Concurring Statement of Commissioner Maureen K. Ohlhausen
In the Matter of POM Wonderful
Docket No. 9344
January 10, 2013

I disagree with the majority's findings of implied disease efficacy and establishment claims with regard to the exhibits detailed below for several reasons. First, several of these exhibits contain claims about the general effects of the POM products on the continued healthy functioning of the body but do not make references to diseases or health-related conditions.[1] Despite the absence of such references or of other suggestive indicators (*e.g.*, strong medical imagery), the majority finds that these exhibits contain *implied* disease-related claims without extrinsic evidence that consumers viewing the exhibits would actually perceive such stronger claims and not simply perceive healthy functioning claims (akin to "structure/function" or "S/F" claims under Food and Drug Administration regulations).[2] I am concerned that, if the Commission too easily finds implied disease efficacy or establishment claims in advertisements for foods, absent extrinsic evidence, then it may tend to undermine an important balance that is struck in the regulation of food, supplement, and drug advertising under the FTC Act and other federal laws.[3]

Second, for a number of advertisements, I believe the majority conflates disease treatment claims with prevention/risk reduction claims. In one instance, they find implied disease treatment claims where the exhibit appears only to claim or suggest that the risk of disease is, or may be, reduced by POM products.[4] Conversely, in several others, they find implied prevention/risk reduction claims (not solely disease treatment claims) for exhibits that describe studies of subjects already suffering from prostate cancer or ED.[5] For all of these exhibits, we lack extrinsic evidence that consumers would perceive all the various claims that the majority finds are implied by the exhibits. Because it seems unlikely that a consumer would assume that any food or food product that lowers the risk of disease is also a viable treatment for that disease, I disagree with the majority's conclusions that such claims are facially present in certain exhibits. Likewise, because it seems unlikely that a consumer would assume that a treatment for existing cancer or heart disease would necessarily prevent the onset of these conditions, I disagree with the majority's conclusion that such claims are facially present in certain other exhibits.

Finally, because a number of exhibits contain descriptions of studies that are highly qualified with terms such as "small study," "initial scientific research," and "promising," "hopeful" or "encouraging" results, I disagree with the conclusion that these exhibits make

[1] *See* Figs. 4, 12, 18-20, 23-25, and 28-33.
[2] The fact that I find these claims more akin to structure/function claims does not mean I take a position on whether Respondents possessed adequate substantiation or otherwise met the requirements to make structure/function claims.
[3] The FTC has long recognized "the importance of consistent treatment of nutrient content and health claims in food advertising and labeling and [sought] to harmonize its advertising enforcement program with FDA's food labeling regulations to the fullest extent possible under the statutory authority of the FTC Act." FTC Enforcement Policy Statement on Food Advertising, (1994), *available at* http://www.ftc.gov/bcp/policystmt/ad-food.shtm.
[4] *See* Fig. 6.
[5] *See* Figs. 10, 17, and 36-39.

establishment claims in the absence of extrinsic evidence supporting such a conclusion.[6] Moreover, the majority argues that the challenged ads reinforce the disease-related establishment claims by mentioning that POM spent millions on research.[7] However, the references to the money spent on research appear to be significantly related to demonstrating the amount of antioxidants in the POM products and the general effects of those antioxidants on the human body. Therefore, we need extrinsic evidence to show that consumers would also take away the impression that the research supporting the disease claims is established and not merely preliminary.

Virtually none of the claims found by the Commission in the challenged exhibits is express – they are deemed to be implied. The Commission may undertake a net impression analysis and find implied claims when it can "conclude with confidence after examining the interaction of all the different elements in [an advertisement] that they contain a particular implied claim." *In re Thompson Med. Co.*, 104 F.T.C. 648, 788-89 (1984); *Telebrands Corp.*, 140 F.T.C. 278, 290 (2004) (citing *Thompson Medical*). When such confidence is lacking (*e.g.*, due to well-qualified claims or contradicting statements), however, "we will not find the ad to make the implied claim unless extrinsic evidence allows us to conclude that such a reading of the ad is reasonable." *Thompson Med. Co.*, 104 F.T.C at 789; *Telebrands*, 140 F.T.C. at 291 (citing *Thompson Med. Co.*).

