EXHIBIT A

MEMORANDUM OF *AMICI CURIAE* IN SUPPORT OF DEFENDANTS' MOTION FOR JUDGMENT ON THE PLEADINGS (FED. R. CIV. P. 12(C))

Brinton M. Wilkins (10713)
11672 South Broadview Way
Sandy, Utah 84092
Telephone: (801) 735-6645
bwilkins@arcuslaw.com

Attorney for National Health Federation and Citizens for Health

IN THE UNITED STATES DISTRICT COURT
DISTRICT OF UTAH, CENTRAL DIVISION

UNITED STATES OF AMERICA, Plaintiff, v. XLEAR, INC., a corporation, and NATHAN JONES, individually and as an Officer of XLEAR, INC. Defendants.	**MEMORANDUM OF *AMICI CURIAE* IN SUPPORT OF DEFENDANTS' MOTION FOR JUDGMENT ON THE PLEADINGS (FED. R. CIV. P. 12(C))** Case No. 2:21-cv-00640-RJS-DBP Judge Robert J. Shelby Magistrate Judge Dustin B. Pead

I. Information Required by DUCivR 7.6(1)(A), 7.6(1)(B), and 7.6(1)(C)

a. Rule 7.1(A), Fed. R. Civ. P., Disclosure Statement

No parent or publicly held corporation owns 10% or more of the stock of either the National Health Federation (the "NHF") or Citizens for Health ("CFH").

b. Identity of *Amici Curiae*

The NHF is a California non-profit 501(c)(4) corporation that has members and educational operations around the world. Organized in January 1955, the NHF is the only non-profit consumer health-freedom organization with an accredited seat on the Codex Alimentarius Commission of the World Health Organization (WHO) and Food and Agricultural Organization (FAO). The NHF's mission is to: (1) protect the health-related rights and freedom of individuals

and healthcare practitioners; (2) educate about health and health freedom; and (3) represent its members in lawmaking, rulemaking, and policy decisions.

CFH is a Washington, D.C.-based non-profit bringing together consumers, practitioners and policy makers, who, as a collective, believe that sound health is the vital foundation of life, liberty and the pursuit of happiness, and is itself a fundamental human right. CFH aims to create a seat at the table in the national healthcare policy debate for advocates of natural health.

c. Interest in the Case

The NHF and CFH's interest in this case stems from the chilling effect the FTC policy at issue in this case has on the dissemination of important information that health practitioners and consumers need to make good healthcare decisions. Consumers have a right to truthful, and not misleading information regarding safe and affordable products they may want to use, and those interests are not advanced either by: (1) imposing costly additional substantiation requirements; or (2) censoring information which may be based on different kinds of evidence. Rather than protecting consumers, this FTC policy favors dangerous and powerful drugs and inhibits the consideration or use of less dangerous and more affordable options. This misguided policy prevents American consumers from making informed decisions about their own health.

In short, this litigation's outcome will affect individual, professional, and business rights relative to the testing, marketing, and use of healthcare-related products and services.

d. Legal Counsel's Participation in Drafting this Memorandum

The legal counsel representing the NHF and CFH authored this Memorandum in part.

II. Public Policy Favors Defendants' Position

In this case, the FTC suggests that any health-related claim (a term that the law does not define) must be supported by substantiation in the form of multiple randomized controlled trials ("RCTs") on the precise finished product in question, similar to the RCTs required for drug approval under FDA regulations. But the products here in question are not FDA-approved drugs, and, as Defendant has argued, there is no substantiation requirement in the FTC Act, let alone a requirement that RCTs support all health-related claims.

The National Health Federation (the "NHF") and Citizens for Health ("CFH") support the clear statutory language of the FTC Act: advertising must be truthful and not misleading. Additionally, the NHF and CFH fully agree with the factual and legal analysis set forth in Defendants' Motion for Judgment on the Pleadings (Fed. R. Civ. P. 12(c)).

But the NHF and CFH would go further. Consumer protection and public policy arguments also undermine the government's position. While a simple, bright-line substantiation test that shifts the burden of proof to Defendants may, in the FTC's view, be easier for the FTC to administer, it is not the law, and it is not in the interests of consumers, science, or innovation. Public policy favors the Defendants' position for at least eight reasons.

a. Individuals Need Healthcare Options, and Those Options Must be Affordable

The FTC assumes that it speaks for all consumers generally. But consumers are human beings first, and as such, every individual is unique, with unique needs and desires. Nowhere is this more true than in healthcare. Every human being differs in genetics, epigenetics, microbiome, health history, physical condition, organ function, needs, hopes, and goals. Consumers are best served by an informed free market with a wide variety of affordable choices, not a one-size-fits-all "best" solution.

