

Dear Scientific Advisory Committee on Alternative Toxicological Methods,

Thank you for the opportunity to make a public comment today. My name is Ashley Haugen and I am the founder and representative of That Water Bead Lady, Inc.

When a metric becomes a target, it ceases to be an effective metric. Moving toward an animal-free alternative toxicology testing system will require an understanding that these models can and will at times promote harmful medical bandwagons. The counterweight to this foreseeable complication, requires robust, real world, human data feedback mechanisms to ensure that harm is mitigated when this inevitable situation occurs.

Belief in bandwagon ideas is not a new phenomenon and sometimes these beliefs do not prove to be harmful; but medical bandwagons are unique because they infiltrate the field of medicine and have far reaching effects on patient care, research, and society at large. A program will reflect the biases of its programmer. Once the medical community accepts a medical bandwagon hypothesis, further research into the accuracy of the bandwagon idea is often considered misleading, labeled inconclusive, or dismissed entirely; curbing research efforts by creating a reluctance to invest funding into the investigation of scientific matters considered settled science.

Just having the genome for a species isn't enough, you need the proteome, you need to program in how a member of that species is put together. And in the construction of an organism we have knowns, we have known-unknowns, and we have unknown-unknowns. And if the key piece of data connects to one of those unknown-unknowns we will be wrong. When it comes to tissue culture, the problem there is that what happens in a tissue culture may not translate to what happens on the organismal level. Effects on a particular tissue can synergise at the organismal level with effects on other tissues. You can try to culture every tissue type, in an organism, and you can try and grow every organ of an organism, and test on that, but to calculate the interplay would require the power of an unknown number of super computers. If you cut it down to just the target tissue types then you bring in unknown-unknowns, non-target tissue types can be vulnerable to toxic effects which are not seen in testing. And using these methods might - might: get you the toxicodynamics of an agent, but it does not get you the toxicokinetics. Toxicodynamics is what the poison does to your body, toxicokinetics is what your body does to the poison. And that is of great importance when you are trying to gauge long-term effects.

We must remember, data gaps leave room for assumptions that have real world impacts on human beings. One such human being is my youngest daughter. In 2017 a birthday gift for my oldest child severely injured and poisoned my one year old baby. The gift, water beads, are currently sold simultaneously as a sensory toy for children and as an soil conditioning agricultural product; they are labeled and heavily marketed as "non toxic", "eco friendly", and "biodegradable". Unfortunately, these claims disam parents and what is not disclosed to consumers is that water beads, because the polymerization process is never 100% complete, can contain residual neurotoxic acrylamide monomers.

Toxic brain encephalopathy, caused by acrylamide monomer poisoning, has affected my daughter's quality of life, yet the assertion continues that water beads are safe and consistently "non toxic". Numerous factors have contributed to the pervasive belief that water beads are safe, but the one I'd like to draw your attention to today is the failure of the current system to effectively capture human data from the real world instances of harm.

Case studies for scientific journals, reports to the CPSC, and calls to Poison Control by clinicians are submitted voluntarily. There are no mandated reporting requirements and therefore no protection for healthcare providers who report harm. Consumers can report concerns and injuries directly to the CPSC, but most of the time, they don't use the standard medical terms that would be most useful to healthcare providers, regulators, and researchers. This makes it harder for stakeholders to effectively use this information to make decisions about research directions and regulations. The NEISS system is located in only 100 hospital emergency rooms, and lacks a sufficient data governance system to make accurate nation wide product injury projection estimates, and poison control center reporting lacks true denominator data. Despite the fact that patients with toy product injuries are often seen by primary care and specialty physicians for initial care, follow-up, and complication management outside of the emergency room, the NEISS is not designed to gather this critical data. A lack of data influences metrics and our understanding of impact.

We do not know the number of children out there who have been harmed by these toxicant containing beads. The majority of physicians lack confidence in the level of training they receive in occupational and environmental medicine; as a result, they are hesitant to consider occupational or environmental diagnoses and may miss connections between injury and disease that those with appropriate OEM and toxicology training would be able to recognize with access to more robust data. Scientists, researchers, and additional stakeholders should be concerned about the weaknesses in our current feedback system in light of my daughter's tragic situation and our family's fight to have the CPSC, Poison Control, and other organizations tasked with protecting children count as a relevant data point.

If talks throughout the development and implementation of alternative computational toxicology approaches do not also include plans to create more robust real-world human data feedback systems, they will cause more human harm than traditional animal testing. Modeling plays a critical part in 21st Century Toxicology, and I believe that when used correctly, taking into account both casual relationships and hypothesis testing, technology should greatly improve hazard and risk assessments of chemicals, and increasingly use animal-free methodologies.

Sincerely,
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References

Cohen, L., & Rothschild, H. (1979). The Bandwagons of Medicine. *Perspectives in Biology and Medicine* 22(4), 531-538. [doi:10.1353/pbm.1979.0037](https://doi.org/10.1353/pbm.1979.0037).

Dentel, C. W. (2020, November 9). *Review of National Electronic Injury Surveillance System Data*. Review of National Electronic Injury Surveillance System Data | Office of Inspector General. Retrieved August 24, 2022, from <https://oig.cpsc.gov/reports/inspection-evaluation/review-national-electronic-injury-surveillance-system-data>

Green-McKenzie, J., Khan, A., Redlich, C. A., Rivera, A., & McKinney, Z. J. (2022). The Future of Occupational and Environmental Medicine. *Journal of occupational and environmental medicine*, 10.1097/JOM.0000000000002676. Advance online publication. <https://doi.org/10.1097/JOM.0000000000002676>

Gummin, D. D., Mowry, J. B., Beuhler, M. C., Spyker, D. A., Brooks, D. E., Dibert, K. W., Rivers, L. J., Pham, N. P., & Ryan, M. L. (2020). 2019 Annual Report of the American Association of Poison Control Centers' National Poison Data System (NPDS): 37th annual report. *Clinical Toxicology*, 58(12), 1360–1541. <https://doi.org/10.1080/15563650.2020.1834219>

Han, S. H., Chen, Y. C., Xian, Z. X., & Teng, Y. S. (2021). Superabsorbent polymer balls as foreign bodies in the nasal cavities of children: our clinical experience. *BMC pediatrics*, 21(1), 273. <https://doi.org/10.1186/s12887-021-02740-x>

National Toxicology Program U.S. Department of Health and Human Services. (2005, February). Acrylamide monograph - National Toxicology Program. NTP-CERHR Monograph on the Potential Human Reproductive and Developmental Effects of Acrylamide. Retrieved September 13, 2022, from https://ntp.niehs.nih.gov/ntp/ohat/acrylamide/acrylamide_monograph.pdf

Spînu, N., Cronin, M., Madden, J. C., & Worth, A. P. (2022). A matter of trust: Learning lessons about causality will make qAOPs credible. *Computational toxicology (Amsterdam, Netherlands)*, 21, 100205. <https://doi.org/10.1016/j.comtox.2021.100205>