**Statement of Commissioner Joshua D. Wright**
Federal Trade Commission v. Kevin Wright; HCG Platinum, LLC;
and Right Way Nutrition, LLC ("HCG Platinum")
December 11, 2014

The Federal Trade Commission ("Commission" or "FTC") announces today a settlement in *HCG Platinum*, a matter involving the advertising and marketing of weight-loss products purportedly containing human chorionic gonadotropin ("HCG"), a hormone produced by the human placenta that has long been falsely promoted by various marketers for weight loss. The FTC alleged in our October 2013 district court complaint that the defendants had made false or unsubstantiated claims that HCG Platinum products would cause rapid and substantial weight loss, were safe, and were clinically proven to burn fat, reduce weight, and lower cholesterol.[1]

Enforcement efforts that challenge false or unsubstantiated claims are an important component of the Commission's mission to protect consumers from economic injury.[2] This matter, where defendants promoted a very low-calorie diet in conjunction with consumption of their HCG products, also raised consumer health and safety issues.[3] I continue to support the Commission's efforts to deter deceptive advertising and voted in favor of issuing the complaint and authorizing this settlement.

I write today to reiterate my view that consent orders in these and other cases involving deceptive advertising should not define the "competent and reliable scientific evidence" required to substantiate claims covered under the terms of the settlement agreement by reference to a *fixed* number of randomized, clinical trials (RCTs).[4] Put simply, a rigid, static, numerical count of RCTs is a poor and unreliable proxy for an accurate measurement of the overall quality and quantity of evidence available to potentially substantiate claims.[5] A bright-line rule requiring a fixed number of RCTs – whether two or otherwise – is not without its benefits. For example, a standard requiring a fixed number of RCTs to substantiate claims covered under the consent order gives the FTC additional certainty when it enforces these orders. However, the decision to

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[1] FTC v. Kevin Wright; HCG Platinum, LLC; et al., No. 2:14CV0258 CW, Compl. ¶ 28 (D. Ariz. Oct. 30, 2013). Prior to filing the complaint, in November 2011, the FTC and FDA jointly issued warning letters to HCG Platinum and six other HCG marketers, advising them that their HCG products were mislabeled drugs under the FDA Act, and warning them that it is unlawful under the FTC Act to make weight-loss claims that are not supported by competent and reliable scientific evidence.

[2] In the Matter of GeneLink, Inc., et al., Statement of Commissioner Joshua D. Wright (Jan. 7, 2014) [hereinafter "Genelink Statement"], http://www.ftc.gov/public-statements/2014/01/statement-commissioner-joshua-d-wright-matter-genelink-inc-foru.

[3] Joint FDA/FTC Warning Letter Concerning Product Labeling of Human Chrorionic Gonadotropin (HCG) Drugs, LaTonya Mitchell, Director, Food and Drug Administration (FDA) Denver District Office; and Dr. Ilisa Bernstein, Acting Director, FDA Office of Compliance to Kevin Wright, HCG Platinum, LLC (Nov. 28, 2011), http://www.ftc.gov/public-statements/2011/11/joint-fdaftc-warning-letter-concerning-product-labeling-human-chrorionic-4.

[4] *See* Genelink Statement, *supra* note 2.

[5] Part II of the consent order requires that, prior to making any representation that a covered product causes weight loss, the defendants must possess and rely upon "competent and reliable scientific evidence" that substantiates such representation. The consent order further defines "competent and reliable scientific evidence" as "at least two adequate and well-controlled human clinical studies . . . when considered in light of the entire body of relevant and reliable scientific evidence, are sufficient to substantiate that the representation is true.

articulate the threshold level of evidence sufficient to substantiate a claim as a bright-line rule or as a more flexible standard inevitably involves tradeoffs between any consumer welfare gains generated by that increase in certainty on the one hand and the cost to consumers of reduced accuracy and less flexibility on the other.[6]

The optimal amount and type of evidence to substantiate any future claim – that is, the standard that best balances consumer welfare losses from deceptive claims against consumer welfare gains from the supply of accurate information – will vary from case to case. A rigid standard establishing a fixed number of RCTs in each case cannot account for the significant variance in quality across RCTs, and thus it runs the risk of overdeterring truthful claims that do not meet this standard. For purposes of quantifying the amount of evidence necessary to substantiate future claims, I believe that a more flexible standard would instead require the respondents to obtain "human clinical testing" of the product at issue that is sufficient in quality and quantity, based upon standards generally accepted by relevant experts.[7]

Consider a potential defendant under a Commission order making the choice between conducting two studies of size N, or one study of size 2N, using the same study design and methodology. Combining the two studies to get a single study of size 2N would result in additional statistical precision and, as a matter of inference, the combined sample would yield greater power and significance. When the Commission evaluates an advertising claim made by a company in the first instance, it could take advantage of the flexibility of the "competent and reliable scientific evidence" standard and determine the larger, more precise, and more powerful study read in conjunction with other forms of scientific evidence is sufficient to substantiate a claim. I see no reason the Commission should impose a more rigid standard when evaluating the claims of defendants under the terms of a consent order.