With respect to the claims described below, such extrinsic evidence is unavailable or inadequate. Although Complaint Counsel offered the expert testimony of Dr. Stewart, he did not conduct his own facial analysis of the challenged advertisements and could not opine on what they meant. IDF 513. Also, unlike in cases such as *Thompson Medical* and *Telebrands*, Complaint Counsel did not introduce copy testing evidence to demonstrate what claims consumers may perceive from well-qualified or contradictory statements in advertisements. Because a number of exhibits contain references to the continued healthy functioning of the body without mentioning disease or health-related conditions, discuss only treatments for patients already suffering certain diseases, discuss risk reduction without mentioning treatment of certain diseases, or contain extensive qualifying language, I do not share the majority's ability to "conclude with confidence," that no extrinsic evidence is needed to read stronger claims between the lines. I am concerned with, and thus disagree with, these particular majority findings.[8]

As our opinion today observes, the Commission has paid particular attention to the balancing of pertinent consumer interests in describing the *Pfizer* factors applicable to the question of what constitutes a reasonable basis for a claim.[9] The Commission also has been clear that our substantiation standards and claims interpretation are inextricably linked. Hence, in delineating standards for prior substantiation, we state "[t]he Commission will take care to assure

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[6] *See* Figs. 4, 6, 12-14, 18-20, 24, 25, and 28-33.

[7] "When an ad represents that tens of millions of dollars have been spent on medical research, it tends to reinforce the impression that the research supporting product claims is established and not merely preliminary." *See* Section IV.A. of the opinion.

[8] Engaging in broad claim interpretation also raises questions about whether this approach qualifies as a case-by-case analysis or is more like a broad prohibition on certain categories of speech, which has implications for First Amendment review of our actions.

[9] *See In re Pfizer Inc.*, 81 F.T.C. 23, 91-2 (1972); *see FTC Policy Statement Regarding Advertising Substantiation*, 104 F.T.C. 839 (1984) (appended to *Thompson Med. Co.*, 104 F.T.C. 648 (1984)) ("*Substantiation Statement*").

that it *only* challenges *reasonable interpretations* of advertising claims."[10] As a procedural matter, we may begin by asking what particular claims – and categories of claims – are being made, and then ask what evidence should be required to substantiate such claims. We must keep in mind, however, that if we are too quick to find stronger claims than the ones reasonable consumers actually perceive, then we will inadvertently, but categorically, require an undue level of substantiation for those claims.

In particular, Congress and the Food and Drug Administration have created carefully drawn boundaries between different types of claims regarding the effect of food and dietary supplement products on nutrition and health. FDA regulations distinguish between various categories of claims that may be associated with food products and dietary supplements – including "qualified health claims," "health claims," and "structure/function" claims – and the level of substantiation required for each category of claim.[11] According to FDA guidance, health claims and qualified health claims expressly or by implication characterize the relationship of a substance to a disease (*e.g.*, heart disease) or health-related condition (*e.g.*, high blood pressure).[12] By contrast, structure/function claims describe the effect that a substance has on the structure or function of the body for maintenance of good health and nutrition but do not make reference to a disease.[13] The FDA imposes different and more stringent requirements on health claims than it does on structure/function claims.[14]

I am concerned that the majority's interpretation of certain exhibits blurs these boundaries and creates an inconsistency between FTC advertising requirements and FDA food labeling and advertising requirements by concluding that the mere mention of "health" or healthy functioning can imply a disease-related efficacy (*i.e.*, a health claim in FDA terms) and that the

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[10] *Substantiation Statement* at 840 n. 3 (emphasis added) ("Notwithstanding … variations in approach, the focus of all Commissioners on reasonable interpretations of claims is intended to ensure that advertisers are not required to substantiate claims that were not made.")

[11] *See generally* FDA, Guidance for Industry: A Food Labeling Guide (September 1994; Revised April 2008; Revised October 2009), *available at* http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodLabelingNutrition/FoodLabelingGuide/default.htm; FDA, Guidance for Industry: Evidence-Based Review System for the Scientific Evaluation of Health Claims – Final (2009), *available at* http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodLabelingNutrition/ucm073332.htm; FDA Guidance for Industry: FDA's Implementation of "Qualified Health Claims": Questions and Answers; Final Guidance (May 12, 2006), *available at* http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodLabelingNutrition/ucm053843.htm.

[12] FDA, Guidance for Industry: A Food Labeling Guide, at 8.Claims H1, Q1.

[13] *Id.* at 8.Claims S1, S7.

