Statement of Chairwoman Edith Ramirez and Commissioner Julie Brill
FTC v. Wright, et al. ("HCG Platinum")
December 11, 2014

The action we announce today – *HCG Platinum*[1] – is the latest in a longstanding effort by the Commission to stop marketers from making deceptive, and often patently false, weight loss claims.[2] Unfortunately, however, this conduct has persisted in the marketplace. We write to express our support for the proposed consent order reached in this matter, including the requirement that the defendants substantiate future weight loss claims with two randomized controlled trials ("RCTs").

The Commission charged defendants with making 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. The original version of the product purportedly contained human chorionic gonadotropin ("hCG"), a hormone produced by the human placenta with a long history of being deceptively promoted for weight loss.[3] The defendants had received an explicit prior warning about marketing their product for weight loss from staff at both the Food and Drug Administration and the Commission, yet they continued to do so.[4]

The proposed order the Commission approves today is comprehensive and reasonable in light of the claims made by these defendants. Among its provisions, Section I of the order prohibits the defendants from making seven presumptively-false claims regarding weight loss products. Section II covers other weight loss claims (to the extent not banned under Section I) and requires that they be substantiated by two independently conducted, adequate and well-controlled human clinical studies. We believe the requirement in Section II, along with the other provisions, is appropriate and well-tailored.

By requiring two RCTs in this case, we take into account the very real and well-recognized principles regarding the benefits of replication in scientific studies, as well as their appropriate application to weight loss marketers who have already violated the law. Replication

[1] Complaint, *FTC v. Wright*, No. 2:14-cv-258-CW (D. Utah filed Oct. 30, 2013) (transferred from D. Ariz. on Apr. 9, 2014).

[2] The Commission filed its first weight loss case in 1927, and, since then, has filed hundreds of actions, including 85 cases in the last ten years alone. Nevertheless, in our 2011 survey of consumer fraud, the FTC reported that more consumers were victims of deceptively-marketed weight loss products than of any of the other specific frauds covered by the survey. *See* KEITH B. ANDERSON, FTC BUREAU OF ECON., Consumer Fraud in the United States, 2011: The Third FTC Survey (2013) at 17, http://www.ftc.gov/sites/default/files/documents/reports/consumer-fraud-united-states-2011-third-ftc-survey/130419fraudsurvey_0.pdf.

[3] *See, e.g.*, *In re. Simeon Mgmt. Corp.*, 87 F.T.C. 1184 (1976), *aff'd*, 579 F.2d 1137 (9th Cir. 1978).

[4] Joint FDA/FTC Warning Letter Concerning Prod. Labeling of Human Chorionic Gonadotropin (HCG) Drugs from LaTonya Mitchell, Dir., Food and Drug Administration (FDA) Denver Dist. Office; Mary K. Engle, Assoc. Dir., FTC Div. of Adver. Practices, and Dr. Ilisa Bernstein, Acting Dir., FDA Office of Compliance to Kevin Wright, CEO, HCG Platinum, LLC (Nov. 28, 2011), http://www.ftc.gov/public-statements/2011/11/joint-fdaftc-warning-letter-concerning-product-labeling-human-chrorionic-4.

reduces the risk that the result obtained in a single study may be due to chance, or may not lend itself to "'generalization due to the uniqueness of the study sample.'" *POM Wonderful LLC*, 155 F.T.C. 1, at 81 (Jan. 10, 2013) (quoting expert testimony with approval). Replication also reduces the risk of unanticipated and undetected biases that may lead to flawed conclusions.[5] Further, it may help guard against the manipulation or falsification of data – issues present in other recent Commission weight loss matters.[6] While the proposed consent order includes other provisions requiring the retention of underlying study data, that alone may not suffice to prevent bias or the falsification or manipulation of data, as the data itself may not necessarily reveal such deficiencies.

Moreover, in testing weight loss products, replication of results through a second RCT is particularly important, because almost any study purporting to find a product capable of causing substantial weight loss is likely to be novel and unexpected. Thus, from a scientific perspective, replication in this context likely only enhances accuracy.

The two RCT standard adopted in this settlement is consistent with the standard endorsed by those in the expert community for weight loss claims. It is also consistent with Commission precedent, as well as the Commission's past orders in weight loss matters. Additionally, requiring two RCTs will further our goal of ensuring that our orders in cases like this one are sufficiently specific to be enforced in court.

For the foregoing reasons, we support the consent order in this matter, including its requirement of two RCTs.

[5] According to experts, bias in science research is almost unavoidable and has become an important field of study and research. Christopher J. Pannucci & Edwin G. Wilkins, *Identifying and Avoiding Bias in Research*, 126 PLAST RECONSTR SURG. 619, (2010), *manuscript available at* http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2917255/.

[6] *See, e.g.*, *FTC v. Applied Food Sci.s, Inc.*, No. 1:14-cv-851 (W.D. Tex. Sept. 8, 2014); *FTC v. Sensa Prods., LLC*, No. 1:14-cv-72 (N.D. Ill. Jan. 8, 2014).