Women's Wellness in the Spotlight

Regulatory Risks & Compliance Strategies

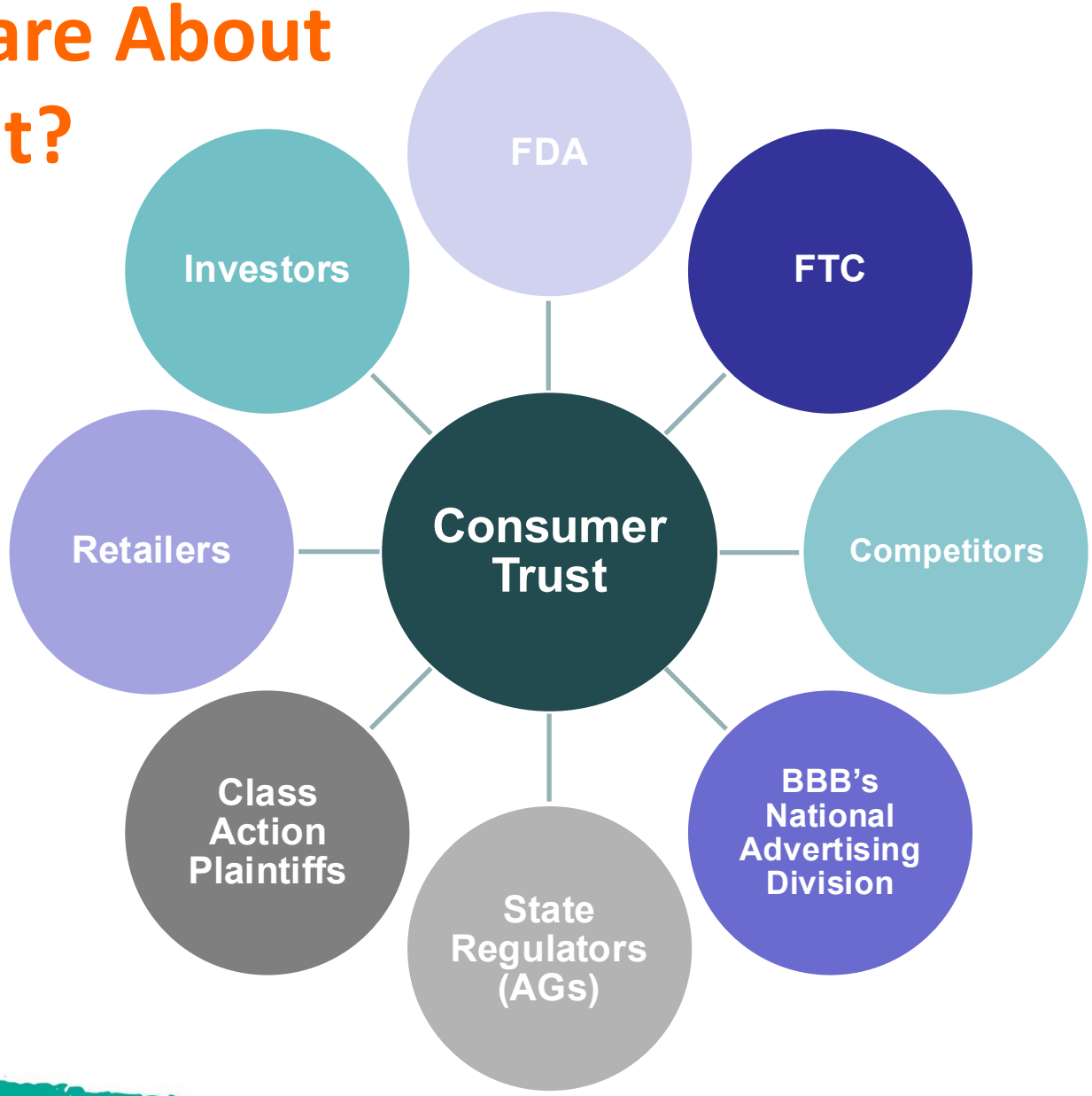
Rend Al-Mondhiry
Amin Wasserman Gurnani LLP
Rend@awglaw.com
June 23, 2026

What We'll Cover

- What's Trending
- The Stakeholders
- Regulatory Considerations
  - Permissible Claims & Products
  - Claim Substantiation
- Influencer Partnerships & Advertising Compliance
- Litigation Trends

What's Trending?

Why Do We Care About Getting It Right?



