Case #7247 (1/9/2024)
**Focus Consumer Healthcare**
***Pamprin Botanicals***
***Challenger**:* *Bayer Consumer Health*
***Product Type**:* *Dietary Supplements*
***Issues**:* *Establishment Claims; Health & Safety Claims; Performance Claims*
***Disposition**:* *Substantiated In Part / Modified-Discontinued In Part*

**<u>Editor's Note</u>: This decision was revised 3.25.24 to reflect the advertiser's decision to withdraw its appeal to the National Advertising Review Board. The revised Advertiser's Statement has been included below.**

**BBB NATIONAL PROGRAMS**

***NATIONAL ADVERTISING DIVISION***

BAYER CONSUMER HEALTH,
*Challenger*,

FOCUS CONSUMER HEALTHCARE,
*Advertiser*.

Case No. 7247
Closed (1/9/2024)

## FINAL DECISION

- A study that measures improvement subjectively and does not control for variables that may materially affect outcomes is not competent and reliable scientific evidence that the product is responsible for the claimed benefits.
- An ingredient's dosage, formulation and route of administration can impact efficacy. A study on the ingredient in the product that has the same dosage, formulation and route of administration provides the most reliable support for a claimed benefit.

## I. Basis of Inquiry

The advertising industry established the National Advertising Division ("NAD") and the National Advertising Review Board ("NARB") in 1971 as an independent system of self-regulation designed to build consumer trust in advertising. NAD reviews national advertising in all media in response to third-party challenges or through inquiries opened on its own initiative. Its decisions set consistent standards for advertising truth and accuracy, delivering meaningful protection to consumers and leveling the playing field for business. Challenger Bayer Consumer Health ("Bayer" or "Challenger") challenged express and implied claims made by Advertiser Focus Consumer Healthcare ("Focus" or "Advertiser") for its Pamprin Botanicals. The following are representative of the claims that served as the basis for this inquiry:

### *A. Express Claims*

- "clinically tested" and "scientifically tested"

- "Ashwagandha – a calming influence"
- "Magnesium – period pain, nope" and "works on period pain"
- "Vitamin B6 – pms less, chill more"
- "Turmeric – cramp pain & puff" and "helps cramps and puffiness"
- "Chasteberry – for a better period"
- "mood support"
- "calm pms symptoms"
- "ease cramps, bloat and moodiness"
- "experience a better period"
- "scientifically tested, to holistically relieve the underlying causes of PMS symptoms"
- "Take 2 capsules daily"
- "2 days pre period to calm pms symptoms"
- "every day during your period to ease cramps, bloat and moodiness"
- "tried and trusted"
- Product is "botanical" and "naturally good for you"
- "all the good stuff, none of the bad"

### *B. Implied Claims*

- Competing products include ingredients that are unsafe or unhealthy.
- Pamprin Botanicals and Pamprin OTCs work together to provide superior relief for PMS symptoms.
- Pamprin Botanicals is all natural.
- The active ingredients are all natural.
- Implied claims that each ingredient in Pamprin Botanicals does the following:
    - Ashwagandha – reduces PMS-related mood swings
    - Magnesium – reduces pain associated with PMS
    - Vitamin B6 – reduces all PMS symptoms, including mood swings
    - Turmeric – reduces PMS-related pain and bloating
    - Chasteberry – reduces all PMS symptoms
- Pamprin Botanicals has been proven to reduce all common symptoms of PMS based on randomized, double-blind placebo-controlled testing of the product.

## II. Evidence Presented

The Challenger provided several studies on ashwagandha,[1] magnesium,[2] vitamin B6,[3] turmeric[4] and chasteberry.[5] Bayer also provided the following declarations:

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[1] Gopa S *et al.*, Effect of an ashwagandha (Withania Somnifera) root extract on climacteric symptoms in women during perimenopause: A randomized, double-blind, placebo controlled study, *J Obstet Gynaecol Res.* 2021 Dec; 47(12): 4414-4425.

[2] Ebrahimi E *et al.*, Effects of magnesium and vitamin b6 on the severity of premenstrual syndrome symptoms, *J Carnig Sci.* 2012 Nov 22;1(4):183-9; Quaranta S *et a*l., Pilot study of the

- A declaration from Nastaran Faghihnia, Director if US Medical Affairs for Nutritional Science at Bayer Consumer Care;
- A declaration from Richard Cleland, a consultant with experience at the Iowa Attorney General's Office and the Federal Trade Commission and a current adjunct professor at the University of Indiana School of Public Health;
- A declaration from Tom Rosholt, a mathematics and statistical analytics consultant.

The Advertiser provided the following evidence in support of its claims:

- A clinical study report from Citrus Labs of a single arm crossover study using Pamprin OTC and Pamprin Botanicals to reduce the severity of common menstrual cycle outcomes.
- A declaration from Frank Anthony, a consultant with 30 years of experience in the OTC consumer product industry.

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efficacy and safety of a modified-release magnesium 250 mg tablet (Sincromag) for the treatment of premenstrual syndrome, *Clin. Drug Investig.* 2007; 27(1):51-8; Walker AF *et al.,* Unexpected benefit of sorbitol placebo in Mg intervention study or premenstrual symptoms: implications for choice of placebo in RCTs, *Med. Hyptheses*. 2002 Mar;58(3):213-20; DeSouza MC *et al*., A synergistic effect of a daily supplement for 1 month of 200mg magnesium plus 50 mg vitamin B6 for the relief of anxiety-related premenstrual symptoms: a randomized, double-blind, cross-over study. *J. Womens Health Gend. Based Med*. 2000 Mar;9(2):131-9; Facchinetti F *et al.,* Oral magnesium successfully relieves premenstrual mood changes, *Obstet. Gynecol.* 1991 Aug;78(2):177-81.

[3] Ebrahimi *et al*., 2012, supra ; Sharma P *et al.,* Role of bromocriptine and pyridoxine in premenstrual tension syndrome, *Indian J Physiol Pharmacol*. 2007 Oct-Dec;51(4):368-74; Kashanian M *et al*., Pyridoxine (vitamin B6) therapy for premenstrual syndrome, *Int. Gynaecol Obstet.* 2007 Jan;96(1):43-4; De Souza *et al*., 2000, supra; Diegoli MS *et al.,* A double-blind trial of four medications to treat severe premenstrual syndrome, *Int J Gynaecol Obstet*.1998 Jul;62(1):63-7; Doll H *et al.*, Pyridoxine (vitamin B6) and the premenstrual syndrome: a randomized crossover trial, *J R Coll. Gen. Pract.* 1989 Sep;39(326):364-8; Kendall KE, Schnurr PP, The effects of vitamin B6 supplementation on premenstrual symptoms, *Obstet. Gynecol.* 1987 Aug; 70(2): 145-9; Hagen I *et al*., No effect of Vitamin B-6 against premenstrual tension, *Acta Obstet. Gynecol. Scand*. 64:667-670.1985; Williams MJ *et al.*, Controlled trial of pyridoxine in the premenstrual syndrome, *J Int. Med. Res*. 1985;13(3):174-9; Abraham E, Hargove J, Effect of Vitamin B-6 on Premenstrual Symptomatology in Women with Premenstrual Tension Syndromes A Double Blind Crossover Study. *Obstet. & Gynecol. Survey,* 36(5): p 259-261, May 1981.

[4] Bahrami A *et al.,* Effects of curcumin on menstrual pattern, premenstrual syndrome, and dysmenorrhea: A triple-blind, placebo-controlled trial, *Phytother. Res.* 2021 Dec;35(12):6954-6962; Fanaei H et al., Effect of curcumin on serum brain-derived neurotrophic factor levels in women with premenstrual syndrome: A randomized, double-blind, placebo-controlled trial, *Neuropeptides.* 2016 Apr;56:25-3; Khayat S et al., Curcumin attenuates severity of premenstrual syndrome symptoms: a randomized, double-blind, placebo-controlled trial, *Complement Ther. Med*. 2015 Jun;23(3):318-24.

[5] The Challenger provided a chart listing 15 studies on Chasteberry.

