WASHINGTON STATE BOARD OF HEALTH

Notice of Public Meeting

Wednesday, November 13, 2024, 9:30 a.m. – 4:00 p.m.
Physical meeting location:
WA Department of Labor & Industries (Auditorium)
7273 Linderson Way SW
Tumwater, WA 98501-5414
Virtual meeting: ZOOM Webinar
(hyperlink provided below)
Language interpretation available

Final Agenda

Time	Agenda Item	Speaker
9:30 a.m.	Call to Order & Introductions	Patty Hayes, Board Chair
9:40 a.m.	1. Approval of Agenda – Possible Action	Patty Hayes, Board Chair
9:45 a.m.	2. Approval of October 8, 2024, Minutes – Possible Action	Patty Hayes, Board Chair
9:50 a.m.	3. Public Comment	Please note: Verbal public comment may be limited so that the Board can consider all agenda items. The Chair may limit each speaker's time based on the number people signed up to comment.
10:10 p.m.	4. Announcements and Board Business	Michelle Davis, Board Executive Director
10:25 a.m.	5. Local Health Jurisdiction Update – Thurston County Public Health & Social Services	Ashley Bell, Board Staff Jen Freiheit, Interim Director, Thurston County Public Health & Social Services
10:45 a.m.	6. 2025 Proposed Meeting Schedule – Possible Action	Michelle Davis, Board Executive Director
10:55 a.m.	Break	
11:10 a.m.	7. Panel – State Agency Response to Per- and Polyfluoroalkyl Substances (PFAS)	Kate Dean, Board Member Shay Bauman, Board Staff Barbara Morrissey, Department of Health Bonnie Brooks, Department of Ecology Claire Nitsche, Department of Health Holly Davies, Department of Health Marissa Smith, Department of Ecology

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Time	Agenda Item	Speaker
12:40 p.m.	Lunch	
1:30 p.m.	8. Petition for Rulemaking WAC 246-290-220, Drinking Water Materials and Additives – Possible Action	Kate Dean, Board Member Shay Bauman, Board Staff
2:00 p.m.	9. Newborn Screening Process and Criteria Review – Possible Action	Kelly Oshiro, Board Vice Chair Kelly Kramer, Board Staff Molly Dinardo, Board Staff
2:25 p.m.	10. Update – School Rule Review Project	Patty Hayes, Board Chair Andrew Kamali, Board Staff
2:45 p.m.	Break	
3:00 p.m.	11. Request for Delegated Rulemaking, WAC 246-282-005 Sanitary Control of Shellfish Minimum Performance Standards to Revise the Reference to the Recently Adopted Model Ordinance – Possible Action	Patty Hayes, Board Chair Shay Bauman, Board Staff Danielle Toepelt, Department of Health
3:20 p.m.	12. Recognizing Board Member Contributions – Possible Action	Patty Hayes, Board Chair Michelle Davis, Executive Director
3:35 p.m.	13. Board Member Comments and Updates	
4:00 p.m.	Adjournment	

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- **To access the meeting online and to register:**
  https://us02web.zoom.us/webinar/register/WN_92RitSU8SECs8P7H9mC4YA

- **You can also dial-in using your phone for listen-only mode:**
  Call in: +1 (253) 215-8782 (not toll-free)
  Webinar ID: 865 4118 5182
  Passcode: 682856

Important Meeting Information to Know:

- Times are estimates only. We reserve the right to alter the order of the agenda.
- Every effort will be made to provide Spanish interpretation, American Sign Language (ASL), and/or Communication Access Real-time Transcription (CART) services. Should you need confirmation of these services, please email wsboh@sboh.wa.gov in advance of the meeting date.
- If you would like meeting materials in an alternate format or a different language, or if you are a person living with a disability and need reasonable modification, please contact the State Board of Health at (360) 236-4110 or by email wsboh@sboh.wa.gov. Please make your request as soon as possible to help us meet your needs. Some requests may take longer than two weeks to fulfill. TTY users can dial 711.

Information About Giving Verbal Public Comment at Hybrid Meetings:

- Individuals may give verbal public comments at the meeting, in-person or virtually, during the public comment period.
- The amount of time allotted to each person will depend on the number of speakers present (typically 1 to 3 minutes per person). We will first call on those who have signed up in advance.
- Sign up **by 12:00 Noon the day before a meeting** to participate in the public comment period:
  - Email the Board or
  - Register through the **Zoom webinar link. The Zoom webinar link is in the meeting agenda located on the** Meeting Information webpage**.**
  - If you are **attending the meeting in person** and did not sign up in advance, you may write your name on the sign-in sheet to provide comments if time allows.

Information About Giving Written Public Comment:

- Please visit the Board's Public Comment webpage for details.

WASHINGTON STATE BOARD OF HEALTH

Draft Minutes of the State Board of Health
October 8, 2024

Hybrid Meeting
ASL (or CART) and Spanish interpretation available
Hilton Garden Inn Yakima
Cascade Ballroom
401 E. Yakima Avenue
Yakima, WA 98901
Virtual meeting: ZOOM Webinar

State Board of Health Members present:

Patty Hayes, RN, MSN, Chair
Kelly Oshiro, JD, Vice Chair
Stephen Kutz, BSN, MPH
Kate Dean, MPA
Socia Love-Thurman, MD
Dimyana Abdelmalek, MD, MPH
Tao Sheng Kwan-Gett, MD, MPH, Secretary's Designee
Michael Ellsworth, JD, MPA, Secretary's Designee

State Board of Health Members absent:

Umair A. Shah, MD, MPH
Melinda Flores, MHCM
Paj Nandi, MPH

State Board of Health staff present:

Michelle Davis, Executive Director
Melanie Hisaw, Executive Assistant
Michelle Larson, Communications Manager
Anna Burns, Communications Consultant
Heather Carawan, Communications Consultant
Molly Dinardo, Health Policy Advisor
Shay Bauman, Health Policy Advisor
Jo-Ann Huynh, Administrative Assistant
Lilia Lopez, Assistant Attorney General
Hannah Haag, Community Engagement Coordinator
Ashley Bell, Equity & Engagement Manager
Cait Lang-Perez, Health Policy Analyst
Lindsay Herendeen, Health Policy Analyst
Miranda Calmjoy, Health Policy Analyst
LinhPhung Huynh, Health Disparities Council Manager
Esmael López, Health Disparities Council Lead Community and Tribal Engagement Coordinator
Gavin Rienne, Health Disparities Council Social Epidemiologist
Andrew Kamali, School Rules Project Manager
Nina Helpling, School Rules Project Policy Advisor
Mary Baechler, School Rules Project Community Engagement Coordinator
Marcus Dehart, School Rules Project Communications Consultant
Kelly Kramer, Newborn Screening Project Policy Advisor

Guests and other participants:
Dave DeLong, Department of Health
Andre Fresco, Yakima Health District
John Thompson, Department of Health

Patty Hayes, Board Chair, called the public meeting to order at 9:30 a.m. and read from a prepared statement (on file).

1. **APPROVAL OF AGENDA**
   Motion: Approve October 8, 2024, agenda
   Motion/Second: Member Kutz/Vice Chair Oshiro. Approved unanimously

2. **ADOPTION OF AUGUST 7, 2024, MEETING MINUTES**
   Motion: Approve the August 7, 2024, minutes
   Motion/Second: Member Dean/Vice Chair Oshiro. Chair Hayes abstained. Approved unanimously

3. **PUBLIC COMMENT**
   Patty Hayes, Board Chair, opened the meeting for public comment and read from a prepared statement (on file).

   Gerald Braude, Jefferson County, highlighted concerns about misinformation and the ethical implications of COVID-19 mandates. G. Braude said the conversation often overlooks the human rights issues faced by those who refused vaccination, especially among marginalized communities. G. Braude contrasted state responses and approaches to mandates. G. Braude reflected on Natalie Chavez comments to Whatcom County Council, about those discriminated against for not taking COVID-19 shots. G. Braude said discrimination was not mentioned in a recent Department of Health (Department) report.

   Bill Osmunson, Retired Dentist, MPH, raised questions about the safety and efficacy of fluoridation in drinking water and shared concerns about the long-term implications of fluoride exposure, particularly its classification as a neurotoxin. B. Osmunson talked about regulatory practices, and the money and risks associated with fluoride, especially concerning cognitive development and IQ. B.Osmunson asked for a reassessment of current standards.

   Anne L. Bennett, Physician Recruiter & Medical Search Consultant, and Longview WA resident, thanked the Board for supporting water fluoridation in communities, saying Community Water Fluoridation is an achievement in oral health for all ages. A. Bennett said that every major health organization supports fluoridation as an essential tool to prevent tooth decay. A. Bennet commented the on benefit and the low cost to retain water fluoridation at safe levels. A. Bennet commented on misleading information being circulated by people outside their community, as access to pediatric dental care is being stretched thin. A. Bennett urged the Board to continue to support water fluoridation at safe, effective levels and to push back on misleading information.

Tao Kwan-Gett, Secretary's Designee, commented that the Department is convening scientists to review the National Toxicology Report as well as the Environmental Protection Agency case and will be presenting the findings to the Board. Chair Hayes thanked Member Kwan-Gett for.

4. **CHENEY WATER RECREATION VARIANCE REQUEST, CHAPTERS** 246-260 & 262 WAC

Patty Hayes, Board Chair, introduced this agenda item, reminding Board Members that the Cheney and Yakima variance requests were briefly discussed at the Board's August meeting. Chair Hayes also reminded the Board that the requests were for two separate locations, each with three similar requests.

Shay Bauman, Board staff, summarized the variance requests for the Cheney Aquatic Center and the Aquatic Center at Martin Luther King (MLK) Jr. Park in Yakima. Shay recommended that the Board consider each of the six variance requests individually, organized by facility, starting with Cheney, followed by Yakima. Shay noted that the Department of Health (Department) recommends granting some variance requests with conditions outlined in the meeting materials. Shay reminded Board Members about the Board's variance request authority (see presentation on file).

David DeLong, Department staff, stated that only the Board is able to grant variances for features not regulated under Chapter 246-262 Washington Administrative Code (WAC), if there is sufficient evidence that the recreational water contact facility will adequately protect public health, safety, and water quality. David mentioned that all water features in the variance relate to diving envelopes, which are required when entering the water from a diving board, platform, or attraction segment where users enter above the water level. David said the Board's actions during the meeting discussion may set important precedents, redefining how this code is applied in the future (see presentation on file).

David introduced the Ninja Cross water feature as the first variance request for discussion and consideration. David outlined the Water Recreation program's evaluation of the Ninja Cross feature and reiterated that a variance may not be required because this feature is designed to have the user enter at or below water level (see presentation on file).

Chair Hayes requested that Board Members pause for discussion.

Stephen Kutz, Board Member, inquired what would happen if a user didn't use the equipment as designed.

David responded that engineering controls and a long list of operational controls were submitted as part of the variance request. Misuse of equipment is also a concern of the manufacturer, so in their installation and user guide, they specified that there should be a lifeguard that oversees the operation of the equipment. David added that if the Board decides this request is a variance, it could place conditions on use. For example, violations of the engineering controls would mean a user could not use the equipment.

Member Kutz commented that the facility might require users to sign waivers that absolve the facility from liability and place responsibility on the user. Member Kutz expressed concern about how kids are protected and whether the facility or manufacturer has legal liability in cases of injury.

David said that legal liability is outside their area of expertise and that misuse is possible, but the idea behind the recommended condition is to teach people about safe use. David added that nothing is 100% protected; however, this kind of rule is as protective as other rules required for other aquatic features.

Kelly Oshiro, Vice Chair, expressed concern that the updated engineering report came in at the last minute (the day before the meeting) and asked David if they had an adequate opportunity to review the report in-depth for the meeting discussion.

David said that this is complex. Based on the Department's understanding of the petitioner, the argument that the difference in velocity from the two different ways of calculating entry into the water is not critical. Instead, the crucial question the Board should consider is whether this request even needs a variance request. David asked if their response helped answer Vice Chair Oshiro's question.

Vice Chair Oshiro said not particularly and cited page 244 of the Board packet which showed pictures of children on the Ninja Cross device. Vice Chair Oshiro inquired about the equipment point of entry and asked why the hanging bars are not considered a point of entry into the pool. Vice Chair Oshiro also asked whether, based on the photos in the report, the equipment would be monitored only to allow one user at a time, the equipment would only include hanging features (unlike the floating lily pads in the photo), and if the water in the photo is 3.5 feet deep.

David said the pictures in the report are from the manufacturer's sales materials and aren't the configurations proposed in the variance request. Only hanging features are requested; no floating pieces of equipment are needed, and the maximum height of the hanging feature will be based on the user's minimum size and arm length. David said that in a worst-case scenario, a user's toes would be in the water, and their arms would be fully extended. David then added that the Board could recommend that more of a user's body be in the water while using the equipment. Still, the Department thought it was a reasonable standard for ensuring entry into the water would be like someone stepping off the pool deck.

Dr. Tao Kwan-Gett, Secretary's Designee, shared Member Kutz's concerns and said that the safest approach is to judge a device, not necessarily based on how it's designed to be used, but rather how it's likely to be used or could be used. Member Kwan-Gett emphasized that if the equipment is unsupervised, it could look like a trapeze, and to truly guard the safety of people using this equipment, the Board must consider how it will be used both when it's supervised and unsupervised.

Shay commented that a helpful point of clarity is that lifeguards and facility oversight must mitigate the misuse of these devices. Shay added from the review of the equipment specifications, the intended use based on the shortest user is that their body will be partially in the water, and that misuse of any piece of equipment or pool, in

general, is always possible, even with supervision.

Kate Dean, Board Member, inquired if there's a mechanism other than a variance, which would require supervision for these individual amenities at an aquatic center.

David responded that the Department often looks at new or unique water features and equipment and issues approvals with conditions. For example, if a feature has inadequate safety rules, the Department can require additional requirements, such as additional lifeguard staff.

Member Dean said David's response satisfied their concern about this piece of equipment.

Dimyana Abdelmalek, Board Member, asked whether there are any other currently approved structures in Washington that present a similar risk.

David said the most comparable piece of equipment is a series of floating obstacles designed for walking across, but there haven't been any Ninja Cross features approved in Washington yet.

Member Kutz added that the Department has provided information about where these features have been installed in other states. Member Kutz then inquired if the Department had contacted those other states to see if there had been any problems or issues with the equipment.

David responded that they had not.

Chair Hayes then asked for a sense of the Board, and whether the Ninja Cross, based on the definition of a diving envelope in the rule, requires a variance.

Shay mentioned to the Board that one of the manufacturers was present and could add several points of clarification, if needed.

Brooke Hanley, NAC Architecture, shared that they helped to assemble the variance packet. Brooke responded to Member Kutz's question regarding whether other similar features have been approved in the state, with one example being at the Great Wolf Lodge. Brooke said the equipment David referred to was a lily pad walk, which is installed across the state in similar water depths to what the Ninja Cross equipment installation proposes.

Vice Chair Oshiro inquired if a variance request was needed for the lily pads.

David acknowledged it was a good question but mentioned they weren't sure, as they had not been asked to conduct a review for a lily pad.

Michelle Davis, Executive Director, commented that Great Wolf Lodge is on Tribal Land, and the Department does not have jurisdiction there unless there is an agreement with the Tribe.

Member Kutz commented that the report notes under the worst-case scenario, a user begins their drop 20 inches above the water's surface.

David said that isn't the conclusion that the Board should come to, and the reason for that is that when the Department first received this issue, their understanding was that users may be as far as 20 inches above water. However, this understanding changed as they learned more about the intended use from the manufacturer. Users' bodies would be partially in the water when using the device.

Member Dean said they were willing to support the Department's recommendation, given that the Board recognizes the importance of supervision of equipment and feels satisfied with the analysis and engineering report completed.

Member Dean then made a motion that the Board adopt the Department's recommendation determining the installation of a Ninja Cross does not require a variance.

Dimyana Abdelmalek, Board Member, seconded the motion with the condition of supervision, stating that will likely be what mitigates misuse and injuries.

Chair Hayes repeated the motion to Board Members to ensure it was captured accurately. Chair Hayes then inquired if the Board could vote that this request doesn't require a variance and apply a condition.

Lilia Lopez, Assistant Attorney General, said they didn't review all the rules to see existing conditions and requirements regarding lifeguards and supervision of equipment. Lilia added that if these requirements do not exist in the rules, then the Board cannot add something here unless it is because it imposes a variance.

Chair Hayes asked staff for the record if other parts of the rule require lifeguarding and supervision at pools where this type of equipment would be installed.

David responded that yes, these pools are required to have lifeguards and that the Department would also require that the device be used in compliance with the manufacturer's recommendations.

Chair Hayes sought clarification on whether a vote in favor of this request would mean that a variance is not required, and if the Department can still require adherence to the rule and the manufacturer's supervision requirement.

David said yes.

Chair Hayes repeated for the record that the Department would apply the manufacturer's recommendation, which would be the addition of direct supervision of the equipment. Chair Hayes said the Board could then move forward with consideration of the equipment not requiring a variance.

Member Kutz inquired whether pools are subject to annual inspections and

licensing by local health jurisdictions, depending on their size and complexity.

Member Kutz also asked if local health departments mandate specific lifeguard supervision requirements.

David said yes, but there is variability from county to county.

Member Abdelmalek asked for clarification on the number of lifeguards required and whether the discussion was about having a single lifeguard on duty or an additional lifeguard to supervise the equipment per the manufacturer's guidelines.

David confirmed that two lifeguards would be needed to meet the requirement.

Vice Chair Oshiro asked for additional clarification on the lifeguard requirements in the rule compared to the manufacturer's guidelines.

Shay clarified that part of the manufacturer's recommendations and the variance request is that the Ninja Cross will have a dedicated lifeguard to supervise swimmers at all times in addition to other lifeguard requirements.

Vice Chair Oshiro recommended following the Board's rule with respect to lifeguard requirements.

Chair Hayes clarified that the Board wants the Department to add the additional lifeguarding requirement through the manufacturer's recommendations.

Member Kutz stated that the question is whether this piece of equipment requires a variance or not, and that is what the Board is voting on here.

Chair Hayes said that is correct, but also with the caveat that Member Abdelmalek added. Chair Hayes then asked Member Dean and Member Abdelmalek to try and restate the motion for the record.

Member Dean said the original motion was that the Board adopt the Department's recommendation in determining that the installation of a Ninja Cross does not require a variance.

Member Abdelmalek added that the Department, through their normal evaluation process, will place a condition on the equipment to include a lifeguard in accordance with the existing WAC as well as the second caveat of a dedicated lifeguard to the equipment per the manufacturer's instructions.

Chair Hayes stated that the Board is linking the manufacturer's instructions which are pointing to an additional lifeguard. Chair Hayes then inquired if Board Members were clear on the motion.

Member Kutz added that the motion sounded good if the Board is clear that the facility must follow the manufacturer's guidelines on supervision.

Member Kwan-Gett pointed out that the manufacturer's recommendations for the Ninja Cross include guidance on signage as well, and inquired if this would be another requirement the facility would need to follow.

Chair Hayes noted that staff were nodding their heads in agreement.

Member Kutz re-emphasized that the facility must follow all manufacturer's recommendations in implementing these devices.

Motion: The Board adopts the Department's recommendation that the installation of a Ninja Cross, as specified, complies with the rules and does not require a variance and that installation and implementation of the Ninja Cross obstacle course is subject to all the conditions recommended in the manufacturer and user guidelines and by the Department of Health.

Motion/Second: Member Dean/Member Abdelmalek. Member Love absent during vote. Approved by majority

David introduced the Aqua Climb water feature as the next variance request for discussion and consideration. David shared that the Aqua Climb is a 5-Alt and 5-high climbing wall that, when used as expected, people enter the water from the wall feet first and is designed with the expectation that users might strike the bottom with their feet. David presented the Department's recommendation to the Board, that this proposed installation aligns with the intent of providing a diving envelope, as participants are unlikely to contact the pool bottom. David said the Department and Spokane Regional Health District recommend that the Board approve this variance request, with eight specified conditions (see presentation on file).

Chair Hayes thanked David for presenting the request and noted for the Board's awareness that they will need to vote on two separate motions for the Aqua Climb. Chair Hayes emphasized that this request pertains to Cheney, and motions for Cheney cannot be combined with those for Yakima. Chair Hayes then asked David if the variance request for the Aqua Climb was substantially different from this request.

David responded that these requests are different because of the installation, the pool water depth, and the proposed height of the wall.

Member Kutz inquired if the Cheney facility meets the minimum depth for diving requirements currently in the Board's rule, or if it requires a waiver.

David responded that this request requires a waiver because although the minimum depth is close to the required depth in the rule, it's not deep enough.

Member Kutz then asked about what the difference in depths were.

David said they would have to go back and look at the Pool and Hot Tub Alliance (PHTA) standards.

Member Dean commented on the high costs associated with building large permanent structures at aquatic facilities, noting that these add-on amenities are becoming increasingly common. Member Dean inquired about the current water recreation rulemaking and whether the Department is considering addressing this type of equipment through rules rather than individual variances.

David responded that this could be considered in the future for rule development, however, if the Department were to adopt the Model Aquatic Health Code outright, then they would follow the manufacturer's recommendations. David added that for this piece of equipment, the manufacturer has different depths for the different configurations of climbing walls.

Member Kutz suggested that a valuable addition, given the newness of this equipment and its potential for becoming more common, would be to require all injuries to be reported to local public health.

Chair Hayes said that could be a consideration for future discussion.

Member Kwan-Gett asked for additional information on envelope safety depths and whether the Board can trust or assess the accuracy of the manufacturer's estimates of the safety envelopes.

David noted that the Department can request engineering reports, like those for these variance requests. David cautioned that the results for both water penetration and velocity depend on the initial assumptions made in the process. In response to Member Kwan-Gett, David emphasized that the Department and the Board can trust the reports if they are knowledgeable about evaluating this equipment and asking the right questions.

Socia Love, Board Member, mentioned that they weren't prepared to vote on the Ninja Cross equipment during the earlier discussion but would be voting on this item. Member Love also expressed appreciation for the Board and Department making their own assessments of the equipment, in addition to the recommendations provided. Member Love raised concerns about multiple users using the equipment simultaneously and was surprised that the manufacturer's recommendations permit several people to use it at the same time.

Motion: The Board moves to grant a variance to WAC 246-262-060(5)(b)(vi), diving envelope requirements, to install a climbing wall as specified by the variance request at the Cheney Aquatic Center, subject to the conditions recommended by the Department of Health and Spokane Regional Health District.

Motion/Second: Member Dean/Member Kutz. Approved unanimously**.**

David noted that a colleague had shared the answer to Member Kutz's earlier question regarding minimum depth and PHTA standards. According to PHTA standards, the deeper part of the wall should be 10.8 feet, so it is nearly a foot deeper than what is shown for the Cheney installation.

David introduced the AquaZip'N Rope Swing as the final variance request for the Cheney facility. David shared that the AquaZip'N Rope Swing is a rope swing plus zip line, and when used as expected, participants enter the water in a body orientation with their heads up. David t presented the Department's recommendation to the Board, that this installation meets the intent of providing a diving envelope because participants are unlikely to contact the pool bottom. David said the Department and Spokane Regional Health District recommend that the Board approve this variance request with seven specified conditions (see presentation on file).

Member Kutz asked if there is a minimum age and height requirement for using this equipment.

David confirmed that there are both minimum and maximum height and weight requirements.

Shay added a point of clarification that users need to pass a swim test to use this equipment.

Member Dean made a motion for the Board to grant the variance.

Motion: The Board moves to grant a variance to WAC 246-262-060(5)(b)(vi), diving envelope requirements, to install an AquaZip'N Rope Swing as specified in the variance request at the Cheney Aquatic Center, subject to the conditions recommended by the Department of Health and Spokane Regional Health District.

Motion/Second: Member Dean/Member Abdelmalek. Approved unanimously.

The Board took a break at 11:33 a.m. and reconvened at 11:42 a.m.

YAKIMA WATER RECREATION VARIANCE REQUEST, CHAPTERS 246-260 & 262 WAC

Patty Hayes, Board Chair, asked Department staff to highlight the differences between these three equipment requests so the Board could focus on any items that hadn't already been discussed during the Cheney equipment requests.

David DeLong, Department staff, introduced the Aqua Climb water feature variance request for MLK Park in Yakima for discussion and consideration. David noted that this climbing wall would use a 3-high configuration, which differs from the Cheney request because it would be a shorter wall placed in less deep water. David then presented the Department's recommendation to the Board, stating that installation provides a similar level of risk to other typical pool uses because participants may contact the pool bottom at a very low velocity. David added that the Department recommends the Board approve the variance request with seven specified conditions (see presentation on file).

Stephen Kutz, Board Member, inquired if the risk is equivalent for this device, compared to the device for Cheney, even though the wall is shorter, and the water is shallower.

David responded that the manufacturer's calculations show that penetration to the safety envelope would result in a lower velocity, meaning a person is moving slower when they contact the floor from falling from the shorter height.

Member Kutz asked if this was the same manufacturer as the Ninja Cross.

David said this is a different manufacturer. David said it is likely that the calculations for the Aqua Climb here are underestimated, but the user should still be contacting the bottom of the pool at a velocity that is similar to stepping off a deck into 3 ft of water.

Vice Chair Oshiro and David discussed and clarified what a measurement on the slide meant (center of gravity of user).

Vice Chair Oshiro offered a motion.

Member Kutz discussed wanting to ensure that the local public health can put additional requirements on this, such as reporting of injuries.

David said injury reporting for serious injuries is already included in WAC. David appreciated the Board's questions about injury reporting because the Department would like to see a more effective method of reporting than what's currently in place.

Motion: The Board moves to grant a variance to WAC 246-262-060(5)(b)(vi), diving envelope requirements, to install a climbing wall as specified by the variance request at the Aquatic Center at MLK Jr. Park, subject to the conditions recommended by the Department of Health.

Motion/Second: Member Oshiro/Member Kutz. Approved unanimously.

David provided briefed the Board on the AquaZip'N Rope Swing.

Vice Chair Oshiro offered a motion.

Member Kutz hope to never see the manufacturer change their minimum levels. We need to be cautious about any future changes by the manufacturer.

Member Abdelmalek discussed looking forward to the new aquatic guidelines as well. Opportunity to ensure uniformity and consistency when we look at these sorts of facilities.

Motion: The Board moves to grant a variance to WAC 246-262-060(5)(b)(vi), diving envelope requirements, to install an AquaZip'N Rope Swing as specified in the variance request at the Aquatic Center at MLK Jr. Park, subject to the conditions recommended by the Department of Health.

Motion/Second: Member Oshiro/Member Dean. Approved unanimously

Vice Chair Oshiro offered a motion for the Yakima Ninja Cross obstacle.

Lilia Lopez, Assistant Attorney General, discussed wanting to clarify that the Board is not applying those conditions. It would be something coming from the Department.

Vice Chair Oshiro offered a revised motion.

Motion: The Board determines that the installation of a Ninja Cross obstacle course, as specified in the variance request, does not require a diving envelope and, therefore, does not require a variance for installation and directs the Department of Health to tell the petitioner that they must follow the manufacturer, installation, maintenance, and user guidelines and all Department of Health's conditions when proceeding with the installation.

Motion/Second: Vice Chair Oshiro/Member Kutz. Approved unanimously.

5. YAKIMA PUBLIC HEALTH

Andre Fresco, Executive Director, Yakima Health District, welcomed everyone to Yakima. Andre thanked the Board for its commitment to the investment in Foundational Public Health Services (FPHS) and said this funding has made it possible to create new systems for the future. Andre described Yakima as a vibrant region with unique challenges, noting its large geographical area and long history as the first health district in the nation. Andre emphasized the importance of cross-training staff to maximize service delivery, especially during the COVID crisis, and highlighted partnerships with state and federal agencies to ensure equitable, real-time services. Andre also discussed ongoing community issues, including groundwater contamination and forever-chemicals, and the need for local partnerships to address these challenges despite limited funding.

Dimyana Abdelmalek, Board Member, asked if the Board should keep certain things in mind about Yakima and its local health jurisdiction.

Andre spoke about Yakima being an agricultural community. When Andre and their wife moved there, they wanted to share with their children the hard work of what it takes to provide food for the community. Transparency is needed in serving this population. People are often focused on vaccines when they think about public health, but there are broader components like water quality and land use.

Andre spoke about the social determinants of health. We are serving people who have struggled and who face barriers to accessing healthcare. The issues facing rural Washington are different than in the cities.

Kate Dean, Board Member, asked what Andre has learned about serving a population of seasonal labor.

Andre said that in the 1970's they were able to attract people to the area who were invested in agriculture. In partnership with the Department of Health (Department), they

have been able to provide Care-A-Vans, serving people without traditional access to care. Andre discussed investment in language access and the importance of working with trusted community messengers on outreach.

Steve Kutz, Board Member, shared appreciation for Andre and said they have seen a lot of changes in bigger cities but the changes in Yakima have been unique. Member Kutz's mom graduated from Davis High School in 1942 and rode to school on a gravel road on her bicycle. One of the largest Tribes in the state is in this area. Member Kutz appreciates Andre's humility and work for the Tribe.

Andre said it's a privilege to extend services to all people in our state. Andre said that their job is to support the team and the department. They've been able to hire nontraditional candidates. They've retained quality people on behalf of this great mission.

Member Kutz mentioned the history of the longest running Washington Administrative Code change in Yakima County.

Dr. Tao Kwan-Gett, Secretary's Designee, thanked Andre for leadership in the state and the work with the local jurisdiction.

Andre loves that Washington has a decentralized public health system and a system of support for others who may never thank you or know what your work is. Being in Yakima County allows for the ability to provide care for people who may be in crisis.

Patty Hayes, Board Chair, highlighted the mutual support given and received with Andre over the years. Chair Hayes is on the FPHS steering committee's Equity Technical Workgroup with Andre and complimented his commitment and love for community.

The Board took a lunch break at 12:30 p.m. and reconvened at 1:10 p.m.

6. RULES BRIEFING – GROUP A PUBLIC WATER SUPPLIES, WAC 246-290-315(8) PFAS EMERGENCY RULEMAKING

Kate Dean, Board Member, reviewed the Board's adoption of emergency rules during its June 12, 2024, Board meeting. Those changes are effective for 120 days, which ends October 22, 2024. If the Board wants to retain those changes, we need to adopt those changes at this meeting for another 120 days.

Shay Bauman, Board staff, provided an update of the three-part rulemaking process with a presentation and corrected a typo to reflect the correct WAC number. Shay stated that the emergency amendments will end on October 22, 2024. There has been a positive impact, and these changes are important to protect people served by Group A public water systems. Over 40 people requested to join an interested parties list since we informed the public about the filing of the permanent rulemaking. Shay described working with the Department's Environmental Justice (EJ) team to conduct an EJ assessment. Shay explained that the abbreviated rulemaking is exploring ways to adopt the federal standards and effective dates into the rule (see presentation on file).

Shay asked for feedback from Board Members on areas of interest for the November Board meeting. Shay will facilitate a panel discussion featuring experts from across the Department of Health (Department) and the Department of Ecology.

Dimyana Abdelmalek, Board Member, thanked Shay for working on this topic. Member Abdelmalek is still learning about the impact of per- and polyfluoroalkyl (PFAS) exposure. Member Abdelmalek wonders as a local public health representative about the dashboard. It's important to understand at an agency level as well as in local communities.

Shay has the goal of having an education session where local representatives, including Tribal Members, present perspectives.

Kelly Oshiro, Board Vice Chair, would like to learn from the Department of Ecology as well as other partners and parts of the agency.

Stephen Kutz, Board Member, asked about the timeline.

Shay noted that the CR-101 for permanent rulemaking was recently filed. Shay described the narrow scope that may allow earlier completion than a typical 18-month to 2-year timeline. Shay noted the section by section review is taking some time.

Member Kutz asked about the connection to the federal levels and what would happen if we created higher standards.

Shay explained that the state action levels (SALs) are what are being considered. Whichever is stricter will apply.

Member Kutz expressed the importance of this rulemaking. Member Kutz said it should take precedence and be done right.

Patty Hayes, Board Chair, asked about any work being done in conjunction with research universities and healthcare systems. How is the system working together? Are providers discussing messages with families? Chair Hayes asked about childcare centers.

Member Dean acknowledged limitations on what we can say during legislative session but asked about what is being done to stem these harmful chemicals from entering our food streams.

Member Kutz thanked Member Dean for bringing the concern of Tribal Members.

Member Abdelmalek asked how we can carry back knowledge to our communities and plug into state efforts.

Shay invited more feedback by e-mail and presented more information about the emergency rulemaking and the amendments. Shay highlighted the changes adopted by the Board.

Member Kutz asked for clarification about the abbreviations of maximum contaminant level (MCL) and state action level (SAL).

Motion: The Board directs staff to file a CR-103E to initiate rulemaking for WAC 246-290-315, to continue to clearly maintain the SALs and associated requirements until the federal standards are effective.

Motion/Second: Member Kutz / Vice Chair Oshiro. Approved unanimously

Vice Chair Oshiro asked about the community members who attended the listening session.

Shay said the meeting was in Camas and that Michelle Larson, Board staff, and Shay attended alongside the Department.

7. INTRODUCTION – SENSE OF THE BOARD

Michelle Davis, Board Executive Director, shared the Board's policy 2001-01 about monitoring and communicating with the Legislature about legislation that pertains to the Board, and said the Board adopts a legislative statement each Biennium, which outlines those priorities that the Board would like staff to monitor and provide feedback to the legislature on.

Executive Director Davis provided the most recent statement by the Board on possible legislative issues and shared that the document needs to be updated for the 2025 legislative session. Executive Director Davis noted the document has grown significantly in recent years and presents a challenge for a small team to be able to provide thoughtful feedback, due to the breadth of the statement.

Executive Director Davis will work with the team to reduce the document so it's more meaningful and asked what the Board priority's issues are and what should remain. Executive Director Davis said the Board's top priority is funding foundational public health services that support the entire system and highlighted the Health Disparities Council request legislation. Executive Director Davis said the Board has partners who will make recommendations, and some of those recommendations may impact Board authority, for example, possible water request legislation by the. Department. The Board may also hear from other partners within the public health system about critical work that they're doing in the public health system. Executive Director Davis hopes to provide an outline of those ideas in November, and then ask for Board adoption of a new statement in January. Staff capacity remains a challenge and the process for following and analyzing bills may need review.

Kelly Oshiro, Board Vice Chair, noted that the legislative policy was last revised in 2012, and another option is to revisit the policy. Vice Chair Oshiro mentioned it may be helpful for the Board to consider prioritizing issues or bills coming in that may adversely impact the public health system. Vice Chair Oshiro stated that providing the Board rulemaking authority Washington Administrative Code for each priority area would be beneficial.

Stephen Kutz, Board Member, stated the Board cannot impact a lot of the previous priorities in Board actions. The Board needs to look at any of the priorities and ask if the Board has the authority to make new rulemaking or determine if it is ongoing rulemaking. If it's not, then maybe it isn't as high a priority, because the Department and local public health are doing the broader public health. Member Kutz shared that looking through a lens of what informs or impacts the work the Board does.

Dimyana Abdelmalek, Board Member, shared their support in the focus being where the Board has authority, or if it's within its role to move the needle. Member Abdelmalek shared the benefits of other partners coming and sharing their priorities, so the Board can maintain visibility and have their perspective informed on the entire public health system while maintaining a core focus on the pieces of work that are within the Board's scope.

Patty Hayes, Board Chair, commented that looking at what triggers a bill analysis may be a good approach and that they see things from the last year could be removed. The Board has a unique voice in some spaces, and if that voice is only used for things that affect rulemaking, or it appears that way, it may diminish the potential of the Board's forum. Chair Hayes said there are ways to prioritize things that could be done in a way that doesn't trigger a big bill analysis but would have a way to get a sense of the Board. In some cases, the Board's unique role as a public forum is different from other portions of the public health system, let alone government. Chair Hayes wants to improve the statement and avoid an overload of staff. Chair Hayes wants to ensure the Board doesn't lose growth, recognition of who this Board is, and the view the Board brings.

Member Kutz stated sometimes members of the public think the Board can address a whole number of things that the Board hears about in public meetings and comments. But it's nothing that the Board really can address. That doesn't mean that the Board doesn't listen to it and take it into account. Member Kutz asked if the Board has weighed in on an initial issue that we didn't impact rulemaking, but had concerns about. Member Kutz shared that it's an important component of being able to do it when it's helpful. Member Kutz stated hearing about legislative priorities and issues that everybody's bringing up and as members when we hear about it, feedback can be provided to Board staff.

Vice Chair Oshiro added Board staff might be able to review the policies again on actions, and bills of interest, and potentially make movement there and the policy, to refine that process.

Executive Director Davis shared that they will review the policy, process and statements with Board staff Executive Director Davis addressed Member Kutz's question and shared times when the Board doesn't necessarily have authority to address critical public health issues, but it has been a priority, such as access to tobacco and vapor products. The Board has monitored tobacco in the past and provided feedback on different legislative proposals because the Board has recognized the impact. Being able to express concern to the legislative committee is a good place for the Board to raise its voice.

Kate Dean, Board Member, shared about the local board of health training last week. New members want to take on everything, such as housing and tackling racism. They understand the desire and it felt a little crushing to think how the accounting department can take on that scope of work. Member Dean sees the value in being able to be a resource for legislators, weigh in on things, and caution about mission creep and pressure on staff. It was suggested to socialize the concept of the social determinants of health. It's important to think about the lens that the Board brings to things. Member Dean shared the lens of social determinants is where public health can kind of help move the needle. Things like housing and behavioral health are hard to tackle programmatically. That may be one place where the Board could capture some of the things that feel a little bit outside of the Board's purview, by talking in terms of the social determinants instead.

Chair Hayes requested all Board Members to continue to think and communicate with Executive Director Davis.

8. UPDATE – SCHOOL RULE REVIEW PROJECT

Patty Hayes, Board Chair, shared that this large project impacts every child and youth in the State and that the school environment is part of a social determinant of health. Chair Hayes stated that four technical advisory committee (TAC) meetings have been held. Last Friday, there was an issue where it was clear a subcommittee was needed. Local public health and the schools will work on bringing back a solution. This will add more workload. It is also clear that the School Rules Project will need more meetings. The timeline can't change but more steps are being added. There is a listening session at the Union Gap School in the Yakima region and there will be a table at the Washington State Public Health (WSPHA) Annual Conference.

Andrew Kamali, Board staff, provided a quick reminder on the proviso. The Legislature was looking for a way forward on developing new school environmental health and safety rules focusing on the minimum standards. The proviso directed the Board to develop a new proposed rule, conduct an environmental justice assessment, do a fiscal analysis, and make implementation recommendations for the rule. The team is currently developing the proposed rule, as well as completing an environmental justice assessment. The fiscal analysis process is about to start. So far, TAC meetings have covered the intro, the purpose, and the applicability sections of the new proposed rule. In the third TAC meeting, they covered some general definitions, severability, variances, appeals, and complaints. The complaint section has been removed due to TAC member feedback and recommendations. In the most recent meeting last Friday, site, assessment, plan, review, and inspections were addressed, which also led to the subcommittee and where discussion of the plan review process for schools will be addressed with information about bathrooms and showers. TAC members meet every two weeks for about six hours, not including preparation time. There will also be a series of listening sessions. The flyer for the first one is included in the meeting materials. The Healthy Environment for All team has provided capacity to offer community compensation as well as food for community members who attend. There are plans to have listening sessions throughout the state, including fully remote or online options. There will also be focus groups as the TAC team has gone through the rule and has language for those who may have more pointed information that they'd like to share

about specific parts of the rule. Andrew reiterated that the goal is minimum safety standards, health and safety standards that are implementable, and that allow enough flexibility for schools and local health jurisdictions to come together and work together and support each other.

Stephen Kutz, Board Member, shared their interest in hearing what the public identifies as issues. As public meetings are held there may start to become a sense of at least focus areas that the Board is being asked to address in the rules. Member Kutz shared they are interested in what a parent with kids or a grandparent has to say.

Chair Hayes stated there is a representative from the Parent Teacher Student Association on the TAC and that member is great about bringing up questions and things from their perspective. One of the challenges that the staff has brilliantly tried to maneuver is a lot of the things that parents might bring up of concern, such as bullying, opioid problems, and children's mental health. One of the things that is going to be an ongoing challenge is making sure, when engaging with the broader public, that they understand really what this is, and do not have any expectations that we're a venue to address these other things.

Chair Hayes informed the Board about their connection with the University of Washington School of Nursing Bothell program. They have a Bachelor of Science in nursing leadership policy course who are pivoting seven students to assist in this project to do additional research that the team identified. They may have some targeted discussions with school nurses. The staff wouldn't have the capacity to do so.

Andrew shared we want to make sure that we capture that community input and hear from parents, students, and teachers.

Dimyana Abdelmalek, Board Member, shared they are excited that we're in a place where we can tackle this work. Member Abdelmalek stated this was one of the things that they learned about early in joining the Board and as a health officer for a local health jurisdiction that does do school inspections, they know how important the support of this framework is.

9. UPDATE – NEWBORN SCREENING PROJECT

Kelly Oshiro, Board Vice Chair, introduced the item. Vice Chair Oshiro discussed the Board's authority to adopt rules for newborn screening and the process for considering conditions for inclusion. Vice Chair Oshiro provided background regarding the Board's previous work on this topic and previewed the upcoming work by the Newborn Screening Project.

Kelly Kramer, Board staff, delivered an update about the Newborn Screening Project's goals and timeline (see presentation on file).

Stephen Kutz, Board Member, asked where the request to consider the condition branched chain ketoacid dehydrogenase kinase (BCKDK) came from. Kelly said it came through the Legislature.

Patty Hayes, Board Chair, requested that future updates include context around funding. Chair Hayes said that there are funding issues around Medicaid, the Department of Health (Department), and legislation that affect the Board's work in this area. Kelly said that the first technical advisory committee (TAC) will address this topic.

Kate Dean, Board Member, asked whether the Board should expect specific recommendations to come out of the first TAC meeting. Kelly said they don't expect to report recommendations to the Board at their next meeting in November.

10. RULES UPDATE – SANITARY CONTROL OF SHELLFISH, CHAPTER 246-282 WAC

Patty Hayes, Board Chair, introduced the item and shared background on the Board staff's progress on this rule.

Shay Bauman, Board staff, shared updates to this rulemaking, including staff efforts to collaborate with industry (see presentation on file).

Stephen Kutz, Board Member, noted that not all Tribes in Washington State may be members of the Northwest Indian Fisheries Commission and requested staff check membership.

Kate Dean, Board Member, asked whether a government-to-government consultation with Tribes is needed for rulemaking. Shay said that Tribal outreach was a focus at the early stages of the rulemaking project. Chair Hayes and Member Kutz discussed how this rule interacts with Tribal shellfish regulations. Shay confirmed that Tribes are regulated by this rule.

The Board took a break at 2:30 p.m. and reconvened at 2:40 p.m.

11. BOARD ANNOUNCEMENTS AND OTHER BUSINESS

Michelle Davis, Board Executive Director, reviewed the items included in the meeting packet. This included the Health Promotion (HP) Committee meeting minutes, the final memorandum of Understanding with the Department of Health, and two petition responses related to Wilson's Disease and Holding Tanks for Sewage Systems.

Executive Director Davis discussed the new Policy Advisor position and that it will be open for applications until October 17. Executive Director Davis asked Board Members to share the open position among their networks.

Executive Director Davis provided updates on the Health Impact Review team and their recent work of completing a review of Senate Bill 5435 at the request of Senator Trudeau. Executive Director Davis provided additional updates on Board staff work including the HP Committee and Health Disparities Council (HDC) meetings. Executive Director Davis discussed their presentation with Chair Hayes at the Local Boards of Health meeting the previous week, and Shay and Andrew's presentation at the Environmental Health Directors meeting. Several staff attended the Centennial Accord meeting and the Affiliate Tribes of Northwest Indians meeting in the previous weeks.

Executive Director Davis mentioned that staff will attend the Washington State Public Health Association Conference in Yakima. Chair Hayes is participating in a panel related to Foundational Public Health Services and the HDC Council Manager will present on the HDC. The School Rule Project team will also hold a community listening session at Union Gap School.

Executive Director Davis concluded by discussing upcoming items. The Board has received a petition related to fluoride and will consider the petition at the November Board meeting. Executive Director Davis will share plans to move ahead with hiring a Deputy to help manage some of the Board's operations and capacity needs.

12. DEPARTMENT OF HEALTH UPDATE AND BE WELL WA

Dr. Tao Kwan-Gett, Secretary's Designee, shared an update from the Department of Health (Department) on the Be Well Washington initiative. Member Kwan-Gett also provided an update on communicable diseases and respiratory illness data (see presentation on file).

Stephen Kutz, Board Member, asked about the efficacy of antiviral medications.

Member Kwan-Gett said we don't yet know how effective that will be. Antiviral medications are expected to be of benefit, but we may not know specifics until we have more experience.

Member Kutz asked about the high-risk side effects of Paxlovid.

Member Kwan-Gett said there are metallic tastes, and that malaise can occur, but the benefits far outweigh the risks.

Dimyana Abdelmalek, Board Member, shared that cost is a factor for some in the community getting Paxlovid. There can also be interactions with other medications. Member Abdelmalek commented that Telehealth was beneficial for access to Paxlovid. Despite clear public health data, it can be difficult for providers to give access. Member Kwan-Gett acknowledged that there are equity concerns for obtaining antiviral medications.

Member Abdelmalek asked about Personal Protective Equipment (PPE)

Member Kwan-Gett said PPE can be requested through the Department of Health's Office of Resilience and Health Security. Member Kwan-Gett can follow up with a contact if needed.

13. BOARD MEMBER COMMENTS

Paty Hayes, Board Chair, requested the Board for comments.

Kate Dean, Board Member, commented that Michelle Davis, Board Executive Director, and Patty Hayes, Board Chair, did a good job at the meeting last week, and acknowledged the major breadth of work for health impact reviews (HIR) and how

quickly work was distributed. Member Dean also noted two presentations from that meeting from public health law centers and said these presentations brought in other perspectives. Member Dean expressed appreciation for Vicki Lowe, who works for Tribal public health in the State and appreciated the Boards involvement.

Chair Hayes thanked Board staff for keeping the meeting on track and their preparation.

Stephen Kutz, Board Member, thanked Board staff for getting everyone up to speed. Member Kutz commented that it may be beneficial to teach the team how an HIR is conducted.

Michelle Davis, Board Executive Director, reported that the HIR process is complicated, and the Board has talented analysts to conduct quick HIRs.

ADJOURNMENT

Patty Hayes, Board Chair, adjourned the meeting at 3:10 p.m.

WASHINGTON STATE BOARD OF HEALTH

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Patty Hayes, Chair

Board of Health: Public Comment and Supplement to our Petition to protect the Public from Harm:

Bill Osmunson DDS MPH November 7, 2024

Washington Action for Safe Water

Money Marketing supports fluoridation. Science disagrees. Fluoridation harms fetuses, infants,

Bobby NBC (1).mp4

children, youth and adults. Listen to RFK's 26 second interview.

C:\Users\14254\Downloads\Bobby NBC.mp4

Fluoridation hit the media with Trump saying he will ban fluoridation. Dictators do that. But dictators also force mass medication. The Board of Health should not be comatose on science until the President recommends stopping fluoridation.

The Board for 75 years has refused the science and laws on fluoridation's lack of benefit and harm and we have provided science for 18 years with 20 petitions to protect our most vulnerable for 14 years.

You do not have a single randomized controlled trial on the benefit of fluoridation.

You do not have a single safety study on fluoride's effect on the developing human brain, thyroid or any cell of the human body.

The National Toxicology Program did not report any safe dosage of fluoride.

The Court was clear, fluoridation is an unreasonable risk. And brain damage is only one risk.

The National Research Council 18 years ago listed about a dozen risks of concern and for 18 years the Board of Health has ignored all of them, failed to study the risks and harmed the developing brains, teeth, bones, thyroid glands, enzymatic system, kidneys, stomach, intestines, heart, and the mitochondria of every cell for most of one, actually three generations, without any warning or caution.

The Board relies on marketing and endorsements from those making the most money on products. Money can cause both conscious and subconscious bias and serious greed. In other words, money cherry picks the evidence, cherry picks reviewers of science, cherry picks authorities, and cherry picks conclusions. Money drives America and our Health Care.

I sold fluoride to patients and applied it to their teeth, thinking I was benefiting my patients. I treated and profited from split, cracked, fractured brittle teeth, not realizing too much fluoride had contributed to the harm. For dentists, fluoridation is a win, win for our bank accounts. And the Board trusts the Fluoridation profiteers for unbiased evidence? That's nonsense and is harming the public.

The Board's words matter, at least for those who trust the Board, such as city authorities.

My attempt in the past has been to find evidence which is concise and reasonably current. New Board members and growing evidence necessitates more inclusion of evidence from the NTP and Court.

The National Toxicology Program Report on Fluoride neurotoxicity.

In late 2015, I nominated fluoride for cancer, thyroid and developmental neurotoxicity for NTP to review. They accepted developmental neurotoxicity; however, both cancer and thyroid are almost as persuasive with scientific studies of harm and should be reviewed by NTP.

The following is a brief concise and accurate report of the NTP report.

I. A brief overview of the NTP report, the final report and some of the politics blocking the report until the court ordered the release. A very important read.

National Toxicology Program Finds No Safe Level of Fluoride in Drinking Water; Water Fluoridation Policy Threatened

March 21, 2023 | Cheikhani

After a 6-year long systematic review of fluoride's impact on the developing brain, a court order has led to the National Toxicology Program (NTP) making public their finalized report that was blocked by US Department of Health and Human Services (HHS) leadership and concealed from the public for the past 10 months. The NTP reported 52 of 55 studies found decreases in child IQ associated with increase in fluoride, a remarkable 95% consistency. The NTP's report says:

"Our meta-analysis confirms results of previous meta-analyses and extends them by including newer, more precise studies with individual-level exposure measures. The data support a consistent inverse association between fluoride exposure and children's IQ."

A meta-analysis is when information from all the relevant studies are combined to get a fuller and unbiased overall picture, rather than just looking at individual studies in isolation.

The NTP's meta-analysis also put the magnitude of harm into perspective:

"[R]esearch on other neurotoxicants has shown that subtle shifts in IQ at the population level can have a profound impact on the number of people who fall within the high and low ranges of the population's IQ distribution. For example, a 5-point decrease in a population's IQ would nearly double the number of people classified as intellectually disabled."

So, while an average drop of 5 IQ points in a population might sound small it is huge from a public health perspective. Furthermore, the NTP acknowledged there was the potential for some people to be more susceptible than average, so those people could lose much more than 5 IQ points. Those susceptible individuals could lose 10, 15, 20 or more IQ points which would likely cause profound lifetime negative consequences.

The five independent peer-reviewers of the NTP report all voted to accept the review's main conclusion and lauded the report. Their comments include: "what you have done is state-of-the-art"; "the analysis itself is excellent, and you thoroughly addressed comments"; "Well done!"; "Findings… were interpreted objectively".

The newly released documents include comments from the NTP's own experts confirming that the report's conclusion that fluoride can lower IQ does apply to communities with water fluoridation

programs. NTP report says the evidence is not just in those who drink water with higher fluoride concentrations exceeding the World Health Organization (WHO) recommended maximum level of 1.5 mg/L. Furthermore, the WHO guideline was set in 1984 to protect against more severe forms of dental fluorosis and neurotoxicity was never considered. Few neurotoxicity studies even existed in 1984.

In numerous responses to comments by reviewers of the report, the NTP made clear that they had found evidence that exposures of at least some people in areas with fluoridated water at 0.7 mg/L were associated with lower child IQ.

For example, when an unnamed government fluoridation proponent claimed:

"The data do not support the assertion of an effect below 1.5 mg/L…all conclusory statements in this document should be explicit that any findings from the included studies only apply to water fluoride concentrations above 1.5 mg/L."

The NTP responded:

"**We do not agree with this comment**…our assessment considers fluoride exposures from all sources, not just water…because fluoride is also found in certain foods, dental products, some pharmaceuticals, and other sources… Even in the optimally fluoridated cities…individual exposure levels…suggest widely varying total exposures from water combined with fluoride from other sources."

