Use of Orally Ingestible Unapproved Prescription Drug Products Containing Fluoride in the Pediatric Population
July 23, 2025 | 9:30am-4pm *(eastern)*

Transcript

Public Comment

Susan C. Winckler, RPh, Esq., Chief Executive Officer, Regan-Udall Foundation for the FDA

Susan C. Winckler (00:00:06):

All right everyone, welcome back. We are now going to move to the public comment portion of today's meeting, for those who pre-registered to provide public comment. I'll note that when we announced this meeting, we announced the availability of the opportunity to provide public comment. And we were able to make spots available to all requesters. In addition to providing them with three and a half minutes to provide comment, we also provided them the opportunity to submit a slide that will display when they provide public comment. But now is when I need to provide the instructions for both our virtual and in-person participants. This is the choreography for how this will actually occur.

(00:00:54):

As I introduce each commenter, I'm also going to then list the next three commenters in the queue. So to be clear, for topic one, these are the three folks who should be getting ready. Peter Pitts, Steven Levy, and Christopher Fox. When I first announce your name, if you are virtual, that is your queue to look for the Zoom prompt to join as a panelist. The second time you hear your name, turn on your camera and prepare to unmute your microphone. And when the speaker, before you completes their remarks, unmute your microphone and wait for my introduction.

(00:01:34):

Our producers will bring you on screen as you are introduced. And you will have up to three and a half minutes to comment. If you do not begin speaking within 10 seconds of my turning the virtual stage over to you, we will move to the next commenter. If time allows, we'll circle back to you at the end of the section's commenters.

(00:01:54):

A countdown clock will display on screen showing the time you have remaining. I will come back on screen when you have about 15 seconds left. And at the three and a half minute mark, we will end your audiovisual support and move to the next public commenter. There is nothing personal about that. It is the passage of time and that three minutes and 30 seconds has passed.

(00:02:17):

For those of you who are here in person, it's quite similar. But the primary cue is if you are here in person, the first time you hear me call your name, come to the side of the stage. Each public commenter will be using the podium to my left to your right. As you're looking at the stage. When you hear your

name a second time, move to the bottom of the stairs. And then when the speaker before you concludes, they will step back. You will move to the podium and they will step down to the stairs after you are at the podium.

(00:02:56):

Same as the virtual commenters, the public commenters have three and a half minutes to speak. There is a countdown clock in front of the stage, and I will begin to make motions over here when you have 15 seconds left. And that will help you with the cue that in fact your time is winding down. And as I noted, to help with traffic control, when you finish your comments, please just step back. Allow the next commenter to step up, and then you may go down the stairs.

(00:03:24):

Topic 1: Clinical Use and Prescribing Considerations for Pediatric Tooth Decay Prevention

So with all of that choreography, that will help us focus on listening to our public comments, which we ask folks to speak to one of four topics. And so we will start with the first topic, which is clinical use and prescribing considerations for pediatric tooth decay prevention. As noted, our first three speakers in this cue will hear first from Peter Pitts, then from Steven Levy, then from Christopher Fox. So production team, are we ready to hear from Peter Pitts? All right, Peter Pitts, please proceed.

Peter Pitts (00:04:11):

Thank you, Susan. My name is Peter Pitts. I'm the president of the Center for Medicine and the Public Interest and a former FDA Associate Commissioner. One of the most important lessons learned from COVID-19 is that absolutes in scientific discourse are the exception. Science evolves and as it does so, we learn through both controlled clinical research and real world evidence, how to use healthcare technologies to better advance the human condition.

(00:04:37):

Fluoride is such a tool. Extensively studied over decades, fluoride has been scientifically validated for its effectiveness in reducing dental cavities, particularly in children. It's incorporated into municipal water supplies, toothpaste, mouth rinses, and dietary supplements. The benefits of fluoride far outweigh its risks. But it is important to note that no healthcare intervention is ever 100% risk-free. One of the most important functions of the Food Drug Administration is to ensure that the safety, efficacy, and quality of fluoride containing drugs and supplements are based on scientific analysis and regular post-marketing surveillance.

(00:05:19):

There exists a subset of fluoride-containing products available only through prescription by a licensed healthcare professional that are marketed and used without FDA approval. These drugs present complex challenges for public health, especially for vulnerable populations such as children. Who are at greater risk for both the benefits and potential harms of fluoride exposure.

(00:05:43):

In our current age of misinformation, where we are urged by senior leaders and our public health establishments to do our own research, emotionally charged anecdotes often trump legitimate scientific inquiry. Such as certainly the case with fluoride. And particularly with use of unapproved prescription drug products containing fluoride in the pediatric population. But the plural of anecdote isn't data. In the absence of solid evidence to the contrary, public health sentiments and the public health actions being driven must not be driven by stories, they must be driven by science.

(00:06:23):

Recently the FDA announced it would begin removing these unapproved products from the marketplace. According to Commissioner McCarry, quote, "When it comes to children, we should err on the side of safety." But actions based on anecdotal evidence is action based on emotion rather than science. It is important to note that no serious or robust data exists to support the contention that these products pose a threat to the public health, but in fairness, absence of evidence is not evidence of absence.

(00:06:56):

Rather than peremptorily removing these products from the market, the FDA should convene a blue ribbon panel of experts to debate the value of these medicines. While simultaneously fielding a comprehensive study of electronic health records to help determine the real world outcomes of these unapproved, but often highly effective interventions. Rather than removing these products, we need to, for example, use the FDA's new tool, AI tool, ELSA, to see where there's smoke, there's fire. The FDA must allow the science of fluoride to evolve. Thank you very much.

Susan C. Winckler (00:07:36):

Thank you. Our public comments in the queue, we will hear from Steven Levy, Christopher Fox, and then Johnny Johnson. And then we will turn to topic two, which addresses safety concerns. So we'll turn now to Steven Levy.

Steven Levy (00:07:53):

Thank you for the opportunity to speak briefly today. I'm an epidemiologist and professor at the University of Iowa College of Dentistry and Public Health. I've conducted applied research concerning fluoride exposures, dental caries, fluorosis, and bone development for more than 40 years and want to make a few key points. Tooth decay continues to be a major debilitating disease for some children, as several physicians reminded us this morning. And it's not practicable to expect most children and families to prevent cavities in children by avoiding excessive sugar intake and good dental hygiene, as mentioned in the May 13th FDA announcement.

(00:08:38):

So fluoride continues to be the best way to prevent cavities. But for a variety of reasons, some children don't have access to fluoridated water. And therefore dietary fluoride supplements continue to be an important way to prevent cavities through the prescriptions from the physicians and dentists. They're recommended by the US Preventive Services Task Force. They provide both systemic and topical fluoride benefits. And studies, including a series by Singh et Al., show that the lowest carries rates are when you have both systemic and topical fluoride. And these supplements are even more important now with two states, Utah and fluoride no longer allowing community water fluoridation.

(00:09:25):

Importantly, supplements also provide parents with individual choice about their children's fluoride exposures, through consultation and shared decision making with their healthcare providers. I also want to emphasize a few things from the editorial I was asked to write for the JAMA Pediatrics issue concerning Dr. Taylor and colleagues meta analysis we heard about earlier. I stated, and I still believe that due to the limitations of the available data and the author's choices about study inclusion and exclusion criteria, analysis and interpretation, their results and conclusions do not properly present our current knowledge about possible associations of fluoride with neuro-development and cognition. So substantial caution is needed in interpreting the possible fluoride linked to IQ.