FDA's Framework

- FDA primarily regulates products based on their intended use
  - Dietary supplements/foods
  - Cosmetics
  - Medical devices
  - Drugs
- No express or implied disease claims unless the product is an FDA-approved drug
- Unlike dietary supplements & food, cosmetics cannot claim to affect the structure or function of the body
  - "Moisturizes skin," "Reduces the appearance of fine lines" vs. "repairs skin at the cellular level," "stimulates collagen production," "removes wrinkles"

- Dietary supplements MUST be intended for ingestion
  - No patches, suppositories, topical creams, eye drops, nasal sprays, injections, sublingual/buccal absorption products
  - Cannot be represented as food – "coffee," "creamer," meal replacement, snack, drink
- Devices are products intended to diagnose, cure, mitigate, treat, or prevent disease, or affect the structure or function of the body primarily through mechanical/physical means **rather than chemical action**
  - Fertility tracking devices, ovulation monitors, pelvic floor trainers, menstrual cups, anti-aging red light masks, vaginal inserts for lubrication/ moisturizing, certain apps & software
  - Device/drug combination products (e.g., microneedling device delivering serum)

Dietary Supplements for Women's Health

- Products marketed for menstrual support, peri/post-menopause, fertility, hormonal balance, and sexual health must comply with FDA's structure/function claim rule
  - **21 CFR § 101.93, Certain types of statements for dietary supplements** → describes what types of claims qualify as structure/function claims + outlines criteria that determine whether a particular statement is a disease claim
  - **(g)(2)**→ "…A statement claims to diagnose, mitigate, treat, cure, or prevent disease if it claims, explicitly or implicitly, that the product… (i) Has an effect on a specific disease or class of diseases; (ii) Has an effect on the characteristic signs or symptoms of a specific disease or class of diseases, using scientific or lay terminology; (iii) ***Has an effect on an abnormal condition associated with a natural state or process, if the abnormal condition is uncommon or can cause significant or permanent harm…"***

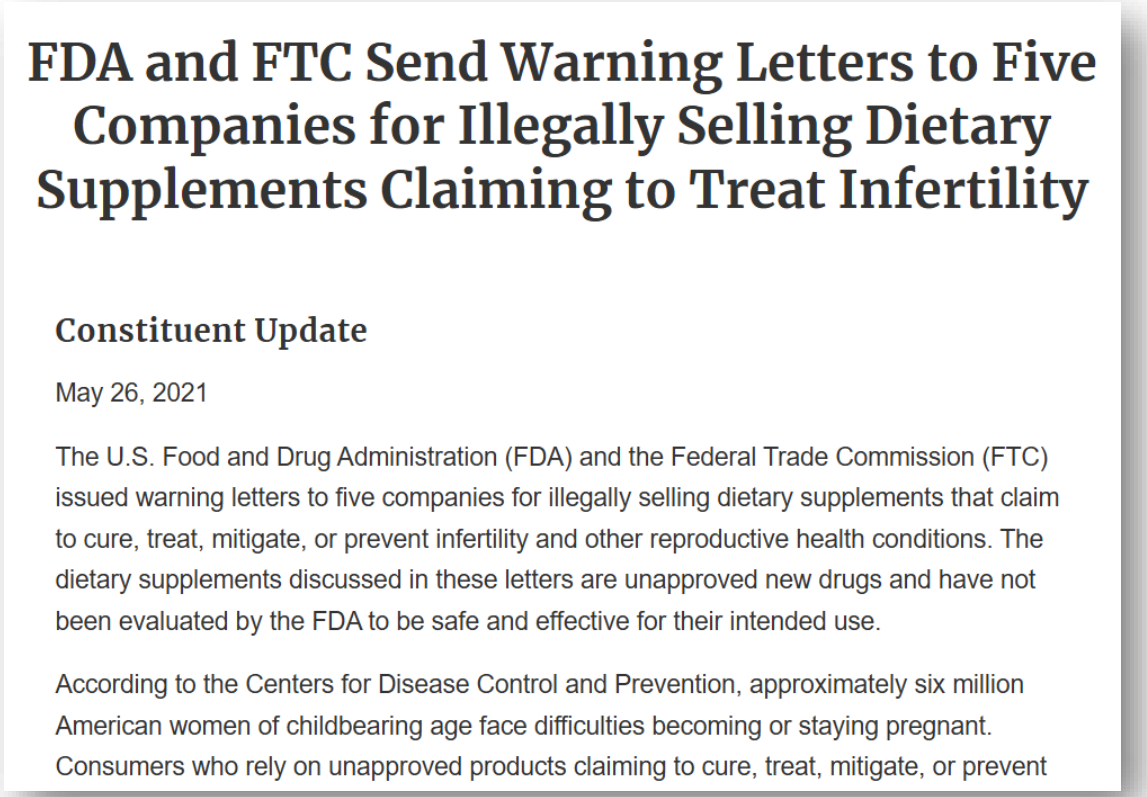
What is a “Natural State or Process”?