Additional NTP responses about the review's relevance to water fluoridation programs:

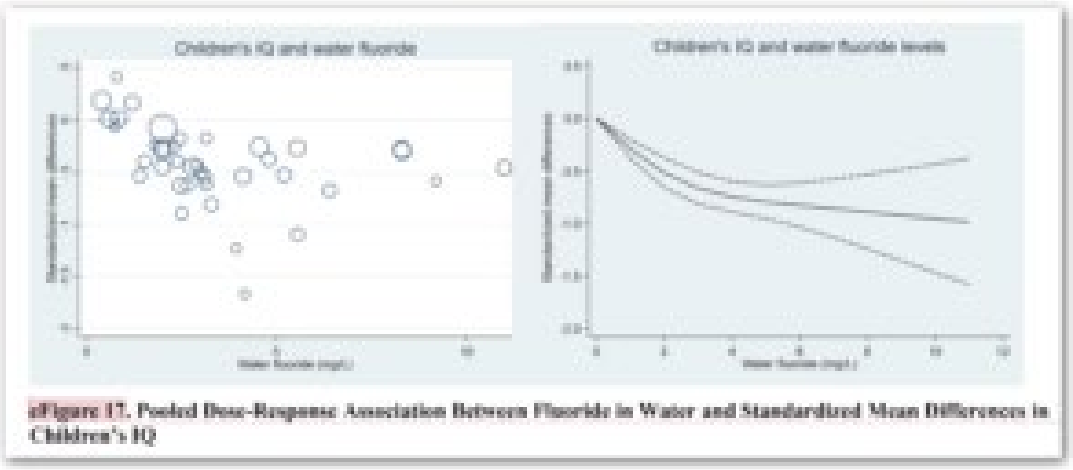
"We have no basis on which to state that our findings are not relevant to some children or pregnant people in the United States."

"Several of the highest quality studies showing lower IQs in children were done in optimally fluoridated (0.7 mg/L) areas…many urinary fluoride measurements exceed those that would be expected from consuming water that contains fluoride at 1.5 mg/L."

The NTP also responded to commenters asking whether their meta-analysis had identified any safe exposure threshold, below which there would be no loss of IQ.

The NTP responded that they found "no obvious threshold" for either total fluoride exposure or water fluoride exposure, referring to a graph in the meta-analysis (NTP's eFigure 17 reproduced below) showing that as water fluoride concentration increased from 0.0 to 1.5 mg/L there was a steep drop in IQ of about 7 points (expressed as "standardized mean difference" units in the graphs). An external peer-reviewer commented on the size of the IQ loss:

"Wow … that is substantial … That's a big deal." {p 1060}



eFigure 17. Pooled Dose-Response Association Between Fluoride in Water and Standardized Mean Differences in Children's IQ

The graph uses standardized mean difference (SMD) units where each -1.0 SMD is equivalent to about -15 IQ points.

In the left-hand graph each circle represents a study. Several have mean water fluoride below 1.5 mg/L. The right-hand graph shows the relationship between fluoride concentration and loss of IQ when all the studies are pooled. This analysis, based on many studies, is strong evidence that fluoride is associated with a substantial loss of IQ at levels of exposure common in people drinking artificially fluoridated water, and there is no observable threshold indicating a "safe" dose.

The NTP's experts further stated that the science showing neurotoxic harm "is a large, consistent and growing database."

Overall, the report provides strong evidence that fluoride is associated with a substantial loss of IQ at levels of exposure common in people drinking fluoridated water.

STAY TUNED! We will be sending out additional bulletins on the NTP report in the coming days.

PLEASE SHARE THIS BULLETIN WITH YOUR LOCAL MEDIA OUTLETS.

See our other press releases on the NTP report below:

March 15: Suppressed Government Report Finding Fluoride Can Reduce Children's IQ Made Public Under EPA Lawsuit

II. The EPA Lawsuit under the Toxic Substance Control Act (This data is provided by FAN and appropriately referenced.

The report of the court proceedings below is followed by earlier evidence. If you must cut to the chase, be sure to read The Judgment

EPA Lawsuit

Under the Toxic Substances Control Act (TSCA) of 1976, a group of non-profits and individuals petitioned the U.S. Environmental Protection Agency (EPA) in 2016 to end the addition of fluoridation chemicals into U.S. drinking water due to fluoride's neurotoxicity. The EPA rejected the petition. In response the groups sued the EPA in Federal Court in 2017. Evidence on fluoride's neurotoxicity was heard by the Court in two phases: a 7-day trial in June 2020, and a 14-day trial in February 2024. As of May 2024, a judgment from the court has yet to be rendered.

Official Court link: Food and Water Watch et al. v. United States Environmental Protection Agency et al.

The Petition

In 2017, Dr. Paul Connett PhD and Dr. Bill Hirzy PhD, on behalf of the Fluoride Action Network (FAN), Food and Water Watch (FWW), Moms Against Fluoridation (MAF), as well as several individuals, served the EPA with a petition calling on the agency to ban the addition of fluoridation chemicals to public water supplies due to the risks these chemicals pose to the brain.

The Petition was submitted under Section 21 of the Toxic Substances Control Act (TSCA) because it authorizes EPA to prohibit the "particular use" of a chemical that presents an unreasonable risk to the general public or susceptible subpopulations. TSCA also gives EPA the authority to prohibit drinking water additives.

The Initial Hearings

EPA denied the petition on February 27, 2017, claiming that: "The petition has not set forth a scientifically defensible basis to conclude that any persons have suffered neurotoxic harm as a result of exposure to fluoride in the U.S. through the purposeful addition of fluoridation chemicals to drinking water or otherwise from fluoride exposure in the U.S." FAN and other plaintiffs then sued the EPA and won a series of favorable court hearings in 2017 and 2018 on plaintiff's standing and trial discovery, while defeating several motions by EPA attempting to dismiss the case.

In late 2019 both FAN and EPA submitted motions for summary judgment in the case in the hopes that the judge would rule on the evidence submitted to the court without the need for a lengthy trial. On December 30, 2019 the Court released its order denying both plaintiffs' and defendant's motions for summary judgment. This means that our case will go forward. Trial is scheduled for two weeks beginning April 20, 2020 and will run for two weeks.

Attorney Michael Connett: "this is the first time in its 43-year history that citizens have been able to successfully bring a suit to court under provisions in TSCA"

Pre-Trial

On March 17, 2020 the Court postponed the April 2020 fluoride lawsuit trial dates due to the coronavirus outbreak. The trial will now be held June 8-19 by Zoom webinar (instead of in person at the courtroom).

In a May 2020 pre-trial hearing, the Court cleared the way for three international experts in neurotoxicity (Dr. Howard Hu, Dr. Philippe Grandjean, and Dr. Bruce Lanphear) to testify on the risks of fluoride in public water supplies on behalf of the plaintiffs. The court also ruled that the purported benefits of community water fluoridation cannot be part of the trial, restricting testimony to the toxic risks under the Toxic Substances Control Act (TSCA) Read the May 2020 trial declarations from our 4 witnesses:

Philippe Grandjean, MD, PhD
Howard Hu, MD, MPH, ScD
Bruce Lanphear, MD, MPH
Kathleen Thiessen, PhD

The First Fluoride Trial (June 8 - 19, 2020)

The first trial in the TSCA fluoride lawsuit took place in June 2020 over Zoom webinar. The trial lasted two weeks and featured testimony from FAN's expert witnesses (Drs Hu, Lanphear, Grandjean, and Thiessen) who are subject matter experts on developmental neurotoxicity and risk assessment, pitted against EPA's witnesses.

Shockingly, EPA did not rely on its own agency experts to defend its position that fluoride is not neurotoxic to humans. Instead it hired an outside consulting company, Exponent, a firm deployed by corporations to deny and downplay the health impacts of chemicals in litigation. Exponent experts attempted to cast doubt on fluoride's neurotoxic effects even as the EPA's own scientists, under subpoena by the plaintiffs, said new research does indeed warrant "an update to the fluoride assessment".

"I think it's a reason for doing an update to the fluoride assessment" - Dr. Joyce Donohue, EPA Office of Water, on recent NIH-funded studies showing fluoride harms the developing brain.

FAN attorney, Michael Connett, gave the opening statement in the trial - a summary of the case that fluoride presents a neurotoxic hazard (a threat to the brain); that this hazard is a risk at doses experienced in fluoridated communities (.7ppm); and that this

risk is an “unreasonable risk” as defined by TSCA. The EPA is represented by lawyers from the Department of Justice (DOJ). The DOJ argued in their opening statement that establishing fluoride as a neurotoxic hazard requires a systematic review and without that, FAN’s case falls.

The first fact witness called by the plaintiffs (FAN) was Dr. Joyce Donohue who has worked in the EPA’s Office of Water since the 1996 and has been their spokesperson on fluoride. Her testimony in the trial was based on a video recording of her deposition in 2019. From this deposition our attorney was able to yield two key concessions:

a) The EPA as of 2019 had no studies to provide a pregnant woman to show her fetus was safe from neurotoxicity. In fact the EPA only had studies showing harm to the fetus.

b) Dr. Donohue recommends EPA and other regulatory bodies do risk assessments of fluoride with neurotoxicity as an end point. All EPA risk assessments on fluoride to date have been based on potential damage to teeth and bones.

FAN’s first expert witness called was Dr. Howard Hu, MD, MPH, ScD, the lead author on a series of key NIH-funded research papers on fluoride and developmental neurotoxicity. Hu’s credentials are very impressive. Dr. Hu came across as knowledgeable and credible and was able to summarize the importance of his research, stressing the importance of a loss of 3 or 4 IQ points at the population level while drawing a striking parallel to lead’s neurotoxicity.
FAN’s second expert witness, Danish scientist and neurotoxicity expert Philippe Grandjean, MD, DMSc, took the stand on day two. Grandjean is the author of the book Only One Chance, in which he warns of the dangers of exposing children to neurotoxicants during early development, especially during the fetal stage. According to many who watched his testimony, Dr. Grandjean left no doubt that fluoridation poses a threat to the brains of children and easily debunked the EPA’s paid experts’ arguments.

FAN asked Dr. Grandjean to do a review of the literature since his famous 2012 meta-analysis to include the most recent US government-funded studies. Grandjean did this review but he went one step further and quantified the risk of IQ loss from fluoride to children based upon the Bashash 2017 and the Green 2019 (Canadian study) mother-offspring studies. For this analysis Grandjean did what is called a Benchmark Dose study (using methods that he and his colleagues have pioneered, and used by the EPA). He concluded that a safe reference dose (RfD) be no higher than 0.15 mg per day to protect against a loss of one IQ point. This is well below fluoride exposure levels experienced by pregnant women (and passed to the fetus) in the Bashash and Green studies.
FAN’s next expert witness was renowned clinical scientist and professor, Dr. Bruce Lanphear… who’s work on lead….. Dr. Lanphear explained that there was no safe level of fluoride exposure with regard to neurotoxicity, and that the effects seen in recent studies are “equal to what we saw with lead in children.”

Next the court watched the deposition video of CDC Oral Health Division Director, Casey Hannan, who confirmed his agency agreed with the National Research Council's 2006 findings that fluorides "interfere with the function of the brain and body by direct and indirect means," among many other stunning admissions, yet did nothing to act upon or study these findings.
Next up in the trial was fact witness Dr. Kristina Thayer, Director of the US EPA's Chemical and Pollutant Assessment Division. Dr. Thayer confirmed the vulnerability of the developing brain to environmental toxins as well as fluoride's known neurotoxicity "at some level."

The next expert witness was veteran risk assessment scientist Kathleen Thiessen, PhD, who was a member of the 2006 NRC committee that reviewed fluoride, and authored around a third of the report. Dr. Thiessen confirmed that the EPA was ignoring the neurotoxic risk from fluoridation because doing so would require them to effectively ban the practice. She also compared the amount of evidence of neurotoxicity from fluoride to other toxins the EPA currently did regulate as neurotoxic, saying "the amount of evidence for fluoride is considerably larger."
The EPA then called their first expert witness, Dr. Joyce Tsuji, PhD from corporate consulting firm Exponent. This is the same scientists-for-hire firm the tobacco industry used to deny lung cancer risk. Dr. Tsuji's answers repeatedly contradicted the testimony from her pre-trial deposition. Eventually FAN attorney Michael Connett was able to get Dr. Tsuji to admit on the stand that "there is enough literature for us to be concerned" about fluoride's neurotoxicity.

The EPA then called their second expert witness, Dr. Ellen Chang (also from Exponent), to discuss the human fluoride/IQ studies. She spent much of her time attacking the quality of the studies linking fluoride to lowered IQ. FAN attorney Michael Connett was successful in exposing Dr. Chang's blatant bias and, in a defining moment at trial, was able to get her to admit that the fluoride/IQ studies from Till (2020), Green (2019), and Bashash (2017) were the most rigorous neurotoxicity studies to date.

Next up was Dr Tala Henry, Director of the EPA's Risk Assessment Division, who has 25 years of risk assessment experience at the agency. Her testimony focused on the many hurdles presented to those who attempt a risk assessment and risk evaluation of a chemical. FAN's attorney Michael Connett dealt a destructive blow to Dr. Henry during cross-examination came when he asked: "you held the plaintiffs to a burden of proof that EPA has not held a single chemical under section 6 [of the Toxic Substances Control Act] before, correct?". Henry replied, "by the words on the page, I guess that's true". The EPA closed its case with a short video segment of Dr. Joyce Donohue, the predominant fluoride expert in the EPA's Office of Water. If anything, this video strengthened our case and did not weaken it.

The last day of trial featured a dramatic moment, as the federal judge surprised everyone by recognizing the key plank in our case, undermining the key argument in the EPA's case. The judge said:
"So much has changed since the petition was filed…two significant series of studies – respective cohort studies – which everybody agrees is the best methodology. Everybody agrees that these were rigorous studies and everybody agrees that these studies would be part of the best available scientific evidence."
The EPA appears to have applied a standard of causation, which from my read of TSCA is not accurate. It's not a proper allocation. It's not the proper standard.'

After closing statements, Judge Chen shared his views on the case and made recommendations. Chen asked the parties whether they could discuss the possibility of an amended petition and re-assessment by the EPA, or start a new petition and have the EPA conduct a proper review. To many observers, it felt as though Chen was intimating that FAN had essentially won the case, but he was giving the EPA a chance to right their original wrongs.

The ending of the first fluoride trial was somewhat unexpected as the judge asked the two parties to work out an agreement. The Court specifically urged the EPA to independently re-assess the hazard posed by fluoridation chemicals and the Judge assigned August 6, 2020 for a status hearing to reconnect with the two sides. When the parties met on August 6, EPA claimed that they "didn't have the resources to do a risk assessment," and were going to let the court record stand without taking any further action. The judge continued to insist the EPA reconsider their position, and also said he wanted to review the updated National Toxicology Program's (NTP) review of fluoride's neurotoxicity, which was due to be released soon.

In August 2020, the Court placed the case in abeyance (on hold) in part to consider the pending findings from the pending NTP report on fluoride neurotoxicity.

Justice Delayed

The Court requested on the last day of the trial that FAN submit a new petition to the EPA to allow them another 90-day opportunity to respond to our original 2016 petition with the addition of all the new studies on fluoride neurotoxicity published between 2017-2020. The Court also requested that FAN include petitioners who were pregnant or planning a pregnancy in light of the science linking early-life exposure to fluoridated water to adverse neurodevelopmental effects in these new studies.

On November 4, 2020, FAN filed a supplement to our original petition to the EPA.
The supplement asked that EPA reconsider their denial of our 2016 Petition.
The supplement has done everything the Court asked us to do with a new petition.
The supplement also responds to the issue of standing by identifying nine members of Food & Water Watch "who are currently pregnant, women who are actively seeking to become pregnant, and/or mothers of infants".

In December 2020, the EPA filed a last ditch motion to attempt to dismiss our landmark case, arguing that plaintiffs lacked standing; a motion they had previously made and were denied. The Court denied the EPA motion as being premature and procedurally improper. The trial will continue, in abeyance, as the Court awaits the EPA's response to FAN's updated petition and an updated draft of the National Toxicology Programs (NTP) monograph on fluoride's neurotoxicity, expected early in 2021.

In January 2021, the EPA denies FAN's supplemental petition, setting the stage for additional hearings and filings in the TSCA fluoride lawsuit. An April 2021 status hearing with the Court focused on FAN's amended petition to the EPA, which the Judge recommended before he placed the trial in abeyance. The amended version has a more detailed list of plaintiffs and includes recent studies that were not a part of the trial. The Court grants FAN's motion to supplement our pleadings to introduce additional evidence on standing, which should satisfy the Judge's prior concerns on this issue and ensure that the case is resolved on the merits.

The Judge reiterates that he is keen to read the NTP's finalized report on fluoride's neurotoxicity as well as other new science on the issue, including an upcoming pooled analysis of the NIH-funded birth cohort studies. To consider this new science, the Judge discussed having a "phase 2 trial" where Plaintiffs and EPA can introduce additional expert testimony on the NTP report and other developments. In June 2021, FAN attorney Michael Connett informs the Court of a new landmark study by Grandjean et al., confirming that very low levels of fluoride exposure during pregnancy impairs the brain development of the child. The paper's authors concluded in the Benchmark Dose (BMD) analysis that a maternal urine fluoride concentration of 0.2mg/L was enough to lower IQ by 1 point. The judge was waiting to see this analysis as well as the final version of the NTP review before moving forward with the case.

In a January 2022 status hearing, the Judge reiterates his desire to wait until the NTP publishes the final version of their review on fluoride's neurotoxicity before continuing with the trial. The NTP report had been delayed, with speculation brewing that dental interests were actively influencing the report's final publication.

In September 2022, FAN filed a motion to lift the pause on the trial in response to the indefinite postponement of the NTP fluoride review. The final publication of the NTP review was expected at the end of 2021, then promised again in early 2022, with May 2022 being the long-awaited release date. May 2022 came and went without any sign of the NTP report.

In October 2022, FAN attorney Michael Connett introduced evidence from Freedom of Information Act (FOIA) documents showing that political pressures had prevented NTP from releasing its long-delayed report [link to new NTP page]. The Court promptly granted our motion to lift the stay on the trial and permit additional discovery into the NTP review.

EPA's objections to using any version of the NTP report besides the "final" version during the trial was based on their concern that the NTP's findings would be made public prematurely. To circumvent this objection, the Court placed the NTP's review under protective order so that it was only made available to the parties involved, the Court, and expert witnesses. The Court urged both parties to come together and find a way to get the current NTP review into the Court's hands "voluntarily," while also leaving the door open for FAN attorney Michael Connett to use "subpoenas or a motion to compel," the release of the long-delayed report.

In December 2022, after extensive negotiations, the Department of Justice (DOJ) agreed to produce a copy of NTP's suppressed report on fluoride. The report is produced under a strict protective order.
FAN Attorney Michael Connett shared with the Court FAN's desire to see the final NTP review from May 2022 available to the public, as well as the communications and criticisms from the CDC and HHS that led to it being blocked. Connett pointed out that FAN had evidence obtained through FOIA requests showing that the American Dental Association (ADA) was already given the NTP review so they could work to discredit it, and therefore there is no justifiable reason for the EPA to continue hiding it from the public.

In January 2023 the Court ruled against EPA's request for additional delay of the trial, acknowledging that "justice delayed is justice denied". The Court sets a timeline for the final phase leading to a verdict.

In February 2023, after being served a subpoena by our attorneys, the NTP agreed to publicly produce their final report that was intended to be published in May of 2022, along with communications between various federal agencies and the NTP about the report. This allows the public to finally see the report and accompanying documents that were blocked from being published by the leadership at U.S. Health and Human Services (HHS) in May of 2022. Internal CDC emails discovered through FOIA by FAN show that the publication was blocked at the last second due to interference from Assistant Health Secretary, Rachel Levine.
The NTP fluoride review was issued in two parts, a monograph and a meta-analysis. The meta-analysis found that 52 of 55 studies found lower IQ with higher fluoride exposures, demonstrating remarkable consistency. Of the 19 studies rated higher quality, 18 found lowering of IQ. The meta-analysis could not detect any safe exposure, including at levels common from drinking artificially fluoridated water.

In March 2023 the Court denied EPA's motion to prevent FAN from conducting depositions into the suppression of the NTP report. Dates are set for the final phase of the TSCA fluoride lawsuit - January 29 thru February 13, 2024.

FAN learned at an October 2023 status hearing the start date for the last phase of our fluoride trial would be pushed back two days to January 31st, 2024. The expiration of the CARES Act means that our attorneys will present live, in-person from the federal courthouse in San Francisco during the second phase of the trial. The trial will be live streamed on Zoom for the public to view.

In a January 2024 pre-trial hearing, FAN attorney Michael Connett introduced evidence that key a EPA witness lied under oath.

The Second Fluoride Trial (January 31 – February 20, 2024)

The second trial in the TSCA fluoride lawsuit took place January 31 – February 13, 2024, at the Federal Courthouse in San Francisco and was live-streamed on Zoom. The trial lasted two weeks and featured testimony from the same FAN expert witnesses seen in the first fluoride trial – Drs. Hu, Lanphear, Grandjean, and Thiessen.

Central to the crux of the case, Connett focused on EPA's admittance that they did not use the appropriate EPA guidelines in their risk evaluation of fluoride and did not follow the Toxic Substances Control Act (TSCA) statutes when evaluating whether fluoride posed an unreasonable risk to the developing brain. Not only did EPA fail to follow TSCA and agency risk assessment rules, but they went further by admitting that they held fluoride to a higher standard than any other chemical. This included the EPA's insistence in discounting high-dose fluoride studies, while EPA has never disregarded higher-dose studies when identifying a hazard with any other chemical.

Connett also honed in on the National Toxicology Program's (NTP) systematic review of fluoride neurotoxicity, and a large body of animal data showing brain harm from fluoride. The NTP review found a large number of studies have been published on fluoride and human IQ. In total they identified 72 human studies of which 64 found a connection between fluoride and IQ deficits. 18 of the 19 studies deemed high quality found that fluoride lowered IQ, a 95% consistency. Connett flagged recent research relied upon by EPA that did not find neurotoxic effects from fetal fluoride exposures as deeply suspicious. He said the authors of these studies were long-time promoters of water fluoridation, compared to FAN expert witnesses, who have all worked with the EPA and have been relied upon as experts on the regulation of environmental toxins by governments around the world and are subject-matter experts on fluoride.

Connett discussed how the exposure level at which a chemical presents a risk for toxic effects (a threshold level) varies substantially across the human population, but the point of a regulatory action is to protect the most vulnerable people in the population. Connett stressed to the Court that "TSCA commands us to protect the vulnerable". Connett then wrapped up by pointing out that roughly two million pregnant women and 400,000 formula-fed babies exposed to fluoride in water are at risk and that TSCA requires the EPA to consider injuries that chemicals pose to sensitive and highly exposed people. The EPA focused their opening statement on the talking point that "the dose

makes the poison," suggesting, in contrast to the actual published research, that there is insufficient compelling evidence that fluoride is a neurotoxin at the current levels used for fluoridation in the U.S. and that therefore water fluoridation doesn't pose a risk to children. EPA named the expert witnesses it will call in the case: David Savitz, Ph.D., who chaired NASEM's committee that peer reviewed the NTP's systematic review; EPA risk assessment expert, Stan Barone, Jr., PhD; and and Jesus Ibarluzea, PhD, authored of the flawed "Spanish" study.

FAN attorney Michael Connett then called our first expert witness to the stand, Howard Hu, MD, MPH, ScD. Dr. Hu has authored more than 320 papers in peer-reviewed journals and published several landmark studies on fluoride and the brain. He also advises the EPA and collaborates with its scientists on issues related to lead exposure.

Connett asked Dr. Hu how he would compare the peer review process that his fluoride studies underwent with other studies he's published. Hu responded that his fluoride studies are "probably the most extensive peer review process I've experienced." Hu also discussed his concerns about the Spanish study the EPA used as a basis to argue fluoride is not toxic at low levels, and criticized the EPA's opening statements, saying that the EPA was presenting data as black and white.

Hu then compared his Canada MIREC cohort study and Hu's more recent MADRES cohort study from the U.S. Both indicate higher levels of fluoride in the urine of pregnant mothers in the third trimester. Hu remarked that the third trimester increase is reminiscent of what we saw with lead: fluoride is stored in the mother's bones and during the third trimester, when fetal bone growth accelerates, the mother's body transfers calcium from her bones, along with any present toxins like fluoride, to the fetus.

Dr. Hu was interviewed by independent journalist Derrick Broze after the first day of court adjourned:
Next up was FAN expert witnesses Bruce Lanphear, MD, MPH, who has studied the impact of toxic chemicals, including lead and pesticides, on children's brain development for over 20 years. Lanphear testified that his research has been almost exclusively funded by federal agencies, including the EPA and the Centers for Disease Control and Prevention (CDC). In fact, Dr. Lanphear's research was cited by the EPA as the principle study upon which the agency based its current regulatory standards for lead in air and water.

Lanphear discussed the findings and methodology used for several landmark human studies funded and vetted by the National Institutes of Health (NIH) on fluoride and the brain that he co-authored. Lanphear stated that out of the 350+ studies he's published, his study was one of the two most rigorously reviewed and scrutinized studies prior to publication in his career due to the "implications for public health policy." His study found a linear dose-response relationship between fluoride and IQ, meaning that the

lowered IQ effect occurred with any level of fluoride exposure and increased as the exposure increased.

There was then discussion of another study he co-authored which found that consumption of infant formula reconstituted with fluoridated water led to excessive fluoride intake and lower IQ scores for both boys and girls compared to their breastfed counterparts who received very low intakes of fluoride. Lanphear also pointed out that studies have consistently found that children in poorer areas were often exposed to more toxins, and the effects of fluoride exposures for their mothers during pregnancy and for the children during formula feeding could compound these effects, making the poor particularly vulnerable to fluoride's effects.

In his testimony, Lanphear addressed the variability of findings in different studies - some find sex-differentiated responses to fluoride and others don't, or some find neurotoxicity at lower levels and some at higher levels. Lanphear said that the same variability exists in toxicity studies for lead, where some studies find greater effects in boys and others in girls. The overall indication is that lead, like fluoride, is toxic and that other factors drive sex differentiation in a particular context.

The discussion then focused on how fluoride could increase hypothyroidism rates in pregnant women, impacting fetal brain development, and how these effects were both increased if the mother was iodine deficient. Lanphear co-authored key studies on these subjects. He pointed out that the 2006 National Research Council report recognized that fluoride was a thyroid disruptor. He also noted that iodine deficiency has been increasing in the United States. FAN attorney Michael Connett asked, "Is there any dispute that hypothyroidism can lead to a lower IQ?" Lanphear: "No."

Lanphear wrapped up his testimony by discussing his work measuring maternal urinary fluoride concentrations of pregnant women. He testified that an average woman living in a fluoridated community has fluoride levels in their urine twice as high as an average woman living in a non-fluoridated community. Connett asked, "What is the cause of this difference?" Lanphear responded, "Fluoridated drinking water."

Journalist Derrick Broze interviewed Dr. Lanphear after his testimony on day two of the trial:
The third expert witness called by FAN was Philippe Grandjean, MD, DMSc. Dr. Grandjean is a physician, a scientist, an internationally known expert in environmental epidemiology, an author, and both a professor of environmental health at the Harvard School of Public Health and the head of the Environmental Medicine Research Unit at the University of Southern Denmark.

Grandjean testified that he has been given grants and/or contracts to advise the EPA, the National Institutes of Health (NIH), the U.S. Food and Drug Administration (FDA), the World Health Organization (WHO), and numerous other government bodies for over 25

years. Dr. Grandjean said he had even been retained by the Department of Justice, which is representing the EPA in our trial, as an expert witness on environmental toxins.

Grandjean is the author or co-author of some 500 scientific papers and is perhaps best known worldwide for his research on the neurotoxicity of mercury, which involved studying the IQ of children born to mothers whose diet was high in mercury. This work led to defining the EPA's safe regulatory levels for mercury in the diet and inspired downward revisions of methyl mercury exposure limits internationally.

Dr. Grandjean has authored or co-authored several studies and reviews on fluoride's neurotoxicity, as well as the first benchmark dose analysis on fetal fluoride exposure which found that a maternal urine fluoride concentration of 0.2 mg/L, which studies show is exceeded 4 to 5 times in pregnant women living in fluoridated communities, was enough to lower IQ by 1 point. In his testimony, Grandjean confirmed that the fluoride the mother is absorbing will pass into the child's brain. "You only get one chance to develop a brain. Once it's harmed, there's nothing you can do." Grandjean says.

Attorney Connett showed a quote from EPA scientist Kristina Thayer, who provided testimony in the first phase of the trial. Dr. Thayer said she believes that animal data supports the biological plausibility of fluoride causing neurotoxic effects in humans. Grandjean agreed with Thayer's opinion. Connett asked Grandjean about the EPA's opening statement in which they claimed that Chinese fluoride studies were looking only at very high levels of fluoride exposure. Grandjean insisted this was not the case, saying that even at lower levels there was evidence of cognitive impacts from fluoride, confirming outright that he felt neurotoxicity was definitely a hazard of fluoride exposure.

Connett then asked about NTP's May 2022 final draft report, which included Grandjean's own studies and found lower IQ in children exposed to fluoride during fetal development. Connett specifically asked about the EPA's claim that the NTP's findings were "driven by studies looking at fluoride levels of 7.0 ppm and higher." Dr. Grandjean replied, "They must have a misunderstanding because that's certainly not correct." He then agreed with the NTP authors' statements that some of the higher-quality studies that found harm were done in optimally fluoridated communities.

Dr. Grandjean then confirmed that over a lifetime of dealing with evidence on neurotoxicants, "Fluoride probably has the largest body of evidence of any of our known or suspected neurotoxicants." Agreeing with NTP's finding that the consistency of association of lower IQ in children in five different countries rules out the possibility that there is a common factor other than fluoride exposure that can account for this outcome, Dr. Grandjean stated: "When it comes to fluoride, we have a massive amount of evidence. There is something very serious going on here that we must take seriously."

Journalist Derrick Broze interviewed Dr. Grandjean after his testimony on day three of the trial:
Next to take the stand was EPA's expert witness Stanley Barone, Ph.D., a risk assessment scientist from the EPA Office of Chemical Safety and Pollution Prevention, testifying as FAN's fact witness to establish EPA's methods for risk evaluation under the Toxic Substances Control Act(TSCA).

Through questioning, Barone explained the EPA's risk assessment method - the method FAN says EPA is failing to apply in the case of fluoride. As an EPA developmental toxicologist, Barone was heavily involved in TSCA's first 10 risk evaluations. Before the trial, the plaintiffs asked Barone to establish the risk evaluation process for the record.

Connett questioned Barone on key elements of the hazard assessment. He asked Barone to confirm that to determine whether a chemical is a hazard - step one in the risk assessment process - there is no need to prove causation. Barone agreed that to establish that a chemical is a hazard, EPA requires proof of association, not causation.

Next, Connett asked Barone whether EPA had ever made a different hazard evaluation for high-dose versus low-dose exposure in any of the risk evaluations it had done to date under TSCA. Barone said he was confused by the question. Judge Chen interjected to pose the question himself. "In the hazard evaluation, is it a binary decision?" Barone said it was. In other words, a chemical poses a hazard or it doesn't. The EPA doesn't differentiate between high and low doses in determining whether something is a hazard. Barone also confirmed that once something has been confirmed as a hazard, medium- and high-quality studies are then used to identify a hazard level. These are points our attorney laid out in his opening remarks.

In what would become a defining moment in the trial, Dr. Barone testified that in his estimation we should have a margin of safety of at least 10x for fluoride to protect the most vulnerable in society. The current margin of safety between fluoridated water at 0.7 ppm and the level that NTP found neurotoxicity, 1.5 ppm, is only 2x. EPA would backpedal from this admission throughout the rest of the trial. Some observers might say this moment forced the EPA to change strategy mid-trial.

FAN attorneys then called to the witness stand Dr. Brian Berridge, DVM, DACVP, Ph.D., who oversaw the completion of the NTP's work, to discuss the NTP fluoride review and the peer-review process.

In December 2023, EPA moved to exclude Berridge's testimony from the trial, arguing it would speak to the political influence exerted to stop the NTP report's publication, rather than to the scientific findings in the report, which are central to the trial. EPA attorneys argued Berridge's testimony would be "unfairly prejudicial" to the agency. Although Berridge commented in an email, obtained by FAN via a FOIA request, that there was an ongoing attempt to modify the report to satisfy interested actors and to

obstruct its publication, FAN did not call on him to speak to that issue, but rather on the integrity of the scientific process in the report's production. In a blow to EPA, Judge Chen said he woul allow Berridge's testimony.

Dr. Berridge testified at trial that he signed off on the May 2022 version of the NTP fluoride review as a final and complete report that was ready for publication.

Read more: What Dr. Berridge Couldn't Tell The Court

FAN Attorney Michael Connett then called veteran risk assessment scientist, Dr. Kathleen Thiessen as the next expert witness. Connett establishes that Dr. Thiessen is the author of a large portion of the 2006 NRC fluoride review, and that she also worked on the 2009 review. Connett asked Thiessen if there is any reasonable doubt that neurotoxicity is a hazard of fluoride exposure. Thiessen replied that "neurotoxicity is a hazard of fluoride exposure, the evidence is abundant".

Connett then asked several questions comparing the NTP review process to the EPA review process, Thiessen says the EPA has not been as open and transparent. That the NTP's communication of its conclusions about fluoride's toxicity was more transparent.

Day six of the second trial in the fluoride lawsuit started off with a bang, as FAN attorneys shared with the Court a new systematic review by Canadian researchers, published the night before, linking fluoride exposure at very low levels to lower IQ in children.

Canada's public health agency, Health Canada, commissioned a team of scientists to study the effects of fluoride on human health, but the agency did not publish the review. The peer-reviewed journal Critical Reviews in Toxicology instead independently published the study. The researchers calculated the "point of departure" for the effects of fluoride on IQ - also known as the "hazard level," the lowest point at which a toxic effect is observed - and found it to be 0.179 milligrams per liter (mg/L) in water.

Levels of fluoride found in drinking water in the U.S. and Canada typically are in the higher range of 0.7 mg/L. The NTP report set the hazard level at 1.5 mg/L, and one of the key studies at the center of the trial set the level even lower than 0.2 mg/L.

Even at a hazard level of 1.5 mg/L, exposure levels for fluoride carry significant risk under TSCA's guidelines, but this new level identified by Canadian researchers would set a risk level even further below current exposure levels.

The findings are important to the trial because the identified hazard level was quite low and also because the authors calculated their hazard level in terms of water fluoridation levels, which they extrapolated from the urinary fluoride levels used in most studies.

The findings also are significant because David Savitz, Ph.D., professor of epidemiology at Brown University and the EPA's first witness, was part of the expert panel that advised Health Canada on how to interpret this study and other data. The expert panel that included Savitz concluded there wasn't enough evidence to lower the amount of fluoride in drinking water based on its neurocognitive effects.

Next, EPA's first key witness, David Savitz, Ph.D. took the stand. Dr. Savitz is a professor of epidemiology at Brown University School of Public Health. He worked with the National Academies of Sciences, Engineering, and Medicines (NASEM) in reviewing the draft NTP fluoride report.

Over nearly three days of testimony, Savitz downplayed the link between fluoride and IQ loss in children. Savitz's testimony supported the EPA's three key arguments:
Data on fluoride's neurotoxic effects for children at current levels of water fluoridation is mixed or uncertain and therefore no action should be taken.
There are limitations to the NTP's conclusions, published in draft form last year, linking fluoride exposure and IQ loss in children at 1.5 milligrams per liter (mg/L).
More recent studies not considered by the NTP cast doubt on the NTP's findings.
However attorney Michael Connett and even Judge Chen pushed back on his conclusions. Connett underscored in his cross-examination that Savitz is an expert in epidemiology but has no experience researching fluoride.

Savitz testified that the Health Canada panel he was on determined that data showing IQ loss in children at existing water fluoridation levels contained too much "uncertainty" to set a hazard level for drinking water, so they advised Health Canada not to change its fluoridation levels.

Under cross-examination, Savitz told the court he sat on that panel at the same time that the EPA was paying him $500 per hour — totaling between $137,000 to $150,000 for 275-300 hours of work — as a litigation expert for the EPA in this trial examining that very question. Judge Chen asked Savitz if Health Canada knew he was serving as an expert witness in this case when they invited him to the panel. Savitz said the agency did.

Regarding his work reviewing the NTP fluoride report, Savitz said NASEM determined the first draft of the NTP's report, which classified fluoride as a neurotoxin, fell short of providing "a clear and convincing argument" that supported its assessment. Savitz told the court he didn't think NTP's conclusions were "wrong" but that they were stated in a way that could be "misused" as a tool for setting or changing water policy on water fluoridation. Savitz said he thought that after the revisions, the communication was "tempered" and "more consistent".

Savitz testified that because two of the four major cohort studies discussed in the trial (MIREC and ELEMENT), found a statistically significant effect of fluoride on IQ at low

levels, and two did not (Odenseand INMA), there was too much uncertainty to definitively conclude that it posed a danger at current levels of water fluoridation. Judge Chen asked, “I take it the converse would also apply? Which is that given this mix [of results] you can’t foreclose that there is an effect at U.S. drinking levels?” Savitz conceded this was true.

Judge Chen asked, given Savitz’s response and the NTP’s findings, if it makes sense to assume that there is a concern about current drinking water levels. Chen also asked Savitz if he took issue with NTP’s conclusion that there is an association between fluoride exposure and lowered IQ at 1.5 mg/L - just over two times current fluoridation levels. Savitz said he had no reason to challenge it, but he hadn’t corroborated it.

Savitz said another flaw was that the NTP used high-quality ecological studies - studies of endemic fluoride in other countries - as some evidence to show the effects of fluoride and that those could be confounded by other variables. Chen pointed out that the studies would have controlled for that issue. Savitz conceded they did.

On cross-examination, Connett also pointed out that in Savitz’s own work on arsenic in China, his team studied endemic arsenic at high concentrations to show evidence for arsenic’s toxic effects. They also used that data to consider toxic exposure levels in the U.S., using the same methods NTP scientists and other researchers were using endemic fluoride data, which Savitz criticized.

Connett also asked Savitz if he believed his own statements on uncertainty by quoting from Savitz’s textbook, “Interpreting Epidemiological Evidence: Connecting Research to Applications.” Savitz wrote in the book that “to claim we have insufficient evidence does not resolve the problem for those who make public health decisions, because inaction is an action.”

Throughout his testimony, Savitz maintained there was no strong evidence for the neurotoxic effects of fluoride exposure at “low levels,” which extended up to 2 mg/L. On cross-examination, Connett presented him with data from the NTP report and also from at least one key study showing this link. Savitz conceded he hadn’t read those studies. In fact, in addition to the NTP report, he said he had read only about 10 studies on fluoride and neurotoxicity. EPA’s risk analyst Dr. Stanley Barone took the stand again as the final in-person witness in nine days of testimony at the Phillip Burton Federal Courthouse in San Francisco. FAN attorneys called Dr. Barone earlier to comment on the EPA’s risk analysis methodology even though he’s an expert witness for the EPA. The EPA called him back to testify to the quality of the evidence on fluoride and IQ for a hazard assessment.

Dr. Barone admitted in his testimony that fluoride is neurotoxic at relatively low levels and that EPA’s key expert on fluoride’s neurotoxicity, David Savitz, conceded flaws in his

own study as our landmark fluoride trial drew to a close. Fluoride causes “neurotoxic harm,” and does so at relatively low levels, Barone admitted under cross-examination.

Barone said there simply isn’t enough data available for EPA to implement its risk assessment process for fluoride. Pharmacokinetic modeling that predicts how a chemical will be absorbed and metabolized by the body, hasn’t yet been done, he said. But on cross-examination, Attorney Michael Connett forced Barone to concede several of the FAN’s key points.

“You do not dispute that fluoride is capable of causing neurodevelopment harm, correct?” Connett asked. “I do not,” Barone said, adding that he said that in his deposition.

“You agree that the current evidence is suggestive that low-dose fluoride causes neurodevelopmental effects? Correct?” Connett asked. Barone said the “hazard ID” - the level at which a toxin causes effects - “is probably in the suggestive range but is highly uncertain.”
“You agree that fluoride is associated with neurotoxic effects at water fluoride levels exceeding two parts per million?” Connett asked. After first evading the question, Barone conceded.

Connett asked if Barone agreed there should be a “benchmark margin of uncertainty” of 10 for fluoride neurotoxicity. That means the lowest allowable human exposure level should be at least 10 times the hazard level, which Barone conceded may be approximately 2 parts per million. Barone said that is generally true for toxic chemicals under TSCA.

Water fluoridation levels in the U.S. are currently 0.7 parts per million, also referred to as milligrams per liter (mg/L), which would place them well above the allowable level if they were regulated through TSCA’s norms.

Barone also conceded that the NTP’s report linking fluoride to neurotoxicity at 1.5 mg/L is a rigorous, high-quality review and that the NTP is one of the world leaders in doing such reviews.

“Do you feel comfortable as a risk assessor,” Connett asked, “exposing pregnant women to a level of fluoride that is so high that the kidney is oversaturated?” Barone avoided answering, commenting instead on other foods containing fluoride.

Connett asked a second time, “Are you comfortable then with a pregnant woman having so much fluoride in her circulating system that their kidney has lost the ability to efficiently process it?”

EPA lawyers objected to the question as “vague and argumentative” but Chen overruled.

Barone then sat in silence for several seconds before responding, “Again, putting this in context, my comfort level I don’t think is germane.”

Connett then turned to the question of the “data gap” or “uncertainty” that Barone and other EPA experts have argued is the basis for not requiring the agency to regulate fluoride.

Connett asked Barone if he agreed that uncertainty about the threshold level at which a chemical causes harm is not a basis for deciding not to do a risk assessment - the process that would likely lead to chemical regulation. Barone agreed but said the weight of the evidence was key. Connett also asked him if he personally agreed that the EPA should “use health protective assumptions” (i.e. an uncertainty factor of 10) when data is lacking. He said he did.

Chen intervened to ask Barone why the EPA couldn’t do its risk assessment with the given information, using a “lowest observed effect level,” or LOEL. “I mean here we have a phenomenon where I think everybody agrees, as you put it, something’s going on,” Chen said, adding:
“And knowing that the EPA is to use health-protective assumptions when the information is lacking, why can’t one approach it from the low-level approach? We seem to know that there’s some level in which something’s going on. There’s adverse effects. We may debate where it is, but wouldn’t it be proper to use even a conservative estimate of LOEL?”
Barone insisted, as he did in earlier testimony, that the data are unclear. But he also conceded the EPA does often use the LOEL in risk assessment. Throughout Barone’s testimony, Connett drew concessions from Barone through “impeachment” — meaning Barone gave responses under cross-examination that contradicted statements he made in his earlier deposition. Connett read from Barone’s deposition testimony to demonstrate he was misrepresenting his responses.

To wrap up the trial and move forward with closing arguments, Judge Chen privately reviewed the recorded deposition of Jesús Ibarluzea, Ph.D., EPA’s final witness.

Dr. Ibarluzea is the author of the “Spanish study” that found fluoride increased IQ in boys by an implausible 15 points. 15 IQ points is enough to turn an average person into a genius, which no chemical has ever been found to do, calling the findings of his study into serious question.

Dr. Ibarluzea pulled out of testifying publicly in the trial after his study was scrutinized by plaintiffs for its ridiculously unbelievable findings.

At the close of the expert testimony, a scheduling change occurred. The Judge ordered that closing statements from both FAN and EPA now take place with a one-week delay,

setting a February 20, 2024, closing date. The judge wanted time to watch deposition videos, look over evidence, and prepare a series of key questions for attorneys.

Closing Arguments

On February 20, 2024, rather than delivering summary closing arguments, attorneys for FAN and EPA responded for nearly three hours to the Judge's detailed questions on technical aspects of the link between low-level fluoride exposure and lower IQ scores in children. The two sides also debated the role of uncertainty in risk assessment.

During the trial, top scientific experts who advised the EPA on understanding and setting hazard levels for other major environmental toxins and who conducted gold-standard "cohort" studies on the link between fluoride and low IQ in children testified for FAN.

They explained the NTP's findings and presented evidence from their own research showing neurotoxic risks - particularly to pregnant women, formula-fed infants and children- posed by water fluoridation.

EPA witnesses conceded fluoride does have neurotoxic effects at relatively low levels but countered that the risk assessment process under TSCA is highly complex and there is too much uncertainty in the data on fluoride's toxicity at current levels of water fluoridation to do a proper risk assessment and regulate the chemical.

It is now up to Judge Chen to decide if the EPA should be required to create a rule banning water fluoridation in the U.S. "Because the regulatory agencies have failed to do their job for decades," plaintiffs' attorney Michael Connett told Brenda Baletti of The Defender, "the court is now in the position of having to do it for them."

"It's not a job the court takes lightly," he said. "It's not a job the court wanted to do, but I think it's a job the court is prepared to do."

The Judgment

On September 24, 2024 the court ruled on behalf of the Fluoride Action Network and the plaintiffs. A U.S. federal court has now deemed fluoridation an "unreasonable risk" to the health of children, and the EPA will be forced to regulate it as such.

The decision is written very strongly in our favor.

Below is an excerpt from the introduction of the ruling:

"The issue before this Court is whether the Plaintiffs have established by a preponderance of the evidence that the fluoridation of drinking water at levels typical in the United States poses an unreasonable risk of injury to health of the public within the meaning of Amended TSCA. For the reasons set forth below, the Court so finds. Specifically, the Court finds that fluoridation of water at 0.7 milligrams per liter ("mg/L") – the level presently considered "optimal" in the United States – poses an unreasonable risk of reduced IQ in children..the Court finds there is an unreasonable risk of such injury, a risk sufficient to require the EPA to engage with a regulatory response…One thing the EPA cannot do, however, in the face of this Court's finding, is to ignore that risk."

Toxic Substances Control Act (TSCA) Lawsuit Timeline Summary

November 2016 — **Watchdog organizations serve the U.S. Environmental Protection Agency (EPA) with a petition calling on the agency to ban the addition of fluoridation chemicals to public water supplies due to the risks these chemicals pose to the brain.**

February 2017 — EPA denies the petition.

April 2017 — **Fluoride Action Network (FAN) and other organizations sue EPA.**

November 2017 — Court holds hearing on EPA's Motion to Dismiss.

December 2017 — Court rules in plaintiffs' favor, denying EPA's motion to dismiss, noting: "the purpose of citizen petitions is to ensure the EPA does not overlook unreasonable risks to health or the environment."

EPA files a motion asking the Court to limit the scope of evidence to the administrative record.

February 2018 — Court rules in plaintiffs' favor, denying the EPA's motion to limit review to the administrative record, thus allowing use of important new scientific studies published since the case was initiated.

October 2018 — Court denies EPA's motion to prevent plaintiffs from deposing an EPA representative on EPA's fluoride safety standards.

April 2019 — Court denies EPA's motion to prevent plaintiffs from deposing additional EPA scientists. Court also denies EPA's motion to prevent plaintiffs from obtaining documents regarding National Toxicology Program (NTP) review of fluoride.

September 2019 — Court denies EPA's motion to delay the trial.

December 2019 — Court denies EPA's motion for summary judgment. This means our case will go forward. Trial is scheduled for two weeks beginning April 20, 2020 and will run for two weeks.

April 2020 — Trial postponed on 3/17/20 due to the coronavirus outbreak.

May 2020 — Pre-trial hearing. Court denies EPA's motion to prevent plaintiffs' experts from testifying at trial. Court grants plaintiffs motion to exclude the issue of fluoride's purported benefits at trial, agreeing that benefits are not relevant to risk evaluations under TSCA.

Trial declarations from plaintiffs' witnesses submitted.

June 2020 — **Court holds a 7-day trial, marking the first time in TSCA's 45 year history that citizen groups have taken a TSCA petition all the way to a federal trial.**

August 2020 — The Court places the case "in abeyance" in part to consider the pending findings from the NTP.

November 2020 — Plaintiffs file supplemental petition to EPA asking the Agency to reconsider its denial.

January 2021 — EPA denies plaintiffs' supplemental petition.

April 2021 — Court grants plaintiffs' motion to supplement their pleadings to introduce additional evidence on standing.

June 2021 — Plaintiffs file motion to lift pause on the trial.

January 2022 — Status hearing. The Judge reiterates his desire to wait until the NTP publishes the final version of their review on fluoride's neurotoxicity before continuing with the trial.

October 2022 — **Plaintiffs introduce evidence showing that political pressures have prevented NTP from releasing its long awaited report. Court grants plaintiffs' motion to lift the stay and permit additional discovery into the NTP review.**

December 2022 — After extensive negotiations, the Department of Justice agrees to produce a copy of NTP's suppressed report on fluoride. The report is produced under a strict protective order.

January 2023 — Status hearing. Court rules against EPA's request for additional delay of the trial, acknowledging that "justice delayed is justice denied". Court sets a timeline for the final phase leading to a verdict.

March 2023 — Court denies EPA's motion to prevent plaintiffs from conducting depositions into the suppression of the NTP report.

October 2023 — Status hearing. The expiration of the CARES Act means that our attorneys will present live from the federal courthouse in San Francisco during the second phase of the trial.

January 16 2024 — Pre-trial hearing. Plaintiffs introduce evidence that key EPA witness lied under oath. The trial will be live streamed on Zoom.

January 31 - February 14 2024 — **Second Phase of Fluoride Trial**

Thanks to Derrick Broze of the Conscious Resistance and Brenda Baletti of Children's Health Defense for their contributions to this detailed overview of the TSCA fluoride lawsuit.

Although I do not expect you to read all the links, certainly some of this information is critical for a thorough understanding of the legal action in the TSCA trial on fluoridation.

Plaintiffs needed five things to win our TSCA lawsuit 1. We need to prove in court that neurotoxicity is a hazard of fluoride exposure. 2. We need to prove in court that this hazard is a risk at the doses ingested in fluoridated areas. 3. We need to prove in court this risk is unreasonable.

Previous to the above report of the court proceedings:

Federal Trial Update: New Supplement To Our TSCA Petition Submitted To Court
November 7, 2020 | Cheikhani
As you might recall, the Court requested on the last day of the trial that we submit a new Petition to the Environmental Protection Agency (EPA) to allow them the opportunity to respond to our original 2016 Petition in regards to the new studies that were published between 2017-2020. The Court also requested that we include Petitioners who were pregnant or planning a pregnancy in light of the science linking early-life exposure to fluoridated water to adverse neurodevelopmental effects in these new studies.
Yesterday's meeting with the Judge
At the very short meeting convened by the Judge, lawyers representing both sides were in attendance. Lead attorney Michael Connett told the Court that he filed, on November 4, a Supplement to our original Petition with the EPA. The Supplement asks that EPA reconsider their denial of our 2016 Petition. The reasons are set forth in the Supplement and its 9 attachments (all listed below). The Supplement has done everything the Court asked us to do with a new Petition. The Supplement also responds to the issue of Standing by identifying nine members of Food & Water Watch "who are currently pregnant, women who are actively seeking to become pregnant, and/or mothers of infants…"
We believe that this is an important and highly readable document and we urge our supporters to read it in full. However, if time is short we have presented excerpts below.
Background to the Supplement
"On November 22, 2016, the undersigned Petitioners submitted a Citizen Petition under Section 21 of the Toxic Substances Control Act ("TSCA"), requesting that the EPA prohibit the addition of fluoridation chemicals to drinking water in order to protect the public, including susceptible subpopulations, from fluoride's neurotoxic risks. After the EPA denied this petition, the Petitioners brought suit in the Northern District of California to challenge

EPA's denial. Following a bench trial in June of 2020, the Court stated that EPA had used an incorrect standard in assessing the evidence that the Petitioners had presented. ..
The Court also noted that much of the evidence that the Petitioners relied upon at trial—including recent studies funded by the National Institutes of Health (NIH)— was not yet available at the time EPA denied the Petition. (Appendix A at 4.) In light of these facts, the Court asked Petitioners to re-submit evidence to the EPA in order to give the Agency an opportunity to give the evidence a "second look" using the "proper standard" at the administrative level, which the Court 'urged' the EPA to do."
"Pursuant to the Court's request, the Petitioners are hereby submitting this Supplement to their Petition and requesting that EPA reconsider its denial of the Petition based on the information presented herein."

