DISSENTING STATEMENT OF COMMISSIONER MAUREEN K. OHLHAUSEN
Federal Trade Commission v. Springtech 77376, LLC, et al. ("Cedarcide Industries")
FTC Matter No. X120042
July 16, 2013

I strongly support the Commission's enforcement efforts against false and misleading advertisements and thus previously voted in this matter to challenge the defendants' claims about their bed bug and head lice infestation products. I voted against these two settlements, however, because I believe the requirement that defendants obtain Food and Drug Administration (FDA) preapproval prior to making head lice treatment claims is inconsistent with Commission precedent and that imposing such a high bar for these types of claims in general may ultimately prevent useful information from reaching consumers in the marketplace.

The Commission's two most recent decisions regarding deceptive health claims do not require FDA preapproval. Instead, in both cases, the Commission imposed our traditional standard of competent and reliable scientific evidence.[1] Notably, in a case decided earlier this year, which involved claims regarding cancer and heart disease treatments, the Commission explicitly declined to adopt an FDA preapproval requirement and instead required defendants to possess and rely upon competent and reliable scientific evidence that, when considered in light of the entire body of relevant and reliable scientific evidence, is sufficient to substantiate that the representation is true.[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 claim and product coverage, 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

[1] In *Daniel Chapter One*, No. 9329, 2009 WL 2584873, at *5 (F.T.C. Aug. 5, 2009), the Commission found that the respondents violated the FTC Act by making deceptive claims that shark cartilage and certain other herbal formulations prevent, treat, and cure cancer. Our order in that case prohibits such representations unless the respondents possess and rely upon competent and reliable scientific evidence, which it defines as "tests, analyses, research, studies, or other evidence based on the expertise of professionals in the relevant area, that has been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results." *Daniel Chapter One*, No. 9329, 2009 WL 5160000, at *1 (F.T.C. Dec. 24, 2009). This definition is consistent with prior Commission cases and guidance to industry. *See Dietary Supplements: An Advertising Guide for Industry*, F.T.C., Bureau of Consumer Protection, http://business.ftc.gov/documents/bus09-dietary-supplements-advertising-guide-industry (last updated April 2001).
[2] In *POM Wonderful, LLC*, No. 9344, 2013 WL 268926 (F.T.C. Jan. 16, 2013) we found that the respondents violated the FTC Act by making deceptive claims that their pomegranate juice-based products treat, prevent or reduce the risk of heart disease, prostate cancer, or erectile dysfunction. The Commission explicitly declined complaint counsel's request to impose an FDA preapproval requirement for the challenged claims even though such claims may have qualified the products as unapproved drugs under the Food, Drug, and Cosmetic Act ("FDCA") or as a "drug" under Section 15 of the FTC Act (which, in and of itself, does not alter our traditional substantiation analysis under the *Pfizer* factors). Instead, our order in that matter prohibits such claims unless the respondents possess and rely upon competent and reliable scientific evidence that, when considered in light of the entire body of relevant and reliable scientific evidence, is sufficient to substantiate that the representation is true. Thus, it would seem rather incongruous to require FDA preapproval for a head lice treatment but not for purported treatments involving cancer or heart disease.
[3] *Pfizer, Inc.*, 81 F.T.C. 23, 91-93 (1972).

the field believe is reasonable for such a claim.[4] Under a *Pfizer* analysis, the head lice treatment claims described in Part II of the stipulated orders do not merit the onerous level of substantiation required to obtain FDA preapproval. Although a head lice infestation can be quite a nuisance, it is not a serious or life-threatening disease or condition.[5] Also, importantly, our complaint in this matter does not challenge any claims regarding the safety of the defendants' products.[6] Thus, it seems unlikely that the consequences of a false claim would involve serious consumer harm. Granted, if the defendants' claims are false, it is likely that some consumers will endure a longer infestation period and perhaps pass the lice along to others. However, obtaining FDA preapproval through either an OTC drug monograph[7] or new drug application[8] process would be quite costly and time-consuming and may discourage those wishing to make claims for other natural products that compete with some FDA-approved products from even trying to develop substantiation. Finally, we may impose directly by order the type of substantiation that experts in the field believe is reasonable (*e.g.*, a well-controlled clinical trial) rather than requiring defendants to undergo the review process of the FDA, which may involve additional considerations unrelated to the challenged claims.[9]

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[4] *Id.*; *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] According to the FDA, head lice do not cause disease. U.S. Food and Drug Administration, *Treating Head Lice*, FDA Consumer Health Information, at 1 (July 2009), http://www.fda.gov/downloads/ForConsumers/ConsumerUpdates/UCM173526.pdf.

[6] The Commission has challenged ads for products containing undisclosed threats to the safety of consumers. *See, e.g., North American Philips Corp.*, 111 F.T.C. 139 (1988) (seller failed to disclose water cleaner added potentially hazardous chemical to water).

[7] U.S. Food and Drug Administration, *Drug Applications for Over-the-Counter (OTC) Drugs*, http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/Over-the-CounterDrugs/default.htm#Guidances (last updated Oct. 18, 2012).

[8] U.S. Food and Drug Administration, *New Drug Application*, http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/NewDrugApplicationNDA/default.htm (last updated Feb. 21, 2013).

