



Executive Offices
1012 14th Street, NW
Suite 205
Washington, D.C. 20005

October 22, 2018

Federal Trade Commission
600 Pennsylvania Avenue, NW
Washington, DC 20580

Re: Comments on proposed consent order “In the Matter of A & O ENTERPRISES INC, a corporation, d/b/a iV BARS INCORPORATED and iV BARS, and AARON K. ROBERTS, a/k/a/ Aaron Keith, individually and as owner and operating manager of A & O ENTERPRISES INC.” (File No. 172 3016)

Dear Members of the Commission,

The Center for Inquiry (CFI) appreciates this opportunity to comment on the proposed consent agreement with regard to claims against A&O Enterprises, Inc. and Aaron K. Roberts (“Respondents”).

CFI Is a Charitable Nonprofit Organization Dedicated to Advancing Evidence-Based Policy

CFI is an educational and advocacy organization that promotes reason and scientific integrity in public affairs. CFI’s vision is a world where people value evidence and critical thinking, where superstition and prejudice subside, and where science and compassion guide public policy. Our comments are submitted not only on behalf of our organization, its employees, and its members but also on behalf of dozens of doctors and scientists associated with CFI and with its affiliate program the Committee for Skeptical Inquiry (CSI)¹ and CFI’s division, the Richard Dawkins Foundation for Reason & Science,² with whom we work on these matters.

Since its inception, CFI has been a prominent advocate of evidence- and science-based policy in all branches of government. In 2016, CFI submitted an amicus brief to the Supreme Court arguing that a Texas law that restricted access to women’s reproductive health care was based on unscientific information gathered by an individual with no medical qualifications. The Court ruled in favor of CFI’s position.

¹ <https://www.csicop.org/>

² <https://www.richarddawkins.net/>



In addition, CFI engages in civic education to improve scientific literacy in the United States. In 2015, as a result of CFI and CSI's efforts, the Associated Press announced that it would no longer use the term *skeptic* to describe individuals who reject the mainstream science of climate change.

A primary focus of CFI's work is preventing public harm from policies, initiatives, or institutions that fail to adhere to known scientific facts or principles. The "alternative medicine" industry, described in detail below, is such an institution.

One of the most egregious examples of harmful "alternative medicine" is homeopathy, a category of products based on the disproven eighteenth-century theory that when diluted to virtually nonexistent concentrations, toxic substances transfer invisible healing properties to ordinary water molecules. Not only is this theory unsupported by evidence, it violates known properties of physics.

In April 2015, CFI testified to the Food and Drug Administration (FDA) about homeopathy's potential harm and the need to hold homeopathic drugs to the same standards of safety and efficacy as conventional medicine.

In November 2015, following the FTC's Homeopathic Medicine & Advertising Workshop, CFI filed comments urging the FTC to stop manufacturers from falsely advertising homeopathy's safety or efficacy until such claims can be scientifically proven.

In November 2016, the FTC issued a staff report on the Homeopathic Medicine & Advertising Workshop, which cited CFI's comments. Concurrent with the report, the FTC issued new enforcement guidance for homeopathic products, which declared that homeopathic products cannot include claims of effectiveness without "competent and reliable scientific evidence." If no such evidence exists, homeopathic products must state this fact clearly on their labeling and state that the product's claims are based only on eighteenth-century theories that have been discarded by modern science.

In July 2018, CFI filed suit against CVS Health, the largest retail pharmacy chain in the United States, for fraudulently marketing homeopathic products in the District of Columbia. That case is currently progressing.

Respondents Appear to Have Misled Consumers in Violation of the Federal Trade Commission Act

According to the FTC's complaint, Respondents are charged with marketing their "iV Bar" line of products as scientifically proven medical treatments for a range of illnesses including several life-threatening diseases.