- From the preamble to the rule:
  - Includes menopause, aging, adolescence, and pregnancy
  - “***Common conditions*** associated with natural states or processes that ***do not cause significant or permanent harm*** will not be treated as diseases under the final rule.”
  - “For example, hot flashes, ***common symptoms*** associated with the menstrual cycle, ordinary morning sickness associated with pregnancy, mild memory problems associated with aging, hair loss associated with aging, and noncystic acne will not be treated as diseases under this provision.”
  - “***Uncommon or serious conditions*** like senile dementia, toxemia of pregnancy, severe depression associated with the menstrual cycle, and cystic acne will continue to be treated as diseases under the final rule.”

What is a “Natural State or Process”?

- Two criteria determine if such a condition will be considered a disease:
  - (1) if the condition is uncommon; or
  - (2) if the condition can cause significant or permanent harm. For purposes of the rule, a condition is uncommon if it occurs in fewer than one-half of those experiencing that stage or process.
- A condition can cause significant or permanent harm if it must be treated effectively to prevent that harm and for which effective treatments are available.
- **Reminders:**
  - Supplements cannot be marketed as alternatives to drugs, e.g., hormone therapy or GLP-1 agonist drugs, or to augment a therapy or drug or prevent or treat certain adverse events associated with a drug/therapy
  - Citations can constitute disease claims depending on the context
  - Pictures, vignettes, or symbols can be claims

FDA Enforcement



FDA and FTC Send Warning Letters to Five Companies for Illegally Selling Dietary Supplements Claiming to Treat Infertility

Constituent Update

May 26, 2021

The U.S. Food and Drug Administration (FDA) and the Federal Trade Commission (FTC) issued warning letters to five companies for illegally selling dietary supplements that claim to cure, treat, mitigate, or prevent infertility and other reproductive health conditions. The dietary supplements discussed in these letters are unapproved new drugs and have not been evaluated by the FDA to be safe and effective for their intended use.

According to the Centers for Disease Control and Prevention, approximately six million American women of childbearing age face difficulties becoming or staying pregnant. Consumers who rely on unapproved products claiming to cure, treat, mitigate, or prevent

- In May 2021, FDA and FTC jointly issued Warning Letters to five companies for illegally marketing dietary supplements making fertility-related claims
  - Implied disease claims for infertility, PCOS, endometriosis, and hormonal disorders; products deemed unapproved new drugs despite being labeled as dietary supplements
- Prenatal and postpartum products — heightened scrutiny given vulnerable population
- Outside of supplements:
  - Anti-aging, skin regeneration, cellular repair claims, skin lightening products; injectable lipolytic products/fillers
  - FDA Website: Warning Letters Related to Cosmetics, Devices vs. Cosmetics

FTC Considerations for Women's Wellness

"For Women" branding — **does it create implied claims?**

- Studies must be good match your product + claims, including study population; **consider life stage**

Advertisers are responsible for **ALL "reasonable" interpretations** of their claims – even those they didn't intend to make

FTC (and NAD) Framework

AMIN WASSERMAN GURNANI

Marketers must have a "**reasonable basis**" for all claims

What is "reasonable" depends on factors such as the type of claim, the product, the consequences of a false claim, the benefits of a truthful claim, the cost of developing substantiation for the claim, and **the amount of substantiation experts in the field believe is reasonable**

How the claim is presented in the **context of the entire ad**, and how it is qualified

- *Is disclosure of qualifying information necessary***?**

For health-related claims, a "reasonable basis" generally means "**competent and reliable science evidence**"

- "*FTC's substantiation standard is a rigorous one, particularly when claims relate to health*"

Competent and Reliable Scientific Evidence

- Defined as “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.”
- The research must be “sufficient in quality and quantity based on standards generally **accepted in the relevant scientific fields**, when considered in light of the **entire body of relevant and reliable scientific evidence**, to substantiate that the representation is true.”