[9] FDA drug approval hinges on a determination that a drug product is both safe and effective. From FDA's point of view, the two attributes are fundamentally linked. For example, extremely safe drugs may be approved even if clinical efficacy is slight, and fairly toxic drugs (such as certain chemo-therapeutic agents) may be approved if they are efficacious in treating life-threatening illnesses. *See* 21 C.F.R. § 312.84(a) ("FDA will consider whether the benefits of the drug outweigh the known and potential risks of the drug and the need to answer remaining questions about risks and benefits of the drug, taking into consideration the severity of the disease and the absence of satisfactory alternative therapy."). Under the FTC Act, it is not our mission to police drug safety or efficacy directly. Advertisers are liable to substantiate material claims that products are safe, just as they are liable to substantiate material claims that products are efficacious. But they are not liable to substantiate claims that they do not make or imply. If an advertiser makes an efficacy claim, but not a safety claim, there are two related reasons why FDA approval standards would be more stringent than FTC substantiation standards. First, FDA approval requires testing two properties (efficacy and safety). Second, FDA approval requires sufficient testing to consider each of those two properties in view of the other. Each of these two reasons implies more extensive testing. Together, they imply more extensive trials still. *See* 21 C.F.R. § 314.50 (content and format of an application); 21 C.F.R. § 314.105 (approval of an application and an abbreviated application). *See also* Food & Drug Admin., *2007 CDER Update: Improving Public Health Through Prescription Drugs* 37 (2007), *available at* http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/WhatWeDo/UCM121704.pdf ("We base decisions to approve a drug—or to keep it on the market if new safety findings surface—on a careful balancing of risk and benefit."); Food & Drug Admin., *FDA's Drug Review Process: Continued*, http://www.fda.gov/Drugs/ResourcesForYou/Consumers/ucm289601.htm (last updated Mar. 3, 2012) ("Once a new drug application is filed, an FDA review team--medical doctors, chemists, statisticians, microbiologists, pharmacologists, and other experts--evaluates whether the studies the sponsor

There is also no reasonable basis to characterize the FDA preapproval provision as heightened fencing-in relief. Fencing-in remedies are designed to prevent future unlawful conduct through "provisions in a final Commission order that are broader in scope than the conduct that is declared unlawful."[10] Past decisions discussing the proper application of fencing-in remedies generally involve the extension of the scope of a final order beyond the specific product, parties, or type of conduct involved in the actual violation.[11] Requiring past violators to meet a higher burden of substantiation would not fence them in – it would only make it more difficult for them to make truthful claims that could be useful to consumers.[12]

The adoption of an FDA preapproval requirement in these two settlements also sends the wrong signal to parties trying to ascertain the level of substantiation required to make health-related claims, especially after our explicit rejection of such a provision in *POM Wonderful*. Some may interpret the adoption of this provision in these settlements as a policy shift that ties the Commission's substantiation requirements to the standards imposed by the FDA,[13] which could potentially chill health-related claims and deprive consumers of useful information.

In sum, I disagree with my colleagues about imposing an FDA preapproval requirement for head lice treatment claims in these two settlements. Because I cannot support such relief, I respectfully dissent.

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submitted show that the drug is safe and effective for its proposed use. No drug is absolutely safe; all drugs have side effects. 'Safe' in this sense means that the benefits of the drug appear to outweigh the known risks.").

[10] *Telebrands Corp. v. FTC*, 457 F.3d 354, 357 n.5 (4th Cir. 2006); *see also, e.g.*, *FTC v. Colgate-Palmolive, Co.*, 380 U.S. 374, 394-395 (1965); *FTC v. Ruberoid Co.*, 343 U.S. 470, 473 (1952); *Kraft, Inc. v. FTC*, 970 F.2d 311, 326 (7th Cir. 1992).

[11] *See, e.g.*, *Colgate-Palmolive, Co.*, 380 U.S. at 395 ("We think it reasonable for the Commission to frame its order broadly enough to prevent respondents from engaging in similarly illegal practices in future advertisements."); *FTC v. Ruberoid Co.*, 343 U.S. at 474-475 (holding that the Commission's order encompassing "wholesalers, retailers, and roofing contractors or applicators" was "reasonably related to the facts," even though only retailers and applicators were affected by Ruberoid's violation); *Telebrands Corp.*, 457 F.3d at 357, 362 (holding that a reasonable relationship existed between Telebrand's violation involving advertisements for an abdominal belt and the Commission's remedy that encompassed future "manufacturing, labeling, advertising, promotion, offering for sale, or distribution of" the actual product as well as that of "any food, drug, dietary supplement, device, or any other product, service or program") (emphasis omitted); *Kraft, Inc. v. FTC*, 970 F.2d at 326 ("The FTC has discretion to issue multi-product orders, so-called 'fencing-in' orders, that extend beyond violations of the Act to prevent violators from engaging in similar deceptive practices in the future."); *Am. Home Prods. Corp. v. FTC*, 695 F.2d 681, 705 (3rd Cir. 1982) ("'Fencing in' often takes the form, as in this case, of a multi-product order.").

[12] A more specific requirement would not "fence in" proven violators; rather, it would "wall off" truthful claims that would be quite valuable to consumers. *See* J. Howard Beales III, Timothy J. Muris & Robert Pitofsky, *In Defense of the Pfizer Factors*, George Mason Law & Economics Research Paper No. 12-49, at 35, May 2012, *available at* http://www.law.gmu.edu/assets/files/publications/working_papers/1249InDefenseofPfizer.pdf.

[13] As I stated in my Concurring Statement to our *POM Wonderful* decision, I am concerned that we interpret and apply the FTC Act consistently with other federal statutes. *POM Wonderful, LLC*, No. 9344, 2013 WL 268926, at *7 n.15 (F.T.C. Jan. 16, 2013) (Ohlhausen, Commissioner, concurring). The FTC Act, however, does not charge the Commission with ensuring that advertisers comply with their obligations under the FDCA. Our charge is limited to requiring adequate substantiation based on our enabling statute and relevant precedent.