U.S. FEDERAL COURT

ACTION NO. 17-CV-02162

FOOD AND WATER WATCH, *et al.* v. U.S. EPA

EXPERT DECLARATION OF PHILIPPE GRANDJEAN, MD, DMSc

PREPARED ON BEHALF OF PLAINTIFFS

20 May 2020

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I, Philippe Grandjean, MD, DMSc, declare that:

1. I am a physician and environmental epidemiologist and serve as both an Adjunct Professor at the Harvard T.H. Chan School of Public Health, and Professor and Chair of Environmental Medicine at the University of Southern Denmark.

2. I was asked by Plaintiffs' counsel to provide an evaluation of the neurological health risks associated with the exposure to fluoride in drinking water.

I. SUMMARY OF QUALIFICATIONS

3. A complete summary of my qualifications and publications can be found in my Curriculum Vitae, which has been marked as Plaintiffs' Exhibit 3 and attached herein.

4. Over the past 25 years, my research has focused on developmental exposures to environmental chemicals and the association with adverse health effects in children, as described in my book "Only One Chance" (2013) published by Oxford University Press.

5. My research has been entirely funded by public sources, mainly the National Institutes of Health (NIH). In 2003-2007, my study of children's vulnerability to environmental immunotoxicants was supported by the U.S. Environmental Protection Agency (EPA). My current funding as principal investigator includes grants from the Superfund Research Program at the National Institute of Environmental Health Sciences and the U.S. Agency for Toxic Substances and Disease Registry (ATSDR).

6. I have published about 500 scientific papers, of which most are research articles in international scientific journals with peer review. My h-index in the Web of Science data base is 70, and my work is cited in scientific journals well over a thousand times every year. Seven of my articles published in the last 10 years have earned the attribute "Highly Cited Paper," i.e., they received enough citations to place them in the top 1% of published papers in the field.

7. My study on the neurodevelopmental effects of prenatal mercury exposure in a birth cohort from Faroe Islands was relied upon by the EPA as the critical study for the Agency's derivation of a

Reference Dose for methylmercury (EPA 2001).

8. I have served as a technical advisor to the World Health Organization on environmental health issues, including five occasions where I was elected Rapporteur. I have also served on, sometimes chaired, or acted as rapporteur for, expert committees under the auspices of the EPA, ATSDR, Food & Drug Administration (FDA); NIH; White House Office of Science and Technology Policy; International Agency for Research on Cancer (IARC), European Commission, European Environmental Agency, European Food Safety Authority, and other organizations. I have also served for over 30 years as Consultant in Toxicology for the Danish Ministry of Health.

9. I am (Founding) Editor-in-Chief of the journal *Environmental Health* (since 2002), which ranks among the most frequently cited journals in the field. I also serve or have served on editorial boards of about a dozen journals within medicine, environmental science, and toxicology. As editor and as reviewer for other major journals, I frequently evaluate manuscripts on environmental epidemiology and toxicology.

10. I have received various awards and honors for my scientific work, including the John R. Goldsmith Award from the International Society for Environmental Epidemiology, which is given to investigators for "sustained and outstanding contributions to the knowledge and practice of environmental epidemiology."

11. I have been retained as an expert on the impact of environmental chemicals on human health by government bodies, including the U.S. Department of Justice (on behalf of the EPA) and the State of Minnesota.

12. I first began studying fluoride in 1980 at the suggestion of Dr. Irving J. Selikoff, who was my mentor at the Mt. Sinai School of Medicine during my two-year Senior Fulbright Scholarship. Upon returning to Denmark, I initiated a series of studies on a cohort of workers who had been occupationally exposed to fluoride. I have remained involved in fluoride research since that time and have published 16 peer-reviewed reports on fluoride exposure and toxicity in humans.

13. In 1984, I drafted the Environmental Criteria Document on fluoride for the World Health

Organization (WHO). Ten years later, I drafted the Criteria Document for an occupational exposure limit value for fluorine for the European Commission. In 2006, I served as a reviewer of the National Research Council's report *Fluoride in Drinking Water: A Scientific Review of EPA's Standards*.

14. During the past 10 years, my research work on fluoride has focused on its developmental effects on the brain. In 2012, I published a meta-analysis of the epidemiological studies on fluoride and IQ (Choi et al. 2012); in 2015, I published an epidemiological study of fluoride and IQ in China (Choi et al. 2015); and, in December of 2019, I published an updated review of fluoride neurotoxicity, which relied in part on the work that I have performed in this case (Grandjean 2019).

15. In addition to my work on fluoride, I also have expertise in Benchmark Dose (BMD) analysis. My experience doing BMD analysis started about 20 years ago in connection with my research on the neurodevelopmental effects of methylmercury in the Faroe Islands that was selected as the critical study for risk assessment by the EPA. Based on this research, the EPA provided me with a contract to produce a BMD analysis of the data, which I carried out in collaboration with my biostatistician colleagues, Dr. Esben Budtz-Jorgensen and Professor Niels Keiding. The EPA relied on this BMD analysis to establish the safe level for methylmercury exposure in the U.S. (U.S. EPA 2001).

16. In 2009, I served on an expert panel that assisted the European Food Safety Authority (EFSA) in developing a guidance document on BMD analysis titled "Use of the Benchmark Dose (BMD) Approach in Risk Assessment."

17. In 2013, Dr. Budtz-Jorgensen and I extended our BMD methodology in collaboration with the International Pooled Lead Study Investigators, which was peer-reviewed and published in the journal *Risk Analysis* (Budtz-Jorgensen et al. 2013). As part of this analysis, we developed a BMD for lead and IQ by analyzing pooled data from multiple different cohort studies. The paper was co-authored by leading scholars on lead neurotoxicity, including Drs. David Bellinger and Bruce Lanphear.

18. More recently, Dr. Budtz-Jorgensen and I conducted an advanced BMD analysis on perfluorinated chemicals, which was published in 2018 in the peer-reviewed journal *PLOS One* (Budtz-Jorgensen and Grandjean 2018). In total, our achievements on BMD approaches and applications have

been published in seven articles so far in international biostatistical and biomedical journals.

19. In addition to my scientific training, I remain mindful, of the importance of translating the results of epidemiological studies in a way that can facilitate public participation in making informed decisions to protect their health, even prior to a "final proof" of causation being available; a final proof that, all too often, has come too late to protect the public from harm, as reviewed most recently in the monograph on *Late Lessons of Early Warnings*, published by the European Environment Agency (EEA Report No 1/2013), for which I served as an editor. As Dr. Selikoff once impressed upon me, "Never forget that the numbers in your tables are human destinies, although the tears have been wiped away."

II. SUMMARY OF OPINIONS

20. The weight of epidemiological evidence leaves no reasonable doubt that developmental neurotoxicity is a serious human health risk associated with elevated fluoride exposure, including those occurring at the levels added to drinking water in fluoridated areas. The IQ losses associated with community water fluoridation are substantial and of significant public health concern.

21. Application of the Benchmark Dose (BMD) methodology to the recent prospective birth cohort data shows that the level of fluoride added to water in fluoridation programs greatly exceeds the science-based limit needed to protect against developmental neurotoxicity.

22. The systematic review conducted by Dr. Ellen Chang, when corrected for its biases and errors in judgment, further supports my opinions on the neurotoxic risks posed by elevated fluoride exposure.

III. SUMMARY OF METHODOLOGY

A. Weight of the Evidence

23. I conducted a weight of the evidence assessment of available research on fluoride neurotoxicity, with an emphasis on the epidemiology. While I place the greatest weight on the strong epidemiological evidence, I also consider toxicokinetics, experimental toxicology data, and background

principles of brain development as part of my comprehensive analysis.

24. My review focuses on the evidence that carries the greatest weight which, as generally accepted, emphasizes the recent prospective cohort studies.

25. My methodology follows the general approach applied by the EPA, in the sense that I did a weight of the evidence analysis that focuses on the best available science (e.g., EPA 2017).

26. In light of my familiarity with the scientific literature on fluoride neurotoxicity, I did not conduct a formal systematic review on this occasion. Instead, my conclusions rely on a comprehensive and thorough review supplemented by a Benchmark Dose analysis of the recent prospective data.

27. I have read and considered the systematic review conducted by Dr. Ellen Chang, which mostly relies on the same evidence and which further confirms and supports my assessment of the literature. My opinions are thus fully informed by the insights offered by a formal systematic search of the literature.

B. Factors Considered When Assessing Epidemiological Literature

28. In evaluating the weight of the evidence, the question must be asked what each study could potentially reveal, given the design and choice of study parameters, including such factors as the precision of the exposure assessment. In the field of epidemiology, there is a well-known bias toward the null, e.g., from imprecise assessment of the exposure, of which epidemiologists (and readers of epidemiology reports) need to be careful, especially when human health is at stake (EPA 2005).

29. The following Table highlights common causes of bias toward the null in epidemiological studies, i.e., reasons that a study might not show the existence of a risk that indeed is present, though hidden due to the bias. While biases in the opposite direction also exist, they are usually of much less significance (Grandjean 2013).

Table 1. Causes of bias toward the null in epidemiology studies (Grandjean 2013a).

Inadequate statistical power in small studies
Lost cases and inadequate follow-up for long-term effects
Exposed or otherwise inappropriate comparison (control) group
Exposure misclassification
Insensitive or imprecise outcome measures
Failure to adjust for confounders with effects in the opposite direction
Disregarding vulnerable subgroups
5% probability level to minimize risk of false positives (Type I error)
20% probability level to minimize risk of false negatives (Type II error)
Pressure to avoid false alarm

30. Studies that do not show a statistical significance are sometimes called "negative," although this term is misleading. Joint analyses of several such studies may well show a significant difference or trend.

31. Observational studies will rarely if ever provide definitive proof of causation, and it is always possible for someone to raise doubts and uncertainties that require additional or improved data to resolve (Michaels 2008). It is important to recognize, however, that the presence of uncertainties often tends to cause underestimations of actual risks, not the opposite. This issue is of importance especially regarding substances that have not yet been studied in the detail desired or cannot be examined in randomized clinical trials. Many unfortunate past errors in regard to industrial chemicals have shown that initial assessments were often erroneous and led to an underestimation of the true risks (European Environment Agency 2001 & 2013).

32. In the context of developmental neurotoxicity, I place greatest weight on prospective studies of population-based birth cohorts followed over time (Grandjean et al. 2008; Grandjean & Landrigan 2014). Birth cohorts are crucial because it is not just the dose that can matter but also the timing of the dosing in regard to the developmental stage of the subjects (Grandjean et al. 2008; Grandjean et al. 2019). Follow-up studies of birth cohorts can thus reveal with greater certainty the

impacts of exposures incurred during early life stages.

C. Benchmark Dose Methodology

33. As part of my assessment in this case, I worked with my biostatistician colleague Dr. Budtz-Jørgensen on a BMD analysis of the prospective cohort data on fluoride and IQ using the same peer-reviewed method that we used for lead (Budtz-Jorgensen et al. 2013).

34. The statistical uncertainty in the BMD estimation is taken into account by calculating its lower one-sided 95% confidence limit, which is called the benchmark dose level (BMDL). The BMDL is then used as the point of departure for calculation of the exposure limit, by dividing the BMDL by an uncertainty factor (usually fixed at 10) to obtain a protective Reference Dose (RfD) or tolerable exposure (EFSA 2009; EPA 2012).

D. Materials Relied Upon

35. In my assessment, I relied upon my existing knowledge of the scientific literature (with citations to specific studies noted in my reports), my own meta-analysis of the epidemiological studies of fluoride and IQ (Choi et al. 2012), the more recent meta-analysis by Duan (2018), all available prospective studies, as well as the reviews by NRC (2006) and NTP (2016).

36. I also considered studies provided by counsel,[1] many of which I was already familiar with, and conducted supplemental searches on PubMed, including searches to see if there were any significant epidemiological studies published that I might have overlooked.

37. A complete list of the studies I relied upon is provided in my expert reports.

IV. GENERAL CONSIDERATIONS

A. Emergence of Brain Development as Vulnerable Target

38. Evidence has been accumulating over several decades that industrial chemicals can cause

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[1] I understand that these studies were provided to EPA's experts as well, including Dr. Chang.

neurodevelopmental disorders that include learning disabilities, sensory deficits, developmental delays, and cerebral palsy (NRC 2000), and current evidence also relates to other neurodevelopmental deficits, such as attention deficit hyperactivity disorder (ADHD) (Bennett et al. 2016). Subclinical stages of these conditions also appear to be common, and the suspicion of a link between neurotoxic chemical exposures and widespread neurobehavioral damage has increased since it was first raised by research demonstrating that lead is particularly toxic to the developing brain across a wide range of exposures (Baghurst et al. 1987; Dietrich et al. 1987; Landrigan et al. 1975; Needleman et al. 1979).

39. The developing human brain is inherently much more susceptible to injury caused by toxic agents than the brain of an adult. This susceptibility reflects the fact that in the nine months of prenatal life the human brain must evolve from a strip of cells along the dorsal ectoderm into a complex organ comprised of billions of precisely located, highly interconnected and specialized cells. Optimal brain development requires that neurons move along precise pathways from their points of origin to their assigned locations, that they establish connections with other cells near and distant, and that they generate intercommunications in meaningful ways (Dobbing 1968; Rice and Barone 2000; Rodier 1995).

40. All of these processes must take place within a tightly controlled time frame, in which each developmental stage must be reached on schedule and in the correct sequence. Due to the extraordinary complexity of human brain development, windows of unique susceptibility to toxic interference occur that have no counterpart in the mature brain, or in any other organ. Because of the unique structure of the human brain and its advanced function, no other species shows similar degree of developmental vulnerability. Thus, if a developmental process in the brain is halted or inhibited, there is little potential for later repair, although plasticity will allow some compensation, and the consequences are therefore likely to be permanent (Dobbing 1968; Rice and Barone 2000).

41. To test chemicals for developmental neurotoxicity, standardized protocols have been developed using rodent models (OECD 2007). However, they may not necessarily be sufficiently sensitive, as rodent brains are far less complex than human brains, and intrauterine brain development is completed at a stage where the human fetal brain is still rapidly developing *in utero* for several more weeks with possible continued impact from maternal transfer of neurotoxicants (Bal-Price et al. 2018).

42. During fetal development, the placenta can offer some protection against unwanted chemical exposures, but it is not an effective barrier against most environmental neurotoxicants (Andersen et al. 2000), including fluoride (NRC 2006). In addition, the blood-brain barrier, which protects the adult brain from many toxic agents, is not completely formed until about 6 months after birth (Adinolfi 1985).

43. Postnatally, the human brain continues to develop, and the period of heightened vulnerability therefore extends over many months through infancy and into early childhood. While most neurons have been formed by the time of birth, growth of glial cells and myelinization of axons continue for several years and is not complete until late teenage years (Rice and Barone 2000; Rodier 1995).

