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FDA Advisory Committee Meeting – Orally Ingestible Prescription Drug Products Containing Fluoride for the Pediatric Population

Docket No. FDA-2025-N-1557

On behalf of Oral Health Kansas, Inc., we thank the U.S. Food and Drug Administration for the opportunity to provide comments about the safety and efficacy of orally ingestible prescription fluoride drug products for the pediatric population.

Oral Heath Kansas is the statewide consumer oral health advocacy organization dedicated to promoting the importance of lifelong oral health by shaping policy and educating the public. For over 20 years, we have advocated for policies that support the oral health and overall health of Kansans.

Fluoride is a naturally occurring mineral. For over 80 years, its use in the prevention of tooth decay has been proven time and again to be safe and effective. Nearly two-thirds of Kansans have access to optimally fluoridated water, but for the remaining third, most of whom are in the Wichita metropolitan area, fluoride supplements are a lifeline. They ensure kids grow up with healthy teeth, confident, and ready to contribute to their communities. When the FDA proposal to remove fluoride supplements was announced, people across Wichita reached out to us to express their alarm. **Kansas families count on fluoride supplements, and they are afraid of what will happen to their children if they can no longer access this valuable supplement.**

Oral health is not just about having a nice smile or pretty teeth. It's about health and the ability to learn and work. Kids who have dental pain cannot concentrate in school and miss class more often than kids without dental pain. People living in poverty have a hard time getting and keeping a job if they do not have good teeth. For the Kansans who do not have access to fluoridated water, fluoride supplements are their best tool to ensure they are as healthy as they can be.

How to get fluoride

People need fluoride in two different ways – systemically and topically.

- Using fluoride toothpaste and getting a fluoride treatment in the dental office are how people get topical fluoride.
- Community water fluoridation or fluoride supplements is how people get fluoride systemically. Ingesting small amounts of fluoride acts as a protective guard for our teeth when it returns through our saliva.

Children especially benefit from systemic fluoride because it helps strengthen their teeth as they are still forming. Both sources of fluoride are needed to get the optimal protection. The protection is a lot like seatbelts and airbags in a car. They both protect people from injury, but they do it in different ways. Having both keeps people as safe as possible. Removing fluoride supplements would be like removing air bags from cars, and countless children would suffer the consequences.

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Who is at risk

The people who are most at risk of poor oral health are children, older adults, people with disabilities, and people living in poverty. These are the populations who also benefit most from either fluoride supplements or optimal levels of fluoride in a community's drinking water. When people do not have access to optimally fluoridated water or supplements, they are at risk for a lifetime of oral health problems.

The following are real-life experiments that demonstrate the effects of eliminating systemic fluoride. While they are about water fluoridation, the same holds true for what would happen if people lost access to fluoride supplements.

- The cities of Calgary and Edmonton in Canada both fluoridated their water and had similar rates of children with tooth decay. When Calgary stopped in 2011, the rate of kids with tooth decay was 146% higher than in Edmonton in just five years.
- When the city of Juneau, Alaska, stopped fluoridating almost 20 years ago, research showed there was an increase in children experiencing cavities in just a few years.

What the experts say

Fluoride supplements have been widely used for decades. They are an effective tool to prevent tooth decay and are well-established to be safe to overall health.

- The **United States Preventive Services Task Force** recommends that primary care clinicians prescribe fluoride supplements starting at age 6 months for children who are at increased risk for dental caries and whose water supply is not optimally fluoridated.¹
- A 2011 **Cochrane Review** found that fluoride supplements taken daily reduced decayed, missing, and filled tooth surfaces in permanent teeth by 24% compared to placebo or no treatment.²
- The American Academy of Pediatrics and the American Dental Association both emphasize that when used under professional supervision, fluoride supplementation is safe and effective.^{3 4}

Fluoride supplements do not cause harm. They improve children's oral and overall health.

Oral Health Kansas strongly urges the FDA to keep fluoride prescription therapies on the market and available to children and families who want them. Families depend on fluoride supplements to keep their children healthy, and we trust dental and medical professionals to make the best recommendations for families. Ensuring these products remain available for pediatricians and dentists to prescribe is critical to improving our nation's oral health and protecting the youngest Americans. There is no alternative if systemic fluoride is not available. Removing fluoride supplements from the market will cause irreparable harm to children.

Please do not let down the thousands of Kansans who depend on fluoride supplements, and please do not take away their choice. We appreciate the FDA's thoughtful consideration of the evidence and its ongoing commitment to protecting children's health.

Sincerely,

Tanya Dorf Brunner, Executive Director tdorf@oralhealthkansas.org

¹ U.S. Preventive Services Task Force. Prevention of Dental Caries in Children Younger Than Age 5 Years: Screening and Interventions. 2021. https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/prevention-of-dental-caries-in-children-younger-than-age-5-years-screening-and-interventions1

² Cochrane Oral Health Group. Tubert-Jeannin et al. Fluoride supplements (for preventing dental caries in children). Cochrane Database of Systematic Reviews. 2011. https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD007592.pub2/full

³ American Academy of Pediatrics. AAP reiterates support for fluoride as FDA plans to pull some supplements from the market. 2025. <a href="https://publications.aap.org/aapnews/news/32182/AAP-reiterates-support-for-fluoride-as-FDA-plans?gl=1*kyc807*ga*MTgxMTA2NDUxNi4xNzQyOTlzMTM2*ga_FD9D3XZVQQ*czE3NTlyNTM5NzUkbzYkZzEkdDE3NTlyNTQwMzlkajMkbDAkaDA.*gcl_au*NDI1MTkwMDE2LjE3NTlyNTM5NzY.*ga_GMZCQS1K47*czE3NTlyNTM5NzYkbzUkZzEkdDE3NTlyNTOwMjlkajE0JGwwJGgw

⁴ American Dental Association. Fluoride – Topical and Systemic Supplements. 2023. https://www.ada.org/resources/ada-library/oral-health-topics/fluoride-topical-and-systemic-supplements