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]

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[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.*

[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.

[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 *Thompson Medical Co.,* 104 F.T.C. 648, 839 (1984), *aff'd,* 791 F.2d 189 (D.C. Cir. 1986), *cert. denied,* 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.

SUMMARY: The consent agreement in this matter settles alleged violations of federal law prohibiting unfair or deceptive acts or practices or unfair methods of competition. The attached Analysis of Proposed Consent Order to Aid Public Comment describes both the allegations in the draft complaint and the terms of the consent order—embodied in the consent agreement—that would settle these allegations.

DATES: Comments must be received on or before February 6, 2014.

ADDRESSES: Interested parties may file a comment at *https://ftcpublic.commentworks.com/ftc/loccitaneconsent* online or on paper, by following the instructions in the Request for Comment part of the **SUPPLEMENTARY INFORMATION** section below. Write ''L'Occitane, Inc.—Consent Agreement; File No. 122 3115'' on your comment and file your comment online at *https://ftcpublic.commentworks.com/ftc/fidelitynationalconsent https://ftcpublic.commentworks.com/ftc/loccitaneconsent* by following the instructions on the web-based form. If you prefer to file your comment on paper, mail or deliver your comment to the following address: Federal Trade Commission, Office of the Secretary, Room H–113 (Annex D), 600 Pennsylvania Avenue NW., Washington, DC 20580.

FOR FURTHER INFORMATION CONTACT: Matthew D. Gold, Federal Trade Commission Western Region, (415–848–5100), 901 Market Street, Suite 570 San Francisco, CA 94103.

SUPPLEMENTARY INFORMATION: Pursuant to Section 6(f) of the Federal Trade Commission Act, 15 U.S.C. 46(f), and FTC Rule 2.34, 16 CFR 2.34, notice is hereby given that the above-captioned consent agreement containing consent order to cease and desist, having been filed with and accepted, subject to final approval, by the Commission, has been placed on the public record for a period of thirty (30) days. The following Analysis to Aid Public Comment describes the terms of the consent agreement, and the allegations in the complaint. An electronic copy of the full text of the consent agreement package can be obtained from the FTC Home Page (for January 7, 2014), on the World Wide Web, at *http://www.ftc.gov/os/actions.shtm.* A paper copy can be obtained from the FTC Public Reference Room, Room 130–H, 600 Pennsylvania Avenue NW., Washington, DC 20580, either in person or by calling (202) 326–2222.

You can file a comment online or on paper. For the Commission to consider your comment, we must receive it on or before February 6, 2014. Write ''L'Occitane, Inc.—Consent Agreement; File No. 122 3115'' on your comment. Your comment—including your name and your state—will be placed on the public record of this proceeding, including, to the extent practicable, on the public Commission Web site, at *http://www.ftc.gov/os/publiccomments.shtm.* As a matter of discretion, the Commission tries to remove individuals' home contact information from comments before placing them on the Commission Web site.

Because your comment will be made public, you are solely responsible for making sure that your comment does not include any sensitive personal information, like anyone's Social Security number, date of birth, driver's license number or other state identification number or foreign country equivalent, passport number, financial account number, or credit or debit card number. You are also solely responsible for making sure that your comment does not include any sensitive health information, like medical records or other individually identifiable health information. In addition, do not include any ''[t]rade secret or any commercial or financial information which . . . is privileged or confidential,'' as discussed in Section 6(f) of the FTC Act, 15 U.S.C. 46(f), and FTC Rule 4.10(a)(2), 16 CFR 4.10(a)(2). In particular, do not include competitively sensitive information such as costs, sales statistics, inventories, formulas, patterns, devices, manufacturing processes, or customer names.

If you want the Commission to give your comment confidential treatment, you must file it in paper form, with a request for confidential treatment, and you have to follow the procedure explained in FTC Rule 4.9(c), 16 CFR 4.9(c).[1] Your comment will be kept confidential only if the FTC General Counsel, in his or her sole discretion, grants your request in accordance with the law and the public interest.