- Several studies on ashwagandha,[6] magnesium,[7] vitamin B6,[8] turmeric[9] and chasteberry.[10]

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[6] Shrilata *et al* (2022) Management of pre-menstrual syndrome with combined Ayurvedic interventions (Ashwagandha vati and Satvavajava chikitsa) – an open label single arm clinical study*;* Gopal *et al* (2021) Effect of an ashwagandha (Withania Somnifera) root extract on climacteric symptoms in women during perimenopause: A randomized, double-blind, placebo-controlled study. J. Obstet. Gynaecol. Res. Vol. 47, No. 12: 4414–4425; Salve *et al* (2019) Adaptogenic and Anxiolytic Effects of Ashwagandha Root Extract in Healthy Adults: A Double-blind, Randomized, Placebo-controlled Clinical Study. *Cureus.* 11(12); Modi *et al* (2012) Clinical evaluation of Ashokarishta, Ashwagandha Churna and Praval Pishti in the management of menopausal syndrome. *AYU Journal*. Vol 33. No 4. p 511-516; Lopresti *et al* (2109) An investigation into the stress-releiving and pharmacological actions of an ashwagandha (Withania somnifera) extract). *Medicine* (2019) 98:37; Steels *et al* (2018) A Double-Blind, Randomized, Placebo-Controlled Trial Evaluating Safety and Efficacy of an Ayurvedic Botanical Formulation in Reducing Menopausal Symptoms in Otherwise Healthy Women. *Journal of Herbal Medicine* https://doi.org/10.1016/j.hermed.2018.01.001; Choudhary et al (2017) Body Weight Management in Adults Under Chronic Stress Through Treatment With Ashwagandha Root Extract: A Double-Blind, Randomized, Placebo-Controlled Trial. *Journal of Evidence-Based Complementary & Alternative Medicine.* Vol 22 (1). p 96-106; Chandrasekhar et al, (2012) A Prospective, Randomized Double-Blind, Placebo-Controlled Study of Safety and Efficacy of a High- Concentration Full-Spectrum Extract of Ashwagandha Root in Reducing Stress and Anxiety in Adults. *Indian Journal of Psychological Medicine*, Vol 34, Issue 3, p 255-262; Auddy *et al* (2008) A standardized Withania Somnifera extract significantly reduces stress related parameters in chronically stressed humans: a double-blind, randomized, placebo-controlled study. *JANA*. Vol 11. No 1. p 50-56.

[7]Gok and Gok (2022) Investigation of Laboratory and Clinical Features of Primary Dysmenorrhea: Comparison of Magnesium and Oral Contraceptives in Treatment. *Cureus* 14(11): e32028; Nezamivand-Chegini *et al* (2022) The Effect of Magnesium Sulfate on Pain Intensity and Menstrual Blood Loss in Students With Primary Dysmenorrhea: A Randomized Controlled Trial. *J of Inflammatory Diseases*. Vol 26. No 3. 115-122; Yaralizadeh, *et al* (2020) Effectiveness of Magnesium on Menstrual Symptoms Among Dysmenorrheal College Students: A Randomized Controlled Trial. International Journal of Women's Health and Reproduction Sciences. 10 (2020): 2-17; Tih et al (2017) Effect of Calcium and Magnesium Supplements on Primary Dysmenorrhea and Premenstrual Syndrome in 19–23 Years Old Women. *Global Medical and Health Communication.* 5(3):159–166; Seifert, B., et al. (1989) Magnesium--a new therapeutic alternative in primary dysmenorrhea. *Zentralblatt fur Gynakologie* 111.11 (1989): 755-760.

[8] Retallick-Brown*, et al* (2020) A pilot randomized treatment-controlled trial comparing vitamin B6 with broad-spectrum micronutrients for premenstrual syndrome. *The Journal of Alternative and Complementary Medicine* 26.2 (2020): 88-97; nga et al (2018) The Effect of Pyridoxine on Prostaglandin Plasma Level in Patients with Primary Dysmenorrhea. *Indones J Obstet Gynecol* Vol 6. No 4. 239-242; Sayehmiri, Kourosh, et al (2016) Effects of vitamin B6 on premenstrual syndrome: A systematic review and meta-analysis." *Journal of Chemical and Pharmaceutical Science* 9.3 : 1346-53; Hasani, Nahid, et al. (2015) Comparison of the effects of relaxation and vitamin B6 on emotional and physical symptoms in premenstrual syndrome. *Evidence Based Care* 5.2 : 75-83; Ebrahimi et al (2012), supra; Fathizadeh et al (2010) Evaluating the effect of magnesium and magnesium plus vitamin B6 supplement on the severity of premenstrual syndrome. *IJNMR 2010*; 15(Special Issue): 401-405; DeSouza et al (2000), supra; Kashanian et al (2006) Pyridoxine (vitamin B6) therapy for premenstrual syndrome. *International Journal of Gynecology & Obstetrics* 96.1 (2007): 43-44; Doll, Helen, et

- "FTC to Tailor Claim Substantiation Requirements to Each Case", The Pink Sheet Daily, October 6, 2010.

## III. Decision

Focus markets both over-the-counter ("OTC") and dietary supplement products that help relieve symptoms associated with premenstrual syndrome ("PMS"). Focus' OTC products for PMS symptom relief include Pamprin Multi-Symptom and Pamprin Max Pain + Energy. In 2023 the Advertiser launched a new dietary supplement intended for PMS symptom relief called Pamprin Botanicals. Bayer, maker of Midol, a competing OTC product for PMS symptom relief, challenged a number of health-related claims made on Pamprin Botanical's product packaging and in its advertising and Amazon product listings.

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al. (1989) Pyridoxine (vitamin B6) and the premenstrual syndrome: a randomized crossover trial. *The Journal of the Royal College of General Practitioners* 39.326 : 364-368.

[9] Talebpour *et al* (2023) Effect of curcumin on inflammatory biomarkers and iron profile in patients with premenstrual syndrome and dysmenorrhea: A randomized controlled trial. *Physiological Reports.* 2023;11:e15763; Ridhati et al (2023) The effect of ginger and turmeric on primary dysmenorrhea. *Jurnal Keperawatan Muhammadiyah Edisi Khusus* ICHIT. P131-140; Hesami *et al* (2021) Randomized, double-blind, placebo-controlled clinical trial studying the effects of Turmeric in combination with mefenamic acid in patients with primary dysmenorrhea. *Journal of Gynecology Obstetrics and Human Reproduction*. Vol 50. 101840; Tabari *et al* (2020) An Investigation of the Effect of Curcumin (Turmeric) Capsule on the Severity and Duration of Dysmenorrhea in Students of Iran University of Medical Sciences. *J Evolution Med Dent Sci* / eISSN - 2278-4802, pISSN - 2278-4748 / Vol. 9 / Issue 46 / Nov. 16, 2020; Okuyan et al (2021) The effect of turmeric on primary dysmenorrhea: Prospective case-control study. *J Surg Med.* 2021;5(7):715-717.

[10] Eltbogen *et al* (2015) Vitex-agnus-castus-Extrakt (Ze 440) for the treatment of symptoms in women with menstrual cycle disorders. *J Gynecol Endocrinol* 2015; 25 (2): 10–5; Van Die et al (2013) Vitex agnus-castus Extracts for Female Reproductive Disorders: A Systematic Review of Clinical Trials. *Planta Med* 2013; 79: 562–575; Zamani et al (2012) Therapeutic Effect of Vitex Agnus Castus in Patients with Premenstrual Syndrome. *Acta Medica Iranica*, Vol. 50, No. 2 (2012); Ma et al (2010) Treatment of moderate to severe premenstrual syndrome with Vitex agnus castus (BNO 1095) in Chinese women. *Gynecological Endocrinology* 26.8 (2010): 612-616; He et al (2009) Treatment for premenstrual syndrome with Vitex agnus castus: A prospective, randomized, multi-center placebo controlled study in China. *Maturitas* 63.1 (2009): 99-103; Pakgohar M, Moradi M, Jamshidi AH, Mehran A. Assessment of Vitex agnus-castus L. extract effect on treatment of premenstrual syndrome. *J Med Plants* 2009; 8: 98–107, 18; ; Schellenberg (2001) Treatment for the premenstrual syndrome with agnus castus fruit extract: prospective, randomised, placebo controlled study. *BMJ* Vol 322. 134-137; Turner et al (1993) A double-blind clinical trial on a herbal remedy for premenstrual syndrome: a case study. *Complementary Therapies in Medicine* 1.2 (1993): 73-77.

