Analysis of Proposed Consent Order to Aid Public Comment
In the Matter of Focus Education, LLC, Michael Apstein, and John Able
File No. 122 3153

The Federal Trade Commission ("FTC" or "Commission") has accepted, subject to final approval, an agreement containing a consent order from Focus Education, LLC ("Focus Education"), Chief Executive Officer, Michael Apstein, and Chief Financial Officer, John Able ("Respondents").

The proposed consent order ("proposed order") has been placed on the public record for thirty (30) days for receipt of comments by interested persons. Comments received during this period will become part of the public record. After thirty (30) days, the Commission will again review the agreement and the comments received, and will decide whether it should withdraw from the agreement or make final the agreement's proposed order.

This matter involves Focus Education's advertising for the ifocus System, which included the Jungle Rangers computer game and comic book, and information on children's behavior, exercise, and diet. The Commission's complaint alleges that the Respondents violated Sections 5(a) and 12 of the Federal Trade Commission Act by making false or unsubstantiated representations that playing the ifocus System's Jungle Rangers computer game improves children's focus, memory, attention, behavior, and/or school performance, including in children with ADHD, and that these improvements were permanent. The complaint also alleges that Respondents violated Sections 5(a) and 12 by making false representations that scientific studies prove these claims.

The proposed order includes injunctive relief that prohibits these alleged violations and fences in similar and related violations. For purposes of the order, "Covered Product" means any product, program, device, or service that purports to alter the brain's structure or function, improve cognitive abilities, behavior, or academic performance, or treat or lessen the symptoms of cognitive abnormalities or disorders, including ADHD.

Part I of the Order prohibits the Respondents from making any representation that the ifocus System or any substantially similar product improves children's cognitive abilities, behavior, or academic performance, including in children with ADHD unless any such representation is non-misleading and the Respondents possess and rely upon competent and reliable scientific evidence. For purposes of this Part, competent and reliable scientific evidence is defined as "human clinical testing of such product that is sufficient in quality and quantity, based on standards generally accepted by experts in the relevant field, when considered in light of the entire body of relevant and reliable scientific evidence, to substantiate that the representation is true. Such testing shall be (1) randomized, double-blind, and adequately controlled; and (2) conducted by researchers qualified by training and experience to conduct such testing." In addition, competent and reliable scientific evidence is subject to the preservation requirements set forth in Part IV.

Part II is a fencing-in provision. It prohibits the Respondents from making any claim about the benefits, performance, or efficacy of any Covered Product unless the claim is non-misleading and the Respondents possess competent and reliable scientific evidence that is sufficient in quality and quantity, when considered in light of the entire body of relevant and reliable scientific evidence, to substantiate that the representation is true. For purposes of this Part, Covered Product is defined as any product, program, device, or service that purports to alter the brain's structure or function, improve cognitive abilities, behavior, or academic performance, or treat or lessen the symptoms of cognitive abnormalities or disorders, including ADHD. Competent and reliable scientific evidence means "tests, analyses, research, or studies (1) that have been conducted and evaluated in an objective manner by qualified persons; (2) that are generally accepted in the profession to yield accurate and reliable results; and (3) as to which, when they are human clinical tests or studies, all underlying or supporting data and documents generally accepted by experts in the field as relevant to an assessment of such testing as set forth Part IV are available for inspection and production to the Commission."

Part III prohibits the Respondents from misrepresenting, in relation to the advertising of any Covered Product, (1) the results of any test, study, or research; or (2) that the benefits of any such Covered Product are scientifically proven.

Part IV requires the Respondents, for human clinical tests or studies, to secure and preserve all underlying or supporting data and documents generally accepted by experts in the field as relevant to an assessment of the test. There is an exception for a "Reliably Reported" test, defined as a test published in a peer-reviewed journal that was not conducted, controlled, or sponsored by Respondents, affiliates, or others in the manufacturing and supply chain. Also, the published report must provide sufficient information about the test for experts in the relevant field to assess the reliability of the results.

Part V contains recordkeeping requirements for advertisements and substantiation relevant to representations covered by Parts I through III of the order.

Parts VI through IX of the proposed order require Respondents to: deliver a copy of the order to principals, officers, directors, managers, employees, agents, and representatives having responsibilities with respect to the subject matter of the order; notify the Commission of changes in corporate structure, discontinuance of current business or employment, or affiliation with any new business or employment that might affect compliance obligations under the order; and file compliance reports with the Commission.

Part X provides that the order will terminate after twenty (20) years, with certain exceptions.

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