



# The FTC's "More Specific" Order Provisions Five Years Later

By John E. Villafranco and Katie Bond

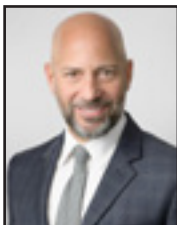
For decades, the vast majority of Federal Trade Commission ("FTC") orders on health-related advertising simply required that the named parties possess "competent and reliable scientific evidence" for future claims.<sup>1</sup>

The orders defined competent and reliable scientific evidence broadly and flexibly as

tests, analyses, research, or studies that have been conducted and evaluated in an objective manner by qualified

persons and are generally accepted in the profession to yield accurate and reliable results.

In 2009, however, a New Jersey federal court dealt held that a dietary supplement company was *not* liable for violating an order requiring competent and reliable scientific evidence.<sup>2</sup> Soon thereafter, at conferences and in interviews, FTC Staff announced plans to revise the standard order language to be more specific. The then-Director of the



**John E. Villafranco** represents clients in advertising substantiation proceedings and investigations conducted by the FTC, state Attorneys General, and before the National Advertising Division of the Council of Better Business Bureaus.

*\*John represents clients in the consumer product and dietary supplement sectors.*



**Katie Bond** provides regulatory counseling and litigation support regarding matters involving the FTC and FDA to marketers of a variety of consumer products, including dietary supplements, foods, weight loss products, cosmetics and sports equipment.

*\*Katie represents clients in the dietary supplements, foods, weight loss products, and cosmetics sectors.*

FTC's Bureau of Consumer Protection explained the plans as follows:

Our experience in bringing enforcement and contempt actions has been that some federal courts seem to have had difficulty, in certain situations, applying the standard injunction . . . As a result, we will be crafting more precise injunctive language in future orders.<sup>3</sup>

On July 14, 2010, the FTC announced the first two orders containing more specific language: one against a dietary supplement company, and the other against a food company that sold nutrition drinks for children.<sup>4</sup> Both orders included prescriptive descriptions of the type of evidence that the named parties must possess. For future claims to treat or prevent diseases, both orders required Food and Drug Administration ("FDA") drug approval, or use of only those claims allowed under an FDA drug monograph.<sup>5</sup> For claims for weight loss (at issue in the dietary supplement case) and to treat stomach upset in children (at issue in the food case), the orders required "at least two adequate and well-controlled human clinical studies."<sup>6</sup> Subsequent FTC orders over the next couple of years included nearly identical "FDA pre-approval" and "clinical trial" provisions.<sup>7</sup> "More specific" order provisions, however, eventually encountered rough waters.

In 2010, POM Wonderful LLC chose to litigate over the more specific provisions, rather than accept a settlement with the FTC. That litigation, although still ongoing, has chipped away at the provisions. Marked disagreement over the provisions has also become apparent among the FTC's five Commissioners, with two new Commissioners Maureen K. Ohlhausen and Joshua D.

Wright, who took office in 2012 and 2013, respectively. Such developments have made the future of more specific order provisions less than certain. This article explores where the provisions stand now. This article first covers the current state of FDA approval provisions, then clinical trials provisions.

## FDA Pre-Approval Provisions

FDA pre-approval provisions, at this point, appear to be in decline, although not necessarily gone forever. The decline is traceable to the POM litigation and skepticism on behalf of the two new FTC Commissioners, Commissioners Ohlhausen and Wright.

FTC Staff investigated POM and several individual officers and owners over allegations that they deceptively promoted pomegranate products as effective in treating or preventing diseases, including heart disease and prostate cancer. The company and all but one individual refused to settle, and in September 2010, FTC staff brought suit before an Administrative Law Judge (ALJ).<sup>8</sup> Staff sought an order containing an FDA pre-approval provision for any future disease claims.<sup>9</sup> The ALJ found the defendants liable for deceptive advertising, but rejected the FDA pre-approval provision.<sup>10</sup> The ALJ instead imposed a requirement for competent and reliable scientific evidence.<sup>11</sup> He stated that imposing the FDA pre-approval provision "would constitute unnecessary overreaching" and that "[t]he competent and reliable evidence standard is established precedent, is reasonably related to the violations found to exist, and is sufficiently clear and precise to guide [the defendants'] future advertising practices."<sup>12</sup> Both sides appealed to the full Federal Trade Commission.

The Commission, too, found the defendants liable and rejected the FDA pre-approval provision.<sup>13</sup> The Commission, however, imposed a clinical trial provision requiring "at least two adequate and well-controlled human clinical studies" for any future disease claims.<sup>14</sup> Without commenting on the FDA pre-approval provision, the Commission stated that the clinical trial provision provided a "clear, bright-line standard."<sup>15</sup> The defendants appealed to the D.C. Circuit, and the case continues. Briefing has focused solely on liability and the clinical trial provision.

