

Statement of Chairwoman Edith Ramirez and Commissioner Julie Brill
In the Matter of GeneLink, Inc. and foru International Corporation
January 7, 2014

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 website stated that the products produced “improvements in everything from blood pressure to eczema to hormonal issues to arthritis.”¹ The Commission alleges that 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

¹ Compl. Exs. G and H.

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

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.”).

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 the D.C. 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,

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 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).

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.

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]").