Analysis of Proposed Consent Order to Aid Public Comment

In the Matter of A & O Enterprises Inc, a corporation, doing business as iV Bars Incorporated and iV Bars, and Aaron K. Roberts, also known as Aaron Keith, individually and as owner and operating manager of A & O Enterprises Inc

File No. 172 3016

The Federal Trade Commission ("FTC" or "Commission") has accepted, subject to final approval, an agreement containing a consent order from A & O Enterprises Inc, a corporation, doing business as iV Bars Incorporated and iV Bars, and Aaron K. Roberts, also known as Aaron Keith ("respondents"). The proposed consent order ("order") has been placed on the public record for 30 days for receipt of comments by interested persons. Comments received during this period will become part of the public record. After 30 days, the Commission will again review the agreement, and the comments received, and will decide whether it should withdraw from the agreement and take appropriate action or make final the agreement's proposed order.

This matter involves respondents' advertising, promotion and sale of intravenous drip cocktails ("iV Cocktails"), including the Myers Cocktail, which contain a mixture of water, vitamins, minerals and amino acids. According to the FTC complaint, respondents made false or unsubstantiated representations that their iV Cocktails are effective treatments for cancer, angina, cardiovascular disease, congestive heart failure, myocardial infarction, multiple sclerosis, diabetes, fibromyalgia and neurodegenerative disorders, and that their cocktails produce fast, lasting results, are safe for all ages and cause no side effects. The FTC also alleges that respondents falsely represented that their iV Cocktails are clinically or scientifically proven to effectively treat the enumerated diseases and produce fast, lasting results. The complaint alleges that respondents' actions constitute unfair or deceptive acts or practices and the making of false advertisements, in violation of Sections 5(a) and 12 of the Federal Trade Commission Act.

The order is designed to prevent respondents from engaging in similar acts or practices in the future. It includes injunctive relief to address these alleged violations and to prohibit similar and related conduct.

- The order defines "covered product" to mean any intravenous therapy, including all of respondents' iV Cocktails, and any intramuscular injection.
- Part I of the order prohibits express or implied claims that any covered product: (1) is an effective treatment for cancer, angina, cardiovascular disease, congestive heart failure, myocardial infarction, multiple sclerosis, diabetes, fibromyalgia, or neurodegenerative disorders, (2) produces fast, lasting results, or (3) cures, mitigates, or treats any disease, unless the claim is supported by competent and reliable scientific evidence that is sufficient in quality and quantity, based on standards generally accepted by experts in the relevant area. It further requires that such substantiation include a randomized, double-blind, and placebo-controlled human clinical trial.

- Part II of the order prohibits express or implied health benefit, efficacy, safety, or side
 effects claims for any covered product, unless the representation is non-misleading, and,
 at the time the representation is made, proposed respondents possess and rely upon
 competent and reliable scientific evidence that is sufficient in quality and quantity to
 support the claim, based on standards generally accepted by experts in the area. It further
 provides that such substantiation must include a randomized, double-blind, and placebocontrolled human clinical trial, when experts generally require such human clinical
 testing to substantiate the representation.
- Part III of the order prohibits respondents, in connection with the advertising, promotion, offering for sale, or sale of any covered product, from misrepresenting, expressly or by implication, that they assembled physicians, biochemists, or physiologists to create, test or approve the products, or that they maintain a research facility, including an iV Bars Research Lab.
- Part IV of the order prohibits respondents, in connection with the advertising, promotion, offering for sale, or sale of any product or service, from making any misrepresentation about the existence, contents, validity, results, conclusions, or interpretations of any test, study, or other research, or that any product or service is scientifically or clinically proven to produce any benefit.
- Part V of the order requires that respondents, with regard to any human clinical test or study upon which they rely to substantiate any claim covered by the order, must preserve all underlying data and documents generally accepted by experts in the field as relevant to an assessment of the test.
- Part VI of the order provides that nothing in the order prohibits respondents from making a representation for any drug that is approved in labeling for such drug under any tentative final or final monograph promulgated by the Food and Drug Administration, or under any new drug application approved by the FDA.

Parts VII through XI are reporting and compliance provisions. Part VII mandates that respondents acknowledge receipt of the order and, for 10 years, distribute the order to certain employees and agents and secure acknowledgments from recipients of the order. Part VIII requires that respondents submit compliance reports to the FTC one year after the order's issuance and submit additional reports when certain events occur. Part IX requires that, for 10 years, respondents create certain records and retain them for at least 5 years. Part X provides for the FTC's continued compliance monitoring of respondents' activity during the order's effective dates. Part XI is a provision "sunsetting" the order after 20 years, with certain exceptions.

The purpose of this analysis is to facilitate public comment on the proposed order. It is not intended to constitute an official interpretation of the complaint or order, or to modify in any way the order's terms.