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Litigation Defense Strategies

SupplySide West Workshop: FDA Lawsuits and Class Action Litigation in the Dietary Supplement Industry

September 26, 2017

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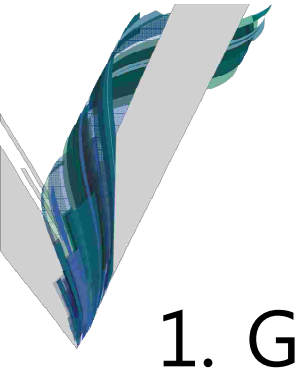
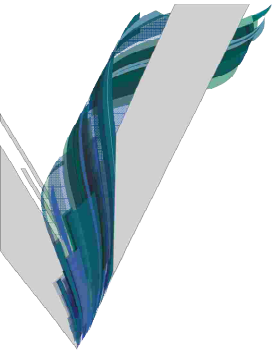


AGENDA

1. Government Investigations
2. Government Litigation
3. Private Plaintiff Threatened Litigation
4. Private Plaintiff Actual Litigation



GOVERNMENT INVESTIGATIONS

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KNOW YOUR REGULATOR(S) & REGULATORY / POLITICAL CLIMATE

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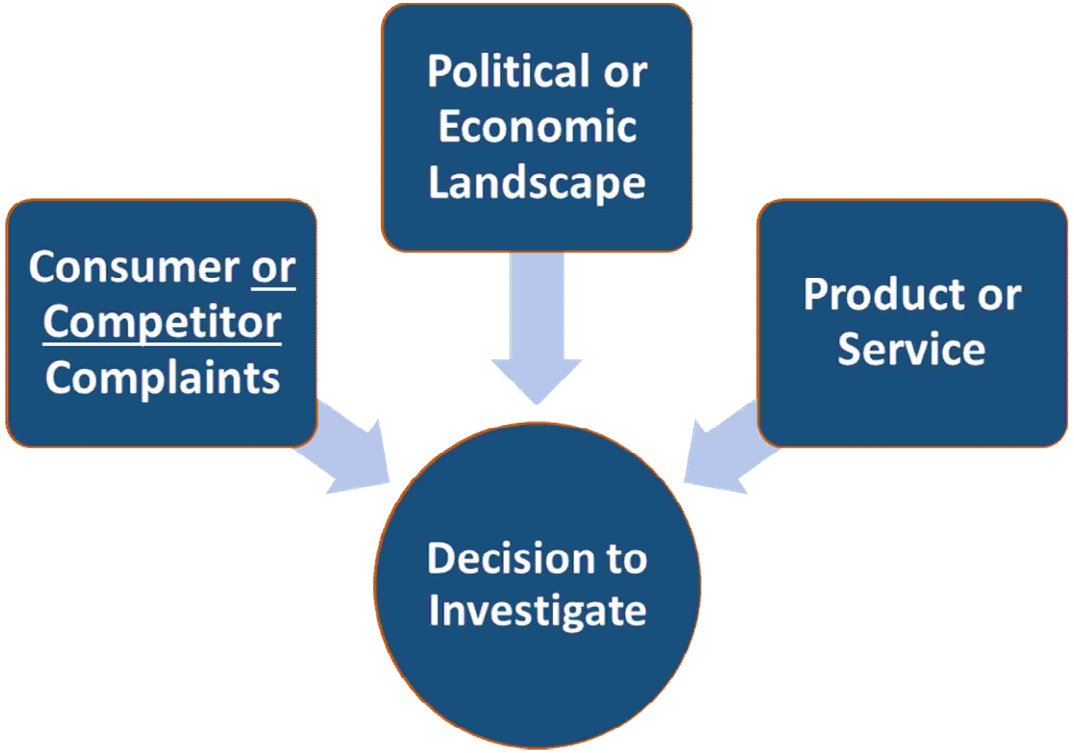
LAUNCH OF AN INVESTIGATION



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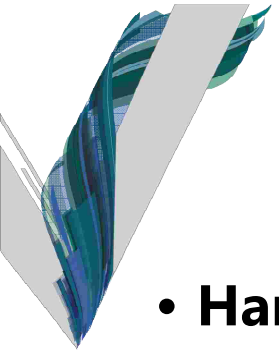

WHAT MOTIVATES GOVERNMENT INVESTIGATORS?

