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 certainty of information about a product's claimed attributes with the risks of both the product itself and the suppression of potentially useful information about it. Under such an analysis, the burden for substantiation for health- or disease-related claims about a safe product, such as a food, for example, should be lower than the burdens imposed on drugs and biologics because consumers face lower risks when consuming the safe product.[5]

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[1] This provision may apply quite broadly in practice given the Commission majority's conclusion in our *POM Wonderful* decision that many of the claims involving the continued healthy functioning of the body also conveyed implied disease-related claims. *See POM Wonderful, LLC*, No. 9344, 2013 WL 268926 (F.T.C. Jan. 16, 2013).
[2] To be clear, however, I am not advocating in favor of permitting "unsubstantiated disease claims," as suggested in the statement of Chairwoman Ramirez and Commissioner Brill. Rather, I am suggesting that consumers would on balance be better off if we clarified that our requirements permit a variety of health- or disease-related claims about safe products, such as foods or vitamins, to be substantiated by competent and reliable scientific evidence that might not comprise two RCTs.
[3] *Pfizer, Inc.*, 81 F.T.C. 23 (1972).
[4] *Id.* at 91-93; *see also FTC Policy Statement Regarding Advertising Substantiation*, 104 F.T.C. 839 (1984) (appended to *Thompson Med. Co.*, 104 F.T.C. 648, 839 (1984)).
[5] The FDA designates most food ingredients as GRAS (generally recognized as safe). 21 C.F.R. § 170.30. Vitamins and minerals are treated as foods by the FDA and are also GRAS. *See* FDA Guidance for Industry: Frequently Asked Questions about GRAS (Dec. 2004), *available at* http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/IngredientsAdditivesGRASPackaging/ucm061846.htm#Q1. As a result, food ingredients, vitamins, and minerals can be combined and sold

Recently, however, Commission orders, including the ones in the matter of GeneLink and foru International, seem to have adopted two RCTs as a standard requirement for health- and disease-related claims for a wide array of products.[6] 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. My concern with GeneLink and foru International and the series of similar orders is that they might be read to imply that two RCTs are required to substantiate any health- or disease-related claims, even for relatively-safe products. It seems likely that producers may forgo making such claims about these kinds of products, even if they may otherwise be adequately supported by evidence that does not comprise two RCTs.[7]

Although raising the requirement for both the number and the rigor of studies required for substantiation for all health- or disease-related claims may increase confidence in those claims, the correspondingly increased burdens in time and money in conducting such studies may suppress information that would, on balance, benefit consumers. 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. In my view, the Commission should apply the *Pfizer* balancing test in a more finely calibrated manner than they have in the GeneLink and foru International orders to avoid imposing "unduly burdensome restrictions that might chill information useful to consumers in making purchasing decisions."[8]

In addition, based on the same concerns about imposing unnecessarily burdensome and costly obligations, I do not support a general requirement that all products be tested by different researchers working independently without an indication that the defendant fabricated or

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to the public without direct evidence on the particular combination realized in the new product. Many products are made up of several common generic ingredients, for which there is little financial incentive to test individually or to retest in each particular combination.

[6] The orders in this matter include as a Covered Product any food, drug, or cosmetic that is genetically customized or personalized for a consumer or that is promoted to modulate the effect of genes. Other cases requiring two RCTs are *POM Wonderful LLC*, Docket No. 9344 (F.T.C. Jan. 10, 2013) (fruit juice); *Dannon Co., Inc.*, 151 F.T.C. 62 (2011) (yogurt); *Nestlé Healthcare Nutrition, Inc.*, 151 F.T.C. 1 (2011) (food); *FTC v. Iovate Health Sci. USA, Inc.*, No. 10-CV-587 (W.D.N.Y. July 29, 2010) (dietary supplement).

[7] Notably, the medical community does not always require RCTs to demonstrate the beneficial effects of medical and other health-related innovations. For example, the recommendation that women of childbearing age take a folic acid supplement to reduce the risk of neural tube birth defects was made without RCT evidence on the relevant population. *See* Walter C. Willett, "Folic Acid and Neural Tube Defect: Can't We Come to Closure?" *American Journal of Public Health*, May 1992, Vol. 82, No. 5; Krista S. Crider, Lynn B. Bailey and Robert J. Berry, "Folic Acid Food Fortification—Its History, Effect, Concerns, and Future Directions," *Nutrients* 2011, Vol. 3, 370-384.

[8] FTC Staff Comment Before the Food and Drug Administration In the Matter of Assessing Consumer Perceptions of Health Claims, Docket No. 2005N-0413 (2006), *available at* http://www.ftc.gov/be/V060005.pdf.

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* is unlikely to impede or inhibit the effectiveness of the ingredients in the Essentially Equivalent Product." Decision and Order at 2, *In the Matter of GeneLink, Inc.* FTC File No. 112 3095 (emphasis added). My point is that the FDA does not require direct evidence regarding *combinations of individual ingredients deemed GRAS* but the order on its face requires scientific evidence demonstrating the effect of such combinations.