[14] "Health claims are required to be reviewed and evaluated by FDA prior to use." FDA, Guidance for Industry: A Food Labeling Guide, at 8.Claims H1. FDA also distinguishes "health claims that meet the Significant Scientific Agreement (SSA) standard," from "S/F claims [that] must be truthful and not misleading and are not pre-reviewed or authorized by FDA."). *id.* at 8.Claims H3. In addition, "FDA does not require conventional food manufacturers to notify FDA about their S/F claims and disclaimers are not required for conventional foods." FDA, Structure/Function Claims, *available at* http://www.fda.gov/Food/LabelingNutrition/LabelClaims/StructureFunctionClaims/ucm2006881.htm. Structure/function claims were specifically authorized by the Dietary Supplement Health and Education Act of 1994, 108 Stat. 4325 (codified as amended in scattered sections of 21 U.S.C.); *see also* Dep't Health & Human Servs., Food & Drug Admin., Regulations on Statements Made for Dietary Supplements Concerning the Effect of the Product on the Structure or Function of the Body, Final Rule, 65 Fed. Reg. 1000 at 1034-35 (Jan. 6, 2000).

mere mention of scientific evidence can imply a related establishment claim. For instance, Figures 12, 20, and 23 seem limited to addressing the product's general health benefits by providing antioxidants and fighting free radicals, and thus potentially reducing the risk of disease, while claiming that these benefits are backed by significant scientific or medical research about prostate or cardiovascular health. Based on the majority's views about these exhibits, it is difficult to imagine any structure/function claims that POM could associate with its products in the marketplace without such claims being interpreted, under the FTC precedent set in this case, as disease-related claims.[15]

A possible (though not plausible) argument for the majority's position is that these exhibits are somehow infused with messages from other ads included in some of POM's advertising campaigns that mentioned specific diseases or health conditions. However, we should not reach such a conclusion in the absence of extrinsic evidence in the record. *Thompson Med. Co.*, 104 F.T.C. at 789; *Telebrands*, 140 F.T.C. 379, 436 (2004) (ALJ Decision), *adopted by* the Commission in *Telebrands*, 140 F.T.C. 278, 281 (2004) (requiring extrinsic evidence even though the ads at issue contained express references to other ads). More generally, we should be careful not to interpret claims so broadly that we undermine distinctions between types of claims, and the substantiation appropriate to them, that Congress and our sister agency have found important to the public's health and wellbeing.

In sum, the majority's findings with regard to the exhibits detailed below in the absence of extrinsic evidence leave questionable room for marketers to make well-qualified and substantiated structure/function type efficacy or establishment claims because of the high risk that such claims will be found to imply the treatment, prevention, or risk-reduction of a disease, or that they are clinically proven.

I incorporate these arguments by reference to my views for specific exhibits in my comments below.

Figure 4. CX0031: "Floss Your Arteries" print advertisement

I disagree with the majority view that this print ad conveyed to a significant minority of reasonable consumers that drinking eight ounces of POM Juice daily treats – rather than prevents or reduces the risk of – heart disease. I also disagree with the majority and would uphold the ALJ's finding that the evidence fails to show that this print ad conveys to a significant minority

[15] I am concerned that, for these exhibits, the majority readings are in conspicuous tension with the express findings and intent of Congress in enacting the Dietary Supplement Health and Education Act of 1994 (DSHEA), wherein Congress provides for structure/function claims that may be made on behalf of dietary supplements. In the statute itself are express findings that healthful diets may reduce the risk of disease and the need for medical intervention; that "consumers should be empowered to make choices about preventive health care programs," *id.* at § 2(8), based on available scientific evidence; and that, "although the Federal Government should take swift action against products that are unsafe or adulterated, the Federal Government should not take any actions to impose unreasonable regulatory barriers limiting or slowing the flow of safe products and accurate information to consumers." *Id.* at § 2(13). Moreover, although the DSHEA regards dietary supplements in particular, FDA has concluded that "structure/function claims may be made on a conventional food provided the effects are derived from the nutritive value of the food." FDA, Guidance for Industry: A Food Labeling Guide, at 8.Claims S1. Hence, "[o]n December 20, 2002, the agency announced its intention to extend its approach to implementing the *Pearson* decision to include health claims for conventional foods (67 Fed. Reg. 78002)." FDA, Guidance for Industry: Evidence-Based Review System for the Scientific Evaluation of Health Claims – Final, at § II (background).

of reasonable consumers that the claims contained in the advertisement are clinically proven. The advertisement's language qualifies that drinking POM Juice "*can* reduce plaque by up to 30%" (emphasis added) and the citation to a study appears in a footnote too small to be clear and conspicuous under our own standards.[16] *See* ID at ¶ 447. Further, the imagery in the advertisement is that of regular hygiene, such as tooth brushing and flossing, not medical imagery related to heart disease that appears in other challenged advertisements where the Commission unanimously found an implied establishment claim.