44. The susceptibility of infants and children to industrial chemicals is further amplified by their relatively increased exposures in regard to body weight, their augmented absorption rates, and diminished ability to detoxify many exogenous compounds as compared to adults (Ginsberg et al. 2004; NRC 1993).

45. In 2005, when I evaluated the evidence of industrial chemicals regarding developmental neurotoxicity, only five substances (arsenic, lead, methylmercury, polychlorinated biphenyls, and toluene) fulfilled our criteria for causal relationship in humans (Grandjean and Landrigan 2006). Eight years later, when we reassessed the evidence, we added six more substances, including fluoride (Grandjean and Landrigan 2014), based on new evidence that had emerged.

46. Our 2014 assessment was focused on *hazard* (i.e., whether fluoride causes developmental neurotoxicity in humans), not on *risk* (i.e., the exposure level at which this hazard may occur). Substantial new evidence published since that time, particularly the prospective birth cohort studies, now permit an assessment of risk.

B. Toxicokinetics During the Fetal Period

47. In my assessment, I considered the toxicokinetics of fluoride, with a particular focus on the uptake, distribution and retention during the fetal period.

48. It is well accepted that fluoride crosses the placenta and reaches the fetus from the mother's blood stream (NRC 2006; WHO 2006).

49. The first documentation of placental transfer in humans was the observation in 1974 (Shen and Taves 1974) that fluoride concentrations in maternal and cord serum correlated well, with the cord blood showing slightly lower concentrations. These findings were replicated in 1986 (Ron et al. 1986), with results suggesting minor deviations depending on gestational age. A more recent study from an area with water-fluoride levels of 0.4-0.8 mg/L showed that cord serum contained about 80% of the concentrations occurring in maternal serum (Opydo-Szymaczek and Borysewicz-Lewicka 2007). Consistent with this, French researchers measured fetal blood concentrations of fluoride after the mothers were administered a small dose of sodium fluoride, and the elevations were statistically significantly higher (2.6 µmol/l) than in a control group (less than 1 µmol/l) (Forestier et al. 1990).

50. A recent study from scientists at the University of California San Francisco (UCSF) further confirms the placental transfer of fluoride (Uyghurturk et al. 2020). In this study, fluoride concentrations were measured in the urine, blood, and amniotic fluid among pregnant women in fluoridated and non-fluoridated areas of Northern California. Each additional 0.1 mg/L of fluoride in water was associated with a significant increase in the fluoride levels in the amniotic fluid ($p < 0.001$), thus confirming the

transplacental passage of fluoride.

51. As would be expected, given the undeveloped nature of the blood-brain barrier during the fetal period, laboratory studies of animals exposed to prenatal fluoride have found significant elevations of fluoride in the brain (McPherson et al. 2018; Mullenix et al. 1995). Similarly, in aborted human fetuses, fluoride concentrations in the brain have been shown to be higher in geographic areas with endemic fluorosis as compared to controls at lower exposures (Du et al. 2008; He et al. 2008).

C. Toxicological Findings

52. Neurotoxicity is a documented hazard of fluoride exposure in laboratory animals (NRC 2006), which supports the plausibility of fluoride causing neurotoxic effects in humans.

53. One of the first U.S. reports on experimental fluoride neurotoxicity emerged when a new method was developed for computerized surveillance of rat behavior. Fluoride was selected for a test of the new methodology and showed clear neurotoxicity (Mullenix et al. 1995). The authors noted that the behavioral effects they observed in the rats are indicative of fluoride's potential ability to cause IQ deficits in humans. This assessment, which was made prior to the publication of any studies of fluoride and IQ in western journals, proved prescient.

54. Since the Mullenix study was published in 1995, many additional animal studies have documented neurochemical and anatomic changes in the brains of fluoride-treated animals. By 2006, the NRC concluded that there was enough neurochemical and anatomic data to conclude that fluoride interferes with brain functions by both direct and indirect means.

55. Among prominent adverse outcome pathways, the NRC concluded that fluoride is an endocrine disrupter that can affect thyroid function at intake levels as low as 0.01 to 0.03 mg/kg/day in individuals with iodine deficiency (NRC 2006).[2] Thyroid toxicity supports the plausibility of fluoride

[2] Large epidemiological studies published since the NRC report suggest that thyroid dysfunction is a relevant risk at elevated fluoride exposures in fluoridated communities, especially in

neurotoxicity because availability of thyroid hormone is crucial for optimal brain development (Rovet 2014).

56. At the time of the NRC's review, there was little data yet available on fluoride's impact on behavior and cognition in animals, but considerable data has since been published. In 2016, the National Toxicology Program (NTP) conducted a systematic review of these behavioral/cognitive studies (NTP 2016). Although NTP did not consider any of the neurochemical/anatomical effects, it still concluded that the evidence is "suggestive of an effect on learning and memory" (NTP 2016, p. vii). The NTP characterized its confidence in the evidence as "moderate" for adult studies, and "low" for the few available developmental studies.

57. Additional animal research on learning/memory has been published subsequent to the NTP review, and most of it has reported adverse effects. As is often the case, the animal studies on learning/memory have limitations or discrepancies but given the general consistency in their findings they continue to be *at least* "suggestive" of fluoride being a neurocognitive hazard.

V. EPIDEMIOLOGICAL STUDIES (CROSS-SECTIONAL)

A. Neurotoxicity from Occupational Fluoride Exposure

58. The neurotoxicity of chemicals is often first discovered from workplace exposures (Grandjean and Landrigan 2006), which are later followed by case reports that involve children or pregnant women from the general population (Grandjean 2013). The same is true of fluoride.

59. Although largely overlooked or ignored, Roholm first reported evidence of nervous system effects in his seminal study of cryolite workers in Copenhagen (Roholm 1937): "The marked frequency of nervous disorders after employment has ceased might indicate that cryolite has a particularly harmful effect on the central nervous system" (p. 178). The nervous system effects reported by Roholm included tiredness, sleepiness, indisposition, headaches, and giddiness (p. 138).

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adults with iodine deficiency (Malin et al. 2018; Peckham et al. 2015).

60. My own mortality study of the cryolite workers studied by Roholm showed an excess of violent deaths (Grandjean et al. 1985), but information on the causes of death did not allow any conclusions on deaths from nervous system disease.

61. One of the challenges with occupational studies of fluoride-exposed workers is that the fluoride exposure usually occurs as part of a mixture. In the 1940s, scientists at the Manhattan Project recorded CNS effects in workers exposed to uranium hexafluoride gas (UF_6). They observed a "rather marked central nervous system effect with mental confusion, drowsiness and lassitude as the conspicuous features" and attributed it to the fluoride rather than uranium (Ferry 1944; Mullenix 2005).

62. Consistent with the observations of the Manhattan Project scientists, published case reports have highlighted difficulties with concentration and memory accompanied by general malaise and fatigue following occupational fluoride exposures (Spittle 1994).

63. More recently, skeletal fluorosis in workers was found to be associated with gradually progressive effects on the normal function and metabolism of the brain and other aspects of the nervous system (Duan et al. 1995), and application of neuropsychological tests (i.e., WHO's Neurobehavioural Core Test Battery) have reported significant associations between workplace fluoride exposures and cognitive problems (Guo et al. 2008; Yazdi et al. 2011).

64. The available evidence from occupationally exposed workers supports the neurotoxicity of fluoride but does not allow any detailed consideration of its dependence on dose, timing, and duration.

B. Neurotoxicity in Endemic Fluorosis Areas

65. Fluoride toxicity has received particular attention in China, where widespread dental fluorosis indicates pervasive high exposures (Wang et al. 2012). Areas with high prevalences of dental (and skeletal) fluorosis are known as "endemic fluorosis" areas.

66. Although microbiologically safe, water supplies from wells, small springs or mountain

sources have created pockets of increased fluoride exposures near or within areas of low exposures, thus representing optimal settings for epidemiological research because only the fluoride exposure would likely differ between nearby neighborhoods. In addition, rural families in China move much less frequently than U.S. families, thus facilitating assessment of impacts from long-term exposures. Chinese researchers took advantage of this fact and published their findings, though mainly in Chinese journals, and according to the standards of science at the time. The early research dates to the 1980s but has not been widely cited, in part because of limited access to Chinese journals, in part because the notion of adverse effects from fluoride intake has often been considered unwelcome.

67. Most of the studies on fluoride neurotoxicity from China, and other countries (i.e., India, Iran, and Mexico), have focused on IQ measures as the endpoint of concern, with the clear majority of these studies reporting inverse associations (i.e., higher levels of fluoride exposure are associated with lower IQ).

68. Many of the studies from China have significant limitations, including lack of information on covariates, missing information on study details, assessment of exposures on a community basis, and use of cross-sectional study designs. The reports have also tended to be relatively brief and simple in design. These deficiencies, which in some cases are rather severe, limit the conclusions that can be drawn, but are unlikely to explain the almost uniformly consistent inverse associations that have been reported.

69. While most of the endemic fluorosis studies have rather simple designs and may have failed to control for confounding factors of possible importance, they also have important strengths, including: 1) Stable populations with stable water-fluoride concentrations; many of the studies specifically limited the populations to those who had lived in the community their entire life. 2) Unlike in the U.S., children in rural China have very little exposure to fluoridated dental products (Zhu et al.

2003), thus making water a more important and reliable metric of fluoride exposure. 3) The studies in endemic fluorosis areas that have controlled for or excluded key confounding factors (arsenic exposure, iodine deficiency, parental education) were still capable of identifying clear associations between elevated fluoride exposure and cognitive deficits (Choi et al. 2012).

70. I will discuss the Chinese research on IQ in fluoride-exposed communities in more detail, but I begin first with studies that have examined other neurotoxicity endpoints, including neuropathological outcomes in aborted fetuses, neurobehavioral effects during infancy, and cognitive deficits and other neurological problems in adults.

1. Neurotoxic Endpoints in Fetuses and Neonates

71. In brain tissue obtained from aborted fetuses in endemic fluorosis areas, electron microscopy showed retarded cell growth in the cerebral cortex, with substantial cytology changes (He et al. 2008). A similar study used stereology to examine nerve cell numbers and volumes in fetal brain tissue and found lower densities (Du et al. 2008). A third study focused on neurotransmitters and receptors and found deviations that suggested neural dysplasia (Yu et al. 2008). Another study of aborted fetal brain tissue showed similar neurotransmitter results (Dong et al. 1993). These studies are consistent with prenatal fluoride exposure causing anatomic and biochemical changes in the fetal brain, as concluded by the NRC. A limiting factor, however, is that the elevated fluoride exposure in these studies came primarily from coal burning, which may have contributed other contaminants besides fluoride that were not assessed.

72. The impact of elevated fluoride in drinking water on neurological behavior in 91 neonates was assessed by Li et al. (2008). The study found that neonates born in an endemic fluorosis area (water-fluoride concentrations of 1.7 - 6.0 mg/L) scored more poorly on the standard Neonatal Behavioral Assessment, and that visual and auditory responses were also deficient, as compared to controls from

areas with less than 1 mg/L (Li et al. 2008). These findings are again consistent with the notion that fluoride can affect the brain during the prenatal period, although neonatal neurological assessments can be somewhat imprecise and may be only weakly predictive of subsequent brain development.

73. In a separate study, infants from an endemic area were examined at ages 3, 6, 9 and 12 months and scored significantly lower in mental and psychomotor development indices than those of the control group (Chang et al. 2017). The exposed group also showed lower birth weight, and it is unclear whether this difference can lead to confounding or if a lower birth weight is a concomitant effect of the fluoride exposure. As with the fetal neuropathology studies, the source of fluoride exposure in this study was coal, not water, which limits the conclusions that can be drawn due to the potential for confounding.

2. Neurotoxic Endpoints in Adults

74. Studies in China using cross-sectional designs have also found cognitive problems and neurological symptoms in adults with skeletal fluorosis living in endemic fluorosis areas. Using neuropsychological tests, including the Wechsler scale, 49 adult fluorosis patients (it is not clear whether the patients were from a coal- or waterborne fluorosis area) were compared with controls and showed deficits in language fluency, recognition, similarities, associative learning, and working memory (Shao et al. 2003). Likewise, cognitive impairment in elderly subjects was clearly elevated in a waterborne fluorosis area, although within-group assessment of urine-fluoride concentrations failed to show a clear gradient of effect (Li et al. 2016). Excess occurrence of neurological symptoms has also been recorded in both adults and children from waterborne fluorosis areas, with headaches being the primary manifestation (Sharma et al. 2009).

3. Childhood IQ

75. As noted above, most of the epidemiological studies on fluoride neurotoxicity have focused on IQ scores in childhood. In 2012, my colleagues and I published a meta-analysis of the

available 27 studies, most of which were published in China[3] (Choi et al. 2012). Because these published studies were conducted independently, we used meta-analysis—a quantitative, formal, statistical technique—to systematically review and assess these published research studies to derive conclusions about the neurotoxicity of fluoride. The outcome of the meta-analysis includes a more precise estimate of the association than any individual study that contributes to the pooled analysis. The variability or heterogeneity in study results was also examined. We did not attempt to generate any dose-response relationship, and the fluoride concentrations were used only for definitions of high and low (reference) groups in each study.

76. Among the 27 studies we reviewed, two involved populations exposed to fluoride from coal burning (Guo et al. 1991; Li et al. 2010); the rest of the studies involved exposure to fluoride through drinking water containing fluoride from soil minerals. The Combined Raven's Test – The Rural Edition in China (CRT-RC) was used to measure the children's intelligence in 16 studies. Other intelligence measures included the Wechsler Intelligence scale (3 studies), Binet IQ test (2 studies), Raven's test (2 studies), Japan IQ test (2 studies), Chinese comparative intelligence test (1 study), and the mental work capacity index (1 study). As each of the intelligence tests used is designed to measure general intelligence, we used data from all eligible studies to estimate the possible effects of fluoride exposure on the children's intelligence. We conducted a sensitivity analysis restricted to studies that used similar tests to measure the outcome (specifically, the CRT-RC, Wechsler Intelligence test, Binet IQ test, or Raven's test), and an analysis restricted to studies that used the CRT-RC. We also performed an analysis that excluded studies with possible concerns about co-exposures, such as iodine status and arsenic exposure, or with non-drinking water fluoride exposure from coal burning, without finding appreciable differences, as described below.

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[3] Two of the 27 studies included in the analysis were conducted in Iran (Poureslami et al. 2011; Seraj et al. 2006), otherwise the study cohorts were populations from China.