Postal mail addressed to the Commission is subject to delay due to heightened security screening. As a result, we encourage you to submit your comments online. To make sure that the Commission considers your online comment, you must file it at *https://ftcpublic.commentworks.com/ftc/loccitaneconsent* by following the instructions on the web-based form. If this Notice appears at *http://www.regulations.gov/#!home,* you also may file a comment through that Web site.

If you file your comment on paper, write ''L'Occitane, Inc.—Consent Agreement; File No. 122 3115'' on your comment and on the envelope, and mail or deliver it to the following address: Federal Trade Commission, Office of the Secretary, Room H–113 (Annex D), 600 Pennsylvania Avenue NW., Washington, DC 20580. If possible, submit your paper comment to the Commission by courier or overnight service.

Visit the Commission Web site at *http://www.ftc.gov* to read this Notice and the news release describing it. The FTC Act and other laws that the Commission administers permit the collection of public comments to consider and use in this proceeding as appropriate. The Commission will consider all timely and responsive public comments that it receives on or before February 6, 2014. You can find more information, including routine uses permitted by the Privacy Act, in the Commission's privacy policy, at *http://www.ftc.gov/ftc/privacy.htm.*

Analysis of Proposed Consent Order To Aid Public Comment

The Federal Trade Commission (''FTC'' or ''Commission'') has accepted, subject to final approval, an Agreement Containing Consent Order from L'Occitane, Inc. (''respondent''). The proposed consent order has been placed on the public record for thirty (30) days for receipt of comments by interested persons. Comments received during this period will become part of the public record. After thirty (30) days, the Commission will again review the agreement and the comments received, and will decide whether it should withdraw from the agreement and take appropriate action or make final the agreement's proposed order.

This matter involves the advertising, marketing, and sale of ''Almond Beautiful Shape'' and ''Almond Shaping Delight'' (collectively, ''the almond products'') by respondent. Respondent has marketed the almond products to consumers through its retail stores and Web site, and through third-party retail outlets.

The almond products are skin creams that contain almond extracts and other ingredients. According to the FTC complaint, respondent promoted the almond products as able to slim and reshape the body.

Specifically, the FTC complaint alleges that respondent represented, in various advertisements, that topical use of Almond Beautiful Shape trims 1.3

[1] In particular, the written request for confidential treatment that accompanies the comment must include the factual and legal basis for the request, and must identify the specific portions of the comment to be withheld from the public record. *See* FTC Rule 4.9(c), 16 CFR 4.9(c).

inches from the user's thighs in just four weeks; topical use of Almond Beautiful Shape significantly slims the user's thighs and buttocks; topical use of Almond Beautiful Shape significantly reduces cellulite; and topical use of Almond Shaping Delight significantly slims the body in just four weeks. The complaint alleges that these claims are unsubstantiated and thus violate the FTC Act. The complaint also alleges that respondent represented, in various advertisements, that scientific tests prove that topical use of Almond Beautiful Shape trims 1.3 inches from the user's thighs in just four weeks; scientific tests prove that topical use of Almond Beautiful Shape significantly reduces cellulite; and scientific tests prove that Almond Shaping Delight significantly slims the body in just four weeks. The complaint alleges that these claims are false and thus violate the FTC Act.

The proposed consent order contains provisions designed to prevent respondent from engaging in similar acts or practices in the future. Specifically, Part I prohibits respondent from claiming that the almond products or any other topically applied product causes substantial weight or fat loss or a substantial reduction in body size. Part I of the order is designed to fence in respondent by ensuring that extreme, scientifically unfeasible claims will not be made in the future.

Part II addresses the slimming claims at issue in this matter. It covers any representation, other than representations covered under Part I, that a drug or cosmetic causes weight or fat loss or a reduction in body size. Part II prohibits respondent from making such representations unless the representation is non-misleading, and, at the time of making such representation, respondent possesses and relies upon competent and reliable scientific evidence that substantiates that the representation is true. For purposes of Part II, the proposed order defines ''competent and reliable scientific evidence'' as at least two randomized, double-blind, placebo-controlled human clinical studies that are conducted by independent, qualified researchers and that conform to acceptable designs and protocols, and whose results, when considered in light of the entire body of relevant and reliable scientific evidence, are sufficient to substantiate that the representation is true.

