



February 17, 2023

VIA EMAIL

Peter C. Marinello, Director
Howard J. Smith, Attorney
Direct Selling Self-Regulatory Council
112 Madison Avenue, 3rd floor
New York, NY 10016
PMarinello@bbbn.org
HSmith@bbbn.org

Re: Modere's Use of Illegal Health and Income Claims to Promote Project 23

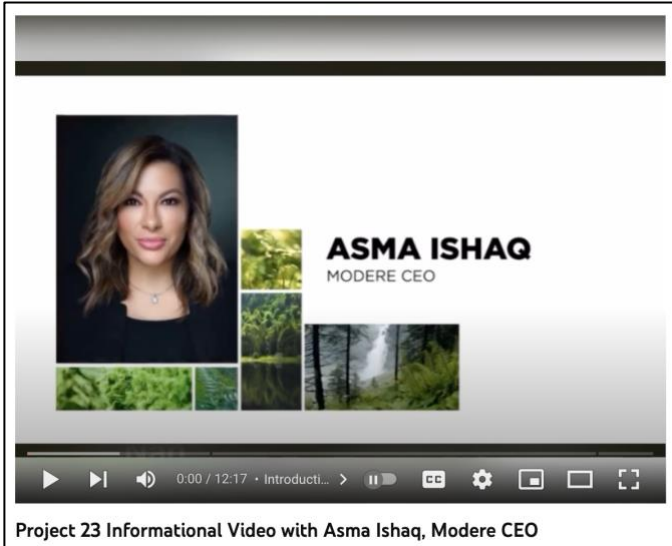
Dear Peter and Howard:

We write to file a complaint with the Direct Selling Self-Regulatory Council against Modere USA, Inc., a California-based multi-level marketing company that sells health and wellness products. In three weeks, Modere will be launching a new line of supplements called "Project 23,"¹ which it and its distributors have been deceptively promoting as able to balance hormones and treat PMS, menopause, acne, anxiety, urinary tract infections, inflammation, and brain fog, among other things.² In addition to making such unsubstantiated health claims about its soon-to-be-launched product line, Modere and its distributors continue to make atypical income claims to market the business opportunity.³

Unsubstantiated Health and Disease-Treatment Claims

Since at least December 2022, Modere and its distributors – who were given a roadmap from the company for how to deceptively market the supplements to exploit women⁴ – have been engaged in a pre-launch marketing campaign that makes a multitude

of unsubstantiated health and disease-treatment claims. The following are some examples:



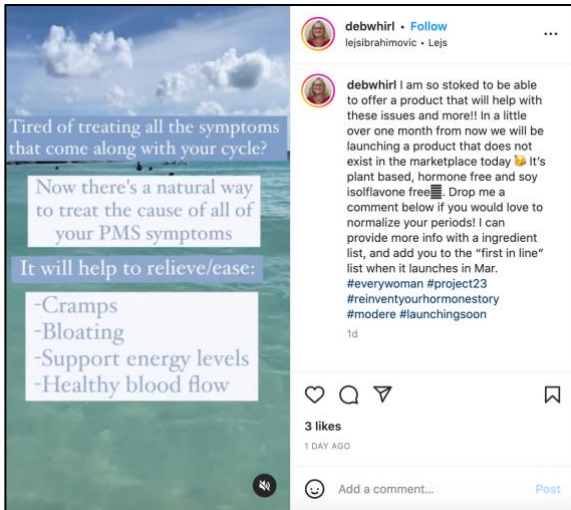
Modere CEO, Asma Ishaq: *“Cultural and societal views about women have made it difficult to discuss what’s happening with our bodies let alone find solutions. ... Whether you’re dealing with unpredictable menstrual cycles, normal symptoms of PMS, occasional hot flashes, night sweats, or a low libido, you know, we often chalk our experiences up to simply being women, you know, but not anymore. Together, we’re going to empower women to reinvent their hormone stories...”*⁵



*“...There is nothing else on the market that does all this without medication or hormone therapies: • painful cramping • uncomfortable bloating • embarrassing periods • tender breasts • uncontrollable mood swings • cyclical acne • hot flashes • night sweats • low or no libido • hormone-related dryness or itchiness • mental clarity • menstrual-related UTIs • iron metabolism • stress and energy • sleep health • cardiovascular health TONIGHT I’m changing my hormone story. YOU can change yours...”*⁶



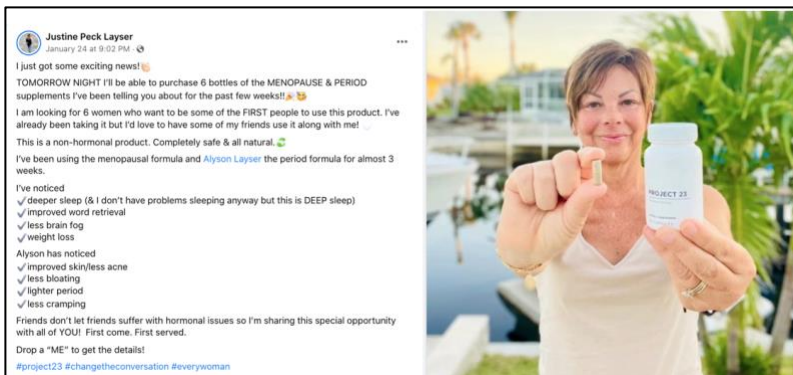
*“...Project 23 takes a unique approach to hormonal health unlike anything else... If you suffer from PMS, cramps, bloating, low energy, low iron levels, UTI's, low libido, mental clarity, thyroid levels, inflammation, skin issues, hot flashes, night sweats, vaginal dryness, mood....basically all the terrible things our hormones and cycles can do to us women...THIS IS FOR YOU! ...”*⁷



*"Now there's a natural way to treat the cause of all of your PMS symptoms[.] It will help to relieve/ease: -Cramps -Bloating -Support energy levels – Health blood flow"*⁸