(00:10:22):

Thus, there's no credible evidence of IQ or neurodevelopmental concerns with fluoride intakes at the levels used in community water fluoridation, or with supplements. Also, the benefits of tooth decay prevention outweigh the risk of mild fluorosis. And we had two recent publications that demonstrated clearly that fluorosis is less evident with time for age nine to 23.

(00:10:48):

Therefore, the bottom line is that since dietary supplements provide important caries preventative benefits for children not receiving fluoridated water. And there's no credible evidence of neurodevelopmental risks from fluoride intakes, from dietary fluoride supplements, the use of dietary fluoride supplements should be expanded, not reduced or banned. Thank you very much.

Susan C. Winckler (00:11:14):

Thank you. So in our queue, we will now next hear from Christopher Fox. Let me do our queue. We'll then hear from Johnny Johnson. Then turn to topic two where we will hear from Audrey Adams and Michael Connett. But now we turn to Christopher Fox. Please proceed.

Christopher Fox (00:11:32):

Thank you. Good afternoon. I'm speaking on behalf of the American Association for Dental, Oral and Craniofacial Research, whose mission is to drive dental, oral, and craniofacial research to advance health and well-being. We thank the FDA and the Reagan-Udall Foundation for convening this critical dialogue. Our position is clear when used under professional supervision, fluoride supplements are a safe, evidence-based, and essential public health tool for children in communities without access to optimally fluoridated water.

(00:12:02):

The United States Preventive Services task force, the American Academy of Pediatrics, and the American Dental Association all recommend fluoride supplementation beginning at six months for children at risk of caries in low-fluoride areas. The scientific evidence supporting this recommendation is robust. A Cochrane review found that daily fluoride supplements reduce cavities in permanent teeth by 24% compared to placebo or no treatment. This intervention becomes even more critical in light of public health data showing that more than half of US children aged six and eight have experienced tooth decay in their primary teeth. And we know the downstream impacts. Missed school days, pain, infections and costly treatment. Fluoride supplements interrupt and help prevent this cascade.

(00:12:49):

Fluoride supplementation is particularly important now as a growing number of municipalities are choosing to remove fluoride from community water systems. Opponents of community water fluoridation have argued in part that removal of fluoride from public water supplies would not be harmful as individuals would still have the choice of using prescription fluoride supplements. Now that choice is under threat. To remove or restrict access to these supplements would disproportionately harm low-income families and rural communities, those already burdened by high caries rates.

(00:13:21):

Concerns have been raised about neurodevelopmental outcomes. But the most credible peer-reviewed evidence shows no adverse effects at recommended fluoride levels. The NTP itself concluded that studies suggesting harm were inconsistent, often conducted in areas with fluoride levels, far exceeding US guidelines, and frequently failed to control for key confounders. Scientific rigor must guide our regulatory decisions. We urge the FDA to focus on high-quality, longitudinal studies that align with risk evaluation protocols used by the EPA and the National Academies of Sciences.

(00:13:55):

In closing, fluoride supplements are safe when prescribed appropriately and they remain a vital preventive tool. Stripping away this option will lead to increased dental caries in poor communities and undermine decades of progress in evidence-based dental care. We strongly urge the FDA to preserve access to pediatric fluoride supplements, and to continue to base its decisions on sound science, clinical best practices, and public health need. Thank you.

Susan C. Winckler (00:14:21):

Thank you. Our next speaker will be Johnny Johnson. And then in the queue we have Audrey Adams, Michael Connett, and Douglass Cragoe. Johnny Johnson, please proceed.

Johnny Johnson (00:14:33):

Thank you for having me. I'm Dr. Johnny Johnson. I'm a pediatric dentist of over 40 years, a clinician and the president of the American Fluoridation Society. Take a look. This is what happens when fluoridation is in place and fluoride supplements are used. When it's stopped and taken away, this increases exponentially. These are health issues that are directly related to an infected tooth. Let's forget about a hole in the tooth. We're talking about entire bodies spreading to brains, hearts to other areas of your body, your lungs. And eventually, yes, people die from dental infections. Let's just call it like it is, this is about the whole body. This is not about a hole in the tooth.

(00:15:23):

Dental decay is the most common chronic disease of adults and children worldwide. It is both an infectious and transmissible disease and it can be prevented. Fluoridation, fluoride supplements are only one tool in our toolkit. Yes, you have to eat a diet that's good. You have to get your teeth cleaned. You have to brush with a fluoridated toothpaste. But all things together, they work together. We can prevent almost 90% or 100% of cavities, folks.

(00:15:53):

Fluoride supplements are effective in reducing cavities. Definitely studies have shown it. The 2011 Cochrane review looked at it as was said before, a 24% reduction in permanent teeth. It was said earlier, primarily didn't show any. Well, that's correct. They saw it in permanent teeth. What's more important, huh? Rest of our lives. Aspirin is also an unapproved FDA drug. Absolutely. Both has issues? Do we have effects, health effects from fluoride supplements? Absolutely not. There are none documented. Aspirin? Anaphylaxis, rice syndrome. There have been several. Are we up here talking about aspirin today? No, we're not. And this is not based on a health issue.

(00:16:40):

You want to read about the communications on getting fluoride supplements withdrawn from the market, you can go on the Fluoride Action Network's website. Every piece that they wrote to the FDA is documented, why it was allowed to be used because it was already in existence before 1938 as another formulation. It absolutely is grandfathered in just as aspirin is.

(00:17:08):

Fluoride Action Network had some representatives here in Will heard from one after me, Michael Connett. His daddy started the Fluoride Action Network, Paul Connett in year 2000 a chemist. They're based in the US. Bill Osmunson is a board director or board member. Used to be the executive director. Michael Connett used to be the executive director after daddy stopped and they couldn't keep up with

us at the American Fluoridation Society giving evidence-based, scientific, credible references and debunking what they're saying.

(00:17:41):

They'll spill out a ton of information and cherry-pick it from data to show what they want it to say. And you've heard that today? Well folks, that's what we exist for. You want references? I'll supply them until the days, 24 hours a day, seven days a week until I die. American Fluoridation Society is the one group that goes and fights these battles on the ground and we don't make up things.

Topic 2: Safety Concerns

Susan C. Winckler (00:18:06):

Thank you. We'll now turn to the second topic, which addresses safety concerns. Our queue for public commenters is Audrey Adams, then Michael Connett, then Douglass Cragoe. I will turn the virtual stage over to Audrey Adams.

Audrey Adams (00:18:29):

Hi, my name's Audrey Adams, and thank you for allowing me to comment today. Children have no ability or rights to refuse ingestible fluoride products such as nursery water or fluoride pills. They rely on their parents to assure those products will cause them no harm. And their parents rely on regulatory agencies to assure that safety. Parents believe fluoride is safe because they've been told so their entire lives from dentists, doctors, and virtually all public health agencies.

(00:19:03):

I was one of those believing parents when my son was born 40 years ago. At age two in 1987, Kyle was diagnosed with a condition I had never heard of before, Autism. His symptoms were severe. He was wild, he was uncontrollable and unreachable. He screamed and cried, arching his back. Kyle had no words to tell me he was in pain, and professionals just said it was just autism. These so-called symptoms of autism continued throughout childhood with intermittent bursts of screaming, jumping, racing. But I had absolutely no idea that Kyle was severely chemically sensitive until he was 13. He suffered all those years and I didn't know it so I couldn't protect him.

