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 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.

Statement of Commissioner Joshua D. Wright

Today the Commission announces five settlements involving the deceptive marketing of a variety of nutritional and dietary supplements, skincare products, and weight-loss remedies. While the course of business conduct, type of product and particular advertising claim at issue in each case differs, all share one common characteristic—the Commission has alleged that, in the course of advertising their products, each of these defendants has made false or unsubstantiated claims about the treatment of certain medical or health conditions.

Cases that challenge false or unsubstantiated claims—especially those involving serious medical conditions—are an important component of our agency's mission to protect consumers from economic injury. Indeed, the aggregate consumer injury in these particular matters is estimated to be $420 million and these settlement agreements will return approximately $33 million to consumers. I fully support the Commission's efforts to deter deceptive advertising and voted in favor of authorizing these particular settlements.

In crafting remedial relief in these cases, the Commission inevitably faces a tradeoff between deterring deceptive advertising and preserving the benefits to competition and consumers from truthful claims. Tailoring remedial relief—including the level of substantiation required—to the specific claims at issue is in the best interests of consumers.[1] I write today to express some of my views on this issue.

Each of the consent agreements announced today includes injunctive relief provisions requiring the settling parties to satisfy a standard of ''competent and reliable scientific evidence'' before again making the claims at issue. Each consent agreement further defines ''competent and reliable scientific evidence'' as requiring, among other things, two adequate and well-controlled human clinical studies (randomized controlled trials or RCTs) of the product. I encourage the Commission to explore more fully whether the articulation and scope of injunctive relief in these and similar settlements strikes the right balance between deterring deceptive advertising and preserving for consumers the benefits of truthful claims. The optimal amount and type of evidence to substantiate a future claim will vary from case to case. Similarly, a fact-specific inquiry may justify specially crafted injunctive relief in certain cases, such as bans, performance bonds or document retention requirements for underlying study data. I look forward to working with my fellow Commissioners to continue to examine and evaluate our formulation of the competent and reliable scientific evidence standard, as well as the ancillary injunctive provisions in consent agreements, in order to best protect consumers from the costs imposed upon them by deceptive advertising while encouraging competition and truthful advertising that benefits consumers.

[FR Doc. 2014–00643 Filed 1–14–14; 8:45 am]

BILLING CODE 6750–01–P

[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), ://
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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. FDA Guidance for Industry Oversight of Clinical Investigations—A Risk-Based Approach to Monitoring (Aug. 2013), ://
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/ 269919. .

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

[1] The Commission's determination of whether an advertiser has adequate substantiation in the first instance depends upon ''a number of factors relevant to the benefits and costs of substantiating a particular claim. These factors include: The type of claim, the product, the consequences of a false claim, the benefits of a truthful claim, the cost of developing substantiation for the claim, and the amount of substantiation experts in the field believe is reasonable.'' FTC Policy Statement Regarding Advertising Substantiation, appended to ., 104 F.T.C. 648, 839 (1984), ' , 791 F.2d 189 (D.C. Cir. 1986), . , 479 U.S. 1086 (1987). Formulating the required level of substantiation for injunctive relief should necessarily be grounded in the factors set forth in this policy statement, although additional considerations might also be relevant.

FEDERAL TRADE COMMISSION

[File No. 122 3115]

L'Occitane, Inc.; Analysis of Proposed Consent Order To Aid Public Comment

AGENCY: Federal Trade Commission.

ACTION: Proposed consent agreement.

[11] Ohlhausen Statement at 2–3.

[12] Commissioner Ohlhausen also obsor, - 9,c. or an ''essentially P,8ivalent product,'' arguing that 9,c.order should authorize ''claims,hPgarding orders do not hP,8ire testing of the combined product. ⁄ Proposed Consent Orders at 3 permit additional ingredients, beyond those in the generally accepted by Pxperts in the field additional ingredients [in the respondent's product]

trial of over 35,000 men contradicted ''considerable preclinical and epidemiological evidence that selenium and vitamin E may reduce prostate cancer risk,'' and that follow-up observational data from 2011 showed a statistically significant ⁄ in prostate cancer in the vitamin E group over placebo).

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 *P* 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 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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(2011) (yogurt); , ., 151 F.T.C. 1 (2011) (food); v. , 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. Walter C. Willett, ''Folic Acid and Neural Tube Defect: Can't We Come to Closure?'' *P* , 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,'' 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), ://
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Continued

relevant to the benefits and costs of substantiating a particular claim. These factors include: the type of claim, the product, the consequences of a false claim, the benefits of a truthful claim, the cost of developing substantiation for the claim, and the amount of substantiation experts in the field believe