### UNITED STATES OF AMERICA BEFORE THE FEDERAL TRADE COMMISSION

COMMISSIONERS: Joseph J. Simons, Chairman Maureen K. Ohlhausen Noah Joshua Phillips Rohit Chopra Rebecca Kelly Slaughter

### 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. **DOCKET NO. C-**

# COMPLAINT

The Federal Trade Commission, having reason to believe that A & O Enterprises Inc, a corporation, and Aaron K. Roberts, individually and as owner and operating manager of A & O Enterprises Inc. (collectively, "Respondents"), have violated provisions of the Federal Trade Commission Act, and it appearing to the Commission that this proceeding is in the public interest, alleges:

- 1. Respondent A & O Enterprises Inc ("iV Bars"), also doing business as iV Bars Incorporated and iV Bars, is a Wyoming corporation with its principal office or place of business at 4101 Centurion Way, Addison, Texas 75001.
- 2. Respondent Aaron K. Roberts, also known as Aaron Keith, is the owner and operating manager of iV Bars. Individually or in concert with others, he controlled or had the authority to control, or participated in the acts and practices of iV Bars, including the acts and practices alleged in this Complaint. His principal office or place of business is the same as that of iV Bars.
- 3. Respondents have advertised, offered for sale, sold, and administered at least 10 different intravenous cocktails ("iV Cocktails") to consumers, including the Myers Cocktail and Immune Booster. Respondents' iV Cocktails or "bags" contain mixtures of water, vitamins, minerals, and amino acids infused directly into the bloodstream through an intravenous drip, typically through a vein in the arm. These iV Cocktails cost \$100.00 or more per session. Respondents refer to these treatments, among other things, as "Intravenous Micro-Nutrient

Therapy," "Intravenous Vitamin Therapy," "Hydration Therapy," or simply "iV Therapy." Respondents claimed that their iV Cocktails could be used to treat consumers suffering from serious diseases, including cancer, congestive heart failure, multiple sclerosis, diabetes, fibromyalgia, and neurodegenerative disorders. Respondents further claimed that their iV Cocktails produced fast, lasting results and, in many instances, were more effective and better tolerated than conventional medical therapies. Respondents also touted their iV Cocktails as hangover cures and a way to replenish fluids and essential vitamins and minerals. In addition, Respondents offered several intramuscular treatments that directly inject mixtures into human muscle. Respondents' iV Cocktails and intramuscular treatments are "drugs," within the meaning of Sections 12 and 15 of the Federal Trade Commission Act.

- 4. Respondents' first and primary iV Bars location is housed in a NextGen Wellness Center, an upscale gym and clinic that independently offers chiropractic care, pain management therapy, physical therapy, medical massages, and counseling. New iV Bars customers create an online account and complete a short health assessment questionnaire when making their first appointment. Respondents have an arrangement with a doctor who does a quick, online review of all health assessment questionnaires that customers submit to iV Bars. Respondents pay the doctor a flat fee of \$250 per month for this service. Shortly before the customer arrives, an iV Bars employee takes about five minutes to mix ingredients obtained from a local compounding pharmacy into the customer's requested iV Cocktail. Once at iV Bars, the customer is asked to sign a release form that discloses risks and releases Respondents from liability. Thereafter an iV Bars nurse seats the customer in one of five oversized reclining chairs and administers the iV Cocktail to them over a 25-45 minute period. Respondents also maintain a "full service mobile vehicle" that allows them to "come right to your door to deliver the treatment of your needs."
- 5. The acts or practices of Respondents alleged in this Complaint have been in or affecting commerce, as "commerce" is defined in Section 4 of the Federal Trade Commission Act.

