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June 24, 2017

United States Department of Health & Human Services National Institutes of Health Food & Drug Administration Centers for Disease Control & Prevention 200 Independence Avenue, S.W. Washington, D.C. 20201

Re: Aluminum Adjuvants

Dear Directors:

Faculty of Medicine

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I am writing to you in regard to aluminum adjuvants in vaccines. This subject is one my laboratory works on intensively and therefore one where I feel that I have some expertise. In particular, we have studied the impact of aluminum adjuvants in animal models of neurological disease, including autism spectrum disorder (ASD). Our relevant studies on the general topic of aluminum neurotoxicity in general and specifically in regard to adjuvants are cited below.

These studies and the broader existing literature regarding aluminum toxicity, lead almost invariably to the conclusion that aluminum in any chemical form is always neurotoxic when administered to humans. Further, I am convinced that aluminum adjuvants in vaccines may contribute to neurological disorders across the lifespan. In adults, such adjuvant may induce macrophagic myofasciitis, a disease with neuropathological aspects. In children, there is growing evidence that aluminum adjuvants may disrupt developmental processes in the central nervous system and therefore contribute to ASD in susceptible children.

Despite the foregoing, the safety of aluminum adjuvants in vaccines has not been properly studied in humans even though, pursuant to the recommended vaccine schedule published by the Centers for Disease Control (CDC), a baby may be injected with up to 3,675 micrograms of aluminum adjuvant by six months of age.

In regard to the above, it is my belief that the CDC's claim on its website that "Vaccines Do Not Cause Autism" is wholly unsupported. Given this, I remain convinced that much more research on the role of aluminum adjuvant in vaccines and neurological disorders, including ASD, is warranted and should be a research priority for the NIH and other funding bodies.

Yours sincerely,

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Relevant Publications (Shaw Laboratory)

- 1. Crepeaux G, Eidi H, David MO, Baba-Amer Y, Tzavara E, giros B, authier FJ, Exley C, Shaw CA, Cadusseau J, Gherardi RK. Non-linear dose-response of aluminium hydroxide adjuvant particles: Selective dose neurotoxicity. *Toxicology*. 375:48-57. (2016).
- Crepeaux G, Eidi H, David M-O, Tzavara E, Giros B, Exley C, Curmi PA, Shaw CA, Gherardi RK, Cadusseau J. Highly delayed systemic translocation of aluminium-based adjuvant in CD1 mice following intramuscular injections. *J. Inorg. Biochem.* 152:199-205. (2015).
- 3. Shaw CA, Li D, Tomljenovic L. Are there negative CNS impacts of aluminum adjuvants in vaccines and immunotherapy? *Immunotherapy*. 6 (10):1055-1071. (2014).
- Shaw CA, Seneff S, Kette SD, Tomljenovic L, Oller Jr JW, Davidson RM. Aluminum-induced entropy in biological systems: Implications for neurological disease. *J Toxicology*. Volume 2014, Article ID 491316. (2014).
- 5. Shaw CA, Kette SD, Davidson RM, Seneff S. Aluminum's role in CNS-immune system interactions leading to neurological disorders. *Immunome Res.* 9:1.
- 6. Shaw CA, Marler TE. Aluminum and the human diet revisited. In: Communicative & Integrative Biology; *Landes Bioscience*. 6:e26369. (2013).
- 7. Shaw CA, Tomljenovic L. Aluminum in the central nervous system (CNS): toxicity in humans and animals, vaccine adjuvants, and autoimmunity. *Immunol Res.* (2013).
- 8. Shaw CA, Li Y, Tomljenovic L. Administration of aluminum to neonatal mice in vaccine in vaccine-relevant amounts is associated with adverse long term neurological outcomes. *J Inorg Chem.* (2013).
- 9. Tomljenovic L, Shaw CA. Mechanisms of aluminum adjuvant toxicity and autoimmunity in pediatric populations. *Lupus*. 21:223-230. (2012).
- Tomljenovic L and Shaw CA. Editorial, Special Issue: The Biochemistry/Toxicity of Aluminum. Current Inorganic Chemistry. 2(1): 1-2. (2012).
- 11. Tomljenovic L and Shaw CA. Do aluminum vaccine adjuvants contribute to the rising prevalence of autism? *J Inorg Biochem.* 105(11):1489-99. (2011).
- 12. Tomljenovic L and Shaw CA. Aluminum vaccine adjuvants: Are they safe? *Current Medicinal Chemistry*. 18:2630 2637. (2011).
- 13. Shaw CA and Petrik MS. Aluminum hydroxide injections lead to motor deficits and motor neuron degeneration. *J Inorganic Biochem.* 103 (11): 1555-62. (2009).
- 14. Petrik MS, Wong MC, Tabata RC, Garry RF, and Shaw CA. Aluminum adjuvant linked to Gulf War illness induces motor neuron death in mice. *J Neuromolecular Medicine*. 9: 83-100. (2007).