fluoride supplements remain an essential tool for high-risk children, particularly in rural or underserved communities where prevention options are limited. In many non-fluoridated communities and among children facing barriers to consistent dental care, ingestible fluoride supplements serve as a critical preventive option to protect against tooth decay.[xix]

Eliminating access to ingestible fluoride supplements threatens to reverse decades of progress in reducing childhood caries and would deepen existing oral health disparities.[xx] Oral health is inseparable from overall health, and pediatric fluoride policy must be grounded in current scientific evidence. Public health policy must account not just for the presence of fluoride in toothpaste or drinking water, but for the real-world limitations and access challenges faced by families across the country. Prescription fluoride remains a necessary and appropriate tool to ensure that no child is left behind simply because of where they live or what they can afford.

Impact of Removal of Orally Ingestible Unapproved Prescription Drug Products/Potential Alternatives

The removal of orally ingestible fluoride products from the market would have significant and harmful effects, particularly on vulnerable pediatric populations in dental care deserts or areas lacking fluoridated water systems. These children already face considerable barriers to preventive oral health care, and eliminating access to orally ingestible fluoride prescription drug products removes a necessary avenue to receiving fluoride and would likely lead to increased rates of untreated caries disease.

There is no equivalent alternative that can easily replace these tools for children who lack consistent access to fluoridated water, fluoride varnish, or routine dental visits.[xxi] The loss of this prescribing option would leave a critical gap in prevention—one that disproportionately affects families already struggling to access care.

The long-term impact would not only be seen in oral health outcomes, but also in increased financial burden. As untreated caries progresses, they often require more invasive—and more

expensive—treatment.[xxii] Removing these prescription products would shift care from prevention to crisis management, placing added strain on public health systems and families alike.

Beyond the clinical and economic toll, we urge the FDA to consider the overall ramifications. These products play an essential role in closing access gaps for children who cannot rely on other sources of fluoride. Continued access, paired with appropriate oversight and research, is the path forward—not elimination.

Conclusion

The American Dental Hygienists' Association applauds the FDA's commitment to public engagement and scientific transparency on this important issue. We strongly support the continued clinical use of orally ingestible fluoride products as a safe, effective, and equitable tool in preventing pediatric tooth decay. We recognize the FDA's responsibility to ensure the safety and efficacy of prescription products, particularly for vulnerable pediatric populations. Balancing thorough safety evaluations with the need to preserve access to essential preventive therapies is a critical and complex undertaking. We urge the FDA to maintain access to these essential fluoride products while advancing patient and provider education, supporting responsible prescribing, and continuing rigorous research.

We welcome ongoing dialogue and stand ready to provide any additional information or assistance the Agency may need throughout this review process.

Additional Supportive References

- CDC Paper affirming community water fluoridation is "an inexpensive means of improving oral health that benefits all residents of a community, young and old, rich and poor alike."
- Disparities in Dental Use and Untreated Caries Prevalence by Income

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[i] https://publications.aap.org/pediatrics/article/134/3/626/74145/Fluoride-Use-in-Caries-Prevention-in-the-Primary?autologincheck=redirected
[ii] https://www.adha.org/education-resources/professional-resources/clinical-practice-resources/fluoride-resources/
[iii] https://www.adha.org/newsroom/statement-fda-action-removes-ingestible-fluoride/
[iv] https://www.nidcr.nih.gov/health-info/fluoride/the-story-of-fluoridation
[v] https://www.cdc.gov/fluoridation/faq/index.html
[vi] https://www.ada.org/topic/Fluoride#sort=%40topicsortdate%20descending&f:@contenttag=[Fluoride]
[vii] https://publications.aap.org/aapnews/news/32182/AAP-reiterates-support-for-fluoride-as-FDA-plans
[viii] https://www.aapd.org/media/Policies_Guidelines/BP_FluorideTherapy.pdf
[ix] https://www.cdc.gov/fluoridation/php/statistics/2022-water-fluoridation-statistics.html
[x] https://www.aap.org/en/news-room/fact-checked/fact-checked-fluoride-is-a-powerful-tool-for-preventing-tooth-decay/
[xi] https://www.cdc.gov/mmwr/volumes/72/wr/mm7222a1.htm
[xii] https://ntp.niehs.nih.gov/sites/default/files/2024-08/fluoride_final_508.pdf
[xiii] https://www.ada.org/resources/ada-library/oral-health-topics/fluoride-topical-and-systemic-supplements

[xiv] https://news.northwestern.edu/stories/2025/05/fluoride-bans-threaten-oral-health-of-rural-and-low-income-kids-pediatrician-warns/?fj=1#:~:text=Fluoride%20strengthens%20enamel%2C%20reverses%20early,many%20children%20living%20in%20poverty.

[xv] https://publications.aap.org/pediatrics/article/134/3/626/74145/Fluoride-Use-in-Caries-Prevention-in-the-Primary?autologincheck=redirected

[xvi] https://www.americashealthrankings.org/explore/measures/water_fluoridation

[xvii] https://www.cdc.gov/mmwr/volumes/72/wr/mm7222a1.htm

[xviii] https://www.ncbi.nlm.nih.gov/books/NBK279515/

[xix] https://www.ada.org/-/media/project/ada-organization/ada/ada-org/files/resources/community-initiatives/ada_fluoride_supplements_overview.pdf

[xx] https://ods.od.nih.gov/factsheets/Fluoride-HealthProfessional/

[xxi] https://www.adha.org/newsroom/adha-statement-on-fda-action-regarding-ingestible-fluoride-prescription-products/

[xxii] https://pmc.ncbi.nlm.nih.gov/articles/PMC10996343/