- **Harm**
  - Actual injuries to consumers
    - Physical
    - Financial
  - Forgone alternative treatments
    - Is a consumer taking an unproven product rather than an approved or accepted course of treatment?
- **Misrepresentations**
  - Is there anything about the history of the interaction between the entity and the government that could be construed as misleading?
  - Is there anything about the marketing of the product that could mislead consumers?
- **Protection of vulnerable population(s)**
- **Repeated "violations"**

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ACTIVITY CONTINUES DESPITE NEW ADMINISTRATION

- FDA is still inspecting companies, still sending Warning Letters
- FTC is still conducting investigations, still filing Complaints
- Expect more activity at state level if the federal government becomes less active

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ACTIVITY CONTINUES DESPITE NEW ADMINISTRATION

- July 2017 blog posted jointly by FTC and FDA
- "Tell the FTC or the FDA if:
  - You bought a dietary supplement that didn't work as advertised – or you had an adverse reaction or illness.
  - You're suspicious that a company is making false or overstated claims in its labeling or marketing. (Watch for claims about so-called "treatments" or "cures" for diseases like Alzheimer's, cancer, heart disease, arthritis, and others. Dietary supplements cannot lawfully claim to diagnose, mitigate, treat, or prevent a disease.)
  - You're concerned about the content, purity, or safety of the product."

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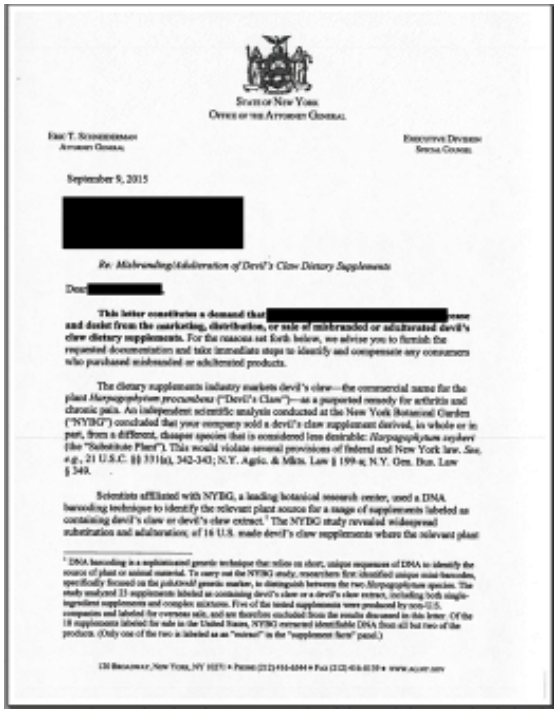
TWO POSSIBLE PATHS: PRIVATE NOTICE OR COURT OF PUBLIC OPINION

CIVIL INVESTIGATIVE DEMAND



STATE OF NEW YORK
OFFICE OF THE ATTORNEY GENERAL

September 9, 2015

Re: Misbranding/Adulteration of Devil's Claw Dietary Supplements

This letter constitutes a demand that [redacted] cease and desist from the marketing, distribution, or sale of misbranded or adulterated devil's claw dietary supplements. For the reasons set forth below, we advise you to furnish the requested documentation and take immediate steps to identify and compensate any consumers who purchased misbranded or adulterated products.

The dietary supplements industry markets devil's claw—the commercial name for the plant *Harpagophytum procumbens* ("Devil's Claw")—as a purported remedy for arthritis and chronic pain. An independent scientific analysis conducted at the New York Botanical Garden ("NYBG") concluded that your company sold a devil's claw supplement derived, in whole or in part, from a different, cheaper species that is considered less desirable: *Harpagophytum zeyheri* (the "Substitute Plant"). This would violate several provisions of federal and New York law. *See, e.g.*, 21 U.S.C. §§ 331(a), 342-343; N.Y. Agric. & Mkts. Law § 199-a; N.Y. Gen. Bus. Law § 349.

Scientists affiliated with NYBG, a leading botanical research center, used a DNA barcoding technique to identify the relevant plant source for a range of supplements labeled as containing devil's claw or devil's claw extract.[1] The NYBG study revealed widespread substitution and adulteration; of 16 U.S. made devil's claw supplements where the relevant plant

[1] DNA barcoding is a sophisticated genetic technique that relies on short, unique sequences of DNA to identify the source of plant or animal material. To carry out the NYBG study, researchers first identified unique mini-barcodes, specifically focused on the *psbA-trnH* genetic marker, to distinguish between the two *Harpagophytum* species. The study analyzed 23 supplements labeled as containing devil's claw or a devil's claw extract, including both single-ingredient supplements and complex mixtures. Five of the tested supplements were produced by non-U.S. companies and labeled for overseas sale, and are therefore excluded from the results discussed in this letter. Of the 18 supplements labeled for sale in the United States, NYBG surveyed identifiable DNA from all but two of the products. (Only one of the two is labeled as an "extract" in the "supplement facts" panel.)