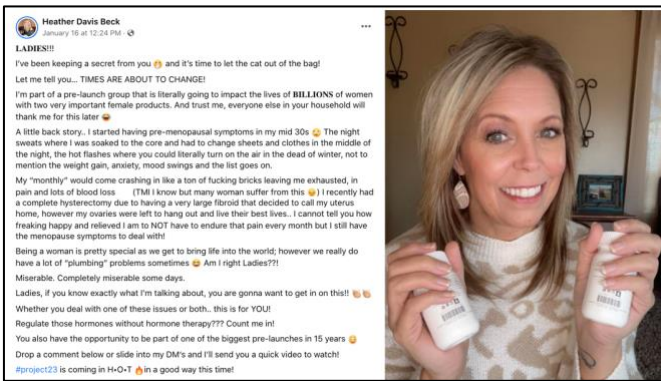
*"...How does ... • No more cramps • More energy • No Bloat • Better Mood • Sleeping sound • No more hot flashes • No more Night sweats • Healthy Libido • Flow not heavy • Stress & Anxiety levels down Sound to you?? ..."*⁹



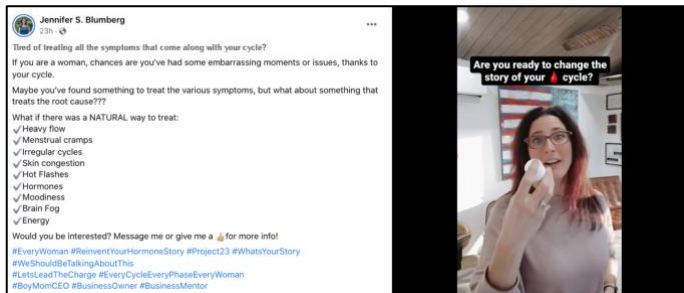
*"...I've been using the menopausal formula and Alyson Layser the period formula for almost 3 weeks. I've noticed ✓ deeper sleep (& I don't have problems sleeping anyway but this is DEEP sleep) ✓ improved word retrieval ✓ less brain fog ✓ weight loss Alyson has noticed ✓ improved skin/less acne ✓ less bloating ✓ lighter period ✓ less cramping ..."*¹⁰



“... Whether you're dealing with unpredictable menstrual cycles, terrible PMS, cramping, low libido, hormonal skin issues, occasional hot flashes or night sweats, we often just accept it as simply part of being a woman. NOT ANYMORE. ... There are 2 formulas - one for menstruating women and one for post menopausal women. This is a product category that does not exist in the marketplace yet. It is going to change lives (and marriages). ... It is about damn time we supported and empowered women to reinvent their hormone stories, optimize how they experience their cycles, and their transition into menopause ...”¹¹



“...Regulate those hormones without hormone therapy??? Count me in!”¹²



“... What if there was a NATURAL way to treat: ✓ Heavy flow ✓ Menstrual cramps ✓ Irregular cycles ✓ Skin congestion ✓ Hot Flashes ✓ Hormones ✓ Moodiness ✓ Brain Fog ✓ Energy... #EveryWoman #ReinventYourHormoneStory #Project23...”¹³



“I feel I lost my Mom to menopause She started in her 40’s and took hormones to help her with symptoms She was looking for some help Racing Heart Lack of sleep Anxiety At age 56 she developed a hormone fed breast cancer ... She passed away 10 years late[r] Now I’m in menopause and my doctor recommended hormone therapy. I’m not against the concept but for me, it’s to [sic] large of a risk ... I am really excited about a new product line Project 23! A unique to hormone health unlike anything else!...”¹⁴

TINA.org has compiled more than 150 examples of such unsubstantiated health and disease-treatment claims made about Modere’s Project 23 supplements (and is continually adding more), all of which are available at www.truthinadvertising.org/evidence/moderes-project-23-health-claims-database.¹⁵

Claims that a product can balance and regulate hormones, as well as treat PMS, menopause, hot flashes, acne, anxiety, urinary tract infections, inflammation, and brain fog, among other things, require substantiation in the form of competent and reliable scientific evidence,¹⁶ as well as prior FDA approval,¹⁷ neither of which Modere has. In fact, in a Q&A inconspicuously posted online, Modere states the following in response to the question “What clinical and/or testing has been done on our P23 formulas?”:

Project 23 delivers intuitive nutrition based on the latest available research surrounding women’s health. Its comprehensive formulas feature potent, hormone-free and soy isoflavone-free ingredients extensively studied and backed by science. Several key ingredients have undergone clinical trials, however, the final Project 23 formula trials are still pending.¹⁸

This material information is not disclosed in any of the marketing claims identified in TINA.org’s investigation. (Of note, Modere and its distributors also fail to disclose in their marketing the material facts that Project 23 is not recommended for women who are

on birth control, are pregnant, or are breastfeeding¹⁹ despite marketing claims that it is for “every women.”²⁰)

In short, Modere and its distributors are violating FTC and FDA law,²¹ as well as using health claims identified by the DSSRC in prior case decisions as being impermissible without competent and reliable scientific substantiation.²² Additionally, such deceptive marketing tactics negatively impact consumers’ economic well-being and may cause serious health consequences as women forego evidence-based medical care²³ for unproven Modere products.

Deceptive Income Claims

Modere and its distributors also use deceptive and unsubstantiated income claims to promote the business opportunity in conjunction with Project 23 promotions. The following are some examples:



“... We can have it all! Health, Wealth, Mom time, Travel + Time freedom, alignment, purpose, give back, and more. ...”²⁴



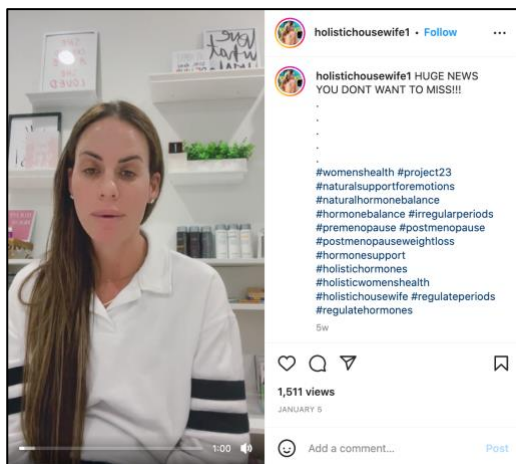
“...People’s lives are being changed, their finances, their health, and their families... This market will be \$48 Billion by 2027 (and up to 58.2B by 2030)!! 🌍 ... #project23”²⁵



“...I’m also going to help a whole lot of people kick their financial struggles to the curb.”²⁶



“How I went from waiting tables all weekend to working online on my own time from magical Bali. ... A friend approached me about working online and creating a freedom lifestyle for ourselves and I thought could this really be true? Do people really get to make an income online and get their time freedom back?? And it turns out it was true. ... Gone are the days where I would work double shifts and burn myself out. 6 years later I am working from Bali with my partner and I no longer have to work for my vacations because I have created a passive income online and that has given me my time freedom and choice back. ... If you’re looking to create an income online send me a message. ... #multiplestreamsofincome”²⁷



“This business has afforded me the opportunity to travel and to live my life, and to design a life that I’ve always wanted ... If we learned anything during the lockdown, it’s that working from home and actually being able to generate an income that is versatile, that is residual, that is long lasting is important, and being able to be with your family is important, but also being able to make money and pay your bills is important too.”²⁸

Additional examples of such deceptive income claims are available at www.truthinadvertising.org/evidence/2023-moder-income-claim-database/.

