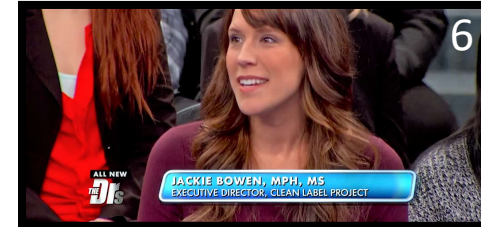
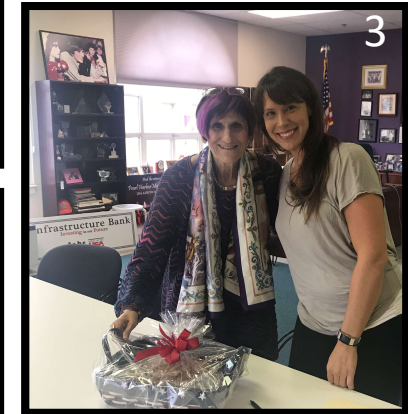


FDA's Scientific Data and Information about Products Containing Cannabis or Cannabis-Derived Compounds *Public Hearing*



About Me

- Clean Label Project Executive Director
- Food & consumer product safety & quality systems engineer
- 15 years with the World Health Organization Collaborating Centre on Food Safety & Water Quality, NSF International
 - ❑ Label Claim Substantiation
 - ❑ FSMA
 - ❑ GFSI benchmarked standards
 - ❑ Certified Organic, Gluten-Free, Non-GMO Project, etc.
 - ❑ Certification compliance and enforcement standards and policies



From top left clockwise: (1) Jackie Bowen (2) Jackie with Dr. Mona Hannah-Attisha- pediatrician who broke the public health drinking water crisis in Flint, MI (3) Jackie with Congresswoman DeLauro (D-Conn.)- Committee on Appropriations for Health & Human Services including Food & Drug Administration (4) Jackie on Washington Post panel with Deputy Undersecretary of Agriculture during Obama Administration under Secretary Vilsack and principal author of the USDA National Organic Program (5) Jackie at the World Health Organization infant and maternal health affiliate, 1000 Days (6) Jackie on the Doctors TV show about Protein Powder



About Clean Label Project

- A national non-profit with the mission to bring truth and transparency to consumer product labeling.
- We believe that sometimes what's NOT on a label is what matters most.
- Food safety attention has largely been focused on short term acute exposure to food-borne pathogens like salmonella, e.coli, and listeria.
- The long term threat of cancers and reproductive disorders linked to industrial and environmental contaminant exposure have largely gone unnoticed, untested, and therefore unregulated in food and consumer products, until now.
- Clean Label Project uses evidence-based statistical modeling to reveal levels of contaminants in America's best selling food and consumer products.
- Together, we are changing the definition of food and consumer product safety in America.

Why did we test the CBD category?

- High growth, premium pricing, previous FDA CBD potency & purity findings, and recent media and academic reports made CBD an interesting category to examine
- Our findings and conclusions are consistent with other studies: systemic quality control issues



¹ Bonn-Miller MO, Loflin MJE, Thomas BF, Marcu JP, Hyke T, Vandrey R. Labeling Accuracy of Cannabidiol Extracts Sold Online. *JAMA*. 2017;318(17):1708–1709. doi:10.1001/jama.2017.11909

² <https://www.nbcnewyork.com/investigations/CBD-Products-Tested-505762921.html>

³ <https://www.businessinsider.com/study-cbd-products-are-mislabeled-and-contain-dangerous-chemicals-2019-4>

⁴ <https://www.nytimes.com/interactive/2019/05/14/magazine/cbd-cannabis-cure.html>

⁵ <https://www.sciencenews.org/article/cbd-product-boom-science-research-hemp-marijuana>

How did we test the category?

- Inspired by the Amazon.com best sellers list & internet search of popular CBD products
- Using consumer chain of custody basket sampling to test 208 best selling CBD products
- Had products tested at two independent accredited analytical chemistry laboratories
- Benchmarked the findings

What did we test for?

- 400+ analytes using ICP-MS, LC-MSMS, & GC-MS
 - Heavy Metals (Total Arsenic, Cadmium, Lead, and Mercury)
 - 300+ Pesticides (including Glyphosate)
 - Plasticizers (Phthalates, BPA, BPS)
 - Potency (actual CBD content)
 - THC
 - Mycotoxins

What products/brands did we test?



and more...