Part III of the proposed order prohibits respondent from making any representation, other than representations covered under Parts I or II, that use of a drug or cosmetic reduces or eliminates cellulite or affects body fat or weight, unless the representation is non-misleading, and, at the time of making such representation, respondent possesses and relies upon competent and reliable scientific evidence that is sufficient in quality and quantity based on standards generally accepted in the relevant scientific fields, when considered in light of the entire body of relevant and reliable scientific evidence, to substantiate that the representation is true. For purposes of Part III, the proposed order defines ''competent and reliable scientific evidence'' as tests, analyses, research, or studies that have been conducted and evaluated in an objective manner by qualified persons, and that are generally accepted in the profession to yield accurate and reliable results.

Part IV of the proposed order addresses the allegedly false claims that scientific tests prove that topical use of Almond Beautiful Shape trims 1.3 inches from the user's thighs in just four weeks; scientific tests prove that topical use of Almond Beautiful Shape significantly reduces cellulite; and scientific tests prove that Almond Shaping Delight significantly slims the body in just four weeks. Part IV prohibits respondent, when advertising any product, from misrepresenting the existence, contents, validity, results, conclusions, or interpretations of any test, study, or research, or misrepresenting that the benefits of the product are scientifically proven.

Part V of the proposed order states that the order does not prohibit respondent from making representations for any drug that are permitted in labeling for that drug under any tentative or final standard promulgated by the Food and Drug Administration (''FDA''), or under any new drug application approved by the FDA. This part of the proposed order also states that the order does not prohibit respondent from making representations for any product that are specifically permitted in labeling for that product by regulations issued by the FDA under the Nutrition Labeling and Education Act of 1990.

Part VII of the proposed order requires respondent to pay four hundred and fifty thousand dollars ($450,000) to the Commission to be used for equitable relief, including restitution, and any attendant expenses for the administration of such equitable relief. To facilitate the payment of redress, Part VI of the proposed order requires L'Occitane to provide to the Commission a searchable electronic file containing the name and contact information of all consumers who purchased the almond products from March 19, 2012 through the date of entry of the order.

Parts VIII, IX, X, and XI of the proposed order require respondent to keep copies of relevant advertisements and materials substantiating claims made in the advertisements; to provide copies of the order to its personnel; to notify the Commission of changes in corporate structure that might affect compliance obligations under the order; and to file compliance reports with the Commission. Part XII provides that the order will terminate after twenty (20) years, with certain exceptions.

The purpose of this analysis is to facilitate public comment on the proposed order, and it is not intended to constitute an official interpretation of the agreement and proposed order or to modify their terms in any way.

By direction of the Commission.

Donald S. Clark,

Secretary.

Statement of Chairwoman Edith Ramirez and Commissioner Julie Brill

We write to explain our support for the remedy imposed against respondents GeneLink, Inc. and foru International Corporation, which we believe to be amply supported by the relevant facts. In this, as in all of the Commission's advertising actions alleging deceptive health claims, the Commission has called for, as proposed relief, a level of substantiation that is grounded in concrete scientific evidence and reasonably tailored to ensure that the conduct giving rise to the violation ceases and does not recur, among other important remedial goals. In our view, the remedy adopted here accomplishes just that, without imposing undue costs on marketers or consumers more generally.

Respondents market and sell genetically customized nutritional supplements and topical skin products. As described in the complaint, this enforcement action stems from claims made by respondents in promotional materials and through testimonials that their products compensate for consumers' ''genetic disadvantages'' and cure or treat serious conditions such as diabetes, heart disease, and arthritis. In a newsletter, for example, respondents represented their products had cured ''a serious diabetic and cardiac patient,'' and an affiliate's Web site stated that the products produced ''improvements in everything from blood pressure to eczema to hormonal issues to arthritis.'' [1] The Commission alleges that

[1] Compl. Exs. G and H.

respondents lacked adequate substantiation for these claims and that they falsely represented that the products' benefits were scientifically proven.