# iV Bars Efficacy Claims

- 6. Beginning at least as early as August 2015, Respondents have disseminated, or caused to be disseminated, advertisements for their iV Cocktails, including through company Facebook, Twitter, and Instagram accounts and company websites, including the *ivbars.com* website (imaged on January 27, 2017), attached as Exhibit A ("iV Bars Website" or "Website"). As described below, the iV Bars Website contained the following statements and depictions, among others:
  - A. On the top section of the Website homepage, Respondents prominently offered "MEDICAL iV TREATMENTS" for, among other things, "CANCER." They also stated, "If you are new to the concept of Intravenous vitamin Therapy, you might be wondering why you're suddenly hearing so much about it. Why [it is] being relied upon by . . . patients suffering from a very serious illness. [It] represents an exciting new paradigm in integrative and functional medicine, allowing us to both prevent and help treat a wide variety of conditions safely and effectively":



(Exhibit A-1)

B. The middle section of the Website homepage titled "The Science Behind iV Bars" stated, "Vitamins, minerals and amino acids enter your bloodstream directly and immediately to help the body to begin healing itself" and claimed that iV Bars treatments were, "Developed by a team of leading medical doctors, naturopathic doctors, biochemists, nutritionists and exercise physiologists":



(Exhibit A-1)

C. The bottom section of the Website homepage titled "Our Success Stories" contained brief endorsements of iV Bars by two sports figures and an international model and a link titled "READ MORE STORIES":



ince using IV Bars, 1 find 1 don't get down an out with the cold and flu." Kellen Winslow Jr., NFL Player

# Our Success Stories



keep up with my busy lifestyle." Kamila Drotlef, International Model

READ MORE STORIES



pains have gone down dramatically." Zenon Konopka, NHL player

# (Exhibit A-1)

Clicking the "READ MORE STORIES" link took consumers to pages titled "SUCCESS STORIES" that described "case studies about different disorders and the effects that iV therapy has had on these conditions":



(Exhibit A-3)

These case study success stories included the following purported results:

### Case #3: Multiple Sclerosis

A 65 year-old male with progressive multiple sclerosis presents to the clinic wheel chair bound. The patient has tried medications, physical therapy and speech therapy. However, there have been little noticeable benefits with regards to his leg strength and neurological function . . . The patient received an intravenous infusion of glutathione. After the first infusion, he reported increased strength in his legs. His physical therapist and caretaker also reported noticing an improvement in his leg strength and ability to walk.

\* \* \*

Case#4: Diabetic peripheral neuropathy/Restless leg syndrome A 65 year-old male presents to the clinic with a ten plus year history of rheumatoid arthritis, diabetes, high blood pressure, neuropathy and restless leg syndrome . . . . The patient was started on intravenous vitamin C and glutathione therapy. After the fourth treatment, the patient's restless symptoms and joint pain was [sic] completely resolved . . . . Although the symptoms have returned, they were not of the same intensity.

\* \* \*

More Success Stories

### Fibromyalgia

Case #3: A 48-year-old woman presented with a six-year history of fairly constant myalgias and arthraigias, with pain in the neck, back, and hip . . . . She was diagnosed by a rheumatologist as possibly having polymyalgia rheumatic, [or] fibromyalgia . . . . The patient was given [a Myers Cocktail]. At the end of the injection, she got off the table and, with a look of amazement, announced her muscle aches and joint pains were gone for the first time in six years. . . . The author has given the Myers' to approximately 30 patients with fibromyalgia, half have experienced significant improvement, in a few cases after the first injection, but more often after three or four treatments.

\* \* \*

### Cardiovascular Disease

Case #5: A 79-year-old man was seen at home in end-stage heart failure, after having suffered four myocardial infarctions. . . . A peripheral angiogram revealed complete occlusion of both femoralpopliteal arteries, with no detectable blood flow to the distal extremities. . . . [T]he cardiologist advised the patient that his heart would not last more than another month . . . . He was treated with weekly [intramuscular] injections . . . . After eight weeks, the IM injections were replaced by weekly IV injections [of Myers Cocktail]. . . . The patient lived for eight years and died at age 87 from multiple organ failure. Of the handful of other patients with angina or heart failure who received IV or IM injections . . . all showed significant improvement.