(00:19:53):

I did not discover that he was hypersensitive specifically to fluoride until he was 14. He had suffered in agony most of his childhood before I learned the horrific effect that all forms of fluoride had on him. Including tap water, toothpaste, fluoride varnishes, and so much more. As I learned the nightmare of sources, I eliminated fluoride in chemical exposures, and finally Kyle got some relief.

(00:20:22):

Children with autism have a much higher rate of chemical sensitivities than typical kids, and they have the least ability to report their pain, verbally anyway. Instead, they communicate with behavior, but we are all slow to understand their meaning. Autism was one in 5,000 when Kyle was diagnosed, and now it's one in 31. If we fail to remove all pediatric fluoride products, we're condemning many thousands of children to a similar tragedy as Kyle's.

(00:20:57):

Studies have linked fluoride with symptoms of autism and ADHD. Symptoms that are clearly indicative of pain. Fluoride promoters insist that it's safe for children because they gain politically and economically. Those of us speaking against fluoride don't. The use of fluoride in any pediatric products is

unconscionable. Children have no voice, no vote, no ability to protect themselves. So it's up to you and me, all of us to protect them. Thank you.

Susan C. Winckler (00:21:34):

Thank you. Our next public commenter will be Michael Connett, followed by Douglass Cragoe, Beverly DeCer and Eve Kimball. I will turn the virtual stage now to Michael Connett.

Michael Connett (00:21:49):

Good afternoon. Thank you for allowing me the opportunity here to provide some comments. I was the lead attorney for the plaintiff's organizations in the case of Food and Water Watch versus EPA, which is the case that resulted in a federal court ruling last fall. Finding that fluoridation of water poses an unreasonable risk to human health. But more relevant to the proceedings today, I filed a citizen petition to the FDA back in 2016, calling on the FDA to ban fluoride supplements.

(00:22:25):

And I encourage the FDA to go back and look at that petition because I set forth in detail the history of these supplements. How they do not qualify as generally recognized as safe and effective, and contrary to what Dr. Johnson said a few minutes ago, fluoride supplements were not used prior to 1938. There was no fluoride supplement to reduce tooth decay prior to 1938.

(00:22:52):

But I want to go to something that Dr. Lewis said earlier, which is that we should put our biases aside. And I certainly agree with that. And I want to read from her, Dr. Lewis's paper from 2014 titled Fluoride and Dental Caries Prevention in Children, which was published in Pediatrics and Review. Dr. Lewis wrote, "The preponderance of strong research evidence supports the relative advantages of fluoride toothpaste over fluoride supplements." And this led Canada, England, Australia, New Zealand, and the European Union to recommend against regular use of fluoride supplements in favor of promoting fluoride toothpaste use in young children. The United States should do the same. FDA should ban these unapproved drugs from the market.

(00:23:48):

The case here is very simple. This is the lowest hanging fruit of all fluoride products on the market today. It's the easiest case to make. The risk-benefit case is clear. First, there's no dispute amongst people familiar with the scientific research that fluoride's predominant, if not exclusive benefit is topical, not systemic. You do not need to swallow fluoride. That was the whole premise of fluoride supplements was to provide a systemic form of fluoride. That is not the way that fluoride works. Point one.

(00:24:17):

Point two, ingestion of fluoride is where the risks come. So whether you're talking about neurodevelopmental effects, thyroid effects, whatever. It's this ingestion of fluoride where you're going to be subjected to that risk. So we want to minimize fluoride ingestion, not promote it.

(00:24:36):

Third, we know and it's well established that fluoride supplements do cause dental fluorosis. There's no dispute about that. And that is a clear visible effect of overexposure to fluoride. Contrary to what Dr. Lewis said, "Mild dental fluorosis is cosmetically objectionable for children who have the condition."

(00:25:00):

Now, this has all been obvious for a long time. I'm going to read a quote from Dr. Burt from the University of Michigan 1999 in a paper called The Case for Eliminating the use of Dietary Fluoride

Supplements for young children. It was published in the Journal of Public Health Dentistry. Actually, I'm not going to be able to read the quote. I'm running out of time, but I strongly recommend you read that paper from 1999, Dr. Brian Burt.

Susan C. Winckler (00:25:23):

Thank you. We'll now move to our next public comment, which will be from Douglass Cragoe. In the queue, we now have Beverly DeCer, Paula Rabin and Tamara Robison. Douglass Cragoe, please proceed.

Douglas Cragoe (00:25:40):

One impact of removing fluoride drugs will be children with higher IQ. For decades, fluoride drugs were widely promoted and prescribed for pregnant women. The belief was that this would benefit the teeth of the unborn baby. This practice is likely still happening to some degree, although it's now widely disapproved by the American Dental Association.

(00:26:07):

In 1966, the FDA said no claims about reduced tooth decay for unborn babies could be made for fluoride drugs given to pregnant women. In 1997, an RCT study showed this was not effective. So after that, finally the ADA said, "We do not approve of giving fluoride to pregnant women." But nobody apologized for getting this wrong. Nobody said, "We made a mistake." Now we have evidence this prenatal fluoride exposure can harm an unborn baby.

(00:26:39):

Another impact will be to reduce fluorosis. Fluoride drugs are known to increase fluorosis. For decades, fluoride drugs were recommended from birth for all infants. But in 1994, the drug schedule was changed. Today, no fluoride drugs are supposed to be prescribed for infants zero to six months of age. Today, the CDC says these toothless young infants get no benefit from any fluoride intake above the tiny adequate intake level of 0.01 milligrams per day. But they do get a fluorosis risk from additional fluoride. These young infants get the adequate fluoride intake from all types of infant formula and breast milk.

(00:27:18):

Once again, nobody apologized or admitted any mistake for the decades of getting it wrong and overdosing infants with fluoride for no benefit. Another impact will be no more negative reactions to fluoride drugs, as this story from the 1950s shows. Dr. Ruben Feldman of Passaic New Jersey had administered fluoride tablets to children and to pregnant women. And reported in 1956 that about 1% of his subjects could not tolerate the drug. The US public health service discontinued support for his research.

(00:27:53):

Today, leading experts in the field of dental research and health care interventions, including the prestigious Cochrane collaboration have concluded that fluoride supplements are neither necessary nor effective. Particularly in the current context of widespread exposure to fluoride toothpaste and topical fluorides. In short, fluoride supplements have become a useless relic of a discredited paradigm.

(00:28:16):

So the other thing is you don't really have to buy fluoride supplements. You can just have your child use a pea-sized amount of fluoride toothpaste. If you think they should ingest it, just have them swallow it, not spit it out or rinse it out. But now I've had fluoridation advocates tell me, "Well, that's not a precise amount. But the only trouble is there's technology right now exists that you can make a dispenser, which you put out a precise pea-sized amount of fluoride toothpaste." It's already in use. And why does

it have to be a precise dose if children are swallowing wide degrees of getting wide differences in fluoride intake from water and foods?

(00:28:54):

But for some reason, they say that these fluoride supplements have to have a precise dose. The best alternative to fluoride drugs for children would be vitamins and minerals known to help build bones and teeth. And there really isn't good evidence these drugs are effective. Thank you.