Modere and its distributors make these claims despite the fact that, according to the company's income disclosure statement, the vast majority of distributors earn little to no money (even before accounting for expenses incurred in the operation or promotion of the business).²⁹ As such, Modere and its distributors are violating FTC law,³⁰ as well as the DSSRC's Guidance on Earnings Claims for the Direct Selling Industry.³¹

Conclusion

TINA.org urges the DSSRC to review the claims being made by Modere and its distributors, and take appropriate action, particularly as the company prepares to launch its Project 23 products starting on March 9.³² Time is of the essence to protect women from these harmful and unsubstantiated disease-treatment claims.

If you have any questions, please do not hesitate to contact us.

Sincerely,



Laura Smith, Esq.
Legal Director
Truth in Advertising, Inc.



Bonnie Patten, Esq.
Executive Director
Truth in Advertising, Inc.

¹ Join us for Modere’s Social Retail Conference this March 9-12, 2023 in Charlotte, North Carolina!, <https://events.shiftingretail.com/>.

² TINA.org’s present investigation into Modere focused solely on Project 23. However, unsubstantiated health and disease-treatment claims promoting other Modere products may also exist.

³ TINA.org previously investigated Modere as part of larger investigations into unsubstantiated disease-treatment claims and atypical income claims used by DSA-member companies, and found that the company engaged in both deceptive marketing tactics. *See* TINA.org’s Modere Health Claims Database, <https://truthinadvertising.org/evidence/modere-health-claims-database/> and TINA.org’s Modere Income Claims Database, <https://truthinadvertising.org/evidence/modere-income-claims-database/>.

⁴ Modere, Project 23: Product FAQ, <https://buzz.shiftingretail.com/article-slug/project-23-product-faq/>; Modere, Project 23 – Social Marketer Prelaunch, <https://buzz.shiftingretail.com/article-slug/project-23-social-marketer-prelaunch/>. *See also* Modere 2023 New Year Kick-Off Event, [https://www.dropbox.com/s/gmmcwks9ln69kca/Modere New Year Kick Off Event Marina Simone Rev3.pptx?dl=0](https://www.dropbox.com/s/gmmcwks9ln69kca/Modere%20New%20Year%20Kick%20Off%20Event%20Marina%20Simone%20Rev3.pptx?dl=0) (“Start creating FOMO with testimonials #ReinventYourHormoneStory in your customer groups”).

Select distributors were also given advance access to Project 23 supplements. *See, e.g.*, Dauri Kowitz Dec. 11, 2022 Facebook post, <https://www.facebook.com/daurik/posts/pfbid02YBW5vjwNnxnhz3qazY3ACzjb6HYRvHduPxJiw45yxU6TMbRX4J4rkjZUNA8iEzmLl> (“A very intimate group of us were flown into Newport Beach, CA this weekend to be part of a focus group and training on a one of its kind, patent-pending, product that literally EVERY woman is going to want!! I will be starting on it later this month as part of the trial, but it won’t be available on the market until March 2023....”)

⁵ Project 23 Informational Video with Asma Ishaq, Modere CEO, <https://www.youtube.com/watch?v=Ug4KjIBgW-g>.

⁶ Denise Kromney Jan. 25, 2023 Instagram post, <https://www.instagram.com/p/Cn22mSmvycF/>.

⁷ Amy Varacalli Jan. 25, 2023 Instagram post, <https://www.instagram.com/p/CnxB2ZGu8Ax/>.

⁸ Deb Whirl Jan. 29, 2023 Instagram post, <https://www.instagram.com/p/CoApHtvLxrg/>.

⁹ Mama Life and Collagen Jan. 26, 2023 Instagram post, <https://www.instagram.com/p/Cn5qVKGDgIN/>.

¹⁰ Justine Peck Laysen Jan. 24, 2023 Facebook post, <https://www.facebook.com/justine.laysen/posts/pfbid0B8KGsjPfcV3cj1KeSpUgmw9gaPevLPePQ5KVeLnLFfaHwTG2U7X4fFgrfL8kmCWA1>.

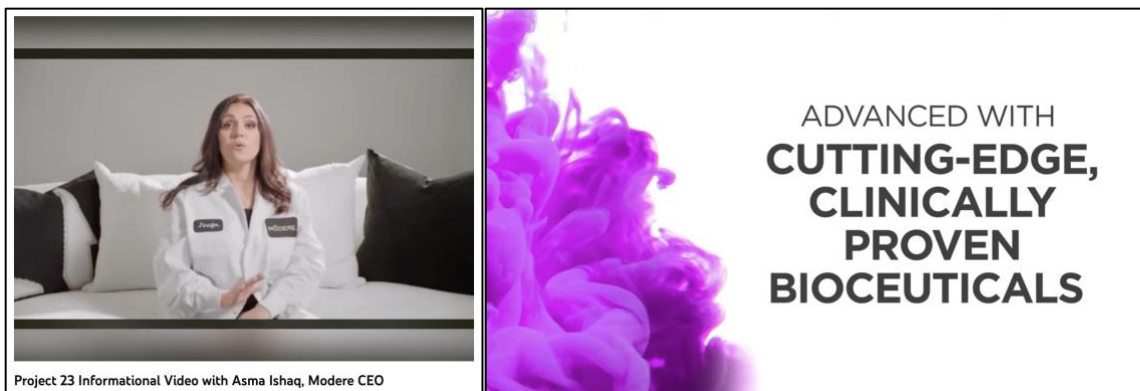
¹¹ Rachel Blachford Jan. 9, 2023 Instagram post, <https://www.instagram.com/p/CnOI9JBLyFt/>.

¹² Heather Davis Beck Jan. 16, 2023 Facebook post, <https://www.facebook.com/heathersbeck/posts/pfbid09fgHCfUKiHwQFvpjvYnbT2X4EuQu4WFqvzuYwke96gZrev7G5g9fRa42tVqka8PNI>.