### *A. Standard of Review*

It is well-established principle of advertising law that the strength of the message drives the level of substantiation required to support an advertising claim.[11] Generally, advertisers must possess a "reasonable basis" for claims disseminated in advertising. It is critical that consumers receive accurate information for health products they purchase; therefore, health-related claims require a higher level of substantiation.[12] Health-related product performance claims generally should be supported by competent and reliable scientific evidence on the actual product itself as marketed to consumers.[13] Competent and reliable scientific evidence, as defined by the Federal Trade Commission ("FTC") includes, "tests, analyses, research, or studies that (1) have been conducted and evaluated in an objective manner by experts in the relevant disease, condition, or function to which the representation relates; and (2) are generally accepted in the profession to yield accurate and reliable results."[14] Additionally, when advertisers rely on studies to support health-related claims, they must ensure that the study is not only competent and reliable but also that the study results relate to the specific benefits being claimed.[15] Claims must be narrowly tailored so that there is a good fit between the advertiser's substantiation and the messages conveyed to consumers by the advertising.

Advertisers that make establishment claims such as "clinically tested," "scientifically tested" or "clinically proven" are also held to a higher standard of proof because the claims are, in essence, a promise that there is scientific evidence that proves or establishes the truth of the Advertiser's claims.[16]

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[11] *Goli Nutrition Inc., (Goli Ashwaghanda Gummies),* Report #7059, NAD/CARU Case Reports (April 2022); *Eli Nutrition, Inc. (TummyZen),* Report #6222, NAD/CARU Case Reports (November 2018).

[12] *Guardian Technologies, LLC (GermGuardian and PureGuardian Air Purifiers and Replacement Filters)*, Report #6319, NAD/CARU Case Reports (November 2019); *3B Medical, Inc. (Lumin CPAP Cleaner*), Report #6300, NAD/CARU Case Reports (August 2019).

[13] FTC, Health Products Compliance Guidance (Dec. 2022), https://www.ftc.gov/system/files/ftc_gov/pdf/HealthGuidance-508.pdf; *Nexus Formulas, LLC (Plavinol)*, Report #6321, NAD/CARU Case Reports (November 2019); *CEBRIA, LLC (Cebria Supplement),* Report #6142, NAD/CARU Case Reports (December 2017).

[14] FTC, Health Products Compliance Guidance (Dec. 2022), supra*; OrganiCare, LLC (FemiClear Vaginal Yeast Infection Treatment),* Report #6347, NAD/CARU Case Reports (February 2020); *Molekule Inc. (Molekule MH1 Air Purifier)*, Report #6314, NAD/CARU Case Reports (October 2019).

[15] FTC, Health Products Compliance Guidance (Dec. 2022), supra*; American Dream Nutrition, LLC (PhytoZon Dietary Supplement)*, Report #5890, NAD/CARU Case Reports (August 2016).

[16] Id. *Julius Zorn, Inc. (Juzo Compression Garments)*, Report #4429, NAD/CARU Case Reports (November 2005) (finding the claim "X Static has been scientifically tested and proven to offer advanced therapeutic benefits" to be an establishment claims requiring a higher evidentiary burden).

It is with these standards in mind that NAD reviews the challenged claims.

### *B. "Clinically Tested" and Other Express Health-Related Claims*

#### 1. Challenged Claims

Bayer challenged the "clinically tested" claim found on the front of Pamprin Botanical's packaging and similar claims such as "clinically tested for safety and efficacy" found on Pamprin's website, and "clinically tested to help support your emotional and physical well-being before, during and after your period, which addresses underlying issues of PMS" that appeared in a post on Pamprin Botanical's Instagram page.

The Challenger objected to similar "scientifically tested" claims found on Pamprin Botanical's Amazon product page. One challenged claim appears as part of a list under the heading "Why Pamprin?" The visual features photos of Pamprin's OTC products as well as Pamprin Botanicals and states "our products are scientifically tested, for efficacy on their own and safe to use in combination." The other challenged claim appears on Amazon product listings in a separate visual featuring only Pamprin Botanicals titled "Why 'Don't Cramp My Style'?" and states "that's why our products are scientifically tested to holistically relieve the underlying causes of PMS symptoms."

Bayer argued that the health-related product performance claims found on product packaging and in Amazon product listings are also misleading. Specifically, Bayer challenged the "mood support" claim found on the front of the product packaging as well as claims that taking 2 Pamprin Botanicals daily can "calm pms symptoms," "ease cramps, bloat and moodiness" and help consumers "experience a better period" as claimed in its Amazon product listing.

Bayer also challenged the implied claim that Pamprin Botanicals has been proven to reduce all common symptoms of PMS based on randomized, double-blind placebo-controlled testing of the product that it argued flowed from the above challenged express claims.

It is well-established that advertisers are obligated to support all messages reasonably conveyed by their advertising, not simply the messages they intended to convey.[17] Absent consumer perception evidence, NAD steps into the shoes of the consumer to determine the messages reasonably conveyed.[18] The Advertiser argued that "clinically tested" claims are different from "clinically proven" claims and do not require the same heightened level of support. NAD cases have consistently found

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[17] *Memory Health, LP (Advertising by Memory Health),* Report #7203, NAD/CARU Case Reports (August 2023).

[18] Id.

that establishment claims such as "clinically tested" convey the same message to consumers as a clinically proven claims.[19] The Advertiser's establishment claims convey more to the consumer than the mere existence of a trial conducted on the product, rather they convey the product has been clinically tested using reliable methods that demonstrated benefits to PMS sufferers.

Similarly, NAD cases have stated that a "clinical" test is "controlled, consistent and reproducible."[20] Accordingly, here one message reasonably conveyed by the "clinically tested" claim on product packaging and Instagram is that Pamprin Botanicals are proven to reduce common symptoms of PMS based on sound methodological science.

2. Advertiser's Evidence

The Advertiser submitted a study conducted by Citrus Labs to support its claims. One hundred women were recruited to participate with 91 subjects completing phase one and 88 subjects completing phase two. Participants filled out a baseline survey about the severity of common menstrual cycle symptoms[21] and went to a third-party lab for a blood draw. Subjects were told to take Pamprin Botanicals two days before their predicted period and then take it every day during their period. Participants completed a survey on the fifth day of their period that was similar to the survey taken at baseline and again went to a third-party lab for a blood-draw. Once their menstrual cycle stopped subjects were instructed to stop taking Pamprin Botanicals.

In phase two subjects were instructed to take Pamprin Botanicals two days before their predicted period and continue to take it each day during their period. During

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[19] *Pendulum Therapeutics, Inc. (Pendulum Glucose Control),* Report #6428, NAD/CARU Case Reports (February 2021) (stating "Clinically shown" is akin to a "clinically proven" claim which is an establishment claim held to a high standard of proof); *USPLabs, LLC (Jack3d Products)*, Report #5576, NAD/CARU Case Reports (April 2013); *NourishLife, LLC (SpeechNutrients Speak)*, Report #5620, *NAD/CARU Case Reports* (August 2013) (NAD has consistently found that a claim that a product is clinically tested conveys a message that those tests yield positive results and reasonable consumers will interpret this claim to convey the same message as a clinically proven claim); *Syntratech Corp. (Syntra-5 Total Body Solution)*, Report # 5150 NAD/CARU Case Reports (March 2010).

[20] *i-Health, Inc. (DSM North America) (Culturelle® IBS Complete Support),* Report #7080, NAD/CARU Case Reports (May 2022); *Advantice Health (Kerasal Fungal Nail Renewal)*, Report #6421, NAD/CARU Case Reports (October 2020) citing *John O. Butler Company (Secure Denture Adhesive Paste)*, Report #3259, NAD/CARU Case Reports (December 1995). See also *Zero Gravity (Perfectio™),* Report #6325R, NAD/CARU Case Reports (July 2020).

[21] For the first 14 questions of the survey subjects rated the severity of their symptoms on the following scale: 1-no symptoms, 2-barely noticeable, 3-mild, 4-moderate, 5-distracting and 6-severe. For the final question of the survey that rated the frequency of using pain medication the following scale was used: 1-never, 2-one dose daily, 3-two doses daily, 4-three doses daily, and 5-four or more doses daily.

this phase, subjects were instructed to take Pamprin OTC in addition to the Pamprin Botanicals product. On the fifth day of their period subjects completed another survey as well as another blood draw from the independent third-party lab.