Susan C. Winckler (00:29:13):

Thank you. Our next public comment will be from Beverly DeCer. In our queue are Paula Rabin, Tamara Robison, and Jay Sanders. Beverly DeCer, please proceed. We cannot hear you.

Beverly DeCer (00:29:40):

Sorry.

Susan C. Winckler (00:29:41):

Yes, please proceed.

Beverly DeCer (00:29:43):

And today I've asked to speak about the issue of fluoride allergy and chemical sensitivity. This problem has not been studied at all by policymakers. My daughter had a severe chronic skin and nail issue for over a decade during her 20s and 30s. After spending thousands of dollars on failed treatment, trying diets and enduring visible disfiguring symptoms, she ultimately learned that she had a fluoride allergy. She was helped by a health writer, not a doctor. Subsequently, I tried to find information, data, studies and professional guidance on fluoride allergy and found none. Fluoride supplements should not be available at all to the public without data and studies on chemical sensitivity, and an educated awareness in the medical profession.

(00:30:46):

If a doctor prescribes fluorides, it's unlikely that they will recognize symptoms of an allergic reaction or chemical sensitivity due to no available data or education. Well, in my opinion, why should a child even be exposed... fluoride is not a naturally occurring component of the disabsorbed by tooth structure, teeth are weakened. And I referenced the Epic book, The Fluoride Deception by Christopher Bryson.

(00:31:21):

Bryson researched fluoridation for 10 years and uncovered a history of purchased science, buried science, corruption, and propaganda. Policymakers can begin to lower the public's exposure to fluoride, a chemical that is slightly less toxic than arsenic, by banning fluoride supplements. Thank you.

Susan C. Winckler (00:31:45):

Thank you. Our next public comment will be provided by Paula Rabin. Then we'll turn to Tamara Robison, Jay Sanders and Brett Kessler. Paula Rabin, please proceed.

Paula Rabin (00:32:03):

Thank you for giving me the opportunity to speak today. My name is Paula Rabin and I'm an optometrist who graduated from the Pennsylvania College of Optometry in 1994. I was diagnosed with hypothyroidism over 20 years ago. And in my search for potential causes and solutions to my own

hypothyroidism, I began to investigate fluoride. When I go to public med center, the NIH library, and I type fluoride into the search bar, there are thousands of research studies that come up. Some of them will indicate that they cannot find a correlation between fluoride and disease. But unfortunately, many, many of them come to the conclusion that increased fluoride levels increase hypothyroidism, cognitive decline, and some cancers.

(00:32:56):

I'd like to read the conclusion of just one of those studies, Public Med ID 31698198, in which the conclusion states, "Our study suggests low moderate fluoride exposure is associated with alterations in childhood thyroid function that may modify the association between fluoride and intelligence." I really encourage people to go to Public Med center and start reading. I've heard other dentists and PhDs here speaking and they say, "Oh, there's no science." Please read the scientific studies yourself. Please do this.

(00:33:33):

If I go to the Amazon book section and I type the word fluoride into the search bar. Over 200 books written by MDs and PhDs and dentists come up. Many of the summaries are warning people that fluoride is a neurotoxin and should not be increased in humans. It is just basic human physiology and chemistry that fluoride and iodine, which are both halogens and similar chemically compete for uptake in the human body. The more fluoride you have, the less iodine you will absorb. And without iodine, you cannot make your thyroid hormone. That's a definition of thyroid hormone. It either contains three or four atoms of iodine. If you're not absorbing your iodine, you're not making thyroid hormone.

(00:34:17):

Fluoride also does not magically leave the human body. There are many studies that indicate that at least 50%, 50% of all ingested fluoride never ever leaves the body. I really wonder for these people who are promoting fluoride, what they think happens to the fluoride in your body and how it leaves, because it doesn't. It accumulates in brain, bone, breast, and thyroid tissue. And the question should not be, does fluoride help cavities? The question should be, does fluoride harm humans? And the answer is yes.

(00:34:49):

Given that there are other modalities out there such as calcium hydroxyapatite, improved dental hygiene, improving diet, those should be tried first before giving out something that is harmful for humans. Thank you.

Susan C. Winckler (00:35:03):

Thank you. Our next public comment will be from Tamara Robison. Then we'll turn to Jay Sanders and Brett Kessler. I'll note we had one request for comment in topic three from Gerald Steele. Gerald, if you are in the virtual webinar, please raise your hand or contact the moderator if you would like to speak. But now let's turn to Tamara Robison for virtual comment. Please proceed.

Tamara Robison (00:35:33):

Hello?

Susan C. Winckler (00:35:34):

Yes, we can hear you.

Tamara Robison (00:35:36):

Okay, great. Good afternoon. My name is Dr. Tamara Robison. I'm a board-certified pediatric dentist and the East Coast representative for the Florida Academy of Pediatric Dentistry. I live and work in a community that has recently had the fluoride removed from the water. And I like to look at the fluoride that was in my water, like the chlorine that is in my water, which at safe levels prevents disease. And you need to account for the studies where fluoride was removed from the water, the caries rate increased and the fluoride was reintroduced to the water systems.

(00:36:12):

Concerns about potential links to fluoride and conditions like thyroid dysfunction, cancer and reduced IQ deserve to be taken seriously. And the majority of studies cited to support these claims are flawed, involving unregulated excessive exposure, fluoride beyond recommend levels. And lacking controls for confounding factors like arsenic and lead. These findings should not be misapplied to well-regulated public health use. The overwhelming scientific consensus affirms that fluoride at recommended levels is safe, effective, and essential for protecting children.

(00:36:49):

The use of fluoride predates the FDA approval process and explains its unapproved status. But fluoride is not unstudied, it is not unsafe. If a regulatory gap exists, this should be addressed through a formal approval process, not the elimination of a valuable public health tool. Every day my clinical autonomy allows me to make decisions based on a child's medical history, caries risk assessment, environmental exposures and social determinants of health. Stripping providers of the right to prescribe fluoride based on individual risk, undermines clinical autonomy, and jeopardizes care from vulnerable populations.

(00:37:29):

The FDA must stand with science and support pediatricians, dentists, and public health experts committed to evidence-based care, honoring the commitment to do no harm. Because of a fear-based misinformation on the use of topical fluoride has been undermined, and a growing number of well-intentioned health-conscious parents are now refusing fluoride varnish in the dental setting, and not using fluoride toothpaste at home. Turning instead to unproven alternatives, without fluoride's decades of safety and efficacy data. This fear-driven shift towards limiting fluoride to only topical use is misguided and unnecessarily puts children at risk for increased suffering.

(00:38:10):

Severe early childhood caries is increasing, and is one of the leading causes of chronic pain, school absences, missed work, lost productivity, and hospitalizations. We as providers are already faced with limited access to operating rooms, and these children in some cases are being asked to wait three to six months for essential procedures. These delays compound physical suffering, worsen disease progression and deepened health inequities. But the impact doesn't stop there, overburdened providers, rising healthcare costs, and a strained hospital system are all part of this compounding toll. Timely surgical care is essential to protect both individual health and the sustainability of our healthcare system.

(00:38:55):

The stakes are too high. I respectfully urge the FDA to postpone the October decision to allow for full transparent scientific review. Collaborate with clinical experts and public health agencies, and ensure continued access to fluoride for high-risk children.