Since the Commission's decision, the FTC has moved away from using FDA pre-approval provisions. The last FTC order to include such a provision was issued in *FTC v. Springtech 77376*, and that order led to a flurry of Commissioner statements. The FTC alleged that Springtech 77376 deceptively advertised products for treating and preventing bed bugs and head lice.<sup>16</sup> The resulting order requires FDA pre-approval for any future claims for treating head lice, although it requires only competent and reliable scientific evidence for future bed bugs claims.<sup>17</sup> The Commission vote in favor was 3-1, with Commissioner Ohlhausen casting the "no" vote. At the time, only four Commissioners, rather than the usual five, were in office. All four issued statements.

Commissioner Ohlhausen contended that the FDA pre-approval provision is "inconsistent with FTC precedent," including the Commission's POM decision, and that "imposing such a high bar . . . may ultimately prevent useful information from reaching consumers."<sup>18</sup> Commissioner Ohlhausen supported, instead, requiring "the type of substantiation that experts in the field

believe is reasonable (e.g., a well-controlled clinical trial).<sup>19</sup> Although Commissioner Wright ultimately supported the *Springtech* order, he stated that he “believe[s] that FDA pre-approval provisions should play a very limited role in FTC orders and that the conditions under which they are appropriate are fairly narrow.”<sup>20</sup> In a joint concurring statement, Chairperson Edith Ramirez and Commissioner Julie Brill repeated language from the Commission’s POM decision, stating that declining to require FDA pre-approval in that case “does not foreclose that we may again conclude, in an appropriate case, that FDA preapproval would be an appropriate remedy.”<sup>21</sup> They believed that *Springtech 77376* was an appropriate case given that false head lice claims could cause “considerable economic and consumer harm,” and “FDA regulates all head lice treatments under a Final Monograph [for over-the-counter drugs],” which *Springtech 77376* failed to follow.<sup>22</sup> They stated that “under [the] circumstances” the provision “is particularly appropriate as it harmonizes . . . obligations under the [Food, Drug, and Cosmetic Act] and the FTC Act.”<sup>23</sup>

In all subsequent cases involving disease claims, the FTC has adopted clinical trials provisions, rather than FDA pre-approval provisions.<sup>24</sup> In May 2014, for instance, the FTC settled with two companies over claims that “genetically customized” dietary supplements could treat or prevent diseases, including diabetes and arthritis.<sup>25</sup> The resulting order requires “at least two adequate and well-controlled human clinical studies” for any future disease claims.<sup>26</sup> The move to clinical trials provisions appears to reflect a compromise among the Commissioners, and/

or a Staff decision that the Commissioners have accepted.

At this point, the FTC appears unlikely to return to using FDA pre-approval provisions as a matter of routine, and if the provisions are resurrected, it will likely be in cases similar to *Springtech* where a drug is at issue. Unlike drugs, products such as foods and dietary supplements are not subject to the FDA drug regime and instead are subject to an array of FDA mechanisms – not mentioned in FDA pre-approval provisions – under which certain disease claims may be pre-approved.

### Clinical Trial Provisions

The FTC Commissioners, at this point, seem to agree that clinical trial provisions are appropriate in many cases – especially those cases involving cause and effect claims that are *not* disease claims. Regardless of any agreement among the Commissioners, however, the future of clinical trial provisions hangs in the balance given the POM litigation.

### FTC Commissioners

Regarding clinical trial provisions for disease claims, Commissioner Ohlhausen has stated that “RCTs [randomized, controlled trials] 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.”<sup>27</sup> She has further stated that the FTC “seem[s] to have adopted two RCTs as a standard requirement for health- and disease-related claims for a wide array of products” and that she is “not willing to support a de facto two-RCT standard . . . for food or other relatively-safe products.”<sup>28</sup>

As for clinical trial provisions for non-disease claims, such as weight loss claims, none of the Commissioners have expressed similar, concrete concerns, although Commissioner Wright has questioned clinical trial provisions generally and suggested that “a fact-specific inquiry may justify [alternative] specifically crafted injunctive relief in certain cases, such as bans, performance bonds or document retention requirements for underlying study data.”<sup>29</sup> While as noted above, Commissioner Ohlhausen is concerned about the resources required for clinical trials on some diseases, she does not believe that studies for “short-term weight loss claims” present the same challenges.<sup>30</sup> Rather, she believes that “such studies can be conducted in a relatively short amount of time at a lower cost than for many other health claims.”<sup>31</sup>

The following trends, upon which the Commissioners largely appear to agree, have emerged for non-disease claims.