The study examined differences from baseline to Month 1 and from baseline to Month 2. According to the survey results, subjects using Pamprin Botanicals during Month 1 experienced a 29.6% improvement in premenstrual cramps, a 33.3% improvement in mood swings and a 28.4% improvement in bloating. Additionally, subjects using Pamprin Botanicals reported using significantly less OTC pain relievers when taking the product as directed. Similar significant symptom improvement was seen in subjects using both the botanical product and Pamprin OTC together in Month 2.

The study also evaluated subjects' blood levels of C-reactive protein and cortisol, biomarkers that have been tied to inflammation. Lower levels of these biomarkers indicate a lower inflammation in the body. The blood draw analysis indicated that there were no significant differences between baseline and other measured time points for C-reactive protein or cortisol.

To supplement both phases of the study subjects were also asked directly about their experience with the Pamprin products during their use and rated their perception of the products on a 1-5 scale with 1 representing strongly disagree and 5 representing strongly agree. The responses to this survey indicate that 65.9% of subjects said they experienced a better overall period and 76.9% said they took fewer OTC drugs to relieve pain.

### 3. Analysis

The challenged advertising includes both "clinically tested" and health-related claims. The FTC's Health Products Compliance Guidance provides that "[r]andomized, controlled human clinical trials ("RCTs") are the most reliable form of evidence and are generally the type of substantiation that experts would require for health benefit claims."[22] The features of a sound methodological study are well-known and generally agreed upon by the scientific community. The study's objectives should be described clearly, and the methodology must be appropriate for obtaining the objectives posed by the study. The study's duration should be sufficient to detect an effect on the outcome and the sample size should be large enough to provide sufficient statistical power, with the study population representative of the target population to which the claim is targeted.[23] A well-designed human clinical trial has been defined to be, at a minimum, double-blind, randomized, and appropriately-

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[22] FTC, Health Products Compliance Guidance (Dec. 2022), https://www.ftc.gov/system/files/ftc_gov/pdf/HealthGuidance-508.pdf.

[23] *Goli Nutrition Inc. (Goli Ashwagandha Gummies),* supra; *First Day Life, Inc. (First Day Daily Enrichment Multivitamin),* Report #6931, NAD/CARU Case Reports (March 2021).

controlled demonstrating that the treatment group experienced statistically significant difference to the 95% confidence level as compared to the control group.[24] Further, the results must translate into meaningful benefits for consumers that relate directly to the performance attributes promised by the advertising.[25] Results that are not clinically meaningful do not provide adequate substantiation.[26]

NAD determined that the Citrus Labs trial suffered from several significant flaws which rendered the study insufficiently reliable to provide a reasonable basis for Pamprin Botanicals' establishment and express health-related claims.

First, the study subjects were permitted to take OTC pain relievers during phase one of the study that could have a material impact on survey results related to menstrual pain and bloating. As a result, it is impossible to know if the benefits perceived by the subjects were from Pamprin Botanicals or from the OTC pain relievers.

Second, the study relies upon the survey results of subjective reactions of study participants, yet the study lacked a control group to serve as a basis for comparison making it difficult to know whether the changes in premenstrual symptoms perceived by the subjects were due to a placebo effect or due to the use of Pamprin Botanicals. As discussed more fully below, PMS intervention trial often have a large placebo effect. Further, FTC Guidance provides that human clinical studies used to support health claims should have a treatment and a control group and the efficacy

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[24] See FTC, Health Products Compliance Guidance (Dec. 2022), supra ("A study that fails to show a statistically significant difference between the treatment and control groups may indicate that the measured effect is merely the result of placebo effect, unrelated improvement over time, or chance."); *Goli Nutrition Inc. (Goli Ashwagandha Gummies),* supra.

[25] See *OrganiCare, LLC, supra; Molekule Inc. (Molekule MH1 Air Purifier),* supra*; Eli Nutrition, Inc., (TummyZen)*, supra; *InterHealth Nutraceuticals, Inc. (Zychrome),* Report #5569, NAD/CARU Case Reports (April 2013); *Neuracel.com, LLC (Neuracel Nerve Pain Relief)*, Report #5907, NAD/CARU Case Reports (Dec. 2015) (NAD stated that in addition to randomization and blinding, competent and reliable scientific evidence should include "sound methodological studies [that] consist of other generally accepted features such as clearly defined study objectives and clinical endpoints, sufficiently large sample sizes to provide sufficient statistical power, a representative study population, and results that are statistically significant and clinically meaningful to consumers"); *Novartis Consumer Health, Inc. (Extra Strength Excedrin)*, Report #4973, NAD/CARU Case Reports (February 2009), NARB Panel #152, September 16, 2009; see also FTC, Health Products Compliance Guidance (Dec. 2022), supra ("Some results that are statistically significant may be too small to provide real consequences for consumer health.").

[26] See *OrganiCare, LLC (FemiClear Vaginal Yeast Infection Treatment),* supra; *The Procter & Gamble Company (Crest Sensitivity Treatment & Protection toothpaste)*, Report #5386, NAD/CARU Case Reports (September 2011); see also FTC, Health Products Compliance Guidance (Dec. 2022), supra.

of the product should be demonstrated by comparing the results of the treatment group to that of the control group.[27]

There may be clinical studies that do not contain a placebo arm, like, for example, when there are ethical considerations around withholding treatment (i.e., life-saving treatments) or a placebo-arm is difficult or impossible to create, but none of those considerations are present in this case, nor did the advertiser show why a placebo was unnecessary. Here, the lack of a placebo arm was compounded because study subjects also knew the purpose of the product. While the study was not open-label, subjects were asked about their premenstrual symptoms to establish a baseline. This could introduce the type of bias that a control group is intended to identify and lead to a large placebo effect because subjects who know the purpose of a study could be led to report perceived benefits from the product.

The Advertiser maintained that controls are not always necessary, citing NAD's decision in *Udo's Oils* to argue that general well-being claims can be supported by non-blinded, non-placebo-controlled clinicals.[28] In the Udo's Oil case NAD found that the advertiser's non-blinded, non-placebo-controlled study could not support a claim that "athletes around the world are experiencing greater strength, improved stamina and faster recovery using Udo's Oil," but that nothing prevented the advertiser from making claims about general well-being or that people reported feeling stronger when taking the product.[29] However, here Focus relies upon an uncontrolled study to support an establishment claim as well as health-related claims that promise symptom relief from cramps, bloat, moodiness and PMS symptoms. The Advertiser is not marketing Pamprin Botanicals product for general well-being but advertising that the product is clinically tested and can ease specific symptoms of PMS.

The Advertiser also argued that even presuming a large placebo effect of 36-43% commonly found in PMS intervention trials was present in this study the results still outperform the expected placebo rate.[30] However, the Challenger's expert opined that substituting a general placebo effect rate from other PMS intervention trials is not appropriate here because the studies cited deviate from the Focus study's treatment mechanism, study population, response scale and definition of "response."[31]

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[27] FTC Health Products Compliance Guidance (Dec. 2022), supra.

[28] *Flora, Inc. (Udo's Oil 3-6-9 Blend),* Report #5389, NAD/CARU Case Reports (October 2011).

[29] *Id.*

[30] Focus argued that the results outperform the substitute placebo rate because 66.8% of subjects experienced improvement on all PMS symptoms.

[31] Focus attributes the general 36-43% placebo effect to Green LJ, O'Brien PMS, Panay N, Craig M on behalf of the Royal College of Obstetricians and Gynaecologists. Management of premenstrual syndrome. BJOG 2017;124:e73–e105 which in turn cites two studies as the basis for the range. Yonkers KA, Brown C, Pearlstein TB, Foegh M, Sampson-Landers C, Rapkin A.

Accordingly, NAD found that relying on a substitute rate of placebo effect did not correct for the failure to include a control in the underlying study.

Finally, NAD noted that the only objectively measurable results from blood tests failed to show statistically significant results for biomarkers tied to inflammation. A study that measures improvement subjectively and does not control for variables that may materially affect outcomes is not competent and reliable scientific evidence that the product is responsible for the claimed benefits. For the foregoing reasons, NAD determined that the Citrus Labs study did not support the challenged establishment or health-related claims and recommended that all "clinically tested," "scientifically tested," "mood support," "calm pms symptoms," "ease cramps, bloat and moodiness" and help consumers "experience a better period" claims be discontinued.

### *C. Ingredient Claims*

Bayer challenged five claims found on Pamprin Botanicals product packaging, website and in Amazon product tile advertising that call out specific ingredients in the product and the benefit they provide to consumers. Each of these claims are health-related claims as defined by the FTC and must be substantiated with competent and reliable scientific evidence.[32]

An ingredient's dosage, formulation and route of administration can impact efficacy. A study on the ingredient in the product that has the same dosage, formulation and route of administration provides the most reliable support for a claimed benefit. In addition, it is well-established that the study population should be representative of the population to which the claim is targeted.[33] Further, all relevant research, both favorable and unfavorable must be considered. Conflicting or inconsistent results raise serious questions as to whether a particular claim is substantiated.[34] It is with these principles in mind that NAD reviewed each challenged ingredient claim.

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Efficacy of a new low-dose oral contraceptive with drospirenone in premenstrual dysphoric disorder. *Obstetrics & Gynecology* 2005;106:492–501 and Freeman EW, Kroll R, Rapkin A, Pearlstein T, Brown C, Parsey K, et al. Evaluation of a unique oral contraceptive in the treatment of premenstrual dysphoric disorder. *Journal of Women's Health & Gender-Based Medicine* 2001;10:561–9.

[32] See FTC Health Products Compliance Guidance (Dec. 2022), supra..

[33] FTC, Health Products Compliance Guidance (Dec. 2022), supra; *Innovix Pharma Inc. (OmegaVia Fish Oil and OmegaVia EPA 500)*, NAD/CARU Case Reports #6974 (April 2022); *Prevention Pharmaceuticals, Inc. (Omax3 Ultra Pure Dietary Supplement)*, NAD/CARU Case Reports #5966, (July 2016); *Good Health Naturally, LLC (Serranol Supplements)*, Report #5441, NAD/CARU Case Reports (March 2012).

[34] FTC Health Products Compliance Guidance (Dec. 2022), supra.

### 1. Ashwagandha ingredient claims

Bayer challenged the express claim "Ashwagandha – a calming influence" as well as the implied claim that Ashwagandha reduces PMS-related mood swings. NAD first considered whether the advertising reasonably conveys the implied message challenged. Reasonable consumers understand that PMS symptoms include irritability and moodiness therefore when Pamprin Botanicals advertising claims that ashwagandha causes "a calming influence" those consumers would reasonably understand that ashwagandha reduces PMS-related moodiness.

Focus submitted nine clinical studies on ashwagandha and argued that the studies show that daily consumption of ashwagandha can reduce stress and cortisol levels. Only the 2008 Auddy study, tested the same dosage of ashwagandha, 125mg daily, found in Pamprin Botanicals.[35] The Auddy study, however, contained a number of flaws that NAD determined rendered the study a poor fit for the challenged claims.

First, more than half of the subjects in the Auddy study were men whose results are not relevant to support a claim that ashwagandha can provide a calming influence for women with PMS symptoms or PMS moodiness.[36] Studies evaluating ashwagandha for general stress in men and women are not relevant to claims Pamprin is making about ashwagandha relieving PMS moodiness.

In addition, the Auddy study had subjects take ashwagandha daily for at least 60 consecutive days which does not match the dosing instruction for Pamprin Botanicals.[37] Pamprin Botanicals dosing instructions tell consumers to take the product two days before your period, during your period and 2 days after menstruation. There is no evidence in the record indicating that results from subjects taking ashwagandha for 60 days can be extrapolated to consumers taking ashwagandha according to Pamprin's much shorter duration and stop and start dosing instructions.

NAD found the other studies submitted by Focus were not a good fit for the challenged claims because the studies differed in dosage, duration, and testing population[38] or tested botanical combinations that included ashwagandha and other

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[35] Auddy *et al* (2008), supra (The Auddy study was a double-blind, randomized placebo-controlled dose ranging study evaluating ashwagandha in subjects with stress. In the 60-day study 130 subjects who were deemed stressed based on a clinical assessment were assigned to a placebo group or treatment group of 125mg ashwagandha daily or 250mg ashwagandha daily for 60 days).

[36] Id. (The Auddy study looked at 130 subjects which included 95 males and 35 females).

[37] Id. (The Auddy study had subjects take a placebo, 125mg of ashwagandha twice daily or 250mg twice daily for 60 days).

[38] Salve *et al* (2019), supra (The Salve study was a double-blind, randomized, placebo-controlled study that had 60 male and female subjects take either a placebo, 125mg of ashwagandha twice daily or 300mg ashwagandha twice daily for 8 weeks); Choudhary et al

ingredients.[39] There was no evidence in the record demonstrating that results from these studies with different dosing, target populations and formulations could be extrapolated to users of Pamprin Botanicals. Accordingly, NAD recommended that the Advertiser discontinue the claim "Ashwagandha – a calming influence" as well as the implied claim that the ashwagandha in Pamprin Botanicals reduces PMS-related mood swings.

### 2. Magnesium Ingredient Claims

Bayer challenged Pamprin Botanical's express claims "Magnesium – period pain, nope" and that Magnesium "works on period pain." Bayer also challenged the related implied claim that magnesium in Pamprin Botanicals reduces pain associated with PMS. Stepping into the shoes of a reasonable consumer, NAD determined that the express claims that Magnesium "works on period pain" and "period pain nope" reasonably conveys a message that Pamprin Botanicals reduces pain associated with PMS.

To support these challenged health claims, the Advertiser's expert referenced a 2017 review that summarized seven studies evaluating the effects of magnesium supplementation on individuals with premenstrual syndrome.[40] NAD found that these studies were not a good fit for the challenged claims because the subjects took a higher dose of magnesium than that found in Pamprin Botanicals[41] and the subjects took the magnesium supplements for a longer period of time than that called for with Pamprin Botanicals. In addition, many of the studies reported effects on anxiety

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(2017), supra (The Choudhary study was double-blinded, randomized, placebo-controlled safety and efficacy study of 38 males and 14 females who took 600mg of ashwagandha (KSM-66) daily for 8 weeks); Chandrasekhar et al, (2012), supra (The Chandrasekhar study studied 41 males and 23 females who took either a placebo or 600mg ashwagandha daily (KSM-66) for 60 days). Additionally, both the Modi and Steels clinical trials tested women going through menopause, which does not match the target audience for a period-symptom-relief product. See Modi *et al* (2012), supra; Steels *et al* (2018), supra.

[39] The Shrilata study tested a different extract of ashwagandha and a much higher dose of 500mg twice daily combined with a form of yoga, counseling and relaxation techniques in women with PMS making it impossible to tell if the resulting effects were specifically from the ashwagandha, the yoga and counseling techniques, difference in dosing or the different extract of ashwagandha. See Shrilata *et al* (2022), supra. Similarly, the Lopresti study tested Soden ashwagandha, an extract that is different from the KSM-66 ashwagandha that is used in Pamprin Botanicals and tested men and women who took 240mg supplement daily for 60 days. See Lopresti et al (2019), supra. The Gopal study looked at a perimenopausal women and directed them to take more than double the amount of ashwagandha found in Pamprin Botancials making it difficult to extrapolate any results. See Gopal et al (2021), supra.

[40] Boyle NB, Lawton C, Dye L. The Effects of Magnesium Supplementation on Subjective Anxiety and Stress-A Systematic Review. Nutrients. 2017 Apr 26;9(5):429. doi: 10.3390/nu9050429. PMID: 28445426; PMCID: PMC5452159.

[41] Pamprin Botanicals includes 160mg of magnesium as magnesium oxide per serving.

related PMS symptoms and not specifically on period pain.[42] Finally, some studies reported no significant difference between treatment group and placebo.[43]

The Advertiser also submitted two studies conducted on women who were students at universities in Turkey and Iran with moderate to severe dysmenorrhea (i.e. period pain). These studies were not a good fit for the challenged claim for a number of reasons. First, the target population were women with dysmenorrhea or significant period pain and not the target audience for Pamprin Botanicals. In addition, both studies allowed women to take pain medication in addition to the magnesium supplement making it impossible to tell if the decrease in symptoms was from the pain medication or from the magnesium.

NAD determined that the Advertiser's support was not a good fit for the challenged claim and recommended that Focus discontinue the express claims "Magnesium – period pain, nope" and that magnesium "works on period pain" as well as the implied claim that the magnesium in Pamprin Botanicals reduces pain associated with PMS.

### 3. Vitamin B6 ingredient claims

Bayer challenged the express claim "vitamin B6 – pms less, chill more" as well as the implied claim that Vitamin B6 reduces all PMS symptoms, including mood swings. Pamprin Botanicals includes 40mg of Vitamin B6 as Pyridoxine HCI per serving. NAD found that one message reasonably conveyed by a "pms less, chill more claim" is that the vitamin B6 in Pamprin Botanicals can reduce all PMS symptoms and help consumers "chill" more or be less moody.

The Advertiser submitted nine clinical trials that involved supplementation with vitamin B6 or vitamin B6 and Magnesium. NAD found that these trials did not support the challenged claims. First, only two of the studies mentioned dosing of 40mg of vitamin B6, the amount found in Pamprin Botanicals. One of those two

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[42] Both Walker studies and the DeSouza study measured 6 symptoms categories: anxiety, cravings, hydration, depression, and other; none of which included pain. See Walker AF et al (2002), supra; Walker, A.F et al (1998) Magnesium supplementation alleviates premenstrual symptoms of fluid retention. *J. Womens Health* 1998, *79*, 1157–1165; DeSouza et al (2000), supra. The Khine study also measured mood changes with the Speilberger State-Trait Anxiety Inventory Premenstrual Tension Scale. See Khine *et al.*, Magnesium (Mg) Retention and Mood Effects After Intravenous Mg Infusion in Premenstrual Dysphoric Disorder. *Biol. Psychiatry* 2006, *594*, 327–333.The Quaranta study evaluated symptom categories including nervous tension, mood swings, irritability and anxiety. Finally, the Fathizadeh study also measured 6 symptom categories including anxiety, cravings, hydration, depression, somatic and other. See Quaranta et al., Pilot study of the efficacy and safety of a modified-release magnesium 250 mg tablet (Sincromag) for the treatment of premenstrual syndrome. *Clin. Drug Investig.* **2007**, *271*, 51–58.

[43] Quaranta et. *al.*, (2007), supra; Ebrahimi et *al.,* (2012), supra; Facchinetti *et al.,* (1991), supra.

studies was referred to in a meta-analysis of vitamin B6 on PMS and, as a result, there were limited details on the study design. The other study used 40mg of vitamin B6 along with 250mg magnesium, a different combination than that found in Pamprin Botanicals. Additionally, each study had supplementation over a longer period of time and included daily supplementation unlike Pamprin Botanicals start and stop use instructions.[44]

The other studies submitted evaluated dosages up to 5 times the amount of vitamin B6 daily than that contained in Pamprin.[45] In addition, the Advertiser pointed to three studies that found no change when dosages of between 50mg and 300mg of vitamin B6 were compared to placebo to treat PMS symptoms.[46] As the FTC notes in its Health Product's Compliance Guidance, inconsistent or conflicting results raise serious questions about the adequacy of an advertiser's support.[47]

While vitamin B6 at different amounts may be found to have an effect on PMS symptoms, NAD found that the studies provided by Focus were not a good fit to support the health claim that vitamin B6 as found in Pamprin Botanicals can help consumers PMS less. Accordingly, NAD recommended that Focus discontinue the claim "Vitamin B6 – pms less, chill more" as well as the implied claim that the vitamin B6 in Pamprin Botanicals reduces all PMS symptoms, including mood swings.

### 4. Turmeric ingredient claims

Bayer challenged the express claim "Turmeric – cramp pain & puff" and "helps cramps and puffiness" as well as the implied claim that turmeric reduces PMS-related pain and bloating. Pamprin Botanicals includes 300mg of turmeric as Curcuma Ionga per serving. Consumers understand bloating to be a symptom of

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[44] The Sayehmiri meta-analysis mentions a test that looked at 40mg of supplementation, but there is no in-depth analysis of the methodology of the clinical. See Sayehmiri, Kourosh, *et al.,* (2016) Effects of vitamin B6 on premenstrual syndrome: A systematic review and meta-analysis." *Journal of Chemical and Pharmaceutical Science* 9.3: 1346-53.

[45] The Kashanian, Retallick Brown and Hasani studies evaluated women who took 80mg of vitamin B6 while the Bunga study evaluated women who took 100mg of vitamin B6. The Ebrahimi study looked at women who took 250mg of vitamin B6. See Kashanian *et al.,* (2007), supra; Retallick Brown *et al.,* (2020), supra; Hasain *et al.* (2015), supra.

[46] De Souza *et al.,* (2000), supra (finding no significant differences between treatments of 50mg Vitamin B6, 250mg magnesium, 250mg magnesium + 40mg Vitamin B6 and placebo when women rated PMS symptoms in six categories); *Hagen I et al* (2015), supra (finding 100mg of Vitamin B6 given daily through the menstrual cycle was no better than placebo in 34 women who suffered from premenstrual tension) *Diegoli MS et al.,* (1998), supra (finding no meaningful difference between treatment with 300mg of pyridoxine (vitamin B6) and placebo for treating premenstrual syndrome). See also Sayehmiri, Kourosh, *et al.,* (2016) supra (noting that previous research on dosage of vitamin B6 has reported contradictory results).

[47] FTC's Health Products Compliance Guidance (Dec. 2022), supra.

PMS and, therefore, one message reasonably conveyed by the advertisement listing turmeric as an ingredient alongside the word "cramp pain & puff" is that the turmeric in Pamprin Botanicals can reduce PMS-related pain and bloating.

As support for its claims the Advertiser provided five studies on turmeric or a compound of turmeric. The Hesami, Tabari and Okuyan studies evaluated the use of turmeric on pain in women with dysmenorrhea or severe period pain, a target population different than that of Focus' product advertised to all women with PMS symptoms. All three studies evaluated 500mg to 1,000mg of turmeric daily, a much larger dose than the 300mg of turmeric found in Pamprin Botanicals.[48] Additionally, the Okuyan study did not have a placebo and studied the difference between females using naproxen, an OTC pain reliever, and naproxen plus 1,000mg of turmeric making it difficult to assess whether the pain reduction was due to the turmeric or the OTC pain reliever.[49]

The Talebpour study specifically evaluated inflammatory biomarkers but included women with severe to moderate dysmenorrhea, a different study population than the Pamprin target audience and evaluated 500mg of turmeric plus 5mg of piperine, 200mg more than that found in Pamprin's product.[50] Additionally, the Talebpour study reported only a significant decrease in one inflammatory biomarker while several others did not show any statistically significant difference from placebo.

For the foregoing reasons, NAD found that the Advertiser's turmeric studies were not a good fit for the challenged claims and recommended that Focus discontinue the claim "Turmeric – cramp pain & puff" and "helps cramps and puffiness" as well as the implied claim that the turmeric in Pamprin Botanicals reduces PMS-related pain and bloating.

### 5. Chasteberry ingredient claims

Bayer challenged the express claim "Chasteberry – for a better period" as well as the implied claim that Chasteberry reduces all PMS symptoms. Pamprin Botanicals includes 45mg of Chaste Tree Extract (Vitex agnus-castus) per serving. In context, NAD found that one message reasonably conveyed by the advertisement is that the chasteberry in Pamprin botanicals reduces PMS symptoms.

The Advertiser provided several studies that show that up to 40mg of chasteberry can have an effect on PMS symptoms if taken every day for a sustained period of time.[51]

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[48] See Hesami *et al*., (2021), supra; Tabari *et al*., (2020), supra; Okuyan *et al.,* (2021), supra.

[49] Okuyan *et al.,* (2021), supra.

[50] Talebpour *et al.,* (2023), supra.

[51] Schellenberg (2012), supra (finding higher improvement in total symptom score for the 20mg chasteberry treatment group versus placebo); He, (2009), supra (finding subjects who took 40mg of chasteberry for 3 cycles reported a significant improvement in their

The Challenger agreed that the weight of these studies support a claim that chasteberry eases various symptoms such as bloating, mood change and discomfort if taken each day for a sustained period of time. None of the studies tested include the same dosing regimen recommended by Pamprin Botanicals which is to take the supplement two days before your period, during your period and two days after. There is no data in the record that indicates that chasteberry will have the same effect if it is taken for a few days a month. Focus argued that the clinical trial on Pamprin Botanicals itself corroborates the claims, however, NAD noted that study lacked a placebo and allowed patients to take OTC pain relievers making it difficult to assess whether the results were due to the supplementation or the OTC products.