Susan C. Winckler (00:39:12):

Thank you. Our next comment will come from Jay Sanders. Then we'll turn to Brett Kessler. And then I'll note again, if Gerald Steele is in the virtual audience, please get the attention of one of the producers. Let's turn now though for public comment from Jay Sanders.

Jay Sanders (00:39:34):

Hello, my name's Jay Sanders. Thanks for taking my comment today on fluoride supplements. In 2016, FDA issued a warning letter to Kirkman Laboratories in which the FDA called on Kirkman to immediately discontinue marketing sodium fluoride drops and tablets. And FDA issued this letter because sodium fluoride drops and tablets are, "unapproved new drugs," and thereby illegal to introduce into interstate commerce. Fluoride drops and tablets are drugs because per 21 USC, section 321 G1 of the US State Code, "They're intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in humans." In this case the prevention of tooth decay.

(00:40:16):

Further, as FDA explains in its warning letter, fluoride drops and tablets are, "New drugs," because they are not generally recognized as, "Safe and effective," for the purpose of preventing dental decay. FDA's conclusion that fluoride tablets are not generally recognized as safe and effective is abundantly supported by recent research, which shows that fluoride ingestion during early childhood causes dental fluorosis and potentially other serious harm. Including impaired brain development, thyroid disruption, and cancer, while providing little, if any role in cavity prevention.

(00:40:50):

As noted by review in the Journal of Public Health Dentistry, "Fluoride supplements when ingested for a preeruptive effect by infants and young children in the United States carry more risk than benefit." Other reviews have reached similar conclusions. Since FDA considers sodium fluoride drops and tablets to be, "New drugs," they can only be legally introduced into interstate commerce if FDA has approved a new drug application. The FDA's warning letter to Kirkland confirms however, that FDA has never approved any new drug application for fluoride drops or tablets.

(00:41:22):

Fluoride drops and tablets were introduced in the '50s and '60s, not the '30s, on the now universally discredited premise on the now universally discredited premise that fluoride's benefit to teeth comes from ingesting fluoride where the teeth are still developing. The Journal of the American Dental Association has explained that, "Fluoride incorporated during tooth development is insignificant to play a significant role in cavity prevention."

(00:41:48):

Both the CDC and the National Resource Council have confirmed this, declaring respectively that, "Fluoride's predominant effect is post-eruptive and topical," and that, "The major anti-caries benefit of fluoride is topical and not systemic." In other words, fluoride works when it's applied directly to the outside of the teeth, and not when swallowed.

(00:42:11):

This new understanding about fluoride's anti-caries mechanism eviscerates the basis for using fluoride drops and tablets. Because, "Tablets and drops for swallowing have little to no local effect." A non-FDA approved drug with poor efficacy, and with the potential to permanently damage the brain and disrupt the endocrine system should not be dispensed to children in the United States. As such, the FDA should take prompt action to remove all fluoride drops and tablets from the market. Thanks for your time and consideration.

Susan C. Winckler (00:42:40):

Thank you. And then our final speaker for topic two, safety concerns will be Brett Kessler. In the queue we have Gerald Steele for topic three, and then we'll turn to topic four where our queue includes Clifton Carey and William Maas. But now we turn to Brett Kessler. Please proceed.

Brett Kessler (00:43:01):

Thank you. Good afternoon everyone. My name is Dr. Brett Kessler. I'm the president of the American Dental Association, the world's oldest and largest dental society representing 159,000 dentists committed to helping patients safely achieve optimal oral and overall health. Today, I'd like to address the concerns some have raised about the safety and necessity of prescription-strength fluoride supplements.

(00:43:27):

Generally accepted evidence has not shown that these products are harmful when used as indicated. For patients who do not have regular access to fluoridated water, especially in rural areas, these products are a vital option to help them maintain good oral health. But they aren't appropriate for everybody, we know that. The age of the patient, the fluoride content in local drinking water and other factors will drive a dentist's decision about whether to recommend these fluoride supplements. The goal is always to achieve the optimal oral health benefit from all fluoride sources combined, no more and no less.

(00:44:06):

Those decisions are best made between the patient and their doctor. Over the last 80 years, there've been way too many charges about fluoride being more harmful than helpful than I can address here. But we do address them in our recently updated fluoridation facts compendium, where we provide simple, evidence-based answers to frequently asked questions about the safety and benefits of fluoride.

(00:44:29):

Today, I'd like to quickly address one claim that FDA flagged in its May 13th press release for this meeting, IQ scores. And it's indicative of essentially all of the claims that have been made against fluoride over the years. Anti-fluoridation advocates have been misrepresenting the previous mentioned NTP report as smoking gun proof that fluoride lowers IQ scores. And it wasn't hard for them to do because we live in an age of noise. Good science doesn't fare well in the cacophony of politically charged voices. Good science is not sensational. It's boring, it's nuanced, it's disciplined, and it's rarely a smoking gun for anything.

(00:45:10):

This NTP report has tarnished its reputation by ignoring confounders like the presence of arsenic and other chemical pollutants. By giving credence to invalid biomarkers. By abandoning the norms of peer review. And by giving license to other fatally flawed research methods. The agency's own website even states that the report does not prove cause and effect. And like many substances are healthy and beneficial when taking in proper doses. That point needs to be made over and over and over and over again.

(00:45:45):

For this proceeding, the message is simple. The body of generally accepted evidence does not support this hypothesis that fluoride exposure diminishes IQ scores. It does not impact the gut microbiome. In fact, it strengthens the oral microbiome. Or does it affect the thyroid function. Certainly not at the levels that we have here in the United States. Yet here we are. I'm hoping we can all take a breath, filter out all

the noise and not give into the anti-fluoride hysteria that we've witnessed since community water fluoridation began over eight decades ago.

(00:46:18):

Prescription strength fluoride supplements are safe, but they're not for everybody. Their use should remain a thoughtful decision made between the dentist, pediatrician, and the patient. It should not be based on noise, but on generally accepted evidence applied responsibly for the public good.

Topic 3: Appropriateness of Pediatric Use Considering Additional Sources of Exposure

Susan C. Winckler (00:46:36):

Thank you. That concludes comments rather on topic two, which was safety concerns. We'll turn now to topic three where we have one request for comment. Topic three is the appropriateness of pediatric use, considering additional sources of exposure. We will hear public comment from Gerald Steele. But allow me to tee up the queue for the next topic, which will be Clifton Carey, William Maas, Sandy Sutton, and JoAnn Gurenlian. So for topic three, Gerald Steel, please proceed.

Gerald Steel (00:47:10):

Thank you for allowing me to comment. I'm a professional engineer and a former attorney. I've studied ingested fluoride for more than 15 years. In this matter, I represent King County citizens against fluoridation. We recommend that the FDA take action to remove from the market unapproved prescription fluoride drops and tablets that are intended to prevent dental caries disease.

(00:47:38):

Today, it's common knowledge that ingested fluoride does not provide any significant benefit and certainly no significant benefit in reducing caries. Fluoridated toothpaste has been widely available since 1975, and is far more safe and effective than ingesting fluoride drops or tablets. Today, there is convincing evidence that fluoride is insignificant and ineffective in preventing or reducing tooth decay disease. If you look at my slide, it shows in red tooth decay decreasing for five year olds in New Zealand from 11 teeth affected down to two teeth affected in the time period from 1930 to 2019.