EPA HAS THE AUTHORITY TO RECONSIDER ITS DENIAL OF A SECTION 21 PETITION

"EPA has the inherent authority to reconsider its denials of Section 21 petitions, as the EPA itself has repeatedly acknowledged. The EPA has explained that: "Although TSCA does not expressly provide for requests to reconsider EPA denials of Section 21 petitions, 'the courts have uniformly concluded that administrative agencies possess inherent authority to reconsider their decisions, subject to certain limitations, regardless of whether they possess explicit statutory authority to do so.'" … As the EPA has explained, "the power to reconsider is inherent in the power to decide." Id. at 24 (quoting Albertson v. FCC, 182 F.2d 397, 399 (D.C. Cir. 1950)) …"

GROUNDS FOR PETITIONERS' REQUEST FOR RECONSIDERATION

1. EPA Used an Incorrect and Impermissibly Stringent Standard of Proof

"At the close of trial in June 2020, the Court observed that EPA has subjected Petitioners' evidence to an incorrect standard of proof. As the Court noted, "EPA appears to have applied a standard of causation … It's not the proper standard." (6/17 Trial Tr. 1131:5-9.)
"TSCA commands that EPA protect against "unreasonable risk," which exists when human exposure to a toxicant is unacceptably close to the estimated hazard level. (6/10 Trial Tr. 471:11-472:9.) At trial, EPA confirmed that 'EPA does not require that human exposure levels exceed a known adverse effect level to make an unreasonable risk determination under TSCA.' (Appendix H at 4.) Thus, EPA does not require proof that human exposures under a given condition of use cause the hazard. In fact, Dr. Tala Henry agreed at trial that EPA has "never once in any of its risk evaluations to date under Section 6 used a causation standard." (6/16 Trial Tr. 987:6-8.) Despite this, Dr. Henry admitted that EPA held Petitioners to a burden of proof where Petitioners needed to prove that human exposure to fluoride in water at 0.7 mg/L causes neurotoxicity. (6/16 Trial Tr. 985-15-987:2.) Dr. Henry thus made the extraordinary admission that EPA 'held the plaintiffs to a burden of proof that EPA has not held a single chemical under Section 6 before.' (6/16 Trial Tr. 987:16-19.)…"

2. Each of the Limitations that EPA Identified with the Fluoride/IQ Studies in the Petition Have Now Been Addressed by High Quality Studies Funded by the NIH

"In its denial of the Petition, the EPA criticized the human studies that Petitioners cited on three primary grounds: (1) the studies were cross-sectional and thus 'affected by antecedent consequent bias';1 (2) the studies failed to adjust for potential confounding factors; and (3) the studies failed to adequately establish a dose-response relationship between fluoride and neurotoxicity. (Fed Reg, Vol. 82, No. 37, p. 11882-83). …

"Following EPA's denial of the Petition in February 2017, a series of prospective cohort studies funded by the National Institutes of Health (NIH) were published which evaluate the impact of individualized measurements of prenatal and early-infant fluoride exposure on standardized measures of neurobehavioral performance between ages 4 and 12 (Bashash 2017, Bashash 2018, Green 2019, Till 2020)."

"These NIH-funded studies address each of EPA's three criticisms of the studies in the Petition…"

3. The National Toxicology Program Has Concluded that Fluoride Is a Presumed Human Neurotoxicant that Lowers IQ in Children

"Petitioners' contention that fluoride is a neurotoxicant has gained powerful new support from the National Toxicology Program's (NTP) recently revised systematic review and meta-analysis…"

A. NTP Agrees that Fluoride Is a Likely Neurodevelopmental Hazard to Humans

"On September 16, 2020, the NTP released its Draft Monograph on the Systematic Review of Fluoride Exposure and Neurodevelopmental and Cognitive Health Effects. The Monograph is a revised version of a draft issued in October 2019, and incorporates the recommendations made by a committee of the National Academy of Sciences (NAS). After making the changes recommended by the NAS, the NTP reconfirmed its conclusion that 'fluoride is presumed to be a cognitive neurodevelopmental hazard to humans.' (p. 2) …"

B. The Relationship Between Fluoride and Neurotoxic Effects Is Unlikely to Be Explained by Confounding or Other Issues of Methodology and Bias

"The NTP reached its hazard conclusion for fluoride after carefully considering issues of study quality and bias, including potential confounding, publication bias, translation bias, and the validity of exposure and outcome assessments. Each of these methodological issues were raised at trial by EPA to question the confidence in the numerous studies reporting neurotoxicity from fluoride exposure. Importantly, the NTP's report makes clear that none of the issues identified by EPA at trial warrant a downgrade in the confidence that fluoride is a human neurotoxicant. In other words, the issues identified by EPA at trial do not explain the overwhelmingly consistent association between fluoride and neurotoxic harm…"

C. The NTP Identified a Large Number of Low Risk-of-Bias Studies Linking Fluoride to Neurotoxicity

"… In total, the NTP identified 31 human studies on fluoride and neurodevelopment that it found to have a relatively low potential for bias (p. 25) and the vast majority of these studies found significant associations between fluoride and adverse effects. This highlights that the association between fluoride and neurotoxicity is not the artifact of poor study design or bias, as EPA argued at trial."

D. The NTP Has Judged the New Zealand Studies that EPA Has Relied Upon to Be at High Risk of Bias

E. The Animal Data Supports the Conclusion that Fluoride Produces Neurodevelopmental Effects

F. The NTP's Recently Retired Director Has Called for Measures to Protect Pregnant Women and Bottle-Fed Babies from the Neurotoxic Effects of Fluoride

"The relevance of the NTP's findings to water fluoridation has recently been highlighted by none other than the recently retired director of the NTP, Dr. Linda Birnbaum. On October 7,

2020, shortly after the NTP released its revised Monograph, Dr. Birnbaum issued a public statement calling for measures to protect pregnant women and bottle-fed babies from the neurotoxic effects of fluoride. Dr. Birnbaum noted that the NTP's conclusion is 'consequential,' given that "about 75 percent of Americans on community water systems have fluoride in their water.'…"

G. Limitations and Weaknesses of NTP's Report

"The NTP Monograph provides an exceptionally comprehensive review of the scientific literature on fluoride neurotoxicity, and provides ample support for its conclusion that fluoride is a neurotoxicant that reduces IQ. There are, however, some limitations and weaknesses with the NTP's analysis that Petitioners wish to bring to the EPA's attention…"

H. Even with Its Limitations, the NTP Monograph Demonstrates that Water Fluoridation Poses an Unreasonable Risk of Neurodevelopmental Harm

"Even with its limitations, the NTP Monograph demonstrates that neurotoxicity is an unreasonable risk of water fluoridation…"

4. Pooled BMD Analysis of the NIH-Funded Birth Cohort Data Confirms that Pregnant Women in Fluoridated Areas Are Exceeding the Dose Associated with IQ Loss

"A team of scientists, including the authors of the NIH-funded studies, have recently completed a pooled benchmark dose (BMD) analysis of the maternal urinary fluoride data from the ELEMENT and MIREC datasets (Grandjean, et al. 2020, in review)… Given that BMD analysis is EPA's preferred method for determining toxicity values and risk estimates, the new pooled analysis provides compelling grounds for EPA to reconsider its denial of the Petition. The analysis, which became publicly available on November 4, 2020, is attached as Appendix G…"

5. Millions of Americans Are at Risk of Harm as a Result of EPA's Failure to Regulate Fluoridation, Including Petitioners

"… Each year, there are approximately 2.5 million pregnancies in fluoridated areas; in utero exposures are thus widespread. (Appendix B at p. 78 ¶ 406.) Many of those exposed in utero will also be exposed during the sensitive neonatal period, with upwards of 1.9 million infants living in fluoridated areas being fed formula at least part of the time, including 400,000 infants who are exclusively formula-fed for their first six months. (Id.) Petitioner Organizations have members who fall within these zones of danger…"

6. EPA Erred in Considering the Purported Dental Benefits of Fluoridation in its Denial of the Petition

"In its denial of the Petition, EPA cited the purported dental benefits of fluoridation as a basis for its denial. This was improper because the Amended TSCA statute forbids risk evaluations from considering 'costs and other nonrisk factors.' 15 U.S.C. § 2620(b)(4)(B(ii). …"

7. EPA Erred in Claiming that Petitioners Failed to Adequately Identify the Chemicals at Issue

"… During the litigation on this matter, the Court considered and rejected each of these arguments, and held that the Petitioners had adequately identified the chemicals at issue, and that there was no merit to EPA's contention that it 'would become obligated to address all conditions of use of the category.'"

List of Documents submitted:

SUPPLEMENT: Petitioners' request to EPA to reconsider their denial of their original TSCA Petition of November 22, 2016. http://fluoridealert.org/wp-content/uploads/tsca.supplement.11-4-20.pdf

Appendix A: Excerpt of Court's August 10, 2020 Order. http://fluoridealert.org/wp-content/uploads/tsca.supplement.appendix-a.11-4-20.pdf

Appendix B: Petitioners' Summary of the Trial Record. Food & Water Watch, et al. v. U.S. Environmental Protection Agency Case No. 17-cv-02162. http://fluoridealert.org/wp-content/uploads/tsca.supplement.appendix-b.11-4-20.pdf

Appendix C: The NIH-funded Studies (Bashash et al. 2017 and 2018; Till et al. 2018 and 2020; Green et al. 2019). http://fluoridealert.org/wp-content/uploads/tsca.supplement.appendix-c.11-4-20.pdf

Appendix D: National Toxicology Program's Revised Monograph on Fluoride Neurotoxicity. http://fluoridealert.org/wp-content/uploads/tsca.supplement.appendix-d.11-4-20.pdf

Appendix E: Dr. Linda Birnbaum's Statement on the NTP Report. http://fluoridealert.org/wp-content/uploads/tsca.supplement.appendix-e.11-4-20.pdf

Appendix F: Additional Details on the Limitations of the NTP Review. http://fluoridealert.org/wp-content/uploads/tsca.supplement.appendix-f.11-4-20.pdf

Appendix G: Pooled BMD Analysis of the ELEMENT and MIREC Datasets. http://fluoridealert.org/wp-content/uploads/tsca.supplement.appendix-g.11-4-20.pdf

Appendix H: Undisputed Material Facts from Trial and Court's Ruling on Dental Benefits. http://fluoridealert.org/wp-content/uploads/tsca.supplement.appendix-h.11-4-20.pdf

Appendix I: The Court's Order Dismissing EPA's Order to Dismiss.
http://fluoridealert.org/wp-content/uploads/tsca.supplement.appendix-i.11-4-20.pdf

A. Most recent. The link to the actual court order is included and must be considered as evidence for the Board.

Federal Court Orders EPA to Regulate Fluoridation of Drinking Water under TSCA

Beveridge & Diamond | Oct 19, 2024 | By Mark N. Duvall

In a groundbreaking decision, a federal district court has ordered the U.S. Environmental Protection Agency (EPA) to regulate the "unreasonable risk" it found to be posed by the fluoridation of drinking water. The order came in the long-running case *Food & Water Watch, Inc. v. EPA*, No. 17-cv-02162-EMC, 2024 WL 4291497 (N.D. Cal. Sept. 24, 2024).

While the court did not specify what EPA must now do, its decision could significantly impact municipal drinking water systems and public health. Supported by the Centers for Disease Control and Prevention, EPA has permitted public water systems to fluoridate their drinking water as a critical measure to control tooth decay for decades. More than three-quarters of the U.S. population today gets their drinking water from fluoridated public sources.

The court order also has substantial implications for the regulated chemical industry and EPA's regulatory processes under the Toxic Substances Control Act (TSCA). This is the first instance of a court ordering EPA to "initiate a proceeding" under TSCA Section 6(a) in response to a citizen petition denied by EPA and subsequently appealed under Section 21 to a federal court. Both industry and the federal government have previously argued that Section 21 does not authorize a court to order *rulemaking* but rather a fact-gathering risk evaluation process akin to that normally required under TSCA for chemicals that EPA itself has identified as potentially presenting unreasonable risks under their conditions of use, in part because Section 21 requires a lower standard of evidence than is required of the usual risk evaluation process. A federal court has now implicitly disagreed with that argument, ordering that EPA "initiate rulemaking" to manage the risks it found to be posed by water fluoridation.

Background

EPA permits public drinking water systems to fluoridate drinking water up to certain levels under the Safe Drinking Water Act. EPA has established an enforceable maximum contaminant level (MCL) for fluoride in drinking water at 4.0 milligrams per liter (mg/L), effectively ensuring that community water systems limit fluoridation to levels that EPA has determined present no known or anticipated adverse effects on human health.

EPA has also set a "secondary" standard for fluoride at 2.0 mg/L or 2.0 ppm. Secondary standards are non-enforceable federal guidelines that address potential cosmetic effects (such as skin or tooth discoloration) or aesthetic effects (such as taste, odor, or color) in drinking water, which state or local governments may implement.

The U.S. Department of Health and Human Services (HHS) recommends the fluoridation of drinking water at 0.7 mg/L to achieve the benefits of preventing tooth decay.

Nevertheless, in 2016, a group of NGOs petitioned EPA under TSCA Section 21 to ban the fluoridation of drinking water entirely, arguing that fluoride has neurotoxic effects when ingested even at the "optimal" concentration identified by HHS and so presents an "unreasonable risk to human health."
EPA denied that petition in 2017, and, pursuant to Section 21, the NGOs appealed that denial to the federal district court for the Northern District of California. The district court judge in the case is Edward Chen, who previously had directed EPA to adopt a TSCA Section 8(a) reporting rule for asbestos in another case that contested EPA's denial of a Section 21 petition. *Asbestos Disease Awareness Org.* v. *EPA,* 508 F. Supp. 3d 707 (N.D. Cal. 2020).

In 2019, Judge Chen denied EPA's motion for summary judgment that had argued that the NGOs were required to comply with all requirements of both Section 6(b) (e.g., provide information equivalent to a risk evaluation) and Section 26 (e.g., provide information reflecting the weight of the scientific evidence). The court did so in part by citing that Sections 6(b) and 26 are not directly incorporated into Section 21, although their provisions may be looked to

for guidance. *Food & Water Watch, Inc. v. EPA*, No. 17-cv-02162-EMC, 2019 WL 8261655 (N.D. Cal. Dec. 30, 2019). Extensive discovery and a trial followed.

TSCA Proceedings

Under TSCA Section 21, any person may petition EPA to "initiate a proceeding" for the issuance, amendment, or repeal of a rule under Section 6(a). 15 U.S.C. § 2620(a). If EPA grants the petition, EPA must start an appropriate rulemaking process to consider the petitioner's requests. However, if EPA denies the petition—as it did here—it must publish a notice detailing the reasons for the denial. If EPA denies or does not respond to a petition within 90 days, then the petitioner may initiate a civil action in federal district court to compel EPA to "initiate a proceeding" for the requested rulemaking, if the court determines, without consideration of costs, that the subject chemical presents an unreasonable risk to human health or the environment under the conditions of use. The resulting rule under Section 6(a) could impose a variety of controls—ranging from a label warning to an outright ban—to manage the chemical's identified risks.

Since Congress substantially overhauled TSCA in 2016, it has not been clear what it would mean to "initiate a proceeding" for a Section 6(a) rule. The statute now generally requires prioritization and risk evaluation as critical predicates to rulemaking, and EPA's risk evaluations must be made according to the "weight of the scientific evidence" and "consistent with the best available science." 15 U.S.C. § 2625(h)-(i). However, under Section 21, a court only needs to decide whether the chemical substance presents an unreasonable risk "by a preponderance of the evidence," arguably a lesser scientific standard. 15 U.S.C. § 2620(b)(4)(B). Section 21 also only enables EPA and a specific petitioner or petitioners to present evidence, whereas the full risk evaluation process that would usually inform Section 6 rulemaking involves more than three years' worth of public participation and comment. Until now, no court had addressed whether a court ordering EPA to "initiate a proceeding" under Section 21 would require EPA to begin the full risk evaluation process or jump directly to rulemaking to manage those risks.

Without substantial analysis, Judge Edward Chen has now provided an answer. He found that the evidence suggests that HHS's "optimal" level of drinking water fluoridation—0.7 milligrams per liter, well below EPA's maximum and target concentrations—"poses an unreasonable risk of reduced IQ in children." The Court then ordered EPA to "initiate *rulemaking* pursuant to Subsection 6(a) of TSCA." Order at 2, 79 (emphasis added). Nevertheless, in a footnote, the Court left the door open for EPA to conduct additional analysis or seek additional information to "put a finer point on [the] risk posed by the condition of use before taking regulatory action." *Id.* at 67 n.33. Thus, it remains unclear to what extent EPA must now begin to draft regulations on the addition of fluoride to drinking water or may instead engage in the deliberative risk evaluation process.

Impacts and Next Steps

This order could significantly impact the chemical industry and municipal drinking water systems. If courts uphold that a TSCA Section 21 citizen's petition can be leveraged to force EPA to skip the statutory chemical prioritization and risk evaluation processes and jump directly to rulemaking, then EPA's chemical regulatory program could foreseeably be overwhelmed by competing priorities. Chemical manufacturers, processors, and users could also potentially face overbroad restrictions due to EPA's having to regulate certain chemicals on the basis of less (and potentially less comprehensive) information.

Drinking water utilities may also want to closely track this issue, which could significantly impact their operations.

Although the district court ordered EPA to initiate rulemaking to address the level of fluoride in drinking water, it remains to be seen what steps EPA will take next. The possibilities include, among others, that EPA will request more information from the public as part of the initiation of rulemaking; that it will appeal the case to the Ninth Circuit (including the district court's earlier ruling about the scope of Section 21); and that it will attempt to move the entire matter to the Office of Water under TSCA Section 9(b) on the basis that the risk

identified by the court “could be eliminated or reduced to a sufficient extent by actions taken under the authorities” of the Office of Water. Stay tuned.

Original article online at: https://natlawreview.com/article/federal-court-orders-epa-regulate-fluoridation-drinking-water-under-tsca

Sincerely,

Bill Osmunson DDS MPH

Washington Action for Safe Water

_____
From: bill teachingsmiles.com
Sent: 11/7/2024 8:01:10 AM
To: DOH WSBOH
Cc:
Subject: Public Comment for November and Supplement to #21 Petition for Rule Change

attachments\9D2C7B0C09284AB1_11 24 PC II.docx

External Email

Board of Health: Public Comment and Supplement to our Petition to protect the Public from Harm:
Bill Osmunson DDS MPH November 7, 2024
Washington Action for Safe Water
Money Marketing supports fluoridation. Science disagrees. Fluoridation harms fetuses, infants, children, youth and adults. Listen to RFK's 26 second interview.
C:\Users\14254\Downloads\Bobby NBC.mp4
Fluoridation hit the media with Trump saying he will ban fluoridation. Dictators do that. But dictators also force mass medication. The Board of Health should not be comatose on science until the President recommends stopping fluoridation.
The Board for 75 years has refused the science and laws on fluoridation's lack of benefit and harm and we have provided science for 18 years with 20 petitions to protect our most vulnerable for 14 years.
You do not have a single randomized controlled trial on the benefit of fluoridation.
You do not have a single safety study on fluoride's effect on the developing human brain, thyroid or any cell of the human body.
The National Toxicology Program did not report any safe dosage of fluoride.
The Court was clear, fluoridation is an unreasonable risk. And brain damage is only one risk.
The National Research Council 18 years ago listed about a dozen risks of concern and for 18 years the Board of Health has ignored all of them, failed to study the risks and harmed the developing brains, teeth, bones, thyroid glands, enzymatic system, kidneys, stomach, intestines, heart, and the mitochondria of every cell for most of one, actually three generations, without any warning or caution.
The Board relies on marketing and endorsements from those making the most money on products. Money can cause both conscious and subconscious bias and serious greed. In other words, money cherry picks the evidence, cherry picks reviewers of science, cherry picks authorities, and cherry picks conclusions. Money drives America and our Health Care.
I sold fluoride to patients and applied it to their teeth, thinking I was benefiting my patients. I treated and profited from split, cracked, fractured brittle teeth, not realizing too much fluoride had contributed to the harm. For dentists, fluoridation is a win, win for our bank accounts. And the Board trusts the Fluoridation profiteers for unbiased evidence? That's nonsense and is harming the public.
The Board's words matter, at least for those who trust the Board, such as city authorities.
My attempt in the past has been to find evidence which is concise and reasonably current. New Board members and growing evidence necessitates more inclusion of evidence from the NTP and Court.

The National Toxicology Program Report on Fluoride neurotoxicity.
In late 2015, I nominated fluoride for cancer, thyroid and developmental neurotoxicity for NTP to review. They accepted developmental neurotoxicity; however, both cancer and thyroid are almost as persuasive with scientific studies of harm and should be reviewed by NTP.
The following is a brief concise and accurate report of the NTP report.

1. A brief overview of the NTP report, the final report and some of the politics blocking the report until the court ordered the release. A very important read.

National Toxicology Program Finds No Safe Level of Fluoride in Drinking Water; Water Fluoridation Policy Threatened
<https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Ffluoridealert.org%2Fcontent%2Fn
toxicology-program-finds-no-safe-level-of-fluoride-in-drinking-water-water-fluoridation-policy-
threatened%2F&data=05%7C02%7CWSBOH%40SBOH.WA.GOV%7C2dfd15c624044a2f256208dcff44991f%

March 21, 2023 | Cheikhani
<https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Ffluoridealert.org%2Fauthor%2Fch

After a 6-year long systematic review of fluoride's impact on the developing brain, a court order has led to the National Toxicology Program (NTP) making public their finalized report
<https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fntp.niehs.nih.gov%2Fntp%2Fabou
that was blocked
<https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Ffluoridealert.org%2Farticles%2Fnt
will-make-blocked-neurotoxicity-report-public-after-fan-legal-action%2F&data=05%7C02%7CWSBOH%40SBOH.WA.GOV%7C2dfd15c624044a2f256208dcff44991f%7C1
by US Department of Health and Human Services (HHS) leadership and concealed from the public for the past 10 months. The NTP reported 52 of 55 studies found decreases in child IQ associated with increase in fluoride, a remarkable 95% consistency. The NTP's report says:
"Our meta-analysis confirms results of previous meta-analyses and extends them by including newer, more precise studies with individual-level exposure measures. The data support a consistent inverse association between fluoride exposure and children's IQ."
A meta-analysis is when information from all the relevant studies are combined to get a fuller and unbiased overall picture, rather than just looking at individual studies in isolation.
The NTP's meta-analysis also put the magnitude of harm into perspective:
"[R]esearch on other neurotoxicants has shown that subtle shifts in IQ at the population level can have a profound impact on the number of people who fall within the high and low ranges of the population's IQ distribution. For example, a 5-point decrease in a population's IQ would nearly double the number of people classified as intellectually disabled."
So, while an average drop of 5 IQ points in a population might sound small it is huge from a public health perspective. Furthermore, the NTP acknowledged there was the potential for some people to be more susceptible than average, so those people could lose much more than 5 IQ points. Those susceptible individuals could lose 10, 15, 20 or more IQ points which would likely cause profound lifetime negative consequences.
The five independent peer-reviewers of the NTP report all voted to accept the review's main conclusion and lauded the report. Their comments include: "what you have done is state-of-the-art"; "the analysis itself is excellent, and you thoroughly addressed comments"; "Well done!"; "Findings… were interpreted objectively".
The newly released documents include comments from the NTP's own experts confirming that the report's conclusion that fluoride can lower IQ
<https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Ffluoridealert.org%2Farticles%2Fsu
government-report-finding-fluoride-can-reduce-childrens-iq-made-public-under-epa-lawsuit%2F&data=05%7C02%7CWSBOH%40SBOH.WA.GOV%7C2dfd15c624044a2f256208dcff44991f%7C
does apply to communities with water fluoridation programs. NTP report says the evidence is not just in those who drink water with higher fluoride concentrations exceeding the World Health Organization (WHO) recommended maximum level of 1.5 mg/L. Furthermore, the WHO guideline was set in 1984 to protect against more severe forms of dental fluorosis and neurotoxicity was never considered. Few neurotoxicity

studies even existed in 1984.
In numerous responses to comments by reviewers of the report, the NTP made clear that they had found evidence that exposures of at least some people in areas with fluoridated water at 0.7 mg/L were associated with lower child IQ.
For example, when an unnamed government fluoridation proponent claimed:
"The data do not support the assertion of an effect below 1.5 mg/L…all conclusory statements in this document should be explicit that any findings from the included studies only apply to water fluoride concentrations above 1.5 mg/L."
The NTP responded:
"We do not agree with this comment…our assessment considers fluoride exposures from all sources, not just water…because fluoride is also found in certain foods, dental products, some pharmaceuticals, and other sources… Even in the optimally fluoridated cities…individual exposure levels…suggest widely varying total exposures from water combined with fluoride from other sources."
Additional NTP responses about the review's relevance to water fluoridation programs:
"We have no basis on which to state that our findings are not relevant to some children or pregnant people in the United States."
"Several of the highest quality studies showing lower IQs in children were done in optimally fluoridated (0.7 mg/L) areas…many urinary fluoride measurements exceed those that would be expected from consuming water that contains fluoride at 1.5 mg/L."
The NTP also responded to commenters asking whether their meta-analysis had identified any safe exposure threshold, below which there would be no loss of IQ.
The NTP responded that they found "no obvious threshold" for either total fluoride exposure or water fluoride exposure, referring to a graph in the meta-analysis (NTP's eFigure 17 reproduced below) showing that as water fluoride concentration increased from 0.0 to 1.5 mg/L there was a steep drop in IQ of about 7 points (expressed as "standardized mean difference" units in the graphs). An external peer-reviewer commented on the size of the IQ loss:
"Wow … that is substantial … That's a big deal." {p 1060}
The graph uses standardized mean difference (SMD) units where each -1.0 SMD is equivalent to about -15 IQ points.
In the left-hand graph each circle represents a study. Several have mean water fluoride below 1.5 mg/L. The right-hand graph shows the relationship between fluoride concentration and loss of IQ when all the studies are pooled. This analysis, based on many studies, is strong evidence that fluoride is associated with a substantial loss of IQ at levels of exposure common in people drinking artificially fluoridated water, and there is no observable threshold indicating a "safe" dose.
The NTP's experts further stated that the science showing neurotoxic harm "is a large, consistent and growing database."
Overall, the report provides strong evidence that fluoride is associated with a substantial loss of IQ at levels of exposure common in people drinking fluoridated water.
STAY TUNED! We will be sending out additional bulletins on the NTP report in the coming days.
PLEASE SHARE THIS BULLETIN WITH YOUR LOCAL MEDIA OUTLETS.
See our other press releases on the NTP report below:
March 15: Suppressed Government Report Finding Fluoride Can Reduce Children's IQ Made Public Under EPA Lawsuit
<https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Ffluoridealert.org%2Farticles%2Fsu
government-report-finding-fluoride-can-reduce-childrens-iq-made-public-under-epa-lawsuit%2F&data=05%7C02%7CWSBOH%40SBOH.WA.GOV%7C2dfd15c624044a2f256208dcff44991f%7C

2. The EPA Lawsuit under the Toxic Substance Control Act (This data is provided by FAN and appropriately referenced.

The report of the court proceedings below is followed by earlier evidence. If you must cut to the chase, be sure to read The Judgment <https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Ffluoridealert.org%2Fkey-topics%2Fepa-lawsuit%2F%23judgement&data=05%7C02%7CWSBOH%40SBOH.WA.GOV%7C2dfd15c624044a2f256208

EPA Lawsuit

The First Fluoride Trial (June 2020) <https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Ffluoridealert.org%2Fkey-topics%2Fepa-lawsuit%2F%23june-2020&data=05%7C02%7CWSBOH%40SBOH.WA.GOV%7C2dfd15c624044a2f256208dcff44991f%7C11d0e

Justice Delayed (2020-2024) <https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Ffluoridealert.org%2Fkey-topics%2Fepa-lawsuit%2F%23justice-2020-2024&data=05%7C02%7CWSBOH%40SBOH.WA.GOV%7C2dfd15c624044a2f256208dcff44991f%7C11d0e

The Second Fluoride Trial (February 2024) <https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Ffluoridealert.org%2Fkey-topics%2Fepa-lawsuit%2F%23february-2024&data=05%7C02%7CWSBOH%40SBOH.WA.GOV%7C2dfd15c624044a2f256208dcff44991f%7C11d0e

The Judgment <https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Ffluoridealert.org%2Fkey-topics%2Fepa-lawsuit%2F%23judgement&data=05%7C02%7CWSBOH%40SBOH.WA.GOV%7C2dfd15c624044a2f256208

Under the Toxic Substances Control Act (TSCA) of 1976, a group of non-profits and individuals petitioned the U.S. Environmental Protection Agency (EPA) in 2016 to end the addition of fluoridation chemicals into U.S. drinking water due to fluoride's neurotoxicity. The EPA rejected the petition. In response the groups sued the EPA in Federal Court in 2017. Evidence on fluoride’s neurotoxicity was heard by the Court in two phases: a 7-day trial in June 2020, and a 14-day trial in February 2024. As of May 2024, a judgment from the court has yet to be rendered.

Official Court link: Food and Water Watch et al. v. United States Environmental Protection Agency et al. <https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.cand.uscourts.gov%2Ffood-and-water-watch-v-us-epa%2F&data=05%7C02%7CWSBOH%40SBOH.WA.GOV%7C2dfd15c624044a2f256208dcff44991f%7C11d

The Petition
In 2017, Dr. Paul Connett PhD and Dr. Bill Hirzy PhD, on behalf of the Fluoride Action Network (FAN), Food and Water Watch (FWW), Moms Against Fluoridation (MAF), as well as several individuals, served the EPA with a petition <https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Ffluoridealert.org%2Fwp-content%2Fuploads%2Fepa-petition.pdf&data=05%7C02%7CWSBOH%40SBOH.WA.GOV%7C2dfd15c624044a2f256208dcff44991f%7C
calling on the agency to ban the addition of fluoridation chemicals to public water supplies due to the risks these chemicals pose to the brain.

The Petition was submitted under Section 21 of the Toxic Substances Control Act (TSCA) because it authorizes EPA to prohibit the "particular use" of a chemical that presents an unreasonable risk to the general public or susceptible subpopulations. TSCA also gives EPA the authority to prohibit drinking water additives.

The Initial Hearings

EPA denied <https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.federalregister.gov%2Fdocu 03829%2Ffluoride-chemicals-in-drinking-water-tsca-section-21-petition-reasons-for-agency-response&data=05%7C02%7CWSBOH%40SBOH.WA.GOV%7C2dfd15c624044a2f256208dcff44991f%7C11 the petition on February 27, 2017, claiming that: "The petition has not set forth a scientifically defensible basis to conclude that any persons have suffered neurotoxic harm as a result of exposure to fluoride in the U.S. through the purposeful addition of fluoridation chemicals to drinking water or otherwise from fluoride exposure in the U.S."

FAN and other plaintiffs then sued <https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Ffluoridealert.org%2Fwp-content%2Fuploads%2Flawsuit.complaint.4-18-17.pdf&data=05%7C02%7CWSBOH%40SBOH.WA.GOV%7C2dfd15c624044a2f256208dcff44991f%7C11d0 the EPA and won a series <https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Ffluoridealert.org%2Fresearchers% trial%2Fthe-timeline%2F&data=05%7C02%7CWSBOH%40SBOH.WA.GOV%7C2dfd15c624044a2f256208dcff44991f%7C of favorable court hearings in 2017 and 2018 on plaintiff's standing and trial discovery, while defeating several motions by EPA attempting to dismiss the case.

In late 2019 both FAN and EPA submitted motions for summary judgment in the case in the hopes that the judge would rule on the evidence submitted to the court without the need for a lengthy trial. On December 30, 2019 the Court released its order <https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Ffluoridealert.org%2Fwp-content%2Fuploads%2Ftsca.court-order.dec-30-2019.pdf&data=05%7C02%7CWSBOH%40SBOH.WA.GOV%7C2dfd15c624044a2f256208dcff44991f%7C11 denying both plaintiffs' and defendant's motions for summary judgment. This means that our case will go forward. Trial is scheduled for two weeks beginning April 20, 2020 and will run for two weeks.

Attorney Michael Connett: "this is the first time in its 43-year history that citizens have been able to successfully bring a suit to court under provisions in TSCA"

Pre-Trial

On March 17, 2020 the Court postponed the April 2020 fluoride lawsuit trial dates due to the coronavirus outbreak. The trial will now be held June 8-19 by Zoom webinar (instead of in person at the courtroom).

In a May 2020 pre-trial hearing, the Court cleared the way for three international experts in neurotoxicity (Dr. Howard Hu, Dr. Philippe Grandjean, and Dr. Bruce Lanphear) to testify on the risks of fluoride in public water supplies on behalf of the plaintiffs. The court also ruled that the purported benefits of community water fluoridation cannot be part of the trial, restricting testimony to the toxic risks under the Toxic Substances Control Act (TSCA) Read the May 2020 trial declarations from our 4 witnesses:

Philippe Grandjean, MD, PhD <https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Ffluoridealert.org%2Fwp-content%2Fuploads%2FEPA-trial-Grandjean-Declaration.pdf&data=05%7C02%7CWSBOH%40SBOH.WA.GOV%7C2dfd15c624044a2f256208dcff44991f%

Howard Hu, MD, MPH, ScD <https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Ffluoridealert.org%2Fwp-content%2Fuploads%2FEPA-trial-Hu-Declaration.pdf&data=05%7C02%7CWSBOH%40SBOH.WA.GOV%7C2dfd15c624044a2f256208dcff44991f%

Bruce Lanphear, MD, MPH
<https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Ffluoridealert.org%2Fwp-content%2Fuploads%2FEPA-trial-Lanphear-declaration.pdf&data=05%7C02%7CWSBOH%40SBOH.WA.GOV%7C2dfd15c624044a2f256208dcff44991f%

Kathleen Thiessen, PhD
<https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Ffluoridealert.org%2Fwp-content%2Fuploads%2FEPA-trial-Thiessen-Declaration.pdf&data=05%7C02%7CWSBOH%40SBOH.WA.GOV%7C2dfd15c624044a2f256208dcff44991f%

The First Fluoride Trial (June 8 - 19, 2020)
The first trial in the TSCA fluoride lawsuit took place in June 2020 over Zoom webinar. The trial lasted two weeks and featured testimony from FAN's expert witnesses (Drs Hu, Lanphear, Grandjean, and Thiessen) who are subject matter experts on developmental neurotoxicity and risk assessment, pitted against EPA's witnesses.

Shockingly, EPA did not rely on its own agency experts to defend its position that fluoride is not neurotoxic to humans. Instead it hired an outside consulting company, Exponent, a firm deployed by corporations to deny and downplay the health impacts of chemicals in litigation. Exponent experts attempted to cast doubt on fluoride's neurotoxic effects even as the EPA's own scientists, under subpoena by the plaintiffs, said new research does indeed warrant "an update to the fluoride assessment".
"I think it's a reason for doing an update to the fluoride assessment" - Dr. Joyce Donohue, EPA Office of Water, on recent NIH-funded studies showing fluoride harms the developing brain.
FAN attorney, Michael Connett
<https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.sirillp.com%2Fprofile%2Fmic
connett%2F&data=05%7C02%7CWSBOH%40SBOH.WA.GOV%7C2dfd15c624044a2f256208dcff44991f%7C
, gave the opening statement in the trial - a summary of the case that fluoride presents a neurotoxic hazard (a threat to the brain); that this hazard is a risk at doses experienced in fluoridated communities (.7ppm); and that this risk is an "unreasonable risk" as defined by TSCA. The EPA is represented by lawyers from the Department of Justice (DOJ). The DOJ argued in their opening statement that establishing fluoride as a neurotoxic hazard requires a systematic review and without that, FAN's case falls.

The first fact witness
<https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Ffluoridealert.org%2Fcontent%2Fth
tsca-trial-day-1-june-8-2020%2F%3FeType%3DEmailBlastContent%26eId%3Dd2727b36-379f-4a5a-835c-f8ed8c91c5e0&data=05%7C02%7CWSBOH%40SBOH.WA.GOV%7C2dfd15c624044a2f256208dcff44991f%
called by the plaintiffs (FAN) was Dr. Joyce Donohue who has worked in the EPA's Office of Water since the 1996 and has been their spokesperson on fluoride. Her testimony in the trial was based on a video recording of her deposition in 2019. From this deposition our attorney was able to yield two key concessions:

a) The EPA as of 2019 had no studies to provide a pregnant woman to show her fetus was safe from neurotoxicity. In fact the EPA only had studies showing harm to the fetus.

b) Dr. Donohue recommends EPA and other regulatory bodies do risk assessments of fluoride with neurotoxicity as an end point. All EPA risk assessments on fluoride to date have been based on potential damage to teeth and bones.

FAN's first expert witness
<https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Ffluoridealert.org%2Fcontent%2Fth
tsca-trial-day-1-june-8-2020%2F%3FeType%3DEmailBlastContent%26eId%3Dd2727b36-379f-4a5a-835c-f8ed8c91c5e0&data=05%7C02%7CWSBOH%40SBOH.WA.GOV%7C2dfd15c624044a2f256208dcff44991f%
called was Dr. Howard Hu, MD, MPH, ScD, the lead author on a series of key NIH-funded

research papers on fluoride and developmental neurotoxicity. Hu's credentials are very impressive. Dr. Hu came across as knowledgeable and credible and was able to summarize the importance of his research, stressing the importance of a loss of 3 or 4 IQ points at the population level while drawing a striking parallel to lead's neurotoxicity.
FAN's second expert witness <https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Ffluoridealert.org%2Fwp-content%2Fuploads%2FEPA-trial-Grandjean-Declaration.pdf%3FeType%3DEmailBlastContent%26eId%3Dd2727b36-379f-4a5a-835c-f8ed8c91c5e0%26eType%3DEmailBlastContent%26eId%3D492bbd66-0721-4212-a207-8c2a94d3d2a4&data=05%7C02%7CWSBOH%40SBOH.WA.GOV%7C2dfd15c624044a2f256208dcff44991f%, Danish scientist and neurotoxicity expert Philippe Grandjean, MD, DMSc, <https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Ffluoridealert.org%2Fwp-content%2Fuploads%2FEPA-trial-Grandjean-Declaration.pdf%3FeType%3DEmailBlastContent%26eId%3Dd2727b36-379f-4a5a-835c-f8ed8c91c5e0%26eType%3DEmailBlastContent%26eId%3D492bbd66-0721-4212-a207-8c2a94d3d2a4&data=05%7C02%7CWSBOH%40SBOH.WA.GOV%7C2dfd15c624044a2f256208dcff44991f% took the stand on day two. Grandjean is the author of the book Only One Chance, <https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fglobal.oup.com%2Facademic%2F one-chance-9780190239732%3Fcc%3Dus%26lang%3Den%26&data=05%7C02%7CWSBOH%40SBOH.WA.GOV%7C2 in which he warns of the dangers of exposing children to neurotoxicants during early development, especially during the fetal stage. According to many who watched his testimony, Dr. Grandjean left no doubt that fluoridation poses a threat to the brains of children and easily debunked the EPA's paid experts' arguments.

FAN asked Dr. Grandjean to do a review of the literature since his famous 2012 meta-analysis <https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Ffluoridealert.org%2Fstudytracker% to include the most recent US government-funded studies. Grandjean did this review but he went one step further and quantified the risk of IQ loss from fluoride to children based upon the Bashash 2017 <https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Ffluoridealert.org%2Fstudytracker% and the Green 2019 <https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Ffluoridealert.org%2Fstudytracker% (Canadian study) mother-offspring studies. For this analysis Grandjean did what is called a Benchmark Dose study (using methods that he and his colleagues have pioneered, and used by the EPA). He concluded that a safe reference dose (RfD) be no higher than 0.15 mg per day to protect against a loss of one IQ point. This is well below fluoride exposure levels experienced by pregnant women (and passed to the fetus) in the Bashash and Green studies.
FAN's next expert witness <https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Ffluoridealert.org%2Fcontent%2Fb 11-20%2F&data=05%7C02%7CWSBOH%40SBOH.WA.GOV%7C2dfd15c624044a2f256208dcff44991f%7C11d0 was renowned clinical scientist and professor, Dr. Bruce Lanphear… who's work on lead….. Dr. Lanphear explained that there was no safe level of fluoride exposure with regard to neurotoxicity, and that the effects seen in recent studies are "equal to what we saw with lead in children."
Next the court watched the deposition video of CDC Oral Health Division Director, Casey Hannan, who confirmed his agency agreed with the National Research Council's 2006 findings that fluorides "interfere with the function of the brain and body by direct and indirect means," among many other stunning admissions, yet did nothing to act upon or study these findings.
Next up in the trial was fact witness Dr. Kristina Thayer, Director of the US EPA's Chemical and Pollutant Assessment Division. Dr. Thayer confirmed the vulnerability of the developing brain to environmental toxins as well as fluoride's known neurotoxicity "at some level."

The next expert witness was veteran risk assessment scientist Kathleen Thiessen, PhD, who was a member of the 2006 NRC committee <https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Ffluoridealert.org%2Fresearchers%
362c-43c4-88e0-
17ad6dcf6c18&data=05%7C02%7CWSBOH%40SBOH.WA.GOV%7C2dfd15c624044a2f256208dcff44991f%
that reviewed fluoride, and authored around a third of the report. Dr. Thiessen confirmed that the EPA was ignoring the neurotoxic risk from fluoridation because doing so would require them to effectively ban the practice. She also compared the amount of evidence of neurotoxicity from fluoride to other toxins the EPA currently did regulate as neurotoxic, saying "the amount of evidence for fluoride is considerably larger."
The EPA then called their first expert witness, Dr. Joyce Tsuji, PhD from corporate consulting firm Exponent. This is the same scientists-for-hire firm the tobacco industry used to deny lung cancer risk <https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fbusiness-ethics.com%2F2016%2F12%2F13%2F1724-big-companies-in-legal-scrapes-turn-to-science-for-hire-giant-
exponent%2F%3FeType%3DEmailBlastContent%26eId%3Dc452729b-dd53-4386-aa0c-
a6f814bc35aa&data=05%7C02%7CWSBOH%40SBOH.WA.GOV%7C2dfd15c624044a2f256208dcff44991f%
. Dr. Tsuji's answers repeatedly contradicted the testimony from her pre-trial deposition. Eventually FAN attorney Michael Connett was able to get Dr. Tsuji to admit on the stand that "there is enough literature for us to be concerned" about fluoride's neurotoxicity.

The EPA then called their second expert witness, Dr. Ellen Chang (also from Exponent), to discuss the human fluoride/IQ studies. She spent much of her time attacking the quality of the studies linking fluoride to lowered IQ. FAN attorney Michael Connett was successful in exposing Dr. Chang's blatant bias and, in a defining moment at trial, was able to get her to admit that the fluoride/IQ studies from Till (2020), Green (2019), and Bashash (2017) were the most rigorous neurotoxicity studies to date.

Next up was Dr Tala Henry, Director of the EPA's Risk Assessment Division, who has 25 years of risk assessment experience at the agency. Her testimony focused on the many hurdles presented to those who attempt a risk assessment and risk evaluation of a chemical. FAN's attorney Michael Connett dealt a destructive blow to Dr. Henry during cross-examination came when he asked: "you held the plaintiffs to a burden of proof that EPA has not held a single chemical under section 6 [of the Toxic Substances Control Act] before, correct?". Henry replied, "by the words on the page, I guess that's true". The EPA closed its case with a short video segment of Dr. Joyce Donohue, the predominant fluoride expert in the EPA's Office of Water. If anything, this video strengthened our case and did not weaken it.

The last day of trial featured a dramatic moment, as the federal judge surprised everyone by recognizing the key plank in our case, undermining the key argument in the EPA's case. The judge said:
"So much has changed since the petition was filed…two significant series of studies – respective cohort studies – which everybody agrees is the best methodology. Everybody agrees that these were rigorous studies and everybody agrees that these studies would be part of the best available scientific evidence."
The EPA appears to have applied a standard of causation, which from my read of TSCA is not accurate. It's not a proper allocation. It's not the proper standard.'

After closing statements, Judge Chen shared his views on the case and made recommendations. Chen asked the parties whether they could discuss the possibility of an amended petition and re-assessment by the EPA, or start a new petition and have the EPA conduct a proper review. To many observers, it felt as though Chen was intimating that FAN had essentially won the case, but he was giving the EPA a chance to right their original wrongs.

The ending of the first fluoride trial was somewhat unexpected as the judge asked the

two parties to work out an agreement. The Court specifically urged the EPA to independently re-assess the hazard posed by fluoridation chemicals and the Judge assigned August 6, 2020 for a status hearing to reconnect with the two sides. When the parties met on August 6, EPA claimed that they "didn't have the resources to do a risk assessment," and were going to let the court record stand without taking any further action. The judge continued to insist the EPA reconsider their position, and also said he wanted to review the updated National Toxicology Program's (NTP) review of fluoride's neurotoxicity, which was due to be released soon.

In August 2020, the Court placed the case in abeyance (on hold) in part to consider the pending findings from the pending NTP report on fluoride neurotoxicity.

Justice Delayed

The Court requested on the last day of the trial that FAN submit a new petition to the EPA to allow them another 90-day opportunity to respond to our original 2016 petition with the addition of all the new studies on fluoride neurotoxicity published between 2017-2020. The Court also requested that FAN include petitioners who were pregnant or planning a pregnancy in light of the science linking early-life exposure to fluoridated water to adverse neurodevelopmental effects in these new studies.

On November 4, 2020, FAN filed a supplement <https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Ffluoridealert.org%2Fwp-content%2Fuploads%2Ftsca.supplement.11-4-20.pdf%3FeType%3DEmailBlastContent%26eId%3D628cf9ee-6fd1-471d-a1a2-d986dbfe943e&data=05%7C02%7CWSBOH%40SBOH.WA.GOV%7C2dfd15c624044a2f256208dcff44991f%
to our original petition to the EPA. The supplement asked that EPA reconsider their denial of our 2016 Petition. The supplement has done everything the Court asked us to do with a new petition. The supplement also responds to the issue of standing by identifying nine members of Food & Water Watch "who are currently pregnant, women who are actively seeking to become pregnant, and/or mothers of infants".

In December 2020, the EPA filed a last ditch motion to attempt to dismiss our landmark case, arguing that plaintiffs lacked standing; a motion they had previously made and were denied. The Court denied <https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Ffluoridealert.org%2Fwp-content%2Fuploads%2Ftsca.court-order.jan-13-2021.pdf&data=05%7C02%7CWSBOH%40SBOH.WA.GOV%7C2dfd15c624044a2f256208dcff44991f%7C11
the EPA motion as being premature and procedurally improper. The trial will continue, in abeyance, as the Court awaits the EPA's response to FAN's updated petition and an updated draft of the National Toxicology Programs (NTP) monograph on fluoride's neurotoxicity, expected early in 2021.

In January 2021, the EPA denies FAN's supplemental petition, setting the stage for additional hearings and filings in the TSCA fluoride lawsuit. An April 2021 status hearing with the Court focused on FAN's amended petition to the EPA, which the Judge recommended before he placed the trial in abeyance. The amended version has a more detailed list of plaintiffs and includes recent studies that were not a part of the trial. The Court grants <https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Ffluoridealert.org%2Fwp-content%2Fuploads%2Ftsca-court-order.may-11-2021.pdf&data=05%7C02%7CWSBOH%40SBOH.WA.GOV%7C2dfd15c624044a2f256208dcff44991f%7C11
FAN's motion to supplement our pleadings to introduce additional evidence on standing, which should satisfy the Judge's prior concerns on this issue and ensure that the case is resolved on the merits.

The Judge reiterates that he is keen to read the NTP's finalized report on fluoride's neurotoxicity as well as other new science on the issue, including an upcoming pooled analysis of the NIH-funded birth cohort studies. To consider this new science, the Judge discussed having a "phase 2 trial" where Plaintiffs and EPA can introduce additional

expert testimony on the NTP report and other developments. In June 2021, FAN attorney Michael Connett informs the Court of a new landmark study <https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Ffluoridealert.org%2Fstudytracker% by Grandjean et al., confirming that very low levels of fluoride exposure during pregnancy impairs the brain development of the child. The paper's authors concluded in the Benchmark Dose (BMD) analysis that a maternal urine fluoride concentration of 0.2mg/L was enough to lower IQ by 1 point. The judge was waiting to see this analysis as well as the final version of the NTP review before moving forward with the case.

In a January 2022 status hearing, the Judge reiterates his desire to wait until the NTP publishes the final version of their review on fluoride's neurotoxicity before continuing with the trial. The NTP report had been delayed, with speculation <https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Ffluoridealert.org%2Fcontent%2Fb 19-
21%2F&data=05%7C02%7CWSBOH%40SBOH.WA.GOV%7C2dfd15c624044a2f256208dcff44991f%7C11d0 brewing that dental interests were actively influencing the report's final publication.

In September 2022, FAN filed <https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Ffluoridealert.org%2Fwp-content%2Fuploads%2Ftsca-plaintiffs.motion-to-lift-stay.sept-12-2022.pdf&data=05%7C02%7CWSBOH%40SBOH.WA.GOV%7C2dfd15c624044a2f256208dcff44991f%7C11 a motion to lift the pause on the trial in response to the indefinite postponement of the NTP fluoride review. The final publication of the NTP review was expected at the end of 2021, then promised again in early 2022, with May 2022 being the long-awaited release date. May 2022 came and went without any sign of the NTP report.

In October 2022, FAN attorney Michael Connett introduced evidence from Freedom of Information Act (FOIA) documents showing that political pressures had prevented NTP from releasing its long-delayed report [link to new NTP page]. The Court promptly granted <https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Ffluoridealert.org%2Fwp-content%2Fuploads%2Ftsca-court-order.abeyance-lifted.oct-28-2022.pdf&data=05%7C02%7CWSBOH%40SBOH.WA.GOV%7C2dfd15c624044a2f256208dcff44991f%7C11 our motion to lift the stay on the trial and permit additional discovery into the NTP review.

EPA's objections to using any version of the NTP report besides the "final" version during the trial was based on their concern that the NTP's findings would be made public prematurely. To circumvent this objection, the Court placed the NTP's review under protective order so that it was only made available to the parties involved, the Court, and expert witnesses. The Court urged both parties to come together and find a way to get the current NTP review into the Court's hands "voluntarily," while also leaving the door open for FAN attorney Michael Connett to use "subpoenas or a motion to compel," the release of the long-delayed report.

In December 2022, after extensive negotiations, the Department of Justice (DOJ) agreed to produce <https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Ffluoridealert.org%2Fwp-content%2Fuploads%2Ftsca.plaintiffs-filed-redacted-notice.12-15-22.pdf&data=05%7C02%7CWSBOH%40SBOH.WA.GOV%7C2dfd15c624044a2f256208dcff44991f%7C11d0 a copy of NTP's suppressed report on fluoride. The report is produced under a strict protective order.
FAN Attorney Michael Connett shared with the Court FAN's desire to see the final NTP review from May 2022 available to the public, as well as the communications and criticisms from the CDC and HHS that led to it being blocked. Connett pointed out that FAN had evidence obtained through FOIA requests showing that the American Dental Association (ADA) was already given the NTP review so they could work to discredit it, and therefore there is no justifiable reason for the EPA to continue hiding it from the

public.

In January 2023 the Court ruled against EPA's request for additional delay of the trial, acknowledging that "justice delayed is justice denied". The Court sets a timeline for the final phase leading to a verdict.

In February 2023, after being served a subpoena <https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Ffluoridealert.org%2Fwp-content%2Fuploads%2F2023_02_14_Order-re-NTP-BSC-Materials.pdf&data=05%7C02%7CWSBOH%40SBOH.WA.GOV%7C2dfd15c624044a2f256208dcff44991f%7 by our attorneys, the NTP agreed to publicly produce their final report that was intended to be published in May of 2022, along with communications between various federal agencies and the NTP about the report. This allows the public to finally see the report and accompanying documents that were blocked from being published by the leadership at U.S. Health and Human Services (HHS) in May of 2022. Internal CDC emails discovered through FOIA by FAN show that the publication was blocked <https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Ffluoridealert.org%2Fcontent%2Ff emails-expose-fluoridation-promoters%2F&data=05%7C02%7CWSBOH%40SBOH.WA.GOV%7C2dfd15c624044a2f256208dcff44991f% at the last second due to interference <https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Ffluoridealert.org%2Fwp-content%2Fuploads%2FPlainitffs-Opp-Brief_FILED.pdf&data=05%7C02%7CWSBOH%40SBOH.WA.GOV%7C2dfd15c624044a2f256208dcff44991f from Assistant Health Secretary, Rachel Levine.
The NTP fluoride review was issued <https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Ffluoridealert.org%2Fcontent%2Fs government-report-finding-fluoride-can-reduce-childrens-iq-made-public-under-epa-lawsuit%2F&data=05%7C02%7CWSBOH%40SBOH.WA.GOV%7C2dfd15c624044a2f256208dcff44991f%7C in two parts, a monograph and a meta-analysis. The meta-analysis found that 52 of 55 studies found lower IQ with higher fluoride exposures, demonstrating remarkable consistency <https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Ffluoridealert.org%2Fcontent%2Fg report-finds-no-safe-level-of-fluoride-in-water-fluoridation-policy-threatened%2F&data=05%7C02%7CWSBOH%40SBOH.WA.GOV%7C2dfd15c624044a2f256208dcff44991f% . Of the 19 studies rated higher quality, 18 found lowering of IQ. The meta-analysis could not detect any safe exposure, including at levels common from drinking artificially fluoridated water.

In March 2023 the Court denied EPA's motion to prevent FAN from conducting depositions into the suppression of the NTP report. Dates are set for the final phase of the TSCA fluoride lawsuit - January 29 thru February 13, 2024.

FAN learned at an October 2023 status hearing the start date for the last phase of our fluoride trial would be pushed back two days to January 31st, 2024. The expiration of the CARES Act means that our attorneys will present live, in-person from the federal courthouse in San Francisco during the second phase of the trial. The trial will be live streamed on Zoom for the public to view.

In a January 2024 pre-trial hearing, FAN attorney Michael Connett introduced evidence <https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Ffluoridealert.org%2Fcontent%2Fe witness-lied-under-oath%2F&data=05%7C02%7CWSBOH%40SBOH.WA.GOV%7C2dfd15c624044a2f256208dcff44991f%7C11 that key a EPA witness lied under oath.
The Second Fluoride Trial (January 31 – February 20, 2024)
The second trial in the TSCA fluoride lawsuit took place January 31 – February 13, 2024, at the Federal Courthouse in San Francisco and was live-streamed on Zoom. The trial lasted two weeks and featured testimony from the same FAN expert witnesses seen in the first fluoride trial – Drs. Hu, Lanphear, Grandjean, and Thiessen.