(Exhibit A-3 to 6)

D. The Website homepage also contained tabs across the top that linked to other pages within the Website, including a tab titled "MEDICAL." On the Medical page, under the heading "Why Drip?," Respondents proclaimed: "IV drips bypass the gut, delivering essential nutrients and fluids directly into the bloodstream . . . . This allows us to detoxify, nourish and rehydrate our cells from the inside out for dramatic, long-lasting and often instant results." Under the Medical page subheadings "Benefits" and "Conditions," Respondents listed numerous diseases and conditions, including "Cancer," "Congestive heart failure," "Diabetes," "Fibromyalgia," and "Neurodegenerative disorders," and claimed that Respondents' iV treatments produce "Fast, lasting results":



E. The iV Bars Website homepage also contained a tab titled "MOBILE" that linked consumers to a page that described Respondents' "full service mobile vehicle" and proclaimed: "We Are Mobile. We Come To You!" The Mobile page contained the same disease claims as the Medical page, listing among the conditions that can be treated "Cancer," "Congestive heart failure," "Diabetes," "Fibromyalgia," and "Neurodegenerative disorders."

(Exhibit A-10)

F. The iV Bars Website homepage also contained a tab titled "SCIENCE" that linked consumers to multiple pages, the first of which was titled "THE SCIENCE BEHIND iV Bars." It stated, "[F]ew people realize that when you swallow a vitamin pill or a multi-vitamin, the body's natural absorption process can render up to 85% of that vitamin useless . . . . When you receive an "iV" the nutrients enter your bloodstream directly and immediately to help the body to begin healing itself":



### (Exhibit A-11)

G. The second page of the Science section began with the question, "ARE YOU GETTING THE NUTRIENTS YOU NEED?" and stated:

Overwhelming scientific evidence confirms that vitamin deficiencies are associated with disease processes and the overall condition of one's health. Vitamin, mineral and antioxidant deficiencies has [sic] been shown to suppress immune function and contribute to chronic degenerative processes such as arthritis, cancer, Alzheimer's, cardiovascular disease and diabetes. This body of research has been reaffirmed by the journal of the American Medical Association (June 19, 2002-Vol 287, No-23).

(Exhibit A-12)

### iV Bars Establishment Claims

H. In addition to the "The Science Behind iV Bars" section of the iV Bars Website homepage (discussed in Part 5.B., above), the Website homepage contained a link titled "ABOUT iV BARS: THE COMPANY" that linked consumers to a page titled "THE COMPANY BEHIND THE BAG." That page contained depictions of men and women dressed in white lab coats looking at test tubes and through microscopes. It declared, "Inspired by the early works of Dr. Myers, Aaron Keith founded iV Bars in 2015. He assembled a world class team of physicians, biochemists and physiologists to create the formulas . . . of iV Bars." Thereafter, under the subtitle "iV Bars Research Labs," Respondents claimed to have an "applied Biology and Chemistry Group" at a purported "iV Bars Labs" comprised of "experienced biologists, chemists, pharmacists, medical and naturopathic doctors and exercise physiologists" to, among other things, "test and approve inject-able formulations that are used in intravenous, subcutaneous and intramuscular administration":

### THE COMPANY BEHIND THE BAG

#### INSPIRATION

Inspired by the early works of Dr. Myers, Aaron Keith founded iV Bars in 2015. He assembled a world class team of physicians, biochemists and physiologists to create the formulas and developed the unique marketing concept of IV Bars. In 2015, on June 1st, iV Bars was sold for the very first time in its home market Texas. This was not only the launch of a completely new product, in fact it was the birth of a totally new product category.



#### iV Bars Research Labs

#### Commitment

The applied Biology and Chemistry Group at iV Bars Labs is comprised of experienced biologists, chemists, pharmacists, medical and naturopathic doctors and exercise physiologists with two major responsibilities.