Disease treatment claims such as these require a rigorous level of substantiation. Based on evidence from genetics and nutritional genomics experts, the Commission has reason to believe that well-controlled human clinical trials (referred to here as ''randomized controlled trials'' or ''RCTs'') are needed to substantiate respondents' claims and that the studies relied on by respondents to back up their claims fall far short of this evidence. Because respondents lacked even one valid RCT for their products, it was unnecessary for the Commission to decide, for purposes of assessing liability, the precise number of RCTs needed to substantiate their claims.

In fashioning an appropriate remedy, however, we are requiring that respondents have at least two RCTs before making disease prevention, treatment, and diagnosis claims. We have the discretion to issue orders containing ''fencing-in'' provisions—''provisions . . . that are broader than the conduct that is declared unlawful.'' *Telebrands Corp.* v. *FTC,* 457 F.3d 354, 357 n.5 (4th Cir. 2006) (citation and internal quotation marks omitted). Here, we believe that the two-RCT mandate is appropriate and reasonably crafted to prevent the recurrence of respondents' alleged unlawful conduct. This requirement conforms to well-recognized scientific principles favoring replication of study results to establish a causal relationship between exposure to a substance and a health outcome. *See, e.g., Thompson Med. Co.,* 104 F.T.C. 648, 720–21, 825 (1984) (requiring two RCTs to support claims of arthritis pain relief and thereby affirming determination that ''[r]eplication is necessary because there is a potential for systematic bias and random error in any clinical trial''), *aff'd,* 791 F.2d 189 (D.C. Cir. 1986).[2] It also provides clear rules for respondents, facilitating the setting of future research and marketing agendas, and preserves law enforcement resources by minimizing future argument over the quantity and quality of substantiation needed for the most serious health claims about respondents' products. Moreover, the deceptive claims alleged in the complaint are the type of significant violations of law for which fencing-in relief is more than justified as an additional safeguard against potential recidivism. *See, e.g., id.* at 834 (ruling that deceptive health claims about topical analgesic for arthritis pain warranted fencing-in, and noting that the seriousness of the violations was ''affected by the fact that consumers could not readily judge the truth or falsity of the claims'').

While not taking issue with respondents' liability as alleged in the Commission's complaint, Commissioner Ohlhausen objects to the Commission's decision to require, as a remedial matter, that respondents have at least two RCTs before representing that their genetic products can cure, treat, diagnose, or prevent a disease. In addition to arguing that the two-RCT requirement is ''unduly high,'' Commissioner Ohlhausen expresses concern that these and other recent Commission orders may lead advertisers in general to believe that they too must invariably have two RCTs to substantiate health and disease claims for a variety of products, leading them to forgo otherwise adequately substantiated claims and depriving consumers of potentially useful information.[3] We respectfully disagree.

There is nothing in our action today that amounts to the imposition of a ''de facto two-RCT standard on health- and disease-related claims.''[4] In this and other recent enforcement actions, the Commission has consistently adhered to its longstanding view that the proper level of substantiation for establishing liability is a case-specific factual determination as to what constitutes competent and reliable scientific evidence for the advertising claims at issue.[5] The same fact-specific approach has guided the Commission's remedial standards. Recent Commission consent orders concerning different types of health claims have variously required two RCTs,[6] one RCT,[7] or more generally defined ''competent and reliable scientific evidence.''[8] Against this backdrop, we are not persuaded that by requiring two RCTs as a remedial matter here, the Commission will create a misperception among advertisers about the substantiation standards that govern liability for deceptive advertising.[9] However, to the extent other marketers look to our orders for signals as to the type of backing required for disease treatment claims, we prefer that they understand that serious claims like those made by respondents must have hard science behind them.