¹³ Jennifer S. Blumberg Jan. 30, 2023 Facebook post, <https://www.facebook.com/jennifer.s.blumberg/posts/pfbid02PC2M315Xq84rc4XSwnQBzXAHwQq7YcQmNeggYGkcygnwyWzsfbq4kvjmJeDNXRMBI>.

¹⁴ Kris Sales Jan. 18, 2023 TikTok post, <https://www.tiktok.com/@krissales11/video/7190164681913371909?lang=en&q=>.

¹⁵ In addition to the deceptive health and disease-treatment claims identified by TINA.org in this investigation, Modere also uses language, such as “cutting-edge, clinically proven bioceuticals,” and imagery, such as featuring the company’s Senior Director of Product Sciences and Development donning a white coat, to convey the false message that the company’s efficacy claims are substantiated by competent and reliable scientific evidence. *See* FTC Health Products Compliance, https://www.ftc.gov/system/files/ftc_gov/pdf/Health-Guidance-508.pdf (“Example 15: The marketer of an unproven weight-loss supplement, through the use of medical images (e.g., people dressed in lab coats, use of the Caduceus symbol) and medical terminology (e.g., ‘medical innovation’ and ‘research center’) on its website, conveys a false claim that the product’s efficacy is backed by scientific proof. A fine print disclosure in the ‘Terms and Conditions’ section of the website states that ‘no clinical study has been performed on the product.’ The statement is inadequate to correct the false scientific proof claim both because it directly contradicts the claim and because it is not clear and conspicuous.”); Project 23 Informational Video with Asma Ishaq, Modere CEO, <https://www.youtube.com/watch?v=Ug4KjIBgW-g>; Project 23 Teaser Video, <https://www.youtube.com/watch?v=3BbkIoWcE-E>; Project 23 Teaser Video – Angela Ciemny, <https://www.youtube.com/watch?v=BFKby6dfR74>.



¹⁶ FTC Advertising Substantiation Principles, <https://www.ftc.gov/sites/default/files/attachments/training-materials/substantiation.pdf>; FTC Health Products Compliance, https://www.ftc.gov/system/files/ftc_gov/pdf/Health-Guidance-508.pdf.

¹⁷ **Hormone balancing:** *See, e.g.,* FDA warning letter to Ayuryoga, Inc., May 19, 2022, <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/ayuryoga-inc-628168-05192022> (“Examples of claims observed on your website and social media websites that establish the intended use of your ... products as drugs include, but

may not be limited to, the following: ... ‘It can help correct hormonal imbalance and helps regulate the menstrual cycle.’’); FDA warning letter to Irie Star LLC, July 6, 2017, <https://www.fda.gov/inspections-compliance-enforcement-and-criminalinvestigations/warning-letters/irie-star-llc-524242-07062017> (“Examples of some of the website claims that provide evidence that your products are intended for use as drugs include... ‘helps balance hormones, ...’ ... ‘assist with hormone balancing, ...’”); FDA warning letter to Star Health & Beauty LLC, May 26, 2017, <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/star-health-beauty-llc-516206-05262017> (“Examples of some of the claims that provide evidence that your products are intended for use as drugs include: ... ‘Women...their first choice in addressing PMS and other hormone related issues.’ ... ‘[I]s helpful for hormonal balancing ...’ ... ‘[W]orks to balance the hormones in the follicle...’”).

PMS treatment: *See, e.g.,* FDA warning letter to Organa International Corp., Oct. 13, 2021, <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/organa-international-corp-613018-10132021> (“Examples of some of the website claims that provide evidence that your products are intended for use as drugs include: ... ‘Potential benefits to health: ... PMS prevention relief...’”); FDA warning letter to Star Health & Beauty LLC, May 26, 2017, <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/star-health-beauty-llc-516206-05262017> (“Examples of some of the claims that provide evidence that your products are intended for use as drugs include: ... ‘Women...their first choice in addressing PMS and other hormone related issues.’ ... ‘Users experience less PMS symptoms, reduced stress and increased vitality.’ ... ‘To relieve cramping...’ ... ‘Assists with menopausal symptoms, helps to regulate menstruation and PMS.’ ... ‘[I]s helpful for hormonal balancing, PMS, weight control...’”); FDA warning letter to Bayer HealthCare Pharmaceuticals, Inc., Oct. 3, 2008, https://oag.ca.gov/system/files/attachments/press_releases/n1677_fda_warning_letter.pdf (“YAZ has not been evaluated for the treatment of premenstrual syndrome (PMS)”). *See also* Premenstrual Syndrome (PMS), The American College of Obstetricians and Gynecologists, <https://www.acog.org/womens-health/faqs/premenstrual-syndrome> (indicating that PMS is a medical condition that is diagnosed by an obstetrician-gynecologist after confirming a pattern of symptoms that may, in some cases, require medication, and which is a target of advertising for many purported PMS products that have either “not been tested or have not been proved to be effective”).

Menopause (and peri- and post-menopause) treatment: *See, e.g.,* FDA warning letter to Bonagens, Nov. 17, 2020, <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/bonagens-609905-11172020> (“Examples of some of the website claims that provide evidence that your products are intended for use as drugs include: ... ‘alleviate the effects of menopausal syndrome...menopausal and sleeping disorders’”); FDA warning letter to Homeocare Laboratories, Inc., June 22, 2020, <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/homeocare-laboratories-inc-603532-06222020> (“Examples of statements on the websites ... that provide evidence of the intended uses of your products include, but are not limited to, the following: ... ‘you’ll get the balancing support women need – especially in the years before menopause –’ ... ‘it’s safe for your long-term use – from perimenopause through post-menopause – for symptom relief’”); FDA warning letter to McDaniel Life-Line LLC, May 16, 2019, <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/mcdaniel-life-line-llc-571303-05162019> (“Examples of claims on your product label and websites ... establishing the intended use of your product include, but may not be limited to, the following: ... It has been historically used for treatment for ... menopause...’”); FDA warning letter to Star Health & Beauty LLC, May 26, 2017, <https://www.fda.gov/inspections-compliance-enforcement-and->

[criminal-investigations/warning-letters/star-health-beauty-llc-516206-05262017](https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/star-health-beauty-llc-516206-05262017) (“Examples of some of the claims that provide evidence that your products are intended for use as drugs include: ... ‘Assists with menopausal symptoms...’”).

Treatment for heavy menstrual bleeding and painful periods, including cramps: *See, e.g.,* FDA warning letter to Ayuryoga, Inc., May 19, 2022, <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/ayuryoga-inc-628168-05192022> (“Examples of claims observed on your website and social media websites that establish the intended use of your ... products as drugs include, but may not be limited to, the following: ... “Indications[:] Fever[.]. . . Heavy menstrual bleeding[.] Dysmenorrhoea (painful periods)[.]...”); FDA warning letter to Best Nutrition Products, Inc., Sept. 7, 2018, <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/best-nutrition-products-inc-556642-09072018> (“Examples of some of the website claims that provide evidence that your products are intended for use as drugs include:... ‘[Wild Yam is] a great remedy for women who suffer from dysmenorrhea (painful menstrual cramps) and uterine pain.’”); FDA warning letter to Madison One Acme Inc, July 26, 2017, <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/madison-one-acme-inc-523881-07262017> (“Examples of some of the claims on your website that provide evidence that your products are intended for use as drugs include: ... ‘Dong Quai is commonly used with other herbs as a remedy for disorders of the menstrual cycle like irregular menstruation..., menstrual cramps (also called dysmenorrhea), and excessive uterine bleeding’... ‘Suffering from menstrual aches and cramps can be a very painful experience. This herbal supplement is a great product to help alleviate cramps...’”); FDA warning letter to Star Health & Beauty LLC, May 26, 2017, <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/star-health-beauty-llc-516206-05262017> (“Examples of some of the claims that provide evidence that your products are intended for use as drugs include: ... ‘To relieve cramping... apply the cream to the abdomen each half hour until the cramping subsides.’”); FDA warning letter to The Herbalist, Inc., May 25, 2017, <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/herbalist-inc-513195-05252017> (“Examples of some of the website claims that provide evidence that your products are intended for use as drugs include, but are not limited to:... ‘Ache-Less is useful for a wide range of conditions related to pain and inflammation, such as menstrual cramps ...’”); FDA warning letter to Aegeia Skin Care, LLC, Feb. 17, 2017, <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/aegeia-skin-care-llc-512736-02172017> (“Examples of some of the website claims that provide evidence that your products are intended for use as drugs include:... ‘Lessens menstrual cramps in women’”); FDA warning letter to Duncan’s Botanical Products, Inc., May 8, 2017, <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/duncans-botanical-products-inc-519077-05082017> (“Examples of some of the claims that provide evidence that these products are intended for use as drugs include: ... ‘excessive menstrual bleeding’ ... ‘Used for menstrual cramps...’”).

Treatment for hot flashes and night sweats: *See, e.g.,* FDA warning letter to Organa International Corp., Oct. 13, 2021, <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/organa-international-corp-613018-10132021> (“Examples of some of the website claims that provide evidence that your products are intended for use as drugs include: ... ‘Potential benefits to health: ... hot flashes...’”); FDA warning letter to Clarke Pharmaceutical Manufacturing, Inc., Feb. 2, 2021, <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/clarke-pharmaceutical-manufacturing-inc-610642-02022021> (“Examples of some of the website claims that provide evidence that your products are intended for use as drugs include:... ‘Natural Progesterone cream

is used in hormone replacement therapy and for treating menopausal symptoms such as hot flashes.”); FDA warning letter to Star Health & Beauty LLC, May 26, 2017, <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/star-health-beauty-llc-516206-05262017> (“Examples of some of the claims that provide evidence that your products are intended for use as drugs include: ... ‘It has a stabilizing effect on the entire endocrine system, calming hot flashes and night sweats, and restoring normal sleep patterns...’”); FDA warning letter to Duncan’s Botanical Products, Inc., May 8, 2017, <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/duncans-botanical-products-inc-519077-05082017> (“Examples of some of the claims that provide evidence that these products are intended for use as drugs include: ... “[T]reatment of ... night sweats”).

Treatment for bloating and breast tenderness: *See, e.g.*, FDA warning letter to Clarke Pharmaceutical Manufacturing, Inc., Feb. 2, 2021, <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/clarke-pharmaceutical-manufacturing-inc-610642-02022021> (“Examples of some of the website claims that provide evidence that your products are intended for use as drugs include: ... ‘This topical progesterone cream is also used for ... treating bloating, breast tenderness...’”).

Treatment for decreased sex drive/low libido: *See, e.g.*, FDA warning letter to Clarke Pharmaceutical Manufacturing, Inc., Feb. 2, 2021, <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/clarke-pharmaceutical-manufacturing-inc-610642-02022021> (“Examples of some of the website claims that provide evidence that your products are intended for use as drugs include: ... ‘This topical progesterone cream is also used for treating ... decreased sex drive...’”).

Acne treatment: *See, e.g.*, FDA warning letter to Young Living Essential Oils Corporate, June 10, 2022, <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/young-living-essential-oils-corporate-615777-06102022> (“Examples of claims found on your websites, as well as your Young Living Consultants’ social media account postings, that provide evidence of the intended uses of your products (as defined by 21 CFR § 201.128) as drugs include, but may not be limited to, the following: ... ‘Can be used to combat acne...’”); FDA warning letter to Earthworks Health, June 7, 2019, <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/earthworks-health-560772-06072019> (“Examples of some of the website claims that provide evidence that your products are intended for use as drugs include: ... ‘[T]reating skin problems like blemishes...and acne’ ... “[C]ontrol acne’...”).

Anxiety treatment: *See, e.g.*, FDA warning letter to Muscle Sports Products, LLC, Sept. 23, 2022, <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/muscle-sports-products-llc-625731-09232022> (“Examples of some of the website claims that provide evidence that your products are intended for use as drugs include: ... ‘Has been noted to have powerful reductions in anxiety.’”); FDA warning letter to Enlifta, LLC, Feb. 18, 2021, <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/enlifta-llc-612253-02182021> (“Examples of some of the website claims that provide evidence that your “Enlifta Mood Elevator” and “Enlifta Anxiety” are intended for use as drugs include: ‘...for the treatment of insomnia and anxiety.’”).