(00:48:31):

The important observation... It also shows in black when Fluoridated toothpaste was introduced, and in blue when Fluoridated water was introduced. The important observation is that the introduction of fluoridated water or fluoridated toothpaste did not change this rate of decreasing tooth decay. We must conclude that the introduction of fluoride was an insignificant factor in the rate of decrease of tooth decay over this time period. Improved diet and improved dental hygiene are likely the significant factors that explain this reduction of tooth decay over time.

(00:49:18):

WHO data shows developed countries have had similar reductions in child tooth decay over similar time periods, whether fluoridated by salt or water or not at all. I have not found any large pro-fluoridation studies that show a statistically significant benefit of ingesting fluoride. If there is no statistically significant benefit, then the FDA should remove from the market unapproved prescription fluoride drugs and tablets that make a caries reduction claim. Thank you.

Topic 4: Impact of Removal of Orally Ingestible Unapproved Prescription Drug Products /Potential Alternatives

Susan C. Winckler (00:50:05):

Thank you. That concludes comment on topic three. And we will move to public comment on topic four, the impact of removal of orally ingestible unapproved prescription drug products containing fluoride, potential alternatives. We will hear first from Clifton Carey. And then our queue includes William Maas, Sandy Sutton, and JoAnn Gurenlian. Let's turn the virtual stage to Clifton Carey, please proceed.

Clifton Carey (00:50:33):

Thank you for allowing me to speak at this meeting. I am Clifton Carey. I'm a scientist who studied fluoride for the last 45 years, and currently a professor at the University of Colorado, School of Dental Medicine. I do not speak for the university. And so I want just with that preamble, I want to state, just in case I've run out of time, that orally ingestible prescription fluoride products must remain available for professional prescription to safeguard children's dental health.

(00:51:08):

Why do I say that? Well, it turns out that if you look at the efficacy of ingested fluoride in very young children. You find that there is various reports up to 50% reduction in caries, and it's even greater in permanent teeth. We've heard the other numbers, but the bottom line is there is an improvement in the reduction of caries. Caries, children caries, 80% of the children who experience caries in the two to five years of age come from low income minority communities disproportionately. This is a problem because fluoride in available having to get prescriptions and everything else means that it's going to cost more money to these people who don't have that extra discretionary income.

(00:52:09):

Now, I will also point out that without having any sort of preventive medicine of fluoride, the caries risk doubles. And so what's going to happen is that if we take the available systemic fluoride out of the environment, then we're going to see a lot of early childhood caries. Childhood caries is a chronic disease that causes a lot of pain. It hinders learning, it's avoidable, and then there's finances associated with it.

(00:52:42):

And I might note that just as a conversation about IQ, it turns out that there is a relationship between the amount of caries you have and lowering the IQ. So it could well be that just the caries status, which is not reported in the Mexican or Canadian studies, is probably a very large and shouldn't be ignored, confounding variable for those outcomes.

(00:53:11):

Okay, so there's proven efficacy. Systemic fluoride is incorporated into the developing tooth before it erupts. This makes the enamel more resistant to caries attacks. And this is important feature, it says it's a different mechanism that provides fluoride early on for long-term protection. There is a bunch of myths that should be also debunked, and I think that we've talked about those a lot. The bottom line is, is that when you talk about the FDA method for unapproved drugs initiative, they have to have an alternative that's available. Otherwise, if you've got an efficacious drug and it has low risks, then there should be an alternative at least. There are none because there's no teeth to put a topical fluoride onto. And with that, thank you.

Susan (00:54:06):

Thank you. Our next public comment will be from William Maas. Then we will hear from Sandy Sutton, JoAnn Gurenlian, and Jennifer Holtzman. I'll turn the stage now to William Maas. Please proceed.

William Maas (00:54:19):

Thank you. For children who otherwise would've had the opportunity to take fluoride supplements, their removal will result in more decay in permanent molars, and in pits and fissures of other permanent teeth. I wish to address two criticisms of supplements. One that the research on effectiveness is outdated or doesn't reflect modern conditions. Second, that supplements can only work topically, because the concentration of fluoride incorporated into enamel is insufficient to protect against dental caries.

(00:54:48):

As noted by Dr. Levy earlier, in 2003, Singh and Spencer in Australia reported that fluoride ingestion during the tooth forming years provides unique protection from tooth decay. Even for children who use fluoride toothpaste and had access to preventive dental care right at school. Their study was able to distinguish pre-eruptive benefits from ingesting fluoride during the tooth forming years, from the topical benefits of fluoride provided later. They found that fluoridated water provides pre-eruptive benefits for children and adolescents above and beyond the post-eruptive topical benefits.

(00:55:28):

Moreover, those benefits were most obvious by preventing caries and pits and fissures of permanent molars, the most caries prone teeth. While fluoride supplements cannot replicate the topical benefits of water fluoridation, they can provide a controlled dosage to replicate the amount of daily fluoride intake for optimal tooth formation.

(00:55:52):

Now, about the claims that the concentration of fluoride enamel provided by ingestion of supplements is insufficient to protect against caries. That was the position of Professor John Featherstone, who 25 years ago provided comprehensive and elegant translations of findings from the laboratory to clinical practice. His explanation of the mechanisms of action of fluoride have guided our use of fluoride for control of caries ever since. Yet, his findings only apply to the smooth surfaces of teeth that are studied in laboratories. Featherstone contended that fluoride present in solution at low levels at the surface of enamel crystals promotes remineralization and creation of crystals that are more resistant to acid. For smooth surfaces, that fluoride in solution is readily available in the dental plaque from topical sources of fluoride.

(00:56:47):

The findings of Singh and Spencer, not from the laboratory, but from observation of actual health outcomes, are consistent with Featherstone's emphasis on the importance of fluoride in solution on the surfaces of the demineralized enamel. Fluoride in the saliva cannot reach the depths of pits and fissures. Instead, it is the fluoride that was previously incorporated in the tooth and released by demineralization, which is now most available in the deepest parts of pits and fissures to control caries.

(00:57:21):

An obvious potential alternative to protect pits and fissures is dental sealants. However, after more than 40 years of active promotion, the most recent national survey confirmed that only one in three youth have even one dental sealant among their eight permanent molars. Don't expect that to improve. The CDC division of oral health, the federal office that has worked most closely with state health programs to promote best practices for dental sealants was eliminated earlier this year. There is no reason for the FDA to deny supplements to families whose healthcare-

Susan (00:57:52):

Thank you. We will now move to comment from Sandy Sutton, which will be followed by JoAnn Gurenlian, Jennifer Holtzman and Jennifer Johnson. So let's turn the stage to Sandy Sutton. Please proceed.

Sandy Sutton (00:58:09):

Thank you. My name is Sandy Sutton. I'm a proud member of the American Waterworks Association, Michigan section, the Michigan Roll Water Association. And I'm the current president of the Michigan Dental Hygienist Association. So thank you for allowing us to come and speak on this important topic today.

(00:58:26):

The Michigan Dental Hygienist Association stands firm in our commitment to protecting the oral health of our residents of our state through prevention. We fully support retaining all forms of fluoride as prevention from oral and systemic disease. As our members see patients, both children and adults in the operatory, through research in state surveillance programs, and in state and mobile dental settings. We see firsthand what happens when there's little to no prevention methods available to our residents. We understand that not all Michiganders have access to dental care, to community water fluoridation, and to things as simple as a toothbrush and toothpaste. To take away a proven method of disease prevention like fluoride supplements is unthinkable.