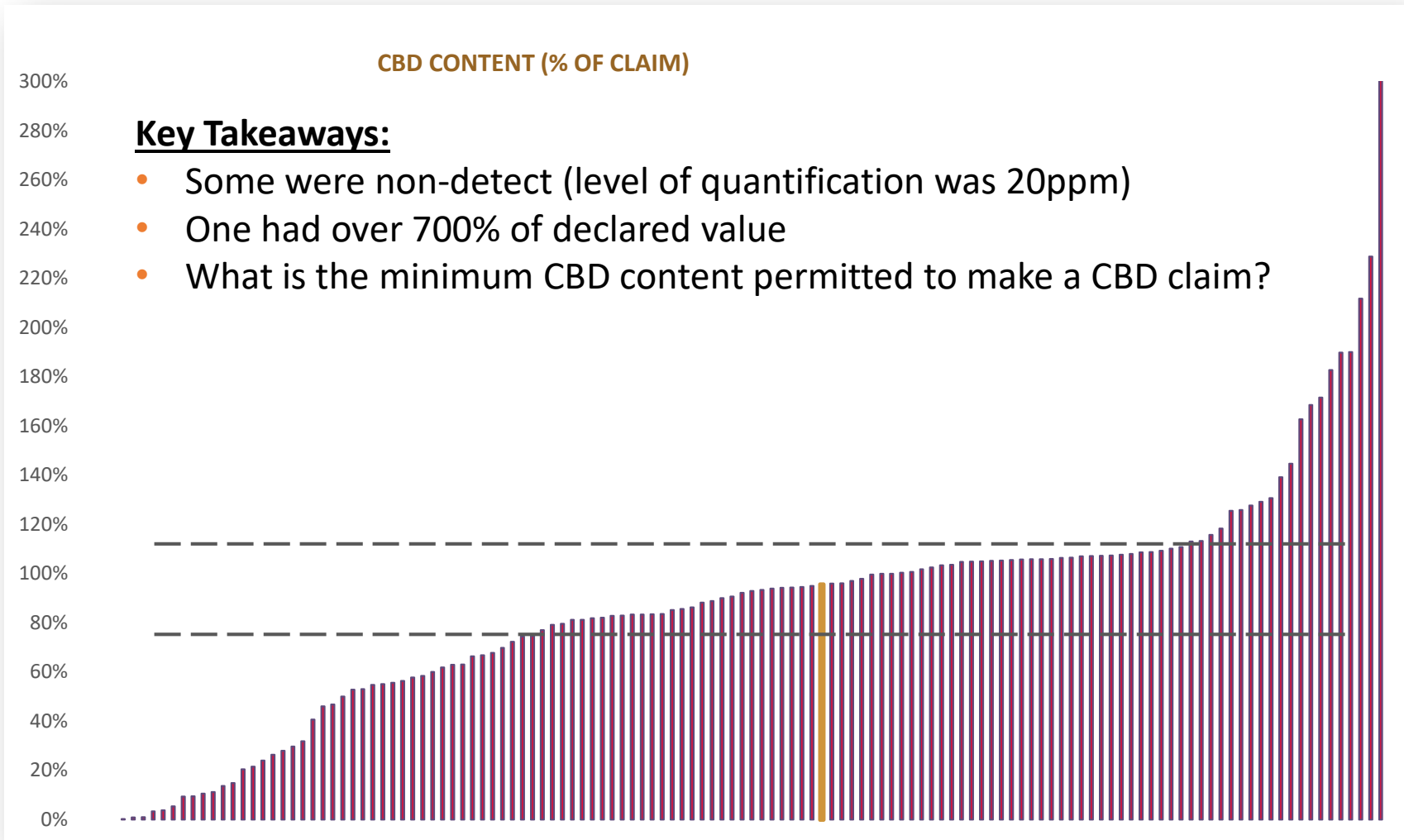


Key Finding #1: Highly Variable Potency & Contamination

PERFORMANCE METRIC	TOP 10 BRANDS AVERAGE	NOTES
Number of contaminants tested	14	This analysis was for over 400 analytes
Inaccurate / Misleading CBD Labeling	>30%	This would be the number of products with +/- 20% of CBD value listed on the label
Average Lead (ppb)	34 ppb	Highest lead average out of all consumer product categories we've tested
Average Pesticides (ppb)	40.9 ppb	Most common pesticide hits: <ul style="list-style-type: none">• Propiconazole (8% of products)• Pyrimethanil (3% of products)• Azoxystrobin (3% of products)
Average Phthalates (ppb)	1,091 ppb	
% Containing THC	45%	