77. The levels of fluoride exposure in the studies we examined, while higher than those associated with fluoridation programs (0.7 mg/L), are not as high as some have claimed. A surprising number of commentators, including the EPA, have only mentioned the *highest* concentration examined in the studies (11.5 mg/L) (Allukian et al. 2018; EPA 2018), although this high concentration occurred in only one of the 27 studies. The majority of studies that reported the water-fluoride level in the exposed group had between 1.5 and 4 mg/L, which is elevated, but only modestly.[4] Similarly, Duan's more recent meta-analysis of waterborne fluoride exposures reported that 18 of 27 studies addressed water-fluoride concentrations below 4 mg/L, and IQ reductions were observed at elevated concentrations of 1 to 2 mg/L (Duan et al. 2018 Table 2).

78. Among the 27 studies, all but one showed random-effect standardized mean difference (SMD) estimates that indicated an inverse association, ranging from -0.95 to -0.10 (one study showed a slight, non-significant effect in the opposite direction). The overall random-effects SMD estimate (and the 95% confidence interval, CI) were -0.45 (-0.56, -0.34). Given that the standard deviation (SD) for the IQ scale is 15, an SMD of -0.45 corresponds to a loss of **6.75 IQ points**.[5] I shall return to this result later. Among the restricted sets of intelligence tests, the SMD for the model with only CRT-RC tests and drinking-water exposure was lower than that for all studies combined, but the difference was not significant, and heterogeneity remained at a similar magnitude in the restricted analyses.

79. Several studies (Hong et al. 2001; Lin et al. 1991; Wang et al. 2001; Wang et al. 2007; Xiang et al. 2003; Zhao et al. 1996) reported other risk factors, such as iodine status, and exposure to arsenic or lead, both neurotoxicants, and our sensitivity analyses showed similar associations between

[4] The fluoride levels in the control groups in the studies often approximated the concentrations (~0.7 mg/L) used in fluoridation programs. Some ill-informed commentators have mistakenly interpreted this to mean that these control levels are thereby safe. This is false. The control groups are not being compared to *lower* or zero fluoride groups, and, as such, provide no information about the safety, or lack thereof, of the control values.

[5] The effect size we found is consistent with the prior meta-analysis of Tang (2008), who reported a mean difference of 5.03 IQ points between the high- and low-fluoride areas.

high fluoride exposure and the outcomes even after exclusion of these studies. Although large tracts of China have superficial fluoride-rich minerals, there is little, if any, likelihood of contamination by other neurotoxicants that would be consistently associated with fluoride concentrations in drinking water and thereby systemically confound the results. For example, follow-up testing documented lower levels of blood-lead concentrations and waterborne arsenic in the high-fluoride community than the control (Xiang et al. 2003; Xiang et al. 2003; Xiang et al. 2013). In some instances, therefore, potential co-exposure to other neurotoxicants may cause reverse confounding (i.e., may attenuate the real relationship between fluoride and IQ), as we have documented for methylmercury exposure from seafood (Choi et al. 2008).

80. Additional IQ studies in endemic fluorosis areas have been published since our 2012 review. As with the previous studies, these newer studies continue to replicate the consistent inverse association between fluoride exposure and IQ, although many—but not all—suffer from similar limitations. Two of the studies reported linear relationships between urinary fluoride excretion and IQ (one study also included plasma-fluoride) among children living in areas with mean water-fluoride contents of 1.4 mg/L and 1.5-2.5 mg/L (Cui et al. 2018; Zhang and Cheng 2015).[6] Another study published since our meta-analysis is the one I conducted with colleagues in China, which I will now discuss.

81. To ascertain the validity of the Chinese reports on fluoride neurotoxicity, we carried out a pilot study in Sichuan using methods commonly applied in neurobehavioral epidemiology (Choi et al. 2015). The children examined had lived in their respective communities since conception. Although we examined only 51 children, our results are consistent with elevated fluoride exposure being a cause of cognitive deficits. Interestingly, negative associations were found for cognitive function tests regarding

[6] These results are consistent with the findings of Ding et al. (2011), who reported a dose-response relationship between urine-fluoride concentrations (range = 0.24-2.84 mg/L) and reduced IQ in a population without any severe dental fluorosis (Ding et al. 2011).

all three measures of fluoride exposure. One was the known water-fluoride concentration at the residence where the child was born and had grown up, another was the child's morning urine-fluoride after having ingested fluoride-free water the night before (neither measure reached formal statistical significance as a predictor of cognitive deficits). The strongest and statistically significant association was seen with the degree of dental fluorosis that served as a marker of early-life fluoride exposure. While the milder forms of dental fluorosis have been considered a cosmetic effect (Aoba and Fejerskov 2002; WHO 2006), our study suggested that fluorosis can serve as a useful marker of early fluoride exposure in studies of neurodevelopmental toxicity.[7]

C. Studies of Fluoride and ADHD in North America

82. Four epidemiological studies have investigated the relationship between fluoride and ADHD behaviors in North America, the most important of which is the prospective cohort study by Bashash (2018). Two of the other three studies examined ADHD-related outcomes in the Canadian Health Measures Survey (CHMS) (Barberio et al. 2017; Riddell et al. 2019).[8]

83. In 2017, Barberio et al. examined two cycles of the CHMS to investigate the relationship between randomly measured urine-fluoride levels (in 3-to-12-year-old children) and parental reports or self-reported learning disabilities. When the two cycles of the CHMS were combined (both including at least 1,100 subjects), unadjusted urine-fluoride was significantly correlated with an increased incidence of learning disabilities. However, this effect lost its statistical significance after controlling for urine dilution by creatinine and specific gravity. The authors concluded that there was no robust association

[7] A prior study that was co-authored by my colleague David Bellinger failed to observe a relationship between dental fluorosis and behavior, as determined from parental questionnaires (Morgan et al. 1998). Due to several weaknesses, the conclusions were cautious and, in the authors' wording, "cannot lay this issue to rest." The relationship between dental fluorosis and neurobehavioral deficits is an issue that thus requires further study, including the possibility that the relationship is only apparent for fluorosis of certain teeth that share windows of susceptibility that overlap the windows of susceptibility for developmental neurotoxicity.

[8] The third study (Malin and Till 2015) was an ecological study that found an association between ADHD and water fluoridation in the U.S. This association was not robust, however, as it lost its significance after adjustment for altitude, although this adjustment is questionable.

between fluoride exposure and reported learning disability among Canadian children at the ages studied.

84. A more sophisticated study using the same CHMS data has now been completed and shows a significant association between fluoridated water and ADHD diagnoses/symptoms (Riddell et al. 2019). The latter study controlled for more potential covariates than Barberio and focused on an older subset of children (6 to 17 years old). Riddell's focus on an older group of children is an improvement because 90% of children with ADHD are diagnosed after age 6 (Riddell et al. 2019). Riddell also focused specifically on ADHD symptoms and diagnoses, rather than the broader category of "learning disabilities." The Riddell team also analyzed fluoride in water as well as in urine and conducted regression analyses to test the association with specific ADHD parameters: i.e., ADHD diagnosis and the hyperactivity/inattention score on the Strengths and Difficulties Questionnaire (SDQ).

85. After adjustment for covariates, including lead exposure, Riddell and colleagues found that fluoridation of the home water supply significantly increased the risk of an ADHD diagnosis. An increase in water-fluoride by 1 mg/L was associated with a (statistically significant) 6-fold higher odds of an ADHD diagnosis in the 710 children known to rely on community water, although this association was not replicated using urine concentrations that may have been more variable. Similar tendencies were seen for the SDQ scores of hyperactivity/inattention, especially among the older youth (not covered by the Barberio study).

86. With its individual exposure data, more specific ADHD outcomes in adolescents, and large effect size, the Riddell study, along with Bashash et al. (2018) that I will discuss below, provide additional weight to the evidence of fluoride being a neurotoxicant at current levels of exposure in fluoridated areas.

VI. EPIDEMIOLOGICAL STUDIES (PROSPECTIVE)

A. Prospective Cohort Studies with Individual Assessment of Prenatal Exposure

87. The most reliable evidence of developmental neurotoxicity is obtained through prospective studies that include real-time recording of information about exposure in early life followed by subsequent clinical assessments of the child. (Grandjean & Landrigan 2014; Grandjean 2008). In our meta-analysis we recommended that prospective studies be conducted to formally evaluate dose-response relations based on individual-level measures over time, including more precise prenatal measurements (Choi et al. 2012). Five such studies have now been conducted, and they have each found significant adverse associations between prenatal fluoride exposure and neurodevelopmental harm (Bashash 2017; Bashash 2018; Green 2019; Valdez-Jiminez 2017), with an additional study finding an association between fluoride exposure during early infancy and IQ loss (Till 2020). The quality of these studies, coupled with the consistency of their findings, also in regard to the cross-sectional studies, add *substantial* weight to the evidence for developmental neurotoxicity from fluoride exposure.

88. I understand that Dr. Hu and Dr. Lanphear will be discussing the ELEMENT and MIREC cohort studies in detail, so I will forego doing so here. As I explained in my initial expert report, these are high-quality studies given their prospective birth cohort design, individual measurements of fluoride exposure, and extensive control for potential confounders.

89. In addition to the ELEMENT and MIREC studies, a prospective birth cohort study has also been published from a separate area of Mexico where there are elevated levels of fluoride in drinking water (Valdez Jiminez 2017). In this study, maternal urine-fluoride (corrected for specific gravity) was examined for its association with scores on the Bayley Scales among 65 children evaluated at age 3-15 months. The mothers in the study had average urine-fluoride concentrations at each of the three trimesters of pregnancy of 1.9, 2.0, and 2.7 mg/L. These fluoride exposure indicators during the first and second trimesters were associated with large and significant reductions in the Bayley Mental Development Index (MDI) (cognitive) score after adjusting for covariates, including gestational age.

While this study is not as robust as the ELEMENT and MIREC studies due to the limited size, its findings are consistent with and reinforce their findings, and add further weight to the neurotoxicity assessment given its prospective cohort design.

B. Prospective Cohort Studies without Prenatal Exposure Assessment

90. Two additional prospective studies have been previously published on fluoride and neurodevelopment (Shannon et al. 1986; Broadbent et al. 2015), both from New Zealand. They have substantial limitations that make them much less informative than the North American studies, including a failure to obtain individual measurements of fluoride exposure, and a failure to ascertain prenatal fluoride exposure.

91. The first of the New Zealand studies was published in 1986 by Shannon. It found no association between childhood behavior (as scored by mothers and teachers) and the duration of time the child had lived in a fluoridated area during the first 7 years of life. The authors, however, made no attempt to ascertain prenatal and early postnatal exposures. Postnatal exposures were measured by simply tallying the number of years a child resided in a fluoridated area, with no distinctions made for the *timing* of postnatal exposure. Under this exposure metric, a child who lived her first year of life in a fluoridated area (a period of increased vulnerability) would be treated the same as a child who lived her seventh year of life in a fluoridated area.

92. A second prospective study from New Zealand was based on a birth cohort established from births in 1972-1973 (Broadbent et al. 2015). The 1,037 children were recruited at age 3 years, and IQ tests were administered at ages 7, 9, 11 and 13 years, and again at age 38. Urine samples were again not available for analysis, and the authors had no individual data on water intake. Instead, the authors compared individuals who had lived for an undefined period of time in a fluoridated area during their first five years of life, with individuals who had not lived in a fluoridated area during their first five

years. No significant differences in IQ were noted using this exposure metric, and this finding was independent of potential confounding variables, including sex, socioeconomic status, breastfeeding, and birth weight.[9]

93. The Broadbent study also made no attempt to ascertain prenatal exposures, including maternal tea consumption, which is an important limitation given the high rate of tea consumption in New Zealand. Tea contains elevated levels of fluoride, and tea consumption can be a major source of fluoride intake among adults (Waugh 2017). During the time that the children in this study were born (1972-1973), New Zealanders consumed as much as 2.6 kg of tea per capita per year (corresponding to 3-4 teabags per day), as compared to the consumption of 0.5 kg in Canada in the approximate time the MIREC cohort was recruited (Grigg 2002). The failure of both New Zealand studies to consider maternal tea consumption may have introduced substantial imprecision into the exposure classification.

94. An additional concern is that the 10% of cohort subjects who had not lived in fluoridated areas very likely received fluoride supplements, which would eliminate much of the (postnatal) difference in exposure between the fluoridated and non-fluoridated areas. In a letter published subsequent to the study, the authors estimated that the average difference in exposure between children in fluoridated vs. non-fluoridated areas was only 0.3 mg/day (Broadbent et al. 2016).

95. Based on the absence of individual measurements of exposure; failure to control for the timing of exposure, including prenatal exposures; and the relatively small difference in postnatal exposures in the Broadbent study, the New Zealand studies provide virtually no information about the neurotoxic impact of early-life fluoride exposures. They carry little weight in my assessment.

VII. SYSTEMATIC REVIEW

96. Although I decided not to conduct a formal systematic review for my weight-of-the-

[9] Despite the fact that lead exposure in this cohort was later reported to cause IQ deficits (Reuben et al. 2017), the authors of the fluoride study chose not to control for exposure to lead or other chemicals that can affect neurodevelopment.

evidence analysis, I had the opportunity to consider and analyze the review conducted by Dr. Ellen Chang of Exponent. As I described in my expert rebuttal report, Dr. Chang's systematic review provides no credible grounds for questioning my assessment of the literature; in fact, it further supports it.

A. Dr. Chang's Systematic Review Confirms that I Considered All Significant Data

97. Dr. Chang stated that her systematic review identified numerous studies that I did not address, with the apparent implication that these studies are somehow at odds with my opinion (p. 8). What Dr. Chang failed to reveal, however, is that the great majority of these studies reported significant associations between fluoride exposure and neurotoxic outcomes, further confirming my own assessment.

98. Of the 31 studies that Dr. Chang has identified and which I did not specifically address, 27 found associations of elevated fluoride exposure with adverse effects.[10] These studies, which provide further *support* for my opinions, were not cited in my report because most are repetitions of the cross-sectional study design in endemic fluorosis areas that I have already discussed at length; some are only available in abstract form;[11] some are secondary analyses of primary studies that I already addressed;[12] and one was not available to me at the time of submitting my report (Till et al. 2020). As explained in my report, I do not consider it necessary to address and discuss each and every paper that reports on fluoride effects, especially when peer-reviewed systematic reviews are available, including our own (Choi et al. 2012). I consider it more informative to examine the various *types* of studies, including toxicokinetics (e.g., distribution of fluoride throughout the body, including transfer through the placenta and blood-brain barrier); toxicological findings from animals; and different endpoints relevant to

[10] Aravind (2016); Asawa (2014), Calderon (2000), Das (2016), Khan (2015), Kundu (2015), Liu (2000); Lu (2019), Manju (2017), Mustafa (2018), Nagarajappa (2013); Qin (1990), Razdan (2017), Rocha-Amador (2007), Rocha-Amador (2008), Rocha-Amador (2009), Saxena (2012), Shivaprakash (2011), Singh (2013), Sudhir (2009), Thomas (2018), Till (2019), Trivedi (2007), Wang (2005), Xiang (2015), and Yu (2018).