(00:59:14):

We're asked why use a supplement when we can use toothpaste? Well, it's the same reason we don't send one firefighter to put out a fire, we send half a dozen. One is not enough. It takes many ways and methods to attack a problem. Fluoride supplements are widely proven to be safe overall health, and valuable tool in providing overall health. Actually, I missed my... Yeah, sorry.

(00:59:45):

The United States Preventive Task Service recommends that primary care clinicians prescribe oral fluoride supplementation starting at six months for children who are at risk for dental caries and for whose water supplies are deficient in fluoride. This recommendation is supported by strong clinical evidence. A 2011 Cochrane Review found that fluoride supplements taken daily reduced decayed, missing, and filled tooth surfaces in permanent teeth by 24% compared to a placebo or no treatment at all.

(01:00:20):

The safety profile of systemic fluoride supplementation when used appropriately is also well established. Adverse effects are rare and primarily limited to mild dental fluorosis when doses exceed recommended levels during early tooth development. Systemic reviews, including the one by the NTP program, found no association between fluoride exposure at recommended levels, which is below 1.5 parts per million, and adverse neurodevelopmental outcomes in children. Our water levels are 0.7, with a range of 0.6 to one part per million. Which when we look at it in a 55 gallon drum of water, it's five drops.

(01:01:07):

The American Academy of Pediatrics and the American Dental Association both emphasized that when used under professional supervision, fluoride supplementation is safe and effective. Fluoride supplements remain a critical preventive healthcare strategy for millions of Americans, especially in rural or low-income communities that don't have access to local and affordable dental care. In these

areas, ingestible fluoride plays a critical role in preventing dental caries. And families should continue to have the right to choose for their children to receive fluoride supplements. Dental caries-

Susan (01:01:44):

Thank you. We will now turn to our next public comment, which will be provided by JoAnn Gurenlian. Our queue is Jennifer Holtzman, Jennifer Johnson and Steven Slott. But I will turn the physical podium over to JoAnn Gurenlian. Please proceed.

JoAnn Gurenlian (01:02:02):

Thank you. My name is Dr. JoAnn Gurenlian. I am the director of Education, Research and Advocacy at the American Dental Hygienists Association. And on behalf of over 220,000 dental hygienists nationwide, we appreciate the opportunity to offer a person-centered, science-based perspective on the critical role of fluoride plays in pediatric dental care.

(01:02:24):

We recognize the FDA's responsibility to ensure the safety and efficacy of prescription drug products, especially those in pediatric care. ADHA is proud to specifically address the impact of the removal of orally ingestible, unapproved prescription drug products and potential alternatives. To clarify, according to the 2023 CDC data, fluoride reduces dental caries by approximately 25% in children. Caries disease, commonly known as cavities or tooth decay is an infection condition, and remains the most common chronic disease among US children. Disproportionately impacting those in underserved communities. For children without access to fluoridated border or regular dental care, orally, ingestible fluoride products are not just beneficial, they are essential.

(01:03:13):

Dental hygienists often serve as primary oral health providers in schools, head start programs, and public clinics. In these settings, the ability to prescribe or administer fluoride ensures timely targeted prevention. Intervening before decay progresses into pain, infection, or emergency care. While fluoride is also present in water and toothpaste, one in three Americans live in a non-fluoridated community. Many families face financial or geographic barriers that limit access to basic dental products or care. Prescription fluoride helps close that gap.

(01:03:47):

Removing orally ingestible fluoride products from the market would have serious public health consequences, especially for vulnerable children in dental care deserts. It would undo decades of progress, deepen health disparities and increase the prevalence of untreated caries. There is no equivalent substitute for fluoride, and furthermore, no professional dental organization endorses an alternative or recognizes any proposed replacements as clinically valid. Beyond worsening oral health outcomes, the financial impact of removal would be significant.

(01:04:20):

As caries goes untreated, it often requires more invasive and more expensive care. Eliminating these products would shift the system from prevention to crisis management, placing added strain on families and the public health infrastructure alike. We urge the FDA to consider the broader ramifications as these products play a critical role in preventing disease in children.

(01:04:42):

Continued access paired with appropriate oversight and research is the path forward, not removal. That's why ADHA strongly urges the FDA to preserve access to these proven evidence-based therapies.

We support ongoing research, public education, and clinical guidance, but restriction is not the solution. Responsible access grounded in science is. Thank you again for your leadership on this issue. ADHA stands ready to support the agency with any additional information or assistance you may need.

Susan (01:05:14):

Thank you. Our next comment will be from Jennifer Holtzman. Then we'll hear from Jennifer Johnson, Steven Slott and Tim Wright. So Jennifer Holtzman, please proceed.

Jennifer Holtzman (01:05:27):

Good afternoon. My name is Dr. Jennifer Holtzman and I'm speaking on behalf of the American Association of Public Health Dentistry. AAPHD was founded in 1937 and represents a specialty of dental public health, as well as professionals from many sectors who are concerned with improving the oral health of the public. When used as recommended ingestible prescription fluoride products are safe and clinically effective to prevent tooth decay. They're recommended for children living in communities with suboptimal levels of fluoride in their drinking water. Who have risk of higher risk of tooth decay throughout their lifespan as a result of lower fluoride exposure during childhood.

(01:06:05):

Children in these same communities frequently experience barriers to accessing care. Including a shortage of dental providers or trouble finding a dentist to accept their insurance. Making access to preventive dental care more difficult.

(01:06:20):

Although fluoride's mechanism of action to prevent tooth decay is primarily topical, there are benefits to systemic ingestion during tooth development as well. Ingestible fluoride products benefit children primarily incorporating fluoride into the structure of developing permanent teeth. But also topically, while tablets or lozenges are chewed or sucked. This dual action working both topically and systemically supports both baby and adult teeth at the same time. And will have a lasting impact on adult teeth throughout the lifespan.

(01:06:54):

It's true that today there are more sources of fluoride than there were when fluoride supplements began to be used decades ago. However, fluoride supplements are only indicated for children with insufficient fluoride exposure from other sources. The only known side effect of having chronically higher fluoride exposure in the US is mild dental fluorosis. Which means having teeth with white specks that are more resistant to tooth decay. Studies show that children, adults, and adolescents are more concerned with the appearance of decayed teeth than the appearance of dental fluorosis.

(01:07:25):

While there are alternative approaches to prevent tooth decay in high-risk children, including fluoride toothpaste and fluoride varnish, ingestible fluoride supplements fill a gap when these approaches are not feasible or not sufficient for optimal tooth prevention. There are currently no high-quality clinical studies that demonstrate an effective alternative to fluoride's ability to reduce tooth decay in children at high risk.

(01:07:48):

Consider this patient. A young child with special healthcare needs that lives in a rural area with suboptimal fluoride in her drinking water. This child is not able to cooperate with regular tooth brushing, and the nearest dentist who takes her insurance is two-hours drive. Her pediatrician determines that

prescription fluoride drops are an important part of the child's care, and the best approach to be able to prevent tooth decay for her lifetime.

(01:08:11):

Situations like this are not uncommon. In 2017, study in Oregon found that 200,000 children enrolled in Medicaid that year, 7% or 13,000 children received a fluoride prescription from a healthcare provider. And approximately three-quarters of those were from medical providers.