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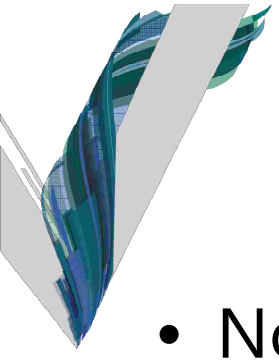
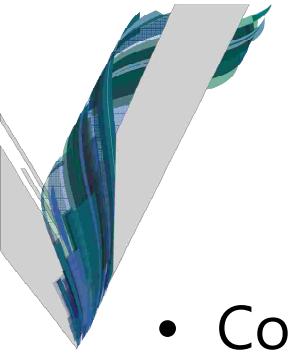


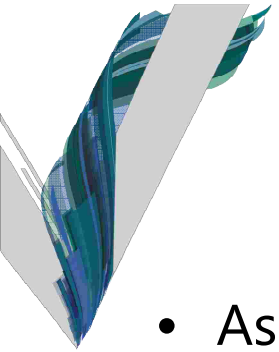
VITAL STEP: ESTABLISH A RESPONSE TEAM

- Notify Board and management and necessary IT and Operations subject matter experts.
- Engage counsel and public relations professionals.
- Take proper steps to preserve responsive materials (e.g., implementation of a document preservation policy).
- Consider collateral consequences such as required public disclosure or notification of counterparties / sources of funding.



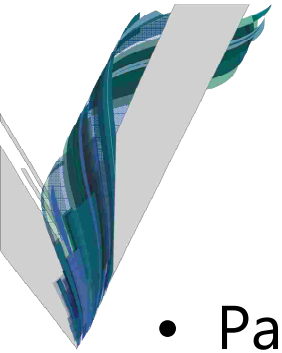
OBTAIN AS MUCH INFORMATION AS YOU CAN

- Communication with enforcement staff/ investigators is key
- What triggered the investigation/enforcement action?
  - Warning Letter response deemed insufficient?
  - Adverse events?
  - Consumer complaints?
  - Competitor complaints?
- Sometimes unable to get certain factual information (e.g., state Attorney General relying on third party evidence)



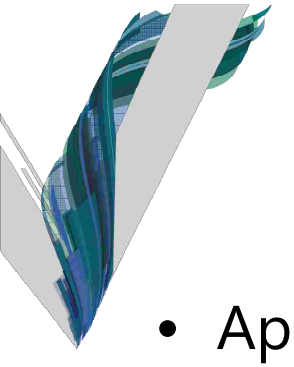
LIMIT THE SCOPE

- Assess scope
- Engage with enforcement staff to limit burden and understand basis for investigation
  - What is scope of government's authority in issuing the request? Has it overstepped bounds of authority?
  - Does request seek potentially privileged materials? Confidential materials of third parties?
  - Does request present technological obstacles and burdens?
  - What modifications can be made to reasonably reduce burden in a way that does not impede agency's investigation?
  - What is realistic amount of time needed to collect and produce materials?



TELL YOUR STORY

- Paper law v. trial law
- Why?
  - Gather the evidence that explains your Why
  - Who, what, where, when is not as important
- If you find yourself discussing the intricacies of a statute or regulation, you likely already lost
- Consider pros and cons of providing additional information and context above and beyond what agency requested



TAKE THE PERSONAL OUT OF IT

- Applies regardless of where you are in the process
- It is simply highly unlikely that the government is "out to get you"
- Don't make decisions based on that presumption
- Recognize business decisions when they arise
- Listen carefully to your outside advisers
  - There is a reason you are paying them

BUT . . . PUT THE PERSONAL IN IT

- Discourage the government from brining enforcement action
- The more the government knows about you, acting in good faith, the less it will want to bring down the proverbial hammer
- It is important that the government sees you as people, not as a faceless organization, as a symbol, or as an example
  - The government needs to see that what it is or will be doing will have a real impact on real people
- Communication is key
  - Tell your Why with the appropriate Who
  - You can learn about the government's personal motivations
    - Don't assume that you know
    - Your own decision-making will be better