We also disagree that the proposed remedy will deny consumers access to useful information about new areas of science. The value of information naturally depends on its accuracy.[10] As

[2] *See also* Geoffrey Marczyk et al., Essentials of Research Design and Methodology 15–16 (2005) (''The importance of replication in research cannot be overstated. Replication serves several integral purposes, including establishing the reliability (*i.e.,* consistency) of the research study's findings and determining . . . whether the results of the original study are *generalizable* to other groups of research participants.'').

[3] Statement of Commissioner Maureen K. Ohlhausen, Dissenting in Part and Concurring in Part [hereinafter Ohlhausen Statement] at 1. In her Statement, Commissioner Ohlhausen also references various weight-loss related enforcement actions announced today by the Commission, including *FTC* v. *Sensa Products, LLC.* Her objections, however, center on the remedy imposed in this matter.

[4] Ohlhausen Statement at 3.

[5] *See, e.g., Bristol Meyers Co.,* 102 F.T.C. 21, 332–38 (1983), *aff'd,* 738 F.2d 554 (2d Cir. 1984); FTC, Dietary Supplements: An Advertising Guide for Industry 10 (Apr. 2001) [hereinafter Dietary Supplements Advertising Guide] (''When no specific claim about the level of support is made, the evidence needed depends on the nature of the claim. A guiding principle for determining the amount and type of evidence that will be sufficient is what experts in the relevant area of study would generally consider to be adequate.'').

[6] *See, e.g., FTC* v. *Skechers U.S.A., Inc.,* No. 1:12–cv–01214–JG (N.D. Ohio July 12, 2012) (prohibiting, as a remedial matter, weight loss claims without two RCTs); *FTC* v. *Labra,* No. 11 C 2485 (N.D. Ill. Jan. 11, 2012) (same); *FTC* v. *Iovate Health Scis. USA, Inc.,* No. 10–cv–587 (W.D.N.Y. July 29, 2010) (same); *Nestlé Healthcare Nutrition, Inc.,* 151 F.T.C. 1 (2011) (requiring two RCTs for claims that any probiotic drink or certain nutritionally complete drinks reduce the duration of acute diarrhea in children or absences from daycare or school due to illness).

[7] *See, e.g., FTC* v. *Skechers U.S.A., Inc.,* No. 1:12–cv–01214–JG (N.D. Ohio July 12, 2012) (prohibiting muscle strengthening claims for any footwear product without one RCT); *FTC* v. *Reebok Int'l Ltd.,* No. 1:11–cv–02046–DCN (N.D. Ohio Sept. 29, 2011) (same).

[8] *See, e.g., NBTY, Inc.,* 151 F.T.C. 201 (2011) (requiring marketer of vitamins to possess ''competent and reliable scientific evidence'' for any claim about the health benefits, performance, or efficacy of any product).

[9] Moreover, as Commissioner Ohlhausen notes, Ohlhausen Statement at 2 n.7, there may be some instances in which the medical community would not require RCTs to demonstrate that a substance treats, prevents, or reduces the risk of a disease. *See, e.g.,* Dietary Supplements Advertising Guide, *supra* note 5, at 11 (explaining that an appropriately qualified claim based on epidemiological evidence would be permitted where ''[a] clinical intervention trial would be very difficult and costly to conduct,'' ''experts in the field generally consider epidemiological evidence to be adequate'' and there is no ''stronger body of contrary evidence''). But, contrary to Commissioner Ohlhausen's contention, the link between folic acid and neural tube birth defects was substantiated using a combination of RCTs and observational epidemiological evidence, as indicated by the articles she cites. *See, e.g.,* Walter C. Willett, *Folic Acid and Neural Tube Defect: Can't We Come to Closure?,* 82 Am. J. Pub. Health 666, 667 (1992).