There is no tension between applying this more flexible standard and the role of replication in bolstering our confidence in observed relationships. For example, under the

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[6] *See, e.g.*, Louis Kaplow, *Rules Versus Standards: An Economic Analysis*, 42 DUKE L.J. 557 (1992-1993). The potential benefits of application of a flexible standard are clear in the context of food and drug claims. *See, e.g.*, Margaret A. Hamburg, Comm'r, Food & Drug Admin., "Why FDA Supports a Flexible Approach to Drug Development," http://blogs.fda.gov/fdavoice/index.php/2014/02/why-fda-supports-a-flexible-approach-to-drug-development/ (responding to a study that indicated more than a third of some drugs were approved on the basis of a single pivotal clinical trial, while still other trials involved only small groups of patients for shorter durations by stating that "Increased flexibility does not mean abandoning standards, and it certainly does not mean abandoning science. Just the opposite. We need to employ the best science in ways that will increase efficiency, productivity and our shared ability to find creative solutions to the challenges that confront us.").

[7] For example, the Commission utilized this approach in its recent *i-Health* consent order:

> For purposes of this Section, competent and reliable scientific evidence shall consist of human clinical testing that is sufficient in quality and quantity, based on standards generally accepted by experts in cognitive science, 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 randomized, double-blind, and placebo-controlled; and be conducted by researchers qualified by training and experience to conduct such testing. In addition, all underlying or supporting data and documents generally accepted by experts in cognitive science as relevant to an assessment of such testing, as set forth and described in the Part of this Order entitled Preservation of Records Relating to Competent and Reliable Human Clinical Tests or Studies, must be available for inspection and production to the Commission.

In the Matter of i-Health, Inc., FTC Docket No. C-4486, Decision and Order at Part I (Aug. 21, 2014), *available at* http://www.ftc.gov/enforcement/cases-proceedings/122-3067/i-health-martek-matter.

circumstances posited above, any gains from replication would be quite limited because little statistical power or precision would be added from a second study. Replication is valuable because it increases our confidence that the underlying relationship is not generated by chance or spurious correlation.[8] Replication is almost always likely to generate some marginal benefit. But the gains from replication may be limited and certainly do not always outweigh their costs.[9] The importance of replication will vary across settings.[10] Thus, it is unsurprising that it is only one of the factors that epidemiologists consider when determining whether an observed relationship is consistent with causality.[11] Accordingly, a more flexible substantiation standard, requiring "human clinical testing," would allow the Commission to emphasize this component in cases where it is most pertinent.[12]

Finally, I do not find persuasive the argument that the "at least 2 RCTs" requirement serves as effective "fencing-in" relief in cases, such as this one, where defendants have failed in the first instance to proffer *any* competent and reliable scientific evidence. A claim either has adequate substantiation or it does not. Requiring defendants – even defendants who have already run afoul of the law – to obtain more scientific evidence than necessary to substantiate their claims is not in the best interests of consumers.[13] I can see no rational economic basis for prohibiting claims the FTC would otherwise deem substantiated if made in the first instance – and thus presumptively beneficial to consumers – merely because the would-be substantiated claim is uttered by a party under order. This approach potentially taxes consumers rather than the defendant. Fencing-in can be achieved with remedial relief more narrowly tailored to the conduct of the defendant on a case-by-case basis rather than by altering the burden of proof applied to analyze the underlying evidence of substantiation.

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[8] *See, e.g.*, FEDERAL JUDICIAL CENTER, REFERENCE MANUAL ON SCIENTIFIC EVIDENCE, at 604 (3rd ed. 2003) ("The need to replicate research findings permeates most fields of science. In epidemiology, research findings often are replicated in different populations. Consistency in these findings is an important factor in making a judgment about causation.") (citation omitted).

[9] On the limits of RCTs, see James Heckman, *Randomization and Social Policy Evaluation*, *in* EVALUATING WELFARE AND TRAINING PROGRAMS, at 201 (C. Manski & I. Garfinkel eds., Harvard Univ. Press 1992); Angus Deaton, *Instruments, Randomization, and Learning about Development*, 48 J. ECON. LIT. no. 2, 424 (2010).

