## CONCURRING STATEMENT OF COMMISSIONER MAUREEN K. OHLHAUSEN

Federal Trade Commission v. Kevin Wright; HCG Platinum, LLC; and Right Way Nutrition, LLC ("HCG Platinum")

December 11, 2014

I join my colleagues in accepting the proposed settlement in *HCG Platinum*, which involves advertising and marketing claims for weight-loss products containing human chorionic gonadotropin, a hormone that various marketers have long falsely promoted for weight loss. The settlement includes a requirement of two randomized controlled trials (RCTs) in its scope of relief. In the narrow instance of a product claiming rapid weight loss, I believe that two RCTs are appropriate substantiation under the Commission's traditional *Pfizer*<sup>1</sup> factors analysis, because such studies can be conducted in a relatively short amount of time at a lower cost than for many other health claims.<sup>2</sup>

However, consistent with my votes in *GeneLink* and *foru International* and other cases, my support for this settlement does not indicate my support for two RCTs as a general standard<sup>3</sup> or other Food and Drug Administration pre-approval requirements<sup>4</sup> to substantiate health- and disease-related claims for food or other relatively-safe products. As I have noted previously, "If we demand too high a level of substantiation in pursuit of certainty, we risk losing the benefits to consumers of having access to information about emerging areas of science and the corresponding pressure on firms to compete on the health features of their products." I reiterate my hope that as we consider future cases involving health- and disease-related claims, the Commission will engage in a further dialogue about our substantiation requirements to discern how best to assess the potential costs and benefits of allowing different types of evidence that may provide a reasonable basis to substantiate such claims.

<sup>&</sup>lt;sup>1</sup> Pfizer, Inc., 81 F.T.C. 23 (1972).

<sup>&</sup>lt;sup>2</sup> See In the Matter of GeneLink, Inc. and foru International Corporation; Federal Trade Commission v. Sensa Products, LLC; Federal Trade Commission v. HCG Diet Direct, LLC; In the Matter of L'Occitane, Inc.; Federal Trade Commission and State of Connecticut v. LeanSpa, LLC, Statement of Commissioner Maureen K. Ohlhausen, at 2 (Jan. 7, 2014), available at <a href="http://www.ftc.gov/public-statements/2014/01/statement-commissioner-maureen-k-ohlhausen-dissenting-part-concurring-part">http://www.ftc.gov/public-statements/2014/01/statement-commissioner-maureen-k-ohlhausen-dissenting-part-concurring-part</a> ("RCTs can be difficult to conduct and are often costly and time-consuming relative to other types of testing, particularly for diseases that develop over a long period of time or complex health conditions. Requiring RCTs may be appropriate in some circumstances, such as where use of a product carries some significant risk, or where the costs of conducting RCTs may be relatively low, such as for conditions whose development or amelioration can be observed over a short time period. Thus, I am willing to support the order requirement of two RCTs for short-term weight loss claims in the Sensa, HCG Diet Direct, L'Occitane, and LeanSpa matters because such studies can be conducted in a relatively short amount of time at a lower cost than for many other health claims.").

<sup>&</sup>lt;sup>3</sup> POM Wonderful, LLC, No. 9344, 2013 WL 268926, at \*64 n.36 (F.T.C. Jan. 10, 2013) (objecting to two-RCT standard for health claims for a food product).

<sup>&</sup>lt;sup>4</sup> Federal Trade Commission v. Springtech 77376, LLC, et al., FTC Matter No. X120042, Dissenting Statement of Commissioner Maureen K. Ohlhausen (July 16, 2013), available at <a href="http://www.ftc.gov/public-statements/2013/07/dissenting-statement-commissioner-maureen-k-ohlhausen">http://www.ftc.gov/public-statement-commissioner-maureen-k-ohlhausen</a>.

<sup>&</sup>lt;sup>5</sup> In the Matter of GeneLink, Inc., supra note 2, at 2.

<sup>&</sup>lt;sup>6</sup> Commissioner Maureen K. Ohlhausen, *Back to the Future on 600 Pennsylvania Avenue*, Remarks Before the ANA Advertising Law and Public Policy Conference, at 7-8 (Apr. 23, 2014), *available at* <a href="http://www.ftc.gov/public-statements/2014/04/back-future-600-pennsylvania-avenue-remarks-maureen-k-ohlhausen">http://www.ftc.gov/public-statements/2014/04/back-future-600-pennsylvania-avenue-remarks-maureen-k-ohlhausen</a>.