Central to the crux of the case, Connett focused on EPA's admittance that they did not use the appropriate EPA guidelines in their risk evaluation of fluoride and did not follow the Toxic Substances Control Act (TSCA) statutes when evaluating whether fluoride posed an unreasonable risk to the developing brain. Not only did EPA fail to follow TSCA and agency risk assessment rules, but they went further by admitting that they held fluoride to a higher standard than any other chemical. This included the EPA's insistence in discounting high-dose fluoride studies, while EPA has never disregarded higher-dose studies when identifying a hazard with any other chemical.

Connett also honed in on the National Toxicology Program's (NTP) systematic review of fluoride neurotoxicity <https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Ffluoridealert.org%2Fcontent%2Fn toxicology-program-finds-no-safe-level-of-fluoride-in-drinking-water-water-fluoridation-policy-threatened%2F&data=05%7C02%7CWSBOH%40SBOH.WA.GOV%7C2dfd15c624044a2f256208dcff44991f% , and a large body of animal data showing brain harm from fluoride. The NTP review found a large number of studies have been published on fluoride and human IQ. In total they identified 72 human studies of which 64 found a connection between fluoride and IQ deficits. 18 of the 19 studies deemed high quality found that fluoride lowered IQ, a 95% consistency. Connett flagged recent research relied upon by EPA that did not find neurotoxic effects from fetal fluoride exposures as deeply suspicious. He said the authors of these studies were long-time promoters of water fluoridation, compared to FAN expert witnesses, who have all worked with the EPA and have been relied upon as experts on the regulation of environmental toxins by governments around the world and are subject-matter experts on fluoride.

Connett discussed how the exposure level at which a chemical presents a risk for toxic effects (a threshold level) varies substantially across the human population, but the point of a regulatory action is to protect the most vulnerable people in the population. Connett stressed to the Court that "TSCA commands us to protect the vulnerable". Connett then wrapped up by pointing out that roughly two million pregnant women and 400,000 formula-fed babies exposed to fluoride in water are at risk and that TSCA requires the EPA to consider injuries that chemicals pose to sensitive and highly exposed people. The EPA focused their opening statement on the talking point that "the dose makes the poison," suggesting, in contrast to the actual published research, that there is insufficient compelling evidence that fluoride is a neurotoxin at the current levels used for fluoridation in the U.S. and that therefore water fluoridation doesn't pose a risk to children. EPA named the expert witnesses it will call in the case: David Savitz, Ph.D., who chaired NASEM's committee that peer reviewed the NTP's systematic review; EPA risk assessment expert, Stan Barone, Jr., PhD; and and Jesus Ibarluzea, PhD, authored of the flawed "Spanish" study.

FAN attorney Michael Connett then called our first expert witness to the stand, Howard Hu, MD, MPH, ScD. <https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Ffluoridealert.org%2Fcontent%2Fts fluoride-trial-witness-spotlight%2F&data=05%7C02%7CWSBOH%40SBOH.WA.GOV%7C2dfd15c624044a2f256208dcff44991f%7 Dr. Hu has authored more than 320 papers in peer-reviewed journals and published several landmark studies on fluoride and the brain. He also advises the EPA and collaborates with its scientists on issues related to lead exposure.

Connett asked Dr. Hu how he would compare the peer review process that his fluoride studies underwent with other studies he's published. Hu responded that his fluoride studies are "probably the most extensive peer review process I've experienced." Hu also discussed his concerns about the Spanish study the EPA used as a basis to argue fluoride is not toxic at low levels, and criticized the EPA's opening statements, saying that the

EPA was presenting data as black and white.

Hu then compared his Canada MIREC <https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.mirec-canada.ca%2Fen%2F&data=05%7C02%7CWSBOH%40SBOH.WA.GOV%7C2dfd15c624044a2f256208dcff44> cohort study and Hu's more recent MADRES <https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fmadres.usc.edu%2Fwelcome%2F> cohort study from the U.S. Both indicate higher levels of fluoride in the urine of pregnant mothers in the third trimester. Hu remarked that the third trimester increase is reminiscent of what we saw with lead: fluoride is stored in the mother's bones and during the third trimester, when fetal bone growth accelerates, the mother's body transfers calcium from her bones, along with any present toxins like fluoride, to the fetus.

Dr. Hu was interviewed by independent journalist Derrick Broze <https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Ftheconsciousresistance.com%2F%> after the first day of court adjourned:
Next up was FAN expert witnesses Bruce Lanphear, MD, MPH, who has studied the impact of toxic chemicals, including lead and pesticides, on children's brain development for over 20 years. Lanphear testified that his research has been almost exclusively funded by federal agencies, including the EPA and the Centers for Disease Control and Prevention (CDC). In fact, Dr. Lanphear's research was cited by the EPA as the principle study upon which the agency based its current regulatory standards for lead in air and water.

Lanphear discussed the findings and methodology used for several landmark human studies funded and vetted by the National Institutes of Health (NIH) on fluoride and the brain that he co-authored <https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Ffluoridealert.org%2Fstudytracker%>. Lanphear stated that out of the 350+ studies he's published, his study was one of the two most rigorously reviewed and scrutinized studies prior to publication in his career due to the "implications for public health policy." His study found a linear dose-response relationship between fluoride and IQ, meaning that the lowered IQ effect occurred with any level of fluoride exposure and increased as the exposure increased.

There was then discussion of another study <https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Ffluoridealert.org%2Fstudytracker%> he co-authored which found that consumption of infant formula reconstituted with fluoridated water led to excessive fluoride intake and lower IQ scores for both boys and girls compared to their breastfed counterparts who received very low intakes of fluoride. Lanphear also pointed out that studies have consistently found that children in poorer areas were often exposed to more toxins, and the effects of fluoride exposures for their mothers during pregnancy and for the children during formula feeding could compound these effects, making the poor particularly vulnerable to fluoride's effects.

In his testimony, Lanphear addressed the variability of findings in different studies - some find sex-differentiated responses to fluoride and others don't, or some find neurotoxicity at lower levels and some at higher levels. Lanphear said that the same variability exists in toxicity studies for lead, where some studies find greater effects in boys and others in girls. The overall indication is that lead, like fluoride, is toxic and that other factors drive sex differentiation in a particular context.

The discussion then focused on how fluoride could increase hypothyroidism rates in pregnant women, impacting fetal brain development, and how these effects were both increased if the mother was iodine deficient. Lanphear co-authored key studies <https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.ncbi.nlm.nih.gov%2Fpmc%2> on these subjects. He pointed out that the 2006 National Research Council report <https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Ffluoridealert.org%2Fresearchers%> recognized that fluoride was a thyroid disruptor. He also noted that iodine deficiency has

been increasing in the United States. FAN attorney Michael Connett asked, "Is there any dispute that hypothyroidism can lead to a lower IQ?" Lanphear: "No."

Lanphear wrapped up his testimony by discussing his work <https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Ffluoridealert.org%2Fstudytracker% measuring maternal urinary fluoride concentrations of pregnant women. He testified that an average woman living in a fluoridated community has fluoride levels in their urine twice as high as an average woman living in a non-fluoridated community. Connett asked, "What is the cause of this difference?" Lanphear responded, "Fluoridated drinking water."

Journalist Derrick Broze interviewed Dr. Lanphear after his testimony on day two of the trial:
The third expert witness called by FAN was Philippe Grandjean, MD, DMSc. <https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Ffluoridealert.org%2Fwp-content%2Fuploads%2FPhillipe-Grandjean-Spotlight-Final.pdf&data=05%7C02%7CWSBOH%40SBOH.WA.GOV%7C2dfd15c624044a2f256208dcff44991f%7C11c Dr. Grandjean is a physician, a scientist, an internationally known expert in environmental epidemiology, an author, and both a professor of environmental health at the Harvard School of Public Health and the head of the Environmental Medicine Research Unit at the University of Southern Denmark.

Grandjean testified that he has been given grants and/or contracts to advise the EPA, the National Institutes of Health (NIH), the U.S. Food and Drug Administration (FDA), the World Health Organization (WHO), and numerous other government bodies for over 25 years. Dr. Grandjean said he had even been retained by the Department of Justice, which is representing the EPA in our trial, as an expert witness on environmental toxins.

Grandjean is the author or co-author of some 500 scientific papers and is perhaps best known worldwide for his research on the neurotoxicity of mercury, which involved studying the IQ of children born to mothers whose diet was high in mercury. This work led to defining the EPA's safe regulatory levels for mercury in the diet and inspired downward revisions of methyl mercury exposure limits internationally.

Dr. Grandjean has authored or co-authored several studies <https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.sciencedirect.com%2Fscienc and reviews on fluoride's neurotoxicity, <https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fehjournal.biomedcentral.com%2F 019-0551-x&data=05%7C02%7CWSBOH%40SBOH.WA.GOV%7C2dfd15c624044a2f256208dcff44991f%7C11d0e217 as well as the first benchmark dose analysis <https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fonlinelibrary.wiley.com%2Fdoi%2 on fetal fluoride exposure which found that a maternal urine fluoride concentration of 0.2 mg/L, which studies show is exceeded 4 to 5 times in pregnant women living in fluoridated communities, was enough to lower IQ by 1 point. In his testimony, Grandjean confirmed that the fluoride the mother is absorbing will pass into the child's brain. "You only get one chance to develop a brain. Once it's harmed, there's nothing you can do." Grandjean says.

Attorney Connett showed a quote from EPA scientist Kristina Thayer, who provided testimony in the first phase of the trial. Dr. Thayer said she believes that animal data supports the biological plausibility of fluoride causing neurotoxic effects in humans. Grandjean agreed with Thayer's opinion. Connett asked Grandjean about the EPA's opening statement in which they claimed that Chinese fluoride studies were looking only at very high levels of fluoride exposure. Grandjean insisted this was not the case, saying that even at lower levels there was evidence of cognitive impacts from fluoride, confirming outright that he felt neurotoxicity was definitely a hazard of fluoride exposure.

Connett then asked about NTP's May 2022 final draft report, which included Grandjean's own studies and found lower IQ in children exposed to fluoride during fetal development. Connett specifically asked about the EPA's claim that the NTP's findings were "driven by studies looking at fluoride levels of 7.0 ppm and higher." Dr. Grandjean replied, "They must have a misunderstanding because that's certainly not correct." He then agreed with the NTP authors' statements that some of the higher-quality studies that found harm were done in optimally fluoridated communities.

Dr. Grandjean then confirmed that over a lifetime of dealing with evidence on neurotoxicants, "Fluoride probably has the largest body of evidence of any of our known or suspected neurotoxicants." Agreeing with NTP's finding that the consistency of association of lower IQ in children in five different countries rules out the possibility that there is a common factor other than fluoride exposure that can account for this outcome, Dr. Grandjean stated: "When it comes to fluoride, we have a massive amount of evidence. There is something very serious going on here that we must take seriously."

Journalist Derrick Broze interviewed Dr. Grandjean after his testimony on day three of the trial:
Next to take the stand was EPA's expert witness Stanley Barone, Ph.D., a risk assessment scientist from the EPA Office of Chemical Safety and Pollution Prevention, testifying as FAN's fact witness to establish EPA's methods for risk evaluation under the Toxic Substances Control Act <https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.epa.gov%2Flaws-regulations%2Fsummary-toxic-substances-control-act&data=05%7C02%7CWSBOH%40SBOH.WA.GOV%7C2dfd15c624044a2f256208dcff44991f%7C11d0e21 (TSCA).

Through questioning, Barone explained the EPA's risk assessment <https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.epa.gov%2Frisk&data=05% method - the method FAN says EPA is failing to apply in the case of fluoride. As an EPA developmental toxicologist, Barone was heavily involved in TSCA's first 10 risk evaluations. Before the trial, the plaintiffs asked Barone to establish the risk evaluation process for the record.

Connett questioned Barone on key elements of the hazard assessment. He asked Barone to confirm that to determine whether a chemical is a hazard - step one in the risk assessment process - there is no need to prove causation. Barone agreed that to establish that a chemical is a hazard, EPA requires proof of association, not causation.

Next, Connett asked Barone whether EPA had ever made a different hazard evaluation for high-dose versus low-dose exposure in any of the risk evaluations it had done to date under TSCA. Barone said he was confused by the question. Judge Chen interjected to pose the question himself. "In the hazard evaluation, is it a binary decision?" Barone said it was. In other words, a chemical poses a hazard or it doesn't. The EPA doesn't differentiate between high and low doses in determining whether something is a hazard. Barone also confirmed that once something has been confirmed as a hazard, medium- and high-quality studies are then used to identify a hazard level. These are points our attorney laid out in his opening remarks.

In what would become a defining moment in the trial, Dr. Barone testified that in his estimation we should have a margin of safety of at least 10x for fluoride to protect the most vulnerable in society. The current margin of safety between fluoridated water at 0.7 ppm and the level that NTP found neurotoxicity, 1.5 ppm, is only 2x. EPA would backpedal from this admission throughout the rest of the trial. Some observers might say this moment forced the EPA to change strategy mid-trial.

FAN attorneys then called to the witness stand Dr. Brian Berridge, DVM, DACVP, Ph.D.,

who oversaw the completion of the NTP's work, to discuss the NTP fluoride review and the peer-review process.

In December 2023, EPA moved to exclude <https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Ffluoridealert.org%2Fwp-content%2Fuploads%2FEPA-Motion-Exclude-Testimony-Brian-Berridge.pdf&data=05%7C02%7CWSBOH%40SBOH.WA.GOV%7C2dfd15c624044a2f256208dcff44991f%7C> Berridge's testimony from the trial, arguing it would speak to the political influence exerted to stop the NTP report's publication, rather than to the scientific findings in the report, which are central to the trial. EPA attorneys argued Berridge's testimony would be "unfairly prejudicial" <https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fchildrenshealthdefense.org%2Fwp-content%2Fuploads%2FEPA-Motion-Exclude-Testimony-Brian-Berridge.pdf&data=05%7C02%7CWSBOH%40SBOH.WA.GOV%7C2dfd15c624044a2f256208dcff44991f%7C> to the agency. Although Berridge commented in an email, obtained by FAN via a FOIA request, that there was an ongoing attempt to modify the report <https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fchildrenshealthdefense.org%2Fde-fluoride-neurotoxicity-closer-final-publication%2F&data=05%7C02%7CWSBOH%40SBOH.WA.GOV%7C2dfd15c624044a2f256208dcff44991f%> to satisfy interested actors and to obstruct its publication, FAN did not call on him to speak to that issue, but rather on the integrity of the scientific process in the report's production. In a blow to EPA, Judge Chen said he woul allow Berridge's testimony <https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fchildrenshealthdefense.org%2Fde-rejects-epa-bid-exclude-witness-fluoride-lawsuit%2F&data=05%7C02%7CWSBOH%40SBOH.WA.GOV%7C2dfd15c624044a2f256208dcff44991f%7C> .

Dr. Berridge testified at trial that he signed off on the May 2022 version of the NTP fluoride review as a final and complete report that was ready for publication.

Read more: What Dr. Berridge Couldn't Tell <https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fchildrenshealthdefense.org%2Fde-brian-berridge-fluoride-trial-public-health%2F&data=05%7C02%7CWSBOH%40SBOH.WA.GOV%7C2dfd15c624044a2f256208dcff44991f%7C1> The Court

FAN Attorney Michael Connett then called veteran risk assessment scientist, Dr. Kathleen Thiessen as the next expert witness. Connett establishes that Dr. Thiessen is the author of a large portion of the 2006 NRC fluoride review, and that she also worked on the 2009 review. Connett asked Thiessen if there is any reasonable doubt that neurotoxicity is a hazard of fluoride exposure. Thiessen replied that "neurotoxicity is a hazard of fluoride exposure, the evidence is abundant".

Connett then asked several questions comparing the NTP review process to the EPA review process, Thiessen says the EPA has not been as open and transparent. That the NTP's communication of its conclusions about fluoride's toxicity was more transparent.

Day six of the second trial in the fluoride lawsuit started off with a bang, as FAN attorneys shared with the Court a new systematic review by Canadian researchers, published the night before, linking fluoride exposure at very low levels to lower IQ in children.

Canada's public health agency, Health Canada, commissioned a team of scientists to study the effects of fluoride on human health, but the agency did not publish the review. The peer-reviewed journal Critical Reviews in Toxicology instead independently published the study. <https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.tandfonline.com%2Fdoi%2F> The researchers calculated the "point of departure" for the effects of fluoride on IQ - also

known as the "hazard level," the lowest point at which a toxic effect is observed - and found it to be 0.179 milligrams per liter (mg/L) in water.

Levels of fluoride found in drinking water in the U.S. and Canada typically are in the higher range of 0.7 mg/L. The NTP report set the hazard level at 1.5 mg/L, and one of the key studies <https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fpubmed.ncbi.nlm.nih.gov%2F341 at the center of the trial set the level even lower than 0.2 mg/L.

Even at a hazard level of 1.5 mg/L, exposure levels for fluoride carry significant risk under TSCA's guidelines, but this new level identified by Canadian researchers would set a risk level even further below current exposure levels.

The findings are important to the trial because the identified hazard level was quite low and also because the authors calculated their hazard level in terms of water fluoridation levels, which they extrapolated from the urinary fluoride levels used in most studies.

The findings also are significant because David Savitz, Ph.D., professor of epidemiology at Brown University and the EPA's first witness, was part of the expert panel that advised Health Canada on how to interpret this study and other data. The expert panel that included Savitz concluded there wasn't enough evidence to lower the amount of fluoride in drinking water based on its neurocognitive effects.

Next, EPA's first key witness, David Savitz, Ph.D. took the stand. Dr. Savitz is a professor of epidemiology at Brown University School of Public Health. He worked with the National Academies of Sciences, Engineering, and Medicines (NASEM) in reviewing the draft NTP fluoride report.

Over nearly three days of testimony, Savitz downplayed the link between fluoride and IQ loss in children. Savitz's testimony supported the EPA's three key arguments:
Data on fluoride's neurotoxic effects for children at current levels of water fluoridation is mixed or uncertain and therefore no action should be taken.
There are limitations to the NTP's conclusions, published in draft form <https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fntp.niehs.nih.gov%2Fsites%2Fdef last year, linking fluoride exposure and IQ loss in children at 1.5 milligrams per liter (mg/L).
More recent studies not considered by the NTP cast doubt on the NTP's findings.
However attorney Michael Connett and even Judge Chen pushed back on his conclusions. Connett underscored in his cross-examination that Savitz is an expert in epidemiology but has no experience researching fluoride.

Savitz testified that the Health Canada panel he was on determined that data showing IQ loss in children at existing water fluoridation levels contained too much "uncertainty" to set a hazard level for drinking water, so they advised Health Canada not to change its fluoridation levels.

Under cross-examination, Savitz told the court he sat on that panel at the same time that the EPA was paying him $500 per hour — totaling between $137,000 to $150,000 for 275-300 hours of work — as a litigation expert for the EPA in this trial examining that very question. Judge Chen asked Savitz if Health Canada knew he was serving as an expert witness in this case when they invited him to the panel. Savitz said the agency did.

Regarding his work reviewing the NTP fluoride report, Savitz said NASEM determined the first draft of the NTP's report, which classified fluoride as a neurotoxin, fell short of providing "a clear and convincing argument" that supported its assessment. Savitz told the court he didn't think NTP's conclusions were "wrong" but that they were stated in a way that could be "misused" as a tool for setting or changing water policy on water

fluoridation. Savitz said he thought that after the revisions, the communication was "tempered" and "more consistent".

Savitz testified that because two of the four major cohort studies discussed in the trial (MIREC <https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.ncbi.nlm.nih.gov%2Fpmc%2 and ELEMENT <https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fsph.umich.edu%2Fcehc%2Feleme), found a statistically significant effect of fluoride on IQ at low levels, and two did not (Odense <https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fonlinelibrary.wiley.com%2Fdoi%2 and INMA <https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.sciencedirect.com%2Fscienc), there was too much uncertainty to definitively conclude that it posed a danger at current levels of water fluoridation. Judge Chen asked, "I take it the converse would also apply? Which is that given this mix [of results] you can't foreclose that there is an effect at U.S. drinking levels?" Savitz conceded this was true.

Judge Chen asked, given Savitz's response and the NTP's findings, if it makes sense to assume that there is a concern about current drinking water levels. Chen also asked Savitz if he took issue with NTP's conclusion that there is an association between fluoride exposure and lowered IQ at 1.5 mg/L - just over two times current fluoridation levels. Savitz said he had no reason to challenge it, but he hadn't corroborated it.

Savitz said another flaw was that the NTP used high-quality ecological studies - studies of endemic fluoride in other countries - as some evidence to show the effects of fluoride and that those could be confounded by other variables. Chen pointed out that the studies would have controlled for that issue. Savitz conceded they did.

On cross-examination, Connett also pointed out that in Savitz's own work on arsenic in China, his team studied endemic arsenic at high concentrations to show evidence for arsenic's toxic effects. They also used that data to consider toxic exposure levels in the U.S., using the same methods NTP scientists and other researchers were using endemic fluoride data, which Savitz criticized.

Connett also asked Savitz if he believed his own statements on uncertainty by quoting from Savitz's textbook, "Interpreting Epidemiological Evidence: Connecting Research to Applications." Savitz wrote in the book that "to claim we have insufficient evidence does not resolve the problem for those who make public health decisions, because inaction is an action."

Throughout his testimony, Savitz maintained there was no strong evidence for the neurotoxic effects of fluoride exposure at "low levels," which extended up to 2 mg/L. On cross-examination, Connett presented him with data from the NTP report and also from at least one key study showing this link. Savitz conceded he hadn't read those studies. In fact, in addition to the NTP report, he said he had read only about 10 studies on fluoride and neurotoxicity. EPA's risk analyst Dr. Stanley Barone took the stand again as the final in-person witness in nine days of testimony at the Phillip Burton Federal Courthouse in San Francisco. FAN attorneys called Dr. Barone earlier to comment on the EPA's risk analysis methodology even though he's an expert witness for the EPA. The EPA called him back to testify to the quality of the evidence on fluoride and IQ for a hazard assessment.

Dr. Barone admitted in his testimony that fluoride is neurotoxic at relatively low levels and that EPA's key expert on fluoride's neurotoxicity, David Savitz, conceded flaws in his own study as our landmark fluoride trial drew to a close. Fluoride causes "neurotoxic harm," and does so at relatively low levels, Barone admitted under cross-examination.

Barone said there simply isn't enough data available for EPA to implement its risk assessment process for fluoride. Pharmacokinetic modeling that predicts how a chemical will be absorbed and metabolized by the body, hasn't yet been done, he said. But on cross-examination, Attorney Michael Connett forced Barone to concede several of the FAN's key points.

"You do not dispute that fluoride is capable of causing neurodevelopment harm, correct?" Connett asked. "I do not," Barone said, adding that he said that in his deposition.

"You agree that the current evidence is suggestive that low-dose fluoride causes neurodevelopmental effects? Correct?" Connett asked. Barone said the "hazard ID" - the level at which a toxin causes effects - "is probably in the suggestive range but is highly uncertain."
"You agree that fluoride is associated with neurotoxic effects at water fluoride levels exceeding two parts per million?" Connett asked. After first evading the question, Barone conceded.

Connett asked if Barone agreed there should be a "benchmark margin of uncertainty" of 10 for fluoride neurotoxicity. That means the lowest allowable human exposure level should be at least 10 times the hazard level, which Barone conceded may be approximately 2 parts per million. Barone said that is generally true for toxic chemicals under TSCA.

Water fluoridation levels in the U.S. are currently 0.7 parts per million, also referred to as milligrams per liter (mg/L), which would place them well above the allowable level if they were regulated through TSCA's norms.

Barone also conceded that the NTP's report linking fluoride to neurotoxicity at 1.5 mg/L is a rigorous, high-quality review and that the NTP is one of the world leaders in doing such reviews.

"Do you feel comfortable as a risk assessor," Connett asked, "exposing pregnant women to a level of fluoride that is so high that the kidney is oversaturated?" Barone avoided answering, commenting instead on other foods containing fluoride.

Connett asked a second time, "Are you comfortable then with a pregnant woman having so much fluoride in her circulating system that their kidney has lost the ability to efficiently process it?"

EPA lawyers objected to the question as "vague and argumentative" but Chen overruled.

Barone then sat in silence for several seconds before responding, "Again, putting this in context, my comfort level I don't think is germane."

Connett then turned to the question of the "data gap" or "uncertainty" that Barone and other EPA experts have argued is the basis for not requiring the agency to regulate fluoride.

Connett asked Barone if he agreed that uncertainty about the threshold level at which a chemical causes harm is not a basis for deciding not to do a risk assessment - the process that would likely lead to chemical regulation. Barone agreed but said the weight of the evidence was key. Connett also asked him if he personally agreed that the EPA should "use health protective assumptions" (i.e. an uncertainty factor of 10) when data is lacking. He said he did.

Chen intervened to ask Barone why the EPA couldn't do its risk assessment with the given information, using a "lowest observed effect level," or LOEL. "I mean here we have a phenomenon where I think everybody agrees, as you put it, something's going on,"

Chen said, adding:
"And knowing that the EPA is to use health-protective assumptions when the information is lacking, why can't one approach it from the low-level approach? We seem to know that there's some level in which something's going on. There's adverse effects. We may debate where it is, but wouldn't it be proper to use even a conservative estimate of LOEL?"
Barone insisted, as he did in earlier testimony, that the data are unclear. But he also conceded the EPA does often use the LOEL in risk assessment. Throughout Barone's testimony, Connett drew concessions from Barone through "impeachment" — meaning Barone gave responses under cross-examination that contradicted statements he made in his earlier deposition. Connett read from Barone's deposition testimony to demonstrate he was misrepresenting his responses.

To wrap up the trial and move forward with closing arguments, Judge Chen privately reviewed the recorded deposition of Jesús Ibarluzea, Ph.D., EPA's final witness.

Dr. Ibarluzea is the author of the "Spanish study" that found fluoride increased IQ in boys by an implausible 15 points. 15 IQ points is enough to turn an average person into a genius, which no chemical has ever been found to do, calling the findings of his study into serious question.

Dr. Ibarluzea pulled out of testifying publicly in the trial after his study was scrutinized <https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fchildrenshealthdefense.org%2Fde
final-witnesses-neurotoxicity-fluoride-
trial%2F&data=05%7C02%7CWSBOH%40SBOH.WA.GOV%7C2dfd15c624044a2f256208dcff44991f%7C11c
by plaintiffs for its ridiculously unbelievable findings.

At the close of the expert testimony, a scheduling change occurred. The Judge ordered that closing statements from both FAN and EPA now take place with a one-week delay, setting a February 20, 2024, closing date. The judge wanted time to watch deposition videos, look over evidence, and prepare a series of key questions for attorneys.
Closing Arguments
On February 20, 2024, rather than delivering summary closing arguments, attorneys for FAN and EPA responded for nearly three hours to the Judge's detailed questions on technical aspects of the link between low-level fluoride exposure and lower IQ scores in children. The two sides also debated the role of uncertainty in risk assessment.

During the trial, top scientific experts who advised the EPA on understanding and setting hazard levels for other major environmental toxins and who conducted gold-standard "cohort" studies on the link between fluoride and low IQ in children testified for FAN.

They explained the NTP's findings and presented evidence from their own research showing neurotoxic risks - particularly to pregnant women,
<https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fpubmed.ncbi.nlm.nih.gov%2F352
formula-fed infants
<https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fpubmed.ncbi.nlm.nih.gov%2F317
and children
<https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fpubmed.ncbi.nlm.nih.gov%2F318
- posed by water fluoridation.

EPA witnesses conceded fluoride does have neurotoxic effects at relatively low levels but countered that the risk assessment process under TSCA is highly complex and there is too much uncertainty in the data on fluoride's toxicity at current levels of water fluoridation to do a proper risk assessment and regulate the chemical.

It is now up to Judge Chen to decide if the EPA should be required to create a rule banning water fluoridation in the U.S. "Because the regulatory agencies have failed to do their job for decades," plaintiffs' attorney Michael Connett told Brenda Baletti of The

Defender, “the court is now in the position of having to do it for them.”

“It’s not a job the court takes lightly,” he said. “It’s not a job the court wanted to do, but I think it’s a job the court is prepared to do.”
The Judgment
On September 24, 2024 the court ruled on behalf of the Fluoride Action Network and the plaintiffs. A U.S. federal court has now deemed fluoridation an “unreasonable risk” to the health of children, and the EPA will be forced to regulate it as such.
The decision
<https://gcc02.safelinks.protection.outlook.com/?url=http%3A%2F%2Ffluoridealert.org%2Fwp-content%2Fuploads%2F2024%2F09%2FCourt-Ruling.pdf&data=05%7C02%7CWSBOH%40SBOH.WA.GOV%7C2dfd15c624044a2f256208dcff44991f%7C1
is written very strongly in our favor.
Below is an excerpt from the introduction of the ruling:
"The issue before this Court is whether the Plaintiffs have established by a preponderance of the evidence that the fluoridation of drinking water at levels typical in the United States poses an unreasonable risk of injury to health of the public within the meaning of Amended TSCA. For the reasons set forth below, the Court so finds. Specifically, the Court finds that fluoridation of water at 0.7 milligrams per liter (“mg/L”) – the level presently considered “optimal” in the United States – poses an unreasonable risk of reduced IQ in children..the Court finds there is an unreasonable risk of such injury, a risk sufficient to require the EPA to engage with a regulatory response…One thing the EPA cannot do, however, in the face of this Court’s finding, is to ignore that risk.”
Thanks to Derrick Broze
<https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Ftheconsciousresistance.com%2F%
of the Conscious Resistance and Brenda Baletti
<https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fchildrenshealthdefense.org%2Fau
baletti%2F&data=05%7C02%7CWSBOH%40SBOH.WA.GOV%7C2dfd15c624044a2f256208dcff44991f%7C1
of Children’s Health Defense for their contributions to this detailed overview of the TSCA fluoride lawsuit.

Although I do not expect you to read all the links, certainly some of this information is critical for a thorough understanding of the legal action in the TSCA trial on fluoridation.

Plaintiffs needed five things to win our TSCA lawsuit 1. We need to prove in court that neurotoxicity is a hazard of fluoride exposure. 2. We need to prove in court that this hazard is a risk at the doses ingested in fluoridated areas. 3. We need to prove in court this risk is unreasonable.

Previous to the above report of the court proceedings:

Federal Trial Update: New Supplement To Our TSCA Petition Submitted To Court
<https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Ffluoridealert.org%2Fcontent%2Fb
6-
20%2F&data=05%7C02%7CWSBOH%40SBOH.WA.GOV%7C2dfd15c624044a2f256208dcff44991f%7C11d0

November 7, 2020 | Cheikhani
<https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Ffluoridealert.org%2Fauthor%2Fch

As you might recall, the Court requested on the last day of the trial
<https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fdefault.salsalabs.org%2FT737286
bb86-4901-8757-55a6a2f75cd2%2F229b4429-cacf-48af-87ba-
5c92fb25a9dc&data=05%7C02%7CWSBOH%40SBOH.WA.GOV%7C2dfd15c624044a2f256208dcff44991f%

that we submit a new Petition to the Environmental Protection Agency (EPA) to allow them the opportunity to respond to our original 2016 Petition in regards to the new studies that were published between 2017-2020. The Court also requested that we include Petitioners who were pregnant or planning a pregnancy in light of the science linking early-life exposure to fluoridated water to adverse neurodevelopmental effects in these new studies.

Yesterday's meeting with the Judge

At the very short meeting convened by the Judge, lawyers representing both sides were in attendance. Lead attorney Michael Connett told the Court that he filed, on November 4, a Supplement to our original Petition with the EPA. The Supplement asks that EPA reconsider their denial of our 2016 Petition. The reasons are set forth in the Supplement and its 9 attachments (all listed below). The Supplement has done everything the Court asked us to do with a new Petition. The Supplement also responds to the issue of Standing by identifying nine members of Food & Water Watch "who are currently pregnant, women who are actively seeking to become pregnant, and/or mothers of infants…"

We believe that this is an important and highly readable document and we urge our supporters to read it in full. However, if time is short we have presented excerpts below.

Background to the Supplement

"On November 22, 2016, the undersigned Petitioners submitted a Citizen Petition under Section 21 of the Toxic Substances Control Act ("TSCA"), requesting that the EPA prohibit the addition of fluoridation chemicals to drinking water in order to protect the public, including susceptible subpopulations, from fluoride's neurotoxic risks. After the EPA denied this petition, the Petitioners brought suit in the Northern District of California to challenge EPA's denial. Following a bench trial in June of 2020, the Court stated that EPA had used an incorrect standard in assessing the evidence that the Petitioners had presented. .. The Court also noted that much of the evidence that the Petitioners relied upon at trial—including recent studies funded by the National Institutes of Health (NIH)—was not yet available at the time EPA denied the Petition. (Appendix A at 4.) In light of these facts, the Court asked Petitioners to re-submit evidence to the EPA in order to give the Agency an opportunity to give the evidence a "second look" using the "proper standard" at the administrative level, which the Court 'urged' the EPA to do."

"Pursuant to the Court's request, the Petitioners are hereby submitting this Supplement to their Petition and requesting that EPA reconsider its denial of the Petition based on the information presented herein."

EPA HAS THE AUTHORITY TO RECONSIDER ITS DENIAL OF A SECTION 21 PETITION

"EPA has the inherent authority to reconsider its denials of Section 21 petitions, as the EPA itself has repeatedly acknowledged. The EPA has explained that: "Although TSCA does not expressly provide for requests to reconsider EPA denials of Section 21 petitions, 'the courts have uniformly concluded that administrative agencies possess inherent authority to reconsider their decisions, subject to certain limitations, regardless of whether they possess explicit statutory authority to do so.'" … As the EPA has explained, "the power to reconsider is inherent in the power to decide." Id. at 24 (quoting Albertson v. FCC, 182 F.2d 397, 399 (D.C. Cir. 1950)) …"

GROUNDS FOR PETITIONERS' REQUEST FOR RECONSIDERATION

1. EPA Used an Incorrect and Impermissibly Stringent Standard of Proof

"At the close of trial in June 2020, the Court observed that EPA has subjected Petitioners' evidence to an incorrect standard of proof. As the Court noted, "EPA appears to have applied a standard of causation … It's not the proper standard." (6/17 Trial Tr. 1131:5-9.)

"TSCA commands that EPA protect against "unreasonable risk," which exists when human exposure to a toxicant is unacceptably close to the estimated hazard level. (6/10 Trial Tr. 471:11-472:9.) At trial, EPA confirmed that 'EPA does not require that human exposure levels exceed a known adverse effect level to make an unreasonable risk determination under TSCA.' (Appendix H at 4.) Thus, EPA does not require proof that human exposures under a given condition of use cause the hazard. In fact, Dr. Tala Henry agreed at trial that EPA has "never once in any of its risk evaluations to date under Section 6 used a causation standard." (6/16 Trial Tr. 987:6-8.) Despite this, Dr. Henry

admitted that EPA held Petitioners to a burden of proof where Petitioners needed to prove that human exposure to fluoride in water at 0.7 mg/L causes neurotoxicity. (6/16 Trial Tr. 985-15-987:2.) Dr. Henry thus made the extraordinary admission that EPA 'held the plaintiffs to a burden of proof that EPA has not held a single chemical under Section 6 before.' (6/16 Trial Tr. 987:16-19.)…"

2. Each of the Limitations that EPA Identified with the Fluoride/IQ Studies in the Petition Have Now Been Addressed by High Quality Studies Funded by the NIH

"In its denial of the Petition, the EPA criticized the human studies that Petitioners cited on three primary grounds: (1) the studies were cross-sectional and thus 'affected by antecedent consequent bias';1 (2) the studies failed to adjust for potential confounding factors; and (3) the studies failed to adequately establish a dose-response relationship between fluoride and neurotoxicity. (Fed Reg, Vol. 82, No. 37, p. 11882-83). …

"Following EPA's denial of the Petition in February 2017, a series of prospective cohort studies funded by the National Institutes of Health (NIH) were published which evaluate the impact of individualized measurements of prenatal and early-infant fluoride exposure on standardized measures of neurobehavioral performance between ages 4 and 12 (Bashash 2017, Bashash 2018, Green 2019, Till 2020)."

"These NIH-funded studies address each of EPA's three criticisms of the studies in the Petition…"

3. The National Toxicology Program Has Concluded that Fluoride Is a Presumed Human Neurotoxicant that Lowers IQ in Children

"Petitioners' contention that fluoride is a neurotoxicant has gained powerful new support from the National Toxicology Program's (NTP) recently revised systematic review and meta-analysis…"

A. NTP Agrees that Fluoride Is a Likely Neurodevelopmental Hazard to Humans

"On September 16, 2020, the NTP released its Draft Monograph on the Systematic Review of Fluoride Exposure and Neurodevelopmental and Cognitive Health Effects. The Monograph is a revised version of a draft issued in October 2019, and incorporates the recommendations made by a committee of the National Academy of Sciences (NAS). After making the changes recommended by the NAS, the NTP reconfirmed its conclusion that 'fluoride is presumed to be a cognitive neurodevelopmental hazard to humans.' (p. 2) …"

B. The Relationship Between Fluoride and Neurotoxic Effects Is Unlikely to Be Explained by Confounding or Other Issues of Methodology and Bias

"The NTP reached its hazard conclusion for fluoride after carefully considering issues of study quality and bias, including potential confounding, publication bias, translation bias, and the validity of exposure and outcome assessments. Each of these methodological issues were raised at trial by EPA to question the confidence in the numerous studies reporting neurotoxicity from fluoride exposure. Importantly, the NTP's report makes clear that none of the issues identified by EPA at trial warrant a downgrade in the confidence that fluoride is a human neurotoxicant. In other words, the issues identified by EPA at trial do not explain the overwhelmingly consistent association between fluoride and neurotoxic harm…"

C. The NTP Identified a Large Number of Low Risk-of-Bias Studies Linking Fluoride to Neurotoxicity

"… In total, the NTP identified 31 human studies on fluoride and neurodevelopment that it found to have a relatively low potential for bias (p. 25) and the vast majority of these studies found significant associations between fluoride and adverse effects. This highlights that the association between fluoride and neurotoxicity is not the artifact of poor study design or bias, as EPA argued at trial."

D. The NTP Has Judged the New Zealand Studies that EPA Has Relied Upon to Be at High Risk of Bias

E. The Animal Data Supports the Conclusion that Fluoride Produces Neurodevelopmental Effects

F. The NTP's Recently Retired Director Has Called for Measures to Protect Pregnant Women and Bottle-Fed Babies from the Neurotoxic Effects of Fluoride

"The relevance of the NTP's findings to water fluoridation has recently been highlighted by none other than the recently retired director of the NTP, Dr. Linda Birnbaum. On

October 7, 2020, shortly after the NTP released its revised Monograph, Dr. Birnbaum issued a public statement calling for measures to protect pregnant women and bottle-fed babies from the neurotoxic effects of fluoride. Dr. Birnbaum noted that the NTP's conclusion is 'consequential,' given that "about 75 percent of Americans on community water systems have fluoride in their water.'…"

G. Limitations and Weaknesses of NTP's Report

"The NTP Monograph provides an exceptionally comprehensive review of the scientific literature on fluoride neurotoxicity, and provides ample support for its conclusion that fluoride is a neurotoxicant that reduces IQ. There are, however, some limitations and weaknesses with the NTP's analysis that Petitioners wish to bring to the EPA's attention…"

H. Even with Its Limitations, the NTP Monograph Demonstrates that Water Fluoridation Poses an Unreasonable Risk of Neurodevelopmental Harm

"Even with its limitations, the NTP Monograph demonstrates that neurotoxicity is an unreasonable risk of water fluoridation…"

4. Pooled BMD Analysis of the NIH-Funded Birth Cohort Data Confirms that Pregnant Women in Fluoridated Areas Are Exceeding the Dose Associated with IQ Loss

"A team of scientists, including the authors of the NIH-funded studies, have recently completed a pooled benchmark dose (BMD) analysis of the maternal urinary fluoride data from the ELEMENT and MIREC datasets (Grandjean, et al. 2020, in review)… Given that BMD analysis is EPA's preferred method for determining toxicity values and risk estimates, the new pooled analysis provides compelling grounds for EPA to reconsider its denial of the Petition. The analysis, which became publicly available on November 4, 2020, is attached as Appendix G…"

5. Millions of Americans Are at Risk of Harm as a Result of EPA's Failure to Regulate Fluoridation, Including Petitioners

"… Each year, there are approximately 2.5 million pregnancies in fluoridated areas; in utero exposures are thus widespread. (Appendix B at p. 78 ¶ 406.) Many of those exposed in utero will also be exposed during the sensitive neonatal period, with upwards of 1.9 million infants living in fluoridated areas being fed formula at least part of the time, including 400,000 infants who are exclusively formula-fed for their first six months. (Id.) Petitioner Organizations have members who fall within these zones of danger…"

6. EPA Erred in Considering the Purported Dental Benefits of Fluoridation in its Denial of the Petition

"In its denial of the Petition, EPA cited the purported dental benefits of fluoridation as a basis for its denial. This was improper because the Amended TSCA statute forbids risk evaluations from considering 'costs and other nonrisk factors.' 15 U.S.C. § 2620(b)(4)(B(ii). …"

7. EPA Erred in Claiming that Petitioners Failed to Adequately Identify the Chemicals at Issue

"… During the litigation on this matter, the Court considered and rejected each of these arguments, and held that the Petitioners had adequately identified the chemicals at issue, and that there was no merit to EPA's contention that it 'would become obligated to address all conditions of use of the category.'"

List of Documents submitted:

SUPPLEMENT: Petitioners' request to EPA to reconsider their denial of their original TSCA Petition of November 22, 2016.
http://fluoridealert.org/wp-content/uploads/tsca.supplement.11-4-20.pd
<https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fdefault.salsalabs.org%2FT30220b
d1d9-4837-b610-8c8e0f0c89c0%2F229b4429-cacf-48af-87ba-
5c92fb25a9dc&data=05%7C02%7CWSBOH%40SBOH.WA.GOV%7C2dfd15c624044a2f256208dcff44991f%
f

Appendix A: Excerpt of Court's August 10, 2020 Order.
http://fluoridealert.org/wp-content/uploads/tsca.supplement.appendix-a.11-4-20.pdf
<https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fdefault.salsalabs.org%2FT70670b
55a3-4362-9915-9db0cc0126bc%2F229b4429-cacf-48af-87ba-
5c92fb25a9dc&data=05%7C02%7CWSBOH%40SBOH.WA.GOV%7C2dfd15c624044a2f256208dcff44991f%

Appendix B: Petitioners' Summary of the Trial Record. Food & Water Watch, et al. v. U.S. Environmental Protection Agency Case No. 17-cv-02162.
http://fluoridealert.org/wp-content/uploads/tsca.supplement.appendix-b.11-4-20.pdf
<https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fdefault.salsalabs.org%2FT1199bf6
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5c92fb25a9dc&data=05%7C02%7CWSBOH%40SBOH.WA.GOV%7C2dfd15c624044a2f256208dcff44991f%

Appendix C: The NIH-funded Studies (Bashash et al. 2017 and 2018; Till et al. 2018 and 2020; Green et al. 2019).
http://fluoridealert.org/wp-content/uploads/tsca.supplement.appendix-c.11-4-20.pdf
<https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fdefault.salsalabs.org%2FTd30ac1
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5c92fb25a9dc&data=05%7C02%7CWSBOH%40SBOH.WA.GOV%7C2dfd15c624044a2f256208dcff44991f%

Appendix D: National Toxicology Program's Revised Monograph on Fluoride Neurotoxicity.
http://fluoridealert.org/wp-content/uploads/tsca.supplement.appendix-d.11-4-20.pdf
<https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fdefault.salsalabs.org%2FTa4c5ef1
3c7f-44c3-96d3-96d49aa701a3%2F229b4429-cacf-48af-87ba-
5c92fb25a9dc&data=05%7C02%7CWSBOH%40SBOH.WA.GOV%7C2dfd15c624044a2f256208dcff44991f%

Appendix E: Dr. Linda Birnbaum's Statement on the NTP Report.
http://fluoridealert.org/wp-content/uploads/tsca.supplement.appendix-e.11-4-20.pdf
<https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fdefault.salsalabs.org%2FT743013
4881-4426-9d3d-5beb65673220%2F229b4429-cacf-48af-87ba-
5c92fb25a9dc&data=05%7C02%7CWSBOH%40SBOH.WA.GOV%7C2dfd15c624044a2f256208dcff44991f%

Appendix F: Additional Details on the Limitations of the NTP Review.
http://fluoridealert.org/wp-content/uploads/tsca.supplement.appendix-f.11-4-20.pdf
<https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fdefault.salsalabs.org%2FTcac135
e30f-4271-b373-bebe827d486b%2F229b4429-cacf-48af-87ba-
5c92fb25a9dc&data=05%7C02%7CWSBOH%40SBOH.WA.GOV%7C2dfd15c624044a2f256208dcff44991f%

Appendix G: Pooled BMD Analysis of the ELEMENT and MIREC Datasets.
http://fluoridealert.org/wp-content/uploads/tsca.supplement.appendix-g.11-4-20.pdf
<https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fdefault.salsalabs.org%2FTf514a77
7b58-4c67-a0e6-c7749903f17a%2F229b4429-cacf-48af-87ba-
5c92fb25a9dc&data=05%7C02%7CWSBOH%40SBOH.WA.GOV%7C2dfd15c624044a2f256208dcff44991f%

Appendix H: Undisputed Material Facts from Trial and Court's Ruling on Dental Benefits.
http://fluoridealert.org/wp-content/uploads/tsca.supplement.appendix-h.11-4-20.pdf
<https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fdefault.salsalabs.org%2FT5e0f709
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5c92fb25a9dc&data=05%7C02%7CWSBOH%40SBOH.WA.GOV%7C2dfd15c624044a2f256208dcff44991f%

Appendix I: The Court's Order Dismissing EPA's Order to Dismiss.
http://fluoridealert.org/wp-content/uploads/tsca.supplement.appendix-i.11-4-20.pdf
<https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fdefault.salsalabs.org%2FT9121f55
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5c92fb25a9dc&data=05%7C02%7CWSBOH%40SBOH.WA.GOV%7C2dfd15c624044a2f256208dcff44991f%

1. Most recent. The link to the actual court order is included and must be considered as evidence for the Board.

Federal Court Orders EPA to Regulate Fluoridation of Drinking Water under TSCA
<https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Ffluoridealert.org%2Fnews%2Ffede
court-orders-epa-to-regulate-fluoridation-of-drinking-water-under-

tsca%2F&data=05%7C02%7CWSBOH%40SBOH.WA.GOV%7C2dfd15c624044a2f256208dcff44991f%7C11d

Beveridge & Diamond | Oct 19, 2024 | By Mark N. Duvall

In a groundbreaking decision, a federal district court has ordered <https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.cand.uscourts.gov%2Fwp-content%2Fuploads%2F2024%2F09%2F17-cv-2162-Food-_-Water-Watch-Inc.-et-al.-v.-EPA-et-al-Opinion.pdf&data=05%7C02%7CWSBOH%40SBOH.WA.GOV%7C2dfd15c624044a2f256208dcff44991f%7C the U.S. Environmental Protection Agency (EPA) to regulate the "unreasonable risk" it found to be posed by the fluoridation of drinking water. The order came in the long-running case Food & Water Watch, Inc. v. EPA, No. 17-cv-02162-EMC, 2024 WL 4291497 (N.D. Cal. Sept. 24, 2024).

While the court did not specify what EPA must now do, its decision could significantly impact municipal drinking water systems and public health. Supported <https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.cdc.gov%2Ffluoridation%2Fa by the Centers for Disease Control and Prevention, EPA has permitted public water systems to fluoridate their drinking water as a critical measure to control tooth decay for decades. More than three-quarters of the U.S. population today gets their drinking water from fluoridated public sources.

The court order also has substantial implications for the regulated chemical industry and EPA's regulatory processes under the Toxic Substances Control Act (TSCA). This is the first instance of a court ordering EPA to "initiate a proceeding" under TSCA Section 6(a) in response to a citizen petition denied by EPA and subsequently appealed under Section 21 to a federal court. Both industry and the federal government have previously argued that Section 21 does not authorize a court to order rulemaking but rather a fact-gathering risk evaluation process akin to that normally required under TSCA for chemicals that EPA itself has identified as potentially presenting unreasonable risks under their conditions of use, in part because Section 21 requires a lower standard of evidence than is required of the usual risk evaluation process. A federal court has now implicitly disagreed with that argument, ordering that EPA "initiate rulemaking" to manage the risks it found to be posed by water fluoridation.

Background

EPA permits public drinking water systems to fluoridate drinking water up to certain levels under the Safe Drinking Water Act. EPA has established an enforceable maximum contaminant level <https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.ecfr.gov%2Fcurrent%2Ftitle 40%2Fchapter-I%2Fsubchapter-D%2Fpart-141%2Fsubpart-G%2Fsection-141.62&data=05%7C02%7CWSBOH%40SBOH.WA.GOV%7C2dfd15c624044a2f256208dcff44991f%7C11d0 (MCL) for fluoride in drinking water at 4.0 milligrams per liter (mg/L), effectively ensuring that community water systems limit fluoridation to levels that EPA has determined present no known or anticipated adverse effects on human health.

EPA has also set a "secondary" standard <https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.ecfr.gov%2Fcurrent%2Ftitle 40%2Fchapter-I%2Fsubchapter-D%2Fpart-143%2Fsubpart-A%2Fsection-143.3&data=05%7C02%7CWSBOH%40SBOH.WA.GOV%7C2dfd15c624044a2f256208dcff44991f%7C11d0e for fluoride at 2.0 mg/L or 2.0 ppm. Secondary standards are non-enforceable federal guidelines that address potential cosmetic effects (such as skin or tooth discoloration) or aesthetic effects (such as taste, odor, or color) in drinking water, which state or local governments may implement.

The U.S. Department of Health and Human Services (HHS) recommends <https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.federalregister.gov%2Fdocu 637%2Fproposed-hhs-recommendation-for-fluoride-concentration-in-drinking-water-for-prevention-of-dental&data=05%7C02%7CWSBOH%40SBOH.WA.GOV%7C2dfd15c624044a2f256208dcff44991f%7C11d0 the fluoridation of drinking water at 0.7 mg/L to achieve the benefits of preventing tooth decay.

Nevertheless, in 2016, a group of NGOs petitioned <https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.epa.gov%2Fpetitions%2Fsup

documents-fluoride-chemicals-drinking-water-section-21-petition&data=05%7C02%7CWSBOH%40SBOH.WA.GOV%7C2dfd15c624044a2f256208dcff44991f%7C11d
EPA under TSCA Section 21 to ban the fluoridation of drinking water entirely, arguing that fluoride has neurotoxic effects when ingested even at the "optimal" concentration identified by HHS and so presents an "unreasonable risk to human health." EPA denied <https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.epa.gov%2Fpetitions%2Fsup
documents-fluoride-chemicals-drinking-water-section-21-petition&data=05%7C02%7CWSBOH%40SBOH.WA.GOV%7C2dfd15c624044a2f256208dcff44991f%7C11d
that petition in 2017, and, pursuant to Section 21, the NGOs appealed that denial to the federal district court for the Northern District of California. The district court judge in the case is Edward Chen, who previously had directed EPA to adopt a TSCA Section 8(a) reporting rule for asbestos in another case that contested EPA's denial of a Section 21 petition. Asbestos Disease Awareness Org. v. EPA, 508 F. Supp. 3d 707 <https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fcasetext.com%2Fcase%2Fasbesto
disease-awareness-org-v-wheeler-1&data=05%7C02%7CWSBOH%40SBOH.WA.GOV%7C2dfd15c624044a2f256208dcff44991f%7C11d0e217
(N.D. Cal. 2020).

In 2019, Judge Chen denied EPA's motion for summary judgment that had argued that the NGOs were required to comply with all requirements of both Section 6(b) (e.g., provide information equivalent to a risk evaluation) and Section 26 (e.g., provide information reflecting the weight of the scientific evidence). The court did so in part by citing that Sections 6(b) and 26 are not directly incorporated into Section 21, although their provisions may be looked to for guidance. Food & Water Watch, Inc. v. EPA, No. 17-cv-02162-EMC, 2019 WL 8261655 (N.D. Cal. Dec. 30, 2019). Extensive discovery and a trial followed.