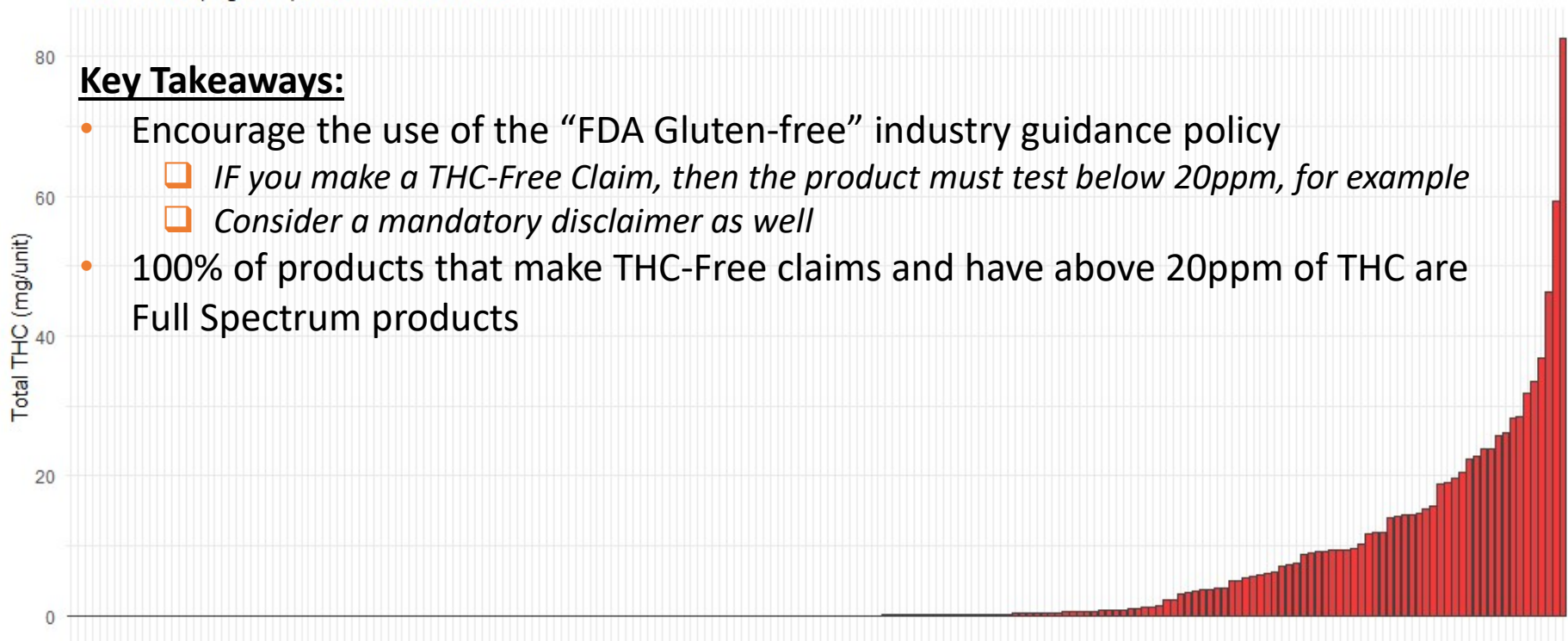
- ❑ Overall, a general disconnect between the brand-reported C of As and products purchased from store shelves
- ❑ Elevated levels of detection result in C of As with non-detects giving unsuspecting brands and consumers a false sense of comfort, security, and compliance

Key Finding #2: CBD Content Varies Widely From Values Listed on the Label



Key Finding #3: THC-Free Does Not Always Mean THC-Free

Total THC (mg/unit) in CBD Products



Key Takeaways:

- Encourage the use of the “FDA Gluten-free” industry guidance policy
 - *IF you make a THC-Free Claim, then the product must test below 20ppm, for example*
 - *Consider a mandatory disclaimer as well*
- 100% of products that make THC-Free claims and have above 20ppm of THC are Full Spectrum products
- *Legal limit of 0.3% THC is based on dry weight in hemp and this limit is being applied to manufactured products*
- *Currently, there is no rule or regulation that says how much THC can be present in a concentrate or a manufactured product*

Thank you!

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