Figure 6. CX0034: Amaze Your Cardiologist

I disagree with the majority view that this print ad conveys to a significant minority of reasonable consumers that drinking eight ounces of POM Juice daily treats – rather than prevents or reduces the risk of – heart disease. I also disagree with the majority and would uphold the ALJ's finding that the evidence fails to show that this exhibit conveys to a significant minority of reasonable consumers that the claims contained in the advertisement are clinically proven because the statement regarding plaque reduction is well-qualified ("*can* reduce plaque by up to 30%" (emphasis added)) and the reference to a study appears in a footnote too small to be clear and conspicuous under our own standards. *See* ID at ¶¶ 465-468.

Figures 10 and 17. CX1426 Ex. I: Antioxidant Superpill Brochure; CX1426 Ex. N: POMx Prostate Newsletter

I disagree with the majority's view that these exhibits convey to a significant minority of reasonable consumers that daily consumption of POM products prevents or reduces the risk of prostate cancer, as opposed to treating prostate cancer. All references to that disease in the exhibit appear rooted in a study of 46 men age 65 to 70 who had been treated for prostate cancer. Further, CX1426 Ex. I specifically references "new studies are under way … in patients *with* prostate cancer" (emphasis added).

Figure 12. CX0109: Heart Therapy

I disagree with the majority and would uphold the ALJ's findings that the evidence fails to show that this print ad conveys to a significant minority of consumers that drinking eight ounces of POM Juice daily prevents or reduces the risk of heart disease or that such claims are clinically proven. The imagery in this ad, which is a POM bottle reclining on a couch, suggests psychotherapy, not treatment for heart disease. The text is qualified with references such as "emerging science," "initial scientific research," and "encouraging results in prostate and cardiovascular health." There is also an exhortation to "keep your heart healthy," without mention of or linkage to a specific disease, which seems more indicative of general structure/function type claims rather than health claims involving disease prevention or risk reduction.

[16] Advertisers cannot use fine print to contradict other statements in an ad or to clear up misimpressions the ad would otherwise leave. *FTC Deception Policy Statement*, appended to *Cliffdale Associates, Inc.*, 103 F.T.C. 110, 180-81 (1984). To be effective, Commission orders require such disclosures to be clear and conspicuous. *E.g., Thompson Med. Co.*, 104 F.T.C. at 842-43. For print ads, for instance, past Commission orders have defined "clear and conspicuous" to mean in a type size and location sufficiently noticeable for an ordinary consumer to read and understand it and in print that contrasts with the background against which it appears. *See, e.g., FTC v. Green Millionaire, LLC*, No. 1:12-cv-01102-BEL (D. Md. filed Apr. 12, 2012) (proposed order granting stipulated permanent injunction), *available at* http://www.ftc.gov/os/caselist/1023204/120416greenmillstip.pdf.

Figures 13-14. CX0120: One small pill for mankind; CX0122: Science Not Fiction
I disagree with the majority and would uphold the ALJ's conclusion that the record does not support a finding that these exhibits convey to a significant minority of reasonable consumers that drinking eight ounces of POM Juice or taking one POMx Pill daily treats prostate cancer or that such claim is clinically proven. The exhibits contain conflicting elements and heavily qualified descriptions of studies, thus suggesting the need for extrinsic evidence to determine what consumers take away. For instance, the exhibits state that "[f]indings from *a small study suggest* … pomegranate juice *may one day prove* an effective weapon" or "[a]n *initial* UCLA medical study … showed *hopeful results* for men with prostate cancer" (emphasis added).

Figures 18-19 and 24. CX0169/CX1426 Ex. L: "The Power of POM;" CX0180/CX1426 Ex. K: "The antioxidant Superpill;" and CX0279: "Science, Not Fiction" print advertisement
I disagree with the majority and would uphold the ALJ's conclusion that the evidence fails to show that these print ads convey to a significant minority of reasonable consumers that taking a POMx Pill daily treats, prevents, or reduces the risk of heart disease and prostate cancer or that these claims are clinically proven. The ads mention the potential benefits for "prostate health" and "heart health," and exhort the consumer to "invest in your health," which are statements likely more correlated to structure/function type claims than to health/disease claims. Moreover, the exhibits discuss the available science with qualifiers such as "preliminary studies," "hopeful results," or "suggests anti-atherosclerosis benefits." In addition, the caduceus symbol in CX0169 is next to the tag line "Reviewed for Safety by the FDA." Further, the text of any statements at the bottom of these exhibits is too small to qualify any claims adequately. Thus, extrinsic evidence would be necessary to conclude that consumers would take away health/disease claims or establishment claims from these ads.