TSCA Proceedings

Under TSCA Section 21, any person may petition EPA to "initiate a proceeding" for the issuance, amendment, or repeal of a rule under Section 6(a). 15 U.S.C. § 2620(a). If EPA grants the petition, EPA must start an appropriate rulemaking process to consider the petitioner's requests. However, if EPA denies the petition—as it did here—it must publish a notice detailing the reasons for the denial. If EPA denies or does not respond to a petition within 90 days, then the petitioner may initiate a civil action in federal district court to compel EPA to "initiate a proceeding" for the requested rulemaking, if the court determines, without consideration of costs, that the subject chemical presents an unreasonable risk to human health or the environment under the conditions of use. The resulting rule under Section 6(a) could impose a variety of controls—ranging from a label warning to an outright ban—to manage the chemical's identified risks.

Since Congress substantially overhauled TSCA in 2016, it has not been clear what it would mean to "initiate a proceeding" for a Section 6(a) rule. The statute now generally requires prioritization and risk evaluation as critical predicates to rulemaking, and EPA's risk evaluations must be made according to the "weight of the scientific evidence" and "consistent with the best available science." 15 U.S.C. § 2625(h)-(i). However, under Section 21, a court only needs to decide whether the chemical substance presents an unreasonable risk "by a preponderance of the evidence," arguably a lesser scientific standard. 15 U.S.C. § 2620(b)(4)(B). Section 21 also only enables EPA and a specific petitioner or petitioners to present evidence, whereas the full risk evaluation process that would usually inform Section 6 rulemaking involves more than three years' worth of public participation and comment. Until now, no court had addressed whether a court ordering EPA to "initiate a proceeding" under Section 21 would require EPA to begin the full risk evaluation process or jump directly to rulemaking to manage those risks.

Without substantial analysis, Judge Edward Chen has now provided an answer. He found that the evidence suggests that HHS's "optimal" level of drinking water fluoridation—0.7 milligrams per liter, well below EPA's maximum and target concentrations—"poses an unreasonable risk of reduced IQ in children." The Court then ordered EPA to "initiate rulemaking pursuant to Subsection 6(a) of TSCA." Order at 2, 79 (emphasis added). Nevertheless, in a footnote, the Court left the door open for EPA to conduct additional analysis or seek additional information to "put a finer point on [the] risk posed by the condition of use before taking regulatory action." Id. at 67 n.33. Thus, it remains unclear

to what extent EPA must now begin to draft regulations on the addition of fluoride to drinking water or may instead engage in the deliberative risk evaluation process.

Impacts and Next Steps

This order could significantly impact the chemical industry and municipal drinking water systems. If courts uphold that a TSCA Section 21 citizen's petition can be leveraged to force EPA to skip the statutory chemical prioritization and risk evaluation processes and jump directly to rulemaking, then EPA's chemical regulatory program could foreseeably be overwhelmed by competing priorities. Chemical manufacturers, processors, and users could also potentially face overbroad restrictions due to EPA's having to regulate certain chemicals on the basis of less (and potentially less comprehensive) information. Drinking water utilities may also want to closely track this issue, which could significantly impact their operations.

Although the district court ordered EPA to initiate rulemaking to address the level of fluoride in drinking water, it remains to be seen what steps EPA will take next. The possibilities include, among others, that EPA will request more information from the public as part of the initiation of rulemaking; that it will appeal the case to the Ninth Circuit (including the district court's earlier ruling about the scope of Section 21); and that it will attempt to move the entire matter to the Office of Water under TSCA Section 9(b) on the basis that the risk identified by the court "could be eliminated or reduced to a sufficient extent by actions taken under the authorities" of the Office of Water. Stay tuned.

Original article online at: https://natlawreview.com/article/federal-court-orders-epa-regulate-fluoridation-drinking-water-under-tsca
<https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fnatlawreview.com%2Farticle%2Ff
court-orders-epa-regulate-fluoridation-drinking-water-under-
tsca&data=05%7C02%7CWSBOH%40SBOH.WA.GOV%7C2dfd15c624044a2f256208dcff44991f%7C11d0e2

Sincerely,
Bill Osmunson DDS MPH
Washington Action for Safe Water

_____
From: Garry Blankenship
Sent: 10/14/2024 7:43:11 AM
To: hcinfo.infosc@canada.ca,DOH
WSBOH,OADS@cdc.gov,sheriff@co.clallam.wa.us,Berry, Allison 2
(DOHi),shahidafatin@gmail.com,ncarr@cityofpa.us,gbsjrmd@sisna.com,mark.ozias,Randy.Johnson@Clallan

Cc:
Subject: Fwd: The Takada paper shows very clearly that the COVID vaccines are not safe

External Email

---------- Original Message ----------
From: Steve Kirsch's newsletter <stevekirsch@substack.com>
To: hisgarness@comcast.net
Date: 10/13/2024 8:38 PM PDT
Subject: The Takada paper shows very clearly that the COVID vaccines are not safe

<https://eotrx.substackcdn.com/open?token=eyJtIjoiPDIwMjQxMDE0MDMzODQ1LjMuNzU2ZDgzZmFjOTM0

For myocarditis, the ROR was 15 for Pfizer and 54 for Moderna. That means Pfizer is very unsafe and Moderna is a train wreck.

Forwarded this email? Subscribe here <https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fsubstack.com%2Fredirect%2F2%
IISNyc60nAxr5gf-ayND210E-
AymKCVB2IBo&data=05%7C02%7Cwsboh%40sboh.wa.gov%7Ce1f631b758eb42b8a8f208dcec5e8486%7C
for more

The Takada paper shows very clearly that the COVID vaccines are not safe
<https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fsubstack.com%2Fapp-
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For myocarditis, the ROR was 15 for Pfizer and 54 for Moderna. That means Pfizer is very unsafe and Moderna is a train wreck.

Steve Kirsch
<https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fsubstack.com%2F%40stevekirsch

Oct 14

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<https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fsubstack.com%2Fapp-link%2Fpost%3Fpublication_id%3D548354%26post_id%3D150195205%26utm_source%3Dsubstack%26is reaction%26r%3D15ift6&data=05%7C02%7Cwsboh%40sboh.wa.gov%7Ce1f631b758eb42b8a8f208dcec5e

<https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fsubstack.com%2Fapp-link%2Fpost%3Fpublication_id%3D548354%26post_id%3D150195205%26utm_source%3Dsubstack%26u Hk_EaSLMFGxEeb4zgwEKIgJiOHtLqc%26r%3D15ift6%26utm_campaign%3Demail-half-magic-comments%26action%3Dpost-comment%26utm_source%3Dsubstack%26utm_medium%3Demail&data=05%7C02%7Cwsboh%40sboh.w

<https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fsubstack.com%2Fapp-link%2Fpost%3Fpublication_id%3D548354%26post_id%3D150195205%26utm_source%3Dsubstack%26u share%26action%3Dshare%26triggerShare%3Dtrue%26isFreemail%3Dfalse%26r%3D15ift6%26token%3D Hk_EaSLMFGxEeb4zgwEKIgJiOHtLqc&data=05%7C02%7Cwsboh%40sboh.wa.gov%7Ce1f631b758eb42b8a

<https://substackcdn.com/image/fetch/w_36,c_scale,f_png,q_auto:good,fl_progressive:steep/https%3A%

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<https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fopen.substack.com%2Fpub%2Fst takada-paper-shows-very-clearly%3Futm_source%3Demail%26redirect%3Dapp-store%26utm_campaign%3Demail-read-in-app&data=05%7C02%7Cwsboh%40sboh.wa.gov%7Ce1f631b758eb42b8a8f208dcec5e8486%7C11d0e217

<https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fsubstack.com%2Fredirect%2F736
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Executive summary

A new paper by Takada
<https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fsubstack.com%2Fredirect%2F736
a3cc-4693-9658-
f86eaed048e9%3Fj%3DeyJ1IjoiMTVpZnQ2In0.PoWkYg8wHoPi84O6BbnZ2dl3zAYJI3AKz0ikcuhTjA4&data=0
, published on August 3, 2024 shows the ROR for myocarditis for Pfizer was 15 and it was 54 for Moderna.

That means the Pfizer vaccine isn't safe, and the Moderna vaccine is 3.6 worse. 54 is a train wreck. You can't give a drug with an ROR of 54. That's insane.

The health authorities should be educating the public on the RORs for the most serious adverse events.

Yet they are silent. Worldwide.

ROR: Reporting Odds Ratio

ROR is a measure used in pharmacovigilance to assess the association between a drug and a specific adverse event by comparing the odds of that event occurring with the drug of interest versus with other drugs.

The formula for calculating ROR is:

<https://substackcdn.com/image/fetch/f_auto,q_auto:best,fl_progressive:steep/https%3A%2F%2Fsubstac

Where:

* A: Number of reports of the specific adverse event for the drug of interest.
* B: Number of reports of other events for the drug of interest.
* C: Number of reports of the specific adverse event for all other drugs.
* D: Number of reports of other events for all other drugs.

In this calculation, the ROR compares proportions rather than accounting for the absolute number of doses given.

Therefore, a drug with an ROR of 15 (like Pfizer) means that the odds of an adverse event occurring for that drug are 15X higher compared to the average odds for other drugs.

That is not safe. That is not even close to safe. That is a disaster.

What it means

The proportion of adverse event reports in the Japanese version of VAERS were 15X higher than the typical drug in the database. But the reports, relative to the total number of reports filed, were 54 times higher for Moderna which is 3.6X higher than Pfizer.

This suggests that:

1. The safety profile of the vaccines do not resemble, in any way, that of a placebo

2. With respect to myocarditis, if you are FORCED to take a vaccine and looking to avoid serious cardiac issues, you'd be a fool to choose Moderna

3. If you are holding Moderna stock, you should get rid of it. Note: it could take the financial market years to figure this stuff out.

Where is the ROR analysis by brand for serious adverse events? Have you seen it?

The health officials should be doing ROR by brand for the top 20 most serious adverse events for the COVID vaccines and informing the public. Why are they not doing this? Do all of them work for pharmaceutical companies?

<https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fsubstack.com%2Fredirect%2F4bd
a7f8-4ad5-812b-
a6f7302ef83c%3Fj%3DeyJ1IjoiMTVpZnQ2In0.PoWkYg8wHoPi84O6BbnZ2dl3zAYJI3AKz0ikcuhTjA4&data=05

The ROR for myocarditis in VAERS

The ROR is 16 in the US VAERS database. In short, the COVID shots are not safe.

<https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fsubstack.com%2Fredirect%2Fb83
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dbff8071696b%3Fj%3DeyJ1IjoiMTVpZnQ2In0.PoWkYg8wHoPi84O6BbnZ2dl3zAYJI3AKz0ikcuhTjA4&data=0

Summary

The FDA and CDC are working to protect the drug companies, not the public.

This paper makes that crystal clear.

I've reached out to my network to produce an ROR report on all the top symptoms from the VAERS data and I'll promote to the public how the CDC and FDA have misled them. They deserve to be recognized for their hard work.

Share

Invite your friends and earn rewards

If you enjoy Steve Kirsch's newsletter, share it with your friends and earn rewards when they subscribe.

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OIcVqxGq9_y2hXEvqCIJ6alvdiu1ZmE%3F%26utm_source%3Dsubstack%26utm_medium%3Demail%26utr

Share
<https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fsubstack.com%2Fapp-
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Restack

548 Market Street PMB 72296, San Francisco, CA 94104

From: bill teachingsmiles.com
Sent: 11/8/2024 10:19:56 AM
To: DOH WSBOH
Cc:
Subject: November Public Comment: Rulemaking WAC 246 290-22

External Email

Public Comment for November 2024. RE: Agenda Item #8
Bill Osmunson DDS MPH
Washington Action for Safe Water

When I started working at my last dental office, they were making over $200,000 a year selling fluoride.
Fluoridation appears to be increasing complete tooth fractures from about 2% of visits without fluoridation to about 7% of visits with fluoridation, add cosmetic treatments and fluoridation is a cash cow for us dentists.
Looking back, I was clearly making money both selling fluoride and treating the harm caused by fluoride. A win, win for my pocket book.
Fluoridation gets even more lucrative. The Board and authorities are some PR firms for dentists. No marketing expenses and powerful government authoritative endorsements.
And insurance companies pay or help pay for the sales and for the treatment.
And we feel we are doing so much good for those poor children.

The fluoridation lobby is seriously biased, both conscious and sub-conscious with known clear conflict of interest.
The Board has relied on money rather than science in promoting fluoridation. (Riches vs Risk)
The Board has refused to obey the law which requires the Board to hold a forum.
The Board has refused to obey Federal law which requires FDA approval for drugs. (Banned)
Neither the NSF, nor any Federal Authority EPA, CDC, FDA, nor any of the three fluoride raw manufacturers under sworn testimony in deposition said they had a single safety study on fluoride - - and in thousands of pages of evidence, neither does the Board.
Trusting money is not science.
The Board does not have a single Randomized Controlled Trial on benefit. Not one.
The Board has failed to include the cost of treating harm in their cost benefit claims. They only consider observation of alleged benefit - - a shocking lack of ethics and science.
The Board has failed to determine a dosage which prevents dental caries nor a dosage a person is ingesting from all sources (not just fluoride in water).
The Board has failed to provide or recommend a label or patient's doctor's oversight.
The Board has failed to provide a margin of safety.
The Board has failed to follow the Safe Drinking Water Act.
The Board has failed to recommend a pharmaceutical grade product.
The Board has failed to recommend Good Drug Manufacturing Practices.
The Board has failed to follow the science of harm to the developing brain, now confirmed by the National Toxicology Program and the U. S. Court.
The Board has failed, in light of current research, to carefully consider the National Research Council list of health risks, which 18 years ago included:

1. Tooth damage,
2. Rheumatoid and osteoarthritic-like pain,
3.

Bone cancer, Bone fractures
4. Thyroid reduction -Diabetes -Obesity

5. Kidney damage
6. Reproductive problems
7. Lower IQ --developmental neurotoxicity
8. Allergies (overactive immune system)
9. Gastrointestinal disorders.

Any review of fluoridation must be science based, rather than just money, and inclusive of all streams of evidence.
We have no conflict of interest and are not paid to provide our time to the Board. Our only concern is for public health.
Sincerely,
Bill Osmunson DDS MPH
Washington Action for Safe Water

From: bill teachingsmiles.com
Sent: 10/8/2024 4:22:00 PM
To: DOH WSBOH
Cc:
Subject: Request and Forum

External Email

Please forward to the Board of Health Members

Dear Board of Health, October 8, 2024
RE: Request for participation and Forum.
After public comment today, Tao mentioned the Department was planning on doing a review of fluoridation. In speaking with him during the break, he did not have specifics on time or contact person, but promised to get me an email address.
RCW instructs the Board, not the Department, to have a forum RCW 43.20.050 <https://gcc02.safelinks.protection.outlook.com/?url=http%3A%2F%2Fapp.leg.wa.gov%2FRCW%2Fdefaul
. I have significant reservations with the Department reviewing science and laws which they have denied and been biased with the evidence since the dawn of fluoridation. The Department has a significant investment of employee, advice, tradition, and money into fluoridation. The job is for the Board, not the Department to have a forum.
Fluoridation is controversial and a review must be transparent and balanced. Cherry picking evaluators will not result in protecting the public from harm.
The WA AGO in 1992 No. 17, "2. The Legislature has authorized the Board of Health to establish, and the Department of Health to enforce, a comprehensive regulatory scheme for public water systems."
RCW 43.20.50 (2) "In order to protect public health, the state board of health shall: (a) Adopt rules for group A public water systems. . . necessary to assure safe and reliable public drinking water and to protect the public health."
The Board's job is to adopt rules, the Department's job to enforce the rules. Turning the job of evaluating fluoridation's risk and lack of efficacy over to the "enforcer" to make a rule is unlikely to protect the public. The Department has for decades and is currently invested in promoting fluoridation. We have submitted 20 petitions to protect the public, rejected to a large extent on the advice of the Department.
Turning over the judgment of fluoridation research and laws to the Department would be similar to asking the fossil fuel industry to evaluate global worming or the tobacco industry to evaluate the risks of smoking tobacco. Explicit, implicit, hidden, unconscious bias is powerful and the Department has all 4.
Members of any review must be from both sides of the controversy or results will not be accepted by many in the community. This is a paradigm shift which requires education on the science. A forum would be valuable in educating the public. . . especially dentists and physicians engrained in the myth of fluoridation's huge benefit without any risk.
My request is for the Department of Health to provide a forum as the law requires and that I be permitted to participate with any evaluation of fluoridation done by the Board and/or Department of Health.
Sincerely,
Bill Osmunson DDS MPH

See also RCW 70.05.060 <https://gcc02.safelinks.protection.outlook.com/?url=http%3A%2F%2Fapp.leg.wa.gov%2FRCW%2Fdefaul

From: Testify Online Survey
Sent: 11/5/2024 8:58:19 AM
To: DOH WSBOH
Cc:
Subject: Survey Response: Testify Online *

The following survey response is submitted:

1.

State Board of Health Meeting Date:

November 13th 2024

2.

Agenda Item or Issue:

Metachromatic Leukodystrophy (MLD) NBS in WA

3.

Your Name:

_____

Emilia I Wilburn

4.

Do you have a professional title?

1. Yes

_____

MPD

5.

Are you representing an organization?

1. Yes

_____

Orchard Therapeutics

6.

Address:

_____

101 Seaport Boulevard, 7th Floor Boston, MA 02210 United States

7.

Email:

_____

emilia.wilburn@orchard-tx.com

8.

Phone Number (Include Area Code):

_____

5208342922

9.

Do you have any special expertise relevant to this topic?

2. No

10.

Are you testifying on a specific proposal under consideration by the board?

2. No

11.

Are you Pro or Con on the proposal?

1. Pro

Not testifying on a specific proposal under consideration by the board.

STATE OF WASHINGTON
WASHINGTON STATE BOARD OF HEALTH
PO Box 47990 • Olympia, Washington 98504-7990

October 24, 2024

Dan Curley
Owner
Cheney Aquatic Center
609 2nd Street
Cheney, WA 99004

Sent via email

Dear Dan Curley:

I'm writing to inform you that the State Board of Health (Board) approved the variance requests for the AquaClimb and AquaZip'N at the Cheney Aquatic Center. Additionally, the Board determined that a variance is not required for the construction of a Ninja Cross as requested. Here's a brief summary of the variance request and Board action.

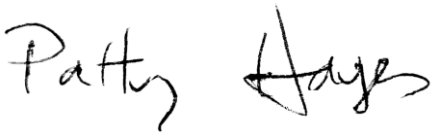
On June 25, 2024, you sent a letter to the Board requesting a variance to a standard in WAC 246-262-060(5)(b)(vi) pertaining to diving envelope requirements. Specifically, your request referred to the installation of an AquaClimb climbing wall, an AquaZip'N rope swing, and a Ninja Cross.

At its meeting on October 8, 2024, the Board approved the installation of the Aqua Climb and AquaZip'N as specified in the variance request subject to the conditions attached to this letter. The Board adopted the Department of Health's recommendation that the installation of a Ninja Cross, as specified in the variance request, complies with the rules and does not require a variance, but is subject to all the conditions recommended in the manufacturer and user guidelines, and by the Department of Health.

This approval allows you to install the equipment as specified in the variance requests with the conditions specified in the attachment.

Thank you for your patience and for the work of your staff and consultants on this matter. If you have questions or need additional information, please contact Shay Bauman, Policy Advisor at 564-669-8929 or Shay.Bauman@sboh.wa.gov.

Sincerely,



Patty Hayes, Chair

Cc: Michelle Davis, State Board of Health
David DeLong, Washington State Department of Health
Steve Main, Spokane Regional Health District
Sandy Phillips, Spokane Regional Health District

STATE OF WASHINGTON
WASHINGTON STATE BOARD OF HEALTH
PO Box 47990 • Olympia, Washington 98504-7990

October 24, 2024

Conditions to the approval of the Aquaclimb and AquaZip'N Rope Swing at the Cheney Aquatic Center

Aquaclimb

1. All manufacturer installation, maintenance, and use guidelines must be followed.
2. The Aqua Climb must be installed as shown on submitted plans with a minimum water depth of 10 ft. under the 5-alt climbing panels, and a minimum water depth of 11 feet under the 5-high climbing panels.
3. Detailed signs specifying user rules must be posted, including the minimum and maximum user height and weight.
4. Only one user may be permitted to occupy the Aqua Climb at one time.
5. A dedicated lifeguard must be provided for the Aqua Climb climbing wall. The lifeguard must control the entry and exit of users.
6. The Aqua Climb climbing wall must be inspected daily and any identified maintenance issues must be addressed prior to opening the wall to users.
7. Lifeguard and operations plans must be developed and submitted to the local health jurisdiction prior to the issuance of a pool operating permit.
8. Only the Krystal clear version may be used in order to promote visibility through the climbing wall structure.

Aqua Zip'N Rope Swing

1. All manufacturer installation, maintenance, and use guidelines must be followed.
2. The Aqua Zip'N must be installed as shown on submitted plans with a minimum water depth of 8ft. under the center of the Aqua Zip'N device.
3. Detailed signs specifying user rules must be posted, including the minimum and maximum user height and weight.
4. Only one user may be permitted at one time.

5. A dedicated lifeguard must be provided for the Aqua Zip'N. The lifeguard must control the entry and exit of users.

6. The Aqua Zip'N must be inspected daily and any identified maintenance issues must be addressed prior to opening the wall to users.

7. Lifeguard and operations plans must be developed and submitted to the local health jurisdiction prior to the issuance of a pool operating permit.

STATE OF WASHINGTON
WASHINGTON STATE BOARD OF HEALTH
PO Box 47990 • Olympia, Washington 98504-7990

October 24, 2024

Ken Wilkinson
Owner
Aquatic Center at MLK Jr. Park
129 N 2nd street
Yakima, WA 98901

Sent via email

Dear Ken Wilkinson:

I'm writing to inform you that the State Board of Health (Board) conditionally approved the variance requests for the AquaClimb and AquaZip'N at the Aquatic Center at MLK Jr. Park. The Board also determined that a variance is not required for the construction of a Ninja Cross as requested. Here's a brief summary of the variance request and Board action.

On June 20, 2024, you sent a letter to the Board requesting a variance to a standard in WAC 246-262-060(5)(b)(vi) pertaining to diving envelope requirements. Specifically, your request referred to the installation of an AquaClimb climbing wall, an AquaZip'N rope swing, and a Ninja Cross.

At its meeting on October 8, 2024, the Board approved the installation of the Aqua Climb and AquaZip'N as specified in the variance request subject to the conditions attached to this letter. The Board adopted the Department of Health's recommendation that the installation of a Ninja Cross, as specified in the variance request, complies with the rules and does not require a variance, but is subject to all the conditions recommended in the manufacturer and user guidelines, and by the Department of Health.

This approval allows you to install the equipment as specified in the variance requests with the conditions specified in the attachment.

Thank you for your patience and for the work of your staff and consultants on this matter. If you have questions or need additional information, please contact Shay Bauman, Policy Advisor at 564-669-8929 or Shay.Bauman@sboh.wa.gov.

Sincerely,

Patty Hayes

Patty Hayes, Chair

Cc: Michelle Davis, State Board of Health
David DeLong, Washington State Department of Health
Justin Law, Washington State Department of Health
Carina Gonzalez, Yakima Health District
Kaitlyn Wolterstorff, Yakima Health District

STATE OF WASHINGTON
WASHINGTON STATE BOARD OF HEALTH
PO Box 47990 • Olympia, Washington 98504-7990

October 24, 2024

Conditions to the approval of the Aquaclimb and AquaZip'N Rope Swing at the Aquatic Center at MLK Jr. Park

Aquaclimb

1. All manufacturer installation, maintenance, and use guidelines must be followed.
2. The Aqua Climb must be installed as shown on submitted plans with a minimum water depth of 6.5 ft.
3. Detailed signs specifying user rules must be posted, including the minimum and maximum user height and weight.
4. Only one user may be permitted to occupy the Aqua Climb at one time.
5. A dedicated lifeguard must be provided for the Aqua Climb climbing wall. The lifeguard must control the entry and exit of users.
6. The Aqua Climb climbing wall must be inspected daily and any identified maintenance issues must be addressed prior to opening the wall to users.
7. Lifeguard and operations plans must be developed and submitted to the local health jurisdiction prior to the issuance of a pool operating permit.

Aqua Zip'N Rope Swing

1. All manufacturer installation, maintenance, and use guidelines must be followed.
2. The Aqua Zip'N must be installed as shown on submitted plans with a minimum water depth of 6ft.
3. Detailed signs specifying user rules must be posted, including the minimum and maximum user height and weight.
4. Only one user may be permitted at one time.
5. A dedicated lifeguard must be provided for the Aqua Zip'N. The lifeguard must control the entry and exit of users.

6. The Aqua Zip'N must be inspected daily and any identified maintenance issues must be addressed prior to opening the wall to users.

7. Lifeguard and operations plans must be developed and submitted to DOH and the Local Health Jurisdiction prior to the issuance of a pool operating permit.

RULE-MAKING ORDER
EMERGENCY RULE ONLY

CR-103E (December 2017)
(Implements RCW 34.05.350 and 34.05.360)

CODE REVISER USE ONLY

OFFICE OF THE CODE REVISER
STATE OF WASHINGTON
FILED

DATE: October 22, 2024
TIME: 12:02 PM

WSR 24-21-138

Agency: State Board of Health

Effective date of rule:

Emergency Rules

☒ Immediately upon filing.

☐ Later (specify)

Any other findings required by other provisions of law as precondition to adoption or effectiveness of rule?

☐ Yes ☒ No If Yes, explain:

Purpose: Testing of drinking water contaminates - State action levels (SALs) and state maximum contaminant levels (MCLs) in WAC 246-290-315.

The State Board of Health (board) has authority under RCW 43.20.050 to adopt rules for group A public water systems that are necessary to assure safe and reliable public drinking water and to protect the public health. Chapter 246-290 WAC, Group A Public Water Supplies, establishes standards and requirements for these water systems. The Department of Health (department) administers the rules.

To ensure safe drinking water, water must be tested for contaminants. The board establishes SALs and MCLs to ensure contaminate levels are below a certain threshold. The board sets criteria for the adoption of SALs and MCLs in WAC 246-290-315 and includes criteria that would apply upon federal adoption of MCLs. WAC 246-290-315(8) states that upon federal adoption of a MCL, the MCL will supersede a less stringent SAL and associated requirements, including monitoring and public notice.

The EPA published new federal standards for per- and polyfluoroalkyl substances (PFAS) on April 10, 2024, with an adoption date of June 25, 2024. These new standards include MCLs. This affects the board's rule and triggers the provision in WAC 246-290-315(8). The federal standards, however, have delayed effective dates for criteria and public health protections that are currently in place for Washington. According to the Washington state rules associated with the SALs, public water systems must notify customers of detections of PFAS above the SAL within 30 days of that detection. This is necessary to allow people the opportunity to protect themselves by using bottled water, securing a filter, or taking other measures. 30-day public notification is not effective for MCLs in the federal standard until April 2029. Without this amendment to WAC 246-290-315, customers served by group A public water systems will no longer be notified of dangerous levels of PFAS in their drinking water, which is a significant reduction in protections.

The board adopted an emergency rule on June 12, 2024, to amend WAC 246-290-315 such that the criteria would apply on the effective date of an MCL as set in the federal standard, not the adoption date, in order to maintain vital public health protections for drinking water safety. Along with the emergency rulemaking, the board initiated a permanent rulemaking to amend the rule language to align with the emergency provision and explore other protections. The CR-101, Preproposal Statement of Inquiry, for the permanent rulemaking was filed as WSR 24-20-093 on September 30, 2024. This 2nd emergency rule continues the emergency rule originally filed on June 24, 2024, as WSR 24-14-016, without change.

Citation of rules affected by this order:
New: None
Repealed: None
Amended: WAC 246-290-315
Suspended: None

Statutory authority for adoption: RCW 43.20.050(2)(a)

Other authority:

EMERGENCY RULE

Under RCW 34.05.350 the agency for good cause finds:

☒ That immediate adoption, amendment, or repeal of a rule is necessary for the preservation of the public health, safety, or general welfare, and that observing the time requirements of notice and opportunity to comment upon adoption of a permanent rule would be contrary to the public interest.

☐ That state or federal law or federal rule or a federal deadline for state receipt of federal funds requires immediate adoption of a rule.

Reasons for this finding: The federal adoption date of the standards was June 25, 2024, at which point the MCLs and relative protections would have superseded the SALs. Because of the delayed effective date, currently active public health protections would have ended on that date. The Board finds that emergency adoption of this rule is necessary to preserve public health.

Note: If any category is left blank, it will be calculated as zero. No descriptive text.

Count by whole WAC sections only, from the WAC number through the history note. A section may be counted in more than one category.

The number of sections adopted in order to comply with:

Federal statute:	New 0	Amended 0	Repealed 0
Federal rules or standards:	New 0	Amended 0	Repealed 0
Recently enacted state statutes:	New 0	Amended 0	Repealed 0

The number of sections adopted at the request of a nongovernmental entity:

New 0	Amended 0	Repealed 0

The number of sections adopted on the agency's own initiative:

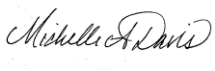
New 0	Amended 1	Repealed 0

The number of sections adopted in order to clarify, streamline, or reform agency procedures:

New 0	Amended 0	Repealed 0

The number of sections adopted using:

Negotiated rule making:	New 0	Amended 0	Repealed 0
Pilot rule making:	New 0	Amended 0	Repealed 0
Other alternative rule making:	New 0	Amended 1	Repealed 0

Date Adopted: October 22, 2024	**Signature:** 
Name: Michelle Davis, MPA	
Title: Executive Director, Washington State Board of Health	

AMENDATORY SECTION (Amending WSR 21-23-097, filed 11/17/21, effective 1/1/22)

WAC 246-290-315 State action levels (SALs) and state maximum contaminant levels (MCLs). (1) The department shall consider the following criteria to select a contaminant for developing a SAL:

(a) Drinking water contributes to human exposure to the contaminant.

(b) The contaminant is known or likely to occur in public water systems at levels of public health concern. Sources of occurrence information include, but are not limited to:

(i) Washington state department of agriculture;

(ii) Washington state department of ecology; and

(iii) Monitoring results reported in accordance with 40 C.F.R. 141.35.

(c) The contaminant has a possible adverse effect on the health of persons exposed based on peer-reviewed scientific literature or government publications, such as:

(i) An EPA health assessment such as an Integrated Risk Information System assessment;

(ii) Agency for Toxic Substances and Disease Registry toxicological profiles;

(iii) State government science assessment; and

(iv) EPA guidelines for exposure assessment such as the EPA exposure factors handbook.

(d) A certified drinking water lab can accurately and precisely measure the concentration of the contaminant in drinking water at and below the level of public health concern using EPA-approved analytical methods.

(2) After consideration of the criteria in subsection (1) of this section, the department may develop a SAL based on the following:

(a) Evaluation of available peer-reviewed scientific literature and government publications on fate, transport, exposure, toxicity and health impacts of the contaminant and relevant metabolites;

(b) An assessment based on the most sensitive adverse effect deemed relevant to humans and considering susceptibility and unique exposures of the most sensitive subgroup such as pregnant women, fetuses, young children, or overburdened and underserved communities; and

(c) Technical limitations to achieving the SAL such as insufficient analytical detection limit achievable at certified drinking water laboratories.

(3) The state board of health shall consider the department's findings under subsections (1) and (2) of this section when considering adopting a SAL under this chapter.

(4) Contaminants with a SAL.

(a) If a SAL under Table 9 of this section is exceeded, the purveyor shall take follow-up action as required under WAC 246-290-320. For contaminants where the SAL exceedance is determined based upon an RAA, the RAA will be calculated consistent with other organic contaminants per WAC 246-290-320(6) or other inorganic contaminants per WAC 246-290-320(3).

TABLE 9
STATE ACTION LEVELS

Contaminant or Group of Contaminants	SAL	SAL Exceedance Based On:
Per- and polyfluoroalkyl substances (PFAS)		
PFOA	10 ng/L	Confirmed detection
PFOS	15 ng/L	Confirmed detection
PFHxS	65 ng/L	Confirmed detection
PFNA	9 ng/L	Confirmed detection
PFBS	345 ng/L	Confirmed detection

(b) If a system fails to collect and submit a confirmation sample to a certified lab within ten business days of notification of the sample results, or as required by the department, the results of the original sample will be used to determine compliance with the SAL.

(5) The department shall consider the following when developing a state MCL:

(a) The criteria in subsection (1) of this section;

(b) Whether regulating the contaminant presents a meaningful opportunity to reduce exposures of public health concern for persons served by public water systems;

(c) The need for an enforceable limit to achieve uniform public health protection in Group A public water systems; and

(d) The need for an enforceable limit to support source water investigation and clean-up of a contaminant in drinking water supplies by responsible parties.

(6) In addition to the requirements in subsection (5) of this section, the department shall:

(a) Meet the requirements of subsection (2) of this section;

(b) Comply with the requirements in RCW 70A.130.010 to establish standards for chemical contaminants in drinking water;

(c) Consider the best available treatment technologies and affordability taking into consideration the costs to small water systems; and

(d) Determine that the probable benefits of the rule are greater than its probable costs, taking into account both the qualitative and quantitative benefits and costs.

(7) The state board of health shall consider the department's findings under subsections (5) and (6) of this section and follow the requirements under chapters 34.05 and 19.85 RCW when adopting a state MCL under this chapter.

(8) ((~~Upon federal adoption of an MCL~~)) When a federal MCL takes effect, the federal MCL will supersede a SAL or a less stringent state MCL, and the associated requirements, including for monitoring and public notice. If the federally adopted MCL is less stringent than a SAL or state MCL, the board may take one of the following actions:

(a) Adopt the federal MCL; or

(b) Adopt a state MCL, at least as stringent as the federal MCL, using the process in subsections (6) and (7) of this section.

STATE OF WASHINGTON
WASHINGTON STATE BOARD OF HEALTH
PO Box 47990 • Olympia, Washington 98504-7990

October 3, 2024

Washington Pharmacy Quality Assurance Commission
PO Box 47852,
Olympia, WA 98504-7852

Subject: Washington State Board of Health Public Comments on Proposed Rules for Prescription Drug Label Accessibility Standards

The Washington State Board of Health (Board) supports the concepts outlined in the Department of Health, Pharmacy Quality Assurance Commission's proposed rules on prescription drug label accessibility standards. We appreciate your efforts in advancing these changes.

The Board believes that access to prescription information in a person's preferred or primary language is a fundamental right. It is essential for this information to be accessible and easy to understand for everyone, particularly for communities that are underserved and face systemic barriers to accessing care. Ensuring this access protects patient health and safety and helps build health equity. When individuals are unable to access quality medical information, their health and well-being are negatively impacted. Lack of language accessibility can result in patient-provider miscommunication, medication errors, delays in care or treatment, injuries, and other adverse health events.[1][2][3] For these reasons, we respectfully submit the following comments on the proposed rules filed under WSR-24-17-046.

During the 2022 legislative session, staff on behalf of the Board and Health Disparities Council conducted a Health Impact Review (HIR) of Engrossed Substitute House Bill (ESHB) 1852.[4] This proposal would have required the Commission to establish requirements for the translation of prescription drug labels and prescription information. The HIR evidence indicated the proposal could lead to more pharmacies offering translated information, improving access to culturally and linguistically appropriate services for people who speak a language other than English (LOTE). This, in turn, would likely enhance health outcomes and reduce health inequities. Although this bill did not pass, in response to the HIR findings, the Board issued recommendations in its 2022 and 2024 State Health Reports to the Governor's Office aimed at expanding access to translation and interpretation of prescription and medical information.

The Board supports the Commission's new rule sections, WAC 246-945-026 through WAC 246-945-029, regarding the accessibility of prescription information for visually impaired or print disabled individuals and providing translation and interpretation for people who speak a LOTE. However, these sections lack considerations and standards around signed languages, such as American Sign Language (ASL), languages that do not have a written form, such as Hmong, or providing culturally appropriate translation

[1] Al Shamsi H, Almutairi AG, Al Mashrafi S, Al Kalbani T. Implications of Language Barriers for Healthcare: A Systematic Review. Oman Med J. 2020;35(2):e122. doi:10.5001/omj.2020.40
[2] Divi C, Koss RG, Schmaltz SP, Loeb JM. Language proficiency and adverse events in US hospitals: a pilot study. International Journal for Quality in Health Care. 2007;19(2):60-67. doi:10.1093/intqhc/mzl069
[3] Twersky SE, Jefferson R, Garcia-Ortiz L, Williams E, Pina C. The Impact of Limited English Proficiency on Healthcare Access and Outcomes in the U.S.: A Scoping Review. Healthcare. 2024;12(3):364. doi:10.3390/healthcare12030364
[4] HIRs are objective, non-partisan, evidence-based analyses, made at the request of the Governor or Legislators, that determine how a legislative or budgetary change may impact health and equity.

through a qualified interpreter. These sections also do not include requirements for pharmacies to provide different modalities to support people who are Deaf, Deaf Blind, or Hard of Hearing.

During recent community engagement, the Board heard from representatives of the Deaf community that materials in written English do not adequately serve those who use ASL or other signed languages. While WAC 246-945-029 requires facilities and practitioners to provide oral and written interpretation services, it does not mention signed interpretation services. **The Board recommends adding language to WAC 246-945-029 to require facilities and practitioners to provide signed interpretation services alongside oral and written services, using various modalities as needed.**

Additionally, the HIR for ESHB 1852 highlighted the importance of culturally appropriate and accurate multilingual translations for prescriptions, as well as the challenges in developing them. For translations to be accurate, they need to replicate the intended meaning of what is being translated. Some common concepts used in prescription instructions in the U.S. may not exist in some cultures. For example, prescription instructions may include taking a pill "once in the morning and once in the evening" but Chinese doesn't have a commonly used equivalent term for the word "evening."[5] Additionally, some languages, like Hmong, do not have a written form. Therefore, alternative methods beyond signage should be considered for conveying prescription information. **The Board recommends including language in the proposed rules and guidance for rule implementation to ensure that translations are accurate, provided by qualified interpreters, and culturally appropriate.**

WAC 246-945-028 covers accessibility of prescription information for "visually impaired or print disabled individuals." It does not include language for Deaf, Hard of Hearing, or Deaf-Blind people. **The Board recommends adding language to the definitions section and WAC 246-945-028 to be inclusive of people with other disabilities, and to support different prescription information modalities other than written materials and oral interpretation.**

WAC 246-945-029 also requires the Commission to create signage for facilities and providers, informing people of their right to oral interpretation and written translation services in the ten most common languages in Washington. Earlier this year, the U.S. Department of Health and Human Services (HHS) issued a final rule under Section 1557 of the Affordable Care Act (ACA) to strengthen non-discrimination protections and advance civil rights in healthcare.[6] Under the final rule, all covered entities must display notices about civil rights under Section 1557 and provide information on free language assistance services and auxiliary aids in the top fifteen languages spoken. **The Board recommends that the Commission align with current HHS rules by providing signage in a minimum of fifteen languages.**

The Board thanks the Commission for considering these comments and looks forward to hearing the outcomes of these proposed rules. If you have any questions or would like additional information, please do not hesitate to reach out to us at wsboh@wa.gov.

Sincerely,

Patty Hayes

Patty Hayes, Chair
Washington State Board of Health

[5] Bailey SC, Hasnain-Wynia R, Chen AH, et al. Developing Multilingual Prescription Instructions for Patients with Limited English Proficiency. Journal of Health Care for the Poor and Underserved. 2012;23(1):81-87.

[6] Nondiscrimination in Health Programs and Activities, 89 Fed. 37522 (2024). 42 CFR Parts 438, 440, 457, and 460, 45 CFR Parts 80, 84, 92, 147, 155, and 156. Accessed October 1, 2024. https://www.govinfo.gov/content/pkg/FR-2024-05-06/pdf/2024-08711.pdf

WASHINGTON STATE BOARD OF HEALTH

Thurston County Public Health Social & Services, Olympia
SBOH Public Meeting - November 13, 2024

Dr. Jen Freiheit

Jen Freiheit, PhD, MCHES
Interim Director
Thurston County Public Health Social & Services, Olympia

Dr. Freiheit has worked in state and local public health leadership roles since 2002 serving health departments and communities in Southeastern Wisconsin and Thurston County, Washington. She currently serves as the Interim Director of Thurston County Public Health & Social Services. She has a deep commitment to impacting public health practice through her passion for organizational change, leadership, and equity with an agenda that includes workforce Development, strategic planning, and emergency preparedness and response. Throughout her long career, she led several responses to emergencies from H1N1 to COVID-19.

Dr. Freiheit currently teaches MPH and DrPH students at the Medical College of Wisconsin as an Adjunct Assistant Professor under the Institute for Health & Equity: courses include Leadership for the Public's Health, Executive & Organizational Leadership, and Community Health Program Planning.

THURSTON COUNTY
WASHINGTON
SINCE 1852

WASHINGTON STATE BOARD OF HEALTH

2025 Meeting Schedule

Proposed to the Board November 13, 2024

Note: Precise location and meeting time will be posted to the Board's website at least two weeks in advance of the meeting.

	Meeting Date	Location
Board	**Wednesday** **January 8, 2025**	**Hybrid:** • **Physical Location; Washington State Department of Labor & Industries, 7273 Linderson Way SW Tumwater, WA 98501-5414, (LNI Auditorium)** • **Virtual Meeting via ZOOM Webinar; hyperlink provided on website and agenda. Public Attendees can pre-register and access the meeting online.**
Board	**Wednesday** **March 12, 2025**	**Hybrid:** • **Physical Location; To Be Determined (TBD), likely Ilani Resort, 1 Cowlitz Way, Ridgefield WA 98642** • **Virtual Meeting via ZOOM Webinar; hyperlink provided on website and agenda. Public Attendees can pre-register and access the meeting online.**
Board	**Wednesday** **April 9, 2025**	**Hybrid:** • **Physical Location; To Be Determined (TBD), likely Tri-Cities, WA** • **Virtual Meeting via ZOOM Webinar; hyperlink provided on website and agenda. Public Attendees can pre-register and access the meeting online.**
Board	**Wednesday** **June 11, 2025**	**Hybrid:** • **Physical Location; To Be Determined (TBD), likely Chelan, WA** • **Virtual Meeting via ZOOM Webinar; hyperlink provided on website and agenda. Public Attendees can pre-register and access the meeting online.** *(note: WA State Association of Local Public Health Officials (WSALPHO) Annual meeting is at Semiahmoo Resort in Blaine, WA, June 3-5, 2025)*
Board	**Wednesday** **July 9, 2025**	**Hold date – meet only if necessary**

Board	**Wednesday** **August 20, 2025** **(3rd Week)**	**Hybrid:** • **Physical Location; To Be Determined (TBD), likely Port Angeles, WA.** • **Virtual Meeting via ZOOM Webinar; hyperlink provided on website and agenda. Public Attendees can pre-register and access the meeting online.**
Board	**Wednesday** **October 8, 2025**	**Hybrid:** • **Physical Location; To Be Determined (TBD), likely Ellensburg, WA.** • **Virtual Meeting via ZOOM Webinar; hyperlink provided on website and agenda. Public Attendees can pre-register and access the meeting online.** *(note: WA State Public Health Association (WSPHA) Annual conference is in Yakima, October 21-23, 2025. The WSALPHO Environmental Public Health Directors meeting is Sept 30-Oct 3 in Leavenworth)*
Board	**Wednesday** **November 19, 2025** **(3rd week)**	**Hybrid:** • **Physical Location; To Be Determined (TBD), likely in Tumwater, WA at LNI or DOH** • **Meeting via ZOOM Webinar; hyperlink provided on website and agenda. Public Attendees can pre-register and access the meeting online.**

Start time is 9:30 a.m. unless otherwise specified. Time and locations subject to change as needed. See the Board of Health Web site and the Health Disparities Council Web site for the most current information.

Last updated 11/13/2024

WASHINGTON STATE BOARD OF HEALTH

Date: November 13, 2024

To: Washington State Board of Health Members

From: Kate Dean, Board Member

Subject: Panel – State Agency Response to Per- and Polyfluoroalkyl Substances

Background and Summary:

On June 12, 2024, in response to the Environmental Protection Agency's adoption of a maximum contaminant level (MCL) for Per- and Polyfluoroalkyl Substances (PFAS), the State Board of Health (Board) initiated three rulemakings to revise the Board's PFAS requirements for drinking water. With this action and prior rulemakings related to PFAS, the Board joins many state agencies working in different capacities to research and mitigate these contaminants.

PFAS are a group of man-made chemicals used in many products for their water, grease, and stain-resistant properties. They've been used in things like non-stick cookware, waterproof clothing, food packaging, and firefighting foam. PFAS do not break down easily in the environment or the human body, which means they can accumulate over time. Studies have linked PFAS exposure to health issues, including certain cancers, immune system effects, and developmental problems in children.

The Board's rulemaking authority pertains to Group A Public Water Systems, which is one piece of the regulatory framework aimed at reducing exposure to PFAS chemicals. Today, representatives from the Department of Health (DOH) and the Department of Ecology (ECY) will present their respective office's efforts towards PFAS mitigation:

- Barbara Morrissey (DOH) will discuss the science and cycle of PFAS and how the chemicals flow from water to secondary sources, including fish and marine life.
- Bonnie Brooks (ECY) will present Ecology's efforts towards toxic clean-up of contaminated sites.
- Claire Nitsche (DOH) will share efforts towards environmental health literacy with the public and health education of PFAS.
- Holly Davies (DOH) and Marissa Smith (ECY) will highlight Washington's efforts to remove PFAS from consumer products and joint efforts between the two agencies.

PFAS are a rapidly evolving issue, and many state and local governments are working to protect communities from these chemicals. Staff will continue to bring educational opportunities to familiarize the Board with the landscape of this work.

(continued on the next page)

This is not an action item.

Staff
Shay Bauman

To request this document in an alternate format or a different language, please contact the Washington State Board of Health at 360-236-4110 or by email at wsboh@sboh.wa.gov. TTY users can dial 711.