- For weight loss claims for dietary supplements or cosmetics, named parties must possess “at least two adequate and well-controlled human clinical studies.”<sup>32</sup>
- For weight loss claims for exercise products or meal replacements, named parties must possess “at least one adequate and well-controlled human clinical study.”<sup>33</sup>
- For non-disease, non-weight loss, cause and effect claims, such as muscle strengthening or improved memory claims, named parties must possess “at least one adequate and well-controlled human clinical study.”<sup>34</sup>

### POM Litigation

At the D.C. Circuit, the POM defendants have argued that the clinical trial provision requiring at “at least

two adequate and well-controlled human clinical studies” to support any future disease claims violates the First Amendment.<sup>35</sup> Specifically, the POM defendants argue that the provision runs afoul of the seminal commercial speech case, *Central Hudson*, which requires any speech regulation to directly advance a substantial government interest and be no broader than necessary.<sup>36</sup> Accepting that the government has a substantial interest in preventing deception, the defendants argue that the provision fails to directly advance that interest given that consumers “will not be better informed” by the FTC suppressing truthful disease claims simply because they are based on something less than two clinical studies.<sup>37</sup> The defendants argue further that the clinical trials provision is broader than necessary given that the FTC has failed to explain why narrower measures, such as requiring disclosures about the level of evidence underlying a claim, would not be adequate.<sup>38</sup>

The FTC, in response, distinguishes between “prescriptive regulations addressed to the public at large,” which it contends must follow *Central Hudson*, and FTC regulatory orders, which it contends must only be “reasonably related” to the defendants’ past violations.<sup>39</sup> An FTC order, the FTC argues, may “impose substantiation requirements that are reasonably related to preventing unlawful conduct even though those requirements may exceed what would be required of companies that have *not* been found liable for deceptive advertising.”<sup>40</sup> The FTC also argues that even if *Central Hudson* applies, the clinical trials provision “directly advances [the government’s interest in preventing deception] by enjoining [the defendants] from making the very type of

false advertising that their challenged advertisements have conveyed.”<sup>41</sup> In an argument that appears only in a footnote, the FTC further contends that the proposed provision will not suppress any accurate, qualified disease claims that explain that the underlying evidence is something less than two clinical trials.<sup>42</sup>

The POM defendants appear to have the better arguments. The plain language of the clinical trials provision appears to require at least two clinical studies for “any” disease claim (qualified or not), and cases in other jurisdictions have held that FTC orders must comport with *Central Hudson* and avoid “ingfring[ing] the defendants’ First Amendment rights.”<sup>43</sup> If the court strikes down the clinical trials provision, the decision would obviously have significant repercussions for the FTC imposing similar provisions in future cases. ▲

1. See, e.g., Modified Final Order, *Daniel Chapter One*, FTC Dock. No. 9329 (Aug 5, 2009); Stipulated Final Judgment, *FTC v. CVS Pharmacy, Inc.*, Civ. No. CA09-420 (D.R.I. Sept. 8, 2009); Stipulated Final Judgment, *Airborne Health Inc.*, Civ. No. 08-05300 (C.D. Cal. Aug. 13, 2008).
2. *FTC v. Lane Labs-USA, Inc.*, Civ. No. 00-cv-3174, slip op (D.N.J. Aug. 11, 2009). The Third Circuit later reversed the decision. See 624 F.3d 575 (3d Cir. 2010).
3. Remarks of David Vladeck, National Advertising Division National Conference, at 3 (Oct. 5, 2009).
4. Press Release, FTC, Nestlé Subsidiary to Settle FTC False Advertising Charges (July 14, 2010); Press Release, FTC, Dietary Supplement Maker to Pay \$5.5 Million to Settle FTC False Advertising Charges (July 14, 2010).
5. Order, *Nestlé HealthCare Nutrition, Inc.*, FTC File No. 092-3087 (Jan. 12, 2011); *FTC v. Iovate Health Sciences USA, Inc.*, Civ. No. 10-CY-587 (W.D.N.Y. July 29, 2010). The Nestlé provision applies to cold and flu claims.

The *Iovate* provision applies to claims to treat or prevent “any disease.”