UTI treatment: *See, e.g.*, FDA warning letter to HIS Enterprise Inc dba Adam’s Secret USA, LLC, Jan. 10, 2023, <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/his-enterprise-inc-dba-adams-secret-usa-llc-646494-01102023>

(“Examples of claims observed on your website and social media websites that establish the intended use of your ... products as drugs include, but are not limited to, the following: ... ‘It is also sometimes used for urinary tract infections (UTIs)...”); FDA warning letter to Young Living Essential Oils Corporate, June 10, 2022, <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/young-living-essential-oils-corporate-615777-06102022> (“Examples of claims found on your websites, as well as your Young Living Consultants’ social media account postings, that provide evidence of the intended uses of your products (as defined by 21 CFR § 201.128) as drugs include, but may not be limited to, the following: ... ‘May ease symptoms of discomfort from a urinary tract infection”); FDA warning letter to New Sun Inc., June 8, 2022, <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/new-sun-inc-626254-06082022> (“Examples of some of the website and product labeling claims that provide evidence that your products are intended for use as drugs include: ... ‘Helps prevent Urinary Tract Infections (UTIs)’ ... ‘helps stop the discomfort of urinary tract infections...”).

Inflammation reduction: *See, e.g.,* FDA warning letter to The Truth Company, LLC, Nov. 14, 2022, <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/truth-company-llc-611501-11142022> (“Examples of some of the website claims that provide evidence that your products are intended for use as drugs include: ... ‘fight inflammation’ ... ‘The research behind it suggests it’s one of the best forms of natural anti-inflammatories out there.’...”); FDA warning letter to Saffron USA LLC, Sept. 23, 2022, <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/saffron-usa-llc-629821-09232022> (“Examples of some of the website claims that provide evidence that your products are intended for use as drugs include: ... ‘Reducing inflammation”); FDA warning letter to Fresh Nutrition Inc, May 27, 2021, <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/fresh-nutrition-inc-612984-05272021> (“Examples of some of the claims observed on your website that provide evidence that your products are intended for use as drugs include: ... ‘Berberine is well regarded for its broad antibacterial, antimicrobial and anti-inflammatory properties’ ... ‘Relief from ... Inflammation’ ...”).

Mood elevation, enhanced sleep, heightened focus: *See, e.g.,* FDA warning letter to Crystal Clear Supplements, Feb. 4, 2022, <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/crystal-clear-supplements-620285-02042022> (“Examples of some of the claims observed on your website, your social media websites, and your products’ packaging that provide evidence that your products are intended for use as drugs include, but may not be limited to, the following: ... ‘#nootropics #anxietyrelief’ and “MOOD ELEVATION - ENHANCED SLEEP- HEIGHTENED FOCUS” on the product image.”); FDA warning letter to VitaStik, Inc., Dec. 1, 2021, <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/vitastik-inc-617713-12012021> (“Examples of some of the claims observed on your website ... and your social media websites ... that provide evidence that your products are intended for use as drugs include, but may not be limited to, the following: ... ‘Current research show ginkgo benefits include improved cognitive function, positive mood, increased energy...”).

Provide mental clarity: *See, e.g.,* FDA warning letter to VitaStik, Inc., Dec. 1, 2021, <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/vitastik-inc-617713-12012021> (“Your website ... also includes various “Category” tags such as ... ‘Mental Clarity / Focus,’... that ... provide evidence of your products’ intended uses.”); FDA warning letter to Eagle Energy USA, Inc., Dec. 1, 2021, <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/eagle-energy-usa-inc-617713-12012021>

[letters/eagle-energy-usa-inc-617712-12012021](https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/eagle-energy-usa-inc-617712-12012021) (“Examples of some of the claims observed ... that provide evidence that your products are intended for use as drugs include, but may not be limited to, the following: ... ‘The seeds from guarana fruit contain stimulants that boost energy while improving mental clarity...’”); FDA warning letter to Umbrella, May 18, 2021, <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/umbrella-612037-05182021> (“Examples of claims observed on your website and Instagram social media website that establish the intended use of your ... products as drugs include, but may not be limited to, the following: ... ‘Within an hour of use, it provides mental stability and clarity...’”); FDA warning letter to Jack B Goods Outlet Store, Nov. 7, 2018, <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/jack-b-goods-outlet-store-566674-11072018> (“Examples of some of the website claims that provide evidence that your ... products are intended for use as drugs include: ... ‘Kratom initially filled this need in providing mental clarity and energy without the crash. Now, these four alternatives can replicate the benefits of Kratom with perfection.’”).

Of note, the FDA has only approved two non-hormone treatments for menopause: a selective serotonin reuptake inhibitor called Brisdelle for the treatment of vasomotor symptoms associated with menopause, and an estrogen agonist/antagonist called Ospheña for the treatment of dyspareunia, a symptom of vulvar and vaginal atrophy due to menopause. *See* Brisdelle Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2013/204516s000lbl.pdf; Ospheña Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2015/203505s005lbl.pdf. *See also* <https://www.fda.gov/consumers/womens-health-topics/menopause>. And as of 2019, the FDA was not aware of any herb or “natural” product that was safe or effective at treating the symptoms of menopause. *See* FDA, Menopause & Hormones, Common Questions, <https://www.fda.gov/media/130242/download>.

¹⁸ Modere, Project 23 – Social Marketer Prelaunch, <https://buzz.shiftingretail.com/article-slug/project-23-social-marketer-prelaunch/>.

On February 15, 2023, Modere’s attorney sent an email to TINA.org regarding its publication entitled “Modere Exploiting Women’s Hormonal Health Issues for Financial Gain,” which is available at <https://truthinadvertising.org/articles/modere-exploiting-womens-hormonal-health-issues-for-financial-gain/>, stating, among other things, that “[t]he FTC’s position is that studies on ingredients in a product can be adequate scientific proof of the efficacy of dietary supplements.” Contrary to this assertion, however, the agency generally views ingredient studies as insufficient on their own to substantiate disease-treatment claims about products and typically requires that advertisers have competent and reliable studies of the actual product to substantiate their claims. *See, e.g., FTC v. Nat’l Urological Group, Inc.*, 645 F. Supp. 2d 1167, 1189 (N.D. Ga. 2008) (the federal district court adopted the FTC’s expert’s position that “a study that uses higher doses of the active ingredients or a different combination of active ingredients would not be sufficient to support the efficacy of another product that used lower doses of the active ingredients or a different combination of the ingredients.”); FTC Health Products Compliance Guidance, https://www.ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf (“A common problem in the substantiation of advertising claims is that an advertiser has valid studies, but the studies don’t support the claim made in its ad. Advertisers should make sure that the research on which they rely isn’t just internally valid, but also relevant to their specific product and to the specific advertised benefit. Therefore, advertisers should ask questions such as: How do the dosage and formulation of the advertised product compare to the product used in the