Provide subject matter expertise in the fields of chemistry, molecular biology, biotechnology, microbiology, to help solve problems for on-going research.

Develop proof-of-concept novel nutraceutical technologies to test and approve inject-able formulations that are used in intravenous, subcutaneous and intramuscular administration.

(Exhibit A-2)

I. The Website Science pages also included a group of pages that began with a depiction of a DNA double helix and the title "SCIENTIFIC EVIDENCE." These pages then described the "FACTS" about the Myers Cocktail, including "published clinical research," and claimed that the Myers Cocktail "has been found to be effective" against a variety of diseases and conditions, including "fibromyalgia" and "cardiovascular disease":



(Exhibit A-14)

### J. The Scientific Evidence pages continued claiming:

The author took over the care of [Dr.] Myers' patients, using a modified version of his iV regimen . . . in order to approximate the doses reported to be safe and effective for the treatment of cardiovascular disease. . . . [T]he modified Myers' cocktail . . . was helpful for a wide range of clinical conditions, often producing dramatic results. . . . Conditions that frequently responded included . . . fibromyalgia . . . . A small number of patients with congestive heart failure [and] angina . . . were also treated with the Myers' and most showed marked improvement. . . . This paper presents a rationale for the use of IV nutrient therapy, reviews the relevant published clinical research, describes personal clinical experiences

using the Myers', and discusses potential side effects and precautions.

(Exhibit A-14)

K. The Scientific Evidence pages thereafter described purported clinical experiences of patients given a Myers Cocktail, including case studies of patients with Fibromyalgia and Cardiovascular Disease (that used the same text as contained in the "Success Stories" section of the Website discussed in Part 5.C., above). The Scientific Evidence pages "Conclusion" section stated, "The Myers' has been found by the author and hundreds of other practitioners to be a safe and effective treatment for a wide range of clinical conditions. In many instances this treatment is more effective and better tolerated than conventional medical therapies."

(Exhibit A-17)

# iV Bars Disclaimers

L. At the bottom of almost all of the iV Bars Website pages, Respondents included the following statement in grayed-out, difficult to read type, "FDA DISCLAIMER THESE STATEMENTS HAVE NOT BEEN EVALUATED BY THE FOOD AND DRUG ADMINISTRATION. THESE PRODUCTS ARE NOT INTENDED TO DIAGNOSE, TREAT, CURE OR PREVENT ANY DISEASE.":

	<u></u>
FDA DISCLAIMER THESE STATEMENTS HAVE NOT BEEN EVALUATED BY THE FOOD AND DRUG ADMINISTRATION THESE PRODUCTS ARE NOT INTENDED TO DIAGNOSE, TREAT, CURE OR PREVENT ANY DISEASE.	
@ 1/82FG 2016   DESIGN: STING MARKETING	PRIVICY POLICY - TERMS & CONDITIONS - CONTACT

(See, e.g., Exhibit A-1)

M. A number of the iV Bars Website pages also contained the following statement:

**Disclaimer**: You should consult your physician before taking vitamins, minerals, nutritional supplements or herbal products. Our vitamins and nutritional supplement products on this site are not intended to diagnose, treat, cure or prevent any disease. Final product ingredients and dosages may vary depending on personal requirements and availability. Statements made here have not been evaluated by FDA.

(Exhibit A-20 to 32)

### iV Bars Safety Claims

N. The iV Bars homepage stated, "Intravenous Vitamin Therapy [can be used] to both prevent and help treat a wide variety of conditions safely and effectively." The Website homepage did not contain a disclaimer or disclosure related to this unqualified safety claim.

(Exhibit A-1)

O. The Website's Medical page and its Mobile page prominently claimed that Respondents' iV treatments are "Safe for all ages" and that they cause "No side effects or down time." The website's Medical page and its Mobile page did not contain disclaimers or disclosures related to these unqualified safety claims.

