Veronica Manfredi, Esquire, Director Quality of Life DG Environment European Commission

26 September 2022

Dear Director Manfredi,

The World Alliance for Mercury-Free Dentistry and our European Network are grateful to the European Commission for bringing Europe to the cusp of mercury-free dentistry. On behalf of the children of the world, we express our gratitude to the Commission for being the co-leader with the Africa region in enshrining into the Minamata Convention on Mercury, at its COP4, the Children's Amendment to the amalgam reduction mandate.

The three-part framework for action should mean that the arrival of mercury-free dentistry in Europe is imminent . . . that mercury-free dentistry must come to the European Union in three years, in 2025 . . . and that *further delays* are no longer acceptable.

First, The Commission, as required by law, formally made its recommendation in 2020—that recommendation being that Europe phase out amalgam. The decision is made!

The mercury law required the Commission to make its former recommendation to Parliament and the Council in 2020 to phase out amalgam. Thus, the Commission, in its seminal "Report from the Commission to the European Parliament and the Council on the reviews required under Article 19 (1) of Regulation 2017/852 on the use of mercury in dental amalgam and products," https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52020DC0378&rid=1, made the recommendation to phase out amalgam:

"The review undertaken makes clear that the phase out of the largest remaining use of mercury in the EU - dental amalgam - is technically and economically feasible."

Second, The Commission advised Parliament that it will complete its work and submit its legislation to Parliament and the Council in 2022—this year. Hence, in the 4th quarter of 2022, it is time to prepare submit the legislation!

In that 2020 report, the Commission advised Parliament and advised the Council that its legislation would be forthcoming in 2022, this year:

"Therefore, the Commission will present to the European Parliament and the Council in 2022 a legislative proposal to phase out the use of dental amalgam."

Third, All stakeholders are on board for mercury-free dentistry—save a shrinking cadre of societal irresponsible dentists who choose not to get training but to remain as Europe's leading mercury polluter and have decided to lobby for delay, delay, delay. Consumers favor mercury-free dentistry by over 90%. Dentists who recognize their societal duty to do minimally-invasive and non-polluting dentistry—by far the majority these days—want amalgam gone. Dental products companies are rapidly exiting making amalgam not only because of decreased consumer demand but because the E.U. device law will not allow them to stay much longer, and are switching to clean technologies. One Member State after another has adopted plans to decrease amalgam use dramatically or to phase it out altogether. Poland, once a major amalgam user, is a pioneer in mercury-free dentistry; amalgam is gone from its public programs. France metropolitan is slow, but has no excuse: its Pacific territory Nouvelle-Calédonie is entirely mercury-free. Almost all the other Member States have phase out plans in full or phase out plans for an expanding number of consumers beyond the current E.U. minimum.

Thus the "final workshop"—run by consultants who did not reference any of this framework—proved to be a major disappointment. **The consultants re-opened the door on one matter after another which had long ago been resolved**—by SCENIHR, by SCHER, by the Mercury Regulation, by the Commission itself:

No, big cavities do not need amalgam—else Sweden, Moldova, Italy, Slovakia, Netherland, Norway, Nepal, Mongolia, Japan, Philippines, Nepal, Tanzania, St. Kitts and Nevis, etc.—could not phase it out . .

. No, countries composed majority of Black and Brown persons do not need amalgam exports for their health—the Commission will lose face atrociously with its African allies if, after acting to end amalgam worldwide for children and many young women, it proclaims that amalgam exports would continue to Africa for such people's "health"! . . . No, training of dentists is not needed; they have had a decade to get ready; any dentist not able to do mercury-free dentistry is either lazy or incompetent—and in any case, the role of the E.U. is not to delay pollution rules and wait for dentists who are playing chicken with the consultants by **intentionally staying trained** . . . No, delay is not needed to determine safety of the alternatives, because they have been adjudged safe repeatedly, including by SCENIR—by contrast, amalgam is not considered safe for vulnerable populations by the U.S. Food and Drug Administration, who in its 2020 Safety Recommendations called for the end of amalgam use in children, in most young women, and in those with kidney or neurological conditions because of the enormous health risks of implanting mercury in the mouth . . . No, a campaign to urge consumers to brush their teeth does not relieve dentists of their duty—it is outrageous that the pro-mercury dental lobby absolves itself of responsibility for its role as Europe's leading mercury polluter by blaming children who do not brush their teeth or adults who eat a candy bar . . . No, separators do not catch even half of the mercury—because most of it walks out of the office implanted in human beings and from there into the environment.

Director Manfredi, civil society is baffled that these consultants are so solicitous of the mercury lobby, the evershrinking old guard of dentistry which refuses to look itself in the mirror to recognize itself as Europe's #1 mercury polluter . . . which refuses to get training that thousands and thousands of dentists got . . . which spends its money lobbying for mercury instead of urging dentists to transition . . . which refuses to pay for the millions and millions of Euros of damages they cause—to the fisherfolk denied the right to earn a living because of dentist polluters, to the undertakers who must buy equipment because dentists implant mercury, to the landlords stuck with mercury clean-up after renting to dentists, onto Member State governments who must pay for clean-up in water systems, and, most tragically, onto parents who see their children brain-damaged by mercury in the fish.