6. *Id.*
7. See, e.g., Order, *Dannon Co., Inc.*, FTC Dock. No. C-4313 (Jan. 31, 2011); Order, *Dreher*, FTC Dock. No. C-4306 (Nov. 4, 2010); Stipulated Order, *FTC v. Central Coast Nutraceuticals, Inc.*, Civil No. 10-C-4931 (N.D. Ill. Jan. 3, 2012); Stipulated Final Judgment, *FTC v. Labra*, Civ. No. 11-C-2485 (N.D. Ill. Jan. 11, 2012).
8. Complaint, FTC Dock. No. 9344 (Sept. 24, 2010).
9. *Id.* at 21-25.
10. Initial Decision, FTC Dock. No. 9344, at 6, 323 (May 17, 2012).
11. *Id.* at 332.
12. *Id.* at 323.
13. Commission Opinion, FTC Dock. No. 9344 (Jan. 10, 2013).
14. *Id.* at 53.
15. *Id.*
16. Complaint, Civ. No. 12-4631 (N.D. Cal. Sept. 5, 2012).
17. Judgment, Civ. No. 12-4631-PJH (N.D. Cal. Dec. 9, 2013).
18. Statement of Commissioner Ohlhhausen, *FTC v. 77376*, FTC Matter No. X120042, at 1 (July 16, 2013).
19. *Id.* at 2.
20. Statement of Commissioner Wright, *FTC v. 77376*, FTC Matter No. X120042, at 1 (July 16, 2013).
21. Statement of Charwoman Ramirez and Commissioner Brill, *FTC v. 77376*, FTC Matter No. X120042, at 1 (July 16, 2013).
22. *Id.* at 1, 2.
- 23.
24. Order, *Genelink, Inc.*, FTC Dock. No. C-4456 (May 8, 2014); Final Judgment and Order, *FTC v. Wellness Support Network, Inc.*, Civ. No. 3:10-cv-4879 JCS (N.D. Cal. Feb. 20, 2014). See also Consent Agreement, *Lornamead, Inc.*, FTC File No. 122-3255 (June 3, 2014) (requiring at least one clinical study for claims to reduce risk of head lice by specific amount or percentage).
25. Press Release, FTC, Companies Pitching Genetically Customized Nutritional Supplements Will Drop Misleading Disease Claims (Jan. 7, 2014).
26. Order, *Genelink, Inc.*, FTC Dock. No. C-4456 (May 8, 2014).
27. Statement of Commissioner Ohlhhausen, *GeneLink, Inc., FTC v. Sensa, FTC v. HCG Diet Direct, LLC, L’Occitane, FTC v. LeanSpa*, at 2 (Jan. 7, 2014).

28. *Id.*
29. Statement of Commissioner Wright, *GeneLink, Inc., FTC v. Sensa, FTC v. HCG Diet Direct, LLC, L'Occitane, FTC v. LeanSpa*, at 1-2 (Jan. 7, 2014).
30. Statement of Commissioner Ohlhausen, *GeneLink, Inc., FTC v. Sensa, FTC v. HCG Diet Direct, LLC, L'Occitane, FTC v. LeanSpa*, at 2 (Jan. 7, 2014). Commissioner Ohlhausen has expressed concerns with requirements for “essentially equivalent product[s]” and researchers working independently of each other. *Id.* at 3.
31. *Id.* at 2.
32. *See, e.g.*, Stipulated Final Judgment, *FTC v. Sensa Products, LLC*, Civ. No. 14cv72 (N.D. Ill. Jan. 8, 2014); Order, *Beiersdorf, Inc.*, FTC Dock. No. C-4335 (Aug. 17, 2011); Order, *L'Occitane, Inc.*, FTC Dock. No. C-4445 (Mar. 27, 2014).
33. Stipulated Final Judgment, *FTC v. Reebok Int'l, Ltd.*, Civ. 1:11 CV2046 (N.D. Ohio Sept. 29, 2011); Stipulated Final Judgment, *FTC v. Fitness Brands*, Civ. No. 12-23065-CIV-AL-TONAGA (S.D. Fla. Aug. 28, 2012); Consent Decree, *United States v. Jason Pharmaceuticals, Inc.*, Civ. No. 12-1476 (D.D.C. Sept. 17, 2012).
34. *See, e.g.*, Stipulated Final Judgment, *FTC v. Reebok Int'l, Ltd.*, Civ. 1:11-CV2046 (N.D. Ohio Sept. 29, 2011); Consent Agreement, *I-Health, Inc.*, FTC File No. 122-3067 (June 9, 2014).
35. Brief for POM Wonderful, *et al.*, *POM Wonderful, LLC v. FTC*, Civ. No. 13-1060, at 37 (Aug. 16, 2013).
36. *Id.* at 38.
37. *Id.* at 47.
38. *Id.* at 51-52. The defendants also argue that the provision amounts to viewpoint discrimination given that government would remain free to rely on any type of evidence in regulating products and marketing. *Id.* at 8.
39. *See* Brief for FTC, *POM Wonderful*, at 74 (Feb. 7, 2013).
40. *Id.* at 73 (emphasis in original).
41. *Id.* at 75.
42. *Id.* at 72, n.33.
43. *FTC v. Direct Mktg. Concepts*, 648 F. Supp. 2d 220, 213 (D. Mass. 2009), *aff'd*, 624 F.3d 1 (1st Cir. 2010); *National Comm'n on Egg Nutrition v. FTC*, 570 F.2d 157, 164 (7th Cir. 1977); *Litton Indus., Inc. v. FTC*, 676 F.2d 364, 371-372 (9th Cir. 1982).