(Exhibit A-7 & 10)

P. Buried in the Website's multiple Science pages was a disclosure that:

Small risks are associated with the intravenous injection process, which may include bruising around the injection site, and are similar to the risks of having your blood drawn for lab tests. Side Effects of treatment can include bruising around the site of the needle stick. Some patients may have a tendency to vascular fragility, and can suffer a phenomenon known as "infiltration", in which the walls of the vein rupture and the iV fluid leaks into the surrounding tissue causing local burning.

(Exhibit A-11)

Q. The Science pages also contained a lengthy discussion of "Side Effects and Precautions" for the Myers Cocktail that revealed a number of safety concerns, including the following statements:

Too rapid administration of magnesium can cause hypo-tension, which can lead to light-headedness or even syncope [temporary loss of consciousness].

\* \* \*

The shift of potassium from the serum to the intracellular space can trigger hypokalemia [low level of potassium in the blood serum]. The author has seen two patients develop severe muscle cramps several hours after receiving a Myers'; both patients had been taking medications known to deplete potassium. Hypokalemia also increases the risk of digoxin-induced cardiac arrhythmias. [One patient] developed an arrhythmia, which required short-term treatment in the intensive care unit.

\* \* \*

For elderly or frail individuals, it may be advisable to start with lower doses[.]

\* \* \*

[H]ypercalcemia can cause cardiac arrhythmias. For that reason, the author has tended to leave calcium out of the Myers' when treating patients with cardiac disease . . . . Anaphylactic reactions to IV thiamine have been reported on rare occasions. Only three such reactions have been identified in the U.S. literature since 1946. However, in the world literature, a total of nine deaths attributed to thiamine administration were reported between 1965 and 1985.

(Exhibit A-16 & 17)

R. The Science pages' ultimate "Conclusion" stated, "The Myers' has been found by the author and hundreds of other practitioners to be a safe and effective treatment for a wide range of clinical conditions."

(Exhibit A-17)

7. After arriving at iV Bars, but before being given an iV treatment, consumers are required to sign a two-page "Consent and Authorization for Intravenous Therapy Procedures" form releasing Respondents from liability ("Release Form"). An example of the Release Form is attached as Exhibit B. This Release Form disclosed that there are "risks" and "potentially dangerous side effects" involved with Respondents' iV treatments and contained the following statements, among others:

Risks: I understand there is risk of mild diarrhea, upset stomach, nausea, a feeling of pain and a warm sensation at the site of the injection, a feeling, or a sense, of being swollen over the entire body, headache and joint pain.

\* \* \*

Uncommon side effects are much more serious than the common side effects of Vitamin injections, and such side effects should be reported to a physician to be evaluated for seriousness. Uncommon and dangerous side effects include: • Headache • Nausea • Diarrhea • Bloating • Constipation • Indigestion or heartburn • Abnormal bleeding • Gastrointestinal hyperactivity • Chest pain • Flushed face • Chills • Fever • upset stomach • Kidney stones • Fingernail weakening • Hair loss • Rapid heartbeat heart palpitations • Restlessness • Muscle cramps and weakness • Dizziness

\* \* \*

I understand the possibility of having an allergic reaction to any of the ingredients found within the Vitamin injection is quite plausible .... If I experience any of these following signs of allergic reactions I should immediately consult my primary health care Physician and discontinue further use of the product. Signs of allergic reactions include, but [sic] not limited to:

- Itching of skin Hives Rashes Wheezing Difficulty breathing
- Swelling of mouth or throat

\* \* \*

When medications are taken in conjunction with the Vitamin Injection, drug interactions could occur. These interactions can either increase your risk of bleeding or block the absorption of the Vitamins into the body.