As shown in Exhibit A of the FTC’s complaint, Respondents’ website clearly describes their intravenous cocktails as medical products, scientifically validated by a research team comprised of experienced scientists, that “prevent and help treat” a range of real and nonexistent diseases. The real diseases include cancer, angina, cardiovascular disease, congestive heart failure, myocardial infarction, multiple sclerosis, diabetes, fibromyalgia, and neurodegenerative disorders. As the FTC explains in its complaint, there is no clinical or scientific support for these claims, nor did Respondents conduct the validating research as they claimed.

Respondents appear to have been aware of the statutory prohibition against their deceptive marketing practices. Although their “iV Bar” website is littered with claims about the efficacy of their products in medically treating a range of illnesses, Respondents’ website includes a difficult-to-find disclaimer that, to the contrary, “Our vitamins and nutritional supplement products on this site are not intended to diagnose, treat, cure or prevent any disease.”

iV Bar Products are marketed on a continuum of purportedly medical products that are unsupported or contradicted by medical science.

Respondents’ “iV Bar” products fall into a continuum of commercial goods and services that, in the absence of scientific evidence proving their safety and efficacy, are marketed as providing health, or medical, benefits. Products on this continuum are variously referred to as “alternative,” “complementary,” “integrative,” or “functional” medicine to convey a misleading sense that evidence of the products’ safety and efficacy derives from a legitimate authority outside the realm of “conventional” science-based medicine. CFI uses the term *alternative* medicine as a shorthand moniker for this continuum of marketing.

The terms *alternative*, *complementary*, and *integrative* do not describe any substantive differences in the methodology used to derive claims about product safety and efficacy. Instead, they are distinguished by their suggested relationship to “conventional” science-based medicine.

Alternative treatments are marketed as substitutes to science-based medicine. *Complementary* treatments are marketed not as substitutes but as treatments administered by a “complementary” practitioner concurrent with the patient’s use of science-based medicine under the supervision of medical professionals. *Integrative* treatments are administered by “conventional” medical institutions in conjunction with science-based medicine as part of a “holistic” model of care that integrates proven science-based treatments with unproven or disproven ones. Any particular pseudoscientific treatment can be described by any of these three terms, depending on how it is administered. However, as discussed further below, these treatments often act as a substitute for science-based care regardless of the marketing term used to describe them.



According to the FTC’s complaint, Respondents’ website marketed their “iV Bar” products as part of “an exciting new paradigm in integrative and functional medicine,” placing these products on the *alternative* continuum.

In addition, Respondents claimed (albeit deceptively) that “naturopathic doctors” collaborated in the development of these products. Naturopathy is one of several pseudoscientific “alternative” disciplines that make unsupported claims about the medical efficacy of their products. Naturopathic schools in the United States include a substantial curricular focus on homeopathy which, as mentioned above, does not and physically cannot work as its marketers claim.

“Alternative” treatments result in the diversion of a significant portion of consumer health care spending to unsafe, unproven substitutes for scientifically validated medical care.

Despite industry attempts to brand *alternative* treatments as *complementary* to or *integrative* with science-based medicine, research has shown that many patients use these treatments as a substitute for, rather than a complement to, science-based medicine. This tendency toward substitution of science-based medicine with *alternative* treatments is discussed further in the following section.

According to the National Center for Complementary and Integrative Health, in 2012 (the most recent year for which data are available), Americans spent \$30.2 billion out-of-pocket for unproven “complementary health approaches.”³ The largest share of this money was paid to “complementary” practitioners such as Respondents. Spending on complementary practitioners was \$14.7 billion.⁴ This is almost 30 percent of what consumers spent on “conventional” science-based medicine.

The prevalence of “alternative” medicine causes demonstrable harms to public health.

The use of “alternative” treatments is associated with public health harms.

These harms can be broken into three distinct categories: the “alternative” product or treatment itself may harm the patient; the patient may eschew science-based medical treatment and remedies and use the alternative treatment instead, thereby suffering from symptoms and effects up to and including death, which could have been prevented by effective science-based treatment; and the financial cost of paying for “alternative” treatments that do not and cannot work.