The Pareto Principle suggests that in a free market about 80% of people will choose the most popular 20% of available solutions, while the remaining 20% will choose one of the remaining 80% of less popular (but much more numerous) options.[1] The needs and choices of that 20% minority are just as important as the majority who choose the most popular options. If the minority's choices are reduced, they will be forced to pick from a smaller pool of less attractive options. And any government action that eliminates options reduces each individual's ability to choose whatever fits the individual best, whether the individual tends to follow the majority or looks for other options.

b. Innovation is Never Popular

In a free market, by definition, innovation tends to be unpopular. New products and services always start with a small initial market of people willing to pay a bit more for a better solution (for them). If the product finds traction, it expands and eventually may become mainstream. If we strip less popular or less orthodox options from the market, innovation will be discouraged if not eliminated.

c. RCTs are Prohibitively Expensive

The current typical cost of a drug approval RCT is now about $19 million.[2] RCT costs vary greatly, depending on the endpoints, institution, and number of participants. But if the FTC intends to put all health claims on parity with FDA drug approval, the cost of these tests, and their effect on market options, will need to be carefully considered through a proper rulemaking (or better yet, legislative) process. Obviously, it will be at much higher prices, and that is not in the interests of consumers.

---

[1] A general overview and summary of the Pareto Principle, its history, justification, and application, is available at: en.wikipedia.org/wiki/Pareto_principle

[2] *See* jamanetwork.com/journals/jamainternalmedicine/fullarticle/2702287#google_vignette

d. RCTs are not "Gold Standard" in this Context

RCTs were not common until the 1940s and 1950s. They were first referred to as "gold standard" only in 1982, twenty years *after* the Kefauver-Harris Amendments to the Federal Food, Drug, and Cosmetic Act of 1938 required RTCs for all new drugs.[3] The FTC now, both implicitly and explicitly, seems to be taking the position that RTCs are the "gold standard" for all healthcare related decisions simply because they are legally required for drugs. But are they?

RCTs are only one tool in the scientific toolbox. While they are certainly the "gold standard" in that they are the most expensive tool, the evidence suggests that RCTs are no better than well- designed observational studies at estimating the effect of an intervention.[4] In addition, because the costs of RCTs are higher, the cost-benefit ratio (value) is lower. They are only the "best" if everything else is equal and cost is no object.[5]

e. Fixed Costs are Regressive and Favor Market Leaders

Pre-market testing is a fixed cost as it does not vary with sales volume. If a pre-market test costs $1 million, it will only add 10% ($1) to a $10 product that sells a million units. But if the same product sells only one thousand units, it will raise the price by $1,000 each.

As this shows, all pre-market fixed costs are regressive; they fall heaviest on less popular products and can significantly reduce the options available in the market. They also protect

---

[3] *See* clinicaltrialsarena.com/features/rct-gold-standard/. *See also* ncbi.nlm.nih.gov/pmc/articles/PMC4101807/.

[4] *See*, *e.g.*, Anglemyer A., Horvath H.T., & Bero L., *Healthcare Outcomes Assessed with Observational Study Designs Compared with those Assessed in Randomized Trials*, Cochrane Database Syst Rev. 2014 Apr 29;2014(4):MR000034. doi: 10.1002/14651858.MR000034.pub2. PMID: 24782322; PMCID: PMC8191367; *and* Concato J., Shah N., Horwitz R.I., *Randomized, Controlled Trials, Observational Studies, and the Hierarchy of Research Designs*, N. Engl. J. Med. 2000 Jun 22;342(25):1887–1892. doi: 10.1056/NEJM200006223422507. PMID: 10861325; PMCID: PMC1557642.