Figure 20. CX0192: What Gets Your Heart Pumping print advertisement
I disagree with the majority and would uphold the ALJ's conclusion that the evidence fails to show that this print ad conveys to a significant minority of reasonable consumers that drinking eight ounces of POM Juice daily prevents or reduces the risk of heart disease or that these claims are clinically proven. In contrast to certain other exhibits, this ad's imagery, a POM bottle in a bikini top, does not include medical imagery but rather invokes sexual attraction. Moreover, the ad contains statements such as "healthy arteries" and "cardiovascular health," which seem similar to structure/function type claims rather than health/disease claims. Further, the ad's references to science are qualified as "initial" scientific research that has uncovered "encouraging" results. Thus, extrinsic evidence would be necessary to conclude that consumers would take away health/disease claims or establishment claims from this ad.

Figure 23. CX0274/CX1426 Ex. C: "I'm Off to Save Prostates" print advertisement
I disagree with the majority and would uphold the ALJ's conclusion that the evidence fails to show that this print ad conveys to a significant minority of reasonable consumers that drinking eight ounces of POM Juice daily prevents or reduces the risk of prostate cancer or that these claims are clinically proven. Statements such as "defending healthy prostates" and "improve prostate health" are more akin to structure/function type claims than to health/disease claims. Moreover, the mention of research in this ad is not tied to any disease generally or cancer specifically. Further, the ad lacks any medical imagery. Thus, the Commission should require extrinsic evidence to find implied health/disease or establishment claims.

Figures 25 and 28-33. CX0280: Live Long Enough; CX0331/CX1426 Ex. J: Healthy Wealthy; CX0328: Your New Health Care Plan; CX0337: First Bottle You Should Open; CX0342/CX0353: Life Insurance Supplement; CX0348/CX0350: 24 Scientific Studies; CX0351/CX0355: Only Antioxidant Supplement Rated X

I disagree with the majority and would uphold the ALJ's conclusion that the evidence in the record fails to show that these print ads convey to a significant minority of reasonable consumers that drinking eight ounces of POM Juice or taking one POMx Pill daily treats, prevents or reduces the risk of heart disease or prostate cancer or that these claims are clinically proven. These ads state "keep you at your healthy best" and "prostate and cardiovascular health" and do not refer to any disease, making the claims akin to structure/function type claims. The imagery regarding pills is linked to the antioxidant power of the product. The studies referenced are strongly qualified, stating that "*preliminary* studies … showed *promising* results for heart health" or that an "*initial* UCLA study … found *hopeful* results for prostate health" (emphasis added). Moreover, any disclaimers at the bottom of the ad are too small to be interpreted in conjunction with other messages. For similar reasons, I also disagree with the majority's view that exhibits CX0351 and CX0355 convey to a significant minority of reasonable consumers that drinking eight ounces of POM Juice or taking one POMx Pill daily treats, prevents, or reduces the risk of erectile dysfunction or that those claims are clinically proven. The statements about the studies referenced are qualified; for instance, the ad refers to a "*preliminary* study on erectile function" (emphasis added) and notes that "further studies are warranted." Thus, the Commission should require extrinsic evidence to find implied health/disease or establishment claims.

Figures 36 and 39. CX0473: Capture of POMWonderful.com Community Website; CX0473: Capture of POMPills.com Websites

I disagree with the majority's view that these exhibits convey to a significant minority of reasonable consumers that taking eight ounces of POM Juice or one POMx Pill daily prevents or reduces the risk of – rather than treats – prostate cancer. Because the science referenced in these exhibits consists of subjects who had already been diagnosed with that disease, I would require extrinsic evidence before finding implied claims of disease prevention or risk reduction.

Figure 37. CX0473: Capture of POMWonderful.com Website

For the same reasons noted for exhibits 36 and 39, I disagree with the majority's view that this exhibit conveys to a significant minority of reasonable consumers that taking eight ounces of POM Juice or one POMx Pill daily prevents or reduces the risk of – rather than treats – prostate cancer. Because the science referenced in this exhibit consists of subjects who had already been diagnosed with cancer, I would require extrinsic evidence before finding such implied claims.