[11] Calderon (2000); Thomas (2018).

[12] Xiang (2015); Wang (2012).

neurotoxicity (e.g., cognitive tests, thyroid function, histological assessments of fetal brain).

99. Conversely, many of the studies that I addressed in my report[13] were not considered by Dr. Chang for unexplained or spurious reasons. Dr. Chang's review, for example, never addressed or considered fluoride's (i) passage through the placenta, (ii) uptake into fetal brain, and (iii) neurochemical and anatomical effects, and she spuriously dismisses the evidence of neurotoxicity in adults as irrelevant to developmental effects in humans (p. 31). In several important ways, therefore, Dr. Chang's review is not as systematic as my own.

100. Dr. Chang's systematic search of the literature identified four papers that reported no significant associations with neurodevelopmental effects and that I did not rely on, but upon inspection, they have no material effect on the conclusions that can be drawn, as I will now discuss.

101. One study highlighted by Dr. Chang is a publication by Spittle and colleagues (Spittle 1998) that Dr. Chang refers to repeatedly throughout her review. Although noted in a lengthy table at the end, Dr. Chang fails to acknowledge in the body of her review that this report is in the form of an abstract and relates to a previous (full) publication (Shannon et al. 1986) that I addressed in my report (and above). I did not cite the Spittle abstract in my report, just as I did not cite abstracts of studies reporting harm.[14] It is standard practice for systematic reviews to omit abstracts, as practiced in systematic reviews conducted by the authoritative Cochrane group (Iheozor-Ejiofor et al. 2015). Dr. Chang provides no justification for including abstracts in her review, such as the one by Spittle (Spittle 1998). Dr. Chang's prominent references to the Spittle abstract is particularly surprising given that it does not describe *any* confounder adjustment,[15] and uses an ecological metric for exposure (group water

13 *E.g.*, Dong (1993); Duan (1995); Ekstrand (1981); Li (2016); Spittle (1994); Guo (2001); Malin (2018); Opydo-Szymaczek (2005, 2007); Peckham (2015); Ron (1986); Salgarello (2016); Shao (2003); Shen & Taves (1974); Yazdi (2011); Yu (2008).

14 Calderon (2000); Thomas (2018).

15 On p. 132 of her Table, Dr. Chang "assume[s]" that the Spittle analysis controlled for the same confounders as the Shannon analysis. I understand that neither Dr. Chang, nor anyone else in her

F level) – features which Dr. Chang has used to dismiss many papers that support the neurotoxicity of fluoride.

102. The other three "no-effect" studies that Dr. Chang cites and that I did not address are similarly unavailing. Two are cross-sectional studies from China which fail to show statistically significant associations between fluoride exposure and IQ,[16] and one is an ecological analysis (Perrott 2018) of the Malin & Till (2015) study on ADHD which I addressed but placed little weight on. As I explained in my report, there are many reasons why an ecological/cross-sectional study can fail to detect an effect even when one is present. The failure of these three studies to find statistically significant effects does nothing to contradict the robust literature that I rely upon, including the prospective birth cohort studies that I placed the greatest weight on. Even Dr. Chang appears to recognize this, as she does not include any of these three studies in her causal analysis, and correctly notes that the analysis by Perrott (Perrott 2018) is a "relatively low quality" ecological study (p. 66).

103. In summary, despite asserting that my review failed to consider "numerous" papers, Dr. Chang's own review confirms that I addressed and considered the most relevant epidemiological studies on cognitive outcomes. Dr. Chang's literature search also confirms that the majority of studies that I did not specifically address are consistent with and further support the association between fluoride and cognitive impairment, in accordance with my conclusions.

B. Dr. Chang's Review Fails to Identify Any Systematic Biases that Explain Fluoride's Consistent Association with Neurodevelopmental Harm

104. Dr. Chang's systematic assessment of study quality provides a lengthy discussion of real or perceived methodological limitations in the available studies. Importantly, however, Dr. Chang failed to identify a likely explanation for how these limitations can explain the consistent adverse associations

office has contacted Dr. Spittle to confirm this statement (Personal email communication with Bruce Spittle, August 13, 2019). According to Dr. Spittle, the abstract provided all important methodological details.

[16] He (2010); Kang (2011).

between fluoride and IQ across both cross-sectional and prospective studies. For example, Dr. Chang referred to "high potential for selection bias" but did not consider how unlikely it is that dozens of studies should all suffer from some particular exposure misclassification or selectivity that would all cause bias *away* from the null, e.g., selection bias that would result in participation of intellectually disabled children only in the high-fluoride group, or residual confounding resulting in bias only away from the null in the many different study settings.

105. Dr. Chang claimed that "methodological uncertainties remain about the assessment of fluoride exposure and neurodevelopmental outcomes; and the reported findings are plausibly explained by confounding, bias, and chance" (p. 9). However, she did not provide any convincing evidence that such issues could have resulted in erroneous conclusions, especially in the high-quality prospective studies.

106. Throughout her analysis, Dr. Chang failed to grapple with the fact that random (i.e., non-differential) error is unlikely to cause a bias away from the null, as is well-known in epidemiology, as I have also discussed in past publications (Grandjean and Budtz-Jorgensen 2007, 2010). Dr. Chang thus did not articulate a plausible basis for why the limitations she claimed to have identified can *systematically* bias the results across the many study settings, including the North American birth cohorts.

107. Dr. Chang described cross-sectional studies as if they are all equal and as if the exposure parameter always represents a current and short-lasting exposure only. In so doing, Dr. Chang failed to acknowledge in her causal analysis that exposure measures in many studies represent long-term community conditions, in some studies also likely covering prenatal exposures, a critical detail.

108. Dr. Chang referred to exaggerated associations that can result from lack of blinding (p. 59), but failed to acknowledge that at least 11 of the studies reporting adverse neurocognitive effects

have clearly been blinded, including the recent birth cohort studies, where the exposure was determined *after* the cognitive tests had been completed. Thus, while lack of blinding can create observation bias, it cannot explain the inverse association between fluoride and IQ because similar associations have been consistently found in studies known to be blinded. Despite producing a 56-page table to address "key characteristics" of the studies, Dr. Chang failed to mention this methodological strength in her summary of the studies (pp. 90-146).

109. Dr. Chang repeatedly highlighted the risk of publication bias, e.g., in the biomedical journal *Fluoride*, which is not indexed by PubMed. However, she does not mention the bias *against* publication, i.e., a bias that acts in the opposite direction. The examples that I mentioned in my report illustrate that such bias exists.[17] Further, Dr. Chang speculated that Chinese-language studies that did not find adverse effects may not have been translated into English (p. 37). Instead of speculating about this, Dr. Chang's systematic review could have included a search of online databases of Chinese-language research (e.g., CNKI) but, for unexplained reasons, did not do so.[18]

110. In summary, although Dr. Chang's systematic assessment of study quality correctly identified limitations in a number of studies, she failed to credibly explain how these limitations can plausibly explain the significant inverse associations that have consistently been found across many study settings and designs.[19] Although I recognize the issues that Dr. Chang has raised and have fully

[17] The desire to use fluoride in caries prevention programs has sometimes made it difficult for researchers, including myself, to present findings of potential toxic effects. In addition to my own personal experiences, published case reports suggest that some studies reporting adverse results have been suppressed, and, in at least one instance, a respected scientist at the Forsythe Dental Institute lost her job after publishing evidence of neurotoxicity.

[18] A search of PubMed for "CNKI database" shows that many systematic reviews include CNKI as one of the databases to retrieve studies, and the Institute of Medicine recommendations for systematic review (which Chang relies on) calls for searching for foreign language studies when appropriate (IOM 2011, p. 8). CNKI is publicly available online at: http://oversea.cnki.net/kns55/default.aspx.

[19] Unable to explain why so many studies have found significant associations between fluoride and IQ, Dr. Chang claims that "most published scientific research findings are anticipated to be false" (p. 38, citing Ioannidis (2005)). Although the original report by John Ioannidis (Ioannidis 2005)

considered them in my assessment, it remains extremely unlikely, if not impossible, that the overwhelming evidence of fluoride neurotoxicity is a mirage caused by bias, as Dr. Chang apparently believes. A far more likely and plausible explanation for the consistent findings in the epidemiological studies is that fluoride is a developmental neurotoxicant that reduces IQ and that this association is strong enough to be apparent also in studies with less-than-ideal designs.

C. Bradford Hill Aspects Support, Rather than Detract from, the Causal Nature of Fluoride's Association with Neurodevelopmental Harm

111. Dr. Chang used the Bradford Hill aspects to evaluate the causal relationship between fluoride and neurotoxicity. As I explained in my rebuttal report, her causal analysis is superficial and pays lip service only to Sir Austin's wise advice. An appropriate and systematic assessment of the Bradford Hill guidelines supports, rather than refutes, the causal relationship between elevated fluoride exposure and IQ loss. I will summarize here:

112. *Strength*: Dr. Chang dismissed the strength of the association between fluoride and IQ on the grounds that a loss of 3 to 5 IQ points is relatively small in comparison with normal, expected variation (p. 69). Under this arbitrarily high standard, other well-known neurotoxicants (e.g., lead, methylmercury, arsenic) would fail Dr. Chang's strength criterion. By failing to consider the strength of association of other well-known neurotoxicants, Dr. Chang subjectively analyzed the data on fluoride in a meaningless vacuum. Had Dr. Chang considered the strength of association for other neurotoxicants, she would have found that the effect size for fluoride actually is actually large, not small (i.e., it rivals the effects of lead), which *supports*, rather than detracts, from a causal relationship.

113. *Consistency*: One of the most compelling aspects about the epidemiological research on

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did provide some stunning examples of how clinical medicine could be misled by single reports, it would be reckless and counterproductive if we were to ignore all published reports, as Dr. Chang seems to prefer. This nihilistic view was also not the intent of the author. In a more recent paper in the same journal, Dr. Ioannidis highlighted the need for balanced review of scientific evidence in the interest of inspiring responsible policy decisions (Ioannidis 2018).

fluoride is how consistent it has been in finding significant associations with IQ (Choi et al. 2012). Dr. Chang obscured this by highlighting non-informative studies that made no attempt to measure or investigate prenatal or early postnatal fluoride exposures (Barberio et al. 2017; Broadbent et al. 2015; Morgan et al. 1998; Shannon et al. 1986; Spittle 1998) as being on the same level as, and contradicting, the highly significant findings from the prospective ELEMENT (Bashash et al. 2017) and MIREC (Green et al. 2019) prospective birth cohort studies (pp. 70-71). A particularly poor judgment by Dr. Chang was to place the Spittle abstract on the same level as the ELEMENT and MIREC studies despite the fact that Spittle's abstract does not describe *any* confounder adjustment. Dr. Chang cited the "mixed" nature of the findings as a basis to conclude that the consistency factor has not been met, while failing to acknowledge the inappropriate apples-to-oranges nature of comparing the prospective ELEMENT/MIREC studies to much, much weaker studies.

114. In her assessment of consistency, Dr. Chang failed to mention the fact that every single prospective birth cohort study with prenatal exposure measurements has found a significant adverse effect of prenatal fluoride on neurodevelopment (Bashash et al. 2017; Bashash et al. 2018; Green et al. 2019; Valdez Jimenez et al. 2017). Dr. Chang also gave short shrift to the consistent association between fluoride exposure and reduced IQ reported in the numerous cross-sectional studies (Choi et al. 2012; Duan et al. 2018; Tang et al. 2008). This latter shortcoming may be a result of Dr. Chang's critical misunderstanding of our meta-analysis (Choi et al. 2012), which I will now address.

115. Dr. Chang claimed that our meta-analysis found an average loss of 0.45 IQ points in the high-fluoride areas and characterizes this as a 10-fold difference with the Tang meta-analysis (Tang et al. 2008). This, however, is not what we reported (see paragraph 78). Because different intelligence scales had been used in the studies considered, we expressed the outcome as a random-effect standardized weighted mean difference estimate, as we clearly explained (Choi et al. 2012). In order to

translate this measure to a difference on the same IQ scale, the joint result must be multiplied by the standard deviation of the IQ scale, i.e., 15. An SMD of -0.45 thus corresponds to a loss of 6.75 IQ points. Contrary to Dr. Chang's mischaracterization, therefore, the results of our meta-analysis are consistent with the Tang meta-analysis, a fact that we actually mention in our published paper (Choi et al. 2012).

116. Dr. Chang's assessment of consistency also entirely ignored the findings from occupational studies, as well as the neuropathology data from examinations of fetal brains in endemic fluorosis areas. As I explained in my report, each of these types of studies is consistent with, and provide support for, fluoride being a neurotoxic agent.

117. *Specificity*: As Kenneth Rothman (2012) and others (Neutra 2018) have emphasized, and as Dr. Chang recognized, lack of specificity between an exposure and an outcome (e.g., asbestos and mesothelioma) does not weigh against or in favor of a causal conclusion.

118. *Temporality*: Dr. Chang's assessment of temporality mirrored her assessment of consistency in that she cited the two New Zealand studies as contradicting the findings from the ELEMENT and MIREC cohorts. Once again, Dr. Chang fails to acknowledge the absence of prenatal or early postnatal fluoride exposure assessments in the New Zealand studies, nor any of the other serious shortcomings of these studies. Instead, Dr. Chang focused on non-differential measurement uncertainties of the urine-fluoride data in the far superior ELEMENT and MIREC cohorts to cast doubt on the findings of these studies. As already discussed in my report, however, the imprecision of the fluoride exposure parameters would likely *bias the results toward the null*, not the reverse. The temporality requirement is thus met with fluoride, as each of the prospective birth cohort studies has found a significant association between early-life exposure to fluoride and the offspring's subsequent performance on neurobehavioral testing. The exposure preceded the effect in these studies, which is

what the temporality factor is supposed to assess.

119. *Biological Gradient*: The ELEMENT and MIREC studies have reported monotonic dose-response relationships between elevated prenatal fluoride exposure and IQ deficits in the offspring (Bashash et al. 2017, Green et al. 2019), as well as ADHD behaviors (Bashash et al. 2018). Dr. Chang dismissed the biological gradient of these effects by showing scatterplots from the ELEMENT and MIREC cohorts without the trend lines. However, this approach proves little insight, other than illustrating the undisputed fact that there is substantial natural variation in IQ across the population and that an appropriate statistical analysis is needed to extract a reliable estimate of the average effect of the toxicant exposure. Similar scatterplots have been published showing the effects of lead and IQ, as can be seen in the figure to the right (Rothenberg & Rothenberg 2005, Figure 1). Lead would thus fail the biological gradient test that Dr. Chang has used for fluoride. Dr. Chang also argued that outliers may have distorted the effects seen in the ELEMENT and MIREC cohorts (p. 77-78), without acknowledging that statistical analyses on the impact of outliers have been conducted and that the results did not meaningfully change (Bashash et al. 2017).