Quality Over Quantity

AMIN WASSERMAN GURNANI

Study Design – randomized, placebo-controlled, double blinded

Sufficient duration and sample size

Between-group statistical significance + *clinically meaningful results*

"Some results that are statistically significant may be too small to provide real consequences for consumer health"

Appropriate exclusion/inclusion criteria

Relevance to the product & claim

Study population relates to the target population for the product + same dosage, formulation, and conditions of use

Claims reflect endpoint(s) measured

Influencer Partnerships: Regulatory Risk

- FTC's Endorsement Guides require **disclosure of material connections** between brands and influencers/endorsers
  - **16 CFR Part 255**
- "Mom-fluencers," OB/GYN influencers, and wellness coaches
  - Specific disclosure and substantiation obligations for material connections (payment, free products, employment, family relationships, or any other connection that might affect the weight consumers give the endorsement)
  - "**Clear and conspicuous**" – must be difficult to miss; buried hashtags like #sp or #partner in a string of other hashtags **do not** qualify
  - Expert endorsers – if an endorser is presented as an expert (e.g., an OB/GYN, nutritionist, or health coach), their endorsement must reflect their **genuine expert opinion** and be supported by **actual expertise**
  - **Reminder:** specific requirements for "doctor recommended" claims

Advertisers cannot outsource compliance to creators & influencers

- Brands must monitor content; take corrective action when posts contain false, unsubstantiated claims or lack disclosures

Litigation Trends: Contaminants

Trace amounts of heavy metals, pesticides, PFAS, or other contaminants that allegedly pose health risks, even where the amount is consistent with cGMPs

Typically tied to a failure to disclose the presence of the microcontaminant based on safety issue, or claims that plaintiffs allege are deceptive and misleading, e.g., "natural," "healthy," "safe," "clean," "pure," "good for you," "good for the planet"

Wide variety of products targeted – prenatals, baby/toddler food, protein powders, cosmetics, period care products

Litigation Trends: “Clean,” “Green” Claims

- “Clean,” “Non-Toxic,” “Free From”
  - Like “natural,” undefined terms subject to consumer reasonable-interpretation standard
  - What does “clean” mean to your target audience?
- “Climate Neutral,” “Ethical,” Stewardship Promises
  - Calculations are allegedly deceptive and/or steps do not negate emissions
  - Failure to meet environmental/social promises, over-promising benefits
  - What does “ethical” and “sustainable” mean?

- **<u>Reminders:</u>**
  - Use of a seal or logo, or third-party certification associated with the use of a seal or logo, does not eliminate the need for substantiation to ***support all claims reasonably communicated*** by the seal/logo
  - Confirm environmental claims are also consistent with FTC’s Green Guides

Litigation Trends: Potency & Label Accuracy

- Supplements increasingly targeted when testing shows overages or underages compared to stated label amounts
- Protein content overstated/miscalculated; calorie and carb misstatements also targeted
  - Courts have allowed cases to proceed based on single-sample testing results; FDA composite method (12 samples) is not a safe harbor
- Ingredient callouts on front-of-pack (e.g., “1000mg”) misleading or false
  - Reasonable consumer would believe the callout is for only one capsule, not a 3-capsule serving size
  - Concentration of Mg in Mg glycinate too low; buffering agents

Litigation Trends: Attacks on Health-Related Claims

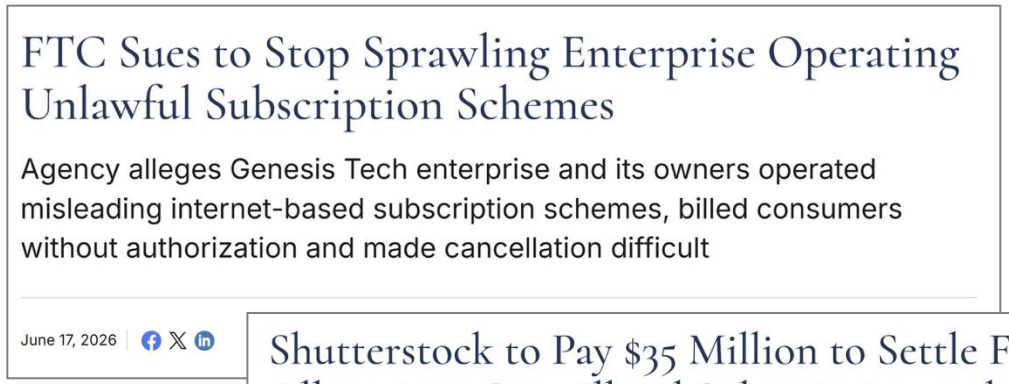
- Claims challenged where underlying science is mixed
  - Preemption defenses not always successful — plaintiffs can plead around DSHEA where claims go beyond permissible S/F language
  - Demands/complaints targeting missing S/F disclaimers on same panel as claims, as required by 21 CFR 101.93(d)
- "Science-backed" and "clinically shown" targeted based on lack of credible human clinical data
  - Totality of evidence standard applies; a single favorable study does not insulate a claim from challenge
- "Stem Cell" and "Age Defying" claims for cosmetics
  - "Experts cited in the complaint explain that plant stem cells cannot survive the manufacturing process, cannot remain active in a cosmetic product, and, even if alive, could not interact with human cells to provide the 'Age Defying' results promised"