STATE ACTIVITIES TO ADDRESS PFAS

PANEL Barbara, Morrissey, DOH
Bonnie Brooks, ECY
Claire Nitsche, DOH
Holly Davis, DOH
Marissa Smith, ECY

Washington State Department of HEALTH

State Programs Working on PFAS

Washington State Department of Ecology

- Enviro. Assessment Program
- Air Quality Program
- Hazardous Waste and Toxics Reduction
  - RCRA
  - Pollution Prevention
  - Climate Pollution Reduction
- Office of Equity and Environmental Justice
- Solid Waste Management Program
  - Biosolids
  - Landfills
  - Industrial
- Toxics Cleanup Program
- Water Quality Program
  - Wastewater
  - Stormwater
- Nuclear Waste Program
  - Cleanup

Washington State Department of Fish and Wildlife

- Toxics Biological Observation System

Washington State Attorney General's Office

- Lawsuit against the manufacturers of AFFF

Washington State Department of Health

- Office of Drinking Water
  - Source Monitoring
  - Policy and Planning
  - Water Quality
  - Engineering and Technical Services
  - Regional Offices
  - Statewide Revolving Fund
  - Operator Certification Program
- Office of Environmental Public Health Sciences
  - Site Assessment and Toxicology
- Office of Public Affairs and Equity
  - Center for Health Promotion and Education

Washington State Department of Agriculture

- Food Protection Task Force
- Animal Health

Washington State Department of Commerce

- Local Government Division
  - Emergency Rapid Response
  - Public Works Board – Construction Loan Program

Panel Outline

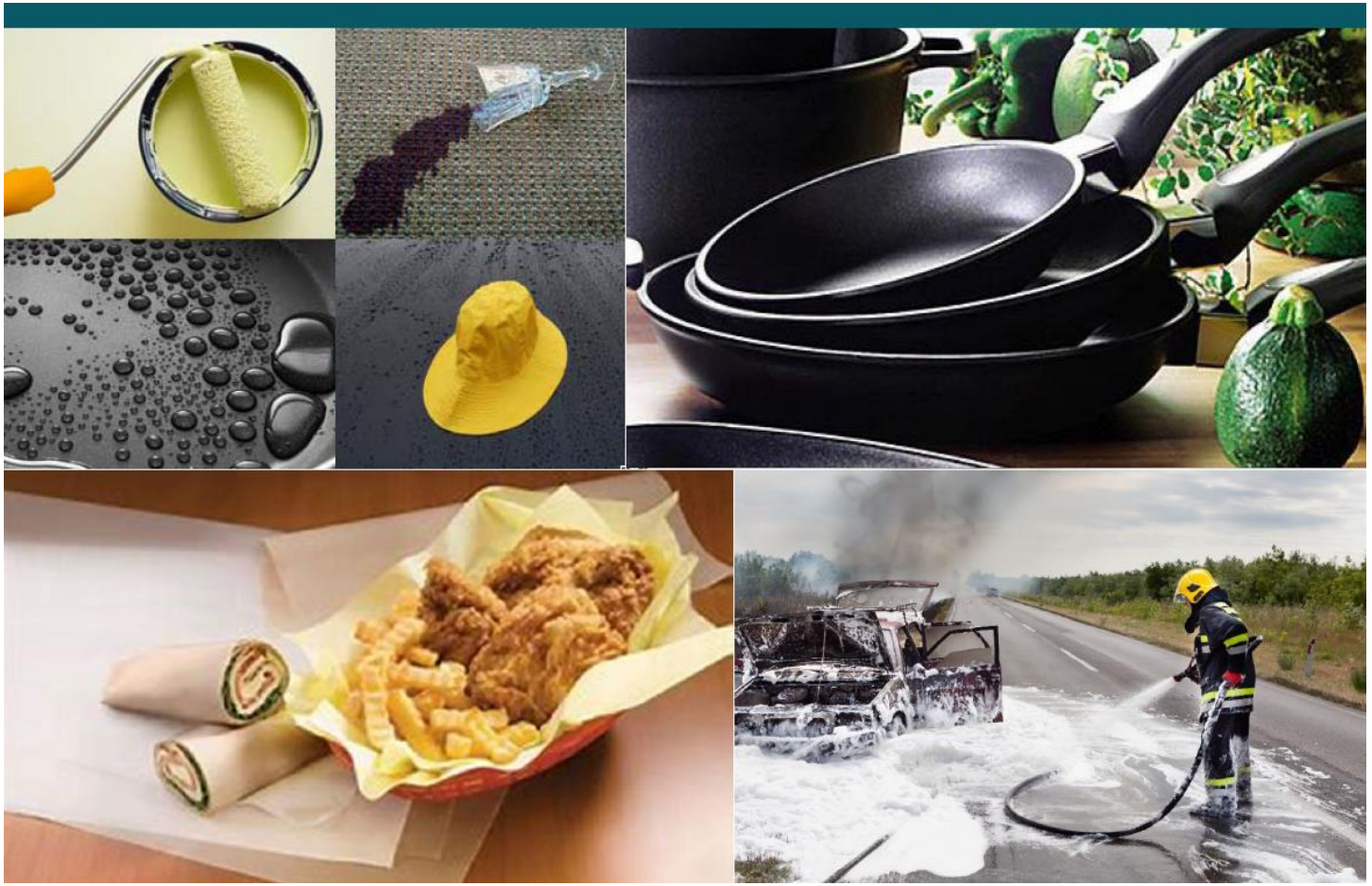
- Overview (Barb)
- PFAS in Foods and Fish (Barb)
- PFAS Clean up Sites (Bonnie)
- PFAS Health Promotion and Education (Claire)
- PFAS in Consumer Products (Holly)
- Safer Products for WA Program (Marissa)

Overview of PFAS

Barb Morrissey (she/her)
Toxicologist
Environmental Public Health Sciences
Washington Dept of Health

barbara.morrissey@doh.wa.gov

Per- and Poly-Fluoroalkyl Substances (PFAS) Nonstick, Stain and Water Resistant, Heat Stable



Some PFAS are PBTs

Persistent in the environment

Bioaccumulate in humans

Toxic at relatively low (ppt) levels

Human Health Effects

https://ATSDR.CDC.gov/PFAS

Research is ongoing to understand the mechanisms of PFAS toxicity. The epidemiological evidence suggests associations between increases in exposure to (specific) PFAS and certain health effects

Increases in cholesterol levels (PFOA, PFOS, PFNA, PFDA)

Lower antibody response to some vaccines (PFOA, PFOS, PFHxS, PFDA)

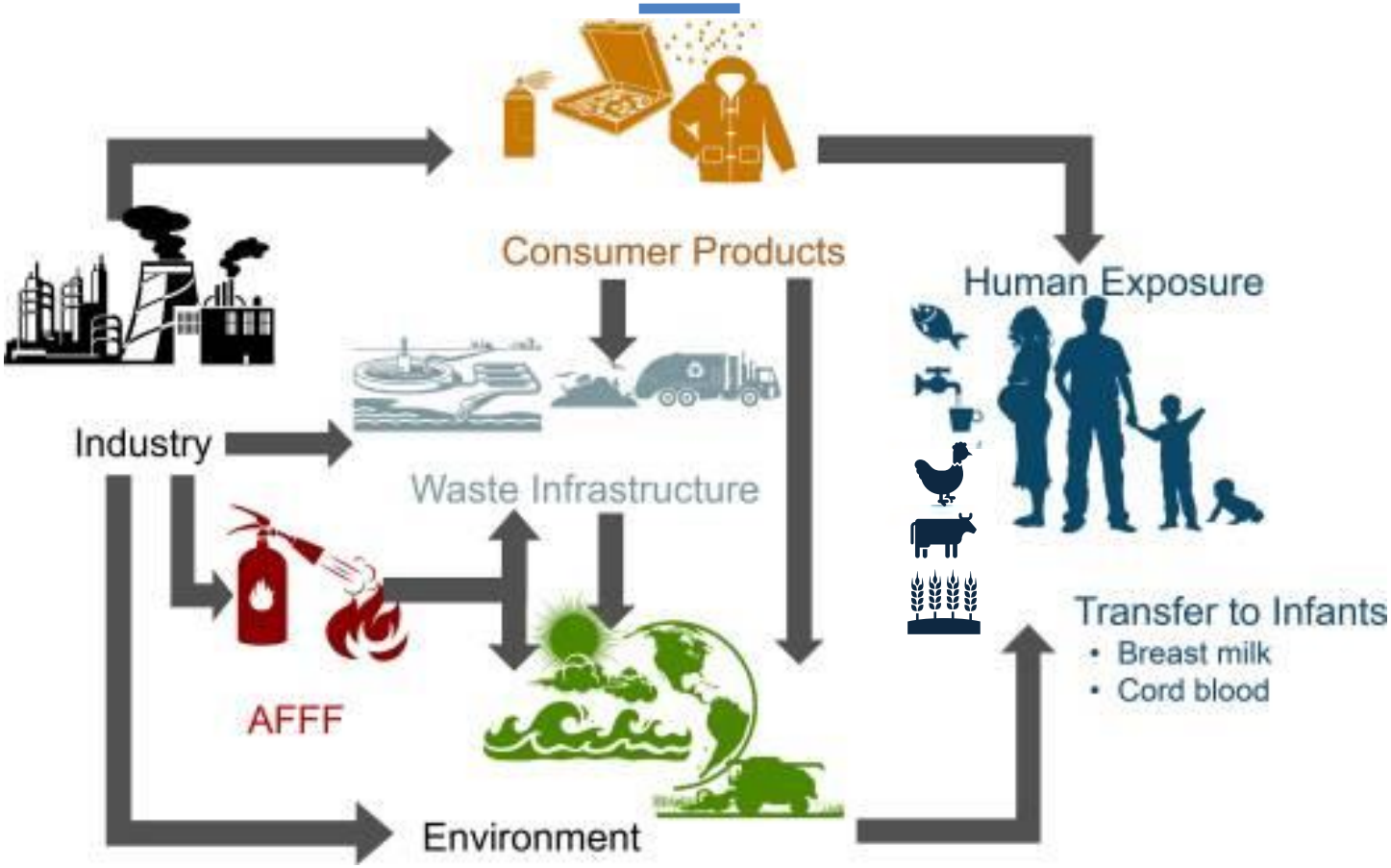
Changes in liver enzymes (PFOA, PFOS, PFHxS)

Pregnancy-induced hypertension and preeclampsia (PFOA, PFOS)

Small decreases in birth weight (PFOA, PFOS)

Kidney and testicular cancer (PFOA)

Exposure Pathways



Modified from Sunderland EM et al. (2019) **A review of the pathways of human exposure to poly- and perfluoroalkyl substances (PFASs) and present understanding of health effects.** https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6380916/

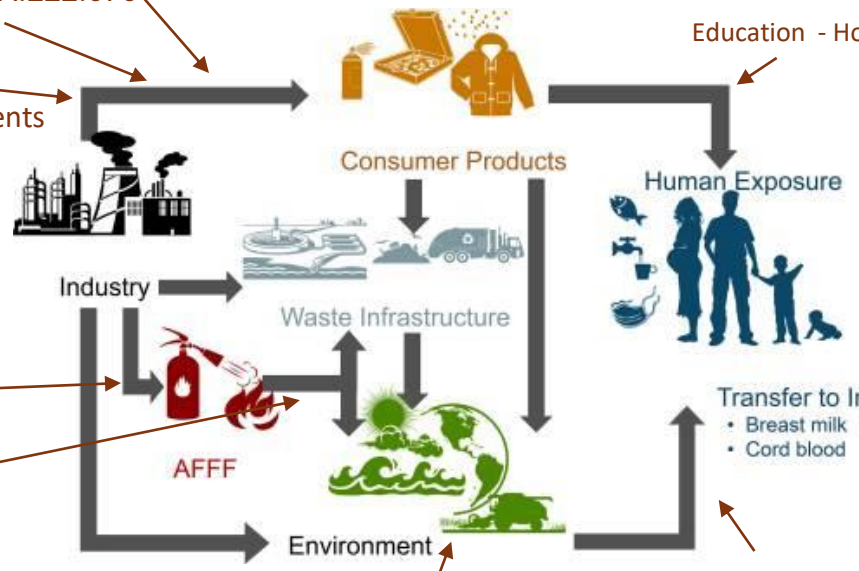
State Action to Address PFAS

Cosmetics (HB 1047)

Ban on PFAS in food contact paper RCW 70A.222.070

Safer Products for WA RCW 70A.350
- Aftermarket stain and water proofing treatments
- Leather and textile furnishings (indoor)
- Carpets and rugs

Education - How to reduce PFAS exposure



Ban on PFAS in firefighting foam RCW 70.75A

Dept of ECY safe foam disposal program

Site Clean-up programs

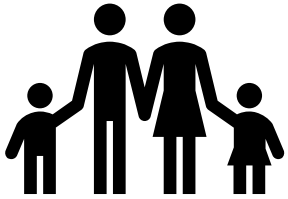
- Drinking water standards
- Fish consumption advisories
- Advice for livestock and gardens

Source: Sunderland EM et al. (2019) **A review of the pathways of human exposure to poly- and perfluoroalkyl substances (PFASs) and present understanding of health effects.** https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6380916/

PFAS in Home-raised Foods

Barbara.Morrissey@doh.wa.gov

PFAS in Drinking Water - Potential Exposure Routes



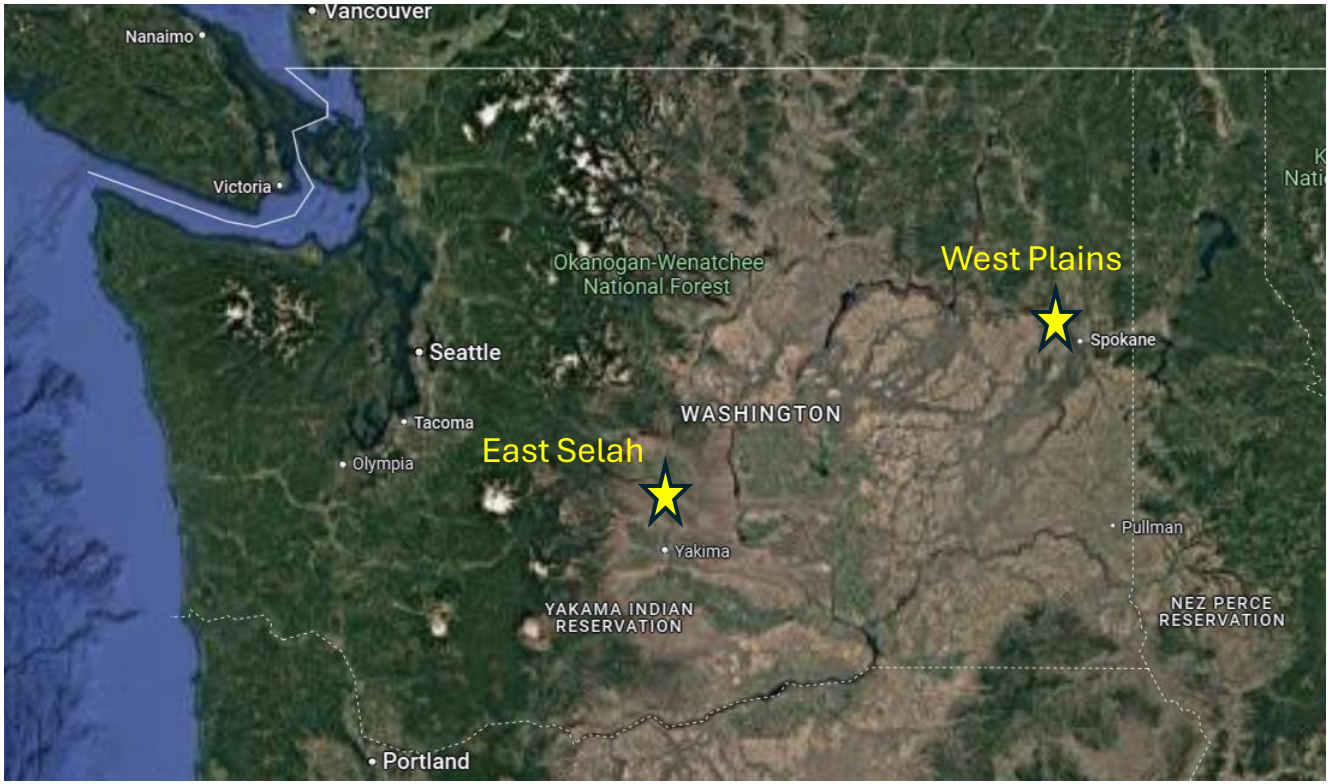
Drinking and cooking With water

Exposure from meats, eggs, milk, and produce

PFAS accumulate in animals and garden raised with that water

Learn more at: https://pfas-1.itrcweb.org/2-6-pfas-releases-to-the-environment/

Rural Communities with PFAS in Private Wells



What We Heard

We need answers NOW about the safety of home-raised meats and eggs

I'm not comfortable eating our livestock, eggs, and produce until we have answers on whether it is safe to do so

Fall is butcher season

A lot of us can't wait a lot longer to find out what to do with the animals, and if in good conscience we can sell to our neighbors

Source: KIMA Action News by Alexandria Rayford Fri, February 3rd 2023

What We Did to Address Concerns

- DOH partnered with USDA Food Safety Inspection Service to test -Dec 2023.
- 11 families volunteered 18 samples for PFAS testing

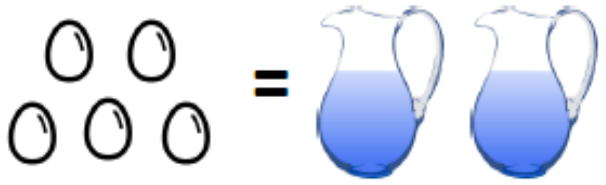
- DOH derived state advice for home-raised foods.
- Provided individualized food safety advice as recommended limits for # servings per week. DOH also made recommendations for how to reduce PFAS uptake into livestock. (March/April 2024)

Results

- Detected PFOS (72%) and PFHxS (44%) of samples.
  - No other PFAS detected.
  - 2 highest in drinking water wells.

- Higher water levels of PFAS correlated with higher levels of PFAS in food.

- **Key Take-away**: Livestock can be an important exposure source.



At one home with approximately 250 parts per trillion (ppt) of PFOS in their well water, adults eating 5 home-raised eggs per week would get the same exposure as drinking 2 liters of that same water every day for a week.

Our Recommended Eating Restrictions

Significant restriction:

Adults: No more than 1 egg/month and 8oz meat/month on average

Child: Do not eat

Moderate restriction:

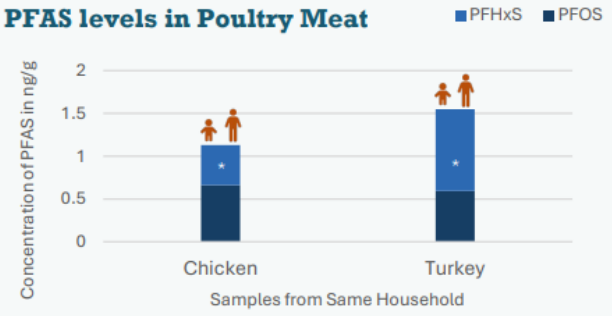
Adults: No more than 4-7 eggs/week and two 8oz servings meat/wk on average

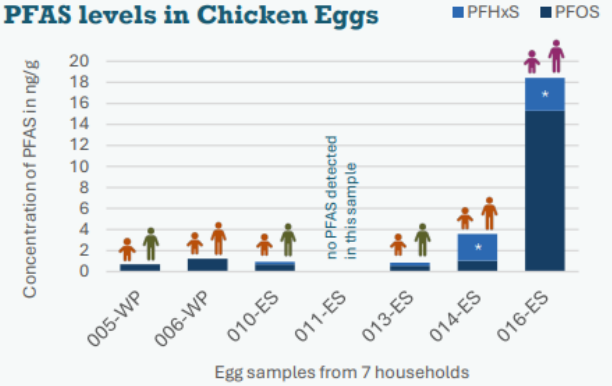
Child: No more than 1-2 eggs/week and 3-4oz meat/week on average

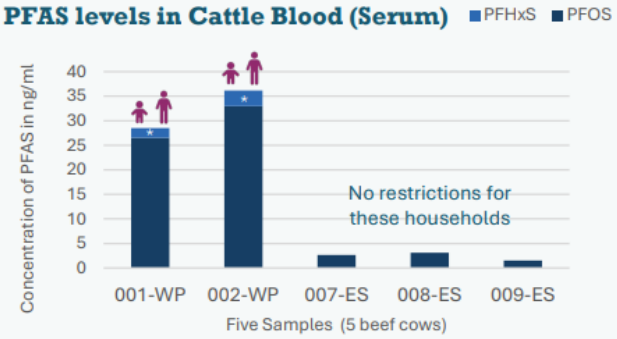
Slight Restriction:

Adults: No more than 7-12 eggs/wk and three 8oz servings meat/wk on average

Child: No more than 3-4 eggs/week and 5-6oz meat/week on average







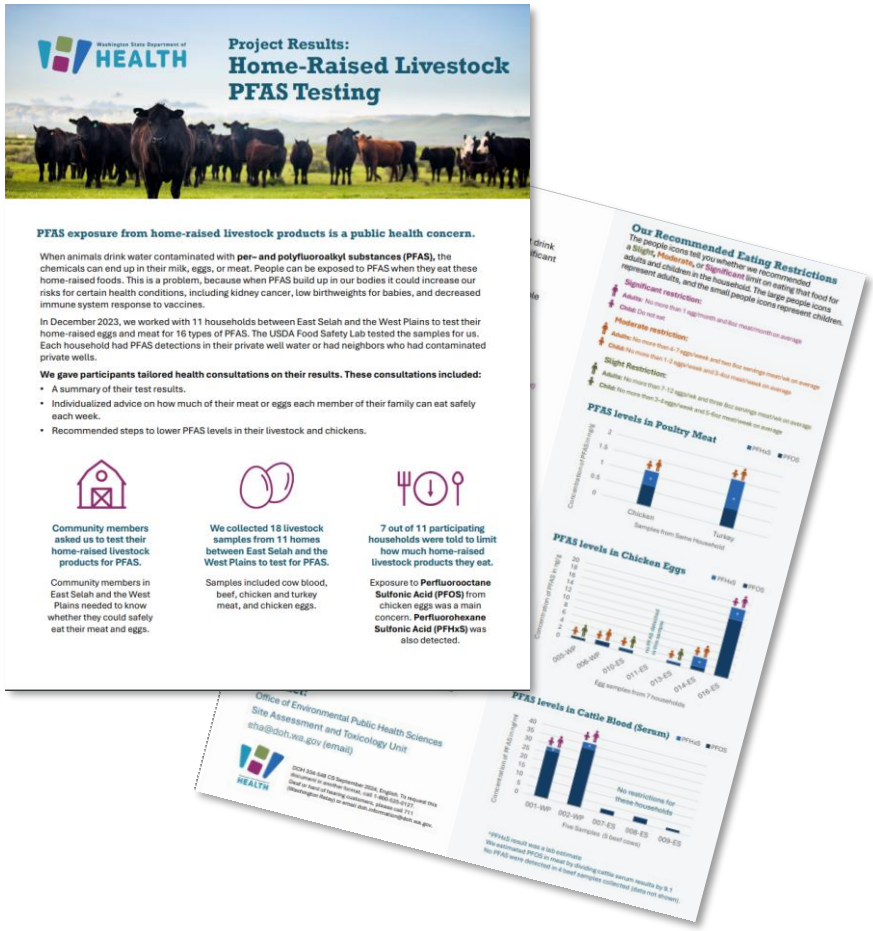
*PFHxS result was a lab estimate
We estimated PFOS in meat by dividing cattle serum results by 9.1
No PFAS were detected in 4 beef samples collected (data not shown).

Key things you can do to reduce PFAS exposure in poultry and cattle

- Forever chemicals are not forever in your animals once you stop the exposure.
    - Switch animals to filtered water
    - Move chicken coop and pen to a new area.
- PFOS concentrates in egg yolk. Eating less yolk and more whites could reduce your exposure
- PFAS concentrate in organ meats of animals, avoid eating liver, kidney and product made from blood.
- Don’t use manure from contaminated animals in food gardens.

Project Outcomes

- Direct testing of livestock can provide more specific and actionable food safety advice.
- Individual health advice was appreciated by participants
- 1-page community factsheet helps disseminate key take-aways widely.
- DOH advocacy for investigating and mitigating livestock exposure pathways is supported by results.



Next Steps

- Offer re-testing at households that acted to lower exposure in their animals.
- Expand testing to more households

Washington State Department of HEALTH

Free

Home-Raised Meat and Egg PFAS Testing

Limited-Time Offer from Washington State Department of Health (DOH)—Sign Up By October 28, 2024!

What We Can Do:

- Free PFAS testing of home-raised eggs and meat from cattle, swine, chickens, and turkeys. Please contact us about other food items. Space is limited.

What You Get:

- Your test results.
- Individual consultation on your test results from DOH, including advice on the safety of eating the meat or eggs and how to reduce your exposure.

To Qualify, You Must:

- ☑ Be a West Plains or East Selah resident with PFAS in your water higher than at least one of these values:
  - PFOS: 4.0 ppt
  - PFOA: 4.0 ppt
  - PFHxS: 10 ppt
- ☑ Have used the water to raise animals at home for personal, family, or friend consumption (not commercial production).

Email, Text, or Call to Sign Up:

Barbara Morrissey — Toxicologist

barbara.morrissey@doh.wa.gov

(564) 999-3485

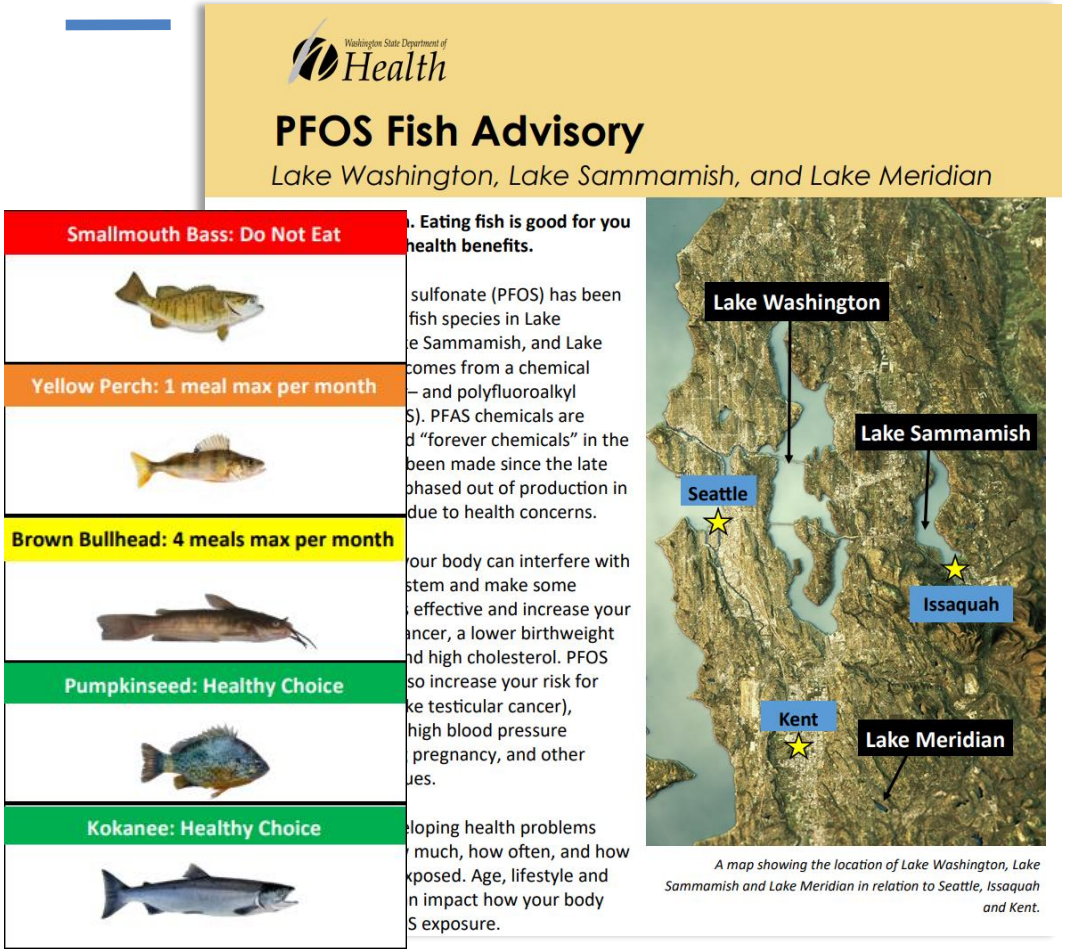
PFAS in Fish and Shellfish

DOH Contact:
Emerson Christie, PhD, Toxicologist
Emerson.Christie@doh.wa.gov

DOH Fish Advisories for PFOS

Fish consumption advisories for PFOS in 3 urban lakes, King Co.

Potentially 9 more in 2025



https://doh.wa.gov/sites/default/files/2022-12/334-471.pdf

DOH testing of Fish and Shellfish

- Top ten species of Market fish in WA (2022)
  - Canned tuna, catfish, cod, flounder, halibut, red snapper, pollock, Chinook salmon, and tilapia
  - All were below current PFOS screening level
  - To inform our fish advisories
- Underway- reconnaissance testing of Puget Sound recreational shellfish for PFAS
  - Preliminary results from recreational shellfish sampling are optimistic, however, additional surveys will be needed

Questions?

Barbara Morrissey, Toxicologist

Environmental Public Health Sciences

Barbara.morrissey@doh.wa.gov

564-999-3485 (cell)

Toxics Cleanup Program PFAS Work

State Board of Health

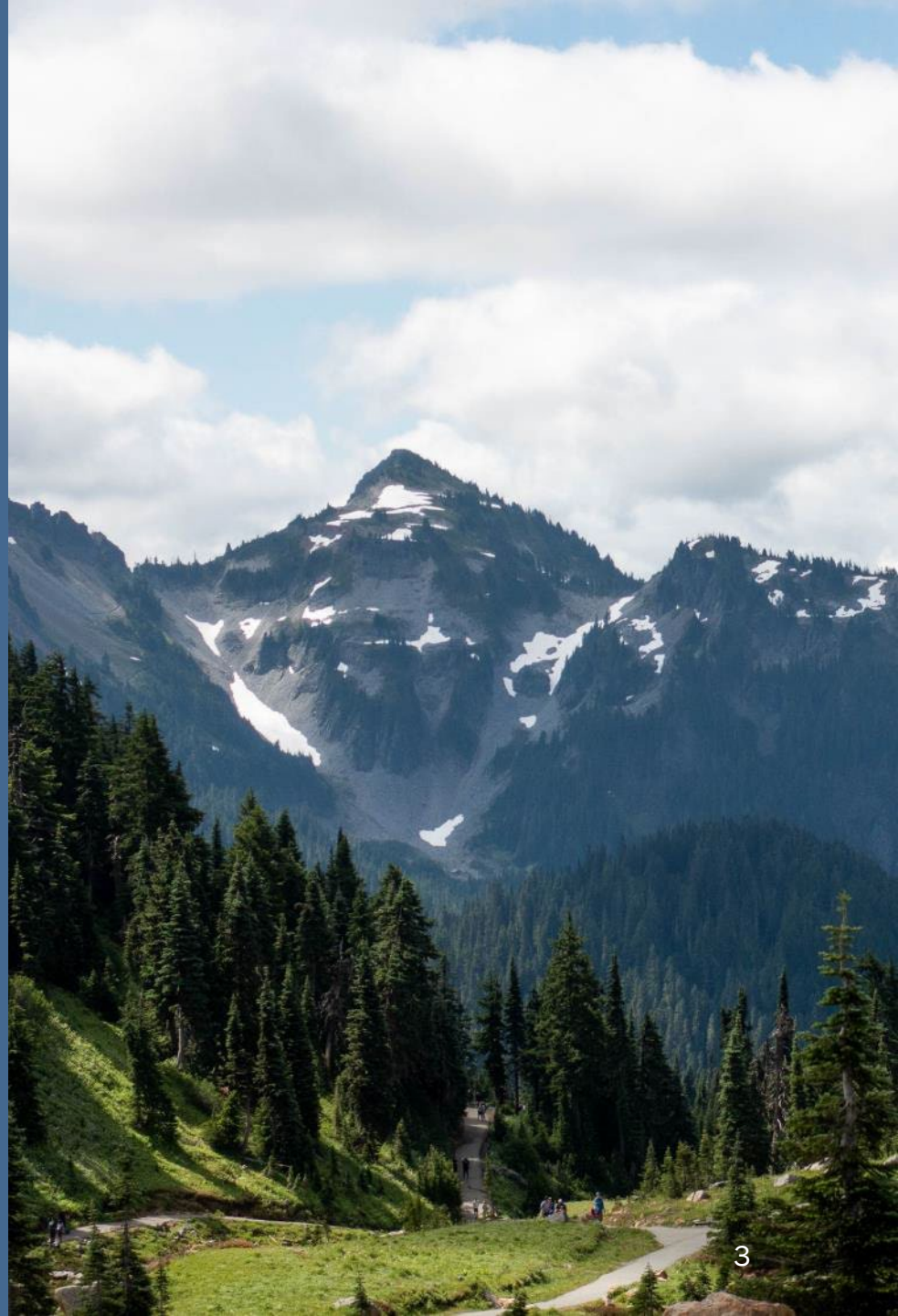
Bonnie Brooks & Barry Rogowski

November 13, 2024

Topics

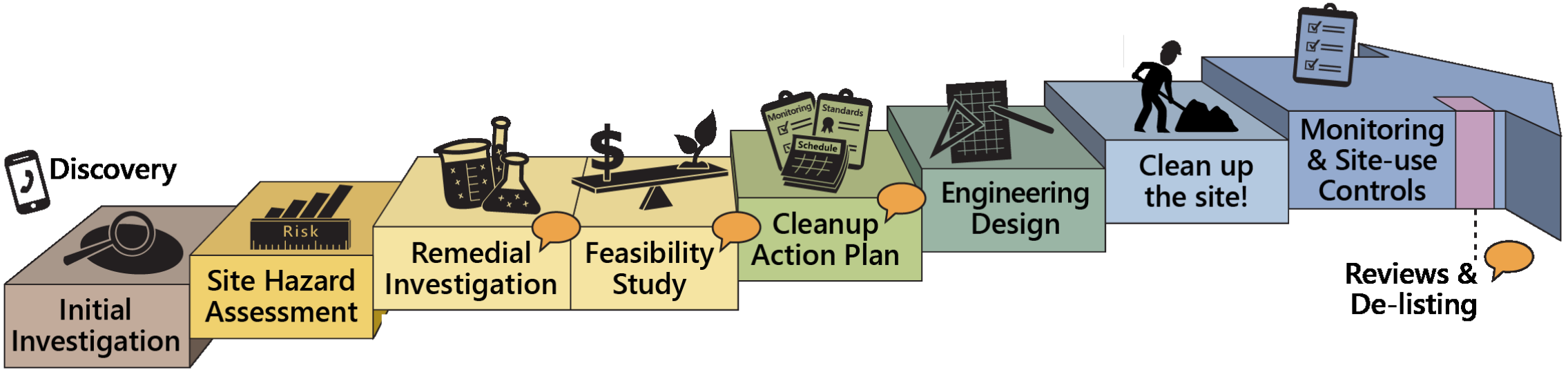
- Toxics Cleanup Program
- PFAS as a hazardous substance
- TCP PFAS Guidance
- TCP PFAS risk-based levels
- PFAS Statewide funding strategy
- TCP PFAS Sites
- Questions

Toxic Cleanup Program (TCP)

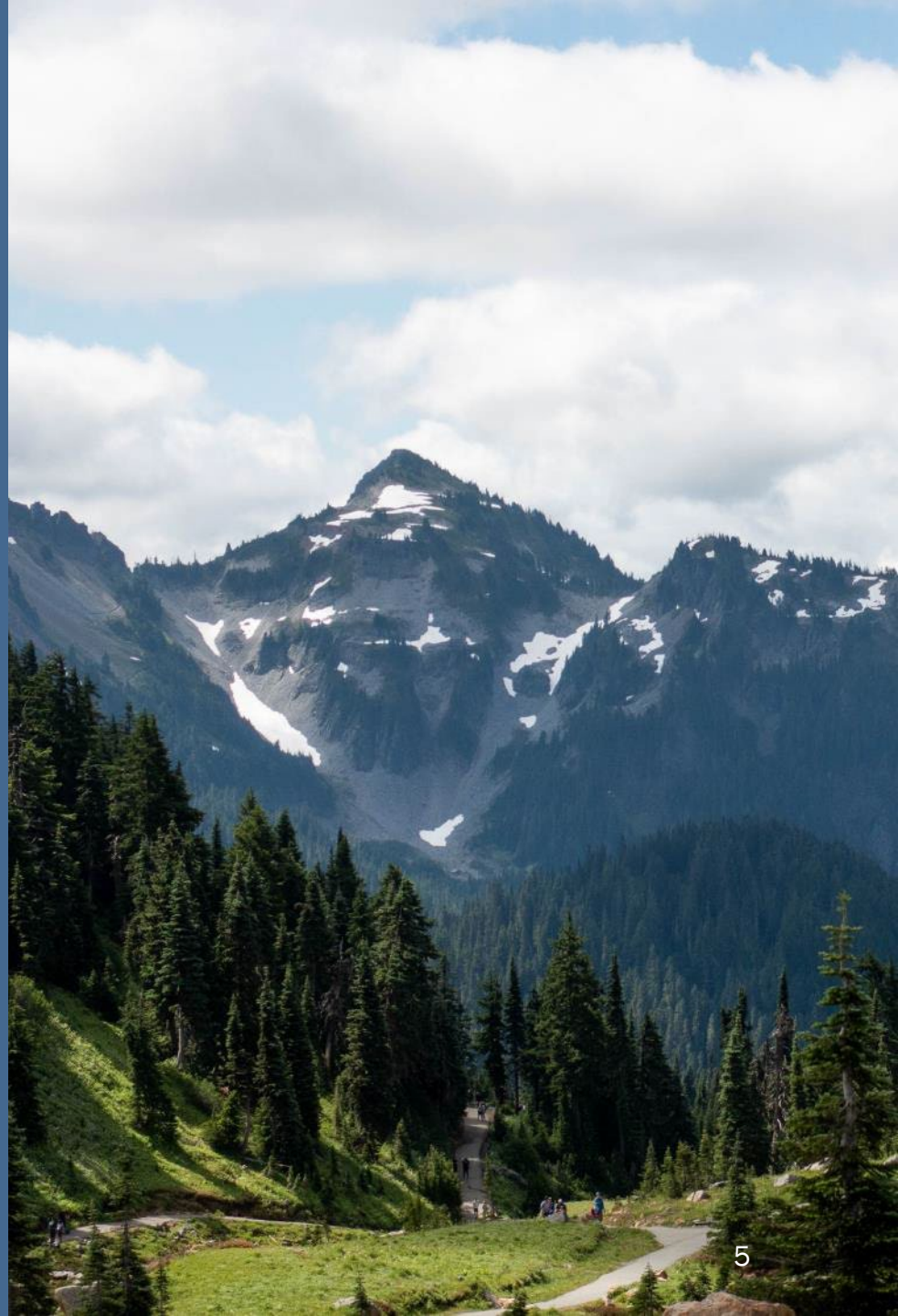


Toxics Cleanup Program (TCP)

- Clean up contaminated sites
- Model Toxics Control Act (MTCA)

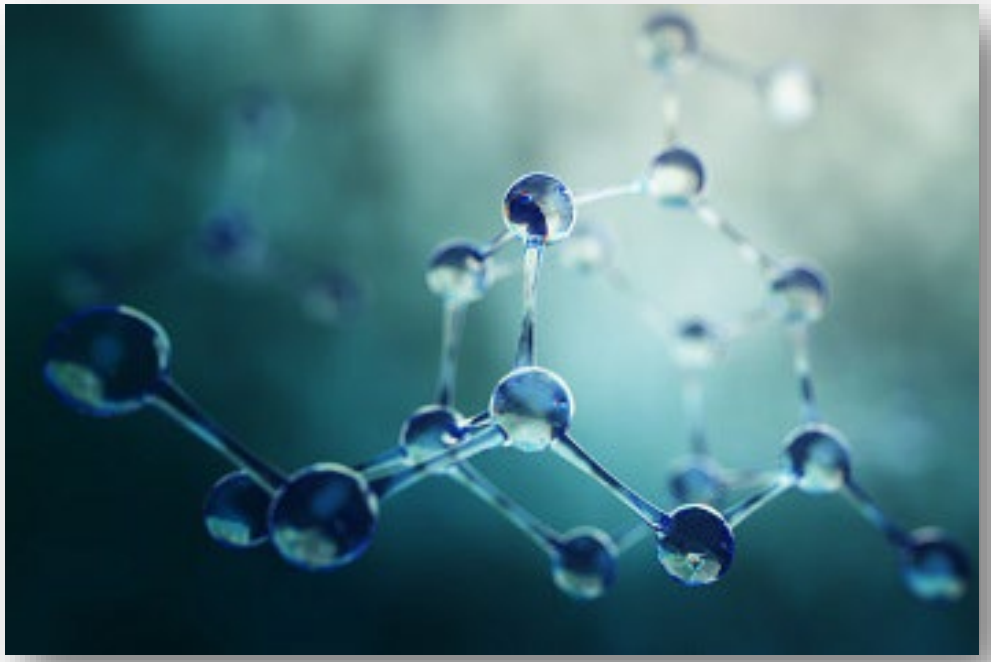


PFAS as a Hazardous Substance



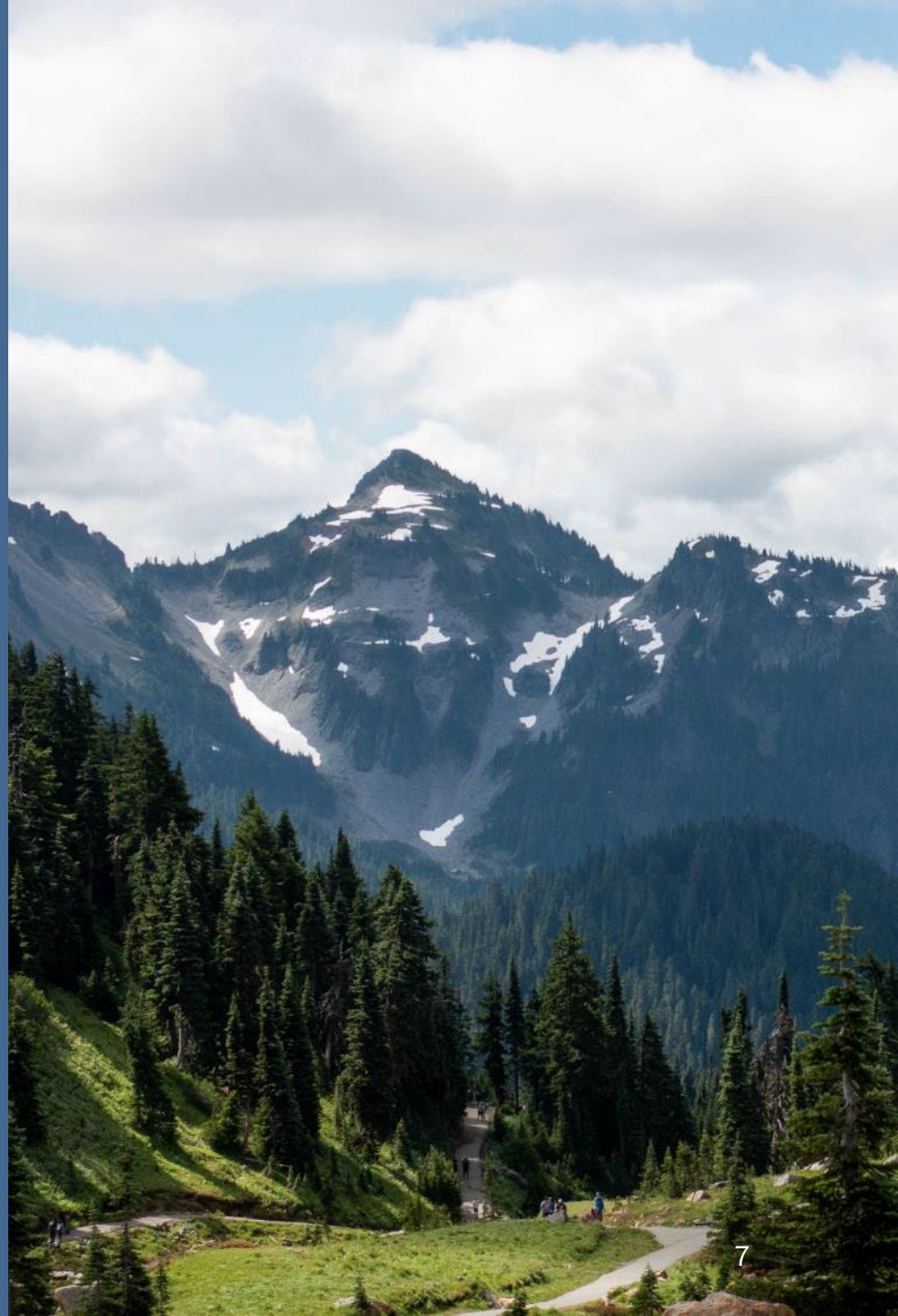
PFAS as a Hazardous Substance

- October 2021: PFAS are hazardous substances under the Model Toxics Control Act (MTCA)
  - Hazardous substances under Ecology's Dangerous Waste Rule are considered hazardous substances under MTCA
- Potential risks to people and ecological receptors
- PFAS releases required to be reported
- July 2024: EPA's CERCLA determined PFOA and PFOS to be hazardous substances



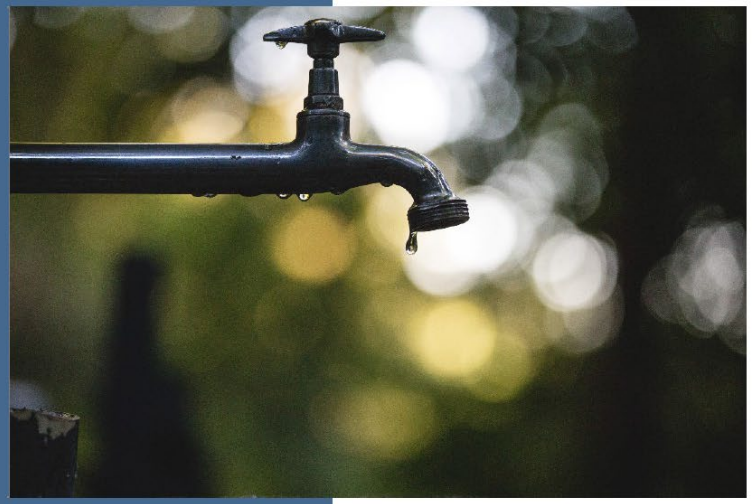
CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act

Toxic Cleanup Program (TCP) Guidance



TCP PFAS Guidance

- Investigating and cleaning up PFAS contaminated sites
- Background
- Screening
- Sampling
- Analytical methods
- TCP risk-based levels (human health, ecological)
- Treatment technologies



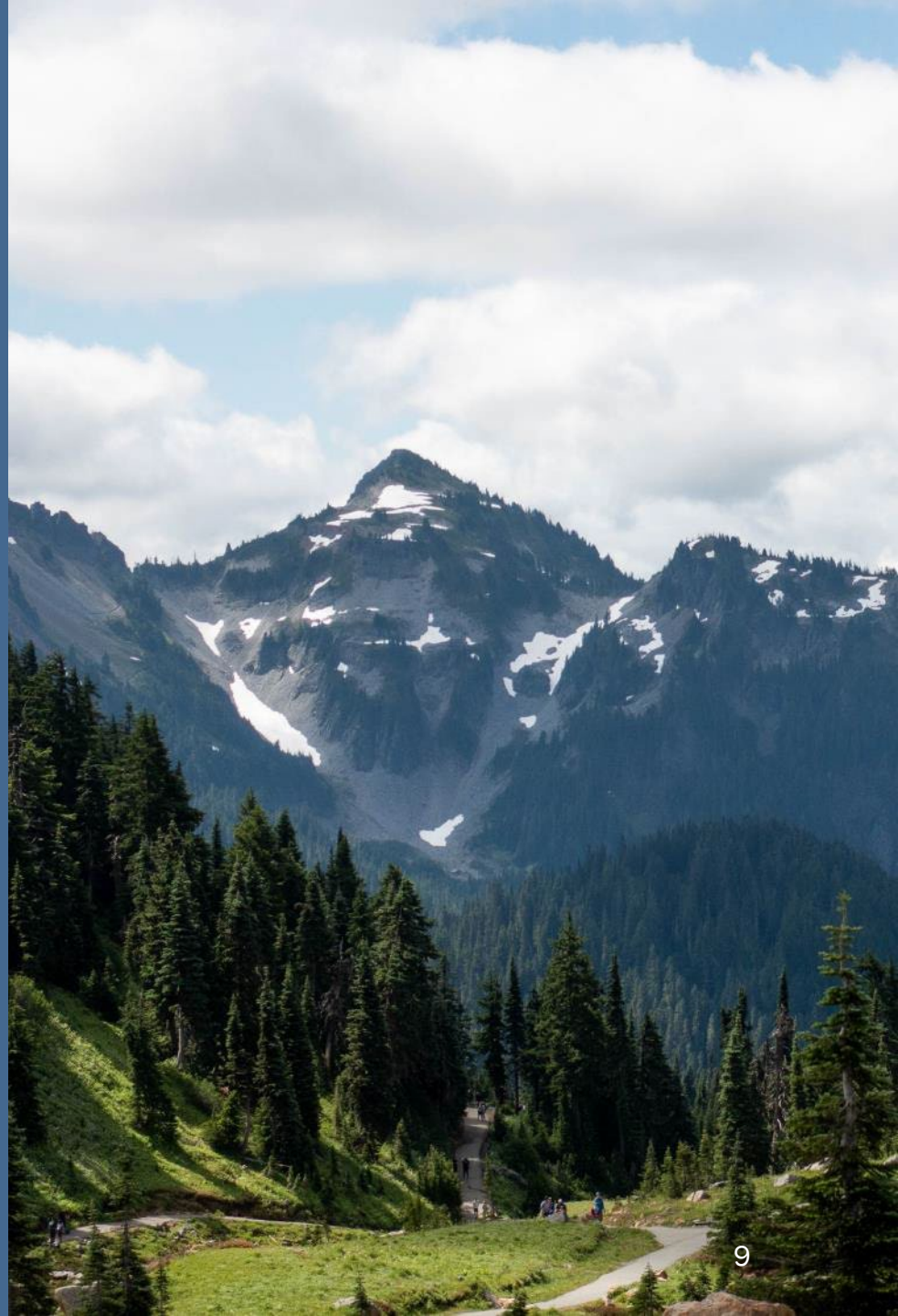
Guidance for Investigating and Remediating PFAS Contamination in Washington State

Toxics Cleanup Program

Washington State Department of Ecology
Olympia, Washington

June 2023 | Publication No. 22-09-058

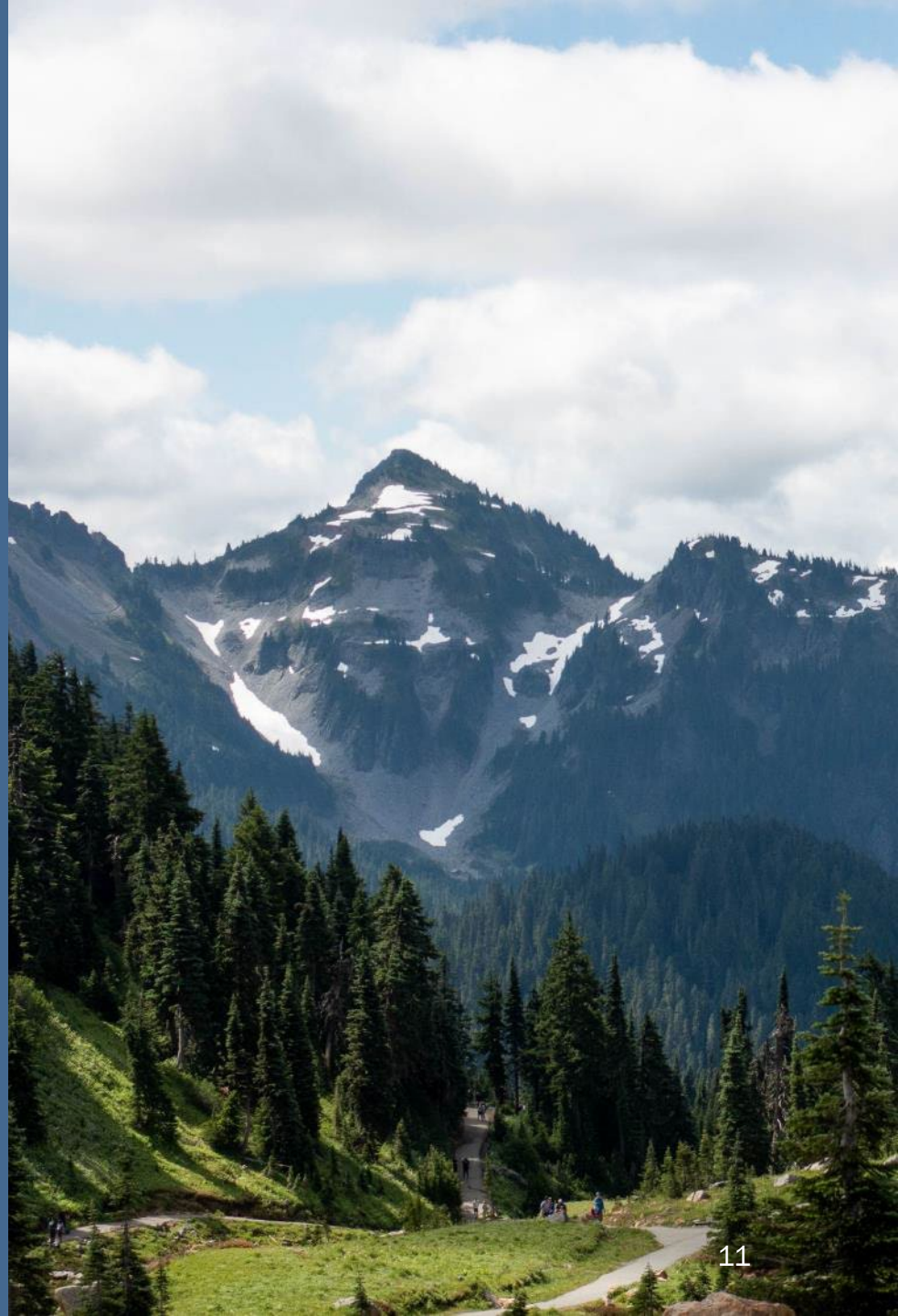
TCP PFAS Risk-Based Levels



TCP PFAS Risk-Based Levels

Media	Human Health	Ecological	Comments
Groundwater	Yes	Not applicable	EPA's MCLs used as groundwater cleanup levels when available
Soil	Yes	Yes	Protects groundwater from PFAS in soil and incidental ingestion
Surface Water	Yes	Yes	EPA's water quality standards used as surface water levels when available
Sediment	In process	In process	2025 or later
Air	To be determined	Not applicable	Will evaluate once more data is available

PFAS Statewide Funding Strategy

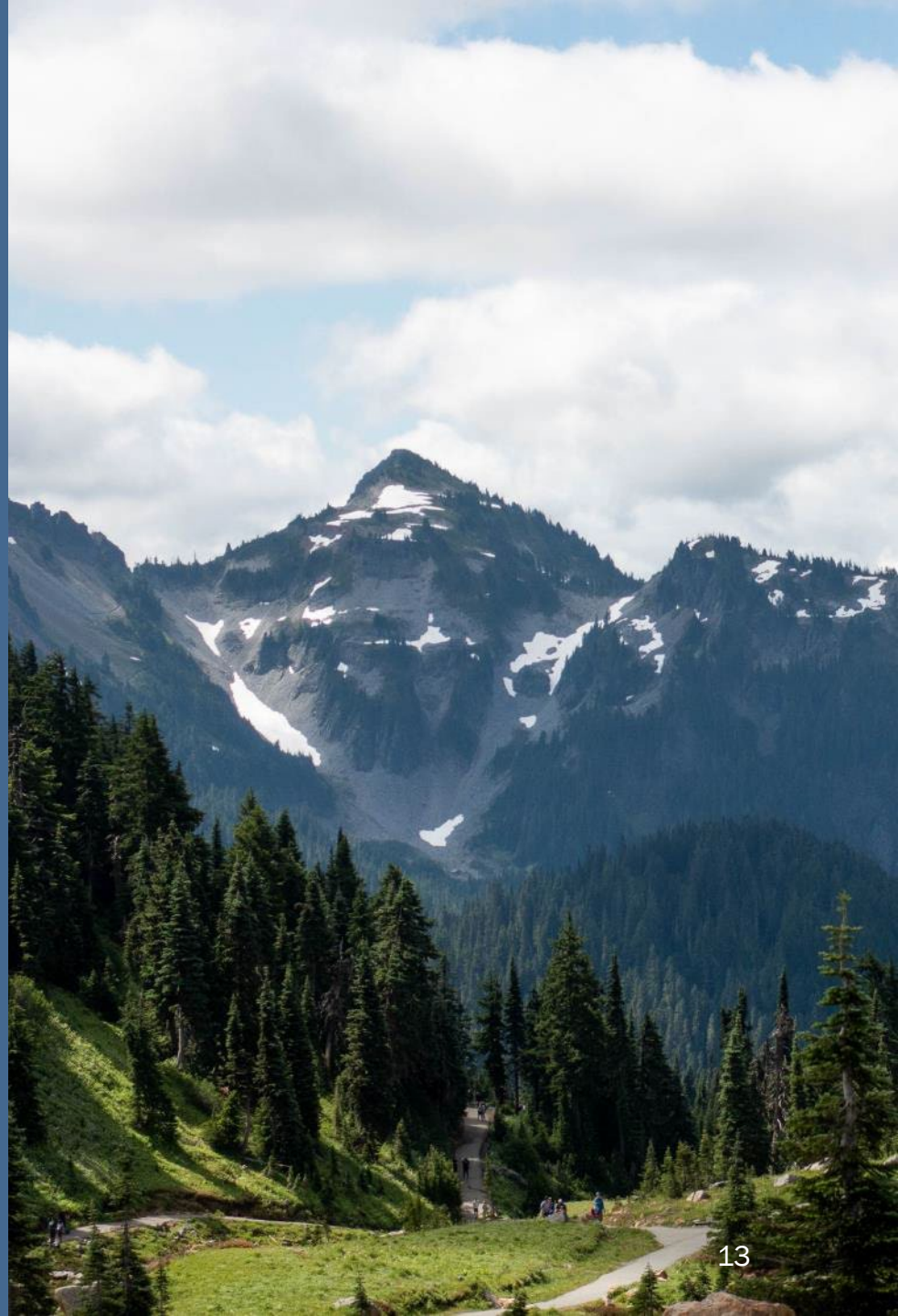


PFAS Statewide Funding Strategy

Resources and Funding Needed

- TCP request for new staff
  - 3 site managers
  - 1 public involvement staff
- TCP request for $3 million
  - Initial sampling
  - Interim actions, including providing safe drinking water

TCP PFAS Sites



TCP PFAS Sites

- 35 Confirmed PFAS sites
  - PFAS has been detected at the site
- 36 Suspected PFAS sites
  - Reason to suspect PFAS is present based on nearby sources
  - Airports, fire stations, fire training centers, etc.
- 935 other potential PFAS sites
  - PFAS might be present based on the type of site
  - Landfills, dry cleaners, metal plating and finishing sites

Dry Cleaners

Landfill Leachate

DoD PFAS Sites

Suspected or Confirmed PFAS in Groundwater & Soil

- *US Navy Air Whidbey Island*
- *Naval Base Kitsap – Bangor*
- Naval Base Kitsap – Keyport
- Naval Base Kitsap - Manchester
- Bremerton Naval Complex
- US Naval Station Pacific Beach
- US Naval Station Everett
- US Navy Radio Station Jim Creek
- US Navy Port Hadlock
- US Navy Jackson Park
- *Joint Base Lewis McChord*
- *Yakima Training Center*

Military Bases

DoD – Department of Defense

Red, italic font = sites with PFAS detections in drinking water

Other PFAS Sites

Suspected or Confirmed PFAS in Groundwater & Soil

- *Bailer Hill Area*
- *Lower Issaquah Valley*
- *State Fire Training Academy*
- *Fairchild Air Force Base*
- *Spokane International Airport*
- *Seattle-Tacoma International Airport*
- Paine Field
- Port of Pasco Big Industrial Park Lagoons
- Marshall Landfill
- Washington Cold Storage

Airports

Red, italic font = sites with PFAS detections in drinking water

Summary

- Contamination presence and severity unknown
  - Not analyzed at many sites where they may be present
- Number of PFAS sites will increase as more areas are sampled and investigated
- Requesting additional resources and funding now
- More resources and funding will be needed in the future

Metal Plating and finishing

Thank you

Bonnie Brooks
Toxicologist
Bonnie.brooks@ecy.wa.gov

Barry Rogowski
TCP Program Manager
brog461@ECY.WA.GOV

Washington State Department of Ecology

- Enviro. Assessment Program
- Air Quality Program
- Hazardous Waste and Toxics Reduction
  - RCRA
  - Pollution Prevention
  - Climate Pollution Reduction
- Office of Equity and Environmental Justice
- Solid Waste Management Program
  - Biosolids
  - Landfills
  - Industrial
- Toxics Cleanup Program
- Water Quality Program
  - Wastewater
  - Stormwater
- Nuclear Waste Program
  - Cleanup

Washington State Department of Fish and Wildlife

- Toxics Biological Observation System

Washington State Attorney General's Office

- Lawsuit against the manufacturers of AFFF

Washington State Department of Health

- Office of Drinking Water
  - Source Monitoring
  - Policy and Planning
  - Water Quality
  - Engineering and Technical Services
  - Regional Offices
  - Statewide Revolving Fund
  - Operator Certification Program
- Office of Environmental Public Health Sciences
  - Site Assessment and Toxicology
- Office of Public Affairs and Equity
  - Center for Health Promotion and Education

Washington State Department of Agriculture

- Food Protection Task Force
- Animal Health

Washington State Department of Commerce

- Local Government Division
  - Emergency Rapid Response
  - Public Works Board – Construction Loan Program

Washington State Department of HEALTH

PFAS – HEALTH PROMOTION AND EDUCATION

Who Am I?