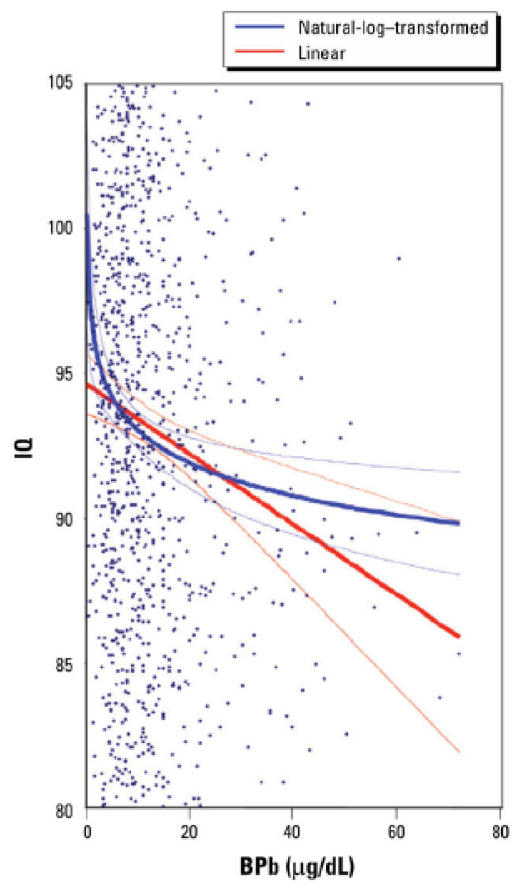

Figure 1. Child blood-lead and IQ. From Rothenberg & Rothenberg 2005.

120. *Plausibility*: Dr. Chang limited her assessment of biologic plausibility to NTP's assessment of learning and memory (NTP 2016) in animal models, and to Dr. Tsuji's expert report. In so doing, Dr.

Chang completely ignored the large body of animal literature showing adverse neuroanatomical and neurochemical effects from fluoride exposure, as already reviewed by the National Research Council (NRC 2006) and by Dr. Thiessen in her report. The NRC concluded that the neuroanatomical and neurochemical effects are sufficient to determine that fluoride interferes with brain function (NRC 2006). Dr. Chang ignored this information in favor of the NTP's more narrow assessment on learning/memory, but even the NTP assessment found suggestive evidence that fluoride impairs learning and memory. In contrast to Dr. Chang's assessment, EPA's own experts on developmental neurotoxicity, including internationally recognized scientists such as William R. Mundy and Kevin M. Crofton (Mundy et al. 2015), have identified fluoride as a chemical with substantial evidence of developmental neurotoxicity.

121. *Coherence*: Dr. Chang dismissed the coherence of fluoridated water reducing IQ on the grounds that IQ scores in US children steadily improved throughout the 20th century (the so-called "Flynn Effect"). Dr. Chang even went so far as to suggest that fluoridation may be responsible for the increased scores, although more plausible explanations are known. Under Dr. Chang's simplistic framework, leaded gasoline could not have reduced IQ and may have increased it, as it was introduced in the early part of the 20th century and IQ scores continued to increase during the entire duration of its use. It is well accepted, however, that low-level lead exposure reduces IQ, and thus the Flynn Effect argument—while perhaps superficially appealing—does *not* demonstrate "incoherence."

122. In her assessment of coherence, Dr. Chang failed to consider other relevant considerations, including the association between neonatal fluoride exposure mediated by infant formula feeding and reduced IQ (Till et al. 2020), as further discussed below. While the studies prior to the recent Canadian analysis did not evaluate the potential role of neonatal fluoride exposure, formula feeding is well established to increase a baby's fluoride exposure, even in areas without fluoridated water (Harriehausen

et al. 2019; Zohoori et al. 2019). Although other factors are of likely importance, the relationship between formula-feeding and reduced IQ is coherent with maternal fluoride exposure during pregnancy being associated with a lowered IQ in the child and supports a causative relationship between early-life exposure to fluoride and IQ deficits.

123. *Experiment*: Dr. Chang ignored the NRC's observation (NRC 2006) that case reports of fluoride toxicity constitute "experimental studies" of neurologic symptomatology following fluoride exposure (NRC, p. 208). The case reports involve "one or more individuals who underwent withdrawal from their source of fluoride exposure and subsequent re-exposures under 'blind' conditions." In most cases, the symptoms (which included lethargy, weakness, and impaired ability to concentrate) "disappeared with the elimination of exposure to fluoride and returned when exposure was reinstated." Although experimental support is not an obligatory criterion (Neutra 2018), the existence of such support should not be missed in what is dubbed a systematic assessment.

124. *Analogy*: I agree with Dr. Chang that "analogies can be drawn to other naturally occurring elements, especially certain metals" like lead (p. 85). As discussed above, many of the exaggerated criteria that she uses to reject a causal relationship between fluoride exposure and IQ could be equally used to erroneously dismiss the causal relationship between low-level lead exposure and IQ.

125. In summary, after correcting for Dr. Chang's errors and biases in judgment, the Bradford-Hill aspects support, rather than detract from, a causal relationship between fluoride in water and neurotoxicity. After analyzing and considering Dr. Chang's systematic review, I have more, not less, confidence that developmental neurotoxicity is a serious risk of elevated fluoride exposure.

VIII. BENCHMARK DOSE (BMD) ANALYSIS

A. Selection of Source Data

126. Regulatory agencies are in overall agreement in using Benchmark Dose (BMD) analyses to

calculate non-cancer health-based limits for dietary intakes of contaminants, such as those found in drinking water (EFSA 2009; EPA 2012).

127. As with the Faroe Islands cohort that the EPA relied upon in its risk assessment for methylmercury, the ELEMENT and MIREC studies are high-quality birth cohorts suitable for dose-response analysis (Bashash et al. 2017; Green et al. 2019). Further, as the data refer to the critical effect in a highly vulnerable population, they constitute appropriate data to use for identifying a safe exposure limit for fluoride. I worked, therefore, with my colleague, Dr. Budtz-Jorgensen, on BMD analyses of these studies, which I describe below.

128. Our selection of the ELEMENT and MIREC studies for BMD analysis is consistent with an analogous assessment conducted by both Dr. Chang and her colleague, Dr. Joyce Tsuji (Tsuji et al. 2015) for another neurotoxicant. In their paper, Drs. Chang and Tsuji sought to determine if the existing RfD for arsenic is adequately protective of neurotoxicity. To answer this question, they conducted a systematic review of the literature to see if there were any studies that would permit a dose-response analysis for quantitative risk assessment. After reviewing the literature, they found a study that, in their judgment, was suitable for the purpose: a study from Bangladesh by Hamadani et al. (2011).

129. The ELEMENT and MIREC studies are at least equally suitable for dose-response analysis as the one study Dr. Chang and Dr. Tsuji found sufficiently reliable to use for their risk assessment of arsenic exposure. As with the Hamadani study, the ELEMENT and MIREC studies have a (i) prospective birth cohort design; (ii) large sample size; (iii) control for potential confounders;[20] (iv) urine measurements[21] of the toxicant of interest during pregnancy; (v) and extended follow-up (up to 5 years

[20] Drs. Chang and Tsuji considered studies to have sufficiently controlled for potential confounders if they controlled for SES or HOME Score and parental education/IQ (Tsuji et al. 2015, p. 93).

[21] As with the ELEMENT and MIREC studies, the Bangladesh study measured prenatal exposure through several samples of maternal urine (adjusted for specific gravity) (Hamadani 2011). The Bangladesh study collected urine twice during the pregnancy (at gestational weeks 8 and 30), which

after birth). In fact, the ELEMENT and MIREC studies have an important advantage: the average arsenic exposure in Bangladesh substantially exceeded exposures in the U.S.,[22] which is not the case with the North American fluoride cohort studies.

130. My calculations of benchmark values for fluoride from the ELEMENT and MIREC cohorts are therefore in accordance with the criteria that Drs. Chang and Tsuji have previously used when generating benchmark calculations for arsenic (where adverse effects were seen in girls, but not boys, at 5 years of age).

B. Selection of Benchmark Response (BMR)

131. The benchmark dose (BMD) is defined as the dose that leads to a specific loss (or degree of abnormality) known as the benchmark response (BMR) in the outcome variable. The BMR must be defined before the analysis (EPA 2012), and general guidelines been developed for the selection of a BMR (EFSA 2009).

132. According to the EPA Clean Air Scientific Advisory Committee, a 1-to-2 IQ point reduction at the population level is "highly significant from a public health standpoint," and should be prevented in up to 99.5% of the population (EPA 2008). Consistent with this, previous BMD analyses of human neurotoxicity have selected 1 IQ point as the BMR (Budtz-Jorgensen et al. 2000; Budtz-Jorgensen et al. 2013; EFSA 2010; Tsuji et al. 2015).

133. Economists have calculated the substantial losses in lifetime incomes from a decrease of 1 IQ point[23] (Gould 2009), as also practiced by economists at the EPA in regulatory impact analyses (EPA 2008).

134. Research on other neurotoxicants (Grandjean 2013) has shown that shifts to the left of IQ

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is a lower number of samples than the MIREC cohort, and roughly the same as the ELEMENT study.

[22] The Bangladesh study addressed a population with mean urinary arsenic levels ranging from 35 to 80 ug/L, which is about 10-to-40 times the levels measured in the US population.

[23] In terms of 2006-dollars, the value of 1 IQ point was calculated to be about $18,000 (Gould 2009; Spadaro and Rabl 2008).

distributions in a population (i.e., reductions in average IQ) can have substantial impacts, especially among those in the high and low ranges of the distribution (Bellinger 2007).

135. Consistent with prior analyses, including our own, we therefore selected 1 IQ point as the BMR (Budtz-Jorgensen et al. 2000; Budtz-Jorgensen et al. 2013).

C. Analyses of ELEMENT and MIREC Data

136. For our BMD analysis, we used the same formula that we used in our prior assessment of lead (Budtz-Jorgensen et al. 2013). The formula is as follows:

> The BMD is defined by
>
> $$f(0) - f(BMD) = BMR \;\rightarrow\; BMD = f^{-1}(-BMR)$$
>
> In a linear model, $(Y = \alpha + \beta d + \varepsilon)$, from which we get $BMD = -BMR/\beta$.
>
> Likewise, the BMDL is defined as a lower one-sided 95% confidence limit of the BMD. In the linear model,
>
> $$BMDL = -BMR/\beta_{lower}$$
>
> where β_{lower} is the one-sided lower 95% confidence limit for β. Information on the (linear) regression coefficients and their standard deviations, from which the confidence intervals can be calculated, is available from the published articles on the two major prospective cohort studies.

137. For the ELEMENT study (Bashash et al. 2017), a linear dose-response model could be used for the effect of urine-fluoride concentrations on both measures of childhood IQ (i.e., the General Cognitive Index (GCI) results at age 4 and IQ results at ages 6-12). In this model, the BMD and BMDL can be calculated based only on the regression coefficient and its precision. In Table 4 of the publication (Bashash et al. 2017), this information is available both for a crude model and for a model A with confounder adjustment. The table below shows the benchmark results for these two models for both the age-4 GCI and school-age IQ.

Table 2. Benchmark dose results (mg/L urine adjusted for creatinine) obtained from the ELEMENT study results **(Bashash et al. 2017).**

Model	GCI BMD	GCI BMDL	IQ BMD	IQ BMDL
Crude	0.133	0.085	0.211	0.121
Adjusted	0.159	0.099	0.200	0.130
Read from plot	0.159	0.102	-	-

138. As these calculations are based on assumptions of Gaussian distributions, we checked the validity by scanning the numbers from the plot in the published article. We tentatively used the *WebPlotDigitizer* software to read the plot shown in the published paper (see Figure 1, page 22) (Bashash et al. 2017), to obtain the individual adjusted GCI results for more accurate BMD calculations. Of the original 287 observations, the software provided 286 observations, probably due to two overlapping observations. Thus, missing a single point only, our calculations based on the scanned data should be considered fairly reliable.

139. Using the standard benchmark approach to epidemiological data and a linear dependency, we find that the BMD for GCI is approximately 0.16 mg/L, and that the BMDL is 0.10 mg/L (bottom line of Table 2). These results are in excellent agreement with the results calculated only from the regression data presented in Table 4 of Bashash et al. (2017).

140. To assess the robustness of the calculation, we included a logarithmic conversion of the exposure parameter. We also used a split linear dose-response curve as in one of our previous studies (Budtz-Jorgensen et al., 2013). These sensitivity analyses showed BMD results that deviated only marginally from the calculation using the default linear association. In conclusion, Table 2 shows

reliable BMD results that have been calculated in accordance with standard EPA procedures.

141. We also conducted a BMD analysis of the MIREC data. As with the ELEMENT study, we calculated the BMD and BMDL from the reported regression coefficients and standard deviations, with the assumption of a Gaussian distribution (Green 2019, Table 2). In addition to calculating the BMD and BMDL from the urine-fluoride data (U-F), we also calculated a BMD and BMDL from the maternal fluoride intake data. Our results are shown in the table below:

Table 3. Benchmark dose results (mg/L urine adjusted for specific gravity, or mg estimated daily intake) obtained from MIREC study results on IQ (Green et al. 2019).

Study	Exposure	Sex	BMD	BMDL
MIREC	Maternal U-F	Both sexes	0.51	0.21
	Maternal U-F	Boys	0.22	0.13
	Maternal U-F	Girls	(–)	0.58
	Maternal F intake	Both sexes	0.27	0.15

142. As shown in the above table, the prenatal BMD for girls is not defined when relying on urine-fluoride, but the BMDL is still meaningful and is, as expected, higher than the other estimates obtained. No sex difference was found when relying on estimated fluoride intake.

143. Overall, the results derived from the two studies are comparable. In the ELEMENT study, the BMDL for maternal urine among ~4-year olds is approximately **0.1 mg/L** (both sexes), while in the MIREC study, it is **0.13 mg/L** (boys) and **0.21 mg/L** (both sexes).[24] The respective BMDL for the 6-to-12-year olds from the ELEMENT study is **0.13 mg/L**, thus overall approximately 0.15 mg/L. Consistent with these maternal urinary excretion values, the BMDL for maternal fluoride *intake* in the MIREC

[24] Based on how the authors reported the data, our BMDL values from the ELEMENT cohort are creatinine-adjusted, while our BMDL values from the MIREC cohort are specific gravity-adjusted.

study is **0.15 mg/day** (both sexes).