(01:08:29):

The AAAPHD urges the FDA to continue allowing ingestible fluoride products to be prescribed for children, by their healthcare professionals. Maintaining access to ingestible fluoride products ensures that all children, regardless of where they live or their ability to access dental care, have a fair chance at a healthy start. Thank you.

Susan (01:08:50):

Thank you. Our next comment will be from Jennifer Johnson. Then in the queue we have Steven Slott and Tim Wright. I'll turn the podium over to Jennifer Johnson. Please proceed.

Jennifer Johnson (01:09:03):

Hello, I'm Jennifer Johnson, a registered dental hygienist. Let me begin by explaining why I believe the term unapproved in the title is misleading. Unapproved implies that we have no scientific basis for allowing fluoride supplements to be dispensed for the prevention of childhood tooth decay. On the contrary, we have very strong basis for supplements to be used in this manner.

(01:09:26):

For more than 40 years, the US Preventive Services Task Force has been viewed as a pillar of integrity in offering guidance on public health practices. The task force is a scientifically independent panel of experts. After it reviewed the evidence on effectiveness of fluoride supplements, it issued a positive recommendation. If you examine its 20 previous reviews, it has rejected recommending a health practice nearly half the time.

(01:09:53):

In addition, a Cochrane Review reported that when no fluoride supplementation was compared to the use of supplements, it was associated with a 24% decrease of decay in permanent teeth. Which is statistically significant.

(01:10:07):

The FDA has raised the question as to whether there are potential alternatives for the use of fluoride supplements. The answer is no. There are no alternatives that have been scientifically and clinically proven to be effective in reducing decay. Topical fluoride does not provide positive pre-eruptive effects of systemic fluoride exposure. This assessment of topical fluoride is backed by peer-reviewed research from Alaska and Canada. Consider the studies in Calgary, Canada where tooth decay among children has increased significantly since Calgary ended fluoridation in 2011.

(01:10:41):

There is no reason to doubt that parents continue to encourage their children to use fluoridated toothpaste. It's likely that they monitor their kids brushing more closely, recognizing that they were no longer receiving sufficient fluoride from their drinking water. Nonetheless, children in Calgary experienced a big spike in decay.

(01:11:00):

Some opponents of fluoride claim that Europe has taken a non-fluoride approach and that we should follow its example. Unfortunately, opponents omit the facts about Europe and fluoride. To clarify, water fluoridation programs exist in England, Ireland, and Spain, reaching about 12 million people. And England has announced plans to expand water fluoridation. Secondly, a number of European nations add fluoride to salt and milk, as a way to prevent decay. Tens of millions of Europeans receive fluoride in this way.

(01:11:32):

Thirdly, several countries that do not fluoridate their water, their salt or their milk operate supervised tooth brushing programs with fluoride toothpaste and/or mouthwash. These programs are often complemented by free dental care provided multiple times a year. The child smile program in Scotland is one example.

(01:11:53):

To summarize, ceasing fluoride supplementation will raise costs of our overburdened healthcare system. Fluoride supplements are the only scientifically proven alternative to water fluoridation. They benefit infants and children up to the age of 16 while their permanent teeth are developing under the gums. It helps the permanent teeth develop stronger and more cavity resistant by becoming incorporated into their tooth structure. To remove this option will result in increased dental cavities, more oral pain, negative impacts on the entire body, a decrease in quality of life and even death. Thank you.

Susan C. Winckler (01:12:32):

Thank you. We'll next hear from Steven Slott and then Tim Wright will provide our final comment. So-

Foundation Team (01:12:42):

He's not here.

Susan C. Winckler (01:12:43):

Well, all right. Well, I wait 10 seconds for Steven Slott, but then we'll turn I'm told. So we need to move the slide forward. Correct?

Foundation Team (01:12:53):

Right.

Susan C. Winckler (01:12:53):

Thank you. Then we'll hear from Tim Wright. Please proceed.

Tim Wright (01:13:00):

Thank you for allowing me to make the following comments on behalf of over 11,000 members of the American Academy of Pediatric Dentistry. Fluorides are used today as a result of discovery that consuming naturally occurring fluorides helps prevent tooth decay without observed negative health outcomes. Children consuming suboptimal amounts of fluoride did not benefit from caries reduction. Respondents through recent survey by the American Academy of Pediatric Dentistry revealed that over half still prescribe supplements for at least some of their patients.

(01:13:30):

Clinical and animal studies have confirmed fluoride supplement consumption reduces dental caries in children. Fluoride supplement use in children even with special healthcare needs populations also show significant reductions. Exposure to fluoride supplements does not cause unhealthy changes to the oral or gut microbiome in children. Fluoride supplements do not kill oral or gut microorganisms. Sodium fluoride at the dosage use of supplements has positive outcomes on the microbiome diversity and composition.

(01:14:02):

Consuming fluoride supplements or optimally fluoridated water does not cause negative neuro, behavioral, or other health concerns in children. Fluoride consumption and the potential for immune damage involving bone marrow, thymus, spleen, immune cells, cytokines, these only occur at very high dosages that would be, in some cases, lethal to humans. The National Toxicology programs have been talked about a lot. And the evidence is clear from that study that there are not toxic effects neurobehavioral at the dosages that are currently used related to water fluoridation. Which would translate to supplement dosages.

(01:14:42):

Long-term IQ studies of fluoride supplement use in prior age of five in children that have been followed through to the age of 38 showed no deleterious effects on the neurobehavioral aspects. The convergence of evidence from human studies strongly supports there are not negative cognitive or neurobehavioral outcomes for children consuming fluoride supplements.

(01:15:06):

So the impacts of removing fluoride supplements from the market will be an increase in dental caries, and substantial morbidity associated with endemic disease. The use of fluoride supplements are increasingly important therapeutically as an option because of the reduction in community water fluoridation. The results of not having access to fluorides will be an increase in dental caries, days children miss from school, increased healthcare costs, increased emergency room visits, increased oral health disparities, and an overall decrease in the quality of life of our children.

(01:15:47):

I think the pictures on the slide illustrate the devastating effects of dental caries. Fluoride is the most effective therapeutic that we have and we do not have a substitute. Fluoride supplements are proven to be an effective and safe tool for controlling dental caries. Systemic fluoride consumption at the concentrations used in supplements are safe. Given the consequences of unchecked tooth decay for a child, and the discomfort and expense of treatment, the FDA is urged to recognize and recommend the continued availability of fluoride supplements. Children die as a result of untreated tooth decay.

Susan C. Winckler (01:16:33):

Thank you.

Tim Wright (01:16:33):

[inaudible 01:16:37].

Susan C. Winckler (01:16:39):

And yet time marches on, but thank you. So that does conclude our public comment section. We were pleased to offer comment slots to all who requested to speak at the meeting, and including folks who had, we set aside time for them for additional commenters who chose not to speak.

Adjourn

(01:17:01):

With that, we conclude today's meeting. I just have to extend a profound thanks to everyone who joined us to make a presentation, to serve as a reactor panelist. Or for the very brave step it takes to say, "I'd like to provide public comment on a topic." Each of you has added to our objective of aspiring to illustrate the many perspectives on the availability of unapproved prescription drug products containing fluoride that are used in the pediatric population.

(01:17:35):

We will be posting a recording and transcript for this meeting on our foundation website, which is reaganudall.org next week. With that, I say thank you. Be well, take care.