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Leslie Wagner Consumer Safety Officer Division of Bacterial, Parasitic and Allergenic Products at CBER at FDA Room 3336 Silver Spring, MD 20993-0002 Leslie.wagner@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 Leslie Wagner:

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 <u>https://www.sciencedirect.com/science/article/pii/S187628592200417X</u>.

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

³ See <u>https://www.icandecide.org/wp-content/uploads/2022/10/CDC-FOIA-regarding-alum-studies.pdf</u> and <u>https://www.icandecide.org/wp-content/uploads/2022/10/NIH-Response-to-Studies-of-Safety-of-Injected-Alum.pdf</u>; 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 <u>https://pubmed.ncbi.nlm.nih.gov/26518400/</u> (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.).