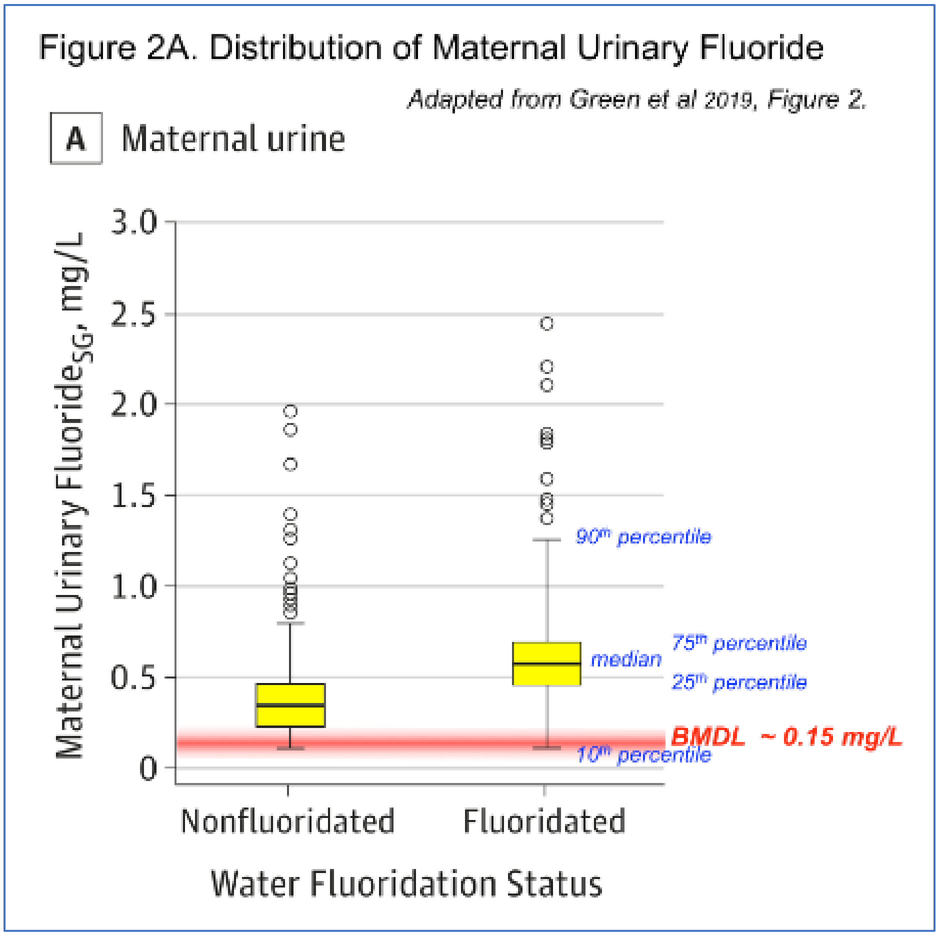
IX. ASSESSMENT OF RISK

A. Comparing BMDLs with Current Exposures in Fluoridated Areas

144. As benchmark dose calculations constitute a routine approach applied by the EPA for establishing safe limits on chemical exposure, the above calculations that rely on overall associations between fluoride exposure and cognitive deficits provide a basis for assessing the risk of cognitive deficits from current fluoride exposure levels.

145. Typically, the EPA uses the BMDL to calculate a Reference Dose (RfD) by dividing by an uncertainty factor for the purpose of accounting for variations in human susceptibility. The default value that EPA uses for the uncertainty factor is 10. Here, if we round up the overall BMDL to **0.2 mg/L**, or about 0.2 mg/day, the RfD would likely be 0.02, which is very much below current exposure levels, especially in communities with fluoridation programs (Till et al. 2018). But, *even if no uncertainty factor is applied, and even if relying on the BMD rather than the BMDL* (both of which would be unusual), the RfD would still be well below current exposure levels in fluoridated areas (Till et al. 2018).

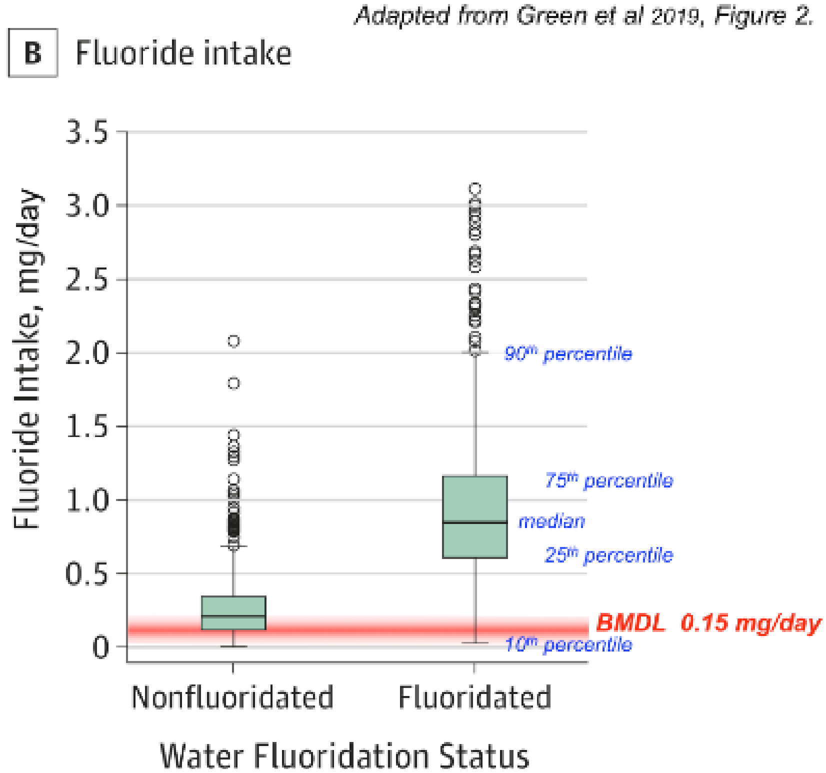
146. The serious risk that we are confronted with can be appreciated by visually comparing the BMDLs against documented exposure levels in fluoridated communities. The following Figure 2A, adapted from Green et al. (2019), compares an overall BMDL for maternal urine-fluoride (0.15 mg/L) with the maternal urine-fluoride concentrations reported in the study. As can be seen, the urine-fluoride levels far surpass the levels associated with IQ loss.



147. The below Figure 2B compares the approximate BMDL for maternal fluoride *intake* from beverages (0.15 mg/day) against the reported fluoride intakes in Green et al (2019). As can be seen, the estimated fluoride intakes in fluoridated areas far surpass the fluoride intake level associated with a clear IQ loss.

Figure 2B. Distribution of Estimated Fluoride Intake

Adapted from Green et al 2019, Figure 2.



148. There are no contemporary large-scale studies of urine-fluoride concentrations in the United States, as the CDC has not yet reported urinary fluoride excretion levels as part of its ongoing National Health and Nutrition Examination Survey (NHANES) studies. One can reasonably infer, however, that urinary fluoride excretion levels in fluoridated areas of the U.S. are generally comparable to those in fluoridated areas of Canada. The reasonableness of this inference is supported by the following facts:

149. Canada and the U.S. add fluoride to water to reach the same target concentration (0.7 mg/L), although empirical data suggests Canadian cities only reach 0.6 mg/L which is slightly less than the U.S. (Till et al. 2018).

150. Fluoridated water is recognized as the largest source of fluoride exposure for adults, particularly when indirect sources are accounted for, such as beverages and foods prepared with the

water, including commercially prepared beverages such as soda and reconstituted juice (EPA 2010).

151. Urine-fluoride has been shown to be a good indicator of total daily fluoride intake, and has a close, linear correlation with the fluoride content in water (Villa et al. 2000; McClure 1944; Smith et al. 1950).

152. The largest study of urine-fluoride levels in the U.S. found that pooled urine samples from healthy young males generally mirrored the fluoride concentration in the drinking water (McClure 1944). Based on U.S. data, therefore, a person drinking water with 0.7 mg/L fluoride would be expected to have about 0.7 mg/L in their urine, which is similar to what was found in the MIREC cohort (Till et al. 2018). Although these U.S. data were published prior to widespread fluoridation, the levels today would, if anything, tend to be *higher* today, not lower because fluoride is now available from more sources than was the case in the 1940s (e.g., including commercial beverages made with fluoridated water, dental products, etc.).

153. To address the lack of contemporary US data on fluoride exposures in pregnant women,[25] the recent UCSF study measured the concentrations of fluoride in urine (and blood[26]) of 48 pregnant women living in fluoridated and non-fluoridated areas of California. As with the Canadian study, the UCSF team had the urine tested by Dr. Angeles Martinez-Mier at the University of Indiana and adjusted the fluoride measurements for specific gravity. The study found an average (specific gravity-adjusted) urine-fluoride concentration of **0.69 mg/L** among pregnant women in areas with at least 0.7 mg/L in the community water, which is clearly in the same range as the MIREC team found in Canada (Uyghurturk

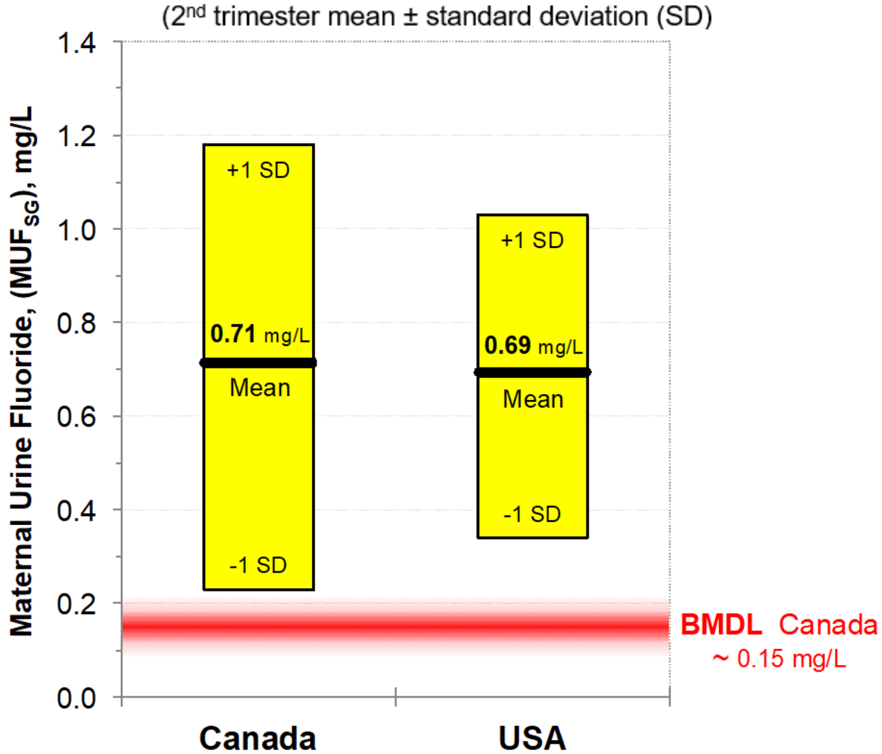
[25] As noted by the UCSF team, there is only one prior published study of urine-fluoride levels among pregnant women in the US: this is the study by Shen & Taves (1974) that I discussed in my expert report. This study found an average of 1.02 mg/L in maternal urine among a group of 16 pregnant women, but the authors did not report the concentrations of fluoride in water.

[26] The study found an average of 0.021 mg/L fluoride in the blood (=1.1 µmol/L) of the women from fluoridated areas (~0.8 mg/L), which is higher than the predicted value (0.015 mg/L = 0.8 µmol/L). As discussed by the NRC, it has been historically estimated that adult populations will have 1 µmol/L in their blood for each 1 mg/L of fluoride in the water (NRC 2006).

2020, Table 2). While the small-scale nature of the study likely introduced some random scatter in the results of the UCSF study,[27] the study supports the general similarity in fluoride exposures in the Canadian and U.S. populations.

154. Finally, the relevance of the Canadian IQ data (Green et al., 2019) to the US can be appreciated by comparing the BMDL to the maternal urine-fluoride concentrations reported by the UCSF team (Uyghurturk 2020). As can be seen in the following Figure 3, maternal urine-fluoride concentrations found in pregnant women in the Californian cohort greatly exceed the BMDL for fluoride-associated IQ loss. This, ultimately, is the most important consideration.

Figure 3. Specific gravity adjusted urine-fluoride concentrations in fluoridated communities of Canada and the U.S. (2nd trimester mean ± standard deviation (SD))



Urine F in Canada from Till 2018, Suppl., Table S4; urine F in USA from Uyghurturk 2020, Table 2.

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[27] The study found some high levels of urine-fluoride in the mid-range fluoride communities (0.3-0.5 mg/L), which slightly skewed the distribution (Uyghurturk 2020, Fig. 2). As the authors note, this may be the result, in part, of the fact that the women had their urine tested while visiting a clinic in San Francisco, which is fluoridated (Uyghurturk 2020, p. 6-7). In the areas with >0.3 mg/L in water, the average (specific-gravity adjusted) fluoride level was 0.74 mg/L (Uyghurturk 2020, Table 5).

B. Comparing Fluoride's Population-Level Effects with Other Causes of IQ Loss

155. In order to compare fluoridation's population-level effects with other neurotoxicant exposures, some approximate estimates of fluoride-associated IQ losses can be made. The calculations rely on several assumptions that are necessary in the absence of actual data and are therefore meant only to identify relative orders of magnitude. On the conservative side, I shall assume that all children are equally vulnerable and that the dose-dependent IQ losses observed in the recent prospective studies can be used to assess the impact on the population at large (i.e., that genetic and other predisposition can be ignored).

156. My analysis focuses on the average difference in maternal urine-fluoride levels between fluoridated and non-fluoridated areas. The Canadian study (Till et al. 2018) showed that this difference is approximately 0.4 mg/L. It bears emphasizing that this difference likely understates the true contribution of fluoridated water because part of the exposure in "non-fluoridated" areas comes from the "halo" effect. The halo effect refers to the fact that many commercial beverages and foods made in fluoridated areas are shipped to and consumed in non-fluoridated areas and that residents from non-fluoridated communities may work or spend time in fluoridation areas.[28]

157. Given the BMD results, an average increase of 0.4 mg/L in maternal fluoride concentrations is above the threshold for developmental neurotoxicity, even if assuming a zero background exposure. Using the dose-dependent losses observed in the recent prospective studies (Bashash et al. 2017; Green et al. 2019), this elevated exposure will correspond to an IQ loss of approximately 2 IQ points.