[10] *Id.* at 600 ("There is no formula or algorithm that can be used to assess whether a causal inference is appropriate based on these guidelines. One or more factors may be absent even when a true causal relationship exists. Similarly, the existence of some factors does not ensure that a causal relationship exists. Drawing causal inferences after finding an association and considering these factors requires judgment and searching analysis, based on biology, of why a factor or factors may be absent despite a causal relationship, and vice versa. Although the drawing of causal inferences is informed by scientific expertise, it is not a determination that is made by using an objective or algorithmic methodology.")

[11] *See id.* at 599 (factors include temporal relationship, strength of the association, dose–response relationship, replication of the findings, biological plausibility (coherence with existing knowledge), consideration of alternative explanations, cessation of exposure, specificity of the association, and consistency with other knowledge).

[12] This concept is already integrated into current order language. For example, the Commission's order in i-Health defines competent and reliable scientific evidence as consisting of human clinical testing that is "*sufficient in quality and quantity*, based on standards generally accepted by experts in cognitive science, when considered in light of the entire body of relevant and reliable scientific evidence, to substantiate that the representation is true." (emphasis added). If the defendant proffers human clinical testing that does not meet this standard, the claim has not been adequately substantiated. There is no need to require a fixed number of studies.

[13] Where there is evidence that defendants may have falsified or fabricated scientific data to produce a study offered to substantiate a claim, a fencing-in provision that requires "at least 2 RCTs" is more appropriately tailored to the circumstances. *See, e.g.*, FTC v. Applied Food Sciences, No. 1:14-cv:00851, Stipulated Order (W.D. Tex. Sept. 10, 2014), *available at* http://www.ftc.gov/enforcement/cases-proceedings/142-3054/applied-food-sciences-inc.

Finally, although the level of substantiation articulated in FTC orders necessarily applies only to the defendants at issue, I am concerned that there is a danger that these heightened requirements will cause a misimpression that such levels of substantiation are required for others, in the first instance.[14]

In light of the above considerations, I believe a more effective way to structure remedial relief would be to impose a baseline requirement that claims have the proper amount of substantiation and, in addition, to provide fencing-in relief by crafting other injunctive relief provisions more specifically tailored to curtail the defendants' illegal conduct. These provisions could include bans, performance bonds or document retention requirements for underlying study data. Indeed, in this case, the settlement order includes both a ban on making certain claims as well as a requirement to preserve documents relating to human clinical tests or studies.[15] I am pleased that the Commission has explored and implemented these alternatives.

Because we have so many tools are our disposal to effectively structure and tailor injunctive relief in ways other than a strict numbering of RCTs, I believe that there is no reason for the Commission to impose the certainty of a bright line requirement at the risk of sacrificing accuracy through a more flexible substantiation requirement.

Continuing to examine and evaluate our formulation of the competent and reliable scientific evidence standard, as well as the ancillary injunctive provisions in consent agreements, will serve to further our mission of protecting consumers from the costs imposed upon them by deceptive advertising while encouraging competition and truthful advertising that benefits consumers.

[14] *See, e.g.*, Randal Shaheen & Amy R. Mudge, *Has the FTC Changed the Game On Advertising Substantiation?*, 25 ANTITRUST 65 (Fall 2010).

[15] FTC v. Kevin Wright; HCG Platinum, LLC; et al., No. 2:14CV0258 CW, Stipulated Final Order at Parts I and VI (Dec. 9, 2014). *See also*, In the Matter of HealthyLife Sciences, LLC, FTC No. 122-3287, Agreement Containing Consent Order at Part I (prohibiting claims that a product such as a patch, cream, wrap, or other product worn on the body or rubbed into the skin will cause substantial or permanent weight loss) and Part VI (requiring preservation of data and documents underlying the studies used for substantiation); In the Matter of Wacoal America, Inc., FTC File No. 132-3095, Agreement Containing Consent Order at Part I (prohibiting claims that the product at issue causes substantial weight or fat loss or a substantial reduction in unclad body size) and Part IX (requiring preservation of data and documents underlying the studies used for substantiation); In the Matter of Norm Thompson Outfitters, Inc., FTC File No. 132-3094, Agreement Containing Consent Order at Part I (prohibiting claims that the product at issue causes substantial weight or fat loss or a substantial reduction in body size) and Part VIII (requiring preservation of data and documents underlying the studies used for substantiation); FTC v. Applied Food Sciences, Inc., FTC File No. 142-3054, Stipulated Final Order § XII (requiring preservation of records relating to competent and reliable human clinical tests or studies).