(Exhibit B-1 & 2)

# Falsity and Lack of Substantiation

- 8. Although Respondents' Website was replete with depictions of men and women dressed in white lab coats looking through microscopes and Respondents claimed to operate an "iV Bars Research Lab" with experienced biologists, chemists, pharmacists, medical doctors, naturopathic doctors and exercise physiologists, no such iV Bars Research Lab exists. In addition, neither Respondents, nor any third party commissioned by Respondents, conducted clinical research, tests, or studies of the safety or efficacy of Respondents' iV Cocktails.
- 9. There has been only one randomized and controlled human clinical trial of an iV Cocktail advertised by Respondents. That pilot study was of the Myers Cocktail given to patients with fibromyalgia. Although the study found a strong placebo effect, it found no statistically significant differences between subjects given the Myers Cocktail and those given a placebo, in any outcome measure, at 8 and 16 weeks. (*See* Intravenous Micronutrient Therapy (Myers' Cocktail) for Fibromyalgia: A Placebo-Controlled Pilot Study. Journal of Alternative and Complementary Medicine (March 2009)).

- 10. The purported substantiation relied on by Respondents for their disease treatment claims consists of anecdotal stories of iV therapy patients and studies and articles regarding individual active ingredients given to animals or humans in significantly different doses, formulations, routes of administration, or regimens than those advertised by Respondents.
- 11. The safety risks and potential complications from Respondents' iV treatments include infection, hypersensitivity and other allergic reactions, drug interactions, infiltration of iV fluid into the soft tissue outside the vain, hematoma, air embolism causing air to enter the vain, blood clots, phlebitis, and cellulitis. Potential side effects include diarrhea, upset stomach, nausea, bloating, constipation, headache, and joint pain. In addition, elderly consumers may be more susceptible to some of these risks and side effects. Respondents' own Website and Release Forms acknowledge many of these risks and side effects.

### <u>Count I</u> False or Unsubstantiated Safety and Efficacy Claims

- 12. In connection with the advertising, promotion, offering for sale, or sale of iV Cocktails, Respondents have represented, directly or indirectly, expressly or by implication, that their iV Cocktails:
  - A. are an effective treatment for cancer;
  - B. are an effective treatment for angina, cardiovascular disease, congestive heart failure, and myocardial infarction;
  - C. are an effective treatment for multiple sclerosis;
  - D. are an effective treatment for diabetes;
  - E. are an effective treatment for fibromyalgia;
  - F. are an effective treatment for neurodegenerative disorders;
  - G. produce fast, lasting results;
  - H. are safe for all ages; and
  - I. cause no side effects.
- 13. The representations set forth in Paragraph 12 are false or misleading, or were not substantiated at the time the representations were made.

### <u>Count II</u> False Establishment Claims

- 14. In connection with the advertising, promotion, offering for sale, or sale of iV Cocktails, Respondents have represented, directly or indirectly, expressly or by implication, that Respondents' iV Cocktails are clinically or scientifically proven to:
  - A. treat cancer;
  - B. treat angina, cardiovascular disease, congestive heart failure, and myocardial infarction;
  - C. treat multiple sclerosis;
  - D. treat diabetes;
  - E. treat fibromyalgia;
  - F. treat neurodegenerative disorders; and
  - G. produce fast, lasting results.
- 15. In fact Respondents' iV Cocktails are not clinically or scientifically proven to:
  - A. treat cancer;
  - B. treat angina, cardiovascular disease, congestive heart failure, and myocardial infarction;
  - C. treat multiple sclerosis;
  - D. treat diabetes;
  - E. treat fibromyalgia;
  - F. treat neurodegenerative disorders; and
  - G. produce fast, lasting results.
- 16. Therefore, the representations set forth in Paragraph 14 are false or misleading.

### **Violations of Sections 5 and 12**

17. The acts and practices of Respondents as alleged in this complaint constitute unfair or deceptive acts or practices, and the making of false advertisements, in or affecting commerce in violation of Sections 5(a) and 12 of the Federal Trade Commission Act.

**THEREFORE**, the Federal Trade Commission this \_\_\_\_\_ day of \_\_\_\_\_, 2018, has issued this Complaint against Respondents.

By the Commission.

Donald S. Clark Secretary

SEAL: