BBB NATIONAL PROGRAMS, INC.
The Direct Selling Self-Regulatory Council

Case Number: 32-2021 – Monitoring Inquiry – Magnetude Jewelry

COMPANY DESCRIPTION

Magnetude Jewelry (or the "Company") is a multi-level direct selling company based in Maryland that sells bio-magnetic interchangeable fashion jewelry to consumers. According to the Company's website, the Company's independent representatives earn money through commission on product sales or recruiting other salesforce members.

BASIS OF INQUIRY

The Direct Selling Self-Regulatory Council ("DSSRC") is a national advertising self-regulation program administered by BBB National Programs, Inc. This inquiry was commenced by DSSRC pursuant to its ongoing independent monitoring of advertising and marketing claims in the direct selling industry.

DSSRC's inquiry concerned one earning claim and several product claims disseminated by both the Company and its salesforce members. The representative earnings claim and product claims that formed the basis of this inquiry were located on the Company's website and on social media accounts of Company salesforce members. Those claims are set forth below:

Earnings Claim

- "Whether you are looking to really go for it and replace your income, or you just want to work part time for some extra vacation money or pay some bills, you are welcome to join us!"

DSSRC informed the Company of its concern that earnings claims such as "replace your income" may convey a message that someone engaging in direct selling of Magnetude Jewelry products is likely to earn a minimum level of income and/or make full-time and/or career level income.

Product Claims

The representative product claims that formed the basis of this inquiry are set forth below:

Product Claim #1: "Improve your mood, your energy, your sleep, decrease PA in and protect yourself against harmful EMF's."

Product Claim #2: "They all protected you from EMF's and 5G and still all have at the healthy elements to boost your vitality on the back of them!"

Product Claim #3: “We use the strongest healthy rare earth neodymium magnets (3000 gauss) to attach our ‘tudes’. These magnets help to protect us from EMF’s (electromagnetic frequencies) that are emitted all around us from cell phones, wifi, computers, cell towers, fluorescent lighting etc. In the modern world we can’t escape being subjected to these frequencies that pull at our own energy and effect our cells, but the neodymium magnets help to close off our own energetic frequencies so that we are not as susceptible to them.

Product Claim #4: “Magnetude Jewelry also has embedded bio-energetic elements; far infrared (FIR), ‘negative ions’, and germanium powder to provide the latest technology for your health and vitality. Far Infrared Energy (FIR) is made up of waves of energy that are invisible to the naked eye that penetrate into the body and gently increase blood supply. The germanium balls emit far infrared rays that can stimulate enzyme activity and metabolism, which helps as an anti-oxidant fighting oxidative stresses that lead to many degenerative diseases. Wearing our necklace may help increase blood flow and carry more oxygen to your cells. Increasing ‘negative ions’ (the feel good ions) helps repel the bad ‘positive ions’ and increase serotonin to give you a sense of well-being. A body in complete balance has a better ability to heal itself.”

DSSRC informed the Company of its concern that a reasonable consumer may interpret such claims, and similar claims, to mean that the Company’s products can help protect consumers against various electromagnetic frequencies that may be harmful. In addition, DSSRC expressed concern that the claims may convey unsubstantiated, health-related and wellness benefits.

COMPANY’S POSITION

Magnetude Jewelry expressed its gratitude to DSSRC for bringing the representative earnings and product claims to the Company’s attention.

Earnings Claims

In response to DSSRC’s inquiry, the Company revised the representative earnings claim identified above to remove the claim “replace your income.” Specifically, the Company replaced the copy that had appeared on its website with the following statement: “Whether you want to work part time for some extra vacation money and pay some bills, or you want to work into making this a meaningful income for you, you are welcome to join us!”

Product Claims

The Company informed DSSRC that it possesses a vast amount of research regarding its products. The Company compiled various research documents and provided them to DSSRC along with a brief summary/explanation of how the research findings support the Company’s product claims.

With respect to Product Claim #1 and Product Claim #2, Magnetude Jewelry removed both claims which had appeared on the Company's Facebook page.

With respect to Product Claim #3 and Product Claim #4, the Company initially provided various research data to DSSRC that the Company maintained support the product claims. Specifically, the Company provided DSSRC with several studies and scientific papers. The Company maintained that the documentation and evidence that it provided:

- researched the effect of ceramic impregnated gloves and FIRs on individuals with Raynaud's syndrome, a vascular disease and demonstrated that FIRs increase blood flow and is clinically effective for pain, arthritis and vascular disease treatment.[1]
- researched the effect that jewelry powders and FIRs have on skin temperature and blood circulation and concluded that FIRs increase the temperature of skin and increased circulation.[2]
- researched the effect of FIR therapy on patients undergoing hemodialysis treatment and found that FIR therapy increased blood flow.[3]
- evaluated the various biological responses in rats and humans when exposed to FIR therapy and indicated that FIR increased blood flow in rats, leveled out the circadian rhythm for better sleep and more restful sleep in rats.[4]

In addition, the Company provided DSSRC with a summary of several studies on FIR. The Company argued that one such study showed that FIR delayed onset of fatigue in muscle contraction with amphibians and that a study of rabbits that had rheumatoid arthritis showed that FIR reduced inflammation. The Company maintained that another study also concluded that FIR helped heal breast tissue after ionizing radiation from x-rays. The Company asserted that this study concluded that FIR was helpful in helping with free radicals and cell damage from ionizing radiation.

During the pendency of this inquiry, Magnetude provided DSSRC with over twenty scientific research articles as to substantiate Product Claim #3 and Product Claim #4.

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[1] Gordon D. Ko & David Berbrayer, *Effect of Ceramic-Impregnated "Thermoflow" Gloves on Patients with Raynaud's Syndrome: Randomized, Placebo-Controlled Study*, 4 ALTERNATIVE MED. REV. 328, 334 (2002).

[2] B. H. Yoo et al., *Investigation of Jewelry Powders Radiating Far-Infrared Rays and the Biological Effects on Human Skin*, J. OF COSMETIC SCI., May/June 2002, at 175.

[3] Qingsong Wan et al., *Effects of Far Infrared Therapy on Arteriovenous Fistulas in Hemodialysis Patients: A Meta-Analysis*, 39 RENAL FAILURE 613 (2017).

[4] Shojiro Inoué & Morihiro Kabaya, *Biological Activities Caused by Far-Infrared Radiation*, 33 INT'L J. OF BIOMETEOROLOGY 145 (1989). According to the Company, this document also demonstrated that in humans, FIR therapy helped with more restful sleep, deeper sleep, and fewer wakeful moments and reduced coldness, stiffness of muscles in the shoulder and legs as well accelerated peripheral blood circulation.

These materials discuss, among other things, the laws of electromagnetic force, the effects of electromagnetic field exposure on the human body, and whether magnet therapy can be beneficial for pain treatment.

According to Magnetude Jewelry, the additional resources the Company provided to DSSRC support, among other things, the following results and observations:

- the static magnetic field emitted from neodymium magnets affected the mitochondria in rats, causing them to lose weight and return to normal activity[5];
- new data that suggests that magnetic fields and magnets interact and communicate with human cells in ways that were previously not understood[6];
- static magnetic treatment can impact blood viscosity and peripheral blood flow[7];
- the possibility of static magnetic treatment as chronic pain treatment in post-polio subjects and evidence that static magnetic fields led to a significant reduction in sciatica pain when the patients used the magnets [8];
- magnets that are significantly weaker than the magnets that Magnetude Jewelry uses can nevertheless produce beneficial results when it comes to sleep quality improvement[9];
- static magnets can be used to reduce edema, swelling caused by excess fluid being trapped in tissue[10];
- magnets can be used to decrease both chronic lower back pain and pain associated with osteoarthritis in the knees and hips[11];
- static magnet therapy increases blood circulation, decreases inflammation, and decreases various types of pain associated in rats with arthritis[12];

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[5] Trent W. Nichols Jr., *Mitochondria of Mice and Men: Moderate Magnetic Fields in Obesity and Fatty Liver*, 79 MED. HYPOTHESES 287, 287-293 (2012).

[6] Shamini Jain et al., *Biofield Science and Healing: An Emerging Frontier in Medicine*, GLOBAL ADVANCES IN HEALTH & MED., November 2015, at 3.

[7] Julia C. McKay et al., *A Literature Review: The Effects of Magnetic Field Exposure on Blood Flow and Blood Vessels in the Microvasculature*, 28 BIOELECTROMAGNETICS 81, 81- 98 (2007).

[8] Carlos Valbona & Carlton F. Hazlewood, *Response of Pain to Static Magnetic Fields in Postpolio Patients: A Double-Blind Pilot Study*, 33 ARCH PHYS MED REHABIL Volume 78 (1997).

[9] Agatha P. Colbert et al., *Magnetic Mattress Pad Use in Patients with Fibromyalgia: A Randomized Double-Blind Pilot Study*, 13 J. OF BACK & MUSCULOSKELETAL REHABILITATION 19, 19-31 (1999).

[10] Dragan Mirkovic, *Magnetic Therapy for Edema in Inflammation: A Physiological Assessment*, 294 AM. J. OF PHYSIOLOGY-HEART & CIRCULATORY PHYSIOLOGY 19, 19-20 (2007).

[11] Tim Harlow et al., *Randomized Controlled Trial of Magnetic Bracelets for Relieving Pain in Osteoarthritis of the Hip and Knee*, 329 BMJ 1450, 1450-1454 (2004); J. Langford & P.W. McCarthy, *Randomised Controlled Clinical Trial of Magnet Use in Chronic Low Back Pain*, CLINICAL CHIROPRACTIC Vol. 8, Iss. 1 (March 2005).

[12] Norimasa Taniguchi et al., *Study on Application of Static Magnetic Field for Adjuvant Arthritis Rats*, EVIDENCE-BASED COMPLEMENTARY & ALTERNATIVE MED., Sept. 2004, at 1.

- static magnetic field and pulsed electromagnetic fields stimulate metabolic activity of chondrocytes (cells found in healthy cartilage) *in vitro*[13];
- use of both static magnetic fields and pulsed electric magnetic fields on knee cartilage tissue samples affect cellular function and significantly increase cellular metabolic function which can be correlated with an increased level of healing[14];
- magnets weaker than the ones used in Magnetude Jewelry products can decrease arthritis-associated knee pain[15];
- magnetic fields have modern medical applications and even low-level magnetic fields[16] can have a significant impact on a variety of biological systems[17];
- magnetic field exposure (using stronger magnets used than in those found in Magnetude Jewelry products) produced both analgesic and anti-inflammatory effects on cells that was similar to low dose naloxone and morphine[18];
- the magnetic portion of an electromagnetic treatment decreased back pain in a statistically significant manner [19];

ANALYSIS AND RECOMMENDATION

Earnings Claim

As the Company did not attempt to substantiate the "replace your income" claim on the Company's official website, DSSRC finds the Company's removal of such claim to be necessary and appropriate.

With respect to Magnetude Jewelry's revised claim ("Whether you want to work part time for some extra vacation money and pay some bills, or you want to work into making this a meaningful income for you, you are welcome to join us!"), DSSRC remained concerned with the unqualified implied claim that an independent salesforce member of the Company could choose to make the business opportunity into a "meaningful income." DSSRC was also concerned with a new claim that appeared on Magnetude Jewelry's

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13 Š Štolfa et al., *Effects of Static Magnetic Field and Pulsed Electromagnetic Field on Viability of Human Chondrocytes* in vitro, 56 PHYSIOLOGICAL RES. 45, 45-49 (2007).

14 Id.

15 Tim Harlow et al., *supra* note 11.

16 Young Jin Kim et al., *Comparative Analysis of Photoplethysmography Under Pulsed Magnetic Field and Low Level Laser Stimulus: Motivation for Blood Flow Increase Using Stimulus on Acupoint LI4*, 19 J. OF MAGNETICS 32, 32-36 (2014).

17 *Id.*

18 Christian Vergallo et al., *In Vitro Analysis of the Anti-Inflammatory Effect of Inhomogenous Static Magnetic Field-Exposure on Human Marcophages and Lympphocytes*, PLoS ONE 8(8) (2013).

19 J. Langford & Peter W. McCarthy, *supra* note 11.

website during the pendency of this inquiry stating "Whether you want to work part time or full time, it is always up to you! You are welcome to join us!"

It is a long-standing principle of advertising that an advertiser has the burden to support all reasonable interpretations of its claims and not simply the messages it intended to convey. Verizon Communications, Inc. (Verizon Wireless Services ("First to 5G"), Report #6258, NAD/CARU Case Reports (May 2019). Here, DSSRC determined that one reasonable interpretation of claims such as "Whether… you want to work into making this a meaningful income for you" and "Whether you want to work part time or full time" is that an individual engaged in the direct selling of Magnetude Jewelry products could earn a substantial, full time or career level income. As DSSRC has stated in previous decisions, if earning full-time or career level income is not what would be expected by the typical company salesforce member, that fact would need to be disclosed along with the typical earnings that can be expected by a company salesforce member. Initial Outfitters, Inc., Case #19-2020. Accordingly, DSSRC recommends that Magnetude Jewelry discontinue the representative earnings claim at issue in this inquiry and any substantially similar earnings claims.

Product Claims

DSSRC acknowledged and appreciated the Company's efforts in removing Product Claim #1 and Product Claim #2.

In addition, DSSRC identified several additional product claims during the pendency of this inquiry. With respect to such claims, the Company took immediate action in order to have the posts in question removed. The Company was successful in doing so and DSSRC appreciated the Company's prompt action. DSSRC determined that the removal of the claims during the inquiry was necessary and appropriate.

As to Product Claim #3 and Product Claim #4, DSSRC acknowledged that Magnetude Jewelry submitted voluminous documentation showing possible benefits, promise and potential therapeutic uses for magnets. Nonetheless, DSSRC was unpersuaded that the submitted materials provided adequate substantiation for the specific product claims at issue in this inquiry for the following reasons.

At the outset, self-regulatory precedent makes clear that in reviewing an advertising claim, DSSRC "must determine whether there is a 'good fit' between the evidence provided in support and the nature of the claims at issue. Advantice Health, LLC (Kerasal Fungal Nail Renewal), Report #6421, NAD/CARU Case Reports (October 2020). Here, despite numerous materials submitted by the Company which it alleged suggested possible health benefits related to magnets, DSSRC determined that the materials submitted are not appropriate to support the specific claims at issue. For example, none of the materials provided by the Company demonstrate that its products "help to protect us from EMF's (electromagnetic frequencies) that are emitted all around us…" or that such EMF's are harmful in the first place as asserted in Product Claim #3. Similarly, while the Company's materials provided encouraging data regarding the therapeutic use of

magnets, the materials do not provide the necessary support for the the express, categorical claim that the Company's products "can stimulate enzyme activity and metabolism, which helps as an anti-oxidant fighting oxidative stresses that lead to many degenerative diseases."

It is the Company's burden to possess the necessary evidence to substantiate all the messages reasonably conveyed by its advertising claims at the time the representations are disseminated to the public.[20] Prior advertising self-regulatory precedent by the National Advertising Division (NAD) is instructive and sets forth the standard DSSRC will apply to health-related claims such as those at issue here:

> NAD does not make distinctions across product or regulatory categories. For example, whether a product is an OTC drug, a dietary supplement, or even a homeopathic remedy, NAD's analysis remains the same: identify the messages reasonably conveyed by the advertising, examine the reliability of the evidence, and if reliable, determine whether the evidence is a good fit for the reasonably conveyed messages. The strength of the messages drives the level of support sufficient to provide a reasonable basis for the claims.[21]

Here, DSSRC determined that the requisite level of support for the subject claims is competent and reliable scientific evidence because the claims at issue are health-related claims that the Company's products protect against EMF's, fight oxidative stresses that lead to many degenerative diseases and provide other powerful health-related benefits.[22] This conclusion is also consistent with the Federal Trade Commission's (FTC) position that advertisers must possess competent and reliable scientific evidence before making claims about pain relief, disease treatment, or health benefits.[23] Further, the claims strongly convey the message to consumers that the promised health benefits are supported by scientific testing.[24] While there is no requisite number of studies required, generally, competent and reliable scientific evidence consists of randomized, placebo-controlled, well-conducted human clinical trials with statistically significant results.[25] While the FTC generally requires two reliable and competent studies to support claims similar in nature to the ones at issue here, DSSRC and other advertising

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[20] https://www.ftc.gov/public-statements/1983/03/ftc-policy-statement-regarding-advertising-substantiation

[21] Mommy's Bliss Inc. (Cough Syrups and Probiotic Drops), Report #6257, NAD/CARU Case Reports (March 2019); Young Living Essential Oils, LLC (Case #13-2020).

[22] Id.; POM Wonderful vs. FTC, United States Court of Appeals for the District of Columbia Circuit (2015) https://www.cadc.uscourts.gov/internet/opinions.nsf/CF44C4FA22F615C585257DDD00549353/%24file/13-1060-1535012.pdf.

[23] See FTC v. Tommie Copper, Inc. and Thomas Kallish; Stipulated Final Judgement and Order for Permanent Injunction and Other Equitable Relief; Civil Action No..7:15-cv-09304-VB; United States District Court for the Southern District of New York (2015).

[24] Advertisers should possess the support that is promised in their advertising. POM Wonderful, supra, at fn 5.

[25] Mommy's Bliss Inc. (Cough Syrups and Probiotic Drops), Report #6257, *NAD/CARU Case Reports* (March 2019).

self-regulatory forums do not rigidly require a specific number of tests. Rather, DSSRC will focus its analyses on the quality, consumer relevance, and reliability of the scientific studies offered in support of the Company's product claims.[26]

Here, Magnetude Jewelry provided DSSRC with a total of twenty-six scientific sources that the Company alleged provided scientific support for their product claims. DSSRC identified a number of issues regarding the use of the materials submitted by the Company to substantiate Product Claim #3 and Product Claim #4.

Meta-Analysis/Literature Reviews

Many of the sources provided by the Company can be categorized as study abstracts, meta-analyses or literature reviews.[27] These research papers consist of independent research of previous experiments done in the field of electromagnetics, far infrared radiation, and the effect of magnets on various biological systems. However, a study abstract or summary does not provide sufficient information so as to rise to the level of competent and reliable scientific evidence.[28] While this type of information may be useful in providing DSSRC with background information and may additionally provide encouraging data, a meta-analysis or literature review is not the type of reliable, reproducible substantiation required to support a health-related product claim. More specifically, because of the number of variables inherent in the testing methodologies used in all of the studies referenced in the meta-analysis (i.e., number of test subjects, length of the studies, the blinding of test subjects and/or test administrators, the strength of the FIR used in the studies, the ages and backgrounds of test subjects, the different statistical analysis of the test data, etc.), it is difficult to determine the relevancy of each individual study cited within the meta-analysis.

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[26] *See* It Works!, DSSRC Case #7-2019; *see* R&D Global d/b/a B-Epic, DSSRC Case #21-2020 (citations omitted).

[27] Agatha P. Colbert et al., *Magnetic Mattress Pad Use in Patients with Fibromyalgia: A Randomized Double-Blind Pilot Study*, 13 J. OF BACK & MUSCULOSKELETAL REHABILITATION 19 (1999); Richard H.W. Funk et al., *Electromagnetic Effects – From Cell Biology to Medicine*, 43 PROGRESS IN HISTOCHEMISTRY AND CYPTOCHEMISTRY 177 (2009); Inoué & Kabaya, *supra* note 4; Shamini Jain et al., *Biofield Science and Healing: An Emerging Frontier in Medicine*, GLOBAL ADVANCES IN HEALTH & MED., November 2015, at 3; Julia C. McKay et al., *A Literature Review: The Effects of Magnetic Field Exposure on Blood Flow and Blood Vessels in the Microvasculature*, 28 BIOELECTROMAGNETICS 81 (2007); Dragan Mirkovic, *Magnetic Therapy for Edema in Inflammation: A Physiological Assessment*, 294 AM. J. OF PHYSIOLOGY-HEART & CIRCULATORY PHYSIOLOGY 19 (2007); David Muehsam & Carlo Venture, *Life Rhythm as a Symphony of Oscillatory Patterns: Electromagnetic Energy and Sound Vibration Modulates Gene Expression for Biological Signaling and Healing*, GLOBAL ADVANCES IN HEALTH & Med., March 2014, at 40; William Pawluk, *Biomagnetic Fields and the Human Body*, DRPAWLUK.UK, https://www.drpawluk.com/education/magnetic-science/biomagnetic-fields/ (last visited Aug. 5, 2020); Fatma Vatansever & Michael R. Hamblin, *Far Infrared Radiation (FIR): Its Biological Effects and Medical Applications*, 4 PHOTONICS & LASERS IN MED. 255 (2012); Wan et al., *supra* note 3.

[28] *See* Aloe Veritas, Inc., DSSRC Case #5-2019 (citing Cerebral Success (SmartX Premium Brain Supplement, Now with Cognizin), Report #5761, NAD/CARU Case Reports (September 2014)).

In Vitro Studies

In vitro studies are a commonly accepted method of scientific experimentation. According to the United States Food and Drug Administration (FDA), *in vitro* testing is testing that is conducted on blood or tissue samples that have been taken from the human body.[29] *In vitro* testing has multiple benefits when compared to *in vivo* testing, such as lower cost of clinical trials, more readily available samples, and the ability to isolate and test individual biomarkers.[30] *In vitro* testing is primarily used to gather signals of possible harm, benefits, and to serve as a hypothesis generator.[31] When analyzing data gathered from *in vitro* testing it is important to consider how closely the *in vitro* system mirrors the biology of the human body and whether the product being tested is proportional in concentration to what would be used in human clinical testing.[32] Any beneficial or detrimental effects that are observed during *in vitro* testing may be predictive of similar outcomes *in vivo*, but are not conclusive of similar outcomes. *In vitro* studies are limited because of the inability of the isolated samples to interact with other biological systems present in the human body.[33] Given this information, *in vitro* data is best used as predictive information for what might happen during *in vivo* testing, but this data should be validated by *in vivo* testing.[34]

The FTC takes the position that, "well-controlled human clinical studies are the most reliable form of evidence," however *in vitro* data will be considered when human research is not feasible and the testing is an acceptable substitute for human research.[35] The Company sent DSSRC three scientific studies involving the effect of magnetic fields on human tissue and blood using *in vitro* testing.[36] While these studies did show that there was a degree of benefit resulting from electric field exposure, DSSRC also determined that the submitted materials did not provide the appropriate level of support for the specific product performance claims at issue in this inquiry.

In addition to the use of *in vitro* data as conclusive data of *in vivo* effects, DSSRC was not convinced of the reliability of the *in vitro* testing for several reasons. For example, in one document in the case record, the Company pointed out that the researchers concluded that magnetic fields could reduce blood viscosity. However, the researchers

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[29] U.S. Food & Drug Admin., *In Vitro Diagnostics*, FDA.GOV, https://www.fda.gov/medical-devices/products-and-medical-procedures/vitro-diagnostics (last updated Oct. 25, 2019).

[30] *See* INST. OF MED., NAT'L RESEARCH COUNCIL & COMM. ON THE FRAMEWORK FOR EVALUATING THE SAFETY OF DIETARY SUPPLEMENTS, *Categories of Scientific Evidence* - In Vitro *Data*, *in* DIETARY SUPPLEMENTS: A FRAMEWORK FOR EVALUATING SAFETY 217 (Inst. of Med. & Nat'l Research Council of the Nat'l Academies, 2005); *see* Nifang Nui & Liewei Wang, In Vitro *Human Cell Line Models to Predict Clinical Response to Anticancer Drugs*, 16 PHARMACOGENOMICS 273 (2015).

[31] Id.

[32] See *id.*

[33] Id.

[34] Id.; *see* Nui & Wang, *supra* note 30.

[35] FED. TRADE COMM'N, DIETARY SUPPLEMENTS: AN ADVERTISING GUIDE FOR INDUSTRY (2001).

[36] Cristian Vergallo et al., *supra* note 18, at 1; Rongjia Tao & Ke Huang, *Reducing Blood Viscosity with Magnetic Fields*, 84 PHYSICAL REV. E 1 (2011); Š Štolfa et al., *supra* note 13.

specifically concluded that, "blood viscosity can be reduced with magnetic fields of 1 T[esla] or above in the blood flow direction."[37] The Company, however, also informed DSSRC that the neodymium magnets that are used in its products range in strength from 0.3 Tesla to 0.4105 Tesla. DSSRC determined that this difference in magnetic strength between the magnets used in the study is significant and the magnets of less strength in the Company's products calls into question the applicability and relevancy of the study's conclusion regarding Magnetude's products. A similar issue arises with respect to another study cited by the Company in which researchers used magnets with a strength of 1.47 T [38] raising concerns about the potential effect that the Company's significantly weaker magnets will have on the human body.

Animal Subject Experiments/Research

With respect to research cited to by the Company that was conducted on animal subjects, DSSRC has previously noted that "the physiology of animals is different than that of humans and, therefore, animal studies are of limited value as animals may respond differently than humans . . . ."[39] DSSRC does recognize that animal studies are useful in evaluating potential reactions in humans and are also a necessary step in scientific research, but it is not considered the type of competent and reliable scientific evidence that is needed to support a health-related product claim. Additionally, this policy is in accord with both the FDA and the FTC.[40] Here, a number of the materials provided by the Company, used animals such as mice as subjects to determine what effect various magnetic fields have on the mice's biological systems.[41] Animal research studies may be helpful in identifying potential benefits or harmful reactions in humans, however these types of studies alone are not conclusive in substantiating health-related product claims targeting a human population.

Inconclusive Data

Another issue DSSRC identified in several of the studies that the Company provided in support of its product claims was the inconclusive nature of the research. A number of the materials provided by the Company concluded that, while there may be various possible health benefits in the application of magnetic fields, there is still not enough research conducted at this time on which to base a conclusion. Additionally, some of the studies provided by the Company indicated that the results obtained may have been due to unidentified confounding variables that affected the results and the data collected.

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37 Tao & Huang, *supra* note 36, at 1.

38 *See* Vergallo et al., *supra* note 18.

39 Aloe Veritas, Inc., *supra* note 28.

40 Id. ("'Further, in accord with the FDA as a general rule, the FTC considers well-controlled human clinical studies to be the most reliable form of evidence, where animal models are considered only if they are widely considered to be acceptable substitutes for human research or where human research is infeasible'").

41 Trent W. Nichols Jr., *supra* note 5; Norimasa Taniguchi et al., *supra* note 12.

For example, in two documents the Company provided, the researchers concluded that magnets may have some beneficial impact when used for pain treatment. However, the researchers in both studies acknowledged that despite their findings, more research in the area is needed before a definitive conclusion is reached.[42]

In four of the documents the Company provided, the researchers concluded that there are possible benefits to using electromagnetic fields and magnets to treat various ailments however, there were also various confounding variables that could not be ruled out which could potentially impact the relevancy of the resulting data.[43] More specifically, in one document, the researchers were unsure if the measured effect of the magnetic bracelets was due to a placebo effect:

> Although the analysis of the per-specification bracelets also suggests a specific effect, the result is only a trend and needs confirmation. Therefore, we cannot be certain whether our data show a specific effect of magnets, a placebo effect, or both.[44]

In another document, the researchers conducted a computer simulation of magnetic field on the lumbar spine. While the researchers did conclude that the device examined promoted repair and consolidation of bone graft material, the researchers were unable to identify the biophysical mechanism that caused this result.[45] Similarly, in another document, the researchers concluded that a, "[m]agnetic knee wrap may significantly facilitate isokinetic quadriceps strength in patients with mild to moderate knee OA."[46] However, the researchers also noted that there were limitations to the study and other variables that could have played a role in the data collected.[47] In another document submitted by the Company, data supported a conclusion that magnets may be used to treat sciatica pain but also could not rule out an effect entirely due to chance.[48]

Lastly, in another document submitted by the Company, the researchers conducted an experiment regarding the effect that jade and tourmaline powder has on

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42 J. Langford & Peter W. McCarthy, *supra* note 11 ("Although the numbers in this study were small, they illustrate the possibility that VAS could be decreased in these patients . . . The results support a larger scale study of static magnetic field application in chronic low back pain"); Carlos Valbona et al., *supra* note 8 (researchers stated that their understanding of pain and pain relief is far from complete and that the exact mechanisms of how magnetic fields interact with the human body is unknown. The researchers identified six specific issues that need to be explored in new research studies on this topic).

43 Chung-Yao Chen et al., *Effect of Magnetic Knee Wrap on Quadriceps Strength in Patients with Symptomatic Knee Osteoarthritis*, 89 ARCHIVES OF PHYSICAL MED. & REHABILITATION 2258 (2008); Tim Harlow et al., *supra* note 11; Suzan Khoromi et al., *Low Intensity Permanent Magnets in the Treatment of Chronic Lumbar Radicular Pain*, 34 J. OF PAIN & SYMPTOM MGMT. 434 (2007); Timothy Wade Stippick & Michael Richard Sheller, *Combined Magnetic Fields Provide Robust Coverage for Interbody and Posterolateral Lumbar Spinal Fusion Sites*, 54 MED. & BIOLOGICAL ENGINEERING & COMPUTING 113 (2016).

44 Harlow et al., *supra* note 11, at 1453.

45 Stippick & Sheller, *supra* note 43.

46 Chen et al., *supra* note 43, at 2258 (emphasis added).

47 *See id.* at 2263 (researchers also stated that further studies are needed).

48 *See* Khoromi et al., *supra* note 43, at 442 ("data do not rule out an effect entirely due to chance").

skin temperature when applied to human skin in the form of a lotion. The study concluded that the lotion raised the skin temperature and hypothesized that this was partly due to the far-infrared rays emitted from the jade and tourmaline.[49] The researchers, however, found that they could not conclusively identify the reason for the rise in skin temperature and concluded only that the results are promising.[50]

Testing Methods

Research that is conducted in a subjective manner or using scientific procedures that may be considered questionable under generally accepted scientific methods may be deemed inadequate and does not constitute competent and reliable scientific evidence. When analyzing offered scientific evidence, DSSRC will focus its inquiry on the quality, reliability, and consumer relevance of the evidence.[51] In this inquiry, DSSRC found the reliability of some of the evidence offered to support the Company's product claims flawed for several reasons.

For example, one study acknowledges that the manufacturer of the magnetic device used in the study funded the, "patient recruitment, nursing staff, measuring devices, and statistical analysis," used in the study.[52] While this alone is not dispositive in determining whether this study is in fact reliable, it does draw the data into question. Additionally, the study concluded by stating that future studies would be beneficial in drawing more complete data observations.[53] Similarly, another study stated that two of the doctors involved in the research are stockholders in the company that manufactures the magnetic devices used.[54] Further, the study administrators acknowledged that a major limitation of their study was the lack of a placebo-control group.[55] The use of a placebo in a study is regarded as important in order to help rule out confounding factors and psychological factors that might influence the results of the proposed treatment. Without the use of a placebo control, researchers cannot effectively rule out the possibility of a confounding factor that may have affected the results of the study.

DSSRC also found an issue in another study that draws the reliability of the results of the study into question. In that study, the researchers conducted an experiment to determine the effect of a pulsed magnetic field stimulus on the human hands.[56] However, the researchers only collected data from a sample size of six participants.[57] GTECH USA, INC. (AirRAM Cordless Stick Vacuum), Report #5704, *NAD/CARU Case Reports* (April 2014) (internal citations omitted)("NAD has concerns about the reliability and repeatability

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49 Yoo et al., *supra* note 2

50 *Id.*

51 *See* It Works!, *supra* note 4; *see* R&D Global d/b/a B-Epic, *supra* note 2.

52 Ko & Berbrayer, *supra* note 1.

53 *See Id.*

54 *See* Neil Segal et al., *Efficacy of a Static Magnetic Device Against Knee Pain Associated with Inflammatory Arthritis*, 5 J. of Clinical Rheumatology 302 (1999).

55 *See id.*

56 *See* Young Jin Kim et al., *supra* note 16.

57 *See id.*

of a study when a small sample size is tested, as small sample sizes increase the possibility results are caused by chance or conditions other than the product itself.")[58]

DSSRC agreed that the results from this study were promising, but also determined that the small sample size of the study called into question the relevancy and conclusiveness of the results of the study.

CONCLUSION

DSSRC appreciated Magnetude's good faith participation in this inquiry and its voluntary efforts to communicate a more accurate message to consumers. With respect to representations that "Whether… you want to work into making this a meaningful income for you" and "Whether you want to work part time or full time." DSSRC determined that these statements could be reasonably interpreted by consumers as implying that an individual engaged in the direct selling of Magnetude Jewelry products could earn a substantial, full time or career level income. Accordingly, because earning career level income would not be generally expected by the typical Magnetude salesforce member, DSSRC recommended that Magnetude Jewelry discontinue the representative earnings claim at issue in this inquiry and any substantially similar earnings claims.

For the reasons set forth above, DSSRC recommends that the Company modify or discontinue claims that its products "help to protect us from EMF's (electromagnetic frequencies) that are emitted all around us from cell phones, wifi, computers, cell towers, fluorescent lighting etc." and "help to close off our own energetic frequencies so that we are not as susceptible to them." Similarly DSSRC recommends that the Company modify or discontinue claims that its products "can stimulate enzyme activity and metabolism, which helps as an anti-oxidant fighting oxidative stresses that lead to many degenerative diseases" and other specific health-related product claims which would require competent and reliable scientific evidence as substantiation.

COMPANY STATEMENT

Magnetude Jewelry is profoundly grateful to the Direct Selling Self-Regulatory Council ("DSSRC") and the outstanding DSSRC representatives with whom it has worked. Working with the DSSRC has been a tremendously beneficial process for us. We greatly respect the insights, position and guidance of the DSSRC regarding the matters involved in this inquiry and consider its input to be absolutely invaluable.

Magnetude Jewelry has zealously attempted to articulate the claims regarding the income opportunity it offers to be legally complaint and fall well within the purview of applicable consumer protection laws and case law. In addition, we have reviewed all of the recent Complaints from the Federal Trade Commission ("FTC") regarding direct selling income claims. Having done so, we believe the income and opportunity claims we make also comply with the FTC's requirements. While we have nothing but the greatest

[58] See Johnson & Johnson (Aveeno Advanced Relief Cold Sore Treatment), Report #4719, *NAD/CARU Case Reports* (September 2007).

respect and admiration for the DSSRC, and we give its opinions great deference, we must acknowledge that reasonable minds can differ regarding a legal conclusion. Nevertheless, we will gladly and earnestly consider further modifications to representations that the DSSRC has cited above. As it has always done, Magnetude Jewelry will continue to carefully scrutinize all of its marketing resources that include income and opportunity claims to ensure compliance with state and federal laws.

With respect to the product claims of Magnetude Jewelry, we have been equally delighted to work with the DSSRC to modify certain of our product claims. Admittedly, the amount of scientific research behind EMFs, Neodymium magnets and their effect on the body is vast and complicated. Indeed, there is far more scientific research available than we could provide to the DSSRC. With the recommendations of the DSSRC, we have modified a myriad of our claims. Nevertheless, we believe have made a compelling case for the substantiation of our product claims. As this voluminous document makes clear, the company has provided a massive amount of scientific substantiation in support of its claims. Notwithstanding this and as we will do for income representations, we will also consider further modifications to the product claims that the DSSRC has cited above.

In closing, Magnetude Jewelry wants to again express its gratitude and appreciation for the great work it is doing for individual direct selling companies, as well as the entire direct selling industry.

(Case No. 32-2021 HJS, closed on 1/22/2021)