[10] In some instances, ''emerging'' scientific evidence has been subsequently contradicted by further research, leading to consumer confusion and potential physical and financial harm. *See, e.g.,* Eric A. Klein *et al., Vitamin E and the Risk of Prostate Cancer, The Selenium and Vitamin E Cancer Prevention Trial (SELECT),* 306 J. Am. Med. Ass'n 1549, 1551 (2011) (reporting that a 2008 randomized, placebo-controlled prospective clinical

Continued

the DC Circuit has emphasized, ''misleading advertising does not serve, and, in fact, disserves, th[e] interest'' of ''consumers and society . . . in the free flow of commercial information.'' *FTC* v. *Brown & Williamson Tobacco Corp.,* 778 F.2d 35, 43 (D.C. Cir. 1985) (citation and internal quotation marks omitted). If respondents wish to rely on emerging science, they can qualify their claims accordingly. Properly qualified claims are lawful and permissible under our proposed orders. *See* Proposed Consent Orders, Part III.

The fact that the ingredients in respondents' products are safe also does not alter our conclusion. Consumers who rely on respondents' claims may forgo important diet and lifestyle changes that are known to reduce the risk of diabetes, heart disease, or arthritis. Or they may forgo treatments that, unlike respondents' products, have been demonstrated to be effective. In addition, respondents charge a premium, over $100 per month, for their customized products. Consumers, therefore, may be deceived both to their medical and economic detriment when a safe product provides an ineffective treatment. *See FTC* v. *QT, Inc.,* 512 F.3d 858, 863 (7th Cir. 2008) (safe but deceptively advertised treatment ''will lead some consumers to avoid treatments that cost less and do more; the lies will lead others to pay too much for [treatment] or otherwise interfere with the matching of remedies to medical conditions''); *Pfizer Inc.,* 81 F.T.C. 23, 62 (1972) (''A consumer should not be compelled to enter into an economic gamble to determine whether a product will or will not perform as represented.''). Unsubstantiated disease claims also harm honest competitors that expend considerable resources on studies or analyses of the existing science and conform their advertising claims accordingly. Allowing companies to rely on ''emerging'' evidence to support disease claims merely because the products in question are safe would risk a ''race to the bottom''—the proliferation of progressively more egregious disease claims, which would harm both legitimate competitors and consumers in the process.

Finally, Commissioner Ohlhausen argues that requiring the RCTs to be conducted by different researchers working independently of each other imposes undue burdens in the absence of evidence that a defendant has fabricated or interfered with a study or its results.[11] This requirement is an important safeguard that lessens the likelihood that researcher bias will affect the outcome of a study and helps ensure that the results are replicable.[12]

In short, we believe the relief obtained by the Commission in this settlement is warranted and strikes the right balance between the need for accuracy in health-related advertising claims and the burden placed on respondents.

Statement of Commissioner Maureen K. Ohlhausen Dissenting In Part and Concurring In Part

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]

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

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 *increase* in prostate cancer in the vitamin E group over placebo).

[11] Ohlhausen Statement at 2–3.

[12] Commissioner Ohlhausen also objects to the Part I requirement that testing be conducted on the product about which the advertising claim is made or an ''essentially equivalent product,'' arguing that the order should authorize ''claims regarding individual ingredients in combined products as long as claims for each ingredient are properly substantiated and there are no known interactions.'' Ohlhausen Statement at 3. In fact, the orders permit that very thing. If there is reliable evidence that the additional ingredients will not interact with the tested product in a way that impacts efficacy, the orders do not require testing of the combined product. *See* Proposed Consent Orders at 3 (defining ''Essentially Equivalent Product'' to permit additional ingredients, beyond those in the tested product, if ''reliable scientific evidence generally accepted by experts in the field demonstrates that the amount and combination of additional ingredients [in the respondent's product] is unlikely to impede or inhibit the effectiveness of the ingredients in the [tested product]'').

[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 CFR 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 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

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 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.

(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.*

[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.