Why do the Commission consultants give such credibility to this self-interested lobby group rehashing already resolved matters about this primitive pollutant from the Garibaldi-Bismarck-Victoria-Czar Alexander era to delay the end of this unnecessary pollution?

The Commission must insist that the consultants finish this year. If the Commission allows the consultant to rehash already-answered question ad infinitum, then the Commission misses the deadline it imposed to submit the legislation this year.

In sum, the astounding and unauthorized announcement by the consultants, at the opening of the workshop, that Europe will not go mercury-free in 2025, or even 2026, is not acceptable. The Commission (not the consultants) decided the end date.

Europe is ready. The end date for the end of amalgam in Europe must be 1 January or 1 July or 31 December 2025. The price of continuing this unnecessary pollution after 2025—a cave-in to the pro-mercury lobby—will ruin lives and cost Euros into the decades of the 2030s, 2040s, and 2050s; it is time to act on behalf of the future of Europe and Europeans.

Below is an annex responding to questions raised by consultants, all of which have previously been addressed and answered by authoritative sources over the past decade.

Sincerely yours,

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Dr. Mihaela Cutui, Timiș College of Dentists, Romania

Charlie Brown, World Alliance for Mercury-Free Dentistry

Sylvia Dove, Consumers for Dental Choice, USA

cc---Aneta Willems, David Grimaud, Jenny Green.

ANNEX: REPLY TO QUESTIONS ALREADY ANSWERED

- Mercury-free alternatives have been proven safe: The consultants' presentation suggested that mercury-free alternatives to amalgam might not be safe despite more than half a century of research and experience to the contrary.[i] As the European Commission's own Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) explained, "Alternative materials have now been in clinical use for more than thirty years, initially in anterior teeth and later also for restorations in posterior teeth. This clinical use has revealed little evidence of clinically significant adverse events... There is no evidence that infants or children are at risk of adverse effects arising from the use of alternatives to dental amalgam."[ii] This conclusion is supported by multiple studies. [iii], [iv], [v] Current government safety regulations are highly capable of vetting new mercury-free dental materials a regulatory scrutiny that amalgam never faced when it came onto the market more than a century ago and its use continued under "grandfather" clauses that excuse older products from meeting current regulatory standards (or any standards at all).
- "Dental health improvement communication campaigns" do not reduce amalgam: The consultants' presentation reintroduces the pointless policy option of "Dental health improvement communication campaigns" a measure that has not even effectively reduced (much less phased out) amalgam use anywhere in the world. Higher-income countries that already have dental health improvement communication campaigns have been among the top amalgam users as the United Nations Environmental Programme noted: "In fact, amalgam use in higher income countries remains a prime target for phase down, with 124 metric tons of mercury consumed for dental applications in the European Union and North America in 2010 alone."[vi] As the World Health Organization concludes, "Despite much effort in health promotion and disease prevention, dental restorations are still needed to re-establish tooth function."[vii]
- "Decreasing the price difference" requires phasing out amalgam: The consultants' presentation raised the policy option of "Decreas[ing] the price difference between dental amalgam and mercury-free alternatives due to social security coverage." Phasing out amalgam use by 2025 is the impetus needed to reform social security coverage of mercury-free alternatives and expose the true costs of amalgam. Already mercury-free fillings are more cost-effective because they are easier (hence, less expensive) to repair than amalgam[viii], can be used in atraumatic restorative treatment (which costs only half as much as amalgam)[ix], and do not have the high environment costs of amalgam.[x], [xi]

As the European Commission has noted,

"[W]ithout legislative action, significant amounts of dental amalgam are still expected to be used in the coming years. This would prolong the associated environmental and health issues associated with the current use of dental amalgam, including significant emissions of mercury to air."[xii]

Every year the European Union does not phase out amalgam, the problem multiplies as more and more people are exposed to the environmental harms and health risks of amalgam use. The phase out of amalgam use is more critical now than ever in the age of COVID because mercury-free techniques like atraumatic restorative treatment (ART, which relies on glass ionomer fillings) can help reduce transmission of illness, as WHO has recognized: "ART also does not generate aerosols, which is particularly beneficial when there is concern about possible airborne transmission of illness, such as during the COVID-19 pandemic."[xiii]

- [i] Jack L Ferracane, Resin composite--state of the art, Dental Materials, Vol.27, issue 1, p.29-38 (Jan. 2011), http://www.ppgo.ufma.br/uploads/files/Dental%20materials%20official%20publication%20of%20the%20Academy%20off%20Dental%20Materials%202010%20FerracaneResin%20composite-State%20off%20the%20art.pdf
- [ii] European Commission Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR), Final opinion on the safety of dental amalgam and alternative dental restoration materials for patients and users (29 April
- 2015), http://ec.europa.eu/health/scientific_committees/emerging/docs/scenihr_o_046.pdf, pp.73,74 [iii] Health Care Research Collaborative of the University of Illinois at Chicago School of Public Health, the Healthier Hospitals Initiative, and Health Care Without Harm, Mercury in Dental Amalgam and Resin-Based Alternatives: A Comparative Health Risk Evaluation (June
- $2012), \\ \underline{https://www.wfpha.org/tl_files/images/Newsletter\%202012/July/Res\%20Colab\%20Amalgam\%20Risk\%20Final.pdf p.6}$