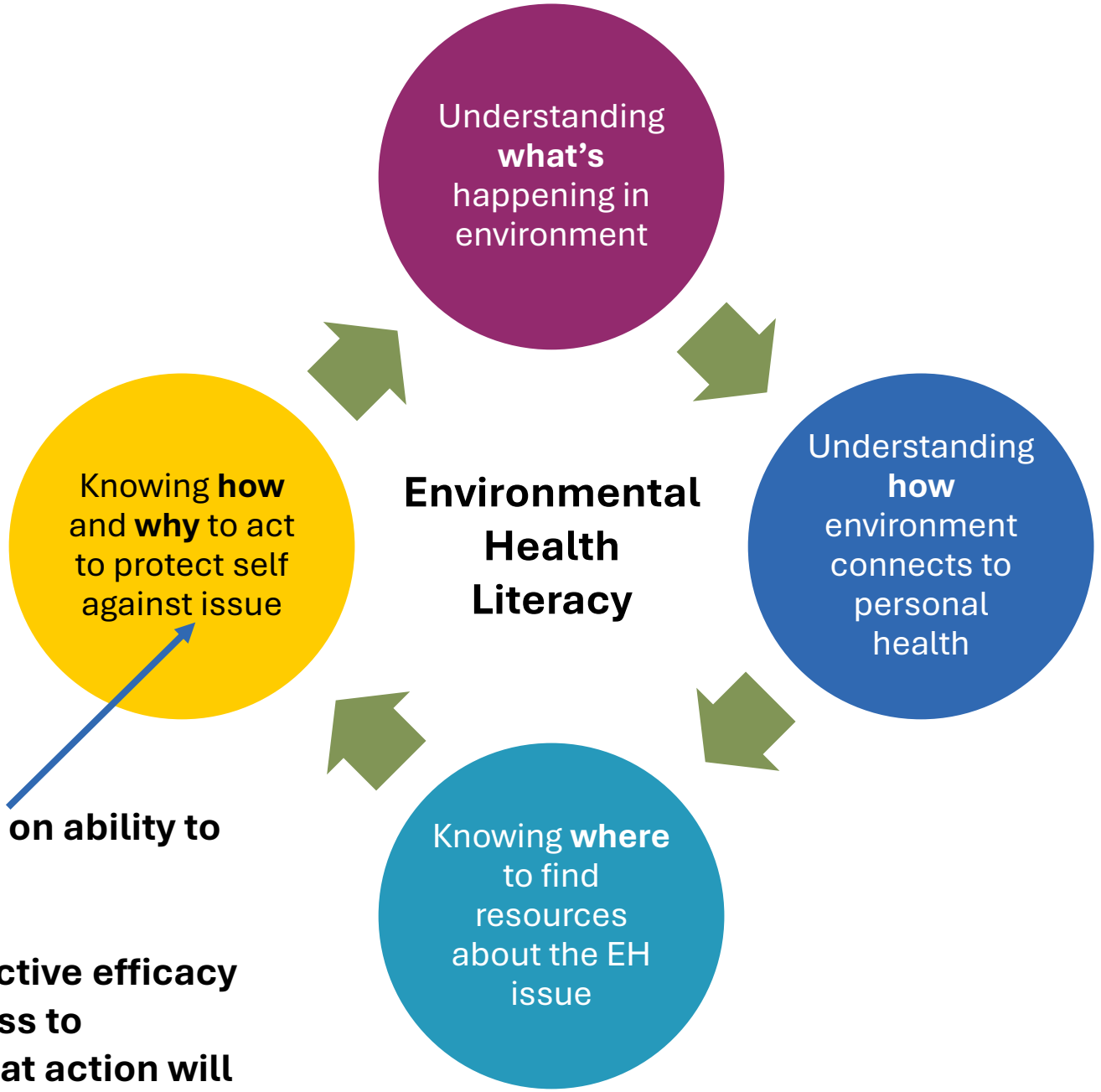
Claire Nitsche (she/her) MPH, MCHES

Health Educator – PFAS

Washington State Department of Health

Claire.Nitsche@doh.wa.gov

Health Education



Important: emphasis is on ability to act!

Requires self and collective efficacy feeling confident, access to resources, the belief that action will bring solution, etc.

Community Listening Sessions: Centering Community Voices

Local and state officials hear from Selah residents affected by drinking water contamination

SANTIAGO OCHOA Yakima Herald-Republic Feb 5, 2023 0

Date: Thursday, Feb. 2nd
Time: 5:30PM-8:00PM
Where: Selah Civic Center

East Selah Community PFAS Listening Session

Join Us!

Come meet several agencies who are working to address PFAS at Yakima Training Center! Share your advice on their efforts and any other concerns.

The goals of this meeting are to:

- Get to know local and state folks working on PFAS issues at Yakima Training Center and other locations in Washington.
- Discuss your concerns, ask questions, learn more about ongoing PFAS contamination efforts, and learn how we can work together.
- Learn about Washington State's PFAS State Action Levels, and how to reduce your PFAS exposure.
- Create a community map of where PFAS have been detected in well water.

Invited Guests:

Yakima Health District — *Dedicated to providing support to our partners and education and outreach to the public about PFAS and potential resources in mitigating elevated levels of PFAS in private and community drinking water wells in Yakima County.*

Washington State Department of Health (DOH) — *Protects the health of the people of Washington by preventing or reducing environmental hazards and ensuring safe and reliable drinking water. DOH also regulates public water systems, issues advice for private wells, and supports local health jurisdictions.*

Washington State Department of Ecology (ECY) — *Responsible for overseeing the investigation and cleanup of contaminated areas and groundwater at the Yakima Training Center.*

Did you know...?

Washington state recommends you act to lower PFAS levels in your drinking water, even if your PFAS levels are under 70ppt.

Come to the listening session to learn more!

AGENDA

5:30PM—6:00PM: Refreshments and community PFAS detection map activity.

6:00PM—6:15PM: Meeting kickoff with invited guest introductions.

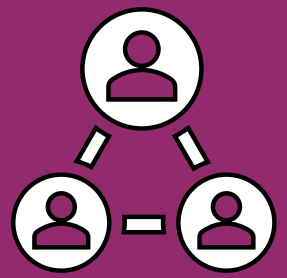
6:15PM—6:30PM: Presentation on Washington's PFAS State Action Levels for drinking water.

6:30PM—8:00PM: Moderated listening session and discussion.

Listening Session Impact on PFAS Situation

Increased community trust through:

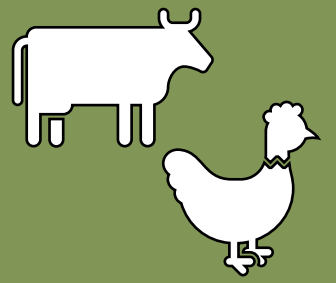
- Transparency
- Collaboration
- Co-created health education/comms materials



Increased agency coordination, collaboration, and activities/action.

Access to:

- Free POU water filters
- Bottled water
- Additional private well testing



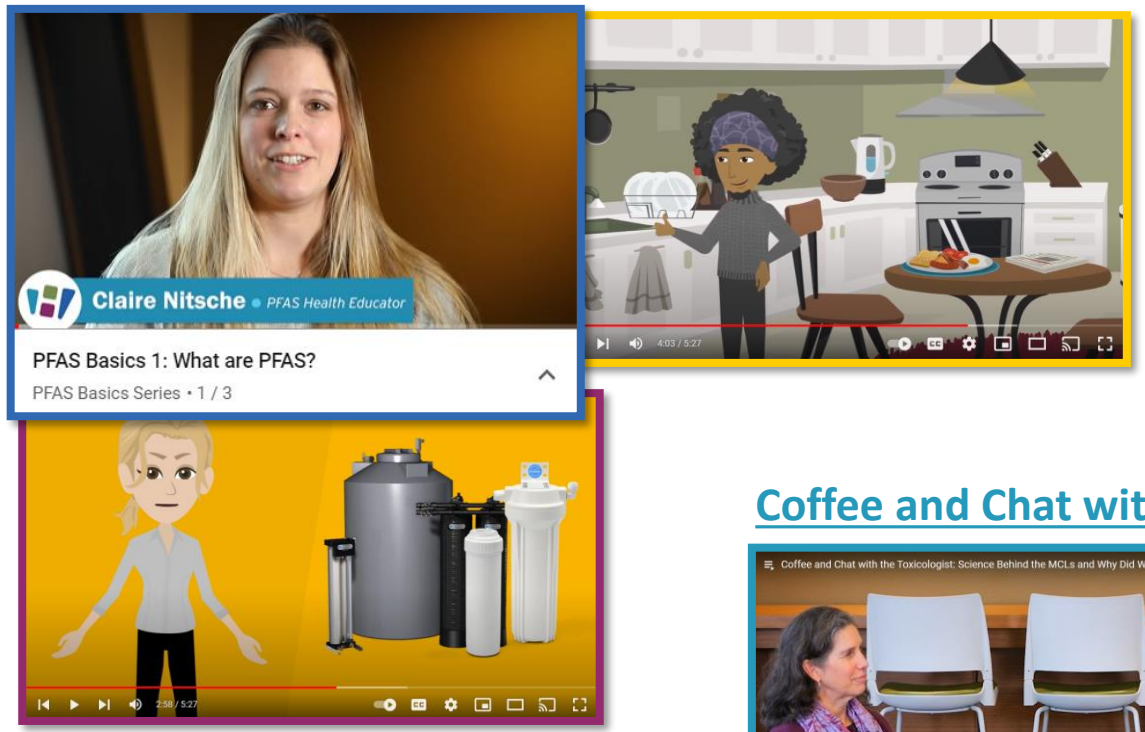
Home-raised livestock testing

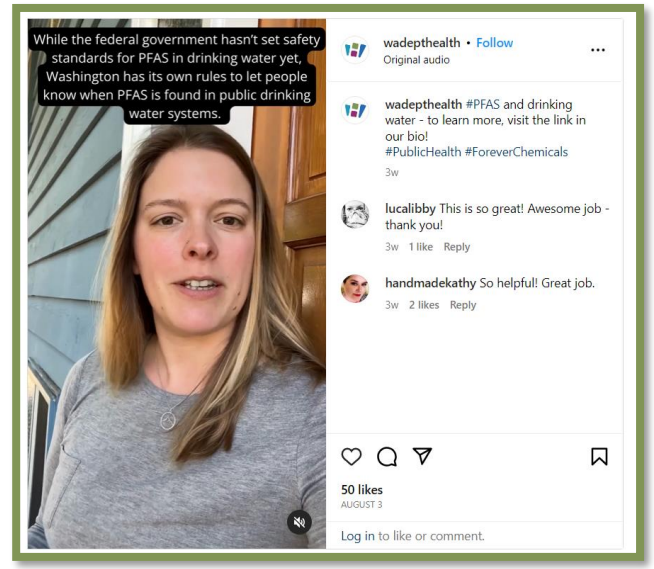
Social Marketing Research

- Market Research Online Community (called “Health Hub” to participants).
- Run by our social marketing contractor, C+C.
- Recruited group of 645 participants that we send agency social marketing studies to in return for a gift card.
  - Representative of Washington state demographics.
- Participants are pre-screened into groups per the study’s focus/aim.
- Two surveys – Oct. 2022 and June 2024 (same cohort).

PFAS Education Materials – "Be Less Governmenty!"

"PFAS Basics" YouTube Series

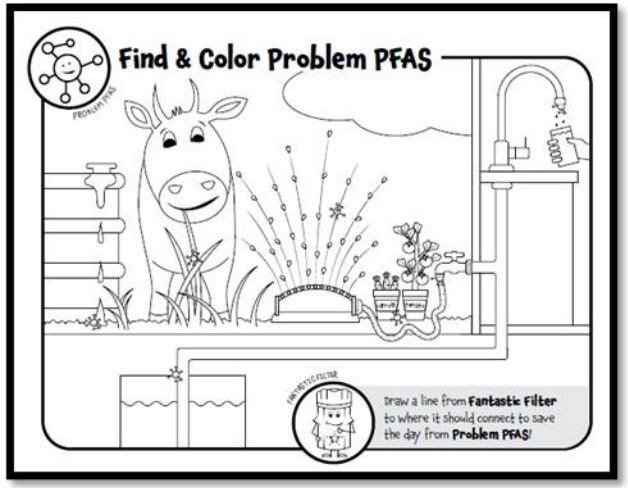




"Tiktoxicology"

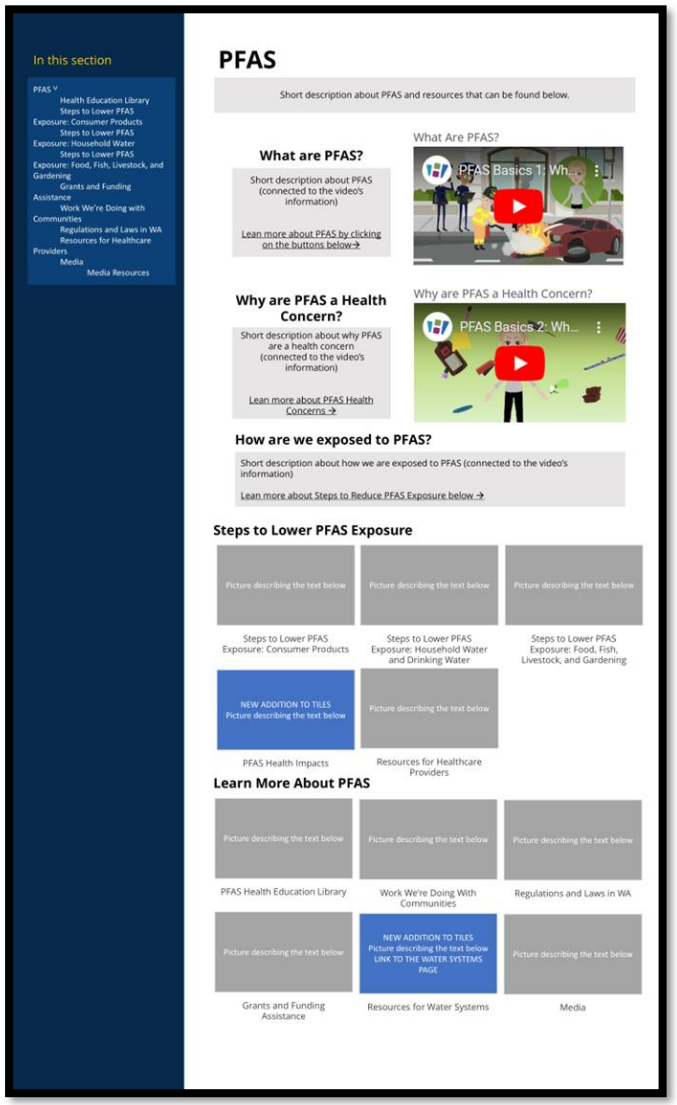
(Instagram, TikTok, Facebook, LinkedIn, X)

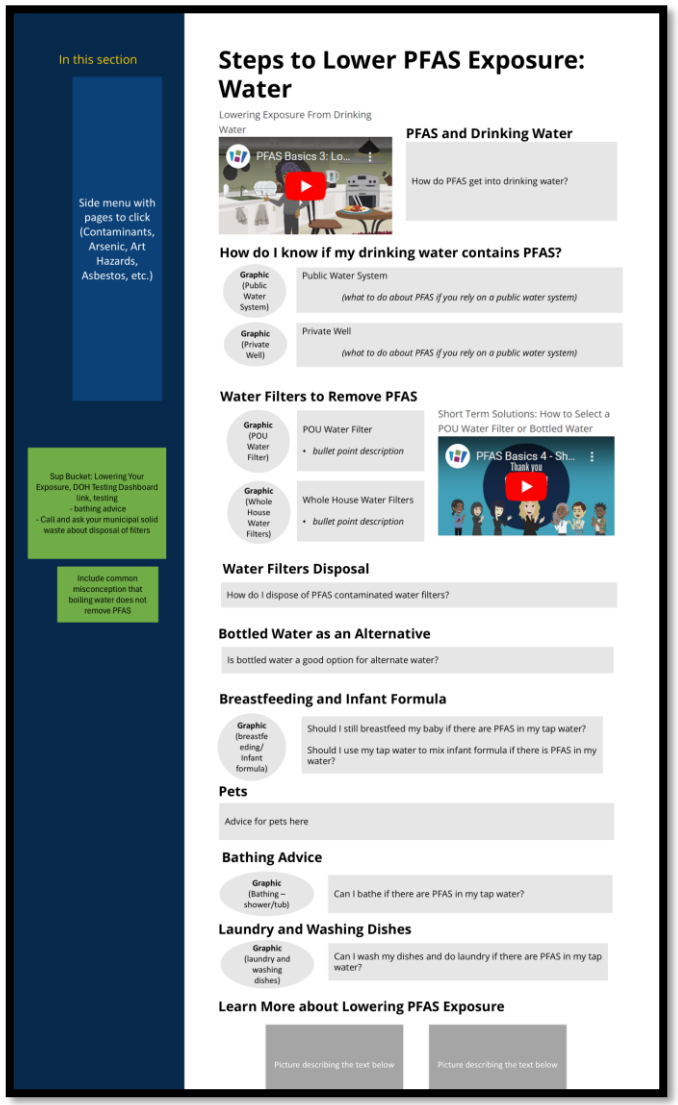
Coffee and Chat with the Experts

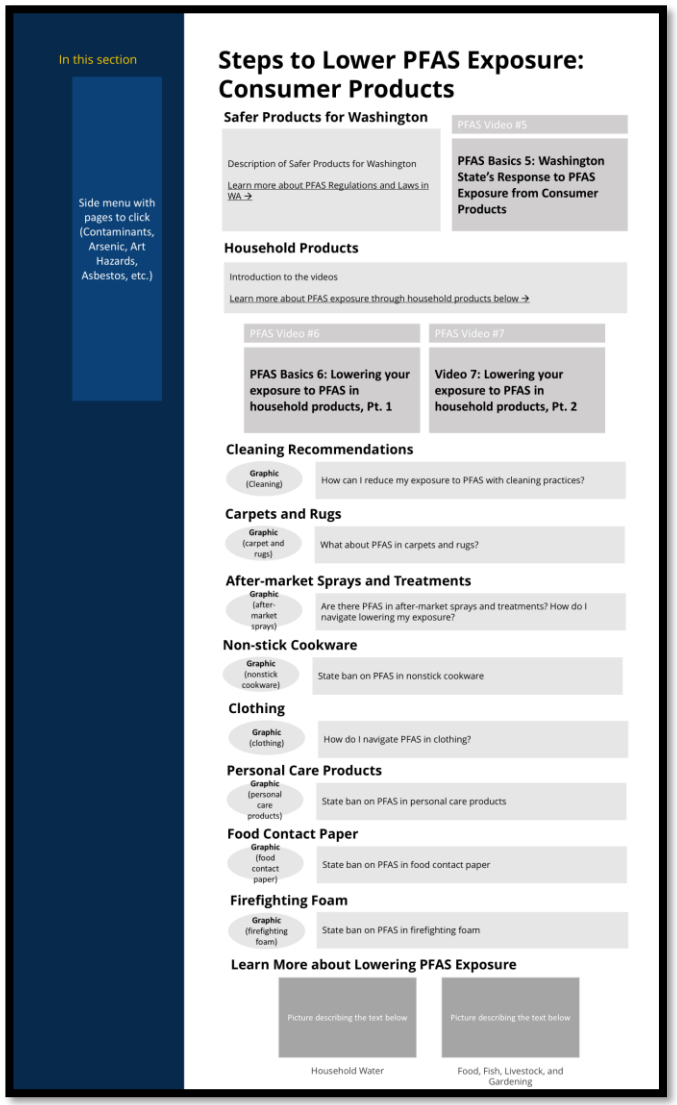


More “Traditional” Health Education Materials

PFAS General Website - 2024 Creative Overhaul







PFAS in Products
State Board of Health, Nov. 13, 2024

Holly Davies, PhD
Office of Environmental Public Health Sciences
Division of Environmental Public Health

Why do toxics in products matter?

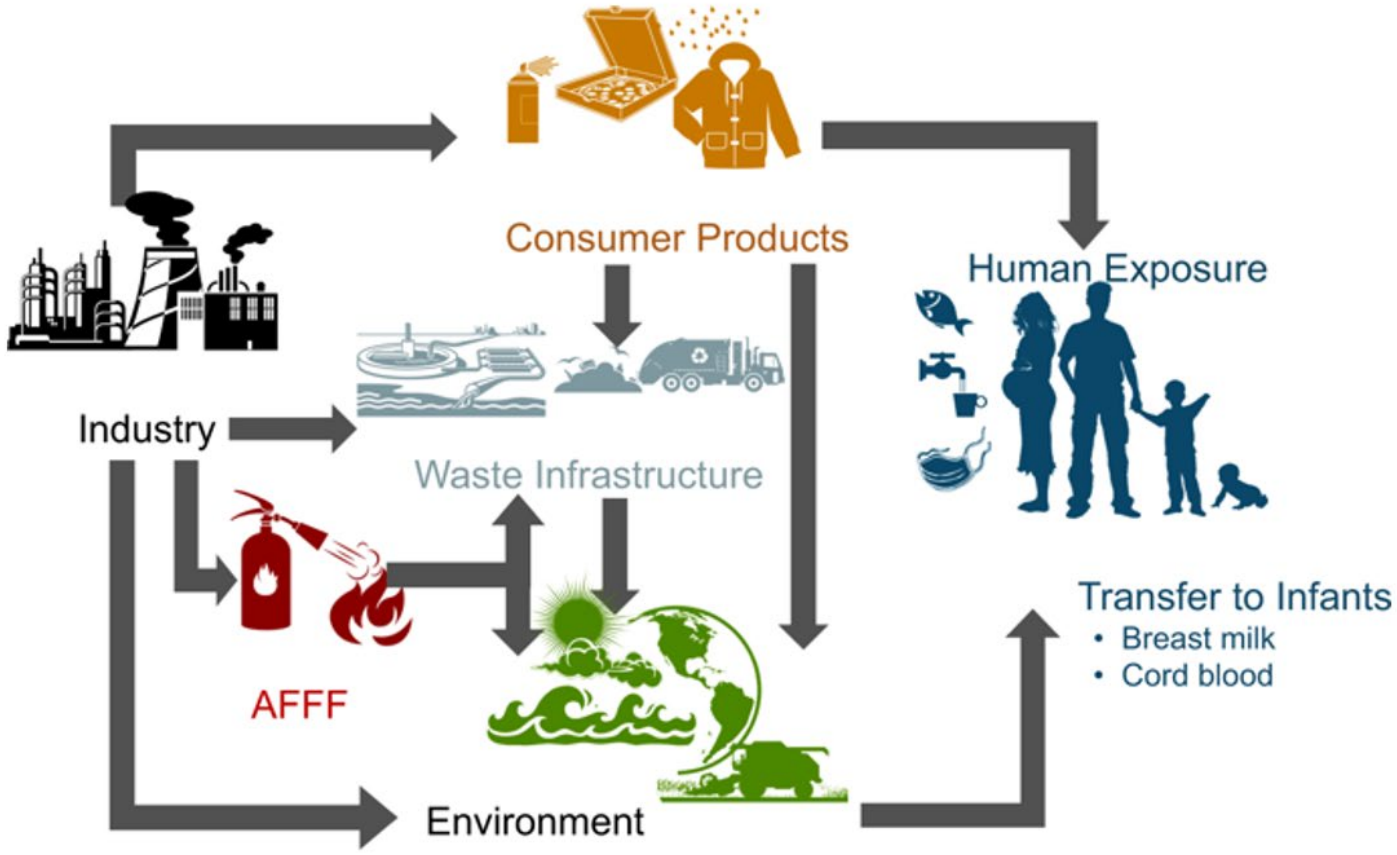
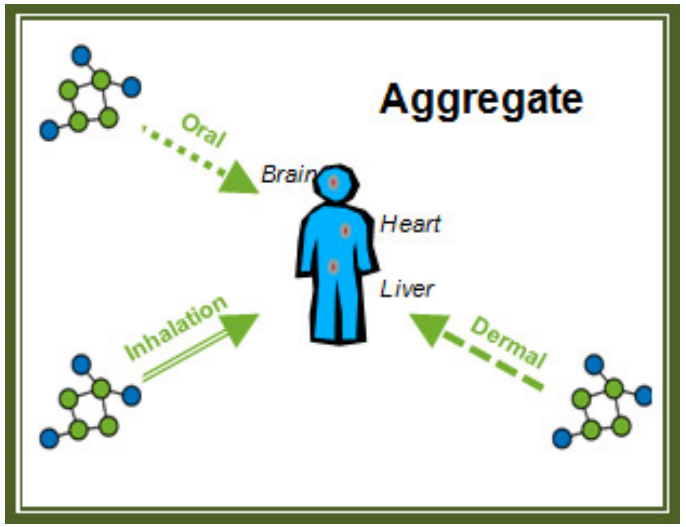
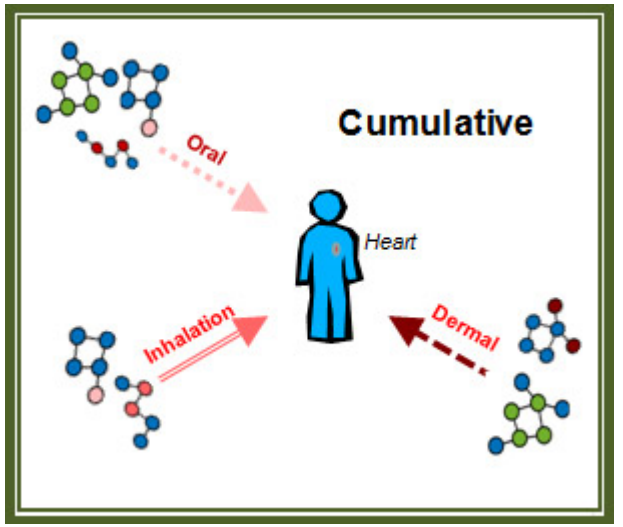


Figure 1 from Sunderland et al. (2019) *Journal of Exposure Science & Environmental Epidemiology 29*(2). doi:10.1038/s41370-018-0094-1

Protecting Human Health

- Prevention
- Safer Alternatives
- Class approach
  - Data gaps
- Aggregate and cumulative exposures
  - Non-chemical stressors
- Disproportionate exposures





Figures from EPA

Community Concerns and Exposures

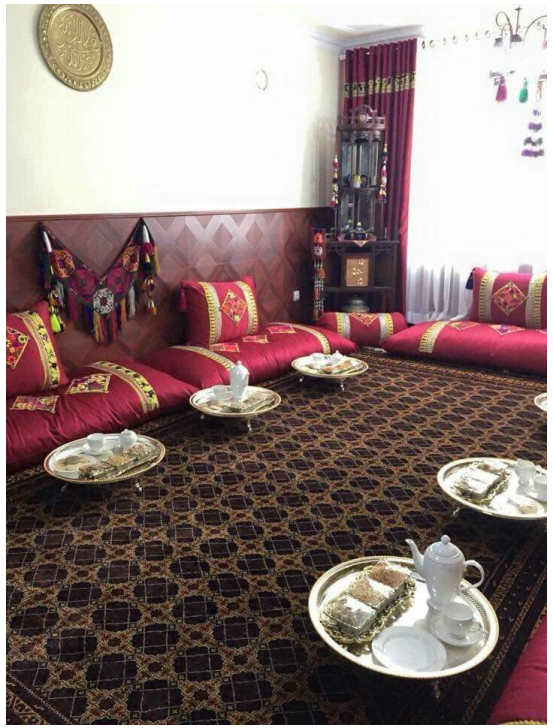
Afghan Health Initiative
Promoting Health through Lived Experience

Toxic-Free FUTURE

- Afghan Health Initiative PFAS Survey
  - Use of sprays at home for water and stain proofing
- Most respondents use these treatments
- More frequent use than we expected
- Respondents appreciated the information

Frequency of use	% respndents
Once	5
Once a year	2
Once every 6 months	30
Once every 3 months	20
Once a month	18
Once a week	25

63%



AHI

Environmental contamination risk-based regulations

- Goal: Set a risk-based limit
- Need: Concentrations of chemicals in environmental media
  - Must be measured
  - Concentration matters
  - Expect variability within a location
- **Question: How much of this chemical is safe?**

Consumer product hazard-based regulations

- Goal: Avoid the chemical in the first place
- Need: Information about chemicals used in products
  - Can be measured or reported
  - Concentration matters less, binary data can be useful
  - Don't expect much variability within a product component
- **Question: Can we avoid using this chemical in the first place?**

PFAS Detection Method Development with Partners

- 2024 legislative budget proviso to UW for one-year project to develop a mobile, non-destructive screening method (XRF)
- Will allow agencies and communities to understand which products are likely to have PFAS, allowing them to reduce exposure
- Compare with established methods
  - PIGE for total fluorine at Notre Dame University
  - Analytical testing by Eurofins
- Select products with input from other organizations
  - Regulations
  - Previous studies
  - Vulnerable populations- children
  - Type of product best suited for XRF

Public Health
Seattle & King County

Hazardous Waste Management Program
GOVERNMENTS WORKING TOGETHER FOR A HEALTHIER AND CLEANER KING COUNTY

ENVIRONMENTAL & OCCUPATIONAL HEALTH SCIENCES
SCHOOL OF PUBLIC HEALTH
UNIVERSITY of WASHINGTON

Questions?

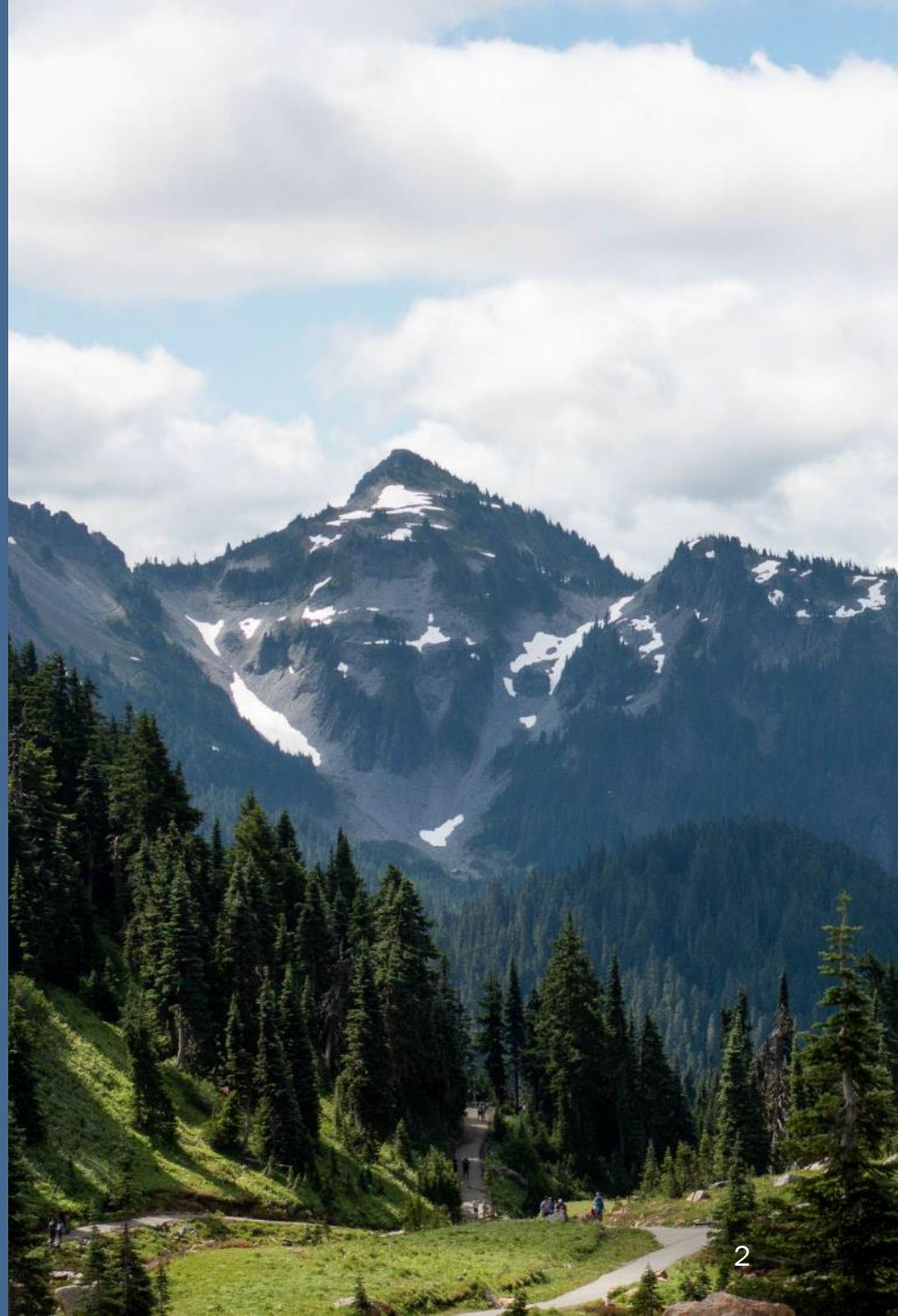
Washington State Department of HEALTH

To request this document in another format, call 1-800-525-0127. Deaf or hard of hearing customers, please call 711 (Washington Relay) or email civil.rights@doh.wa.gov.

Actions to reduce PFAS exposure

November 13, 2024

Statewide Funding Strategy



Statewide Funding Strategy

The 2023 proviso requires Ecology, in consultation with DOH, to develop a multiyear statewide funding strategy to address PFAS reduction, mitigation, and cleanup.

Focus on funding for future capital projects in three areas:

- Safe drinking water
- Managing environmental contamination
- Evaluating PFAS waste management options

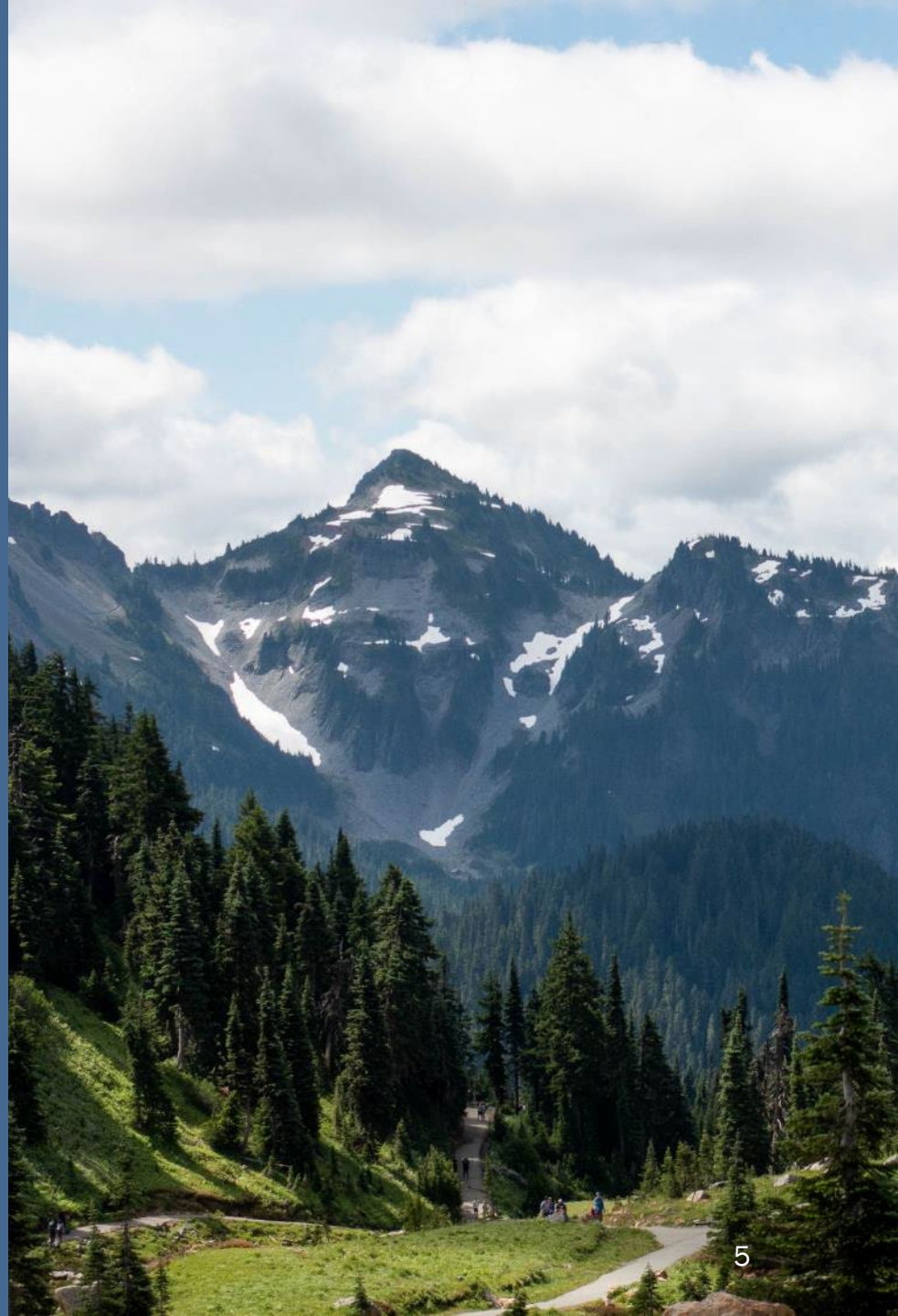
Proviso directs us to look at funding other than MTCA Capital.

Strategic Initiatives

Overarching goals that apply to all recommended actions:

- Create a new implementing body to coordinate statewide PFAS actions.
- Coordinate statewide funding with a unified fund.
- Coordinate multi-state efforts with federal action and funding.
- Incorporate considerations for overburdened communities and vulnerable populations.

Safer Products for Washington Updates



Safer Products for Washington Implementation Process

DEPARTMENT OF ECOLOGY
State of Washington

Phase 1

PRIORITY CHEMICAL CLASSES

Select priority chemicals and chemical classes to focus on during the cycle.

Phase 2

PRIORITY CONSUMER PRODUCTS

Identify which consumer products contain these chemicals and can harm people and the environment.

Phase 3

REGULATORY ACTIONS

Determine whether we'll regulate when these chemicals are used. Will we require notice, restrict/prohibit, or take no action?

Phase 4

RULEMAKING

Restrict the use of chemicals in products or require reporting to keep people and the environment safer.

Back to Phase 1

Current Efforts

- **First Rule** adopted May 2023.
  - Restriction on PFAS in carpets and rugs, indoor furniture and furnishings, and aftermarket treatments
  - Reporting requirement for PFAS in outdoor furniture
  - Chapter 173-337 WAC
- **Current Rulemaking** focused on reducing PFAS in products.
- **Work in Preparation:** Identifying priority products for future potential rulemaking.

Current Rulemaking

- Recommended regulatory determinations:
  - Restrictions on PFAS in
    - Most types of apparel
    - Cleaning products (including automotive washes)
  - Reporting on PFAS in
    - Apparel for extreme and extended use products (examples: white water kayaking and mountaineering)
    - Gear and shoes
    - Firefighting PPE
    - Waxes and polishes for floors, skis, and automotives
    - Cookware and kitchen supplies
    - Hard surface sealers
- Rule must be adopted by December 2025

Work in Preparation: Identifying products that contain PFAS

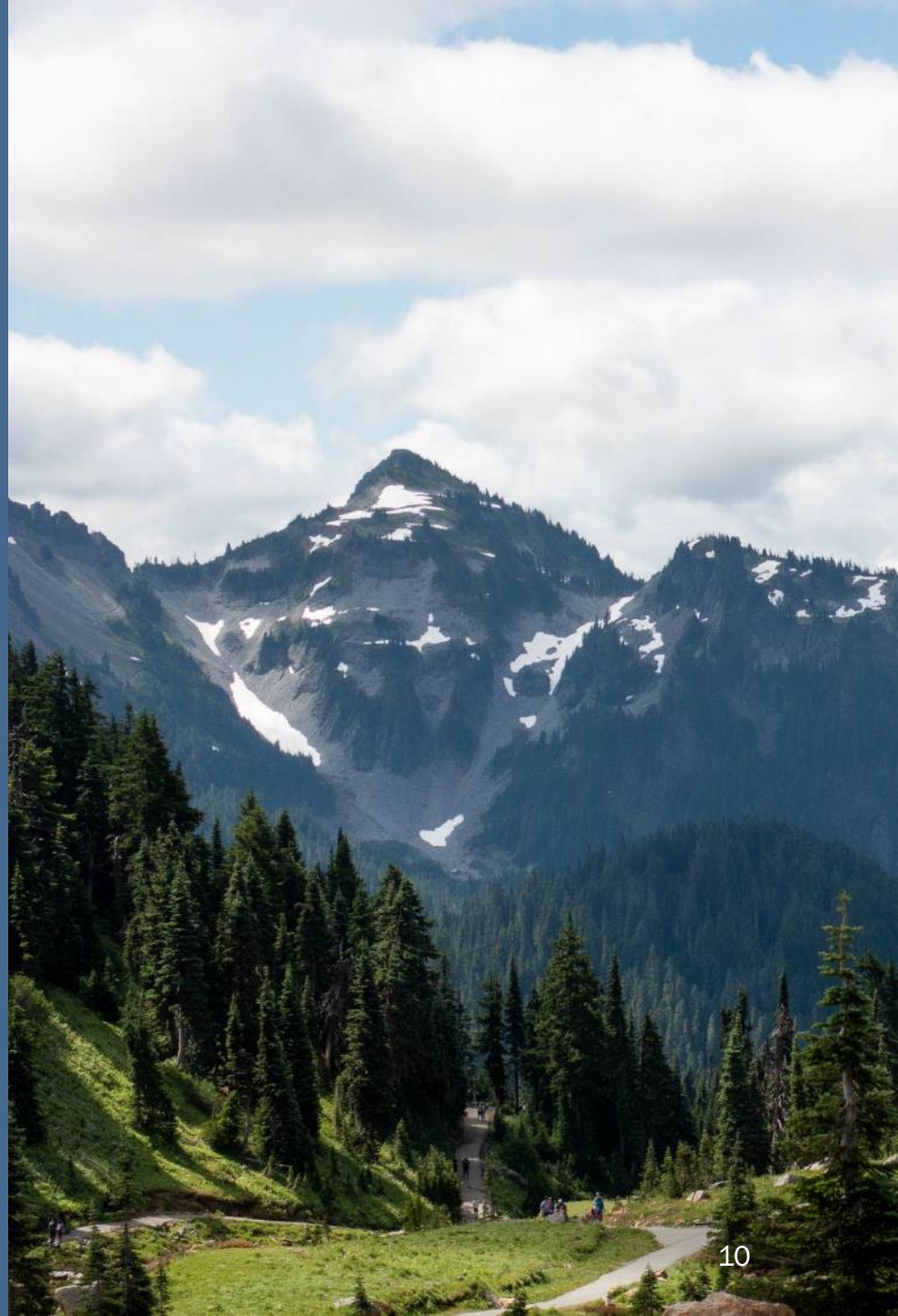
New products:

1. Artificial Turf
2. Architectural Paints

Continuing work on:

1. Hard Surface Sealers
2. Cookware and kitchen supplies
3. Firefighting PPE
4. Floor waxes and polishes

Toxic Free Cosmetics Update



The law

Toxic-Free Cosmetics Act (Ch. 70A.560 RCW)

1. **Restriction**: Restricts the *manufacture*, *distribution*, and *sale* of cosmetic products that contain certain chemicals.
2. **Rulemaking**: Gives us the authority to conduct rulemaking to identify and restrict formaldehyde-releasing chemicals used in cosmetics.
3. **Technical assistance**: Directs us to provide technical support to small businesses that make or use cosmetic products.

Restricted chemicals and chemical classes

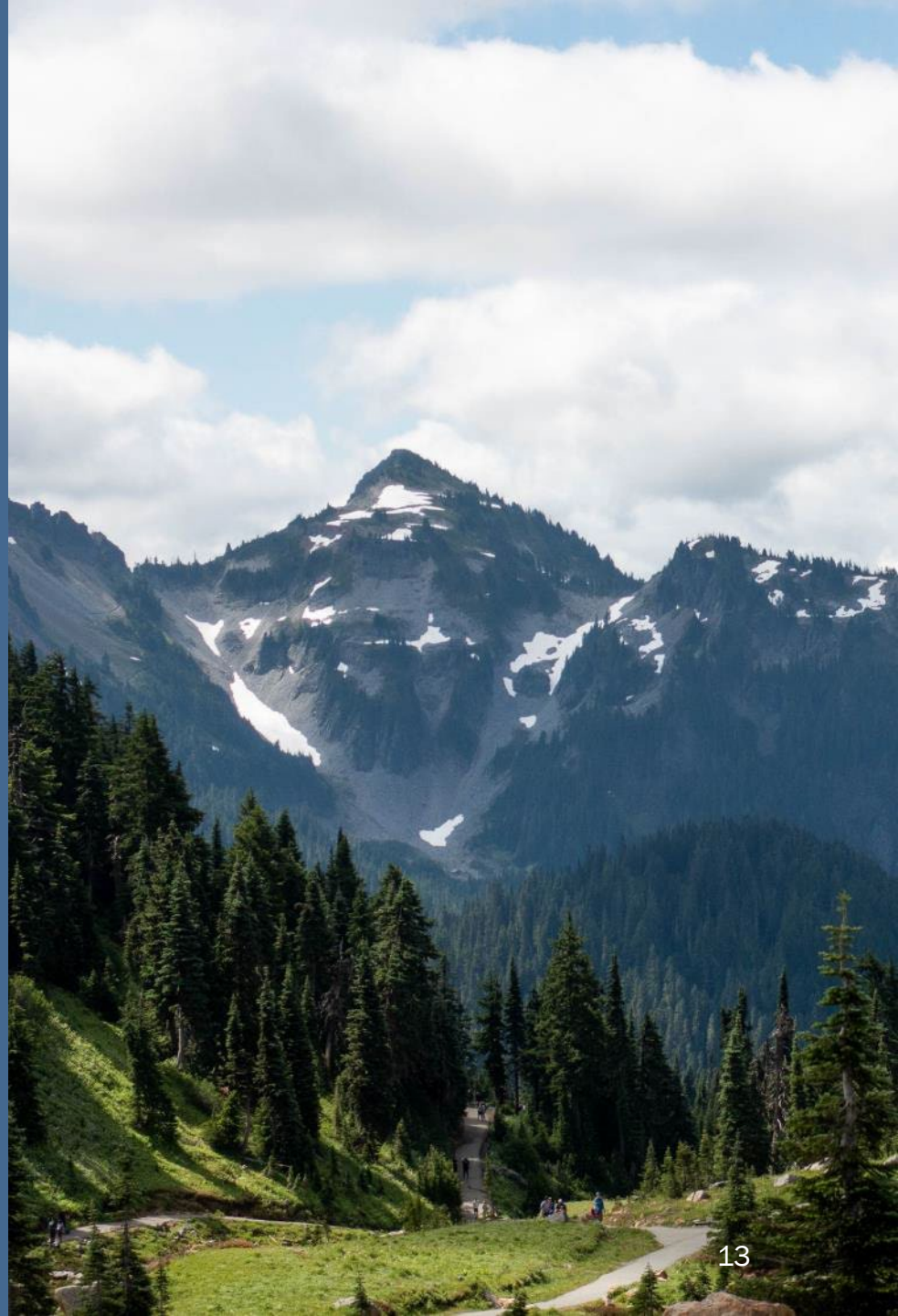
Chemicals

1. Formaldehyde (CAS 50-00-0)
2. Methylene glycol (CAS 463-57-0)
3. Triclosan (CAS 3380-34-5)
4. m-Phenylenediamine and its salts (CAS 108-45-2)
5. o-Phenylenediamine and its salts (CAS 95-54-5)

Chemical classes

6. o-Phthalates (several CAS)
7. PFAS (several CAS)
8. Mercury (CAS 7439-97-6) and mercury compounds
9. Lead (CAS 7439-92-1) and lead compounds

Thank you!



Chapter 173-337 WAC 2025 Restrictions

January 1, 2025, Restrictions

Chemical	Product
PFAS	Aftermarket stain- and water resistance treatments
PFAS	Carpets and rugs
Ortho-phthalates	Fragrances in beauty and personal care products
Ortho-phthalates	Vinyl flooring
Organohalogen flame retardants (OFRs)	TVs and displays
Flame retardants	Other recreational products made from polyurethane foam
Alkylphenol ethoxylates	Laundry detergent, 1000 ppm limit
Bisphenols	Drink cans

Chapter 173-337 WAC 2025 reporting

January 31, 2025, Reporting:

Chemical	Product
PFAS	Leather and textile furniture and furnishing intended for **outdoor** use
Organohalogen flame retardants	Electric and electronic (EE) products with plastic external enclosures, intended for **outdoor** use
Flame retardants	Recreational covered wall padding made from polyurethane foam
Bisphenols	Food cans

Chapter 173-337 WAC 2026 Restrictions

January 1, 2026, Restrictions:

Chemical	Product
PFAS	Leather and textile furniture and furnishing intended for **indoor** use
Bisphenols	Thermal paper

Chapter 173-337 WAC 2027-2028 Restrictions

January 1, 2027, Restriction:

OFRs	Other EE products for Group 1 entities

January 1, 2028, Restriction:

OFRs	Other EE products for Group 2 entities

WASHINGTON STATE BOARD OF HEALTH

Date: November 13, 2024

To: Washington State Board of Health Members

From: Kate Dean, Board Member

Subject: Petition for Rulemaking WAC 246-290-220, Drinking Water Materials and Additives – Possible Action

Background and Summary:

The Administrative Procedure Act (RCW 34.05.330) allows any person to petition a state agency for the adoption, amendment, or repeal of any rule. Upon receipt of a petition, the agency has sixty days to either (1) deny the petition in writing, stating the reasons and, as appropriate, offer other means for addressing the concerns raised by the petitioner, or (2) accept the petition and initiate rulemaking.

On October 3, 2024, the State Board of Health (Board) received a petition from Washington Action for Safe Water and Bill Osmunson, DDS MPH. The petitioners request the Board consider amending WAC 246-290-220, Drinking Water Materials and Additives, within the Group A Public Water Supplies rules.

The Board has the authority under RCW 43.20.050 to adopt rules for Group A public water systems as defined in RCW 70A.125.010. Chapter 246-290 WAC establishes the standards for these water systems related to their design, construction, sampling, management, maintenance, and operation practices. The purpose of these rules is to define basic regulatory requirements and to protect the health of consumers using public drinking water supplies.