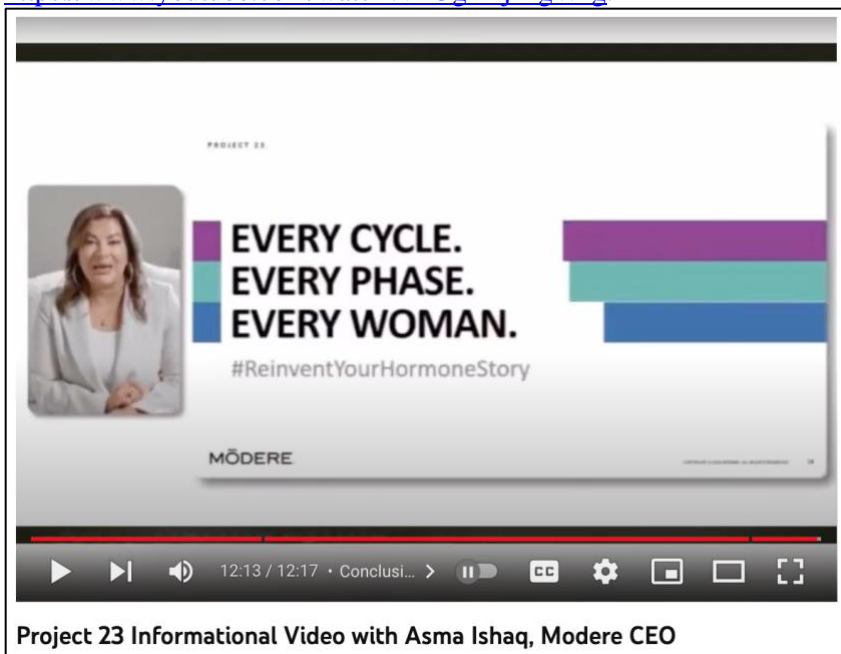
study? Is the ingredient or combination of ingredients in the advertised product the same as what was used in the study?”).

Further, even if studies on the ingredients in Project 23 supplements were adequate substantiation, which they are not, Modere has not provided any such studies.

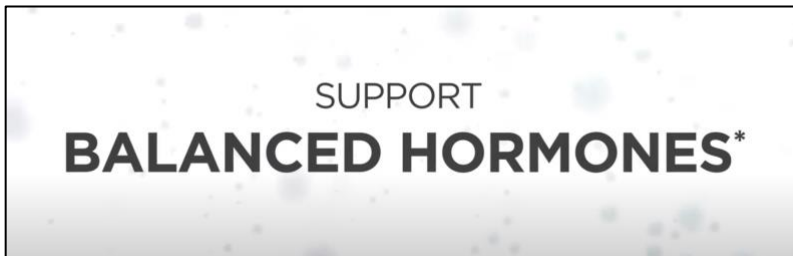
It is also worth noting that some of the conditions Modere claims Project 23 can treat, such as PMS and hot flashes, involve or originate in the brain. *See* Kimberly Yonkers et al., Premenstrual Syndrome, 371 *Lancet* 1200 (2008), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3118460/>; Dealing with the Symptoms of Menopause, Harvard Health Publ’g, Mar. 21, 2017, <https://www.health.harvard.edu/womens-health/dealing-with-the-symptoms-of-menopause>; The N. Am. Menopause Soc’y, Menopause FAQs: Hot Flashes, <https://www.menopause.org/for-women/menopause-faqs-hot-flashes>; Stephanie Padilla et al., A Neural Circuit Underlying the Generation of Hot Flashes, 24 *Cell Reps.* 271 (2018), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6094949/>; Susan Dominus, Women Have Been Misled About Menopause, *N.Y. Times*, Feb. 1, 2023 (updated Feb. 5, 2023), <https://www.nytimes.com/2023/02/01/magazine/menopause-hot-flashes-hormone-therapy.html>. Thus, for Project 23 to be able to effectively treat these conditions, it would need to cross the blood-brain barrier. *See* William Pardridge, Drug Transport Across the Blood-Brain Barrier, 32 *J. Cerebral Blood Flow & Metabolism* 1959 (2012), <https://ncbi.nlm.nih.gov/pmc/articles/PMC3494002/>. There is no evidence that Project 23 supplements have this capability.

¹⁹ Project 23 FAQ and Ingredients, <https://www.youtube.com/watch?v=PxpqkZT3y8>; Modere, Project 23 – Social Marketer Prelaunch, <https://buzz.shiftingretail.com/article-slug/project-23-social-marketer-prelaunch/>.

²⁰ *See, e.g.*, Project 23 Informational Video with Asma Ishaq, Modere CEO, <https://www.youtube.com/watch?v=Ug4KjBgW-g>.



²¹ Of note, even some of Modere’s health claims that begin with the word “Support” or other similar language, such as “Support Balanced Hormones,” constitute implied disease-treatment claims. See FTC Health Products Compliance Guidance, https://www.ftc.gov/system/files/ftc_gov/pdf/Health-Guidance-508.pdf (“Depending on how it is phrased or the context in which it is presented, a statement about a product’s effect on the normal ‘structure or function’ of the body may also convey to consumers an implied claim that the product is beneficial for the treatment of a disease. If elements of an ad imply that the product also provides a disease benefit, the advertiser must be able to substantiate the implied disease claim even if the ad contains no express reference to a disease.”). See also Modere Project 23 Teaser Video – Angela Ciemny, <https://www.youtube.com/watch?v=BFKby6dfR74>.