[iv] Yin et. al., Associations of blood mercury, inorganic mercury, methylmercury and bisphenol A with dental surface restorations in the U.S. population, NHANES 2003–2004 and 2010–2012, Ecotoxicity and Environmental Safety (2016), https://www.ncbi.nlm.nih.gov/pubmed/27639196

[v] KEMI, Bisfenol A

(2/11), http://www.kemi.se/Documents/Publikationer/Trycksaker/Rapporter/Rapport2_11_BisfenolA.pdf, page 9 [vi] UNEP, Lessons from Countries Phasing Down Dental Amalgam

Use (2016), https://wedocs.unep.org/bitstream/handle/20.500.11822/31212/Dental.pdf?sequence=1&isAllowed="y">https://wedocs.unep.org/bitstream/handle/20.500.11822/31212/Dental.pdf?sequence=1&isAllowed="y">https://wedocs.unep.org/bitstream/handle/20.500.11822/31212/Dental.pdf?sequence=1&isAllowed="y">https://wedocs.unep.org/bitstream/handle/20.500.11822/31212/Dental.pdf?sequence=1&isAllowed="y">https://wedocs.unep.org/bitstream/handle/20.500.11822/31212/Dental.pdf?sequence=1&isAllowed="y">https://wedocs.unep.org/bitstream/handle/20.500.11822/31212/Dental.pdf?sequence=1&isAllowed="y">https://wedocs.unep.org/bitstream/handle/20.500.11822/31212/Dental.pdf?sequence=1&isAllowed="y">https://wedocs.unep.org/bitstream/handle/20.500.11822/31212/Dental.pdf?sequence=1&isAllowed="y">https://wedocs.unep.org/bitstream/handle/20.500.11822/31212/Dental.pdf?sequence=1&isAllowed="y">https://wedocs.unep.org/bitstream/handle/20.500.11822/31212/Dental.pdf?sequence=1&isAllowed="y">https://wedocs.unep.org/bitstream/handle/20.500.11822/31212/Dental.pdf?sequence=1&isAllowed="y">https://wedocs.unep.org/bitstream/handle/20.500.11822/31212/Dental.pdf?sequence=1&isAllowed="y">https://wedocs.unep.org/bitstream/handle/20.500.11822/31212/Dental.pdf?sequence=1&isAllowed="y">https://www.handle/20.500.11822/31212/Dental.pdf?sequence=1&isAllowed="y">https://www.handle/20.500.11822/31212/Dental.pdf?sequence=1&isAllowed="y">https://www.handle/20.500.11822/31212/Dental.pdf?sequence=1&isAllowed="y">https://www.handle/20.500.11822/31212/Dental.pdf?sequence=1&isAllowed="y">https://www.handle/20.500.11822/31212/Dental.pdf?sequence=1&isAllowed="y">https://www.handle/20.500.11822/31212/Dental.pdf?sequence=1&isAllowed="y">https://www.handle/20.500.11822/31212/Dental.pdf

[vii]Future Use of Materials for Dental

Restoration, WHO (2011), http://www.who.int/oral_health/publications/dental_material_2011.pdf
[viii] Niek J.M. Opdam, Longevity of repaired restorations: A practice based study, Journal of Dentistry 40 (2012) 829 –

835, https://www.researchgate.net/profile/Niek Opdam/publication/228441700 Longevity of repaired restorations A practice based study/links/0c96052766a325245a000000.pdf

[ix] Pan American Health Organization, Oral Health of Low Income Children: Procedures for Atraumatic Restorative Treatment

(PRAT) (2006), http://new.paho.org/hq/dmdocuments/2009/OH top PT low06.pdf ("The costs of employing the PRAT [procedures for atraumatic restorative treatment] approach for dental caries treatment, including retreatment, are roughly half the cost of amalgam without retreatment.").

[x]Concorde East/West, The Real Cost of Dental Mercury (March

2012), http://www.zeromercury.org/index.php?option=com-phocadownload&view=file&id=158%3Athe-real-cost-of-dental-mercury&Itemid=70, pp.3-4

[xi] Lars D. Hylander & Michael E. Goodsite, Environmental Costs of Mercury Pollution, Science of the Total Environment 368 (2006) 352-

 $370, \underline{\text{http://www.aikencolon.com/assets/images/pdfs/Nikro/MercuryVacuum/STOTENbestpaper.pdf}$

[xii] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52020DC0378&rid=1

[xiii] WHO, Prevention and treatment of dental caries with mercury-free products and minimal intervention, https://apps.who.int/iris/bitstream/handle/10665/352480/9789240046184-eng.pdf?sequence=1&isAllowed=y