158. Because about two-thirds of the U.S. population receives fluoridated drinking water, one can assume that a similar proportion of the 4 million annual U.S. births (i.e., more than 2.5 million

[28] This widespread dispersal of fluoridated water in commercial products helps to explain the relatively high urine-fluoride levels now seen in non-fluoridated communities versus the situation back in the 1940s (Till et al. 2018).

births) are affected by fluoridation-associated exposure increases. With the 2-point average IQ loss associated with fluoridation, the 2.5 million births will lose a total estimated number of 5 million IQ points annually.

159. This approximate estimate can be compared with calculations made by Professor David Bellinger on IQ losses due to major pediatric diagnoses affecting 0-to-5-year-old children (Bellinger 2012). According to CDC data and Bellinger's calculations, the top pediatric etiologies for IQ loss are preterm birth at 34 million IQ points lost and lead exposure representing 23 million IQ points lost. For fluoridation, the estimate for children aged 0 to 5 years is approximately 25 million IQ points. Even if this estimate is somewhat imprecise, and unevenly distributed, the order of magnitude is likely to be correct and is very considerable.

160. Finally, even if we assume that a threshold exists at approximately 0.8 mg/L in maternal urine (as suggested by mere inspection of the IQ plots in the ELEMENT study for the 6-to-12-year-old cohort members), water fluoridation would still result in substantial IQ losses. As documented in the MIREC study, the 75th percentile maternal urine-fluoride levels (adjusted for creatinine) are 1.04 mg/L in the fluoridated areas versus 0.52 mg/L in the non-fluoridated areas (Till et al. 2018, Table S4). In fluoridated areas, pregnant women above the 75th percentile are already at least 0.29 mg/L above the hypothetical threshold, and thus 25% of the children would then experience an average IQ loss of at least 1.5 points. This would amount to over 4.5 million lost IQ points among 0-to-5-year-olds. Even this smaller amount of IQ losses exceeds the IQ losses attributed to methylmercury exposure in the U.S. (Grandjean et al. 2012).

161. I have made these calculations only to illustrate the significance and impact of neurotoxicity outcomes from fluoridation exposures, and I offer these crude estimates to emphasize my concern that developmental neurotoxicity due to early-life exposure to fluoride is a serious public health

hazard with substantial societal impacts that must be controlled.

X. CONCLUSIONS

162. Recent research has shown that the most vulnerable life stage for many toxicants, particularly those that adversely affect the brain, is during intrauterine and early postnatal development. Fluoride fits into this paradigm, and efforts to control human fluoride exposures must therefore focus on pregnant women and small children.

163. Research on fluoride-exposed workers and laboratory animals suggest that elevated fluoride exposure is toxic to the brain and nerve cells. Epidemiological studies have identified links to learning, memory, and intelligence deficits, though most of the past studies focused on populations with fluoride exposures higher than those typically provided by U.S. water supplies.

164. Epidemiology studies of birth cohorts from the most recent years document that adverse effects on brain development happen at elevated exposure levels that occur widely in North America, in particular in communities with fluoridated drinking water. These new prospective studies are of very high quality and show very similar results, thus leaving little doubt that developmental neurotoxicity is a serious risk associated with elevated fluoride exposure. This evidence shows that community water fluoridation is associated with IQ losses that are substantial and of economic and societal concern.

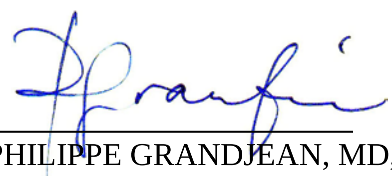
165. Applying methods for standards setting routinely used by the EPA (i.e., Benchmark Dose analysis), the recent studies on IQ deficits in children allow the estimation of a recommended limit that would protect against neurotoxicity. Such calculations show that current allowable limits for fluoride in drinking water and the levels of fluoride added in community water fluoridation programs both greatly exceed a science-based limit that would protect against developmental neurotoxicity.

166. The evidence on fluoride neurotoxicity in the general population is fairly recent and

unlikely to represent the full toxicological perspective, including adverse effects that may occur at longer delays. As has been seen on numerous occasions, the evidence available today may well underestimate the true extent of the fluoride toxicity. With a reasonable degree of scientific certainty, I therefore consider the elevated levels of fluoride exposure in the U.S. population as a serious public health concern.

I declare under penalty of perjury, under the laws of the United States, that the foregoing is true and correct to the best of my knowledge and belief.

Executed on May 20, 2020, in Copenhagen, Denmark.



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Academic degrees
1974, M.D., University of Copenhagen
1975, Diploma in basic medical research, University of Copenhagen
1979, D.M.Sc. (dr.med.), University of Copenhagen

Chronology of employment

1974-1975	Postgraduate training fellowship, University of Copenhagen
1975-1978	Research fellow, Institute of Hygiene, Univ. Copenhagen
1978-1980	Senior research fellow, University of Copenhagen Visiting fellow, Department of Community Medicine, Mount Sinai School of Medicine, New York
1980-1982	Director, Department of Occupational Medicine, Danish National Institute of Occupational Health
1982-	Professor of Environmental Medicine, Odense University
1983-2017	Consultant in Toxicology, Danish Health Authority
1994-2002	Adjunct Professor of Public Health (Environmental Health) and Neurology, Boston University School of Medicine, Boston
2003-	Adjunct Professor of Environmental Health, Harvard T.H. Chan School Public Health, Boston

Awards and honors
Prize essay in medicine, University of Copenhagen (1972)
Fulbright senior research scholarship (1978)
Keynote speaker, Odense University anniversary (1983)
Gitlitz Memorial Lecture, Association of Clinical Scientists, USA (1985)

Fellow, Collegium Ramazzini (1987)
Knight of the Dannebrog, awarded by the Queen of Denmark (1990)
The Dannin prize for medical research (1991)
Fellow, American Association for the Advancement of Science (1994)
Irish Congress Lecturer, Royal College of Physicians of Ireland and Irish Society of Toxicology (1996)
Knight of the Dannebrog, First Degree, awarded by the Queen of Denmark (2003)
'Mercury madness award' for excellence in science in the public interest from eight US environmental organizations (2004)
Emeritus Fellow, International Union of Pure and Applied Chemistry, IUPAC (2009)
Honorary Research Award, International Order of Odd Fellows (2010)
Science Communication Award, University of Southern Denmark (2012)
Bernardino Ramazzini Award (2015)
Basic & Clinical Pharmacology & Toxicology Nordic Award (2015)
Margrethegaarden honorary prize (2016)
John R. Goldsmith Award, International Society for Environmental Epidemiology (2016)

<u>Editorial boards</u>

American Journal of Industrial Medicine (1987-2017)
Applied Organometal Chemistry (1985-1991)
Arbejdsmiljø (Occupational Environment, in Danish, 1983-1990)
Archives of Environmental Health (European Editor, 1986-1992)
Archives of Toxicology (1987-)
Biomarkers (1996-2001)
Central European Journal of Occupational and Environmental Medicine (2015-)
Critical Reviews in Toxicology (1985-2012)
Danish Medical Bulletin (1994-2003)
Environmental Health (Editor-in-Chief, 2002-)
Environmental Health Perspectives (2003-)
Environmental Research (1981-1994 and 2014-2017, Associate Editor, 1995-2014)
Industrial Health (2000-2005)
International Journal of Hygiene and Environmental Health (2001-)
International Journal of Occupational and Environmental Health (1994-2011)
International Journal of Occupational Medicine & Environ Health (1991-
Journal of Clean Technology, Environmental Toxicology, and Occupational Medicine (1992-1998)
Journal of Environmental Medicine (1998-1999)
Naturens Verden (Natural Science, in Danish) (1987-1991)
Ugeskrift for Læger (Danish Medical Journal, in Danish) (1991-2007)

<u>Scientific societies</u>

American Association for the Advancement of Science (Fellow, 1994)
American Public Health Association
Collegium Ramazzini (Fellow, 1987; Member of the Council, 2005-2013)
Danish Medical Association

Danish Societies of Clinical Chemistry, Epidemiology, Occupational and Environmental Medicine, and Public Health
Faroese Society of Science and Letters
International Society for Environmental Epidemiology

Teaching experience

Professor of Environmental Medicine, Odense University (University of Southern Denmark) (1982-). Member of curriculum committee. Coordinator, Global Health class.
Adjunct Professor of Public Health (Environmental Health) and Neurology, Boston University School of Medicine, Boston (1994-2002)
Adjunct Professor of Environmental Health, Harvard T.H.Chan School of Public Health, Boston (2003-)
Invited teacher, École des hautes études en santé publique (EHESP, French school of public health) (2009-)
International: Numerous teaching assignments, including guest lectures at universities and related tasks, e.g. as external examiner, National University of Singapore (1995). External evaluator of PhD theses from other universities, including University of Sydney and University of South Pacific (Fiji).

Research support as Principal Investigator since 2000

2000-2006 NIEHS
Mercury associated neurobehavioral deficit in children
2001-2003 Nordic Arctic Research Programme (NARP)
Changing patterns of biomagnified pollutants in the northern marine environment
2001-2004 Danish Medical Research Council
Exposure assessment for endocrine disruptors
2002-2004 Danish Medical Research Council
Environmental epidemiology research
2003-2004 European Commission
Assessment of Neurobehavioral Endpoints and Markers of Neurotoxicant Exposures (ANEMONE)
2003-2005 Danish Medical Research Council
Research in hormone related substances
2003-2006 NIEHS ES11687
Effects of perinatal disruptors in children
2003-2007 EPA STAR RD-83075801-0
Children's vulnerability to environmental immunotoxicant
2004-2011 NIEHS ES12199
Epidemiology of immunotoxicant exposure in children
2006-2011 NIEHS ES13692
Health effects of lifetime exposure to food contaminants
2006-2012 NIEHS ES14460
Three-generation human study of reproductive effects of marine food contaminants
2008-2012 Danish Council for Strategic Research
Environmental pollutant impact on antibody production against current and new childhood vaccines
2007-2013 NIEHS ES009797

Mercury associated neurobehavioral deficit in children
2011-2017 NIEHS ES012199
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Immunotoxity in Humans with Lifetime Exposure to Ocean Pollutants
2013-2019 NIEHS ES021477
Glucose Metabolism in Adults Prenatally Exposed to Diabetogenic Pollutants
2013-2018 NIEHS ES021372
Pollutant-related diabetes in the Nurses' Health Study II
2014-2020 NIEHS ES023376
Gut Microbiome in Adults with Early Life Exposures to Environmental Chemicals

Major Current Funding as Principal Investigator

2017-2020 NIEHS ES026596
Inflammation and metabolic abnormalities in pollutant-exposed children
2017-2022 NIEHS P42ES027706
Sources, Transport, Exposure and Effects of PFASs (STEEP)
2019-2024 ATSDR TS000313
Assessment of PFAS exposures and health effects in two Massachusetts communities with PFAS drinking water contamination
2019-2023 NIEHS ES030394
Vulnerability During Infancy to Immunotoxic Contaminant Exposures

Major committees, boards and elective offices

Danish:

Danish Medical Association: Member, Prevention Council (2011-2014)
Danish Medical Research Council: Consultant on environmental medicine (1985-1990); Member, Joint Research Council Committee on Environmental Research (1986-1991); Member of DMRC (1992-1998)
Danish Society of Community Medicine: Secretary (1977-1978)
Danish Society of Industrial Medicine: Board Member (1974-1983)
Ministry of Education: Member, Committee on Toxicology (1984-1986); Member, Committee on Environmental Education (1986-1987)
Ministry of the Environment: Member, Council on Environmental Chemicals (1983-1989); Member, Environmental Appeal Board (1986-2010); Member, Environmental Research Council (1990-1992); Member, Advisory Committee on Pesticide Research (1995-2004 and 2018-2020); Member, Advisory Committee on Arctic Research (1996-2004)
Ministry of Health: numerous committee appointments; Chair, Committee on Risk Perception (2000-2001)
Ministry of Labour: Consultant on Occupational Health, Council on Occupational Safety and Health (1983-1993); Member, Occupational Health Council Research Committee (on behalf of the Danish Medical Research Council) (1984-1990 and 1999-2003)
Ministry of Research: Chair, Committee on Research at the Faroe Islands (1995-1996); Member, Committee on Scientific Dishonesty (2004-2006); Chair, Program Committee on Non-Ionizing Radiation (2004-2009)
Odense University (from 2000 University of Southern Denmark), elected

offices: Chairman, Institute of Community Health (1982-1985; 1996-1999); Member of Executive Committee, Institute of Community Health (from 2000 Institute of Public Health) (1986-1995; 2000-2005); Member, Faculty Research Committee (1983-1985); Member, Curriculum Committee (1984-1986); Member, Faculty Council (1985-1993); Vice-Dean (1991-1993); Member, Scientific Integrity Committee (2003-2022)

United States and international:

Academy of Finland: member of panel evaluating the National Institute of Public Health (1995), site visit of center of excellence (2001)

Agency for Toxic Substances and Disease Registry: Workshop Rapporteur, Neurobehavioral Test Batteries for Use in Environmental Health Field Studies (1992); Member, Expert Panel of Mercury (1998)

Association of Schools of Public Health in the European Region: Treasurer (1975-1977)

BioMedCentral: Member, Editors Advisory Group (2011-2013)

Boston Environmental Hazards Center: Consultant (1994-1999)

Collegium Ramazzini: President, International Conference, The precautionary principle: Implications for research and prevention in environmental and occupational health (2002); Member, Executive Council (2005-2013)

Commission of the European Communities: National Expert, Working Party on Environmental and Lifestyle-Related Diseases (1988-1990); ad hoc Consultant for evaluation of research applications; ad hoc Scientific Advisor on Risk Assessment (2009-); Member, Scientific Committee on Emerging and Newly Identified Health Risks; – Working group on Dental Amalgam (Human Health)(2012-2013)

European Environment Agency: Member, Scientific Committee (2012-2020)

European Food Safety Authority: Member, Panel on Contaminants in the Food Chain responsible for 85 opinions (2003-2009); Member of Working Groups on mercury, polychlorinated biphenyls, cadmium, lead, and benchmark dose

Food Advisory Committee, U.S.FDA, Methylmercury: invited expert (2002)

INMA (Infancia y Medio Ambiente), Spain: Member, Project Steering Committee (2010-)

Institut de Recherche Santé, Environnement et Travail, France: Member, Board of Advisers (2015-)

International Agency for Research on Cancer: Member of Task Group, Monographs on the Evaluation of Carcinogenic Risks to Humans, Vol. 47 (1988), Vol. 49 (1989), as chairman, Vol. 58 (1993), and as Subgroup chair, Vol. 100C (2009)

