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SENT VIA EMAIL AND FEDEX

Mark Walderhaug, PhD Associate Office Director Risk Assessment Office at CBER at FDA Room 5270, Mail Stop HFM-210 Silver Spring, MD 20993-0002 Mark.walderhaug@fda.hhs.gov

Re: Daley, et al., Association Between Aluminum Exposure from Vaccines Before Age 24 Months and Persistent Asthma at Age 24 to 59 Months (May 20, 2022)

Dear Dr. Walderhaug:

We write on behalf of Informed Consent Action Network ("ICAN"). Members of Centers of Disease Control and Prevention's Immunization Safety Office recently published a study titled Association Between Aluminum Exposure From Vaccines Before Age 24 Months and Persistent Asthma at Age 24 to 59 Months.¹ The study states that, "a recent report concluded that 'little to none of ingested aluminum appears to be absorbed' through the gastrointestinal tract, and we are unaware of any studies demonstrating an immunologic response to ingested aluminum in humans." It follows, then, that studies concerning ingested aluminum cannot be used to support the safety of injected aluminum. Yet, the studies relied upon to claim that injecting aluminum adjuvant in vaccines is safe rely on studies concerning the safety of ingested aluminum.² ICAN has previously requested studies on the safety of injected aluminum and none could be located.³

Can you please provide the studies you rely upon to support the safety of injected aluminum?

Very truly yours,

Aaron Siri, Esq.

Elizabeth A. Brehm, Esq.

¹ See https://www.sciencedirect.com/science/article/pii/S187628592200417X.

² See https://www.cdc.gov/vaccinesafety/concerns/adjuvants.html

³ See https://www.icandecide.org/wp-content/uploads/2022/10/NIH-Response-to-Studies-of-Safety-of-Injected-Alum.pdf; see also Glanz et al., 2015, Cumulative and episodic vaccine aluminum exposure in a population-based cohort of young children, Vaccine 33:6736–6744, available at https://pubmed.ncbi.nlm.nih.gov/26518400/ (stating, "To date, there have been no population-based studies specifically designed to evaluate associations between clinically meaningful outcomes and non-antigen ingredients, other than thimerosal.).