²² See, e.g., DSSRC Case #97-2022: Administrative Closure – Unicity International, Inc., Dec. 16, 2022, <https://bbbprograms.org/programs/all-programs/dssrc/ccd/dssrc-unicity> (recommending the removal of the following health claims, among others: “helps you overcome...frequent infections (urinary tract, bronchitis, respiratory, etc.); inflammation;...”); DSSRC Case #94-2022: Administrative Closure – Tealightful Treasures, Inc., Dec. 13, 2022, <https://bbbprograms.org/programs/all-programs/dssrc/ccd/dssrc-TealightfulTreasures> (recommending the removal of the following health claims, among others: “May reduce anxiety; may promote sleep; ... anti-inflammatory...ease menstrual pains...”); DSSRC Case #91-2022: Monitoring Inquiry – Kannaway, LLC, Nov. 8, 2022, <https://bbbprograms.org/programs/all-programs/dssrc/ccd/case-91-2022-kannaway> (recommending the removal of the following health claims, among others: “Treat pain, stress, inflammation, anxiety, ...”; “We all have different ailments from tendinitis to arthritis, diabetic neuropathy, menstrual cramps, shin splints, and carpal tunnel (the list goes on). Do you believe that it has helped ALL of us?”); DSSRC Case #88-2022: Monitoring Inquiry – B-Epic Worldwide, LLC, Oct. 13, 2022, <https://bbbprograms.org/programs/all-programs/dssrc/ccd/dssrc-88-B-EpicWorldwide> (recommending the removal of the following health claims, among others: “Do you suffer from anxiety? Do you have chronic pain? Minimize feelings of stress and anxiety; Help manage pain and reduce inflammation; Promote relaxation; Assist in relieving insomnia.”; “Do you suffer with stress and/or anxiety 🤔 😞? Both emotional and physical stress can put a huge strain on our bodies ability to function properly. Our elev8 capsules contain adaptogenic herbs 🌿 or ‘adaptogens’ along with other natural ingredients which help the body deal with stress naturally along with more energy ⚡, mental clarity, combating fatigue 😴 and providing 100% bioavailable phytonutrients to improve overall health.”; “-Improve mood, concentration and sleep depth.”); DSSRC Case #13-2020: Challenge – Young Living Essential Oils, LLC, Feb. 19, 2020, https://assets.bbbprograms.org/docs/default-source/dssrc/decisions/2020-02-20-young-living-decision.pdf?sfvrsn=b8e87746_8 (recommending the removal of the following health claims, among others: “How I cured my UTI in 3 days...”); DSSRC Case #8-2019: Monitoring Inquiry – New U Life, Mar. 27, 2020, <https://bbbnp-bbbp-stf-use1-01.s3.amazonaws.com/docs/default-source/dssrc/decisions/case-8-2019-monitoring-inquiry-new-u-life.pdf> (recommending the removal of the following health claims, among others: “Two month update: - Huge improvement in sleep.... - Mood has greatly improved, zero PMS after 6

weeks. Focus has improved. More alert, improved energy. ... I'm no longer bloated and can see my waistline changing.... #hormonesmatter ... #optimizinghormonelevels"); DSSRC Case #5-2019: Government Referral Reports – Aloe Veritas, Inc., Oct. 3, 2019, <https://bbbprograms.org/programs/all-programs/dssrc/ccd/case-number-5-2019> (recommending the removal of the following health claims, among others: "...Aloe vera is excellent for healing as it reduces poisons & toxins in the intestinal tract so that they don't travel up to the liver. This makes it highly beneficial for ... acne, ..., bloating, ... brain fog, ... uti's").

²³ Not only does Modere convey the message that Project 23 can be used in lieu of hormone therapy, but, in some cases, the company and its distributors advocate against hormone therapy. *See, e.g.,* ; Project 23 – Social Marketer Prelaunch, <https://buzz.shiftingretail.com/article-slug/project-23-social-marketer-prelaunch/> (“Q: Why are hormones and soy isoflavones undesirable for hormonal health? A: Long-term use of hormones and soy isoflavones has been linked to an increased risk of certain cancers and should only be done under the supervision of a doctor.”); Kris Sales Jan. 18, 2023 TikTok post, <https://www.tiktok.com/@krissales11/video/7190164681913371909?lang=en&q=> (“I lost my mom to a hormone fed breast cancer. She was taking hormone therapy. I'm high risk so I'm excited about project 23! #menopausemom #momsover40 #menopausesymptoms”).

Of note, the North American Menopause Society takes the position that the benefits of hormone therapy generally outweigh the risks. *See* NAMS Position Statement, The 2022 hormone therapy position statement of The North American Menopause Society, 2022 <https://www.menopause.org/docs/default-source/professional/nams-2022-hormone-therapy-position-statement.pdf>; *See also* Susan Dominus, Women Have Been Misled About Menopause, N.Y. Times, Feb. 1, 2023 (updated Feb. 5, 2023), <https://www.nytimes.com/2023/02/01/magazine/menopause-hot-flashes-hormone-therapy.html>.

²⁴ Kelsey Armstrong Jan. 29, 2023 Instagram post, <https://www.instagram.com/p/CoBgJ9hs9/J/>.

²⁵ Karen DeRollo Jan. 27, 2023 Facebook post, <https://www.facebook.com/mariabaseball/videos/568764314869679>.

²⁶ Kate Knepper Jan. 15, 2023 Instagram post, <https://www.instagram.com/p/CndU7GkI4fD/>.

²⁷ Karen Louise Jan. 17, 2023 Instagram post, <https://www.instagram.com/p/CniZKHNPjht/>.

²⁸ Holistichousewife1 Jan. 5, 2023 Instagram post, <https://www.instagram.com/p/CnDhbyMNIv/>.

²⁹ Modere 2021 Income Disclosure Statement, https://res.cloudinary.com/modere-na/shiftingretail/tools/documents_media/education_compliance/us_ca_en_income_disclosure_statement.pdf.

³⁰ FTC Business Guidance Concerning Multi-Level Marketing, <https://www.ftc.gov/business-guidance/resources/business-guidance-concerning-multi-level-marketing>; FTC alleges Neora, formerly known as Nerium, operates an illegal pyramid scheme, Nov. 4, 2019, <https://www.ftc.gov/business-guidance/blog/2019/11/ftc-alleges-neora-formerly-known-nerium-operates-illegal-pyramid-scheme>; Redress checks and compliance checks: Lessons from the FTC's Herbalife and Vemma cases,

<https://www.ftc.gov/business-guidance/blog/2017/01/redress-checks-and-compliance-checks-lessons-ftcs-herbalife-and-venma-cases>.

³¹ BBB National Programs, Direct Selling Self-Regulatory Council, Guidance on Earnings Claims for the Direct Selling Industry, https://assets.bbbprograms.org/docs/default-source/dssrc/dssrc_guidanceonearningsclaimsforthedirectsellingindustry.pdf?sfvrsn=4ecfd36_30&_ga=2.224107097.335102959.1675110126-1249443603.1665065824&_gl=1*191ol41*_ga*MTI0OTQ0MzYwMy4xNjY1MDY1ODI0*_ga_FXP6NWPNYM*MTY3NTE5MjI1Mi42MS4xLjE2NzUxOTM2ODAuNjAuMC4w.

³² Join us for Modere's Social Retail Conference this March 9-12, 2023 in Charlotte, North Carolina!, <https://events.shiftingretail.com/>.