STATEMENT OF COMMISSIONER MAUREEN K. OHLHAUSEN
DISSENTING IN PART AND CONCURRING IN PART
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
January 7, 2014

I strongly support the Commission's enforcement efforts against false and misleading advertisements and therefore have voted in favor of the consent agreements with Sensa Products, LLC; HCG Diet Direct, LLC; L'Occitane, Inc.; and LeanSpa, LLC, despite having some concerns about the scope of the relief in several of these weight-loss related matters. I voted against the consent agreements in the matter of GeneLink, Inc. and foru International Corporation, however, because they impose an unduly high standard of at least two randomized controlled trials (or RCTs) to substantiate *any* disease-related claims, not just weight-loss claims. Adopting a one-size-fits-all approach to substantiation by imposing such rigorous and possibly costly requirements for such a broad category of health- and disease-related claims[1] may, in many instances, prevent useful information from reaching consumers in the marketplace and ultimately make consumers worse off.[2]

The Commission has traditionally applied the *Pfizer*[3] factors to determine the appropriate level of substantiation required for a specific advertising claim. These factors examine the nature of the claim and the type of product it covers, the consequences of a false claim, the benefits of a truthful claim, the cost of developing the required substantiation for the claim, and the amount of substantiation experts in the field believe is reasonable for such a claim.[4] One of the goals of the *Pfizer* analysis is to balance the value of greater

otherwise interfered with a study or its results.[9] Where defendants have fabricated results, as our complaint against Sensa alleges, a requirement of independent testing may be appropriate, but a simple failure to have adequate substantiation should not automatically trigger such an obligation. In other cases, where there is some concern about a sponsor or researcher biasing a study, our orders may address this in a less burdensome way by requiring the producer making the disease-related claims to provide the underlying testing data to substantiate its claims, which we can examine for reliability. Similarly, the requirement to test an "essentially equivalent product," which appears to be more rigorous than FDA requirements for food and supplement products, can significantly and unnecessarily increase the costs of substantiation, again potentially depriving consumers of useful information. Instead, Commission orders should clearly allow claims regarding individual ingredients in combined products as long as claims for each ingredient are properly substantiated and there are no known relevant interactions.[10]

It is my hope and recommendation that as we consider future cases involving health- and disease-related claims, the Commission and its staff 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 might provide a reasonable basis to substantiate such claims. Although I am willing to support liability for failures to have adequate substantiation for health- and disease-related claims under certain circumstances, I am not willing to support a de facto two-RCT standard on health- and disease-related claims for food or other relatively-safe products.

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[9] The FDA does not require independent testing for clinical investigational studies of medical products, including human drug and biological products or medical devices, and it permits sponsors to use a variety of approaches to fulfill their responsibilities for monitoring. *See* FDA Guidance for Industry Oversight of Clinical Investigations—A Risk-Based Approach to Monitoring (Aug. 2013), *available at* http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM269919.pdf.

[10] Although the statement by Chairwoman Ramirez and Commissioner Brill asserts that the orders in GeneLink and foru International permit claims for individual ingredients in combined products as long as the claims for each ingredient are properly substantiated and there are no known interactions, the orders actually require that "reliable scientific evidence generally accepted by experts in the field demonstrate that the amount and *combination of additional ingredients*