³ <https://nccih.nih.gov/research/statistics/NHIS/2012/cost/american-out-of-pocket-spending-complementary-health-approaches>

⁴ *Id.*



The tendency toward substitution of science-based medicine with “alternative” treatments poses a demonstrable risk to patient health. Research has shown that mortality rates are significantly higher for patients who choose “alternative” treatments for certain life-threatening illnesses.

The fraudulent claim to treat cancer is among the most egregious made by Respondents in marketing their “iV Bar” products. The danger posed to cancer patients by the use of “alternative” treatments is well substantiated. Research has shown that “alternative” medicine use is associated with a substantial increase of death risk in cancer patients through the substitution effect. The use of “alternative” treatments for cancer is associated with a higher likelihood that a patient will refuse conventional therapies including surgery, chemotherapy, radiation therapy, and hormonal therapy.

The risk of harm from “alternative” cancer treatments falls disproportionately on cancer patients from certain vulnerable demographic groups. An August 2017 peer-reviewed scientific research article published in the *Journal of the National Cancer Institute* found that patients who used “alternative” treatments in lieu of conventional cancer treatment (CCT) were more likely to be younger, female, and to have a higher cancer stage than patients who chose CCT.

These patients experienced a significantly higher risk of death associated with their use of “alternatives” to CCT. The risk of death from breast cancer increased more than fivefold, the risk of death from colorectal cancer more than fourfold, and the risk of death from lung cancer more than twofold.

This substitution effect occurs even for products marketed as “complementary” to science-based medicine. In October 2018, another peer-reviewed scientific research article, published in *JAMA Oncology*, found that cancer patients who used “complementary” treatments also had an increased risk of death associated with their substitution of supposedly “complementary” treatments for CCT.

This risk is significantly compounded by fraudulent marketing that misrepresents, obscures, or omits information about the risks posed by an “alternative” treatment. Respondents clearly engaged in false marketing of their “iV Bar” products, for which there is no evidence of any benefit in the treatment of disease as claimed by Respondents.

Additionally, Respondents claimed in their marketing that “naturopathic doctors” collaborated in the development of their “iV Bar” products.⁵ Naturopathy is a pseudoscientific discipline that mimics the language of science-based medicine while almost wholly disregarding scientific principles. The FTC found that the respondents had not actually assembled a research team in

⁵ Exhibit A - 1



the development of its products. This deception placed vulnerable consumers at demonstrable risk of harm and did so to enable the manufacturer to make greater profits. However, even if Respondents had assembled such a team, the inclusion of naturopaths would itself demonstrate Respondents' disregard for the scientific principles that underlie evidence-based medical care.

The FTC Should Take Action Against Respondents

Given the substantial risk posed to consumers by the marketing of disproven "alternative" treatments, including for cancer, Respondents must be disallowed to market their products as effective treatments for any illness for which there is insufficient evidence of their products' safety and efficacy.

CFI agrees with each of the provisions imposed on Respondents in Parts I–IV of the proposed Consent Order. These provisions are necessary to protect consumers from future deception by Respondents and from demonstrable health risks posed by the specific nature of the deception described by the FTC's complaint.

CFI agrees with the provisions imposed on Respondents in Part V of the proposed Consent Order. These provisions are necessary to ensure transparency into Respondents' claims about product safety and efficacy sufficient to inform FTC charges against Respondents for any further violations.

Given the nature and degree of the Respondents' deception with regard to the safety and efficacy of their products in the treatment of deadly illnesses for which "alternative" treatments have been shown to increase the risk of patient harm, CFI urges the FTC, in accordance with its authority under Section 13(b) of the FTC Act, 15 U.S.C. Sec. 53(b), to seek monetary restitution for all consumers who were defrauded by Respondents.

If you have any questions about our comments, please contact Jason Lemieux at jlemieux@centerforinquiry.org.

Sincerely,


Robyn Blumner
President and CEO
Center for Inquiry




Nicholas Little
Vice President and General Counsel, Legal Director
Center for Inquiry


Jason Lemieux
Director of Government Affairs
Center for Inquiry