[1] The Commission's determination of whether an advertiser has adequate substantiation in the first instance depends upon ''a number of factors

Continued

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.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–14–0916]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) publishes a list of information collection requests under review by the Office of Management and Budget (OMB) in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these requests, call (404) 639–7570 or send an email to *omb@cdc.gov.* Send written comments to CDC Desk Officer, Office of Management and Budget, Washington, DC 20503 or by fax to (202) 395–5806. Written comments should be received within 30 days of this notice.

Proposed Project

Evaluation of Core Violence and Injury Prevention Program (Core VIPP)—Revision—(0920–0916, Expiration 1/13/2014)—National Center for Injury Prevention and Control (NCIPC), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Injuries and their consequences, including unintentional and violence-related injuries, are the leading cause of death for the first four decades of life, regardless of gender, race, or socioeconomic status. More than 179,000 individuals in the United States die each year as a result of unintentional injuries and violence, more than 29 million others suffer non-fatal injuries and over one-third of all emergency department (ED) visits each year are due to injuries.[1] In 2000, injuries and violence ultimately cost the United States $406 billion, with over $80 billion in medical costs and the remainder lost in productivity.[1] Most events that result in injury and/or death from injury could be prevented if evidence-based public health strategies, practices, and policies were used throughout the nation.

CDC's National Center for Injury Prevention and Control (NCIPC) is committed to working with their partners to promote actions that reduce injuries, violence, and disabilities by providing leadership in identifying priorities, promoting tools, and monitoring effectiveness of injury and violence prevention, and to promote effective strategies for the prevention of injury and violence and their consequences. One tool NCIPC will use to accomplish this goal is through the use of the Core Violence and Injury Prevention Program (Core VIPP). This program funds state health departments (SHDs) to build their capacity to disseminate, implement, and evaluate evidence-based/best practice programs and policies. This evaluation will consider the implementation and outcomes of Core VIPP during the five-year funding period from August 2011 to July 2016. The Core VIPP will support funded states in building capacity and achieving health impact in their states. The key components of violence and injury prevention (VIP) capacity for Core Base Integration Component (BIC) VIPP are defined as: infrastructure, evaluation, strategies, collaboration, and surveillance.

CDC requests OMB approval to continue to collect program evaluation data for Core VIPP for an additional three-year period. The purpose of the evaluation is to track states' progress toward: (1) Achieving the Performance Measures identified in the Funding Opportunity Announcement (FOA); (2) building and/or sustaining their VIP capacity; and (3) achieving their focus area SMART (Specific, Measurable, Attainable, Reasonable, and Time-bound) objectives. The ability of states to make progress towards their SMART objectives will serve as a measure of Core VIPP's impact on the burden of violence and injury related morbidity and mortality in funded states.

The primary data collections methods will be used in the evaluation include: (1) Interim and annual progress reports, (2) online surveys, and (3) interviews. The progress reports will track states' performance measures and the activities stated in the Core VIPP FOA and monitor states' progress toward their focus area SMART objectives; the online survey will be used to measure grantees' changes in VIP capacity. Interviews will be used to provide more in-depth information about the key facilitators and barriers states have encountered while implementing their violence prevention programs.

The table below details the annualized number of respondents, the average response burden per interview, and the total response burden for the surveys and telephone interviews. Estimates of burden for the survey are based on previous experience with evaluation data collections conducted by the evaluation staff. The State of the States (SOTS) web-based survey assessment will be completed by 20 Core Funded State Health Departments (SHDs) and will take 3 hours to complete. The SOTS Financial Module will also be completed by the 20 BIC funded SHD and will take 1 hour to complete. The supplemental SOTS Survey Questions will be completed by 20 BIC funded SHDs and take 1.5 hours to complete. The BIC telephone interviews will take 1.5 hours and will be completed by the 20 Core funded SHDs.

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 *Thompson Medical Co.,* 104 F.T.C. 648, 839 (1984), *aff'd,* 791 F.2d 189 (D.C. Cir. 1986), *cert. denied,* 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.

[1] Finkelstein EA, Corso PS, Miller TR, Associates. *Incidence and Economic Burden of Injuries in the United States.* New York: Oxford University Press; 2006.