EXPERTS CAN MAKE THE DIFFERENCE

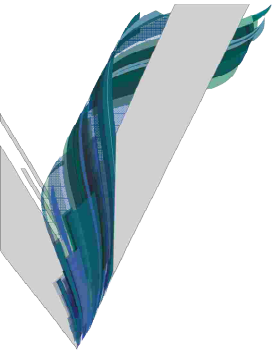
- Scientific/highly technical issues
  - E.g., The identity of a particular botanical
- Questions of substantiation
  - The FTC standard of competent and reliable scientific evidence has been defined in FTC case law as "tests, analyses, research, studies, or other evidence based on the expertise of professionals in the relevant area, that has been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results."
  - Cutting-edge science
  - Consider use of experts for substantiation in the regular course of business
- Government may wish to avoid a "battle of the experts" in court

NEGOTIATED SETTLEMENTS

- Negotiate in good faith
- Mitigating factors
  - Examples in substantiation context:
    - Consumers who continued to purchase product (and were clearly happy with it)
    - Continuity sales that were started before claims at issue were made
    - A product that clearly provided a benefit to consumers
  - Inability to pay
  - Comprehensive compliance program
- What can you offer?
  - Be creatively proactive – if you want to resolve matter
  - Enforcement actions do not need to be zero sum games
    - Look for "win-win" opportunities
  - Can you make changes that will both help your business and address government concerns?
    - Good example is a recent settlement between the Department of Justice and GNC

NEGOTIATED SETTLEMENTS (CONT'D)

- For certain types of negotiated settlements, there is little room for negotiation of language of settlement agreement
  - FDA consent decree language for alleged GMP violations is "standard" and DOJ/FDA are frequently unwilling to make many changes
  - FTC consent decree language for unsubstantiated claims similarly "template;" difficult to get many changes
  - Other types of settlements (e.g., state Attorneys General, county District Attorneys) might provide more room for negotiation of language
- Keep in mind settlement will be public; almost always a government press release with one-sided portrayal of facts
  - Potential follow-on lawsuits



GOVERNMENT LITIGATION

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WHAT MOTIVATES COURTS/JURIES?

- Go back to first principles
  - The Why is key
- Common sense above all else
  - Good example is the court decision in the Bayer litigation with the Department of Justice (and the Federal Trade Commission)
  - Another good example is the court decision in the Hi-Tech litigation with the Department of Justice (and the Food and Drug Administration)

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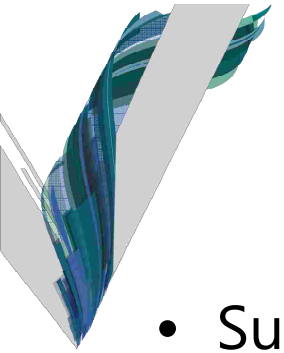
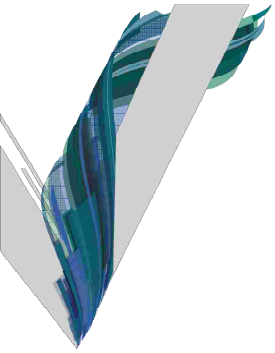


EXPERTS CAN BE KEY

- Substantiation: A "battle of the experts" in court
- FTC: not a great track record in substantiation "battle of the experts" when litigated
  - FTC v. Garden of Life
  - FTC v. Basic Research
- FDA: Good Manufacturing Practices (GMPs) leave a lot of room for interpretation
  - Did the company's practice meet the *regulatory* requirements?



PRIVATE PLAINTIFF THREATENED LITIGATION

AVOIDING PRIVATE LITIGATION

- Monitor trends:
  - Plaintiff's attorneys will stick with a theme once they are successful
  - Monitor recent lawsuits filed
  - Ask your attorneys about recent trends they have seen (might not be public)
- Take customer complaints seriously
- Have robust substantiation files/ compliance practices in place
- Plaintiff's attorneys monitor governmental actions (e.g., FDA Warning Letters)

EVALUATE THE STRENGTH OF THE PLAINTIFF'S CASE

- You most likely are more familiar with the relevant laws than the plaintiff's attorney
  - Is the plaintiff misconstruing (or confusing) the law?
- You definitely know your product(s) and substantiation better than the plaintiff's attorney
- Understand the burden of proof:
  - Does the plaintiff have a burden to demonstrate that the claims are false?
- Understand case law, the likely/potential court (e.g., Is the District known to be plaintiff friendly?)