The petitioners request that The Board amend WAC 246-290-220 to include a new subsection related to water fluoridation that states either of the following:

- The Board of Health does not recommend adding fluoridation chemicals to water with the intent to treat humans or animals; or
- In keeping with the Federal Safe Drinking Water Standards, the Board of Health does not recommend chemicals, including fluoride compounds, be added to the water with the intent to treat or prevent disease in humans or animals.

The petitioner included attachments to support the request, located in the Board materials. Shay Bauman, Board Staff, will present the Board Members with information related to the petition and recommendations.

(continued on the next page)

Recommended Board Actions:

The Board may wish to consider and amend, if necessary, the following motions:

The Board declines the petition for rulemaking to amend WAC 246-290-220 for the reasons articulated by Board Members. The Board directs staff to notify the petitioner of the Board's decision.

OR

The Board accepts the petition for rulemaking to explore the proposed amendment to WAC 246-290-220 to consider additional language related to water fluoridation. The Board directs staff to notify the requestor of its decision and to file a CR-101, Preproposal of Inquiry, to further evaluate the request and possible rule change.

Staff

Shay Bauman, Policy Advisor

WASHINGTON STATE BOARD OF HEALTH

Secondary Packet Info Sheet

Agenda Item 8

Drinking Water Materials and Additives

Supporting Materials

Due to the large file size, this agenda item requires a separate packet for posting online.

Included in this packet are all Agenda Item 8 materials:

a. Cover Memo
b. Secondary Packet Info Sheet
c. Petitions Policy
d. Petition
e. Court Ruling (attachment to petition)
f. Supplemental Materials
g. WAC 246-290-220
h. Presentation

WASHINGTON STATE BOARD OF HEALTH

Date: November 13, 2024

To: Washington State Board of Health Members

From: Kelly Oshiro, Board Chair

Subject: Newborn Screening Technical Advisory Committee, Review of Newborn Screening Process and Criteria

Background and Summary:

The Washington State Board of Health (Board) has the authority under RCW 70.83.050 to define and adopt rules for screening Washington-born infants for hereditary conditions. WAC 246-650-010 defines the conditions, and WAC 246-650-020 lists the conditions for which all newborns are to be screened.

The Board convenes a technical advisory committee (TAC) to review conditions and make recommendations to Board regarding possible inclusion in the newborn screen (NBS) panel. The TAC evaluates candidate conditions using the Board's guiding principles and an established set of criteria. Before the Board convenes a TAC, sufficient scientific evidence should be available to apply the Board's criteria for inclusion, which may require a preliminary review. This is known as the qualifying assumption. The Board's process and criteria were last reviewed in 2014 and 2015.

Since 2022, the Board has received five petitions requesting the addition of new conditions to the screening panel. These conditions were: congenital Cytomegalovirus (cCMV), Mucopolysaccharidoses II (MPS II), Guanidinoacetate methyltransferase (GAMT) deficiency, Arginase 1 deficiency (ARG1-D), and Wilson's Disease. The Board convened TACs for cCMV, ARG1-D and GAMT. The TACs recommended adding ARG1-D and GAMT, but not cCMV. The Board accepted the TAC recommendations and ARG1-D and GAMT will be added when funding is available. During the 2024 legislative session, the Legislature required the Board to review branched-chain ketoacid dehydrogenase kinase (BCKDK) deficiency and re-review cCMV. Staff also anticipate reviewing MPSII and Wilson's disease in Spring 2025. The Department of Health (Department) is currently monitoring five to seven other potential conditions that may be proposed for review soon.

Given the recent increase in condition review requests and anticipated workload, the Board and Department acknowledged the need to review and update the current process and convened a TAC to identify strategies to streamline the condition review request process, modernize the evaluation criteria, and strengthen the overall process to address current program demands.

(continued on the next page)

Washington State Board of Health
November 13, 2024, Meeting Memo

The TAC met on October 28, 2024 to review Washington's current process and criteria. Staff presented information about the federal new condition nomination and review process and potential options to update the Board's current process. The TAC voted and proposed the following recommendations for the Board's consideration:

1) All conditions added to the Federal Recommended Uniform Screening Panel (RUSP) meet the Board's qualifying assumption.
2) The Board should continue convening TACs to review these conditions in order to determine if they should be added to Washington's mandatory newborn screening panel using Washington's criteria.
3) The Board should convene a TAC to review a condition within two years of its addition to the RUSP.

The TAC also began reviewing the five newborn screening criteria. During discussions, TAC members suggested initial updates to the criteria such as strengthening definitions of "available treatment" and "screening test sensitivity and specificity" and considering community resources. TAC members will continue this review at the next TAC meeting.

I have invited Kelly Kramer, Board Staff, to provide an overview of the TAC's process and criteria review recommendations.

Recommended Board Actions:

The Board may wish to consider one of the following motions:

The Board declines the Newborn Screening Technical Advisory Committee's (TAC's) recommendation for the Board to assume that conditions on the Federal Recommended Uniform Screening Panel meet the Board's qualifying assumption. The Board directs the TAC to continue reviewing the newborn screening process criteria and make recommendations to the Board.

OR

The Board accepts the Newborn Screening Technical Advisory Committee's (TAC's) recommendation for the Board to assume that conditions on the Federal Recommended Uniform Screening Panel meet the Board's qualifying assumption and directs staff to update the Board newborn screening process document accordingly. The Board also directs the TAC to continue reviewing the newborn screening criteria and provide recommendations to the Board.

Staff

Kelly Kramer

Washington State Board of Health

Overview of TAC Review of NBS Process and Criteria

Kelly Kramer, Policy Advisor – November 13, 2024

WASHINGTON STATE BOARD OF HEALTH

Overview

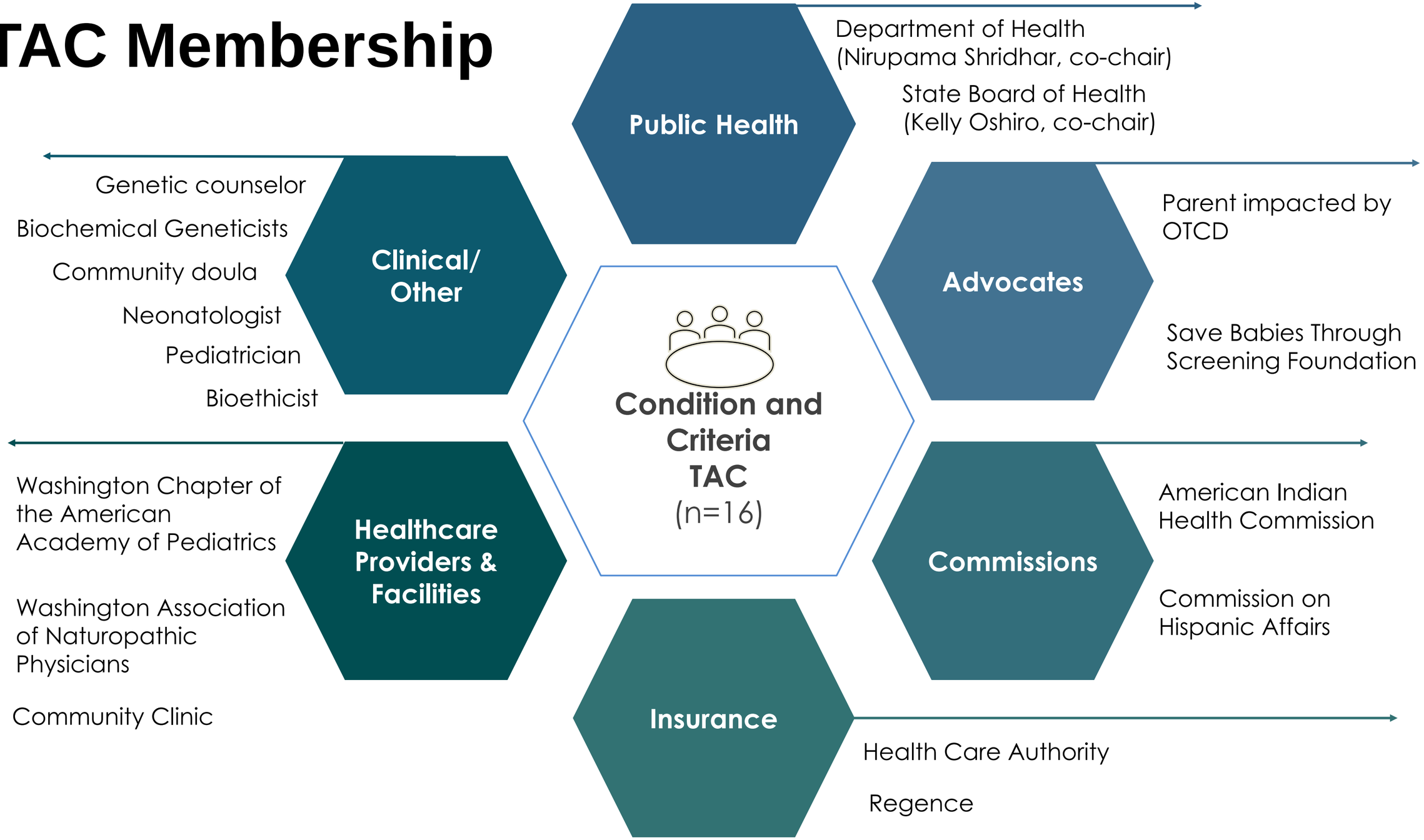
- Technical Advisory Committee Overview
- Options for condition review
- Voting results
- Discussion and next steps

TAC Purpose

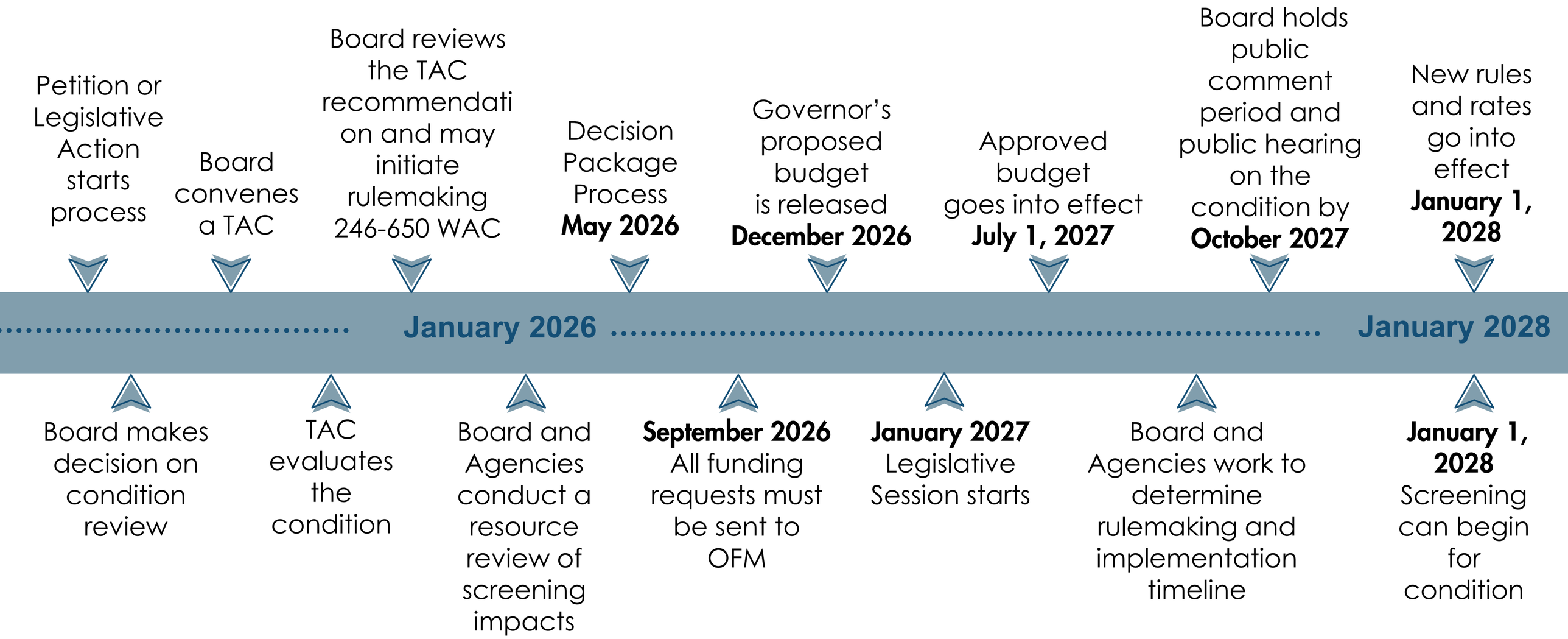
TAC convened October 28 to review the Board’s current process and criteria for adding conditions to the mandatory newborn screening panel to:

- Address rapid advancements in newborn screening
- Streamline condition review process
- Modernize five criteria and strengthen overall process

TAC Membership



NBS Process Timeline



Timeline Annotations 1-5

1. If a condition review request is made through a petition, the Board has 60 days to review and respond to the petition.

2. Adding a new condition may require the DOH and HCA to request an increase to the newborn screening fee. An increase may cover the cost of the new test(s), staff time, follow-up services for babies with positive screens, and other programmatic and administrative expenses.

3. If there is an FDA-cleared kit for the new test(s), the time to implementation can follow the above schedule. If not, implementation will take longer. The FDA modified LDT oversight in May 2024. The WA PHL can perform LDTs already in effect when the rule change was made. Any modification or new LDT must be approved through the FDA.

4. Agency division concept papers for DP budget requests must be submitted in the spring (May), after the most recent Legislative session, for agency review and consideration. Once the agency has approved the request, formal DP development occurs through the end of July/early August. Agency DP approvals depend on the state budget. If OFM is cautioning agencies that there's a tight budget, getting new DP requests approved can be challenging.

5. Each year, January 1 and July 1, updated MCO rates typically go into effect.

List of Abbreviations/Acronyms

- Decision Package (DP)
- Food and Drug Administration (FDA)
- Laboratory-Developed Test (LDT)
- Managed Care Organization (MCO)
- Office of Financial Management and Budget (OFM)
- Public Health Lab (PHL)
- Technical Advisory Committee (TAC)
- Washington Administrative Code (WAC)
- Washington State Board of Health (Board)
- Washington State Department of Health (DOH)
- Washington State Health Care Authority (HCA)

Options for Condition Review

Option One

Ad Hoc Only

Washington's current process

Conditions nominated for review through petition or legislative direction

Review for evidence to ensure Qualifying Assumption met

Determine if TAC may convene

Option Two

RUSP Alignment +Ad Hoc Committee

Washington newborn screening panel follows federal panel

- Recommended Uniform Screening Panel (RUSP)

Still allow condition nomination through petition or legislative direction

Option Three

RUSP Meets WSBOH Qualifying Assumption + Ad Hoc Committee

Conditions on the RUSP would assume Qualifying Assumption met

- Evidence review not needed by SBOH

All RUSP conditions reviewed by a TAC

Still allow condition nomination through petition or legislative direction

Condition Review Voting Summary

Option	Vote
1. Ad Hoc Only (current process)	0
2. RUSP Alignment + Ad Hoc	4
3. RUSP Meets WSBOH Qualifying Assumption + Ad Hoc	12
4. Unsure or I need more information	0

Condition Review Voting Summary

Do you recommend that the Board put a timeline in place for reviewing RUSP nominated conditions?	**Vote**
Yes	15*
No	0

If you recommend a timeframe, how long would you like it to be?	**Vote**
Two-year review process	14
Other	1

*One TAC member abstained from this round of voting.

Criteria Review Discussion

Preliminary discussion of the five criteria

1. Available Screening Technology
   - **Suggestion: provide benchmarks for sensitivity, specificity, false positives, false negatives**
2. Diagnostic Testing and Treatment Available
   - **Suggestion: define “available treatment”**
3. Prevention Potential and Medical Rationale
4. Public Health Rationale
   - **Suggestion: consider available resources for all of Washington, especially rural communities. Also focus on outreach and education.**
5. Cost-benefit/Cost-effectiveness

TAC suggests continuing criteria review at the next TAC meeting

Board Member Discussion

For Board Member discussion

- Does the Board agree with the TAC’s recommendation for condition review, the Federal RUSP meets the Qualifying Assumption?
- Does the Board agree with the 2-year timeframe to review RUSP conditions?

If the Board agrees to move forward with the TAC's recommendations, some considerations:

- How to respond to petitions for conditions that are undergoing review by the federal committee?
- How to respond to petitions for conditions that have been previously denied by the federal committee?

Board Member Next Steps

Possible action: The Board may consider the following-

- The Board declines the Newborn Screening TAC's recommendation for the Board to assume that conditions on the Federal RUSP meet the Board's qualifying assumption

OR

- The Board accepts the Newborn Screening TAC's recommendation for the Board to assume that conditions on the Federal RUSP meet the Board's qualifying assumption. The Board directs staff to update WSBOH NBS Process and Criteria document and include 2- year timeframe to review RUSP conditions. TAC continue review of criteria at next TAC meeting.

WASHINGTON STATE BOARD OF HEALTH

THANK YOU

To request this document in an alternate format, please contact the Washington State Board of Health at 360-236-4110, or by email at **wsboh@sboh.wa.gov** | TTY users can dial 711

ACCESSIBILITY AND THE AMERICANS WITH DISABILITIES ACT (ADA)

- The Washington State Board of Health (Board) is committed to providing information and services that are accessible to people with disabilities. We provide reasonable accommodations, and strive to make all our meetings, programs, and activities accessible to all persons, regardless of ability, in accordance with all relevant state and federal laws.
- Our agency, website, and online services follow the Americans with Disabilities (ADA) standards, Section 508 of the Rehabilitation Act of 1973, Washington State Policy 188, and Web Content Accessibility Guidelines (WCAG) 2.0, level AA. We regularly monitor for compliance and invite our users to submit a request if they need additional assistance or would like to notify us of issues to improve accessibility.
- We are committed to providing access to all individuals visiting our agency website, including persons with disabilities. If you cannot access content on our website because of a disability, have questions about content accessibility or would like to report problems accessing information on our website, please call (360) 236-4110 or email wsboh@sboh.wa.gov and describe the following details in your message:
    - The nature of the accessibility needs
    - The URL (web address) of the content you would like to access
    - Your contact information

We will make every effort to provide you the information requested and correct any compliance issues on our website.

Washington State Department of HEALTH

WASHINGTON STATE BOARD OF HEALTH

Newborn Screening Technical Advisory Committee (TAC)

Newborn Screening Technical Advisory Committee (TAC) Charter

Start Date: October 28, 2024 **End Date:** June 30, 2025 (tentative)
Members: See TAC Membership Addendum A

OBJECTIVE

Serve as an expert advisory committee on newborn screening for the Washington State Board of Health (Board). Review and recommend possible updates to the Board's current newborn screening process and criteria. Additionally, evaluate several candidate conditions for potential inclusion in the Washington State mandatory newborn screening panel and provide recommendations to the Board.

BACKGROUND

The Board establishes the rules for newborn screening in Washington, including deciding which conditions all newborns must be tested for at birth. To make these decisions, the Board assembles a multidisciplinary Technical Advisory Committee (TAC) comprised of family representatives and representatives from healthcare, social services, advocacy organizations, public health, and more. Using available evidence, the TAC then assesses candidate conditions using guiding principles and five newborn screening criteria to determine which conditions should be added to the panel.

KEY ACTIVITIES

This TAC is being convened to complete the following key activities:

- Review the Board's current newborn screening candidate condition review process and criteria and identify opportunities for improvement.
- Determine whether branched-chain ketoacid dehydrogenase kinase (BCKDK) deficiency meets the Board's criteria for newborn screening panel inclusion and provide a recommendation to the Board. This is a requirement of Senate Bill 6234 (Chapter 105, Laws of 2024).
- Determine whether congenital cytomegalovirus (cCMV) meets the Board's criteria for newborn screening and provide a recommendation to the Board. This is a requirement of Senate Bill 5829 (Chapter 96, Laws of 2024).
- Review other possible candidate conditions recently brought in front of the Board between 2024 and 2025.

TAC TIMELINES (Tentative)

- Meeting 1, Process and Criteria Review – Monday, October 28, 2024
- Meeting 2, BCKDK Deficiency Review – January 2025
- Meeting 3, cCMV Review – February 2025

COMMITTEE NORMS AND EXPECTATIONS

- Be here now and stay purpose-oriented
- Listen for understanding; seek clarification and resist assumptions
- Appreciate the strength of diverse cultures and perspectives
- Engage respectfully; see with new eyes and hear with new ears
- Move up into a speaking role; move into a listening role
- Stay on topic and mind the time
- Assume positive intent; acknowledge and repair harms
- Try to avoid speaking with someone else is speaking
- Commit to using inclusive language in committee discussions and if possible, try to avoid using idioms or slang terms
- State your name each time you begin talking, and speak at a moderate pace to ensure language interpreters can appropriately translate what is being said
- Use acronyms where possible after introducing technical terms or proper nouns and encourage other committee members to do the same.

Washington State Department of HEALTH

WASHINGTON STATE BOARD OF HEALTH

Newborn Screening Technical Advisory Committee (TAC)

Newborn Screening Technical Advisory Committee (TAC) Charter

DECISION MAKING

- Proposed voting methods: This committee will use anonymous voting via Microsoft Forms and open discussion of results to inform committee decisions and recommendations.
- Proposed Primary or Alternative Member voting: Both primary and alternative TAC Members may attend these meetings, however, if both are in attendance the primary TAC member will be responsible for speaking and voting during the meeting. The alternative member only speaks and votes when the primary is not in attendance.

INFORMATION SHARING

The Newborn Screening TAC planning team will:

- Email and post meeting materials at least 48 hours before the scheduled meeting.
- Email updates and notices to TAC members and designated alternatives.
- Post information on the Newborn Screening Criteria Review Project webpage.

RESOURCES/REFERENCE MATERIALS

- Chapter 246-650 WAC – Newborn Screening.
- Washington State Board of Health Process to Evaluate Conditions for Inclusion in the Required Newborn Screening Panel.
- Washington Department of Health Newborn Screening Webpage

Washington State Department of HEALTH

WASHINGTON STATE BOARD OF HEALTH

Newborn Screening Technical Advisory Committee (TAC)

NBS TAC Membership

MEMBER	ALTERNATE	REPRESENTING
Kelly Oshiro, JD WSBOH Co-Chair Assistant Attorney General		Washington State Board of Health (WSBOH)
Nirupama Shridhar, MPH, PhD DOH Co-Chair State Genetics Coordinator		Department of Health (DOH)
Joan Chappel, RN, MSN Nursing Consultant Advisor/Supervisor	**Melissa Kundur, RN** Occupational Nurse Consultant	Washington Health Care Authority (HCA)
Byron Raynz Parent Advocate		Parent/Child Advocacy
Emily Shelkowitz, MD Pediatrics, Medical Genetics		Pediatric Specialty Care, Seattle Children's Hospital Biochemical Genetics
Eric Leung, MD Neonatologist		Neonatology and Washington Chapter of the American Academy of Pediatrics (WCAAP)
Heather Hinton, MS Certified Genetic Counselor		Genetic Counseling, MultiCare Yakima Memorial
Joon-Ho Yu, MPH, PhD Pediatrics/Public Health Bioethicist		Bioethics, Department of Epidemiology, University of Washington Bioethics, Treuman Katz Center for Pediatric Bioethics and Palliative Care
Kristine Alexander Senior Medical Policy Research Analyst		Private Insurers, Regence Health Plans
Krystal Plonski, LAc EAMP, ND, FABNP Naturopathic Pediatrics and Acupuncturist		Naturopaths, Seattle Children's Hospital, and Washington Association of Naturopathic Physicians (WANP)

Washington State Department of HEALTH

WASHINGTON STATE BOARD OF HEALTH

Newborn Screening Technical Advisory Committee (TAC)

NBS TAC Membership

MEMBER	ALTERNATE	REPRESENTING
Lisa McGill Vargas, MD Neonatologist	**Rucha Shukla, MD** Neonatologist	Pediatrics, Neonatal-Perinatal Medicine, Sacred Heart Medical Center Neonatology Intensive Care Unit (NICU)
Peggy Harris Public Health and Children's Health Advocate		Parent/Child Advocacy, Save Babies Through Screening Foundation
Priyanka Raut, DNP, MHS, RN Senior Director of Nursing		Pediatrics, Yakima Valley Farmworkers Clinic
Roberta (Bobbie) Salveson, ARNP, PhD Pediatric Nurse Practitioner, Medical Genetics		Pediatric Specialty Care, Mary Bridge Children's Hospital Biochemical Genetics
Taylor Kaminski, Community Doula		Perinatal and Postpartum Care, Global Perinatal Services
María Sigüenza Executive Director		State Commissions, Commission on Hispanic Affairs

NBS TAC Staff Support

Kelly Kramer
WSBOH Newborn Screening Policy Advisor

John Thompson
DOH Director of Newborn Screening

Megan McCrillis
DOH Newborn Screening Policy Advisor

Molly Dinardo
WSBOH Policy Advisor

Crystal Ogle
WSBOH Administrative Assistant

Michelle Larson
WSBOH Communications Manager

Anna Burns
WSBOH Communications Consultant

Washington State Department of HEALTH

WASHINGTON STATE BOARD OF HEALTH

Newborn Screening Technical Advisory Committee (TAC)

Newborn Screening Process and Criteria Review Technical Advisory Committee (TAC) Problem Statement:

KEY POINTS:

- Newborn screening programs across the U.S. are struggling to keep pace with rapid advancements in technology and treatments, compounded by inadequate resources and infrastructure.
- Washington, like many other states, is facing challenges with the growing number of requests to add new conditions to its required newborn screening panel. Evaluating these conditions takes a lot of time and resources.
- To address this issue, the Washington State Board of Health and the Department of Health are forming a TAC. The TAC will help to identify strategies to streamline the condition review request process, modernize the evaluation criteria, and strengthen the overall process to address current demands better.

OVERVIEW:

Over the last 60 years, newborn screening has emerged as a major public health achievement in the United States (CDC, 2011). Rapid advancements in screening technology and treatments for rare diseases pose a challenge for newborn screening programs nationwide, which struggle to keep up with these developments (Watson et.al, 2022). Many state programs face significant obstacles, including inadequate resources, limited funding, and insufficient infrastructure for equipment, staffing, and follow-up services necessary to test for new conditions.

In Washington State, the Newborn Screening Program, managed by the Department of Health, utilizes dried blood spot samples to identify rare but treatable health conditions in newborns. Annually, the program conducts approximately 12 million tests on over 172,000 specimens from about 84,000 births, identifying about 200 cases of the 32 conditions currently on the state's screening panel (DOH, n.d.). Early detection through this screening saves lives and improves health outcomes.

Washington law (RCW 70.83.050) requires that the Washington State Board of Health (Board) establish rules for newborn screening, detailed in Chapter 246-650 WAC. This includes WAC 246-650-020, which specifies the conditions for which all newborns must be screened.

The public, Legislature, Department staff, or Board members can request the Board to review potential new conditions for inclusion in the screening panel. The Board may convene an advisory committee to evaluate these conditions based on three guiding principles and an established set of five newborn screening criteria. The process and criteria were last reviewed in 2015.

Since 2023, the Board has received four petitions for new conditions to be considered for the screening panel. These conditions were: Mucopolysaccharidoses II (MPS II), Guanidinoacetate methyltransferase (GAMT) deficiency, Arginase 1 deficiency (ARG1-D), and Wilson's Disease. Additionally, by 2025, at the Legislature's direction, the Board must review two other conditions: branched-chain ketoacid dehydrogenase kinase (BCKDK) deficiency and congenital cytomegalovirus (cCMV). The Department is also monitoring 5-7 other potential conditions that may soon be proposed for review.

Given the increased volume of requests and anticipated workload, the Board and Department recognize the need to review and update the current process. The purpose of convening this Technical Advisory Committee (TAC) is to identify strategies to streamline the condition review request process, modernize the evaluation criteria, and strengthen the overall process to address current demands better.

NBS Process Timeline

Petition or Legislative Action starts process

Board convenes a TAC

Board reviews the TAC recommendation and may initiate rulemaking 246-650 WAC

Decision Package Process **May 2026**

Governor's proposed budget is released **December 2026**

Approved budget goes into effect **July 1, 2027**

Board holds public comment period and public hearing on the condition by **October 2027**

New rules and rates go into effect **January 1, 2028**

January 2026 ..... **January 2028**

Board makes decision on condition review

TAC evaluates the condition

Board and Agencies conduct a resource review of screening impacts

September 2026 All funding requests must be sent to OFM

January 2027 Legislative Session starts

Board and Agencies work to determine rulemaking and implementation timeline

January 1, 2028 Screening can begin for condition

Washington State Department of HEALTH

WASHINGTON STATE BOARD OF HEALTH

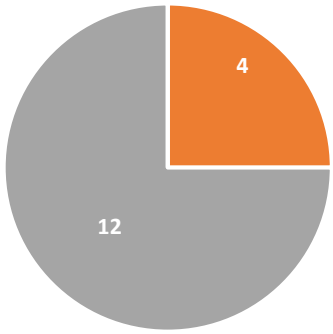
Newborn Screening Technical Advisory Committee (TAC)

Meeting to Review the Process and Criteria for Adding a Condition to the Mandatory Panel

TAC Member Voting Summaries and Comments

The following is a compilation of TAC members' comments when voting on the condition review process options to recommend to the Board. Each voting option summarizes and organizes comments from the TAC member discussion.

Options for Condition Review Process

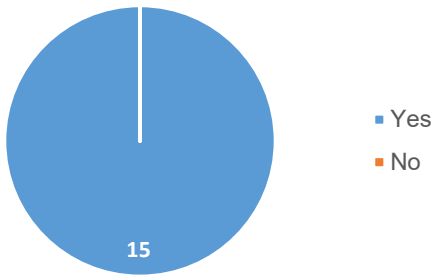
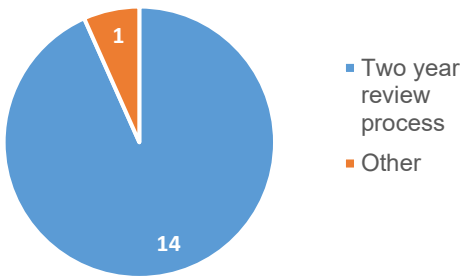


Voting Options	Comments and Major Themes
1. Ad Hoc Only (current process – no changes recommended)	*No comments.*
2. RUSP Alignment + Ad Hoc Committee (all RUSP conditions added to the WA panel, only review non-RUSP conditions)	• RUSP alignment is more equitable, with fewer disparities for screening among states. • This option may speed up adding conditions to the mandatory panel. • Least expensive of the options. • Concern for overwhelming the healthcare system. • Distrust in the federal committee making appropriate recommendations. • Lack of clinical perspective on the federal committee.

(continued on the next page)

3. RUSP Meets WSBOH Qualifying Assumption + Ad Hoc Committee (a TAC would still review RUSP conditions, but through an abbreviated review process; non-RUSP-conditions follow a regular process)	• Washington has a robust process to review conditions. • Recommendation for standing committee to meet consistently. Ad hoc committees are not as effective. • This option would allow a review of access to resources for all babies in Washington, especially in more rural areas.
4. Unsure or I need more information before voting	*No comments.*

Timeframe for Reviewing Recommended Uniform Screening Panel (RUSP) Conditions

Voting Options	Comments and Major Themes
1. Do you recommend that the Board put a timeline in place for reviewing RUSP nominated conditions? 	*No comments.*
2. If you recommend a timeframe, how long would you like it to be? 	• Other states who are aligned with the RUSP have a timeframe of 2 years. • With this two-year timeline, try to utilize the WA biennial legislative cycle. For example, review and make recommendations on recently added RUSP conditions during a short legislative session year. Decision package with NBS fee increase sent to legislature the following May. Budget requests are best during long sessions.

3. If you selected “other” please specify.	• “18 months.”

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Washington State Board of Health

PROCESS TO EVALUATE CONDITIONS FOR INCLUSION IN THE REQUIRED NEWBORN SCREENING PANEL

The Washington State Board of Health (Board) has the duty under RCW 70.83.050 to define and adopt rules for screening Washington-born infants for heritable conditions. Chapter 246-650-020 WAC lists conditions for which all newborns must be screened. Members of the public, staff at Department of Health (Department), and/or Board members can request that the Board review a particular condition for possible inclusion in the newborn screening (NBS) panel. T~~In order t~~o determine which conditions to include in the ~~newborn screening~~NBS panel, the Board convenes a~~n~~ newborn screening technical advisory committee (TAC) to evaluate candidate conditions using guiding principles and an established set of criteria.

Th~~e following~~ is document ~~is a description of~~describes the Qualifying Assumption, Guiding Principles, and Criteria ~~which~~ the Board has approved ~~in order to~~to evaluate conditions for possible inclusion in the newborn screening panel. The ~~Washington State Board of Health~~Board and Department ~~of Health~~ apply the qualifying assumption. The Board appointed Newborn Screening ~~Advisory Committee~~ TAC applies the following three guiding principles and evaluates the five criteria ~~in order~~ to make recommendations to the Board on which condition(s) to include in the state's required NBS panel.

QUALIFYING ASSUMPTION

Before ~~an~~ the Board convenes a TAC~~advisory committee is convened~~ to review a candidate condition against the ~~Board's~~ five newborn screening ~~requirements~~criteria, ~~a~~ staff should complete a preliminary review ~~should be done~~ to determine whether ~~there is sufficient scientific evidence~~sufficient scientific evidence is available to apply the criteria for inclusion. If the candidate condition is on the Health Resources and Services Administration (HRSA) Recommended Uniform Screening Panel (RUSP), the Board and Department will ~~assume~~ consider ~~it meets~~ the qualifying assumption met and convene a TAC.

A note on the RUSP: The RUSP is a list of conditions that the Secretary of the Department of Health and Human Services (HHS) recommends states screen for as part of their newborn screening programs. Once a new condition has been recommended by the HHS Secretary, the Board and Department will review it for possible inclusion in the Washington NBS panel within two years of the recommendation.

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THREE GUIDING PRINCIPLES

Three guiding principles govern all aspects of the evaluation of a candidate condition for possible inclusion in the NBS panel.

- Decision to add a screening test should be driven by evidence. For example, test reliability and available treatment have been scientifically evaluated, and those treatments can improve health outcomes for affected children.
- All children who screen positive should have reasonable access to diagnostic and treatment services.
- Benefits of screening for the disease/condition should outweigh harm to families, children and society.

CRITERIA

1. Available Screening Technology: Sensitive, specific and timely tests are available that can be adapted to mass screening.

2. Diagnostic Testing and Treatment Available: Accurate diagnostic tests, medical expertise, and effective treatment are available for evaluation and care of all infants identified with the condition.

3. Prevention Potential and Medical Rationale: The newborn identification of the condition allows early diagnosis and intervention.
Important considerations:

- There is sufficient time between birth and onset of irreversible harm to allow for diagnosis and intervention.
- The benefits of detecting and treating early onset forms of the condition (within one year of life) balance the impact of detecting late onset forms of the condition.
- Newborn screening is not appropriate for conditions that only present in adulthood.

4. Public Health Rationale: Nature of the condition justifies population-based screening rather than risk-based screening or other approaches.

5. Cost-benefit/Cost-effectiveness: The outcomes outweigh the costs of screening. All outcomes, both positive and negative, need to be considered in the analysis. Important considerations to be included in economic analyses include:

- The prevalence of the condition among newborns.
- The positive and negative predictive values of the screening and diagnostic tests.
- Variability of clinical presentation by those who have the condition.
- The impact of ambiguous results. For example the emotional and economic impact on the family and medical system.
- Adverse effects or unintended consequences of screening.

RCW 70.83.020

Screening tests of newborn infants.

(1) It shall be the duty of the department of health to require screening tests of all newborn infants born in any setting. Each hospital or health care provider attending a birth outside of a hospital shall collect and submit a sample blood specimen for all newborns no more than forty-eight hours following birth. The department of health shall conduct screening tests of samples for the detection of phenylketonuria and other heritable or metabolic disorders leading to intellectual disabilities or physical defects as defined by the state board of health: PROVIDED, That no such tests shall be given to any newborn infant whose parents or guardian object thereto on the grounds that such tests conflict with their religious tenets and practices.

(2) The sample required in subsection (1) of this section must be received by the department [of health] within seventy-two hours of the collection of the sample, excluding any day that the Washington state public health laboratory is closed.

[**2014 c 18 § 1**; **2010 c 94 § 18**; **1991 c 3 § 348**; 1975-'76 2nd ex.s. c 27 § 1; **1967 c 82 § 2**.]

RCW 70.83.030

Report of positive test to department of health.

Laboratories, attending physicians, hospital administrators, or other persons performing or requesting the performance of tests for phenylketonuria shall report to the department of health all positive tests. The state board of health by rule shall, when it deems appropriate, require that positive tests for other heritable and metabolic disorders covered by this chapter be reported to the state department of health by such persons or agencies requesting or performing such tests.

[**1991 c 3 § 349; 1979 c 141 § 113; 1967 c 82 § 3.**]

RCW 70.83.050

Rules and regulations to be adopted by state board of health.

The state board of health shall adopt rules and regulations necessary to carry out the intent of this chapter.

[**1967 c 82 § 5.**]

WASHINGTON STATE BOARD OF HEALTH

Share Your Ideas for School Environmental Health and Safety

We all want our children to be safe and healthy at school. Help us make **new minimum standards for environmental health and safety**, covering areas like water quality, air quality, and playground safety.

The Washington State Board of Health is working on new standards, which will apply to all public and private K-12 schools, affecting over a million Washington children.

We invite community members, families, teachers, and school staff to share your ideas and priorities. Your suggestions will help us create the best rules possible for all our children!

Our school rules team wants to hear your ideas and priorities for the new rules for **school environmental health and safety**.

School Environmental Health and Safety Rule Project

Listening Session

Spokane Listening Session
Date: **November 19, 2024**
Time: **6:00 p.m.**
Location: **Shadle Park High School**
Cafeteria
4327 North Ash Street
Spokane, WA 99205

ASL and Spanish interpreters will be available.

- Children and students are welcome.
- Snacks will be available.
- Gift cards will be available.

Get updates
Subscribe at School Rule Project Interest Form by scanning the QR code below:

WASHINGTON STATE BOARD OF HEALTH

Comparta sus ideas sobre la salud y seguridad ambiental para las escuelas

Todos queremos que nuestros hijos estén seguros y sanos en la escuela. Ayúdenos a formular **nuevas normas mínimas de salud y seguridad ambiental** que abarquen ámbitos como la calidad del agua, la calidad del aire y la seguridad en los patios.

La Mesa Directiva de Salud del Estado de Washington está trabajando en nuevas normas que se aplicarán a todas las escuelas primarias y secundarias públicas y privadas, y afectarán a más de un millón de niños de Washington.

Invitamos a los miembros de la comunidad, las familias, los profesores y el personal escolar a compartir sus ideas y prioridades. Sus sugerencias nos ayudarán a crear las mejores normas posibles para todos nuestros niños.

Nuestro equipo encargado de formular reglas escolares quiere escuchar sus ideas y prioridades sobre las nuevas normas de salud y seguridad ambiental para las escuelas.

Proyecto de normas de salud y seguridad ambiental para las escuelas

Sesión de escucha del condado de Spokane

Fecha: 19 de noviembre de 2024
Hora: 6:00 p. m.
Lugar: Shadle Park High School
Cafeteria
4327 North Ash Street
Spokane, WA 99205

Habrá intérpretes de ASL (por su sigla en inglés, Lenguaje de Señas Americano) y de español disponibles.

- Los niños y los estudiantes son bienvenidos.
- Habrá bocadillos.
- Habrá tarjetas de regalo.

Obtenga actualizaciones
Suscríbase al formulario de interés del proyecto de normas escolares escaneando el código QR que aparece a continuación:

WASHINGTON STATE BOARD OF HEALTH

Date: November 13, 2024

To: Washington State Board of Health Members

From: Patty Hayes, Board Chair

Subject: Request for Delegated Rulemaking, WAC 246-282-005 Sanitary Control of Shellfish Minimum Performance Standards to Revise the Reference to the Recently Adopted Model Ordinance – Possible Action

Background and Summary:

On September 3, 2024, the National Shellfish Sanitation Program (NSSP) released the 2023 revision to its *Guide for the Control of Molluscan Shellfish* (guide). The guide consists of a Model Ordinance, supporting guidance documents, recommended forms, and other related materials. This new version supersedes the 2019 version referenced in WAC 246-282-005(1)(a).

The Department of Health (Department) is requesting delegation of rulemaking authority from the State Board of Health (Board) to adopt by reference the newest version of the Model Ordinance. For prior revisions, the Board has delegated rulemaking authority to the Department.

The Delegation Memo provided by the Department outlines how this request conforms with the Board's delegation criteria and the need for the rule change. Danielle Toepelt with the Department will present the delegation request for Board Members to consider.

Recommended Board Actions:

The Board may wish to consider and amend, if necessary, the following motion:

The Board moves to delegate rulemaking authority to the Department of Health to adopt by reference the newest version of the NSSP *Guide for the Control of Molluscan Shellfish.*

Staff

Shay Bauman, Policy Advisor

Board Authority

RCW 43.20.050

Powers and duties of state board of health—Rule making—Delegation of authority—Enforcement of rules.

(1) The state board of health shall provide a forum for the development of public health policy in Washington state. It is authorized to recommend to the secretary means for obtaining appropriate citizen and professional involvement in all public health policy formulation and other matters related to the powers and duties of the department. It is further empowered to hold hearings and explore ways to improve the health status of the citizenry.

In fulfilling its responsibilities under this subsection, the state board may create ad hoc committees or other such committees of limited duration as necessary.

(2) In order to protect public health, the state board of health shall:

(a) Adopt rules for group A public water systems, as defined in RCW 70A.125.010, necessary to assure safe and reliable public drinking water and to protect the public health. Such rules shall establish requirements regarding:

(i) The design and construction of public water system facilities, including proper sizing of pipes and storage for the number and type of customers;

(ii) Drinking water quality standards, monitoring requirements, and laboratory certification requirements;

(iii) Public water system management and reporting requirements;

(iv) Public water system planning and emergency response requirements;

(v) Public water system operation and maintenance requirements;

(vi) Water quality, reliability, and management of existing but inadequate public water systems; and

(vii) Quality standards for the source or supply, or both source and supply, of water for bottled water plants;

(b) Adopt rules as necessary for group B public water systems, as defined in RCW 70A.125.010. The rules shall, at a minimum, establish requirements regarding the initial design and construction of a public water system. The state board of health rules may waive some or all requirements for group B public water systems with fewer than five connections;

(c) Adopt rules and standards for prevention, control, and abatement of health hazards and nuisances related to the disposal of human and animal excreta and animal remains;

(d) Adopt rules controlling public health related to environmental conditions including but not limited to heating, lighting, ventilation, sanitary facilities, and cleanliness in public facilities including but not limited to food service establishments, schools, recreational facilities, and transient accommodations;

(e) Adopt rules for the imposition and use of isolation and quarantine;

(f) Adopt rules for the prevention and control of infectious and noninfectious diseases, including food and vector borne illness, and rules governing the receipt and conveyance of remains of deceased persons, and such other sanitary matters as may best be controlled by universal rule; and

(g) Adopt rules for accessing existing databases for the purposes of performing health related research.

(3) The state board shall adopt rules for the design, construction, installation, operation, and maintenance of those on-site sewage systems with design flows of less than three thousand five hundred gallons per day.

(4) The state board may delegate any of its rule-adopting authority to the secretary and rescind such delegated authority.

(5) All local boards of health, health authorities and officials, officers of state institutions, police officers, sheriffs, constables, and all other officers and employees of the state, or any county, city, or township thereof, shall enforce all rules adopted by the state board of health. In the event of failure or refusal on the part of any member of such boards or any other official or person mentioned in this section to so act, he or she shall be subject to a fine of not less than fifty dollars, upon first conviction, and not less than one hundred dollars upon second conviction.

(6) The state board may advise the secretary on health policy issues pertaining to the department of health and the state.

[**2021 c 65 § 37**; **2011 c 27 § 1**; **2009 c 495 § 1**; **2007 c 343 § 11**; **1993 c 492 § 489**; **1992 c 34 § 4**. Prior: **1989 1st ex.s. c 9 § 210**; **1989 c 207 § 1**; **1985 c 213 § 1**; **1979 c 141 § 49**; **1967 ex.s. c 102 § 9**; **1965 c 8 § 43.20.050**; prior: (i) **1901 c 116 § 1**; **1891 c 98 § 2**; RRS § 6001. (ii) **1921 c 7 § 58**; RRS § 10816.]

STATE OF WASHINGTON
DEPARTMENT OF HEALTH
DIVISION OF ENVIRONMENTAL PUBLIC HEALTH
PO Box 47820 • Olympia, Washington 98504-7820
(360) 236-3000 • 711 Washington Relay Service

November 13, 2024

TO: Michelle Davis, Executive Director
Washington State Board of Health

FROM: Lauren Jenks, Assistant Secretary
Division of Environmental Public Health

SUBJECT: State Board of Health Rule Making Authority Delegation Request- WAC 246-282-005, Minimum performance standards, Sanitary Control of Shellfish.

The Department of Health (department) is requesting delegation of rule-making authority from the State Board of Health (board) to amend WAC 246-282-005 to adopt by reference the 2023 revision to the National Shellfish Sanitation Program's (NSSP) *Guide for the Control of Molluscan Shellfish*.

Changes to the rule under this delegation request, if approved, will be limited to amending subsection (1)(a) in WAC 246-282-005, to update the current reference from the 2019 version of the *Guide for the Control of Molluscan Shellfish* to the 2023 version.

WAC 246-282-005 sets minimum performance standards for any person engaged in a shellfish operation or possessing a commercial quantity of shellfish or any quantity of shellfish for sale for human consumption. One of the standards adopted by reference in this WAC section is the NSSP's *Guide for the Control of Molluscan Shellfish*, which consists of a Model Ordinance, supporting guidance documents, recommended forms, and other related materials. The NSSP releases a revision to the *Guide for the Control of Molluscan Shellfish* every odd year. On September 3, 2024, the 2023 revision to the Model Ordinance was released, superseding the 2019 version currently referenced in WAC 246-282-005(1)(a).

This rule change is needed because the department cannot enforce the 2023 Model Ordinance without adopting this current version. Department staff have reviewed the changes in the 2023 Model Ordinance and determined that they will not impact the rules that are currently open as part of the Sanitary Control of Shellfish project.

For prior revisions, the board has delegated rule-making authority to the department to make this change. If granted rule-making authority, the department will use an exception rule-making process and anticipates completing this project by May 2025.

Conformance with the State Board of Health Delegation Criteria:
The board's policy (Policy Number 2000-001) for Considering Delegation of Rule to the Department of Health provides the following elements for consideration*:*

The extent to which the proposed rule revision is expected to include editorial and/or grammatical changes that do not change the substance of the rule:

- The department does not anticipate the inclusion of editorial or grammatical changes in the proposed rule revision.

The extent to which the proposed rule may make significant changes to a policy or regulatory program.

- The scope of the proposed rule will be limited to changing the "2019" to "2023" in WAC 246-282-005 (1)(a). The changes in the 2023 Model Ordinance do not affect the regulations in chapter 246-282 WAC.

The extent to which the proposed rule seeks to adopt federal requirements in which the state has little or no discretion.

- The scope of the rule change will be limited to changing the "2019" to "2023" in WAC 246-282-005(1)(a) to adopt by reference the newest version of the federal NSSP Model Ordinance.

The extent to which the substance and direction of the proposed rule is expected to have broad public and professional consensus.

- The department does not anticipate any controversy or opposition to this rule change. The process of updating WAC 246-282-005 to adopt the most recent version of the *Guide for the Control of Molluscan Shellfish* is one that interested parties are familiar with.

The extent to which the rule revision process would benefit from the board's role as a convener of interested parties.

- The department will keep interested parties engaged and informed throughout rule-making process via an up-to-date webpage and GovDelivery notifications that will be distributed using existing listservs. The department will have a formal comment period, as well as hold a public hearing.

For additional information, please contact Todd Phillips, Director of the Office of Environmental Health and Safety, at 360-236-3302 and todd.phillips@doh.wa.gov.

Washington State Department of HEALTH

Request for Delegated Rulemaking
WAC 246-282-005
Shellfish 2023 Model Ordinance

State Board of Health Meeting
November 13, 2024

Presenter

Dani Toepelt, R.S.

Section Manager

Shellfish Licensing & Certification

@WADeptHealth

Background Information

- WAC 246-282-005 sets minimum performance standards for shellfish operators.
- WAC 246-282-005(1)(a) adopts by reference the 2019 version of F.D.A.'s National Shellfish Sanitation Program's (NSSP) *Guide for the Control of Molluscan Shellfish*, which includes the Model Ordinance.
- The Model Ordinance is revised every odd year.
  - No revision was released in 2021, due to the COVID-19 pandemic.
- On September 3, 2024, the FDA released the 2023 version of the Model Ordinance.

Background Information

- Adopting the current version will allow the shellfish industry to continue to export shellfish products outside of the state of Washington and the Department to enforce the 2023 Model Ordinance.

- The changes in the 2023 Model Ordinance will not impact the rules that are currently open as part of the Board's Sanitary Control of Shellfish rulemaking.

- Historically, the Board has delegated rulemaking authority to the Department to update the incorporation by reference in WAC 246-282-005(1)(a).

Potential Changes to Rule

WAC 246-282-005, Minimum performance standards.

(1) Any person engaged in a shellfish operation or possessing a commercial quantity of shellfish or any quantity of shellfish for sale for human consumption must comply with and is subject to:

(a) The requirements of the U.S. Food and Drug Administration National Shellfish Sanitation Program (NSSP), Guide for the Control of Molluscan Shellfish (~~2019~~ 2023) (copies available through the U.S. Food and Drug Administration, Shellfish Sanitation Branch, and the Washington state department of health, office of shellfish and water protection);

(b) The provisions of 21 Code of Federal Regulations (C.F.R.), Part 123 - Fish and Fishery Products, adopted December 18, 1995, by the United States Food and Drug Administration, regarding Hazard Analysis Critical Control Point (HACCP) plans (copies available through the U.S. Food and Drug Administration, Office of Seafood, and the Washington state department of health, office of food safety and shellfish programs); and

(c) All other provisions of this chapter.

(2) If a requirement of the NSSP Model Ordinance or a provision of 21 C.F.R., Part 123, is inconsistent with a provision otherwise established under this chapter or other state law or rule, then the more stringent provision, as determined by the department, will apply.

SBOH Delegation Considerations

- The scope of the rule change will be limited to changing the “2019” to “2023” in WAC 246-282-005(1)(a).
- The changes in the 2023 Model Ordinance do not impact the rules currently open as part of the Board’s Sanitary Control of Shellfish rulemaking.
- The department does not anticipate any controversy or opposition to this rule change.
- The department will use an exception rulemaking process.
- The department will keep interested parties engaged and informed via an up-to-date webpage and GovDelivery notifications that will be distributed using existing listservs. The department will have a formal comment period, as well as hold a public hearing.

Questions?

To request this document in another format, call 1-800-525-0127. Deaf or hard of hearing customers, please call 711 (Washington Relay) or email civil.rights@doh.wa.gov.

STATE OF WASHINGTON
WASHINGTON STATE BOARD OF HEALTH
PO Box 47990 • Olympia, Washington 98504-7990

WHEREAS the Washington State Board of Health was established by the State Constitution in 1889;

WHEREAS the Board provides a forum for developing public health policy in Washington State and is empowered to hold hearings and explore ways to improve the health status of people in Washington;

WHEREAS Kate Dean was appointed to the Board in February 2023 by Governor Inslee to represent county elected officials who serve on local boards of health;

WHEREAS Member Dean has served as the Chair of the Board's Environmental Health Subcommittee since December 2023. In this role, she provided leadership on pressing environmental health issues such as on-site sewage systems, shellfish sanitation, drinking water quality, and water recreation;

WHEREAS Member Dean has dedicated over 25 years to revitalizing communities. She was elected to the Jefferson County Board of Commissioners in 2017, where she prioritizes tackling complex issues that face rural communities and seeking multi-benefit solutions that create equitable outcomes for impacted people, the environment and local economies. She also served her communities as an entrepreneur, community and economic development practitioner, and the Vice Chair of the Puget Sound Partnership Leadership Council;

WHEREAS Member Dean has championed issues related to drinking water, including regulating contaminants such as per- and polyfluoroalkyl substances (PFAS). She is widely regarded by her colleagues for her thoughtful questions and insights, which encourage critical thinking among staff and fellow Board members;

WHEREAS Member Dean has consistently prioritized equity in her work, championing initiatives that address the needs of Tribes, rural communities, and historically marginalized groups, ensuring that all voices are heard and considered in public health decision-making;

WHEREAS Member Dean has accomplished this and more during her time as a Board member;

THEREFORE, BE IT RESOLVED that the Board thanks and recognizes Kate Dean for her dedicated and outstanding service to the people of Washington State as a member of the Washington State Board of Health, for her commitment to protecting and advancing public health, and for demonstrating an unwavering commitment to integrity and making difficult decisions for the greater good.