[5] *See* Bramwell & Warnock, *Rethinking Medicine: Harmonizing Science and Herbal Tradition* (Mount Pleasant, SC: Palmetto Publishing, 2024), Chapter 1.

market leaders with established market share, at the expense of innovators and smaller competitors with smaller sales. If the FTC is serious about its statutory mission of keeping markets competitive, it should avoid universal fixed-cost requirements like demanding RCTs for all healthcare related products.

f. RCTs Favor Harsh Drugs

Putting all health claims on parity with approved drugs is a false parity. Drugs are tested for safety and efficacy because they are new, untested, unknown compounds with patent exclusivity to recover some fixed costs. Once a drug is approved, no further RCT testing is required. And when a drug goes off patent, generic versions do not have to repeat that testing because they are assumed to work the same as the version already approved, even if the manufacturer and excipients change.

Requiring non-drug products to get RCT testing for substantiation is to require all products to bear costs that generic drugs do not currently bear. Non-drugs do not warrant this kind of testing, and manufacturers of non-drugs—particularly small-scale manufacturers—cannot economically bear or recover from such a requirement. This essentially gives a market advantage to harsh drugs, which are one of the leading causes of death in America and throughout the world.[6] Consumers want more, safer, and cheaper options, which the current FTC policy does not serve, and which, instead, advantages manufactured pharmaceuticals over other healthcare options.

[6] *See* blogs.bmj.com/bmj/2016/06/16/peter-c-gotzsche-prescription-drugs-are-the-third-leading-cause-of-death/ *and* hub.jhu.edu/2016/05/03/medical-errors-third-leading-cause-of-death/

g. RCTs Deter Product Innovation

Conclusions from RCTs are limited by the design of the study that produced them. The FTC implicitly acknowledges this when they insist that RCTs must be on the exact formula used in the claim. Under this logic, if a formula changes in any way, all RCTs using it would have to be redone from scratch. This is not the practice for generic drugs now.

Yet common sense indicates that a test on a formula that is nearly identical to the one in question should be probative, at the very least. Similarly, a test on an ingredient in a larger formula will also have probative value. Scientists commonly consider similar and adjacent tests when designing their own experiments; and published findings commonly even suggest paths for future experimentation by others.

Given the high cost of RCTs and their applicability only to one specific formula (at least under current FTC guidance), the cost of making even a minimal change to a formula is extreme. The identical-or-nothing position advanced by the FTC defies both good science and common sense and provides a significant barrier to any future change or innovation to an established formula.

h. Science Has no Fixed Standard

Science is not a democracy. The majority is not necessarily right. Furthermore, it is always the minority, by definition, which makes new discoveries. Science does not progress in discrete steps; it advances by degrees, with conflicting evidence, and vigorous discussion and disagreement. There is no single kind of test or experiment that is more valid than others (provided the experiment is well-designed), and no evidence is ever fully conclusive. For

instance, repeated RCTs often fail to replicate confirmatory results, which has led to a replication crisis in current science.[7]

The law can no more determine what kind of scientific tests are acceptable than it can determine in advance what kinds of legal evidence are most credible. All evidence must be weighed and sifted with the best evidence eventually prevailing. Evidence that is clearly false or is intended to mislead the court is perjury and should be prosecuted. We require our evidence to be the truth, the whole truth, and nothing but the truth; but we do not interpose additional requirements. Even hearsay may be weighed and considered in appropriate circumstances. For exactly this reason, the statutory "truthful and not misleading"[8] standard is the proper standard for scientific questions related to products that are not drugs, not the FTC's cramped and non-statutory requirement that all health-related claims be subjected to RCTs.

Conclusion

Although the facts and the law as set out in Defendants' motion are dispositive, the court should also avoid being distracted from the clear statutory law by any claim or assumption that FTC policy is somehow protecting consumers. In this case, the FTC's policy only benefits its own bureaucracy and the large and well-funded traditional healthcare industry.

DATED this _____ day of _____ 2024

_____
Brinton M. Wilkins

[7] *See* Hanin L., *Why Statistical Inference from Clinical Trials is Likely to Generate False and Irreproducible Results*, BMC Med. Res. Methodol. 2017 Aug 22;17(1):127. doi: 10.1186/s12874-017-0399-0. PMID: 28830371; PMCID: PMC5568363. *See also* Ioannidis J.P.. *Contradicted and Initially Stronger Effects in Highly Cited Clinical Research*, JAMA. 2005 Jul 13;294(2):218–228. doi: 10.1001/jama.294.2.218. PMID: 16014596.

[8] *See* 21 U.S.C. § 343(r)(6)(B): "[A] statement for a dietary supplement may be made if . . . the manufacturer of the dietary supplement has substantiation that such statement is truthful and not misleading."