International Commission on Occupational Health: Danish Delegation Secretary (1982-90); Member, Scientific Committee on the Toxicology of Metals (1987-); Member of the Board (1990-1996)

International Programme on Chemical Safety: Member of Task Group, Environmental Health Criteria, Vol. 36 (1984) and 72 (1986)

International Society for Environmental Epidemiology: Councillor (1991-1994)

International Union of Pure and Applied Chemistry: Member, Subcommittee on the Toxicology of Nickel (1979-1989); Titular

Member (1985-1991) and Chairman (1987-1991), Commission on Toxicology; Chairman, Subcommittee on Risk Assessment (1985-1989)
Instituto de Saude Ambiental, Lisboa, Portugal: Member, External Advisory Committee (2018-2020)
Karolinska Institute (Stockholm, Sweden): Member of international evaluation panel on environmental medicine (1993)
Ministry for Scientific Policy (Belgium): Consultant on national research program on health hazards (1990 and 1994)
National Institutes of Health (USA): Member of Special emphasis panels (2009-)
NATO Priority Area Panel on Environmental Security: Member (1996-1997)
Norwegian Research Council: ad hoc reviewer (2001-2008); Chairman of Environment and Health Review Group (2009-2010); member of steering committee (2011-2015)
Prenatal Programming and Toxicity (PPTOX) conferences: Organizer/ Chair/Co-chair, Torshavn (2007), Miami (2009), Paris (2012), Boston (2014), Kita-Kyushu (2016), Torshavn (2018)
Society of Occupational and Environmental Health: Member, Governing Council (1990-1993)
Swedish Council for Work Life Research: Member, Priority Committee on Chemical Health Risks (1997-1998)
U.N.Environment Programme: Member, Global Mercury Assessment Working Group (2002)
U.S. Environmental Protection Agency: Member, SAB/SAP Endocrine Disruptor Screening Program Subcommittee (1998-1999); Member, Food Quality Protection Act (FQPA) Science Review Board (SRB)(1999-2003)
White House Office of Science and Technology Policy: Team leader and presenter, Workshop on Scientific Issues Relevant to Assessment of Health Effects from Exposure to Methylmercury (1998)
World Health Organization: Temporary Adviser or Consultant on several occasions, five times elected Rapporteur; Member, European Advisory Committee on Health Research (2011-2017)

Books

1. Grandjean P, ed. Standards setting. Copenhagen: Occupational Health Foundation, 1977, 210 pp.
2. Grandjean P, Nielsen T. Organiske blyforbindelser, forurening og toksikologi (Organolead compounds, pollution and toxicology, in Danish). Report No. SNV PM 879. Stockholm: Naturvårdsverket, 1977, 78 pp.
3. Grandjean P. Occupational health aspects of construction work. EURO Reports and Studies 86. Copenhagen: World Health Organization, Regional Office for Europe, 1983, 28 pp. (also published in German, French and Russian)
4. Grandjean P, ed. Biological effects of organolead compounds. Boca Raton, FL: CRC Press, 1984, 278 pp.
5. Grandjean P, Tarkowski S, eds. Toxic oil syndrome: mass food poisoning in Spain. Copenhagen: World Health Organization, Regional Office for Europe, 1984, 92 pp. (also published in Spanish)
6. Grandjean P. Miljø og forebyggelse. (Environment and prevention, student's guide in Danish). Copenhagen: F.a.d.L.'s Forlag, 1984, 109 pp.
7. Gilioli R, Grandjean P, Johnson B, Seppäläinen AM, Tarkowski S, eds. Neurobehavioural methods in occupational and environmental health. Environmental Health No. 3. Copenhagen: World Health Organization, Regional Office for Europe, 1985, 209 pp.
8. Grandjean P, ed. Neurobehavioural methods in occupational and environmental health. Environmental Health No. 6. Copenhagen: World Health Organization, Regional Office for Europe, 1985, 72 pp.
9. Grandjean P, ed. Miljømedicin (Environmental medicine, textbook in Danish). Copenhagen: F.a.d.L.'s Forlag, 1986, 257 pp.
10. Grandjean P, ed. Trace elements in human health and disease: extended abstracts. Environmental Health No. 20. Copenhagen: World Health Organization, Regional Office for Europe, 1987, 230 pp.
11. Grandjean P, ed. Trace elements in human health and disease: symposium report. Environmental Health No. 26. Copenhagen: World Health Organization, Regional Office for Europe, 1987, 134 pp.
12. Grandjean P, Kimbrough RD, Rantanen J, Tarkowski S, Yrjänheikki E. Assessment of health risks in infants associated with exposure to PCBs, PCDDs and PCDFs in breast milk. Environmental Health No. 29. Copenhagen: World Health Organization, Regional Office for Europe, 1988, 116 pp.
13. Grandjean P, ed. Miljømedicin, 2. udg. (Environmental medicine, 2nd ed., textbook in Danish). Copenhagen: F.a.d.L.'s Forlag, 1988, 311 pp.
14. Kimbrough RD, Mahaffey KR, Grandjean P, Sandø SH, Ruttstein DD. Clinical Effects of Environmental Chemicals: A Software Approach to Etiologic Diagnosis. New York: Hemisphere, 1989, 110 pp. and one floppy disk.
15. Grandjean P. Skin Penetration: Hazardous Chemicals at Work. (Published on behalf of the Commission of the European Communities.) London: Taylor and Francis, 1990, 187 pp.
16. Grandjean P, ed. Ecogenetics: Genetic Predisposition to Toxic

Effects of Chemicals. London: Chapman & Hall, 1991, 288 pp.
17. Grandjean P, ed. Miljø, sundhed og samfund (Environment, health and society, in Danish). Copenhagen: Nyt Nordisk Forlag, 1991, 453 pp.
18. Grandjean P, Brown SS, Reavey P, Young DS, Rej R (eds). Biomarkers of Chemical Exposure. Proceedings of the Arnold O. Beckman/IFCC European Conference on Environmental Toxicology. Clin Chem 1994; 40 (issue 7B).
19. Toppari J, Larsen JC, Christiansen P, Giwercman A, Grandjean P, Guillette LJ, Jr, Jégou B, Jensen TK, Jouannet P, Keiding N, Leffers H, McLachlan JA, Meyer O, Müller J, Rajper-DeMeyts E, Scheike T, Sumpter J, Skakkebaek N. Male reproductive health and environmental chemicals with estrogenic effects. Copenhagen: Danish Environmental Protection Agency, 1995, 166 pp.
20. Grandjean P, Brown SS, Reavey P, Young DS, Sampson E (eds). Biomarkers. Proceedings of the Second Arnold O. Beckman/IFCC European Conference on Environmental Toxicology. Clin Chem 1995; 41 (issue 12B).
21. Grandjean P. Farlig forurening (Dangerous pollution, in Danish). Copenhagen: Nyt Nordisk Forlag and National Board of Health, 1998, 174 pp.
22. Grandjean P ed. Human health effects of environmental mercury exposure (special issue). Environ Res 1998; 77 (67-177).
23. Grandjean P, Sofritti M, Minardi F, Brazier J (eds). The Precautionary Principle. Implications for research and prevention in environmental and occupational health. Eur J Oncol Library 2003; 2: 1-245. Also published in Int J Occup Med Environ Health 2004; 17: 3-201.
24. Grandjean P (ed). Prenatal programming and toxicity. Basic Clin Pharmacol Toxicol. 2008; 102(2): 71-273.
25. Gee D, Grandjean P, Hansen SF, van den Hove S, MacGarvin M, Martin J, Nielsen G, Quist D, Stanners D, eds. Late Lessons from Early Warnings, volume II (EEA Report No 1/2013). Copenhagen, European Environment Agency, 2013, 746 pp.
26. Grandjean P. Only one chance. How Environmental Pollution Impairs Brain Development – and How to Protect the Brains of the Next Generation. New York: Oxford University Press, 2013 (232 pp.).
27. Grandjean P, Hermann P. Kemi på hjernen – går ud over enhver forstand. København: Gyldendal, 2015 (334 sider).
28. Grandjean P. Cerveaux en danger (Brains in danger, in French). Translated by Odile Demange. Paris: Buchet Chastel, 2016 (336 pp.).
29. Kishi R, Grandjean P, eds. Health Impacts of Developmental Exposure to Environmental Chemicals. Singapore: Springer, 2020 (555 pp.)

Publications in international peer-reviewed journals

1. Grandjean P, Holma B. A history of lead retention in the Danish population. Environ Biochem Physiol 1973; 3: 268-73.
2. Grandjean P. Lead in Danes, historical and toxicological studies. Environ Qual Saf 1975; Suppl. Vol. 2: 6-75.
3. Grandjean P. Possible effect of lead on egg-shell thickness in kestrels 1874-1974. Bull Environ Contam Toxicol 1976; 16: 101-6.
4. Grandjean P. Regional distribution of lead in human brains. Toxicol Lett 1978; 2: 65-9.
5. Nielsen T, Jensen KA, Grandjean P. Organic lead in normal human brains. Nature (Lond.) 1978; 274: 602-3.
6. Grandjean P. Lead concentration in single hairs as a monitor of occupational lead exposure. Int Arch Occup Environ Health 1978; 42: 69-81.
7. Grandjean P, Lintrup J. Erythrocyte-Zn-protoporphyrin as an indicator of lead exposure. Scand J Clin Lab Invest 1978; 38: 669-75.
8. Grandjean P, Arnvig E, Beckmann J. Psychological dysfunctions of lead-exposed workers: Relation to biological parameters of exposure. Scand J Work Environ Health 1978; 4: 295-303.
9. Grandjean P. Widening perspectives of lead toxicity, a review of health effects of lead exposure in adults. Environ Res 1978; 17: 303-21. (Also published as a special report to the U.S. National Institute of Environmental Health Sciences)
10. Grandjean P. Occupational lead exposure in Denmark: Screening with the haematofluorometer. Br J Ind Med 1979; 36: 52-8.
11. Grandjean P, Nielsen OV, Shapiro IM. Lead retention in ancient Nubian and contemporary populations. J Environ Path Toxicol 1979; 2: 781-7.
12. Grandjean P, Nielsen T. Organolead compounds, environmental health aspects. Residue Rev 1979; 72: 97-148.
13. Arnvig E, Grandjean P, Beckmann J. Neuropsychological effect of heavy lead exposure determined with psychological tests. Toxicol Lett 1980; 5: 399-404.
14. Hertz MM, Bolwig TG, Grandjean P, Westergaard E. Lead poisoning and the blood-brain barrier. Acta Neurol Scand 1981; 63: 286-96.
15. Grandjean P, Selikoff IJ, Shen SK, Sundermann FW Jr. Nickel concentrations in plasma and urine of shipyard workers. Am J Ind Med 1981; 1: 181-9.
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19. Grandjean P, Lintrup J. Sources of variation in fluorometry of zinc-protoporphyrin in blood. Scand J Work Environ Health 1981; 7: 311-2.
20. Grandjean P, Olsen NB, Hollnagel H. Occupationally related lead exposure in the general population. Scand J Work Environ Health 1981;

7: 298-301.
21. Grandjean P. Occupational fluorosis through 50 years: clinical and epidemiological experiences. Am J Ind Med 1982; 3: 227-36.
22. Nielsen OV, Grandjean P, Bennike P. Chemical analyses of archaeological bone samples: Evidence for high lead exposure on the Faroe Islands. J Dan Archaeol 1982; 2: 145-8. (also published in Faroese: Blyggj i føroyingum, Mondul 1983; 9: 27-31)
23. Grandjean P. Storage depots in the body: Passive retention or time bomb? (Editorial) Am J Ind Med 1983; 4: 489-90.
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25. Grandjean P, Thomsen G. Reversibility of skeletal fluorosis. Br J Ind Med 1983; 40: 456-61.
26. Grandjean P. Lead poisoning: Hair analysis shows the calendar of events. Hum Toxicol 1984; 3: 223-8.
27. Grandjean P, Hansen ON, Lyngbye K. Analysis of lead in circum-pulpal dentin of deciduous teeth. Ann Clin Lab Sci 1984; 14:270-5.
28. Eskildsen J, Grandjean P. Lead exposure from lead pellets: Age-related accumulation in mute swans. Toxicol Lett 1984; 21: 225-9.
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31. Grandjean P. Reference intervals for toxic metals: Problems and prospects. Ann Clin Lab Sci 1986; 16: 67-74.
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38. Grandjean P, Berlin A, Gilbert M, Penning W. Preventing percutaneous absorption of industrial chemicals: The "skin" denotation. Am J Ind Med 1988; 14: 97-107.
39. Lyngbye T, Hansen ON, Grandjean P. Bias resulting from non-participation in childhood epidemiological studies: A study of low-level lead exposure. Scand J Soc Med 1988; 16: 209-15.

40. Grandjean P. Ancient skeletons as silent witnesses of lead exposures in the past. CRC Crit Rev Toxicol 1988; 19:11-21.
41. Madsen HHT, Skjødt T, Jørgensen PJ, Grandjean P. Blood lead levels in patients with lead shot retained in the appendix. Acta Radiol 1988; 29: 745-6.
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43. Lyngbye T, Hansen ON, Grandjean P. Neurological deficits in children: Medical risk factors and lead exposure. Neurotoxicol Teratol 1989; 10: 531-7.
44. Grandjean P, Hollnagel H, Hedegaard L, Christensen JM, Larsen S. Blood lead-blood pressure relationships: Alcohol intake and hemoglobin as confounders. Am J Epidemiol 1989; 129: 732-9.
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46. Grandjean P, Jensen BM, Sandø SH, Jørgensen PJ, Antonsen S. Delayed blood regeneration in lead exposure: An effect on reserve capacity. Am J Publ Health 1989; 79: 1385-8.
47. Grandjean P. Bone analysis: Silent testimony of lead exposures in the past. Medd Grønland Man Soc 1989; 12: 156-60.
48. Grandjean P, Hørder M, Thomassen Y. Fluoride, aluminum and phosphate kinetics in cryolite workers. J Occup Med 1990;32:58-63.
49. Grandjean P, Kristensen K, Jørgensen PJ, Nielsen GD, Andersen O. Trace element status in alcoholism before and during disulfiram treatment. Ann Clin Lab Sci 1990; 20: 28-35.
50. Nielsen GD, Jepsen LV, Jørgensen PJ, Grandjean P, Brandrup F. Nickel-sensitive patients with vesicular hand eczema: Oral challenge with a diet naturally high in nickel. Br J Dermatol 1990; 122: 299-308.
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64. Grandjean P, Nielsen GD, Jørgensen PJ, Hørder M. Reference intervals for trace elements in blood: Significance of risk factors. Scand J Clin Lab Invest 1992; 52: 321-337.
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intrauterine and postnatal exposures. Clin Chem 1994; 40: 1395-1400.
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