Accordingly, NAD recommended that Focus discontinue "Chasteberry – for a better period" claims and any implied claim that the chasteberry in Pamprin Botanicals reduces PMS symptoms.

### *D. "Natural" and Related Claims*

Bayer challenged several express and implied claims that Pamprin Botanicals is natural. Additionally, Bayer argued that one of Pamprin's express claims about its natural ingredients conveys a disparaging message that other products are not natural.

#### 1. Challenged Advertising

Bayer challenged Pamprin's use of the express claim "naturally good-for-you" when describing five ingredients found in the Pamprin Botanicals supplement. An Amazon product tile titled "naturally good-for-you ingredients" lists five ingredients found in the product followed by the benefit the ingredient provides the consumer.[52] Each ingredient is marked with leaf imagery. The Challenger argued that the message conveyed is that the active ingredients are all-natural and that Pamprin Botanicals is an all-natural product.

Additionally, Bayer argued that in the context of other natural claims the use of "botanical" in the product name, along with the leaf imagery on the product packaging and throughout the product's advertising conveys the message that Pamprin Botanicals is all-natural product.

Bayer also challenged the express claim found on an Amazon product tile stating "All the Good stuff None of the Bad." The product tile features the title "All the Good stuff. None of the Bad" and includes six circles highlighting six specific product attributes including "Gluten Free" with a wheat visual, "Vegan Capsule" with a plant

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premenstrual syndrome diary score than those who took placebo); Schellenberg (2001), supra (finding patients who received 20mg a day of chasteberry for 3 cycles had significant improvement in PMS symptoms compared with placebo).

[52] The five ingredients are ashwagandha, vitamin B6, chasteberry, magnesium and turmeric.

visual, “Non GMO” with a plant visual, “Dye-Free Capsule” with a color splash visual, “Cruelty Free” with a bunny visual and “Clinically Tested” with a beaker visual. Bayer argued this claim falsely disparages competitive products by conveying the message that competing products include ingredients that are unsafe or unhealthy.

Focus maintained that the “naturally good-for-you ingredients” claim and the use of the term “botanical” in the product name does not imply that the product is all-natural. Similarly, the Advertiser argued that product tile touting six attributes of Pamprin Botanicals does not convey a message about other products being bad, but rather makes a monadic claim about important features of its product.

2. Analysis

NAD evaluated whether the challenged advertising “naturally good-for-you ingredients” conveyed the message that Pamprin Botanicals is an all-natural product and that its active ingredients are all natural.

The “naturally good-for-you ingredients” claim that appears on the Amazon product tile lists Ashwagandha, Vitamin B6, Chasteberry, Magnesium and Turmeric alongside a leaf visual, NAD found that the product tile did not convey the message that the Pamprin Botanical product as a whole is a natural product because the tile specifically refers to the listed ingredients and does not reference the product as a whole nor does it feature a visual of the product.[53] NAD determined, however, that one message reasonably conveyed is that these listed ingredients Ashwagandha, Vitamin B6, Chasteberry, Magnesium and Turmeric alongside a leaf visual, are natural. There is no evidence in the record as to whether the five ingredients listed are indeed natural. NAD recommended that the Advertiser modify its advertising to remove the “naturally good-for-you ingredients” claim and avoid conveying the message that Pamprin Botanicals’s active ingredients are all-natural.

NAD next evaluated the use of the term “botanical” in the product name and whether the name along with other “natural” claims convey a message that the Pamprin Botanical product is all-natural. As a general rule, absent extrinsic evidence that consumers have been confused or misled, NAD will not require an advertiser to change the name of a product simply because a challenger suspects that it may be

[53] NAD determined this case was different from Zarbee Naturals as that case featured the Zarbee Natural name on each product in its line causing NAD to determine that consumers would expect the line of product to include natural active ingredients. Here, Pamprin Botanicals is one product and only mentions the word “natural” in one of its Amazon product tiles. NAD did not consider this to be a claim that its product as a whole is all natural. See *Zarbee’s Inc. (Zarbee’s Naturals Remedies and Supplements),* Report #6927, NAD/CARU Case Reports (December 2020).

misleading.[54] When the product name makes an expressly false claim, however, extrinsic evidence of consumer confusion is not required to recommend a product name change.[55] When considering whether a challenged product name communicates an express claim, NAD looks at whether the product name conveys a clear, specific, or objectively provable claim, independent of the rest of the advertising claims and context in which it is presented.[56]

Here, NAD determined that the name "Pamprin Botanicals" is not expressly false. "Botanical" is defined as "of or relating to plants or botany" or "derived from plants"[57] and ingredients in the product such as ashwagandha and turmeric are related to plants. Nothing in the plain language of the name conveys the message that all ingredients in Pamprin Botanicals are plant based or that it is an all-natural product. Given the lack of evidence of consumer confusion and NAD's conclusion that "botanical" is not an expressly false claim, NAD concluded that the name Pamprin Botanical did not require modification.

Even considering the name Pamprin Botanicals, along with the leaf imagery on the product and the one "naturally good-for-you ingredients" claim found on one Amazon product tile, it is not reasonable for consumers to take away the message that the entire Pamprin Botanicals product is all-natural. The Challenger pointed to the *Zarbees Naturals case,*[58] in which NAD found that where key ingredients were not derived from natural processes, the product name, "Zarbee's Naturals" reasonably conveys a misleading message. Here, however, as discussed more fully above, the term "botanical" is not the same as an all-natural or naturally derived claim.

NAD next considered the claim "all the good stuff, none of the bad" to determine if it conveys the message that competing products include ingredients that are unsafe or unhealthy. In evaluating the claims NAD looked to a previous case that dealt with characterization of ingredients as "bad." In *Petco Animal Supplies Inc.* NAD found that the claim "bye bye bad stuff" when referring to artificial ingredients was not puffery and in fact conveyed a message that artificial ingredients are "bad stuff" a claim that was not supported.[59] Similarly here, one message reasonably conveyed by

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[54] *One Health Certification Foundation (Certification of Poultry Products),* Report #7129, NAD/CARU Case Reports (February 2023); *Safe Catch, Inc. (Pouched and Canned Tuna)*, Report #6911, NAD/CARU Case Reports (July 2021).

[55] Id.

[56] *Safe Catch, Inc. (Pouched and Canned Tuna),* supra.

[57] See *Botanical*, Merriam-Webster, https://www.merrian-webster.com/dictionary/botanical

[58] *Zarbee's Inc. (Zarbee's Naturals Remedies and Supplements),* supra.

[59] *Petco Animal Supplies, Inc. (Petco "No Artificial Ingredients" Campaign),* Report #6357, NAD/CARU Case Reports (April 2020).

the product tile is that the six attributes found in the circles (i.e. "gluten-free") are the good stuff and any products that are not free of these six attributes are "bad," unhealthy, or not good for consumers. There is nothing in the record to support the claim that competitor's products that have these six attributes are "bad." While these consumers may look for products that avoid certain ingredients or attributes, characterizing those attributes as "bad" requires evidence that the attributes are "bad" for consumers. Advertisers are free to highlight positive product attributes of their products but may not falsely denigrate other products for not having those same qualities. NAD recommended that the Advertiser modify the claim "all of the good stuff, none of the bad" to avoid conveying the message that competing products include ingredients that are unsafe or unhealthy.

### *E. "Tried and Trusted"*

Bayer challenged the express claim that Pamprin Botanicals is "tried and trusted" because the Pamprin Botanicals product is new to the market and therefore it is misleading to claim that it is "tried and trusted." Focus argued that this claim is supported by the clinical study conducted on Pamprin Botanicals.

NAD stepped into the shoes of the reasonable consumer to determine the message conveyed by the "tried and trusted" claim and determined that the context of the Amazon product tile refers to Pamprin as a brand as "tried and trusted." Although Bayer argued that "tried and trusted" referred to the newly-released Pamprin Botanicals product, the title of the advertisement states "Why Pamprin?" and explains that the brand was born in the 60s and positioned itself as "period people," and has been revolutionizing period symptoms ever since. After this explanation the advertisement states "we are tried and trusted" and all three Pamprin products (two OTC products and the dietary supplement product) are featured on the side of the advertisement. NAD concluded, in context, that the "tried and trusted" claim refers to Pamprin's history and that no modification was necessary.

