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## **Oral comments for NASEM committee on revised NTP monograph**

I'm Chris Neurath, the research director for Fluoride Action Network. We will be submitting today detailed comments to the NASEM committee that address specific issues, both strengths and weaknesses.

I'll just touch on the main strengths and weaknesses in my oral comments.

### **STRENGTHS**

The revised and updated review has identified substantially more higher quality studies with the number going from 18 to 29.

Of the 29 higher quality studies, 27 found statistically significant adverse effects, which is a very high degree of consistency.

The NTP has addressed recommendations of both NASEM and FAN to improve the clarity and validity of quality scoring methods.

The addition of meta-analyses also improves clarity of the evidence.

The conclusion of "presumed developmental neurotoxicity" has thus grown substantially stronger and is solidly supported by the body of evidence.

### **WEAKNESSES**

Our written submission has detailed discussion of weaknesses.

By far the greatest weakness is the *ad hoc* section titled "Generalizability to the US Population". This is, in effect, a risk assessment requiring a valid exposure assessment and dose-response assessment, but NTP has done neither. The NTP's methods lead to an underestimate of the confidence that fluoride causes harm at exposures below 1.5 mg/L.

The NTP made the fundamental error of equating drinking water concentration with internal dose.

The NTP's exposure assessment consisted of a single one-sentence footnote referenced to a CDC database that is restricted and not available to the public.

There was no proper dose-response assessment. The only planned dose-response assessment was a dose-response meta-analysis, yet it was not carried out for the 10 highest quality studies with individual-level exposure data. These 10 highest quality studies were also those finding effects at the lowest doses. The failure to conduct a dose-response meta-analysis on the strongest studies at low doses leads to a severe underestimate of the confidence of adverse effects at low doses.

For the dose-response meta-analysis of group-level studies, NTP improperly used just the mean doses to define doses, even though many studies had a wide range of exposures in each exposure group, including exposures that fell below the cut-off level 1.5 mg/L.

We are conducting a dose-response meta-analysis with the 10 individual-level studies and will supply it to the NAS.

When proper dose-response assessments are made with the 29 higher quality studies, we found remarkable consistency of adverse effects. 18 studies were at exposures below 1.5 mg/L and 17 of those found adverse effects.

Therefore, the evidence below 1.5 mg/L is as strong and consistent as that above 1.5 mg/L.

Finally, a fundamental goal of the OHAT systematic review method is to ensure consistency of NTP evaluations across different chemicals. However, when comparing the fluoride monograph to those for other chemicals we find a dramatic double-standard, with fluoride needing to pass a far higher bar to reach a conclusion of presumed hazard than other chemicals. We believe the NASEM committee and NTP must take a larger perspective and ensure fluoride is treated in the same way as any other chemical being evaluated by NTP.