UNDERSTAND THE PLAINTIFF'S MOTIVATION

- Monetary settlement?
- Changes to business practices?
- Changes to product formulation?
- Changes to advertising?

- Helps you understand what you might be able to offer

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NEGOTIATED SETTLEMENTS

- Much more room to negotiate language of settlement
- Settlement not necessarily public
  - Pros and cons
- Consider need for Attorney General sign-off in certain situations (e.g., California's Proposition 65)

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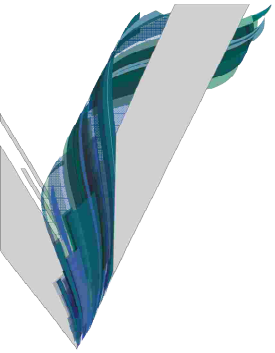

PRIVATE PLAINTIFF ACTUAL LITIGATION

CONSIDER THE FOUNDATION OF THE LAWSUIT – WHAT STATUTE?

- Private plaintiffs typically assert violations of state consumer protection statutes
- In California, for example, plaintiffs may bring a lawsuit pursuant to the following statutes:
  - **Unfair Competition Law (UCL)** – *CA Business and Professions Code §§ 17200 et seq.*
  - **False Advertising Law (FAL)** – *CA Business & Professions Code §§ 17500 et seq.*
  - **Consumers Legal Remedies Act (CLRA)** - *CA Civil Code §§ 1750 et seq.*

  But frequently based on alleged violations of federal laws (*e.g.,* FDCA)

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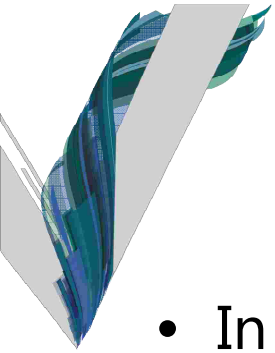
IS PREEMPTION A POTENTIAL DEFENSE?

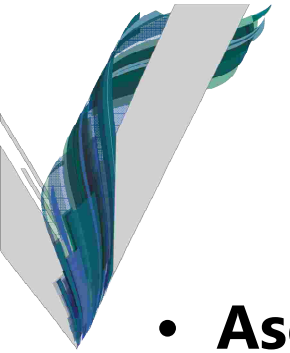
- Federal preemption of state law is a potential defense in food & dietary supplement labeling lawsuits
- FDCA/NELA contain express preemption provisions
- States are prohibited from imposing requirements relating to food that are not "identical" to an applicable federal food labeling standard
  - The words of the federal and state laws need not be identical—The question is whether the obligations differ

- USDA approves certain meat and poultry labels
- Be careful of required language vs. permitted language



USE OF CONSUMER SURVEYS

- In a lawsuit alleging false or misleading advertising, is there a dispute over what the advertisement (or a disclaimer) means to consumers?
  - Hiring an expert to conduct a well-designed survey of consumer perceptions may be an option
    - Do not attempt to conduct the survey on your own– you will need an expert who knows how to appropriately design and conduct the survey
      - Questions must not lead, the presentation to survey participants is of key importance, respondent base should not be biased
    - Be prepared to get results that are negative (may harm your position)



EXPLOIT CLASS ACTION WEAKNESSES

- **Ascertainability** – plaintiffs required to present an available method to identify class members based on objective criteria
- **Commonality** – required to show that there are questions of law or fact common to the class
- **Typicality** - required to show that the claims or defenses of the representative parties are typical of the claims or defenses of the class

WHAT MOTIVATES COURTS/JURIES?

- Go back to first principles
  - The "Why" is key
- Reasonableness of actions taken by company
- Reasonableness of claims made by plaintiff

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QUESTIONS??

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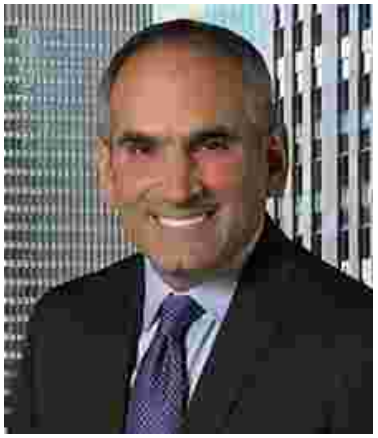

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