### *F. Claims that Pamprin's dietary supplement and Pamprin OTC products work together*

Bayer challenged several claims that it argued communicate that Pamprin Botanicals can boost the efficacy of Pamprin's Multi-Symptom OTC product. Bayer asserted that these claims amount to impermissible disease claims according to the FDA.

#### 1. Challenged Claims

Amazon's product description of Pamprin Botanicals states "[w]e've developed a holistic approach to managing your period. Our medicinal products, like Pamprin Multi-Symptom, stand well alone but work so nicely in combination with the Pamprin Botanicals PMS, Period & Mood Support supplement to take good care of the whole you." An Amazon product tile titled "Take 2 Capsules Daily" describes how taking 2 capsules of Pamprin Botanicals daily helps 2 days pre-period, during your period and 2 days post-period to provide relief from PMS symptoms. An asterisk

appears next to the "during your period" phrase and a small disclaimer attached to the asterisk explains "for those more difficult days it's safe to add Pamprin Multi-Symptom or Max Pain + Energy to your period strategy for maximum relief." Another Amazon product tile is titled "Friends with Legit Benefits" and states, "It's time to develop a better period strategy. Time to take advantage of both supplemental and medicinal products, so you are fully cared for" and features Pamprin Botanicals alongside both of Pamprin's OTC products.

Bayer argued that these claims together communicate a message that the Pamprin Botanicals product works alongside the OTC product to increase the effect of the OTC product. The Advertiser asserted that it's advertising merely cross-markets two different Pamprin products to the same audience and does not communicate that its dietary supplement product augments its other drug products.

### 2. Analysis

NAD routinely reviews the truthfulness and accuracy of claims concerning products under FDA's purview. It is well-established that when a product is subject to FDA regulation or review, NAD will harmonize its recommendations with the related regulatory framework.[60] NAD's role, however, is not to enforce FDA regulatory compliance and NAD lacks the authority to determine if advertising claims violate FDA regulations.[61] Accordingly, NAD does not review whether the challenged claims constitute prohibited "disease claims" in violation of FDA regulations or are instead "structure/function claims" as defined and permitted by the FDA.[62] Rather, regardless of whether the advertised product is a drug or dietary supplement, NAD identifies the messages reasonably conveyed by the advertising claims, examines the

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[60] *Hisamitsu America, Inc. (Salonpas Pain Relief Patch Large),* Report #6918, NAD/CARU Case Reports (February 2021).

[61] See e.g., *i-Health, Inc. (DSM North America) (Culturelle IBS Complete Support),* Report #7080, NAD/CARU Case Reports (May 2022); *Bayer HealthCare LLC (Claritin-D),* Report #6269, NAD/CARU Case Reports (April 2019); *Kramer Laboratories, Inc. (The Original FungiNail Toe & Foot Brand and Fungi-Nail Nailner),* Report #6141, NAD/CARU Case Reports (December 2017).

[62] The Federal Food Drug & Cosmetic Act ("FDCA") allows dietary supplements to feature "structure/function claims" that describe the role of a nutrient or dietary ingredient intended to affect the structure or function of the human body (e.g., "calcium builds strong bones") or characterize the documented mechanism of action by which a nutrient or dietary ingredient acts to maintain such structure or function, but may not expressly or implicitly represent that a dietary supplement can diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases or signs or symptoms of a specific disease (i.e., a "disease claim"). See 21 C.F.R. §101.93(f)-(g).

reliability of the evidence provided by the Advertiser, and determines if the evidence is a good fit for the reasonably conveyed messages.[63]

To evaluate the message reasonably conveyed by the advertising NAD stepped into the shoes of the reasonable consumer. NAD determined that all three pieces of advertising challenged suggest that the dietary supplement works together or in combination with Pamprin's OTC products to provide complete well-rounded care for the consumer. For example, the product description on Amazon states that Pamprin Multi-Symptom "stand[s] alone but work so nicely in combination… to take good care of the whole you" and the Amazon product tiles state to use both products "so you are fully cared for." The advertising ties benefits to using the products in combination, and reasonably implies that the combination works better than a single product by itself. Telling consumers to develop "a better period strategy" and immediately thereafter telling consumers to take advantage of both the supplemental and medicinal products they offer reasonably conveys the message that superior relief can be obtained by using both products. In fact, the disclaimer touting both products specifically states that it's safe to add either Pamprin OTC product "to your period strategy for maximum relief."

For the foregoing reasons, NAD found that the message reasonably conveyed by the Amazon product description and product tiles is that Pamprin Botanicals and Pamprin OTCs work together to provide superior relief for PMS symptoms. NAD determined that the Citrus Labs study evaluating both Pamprin Botanicals and Pamprin OTC did not meet the standard for competent and reliable scientific evidence; therefore, NAD found the Advertiser did not provide reliable substantiation for the implied claim. NAD recommended that the Advertiser modify its advertising to avoid conveying the message that Pamprin Botanicals and Pamprin OTCs work together to provide superior relief for PMS symptoms.

## IV. Conclusion

NAD recommended that all "clinically tested," "scientifically tested," "mood support," "calm pms symptoms," "ease cramps, bloat and moodiness" and help consumers "experience a better period" claims be discontinued. NAD recommended that the Advertiser discontinue the following ingredient claims:

- "Ashwagandha – a calming influence" as well as the implied claim that the ashwagandha in Pamprin Botanicals reduces PMS-related mood swings.
- "Magnesium – period pain, nope" and that Magnesium "works on period pain" as well as the implied claim that magnesium in Pamprin Botanicals reduces pain associated with PMS.

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[63] *Optivida Health (Optivida Silver Liquid Solution),* Report #6372, NAD/CARU Case Reports (June 2020).

- "Vitamin B6 – pms less, chill more" as well as the implied claim that the vitamin B6 in Pamprin Botanicals reduces all PMS symptoms, including mood swings.
- "Turmeric – cramp pain & puff" and "helps cramps and puffiness" as well as the implied claim that the turmeric in Pamprin Botanicals reduces PMS-related pain and bloating.
- "Chasteberry – for a better period" claims as well as the implied claim that the chasteberry in Pamprin Botanicals reduces PMS symptoms.

NAD recommended that the Advertiser modify its advertising to remove the "naturally good-for-you ingredients" claim and avoid conveying the message that Pamprin Botanical's active ingredients are all-natural.

NAD concluded that the name Pamprin Botanicals did not require modification.

NAD recommended that the Advertiser modify the claim "all of the good stuff, none of the bad" to avoid conveying the message that competing products include ingredients that are unsafe or unhealthy.

NAD concluded, in context, that the "tried and trusted" claim refers to Pamprin's history and that no modification was necessary.

NAD recommended that the Advertiser modify its advertising to avoid conveying the message that Pamprin Botanicals and Pamprin OTCs work together to provide superior relief for PMS symptoms.

## V. Advertiser's Statement

Focus Consumer HealthCare will appeal NAD's decision, which is incorrectly based on a rigid substantiation standard applicable to prescription drugs. As a federal court agreed in *U.S. v. Bayer Corp.,* this is not and has never been the standard for dietary supplement claims. Decades of law and regulatory guidance support a finding that the breadth of studies on the individual ingredients in Pamprin Botanicals coupled with a well-designed clinical trial constitute competent and reliable scientific evidence in support of the supplement claims at issue. Focus supports industry self-regulation and looks forward to presenting its position to the National Advertising Review Board.

## Revised Advertiser's Statement:

Focus Consumer HealthCare will comply with NAD's decision, despite its belief that the decision is incorrectly based on a rigid substantiation standard applicable to prescription drugs. As a federal court agreed in *U.S. v. Bayer Corp.,* this is not and has never been the standard for dietary supplement claims. Decades of law and regulatory guidance support a finding that the breadth of studies on the individual ingredients in Pamprin Botanicals coupled with a well-designed clinical trial constitute competent and reliable scientific evidence in support of the supplement

claims at issue. Nevertheless, Focus supports industry self-regulation and will take NAD's recommendations into consideration as it develops future advertising.