Class Action Trends: Other Targets to Watch

AMIN WASSERMAN GURNANI

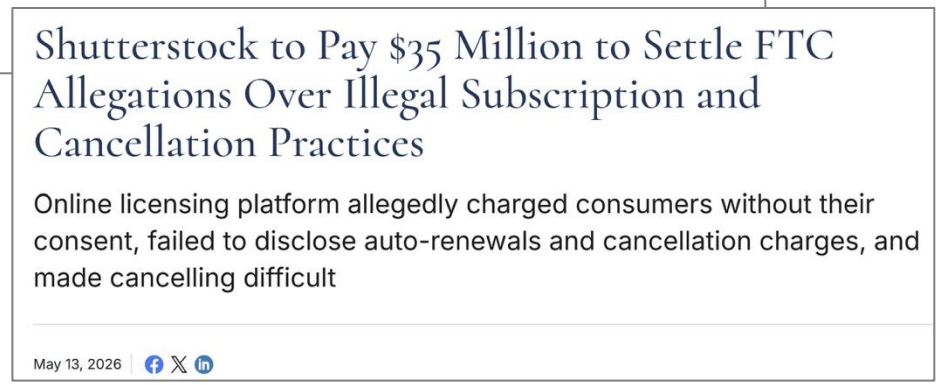
- Serving size, packaging deception
  - Slack-fill cases; “scoops” where stated serving is misleading
- “Health Halos”
  - “Phenomenon where people may perceive a food product (or drink or supplement) as healthy based on a single claim — even if the snack is not-so-angelic.” *NY Times*
  - Claims targeted include protein claims, “wholesome,” “gut healthy,” “backed by science,” and other implied healthy claims
  - Consider levels of **added sugar**
- Beyond the label
  - Deceptive pricing: false discounts, hidden fees, shelf v. checkout price
  - Privacy: use of website tracking software
  - Website accessibility: lack of ADA compliance

- **Subscription & Auto-Renewal**
  - Difficult cancellation flows and lack of clear disclosures at point of purchase increasingly litigated
  - **FTC priority as well**


FTC Sues to Stop Sprawling Enterprise Operating Unlawful Subscription Schemes

Agency alleges Genesis Tech enterprise and its owners operated misleading internet-based subscription schemes, billed consumers without authorization and made cancellation difficult

June 17, 2026


Shutterstock to Pay $35 Million to Settle FTC Allegations Over Illegal Subscription and Cancellation Practices

Online licensing platform allegedly charged consumers without their consent, failed to disclose auto-renewals and cancellation charges, and made cancelling difficult

May 13, 2026

Political Uncertainty & Shifting Enforcement Priorities

- Rise of “MAHA Moms,” wellness influencers, and scrutiny of ingredients used in women’s products
- Wave of state legislation targeting contaminants in prenatal products, warnings for products containing “synthetic” ingredients, ingredient bans, PFAS bans/restrictions, ingredient lists for menstrual products

Consumer News

Consumer Alert: Menopause Supplements

Proceed with caution when it comes to menopause marketing.

TINA.ORG

Takeaways & Risk Mitigation Strategies

AMIN WASSERMAN GURNANI

Audit all claims across ALL channels — label, website, social media	Consider the **overall context** **Common vs. abnormal**
Don’t overpromise on what your product can deliver!	Maintain a living substantiation files; update when new science emerges Carefully **relevance of the study** & **totality of the evidence**
Train & monitor influencers	Agreements/guidelines that outline compliance responsibilities Document training and **compliance monitoring**
Test regularly for potency and contaminants; understand all reasonable takeaways from product marketing	
Monitor state legislation and social media trends (seriously!)	

Questions?

Rend@awglaw.com