Strategies to Level the Playing Field

Moderator: John Claud, Assistant Director, Consumer Protection Branch, DOJ

Panelists: Lisa Dwyer, Partner, King & Spalding and Charles Jolly, Of Counsel, Baker Donelson

While Mr. Claud appears today in his official capacity,
his views and analyses are not necessarily intended to impart any formal policies of the Department of Justice.

Consumer Protection Branch

- **Main DOJ component of approximately 75 prosecutors & civil enforcement attorneys.**
- **Office here in Washington; travels to and works with USAOs in all 94 Federal Districts.**
- **Leads DOJ efforts to enforce criminal and civil laws that protect Americans' health, safety, economic security, and identity integrity.**
  - **Titles 18 and 21 Offenses**
  - **Primary DOJ authority over FDCA and FTCA (JM 4-1.313.8-9)**
- **Represents the FDA, FTC and other consumer protection agencies in defensive litigation.**
- **https://www.justice.gov/civil/consumer-protection-branch**

The Problem: Unlevel Playing Fields

- FDA has a daunting task
  - FDA-regulated products account for 25¢ of every dollar spent by consumers annually
- FDA has inadequate resources to police all FDCA violators
- When a competitor violates the law, it can
  - Jeopardize law-abiding companies' ability to recoup investment
  - Put the public at risk

Traditional Strategies Often Inadequate

- CPs cannot be used to request enforcement actions
  - CPs can ask FDA to issue, amend, or revoke, a regulation or order, or to take or refrain from taking any other "administrative action"
  - "Administrative actions" do not include "enforcement actions" – 21 C.F.R. §§ 10.30(k), 10.25(a), 10.3
- Trade complaints often do not work
  - FDA has competing priorities and often focuses on violations that present the largest risks to public health
  - FDA "*is treading lightly in its enforcement of advertising regulations because of First Amendment concerns*." Pink Sheet, 9/23/18 (citing Dr. Woodcock)

NO PRIVATE CAUSE OF ACTION UNDER THE FDCA

And the FDA Regulated Industry was Different as well:

The 1938 Act Introduced the Concept of "New Drugs"

- Concern that Inconsistencies would arise if parties other than FDA were litigants.
- Concerns that only FDA had the necessary expertise to coherently regulate pharmaceutical, food and cosmetic products.

21 U.S. Code § 337. Proceedings in name of United States; provision as to subpoenas.

(a) Except as provided in subsection (b) of this section, all such proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States. Subpoenas for witnesses who are required to attend a court of the United States, in any district, may run into any other district in any proceeding under this section.

(b)(1) A State may bring in its own name and within its jurisdiction proceedings for the civil enforcement, or to restrain violations, of section 341, 343(b), 343(c), 343(d), 343(e), 343(f), 343(g), 343(h), 343(i), 343(k), 343(q), or 343(r) of this title if the food that is the subject of the proceedings is located in the State.

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What in FDA's World has Changed?

(a lot)

Importantly:

- The 1962 Amendments (and DESI)
- The Review of Over-the-Counter ("Monograph") Drugs
- The Medical Device Amendments
- DSHEA
- The Size, Shape and Personality of the Regulated Industry Considered as a Whole

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Emergence of ‘Flying Under the Radar’ As a Regulatory Strategy

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Example

21 CFR 350.50. Labeling of antiperspirant drug products.

(d) *Directions.* The labeling of the product contains the following statement under the heading “Directions”: “apply to underarms only”.

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“Wishful Thinking” regarding FD&C Act Amendment

- Follow the *Qui Tam* model and provide notice to FDA
- Provide opportunity for FDA to intervene
- Focus on injunctive relief and attorney’s fees in appropriate cases -- not damages
- Provider a mechanism for an inexpensive and prompt agreed resolution
- Focus on Dietary Supplements, Monograph Drugs, Consumer Facing Communications

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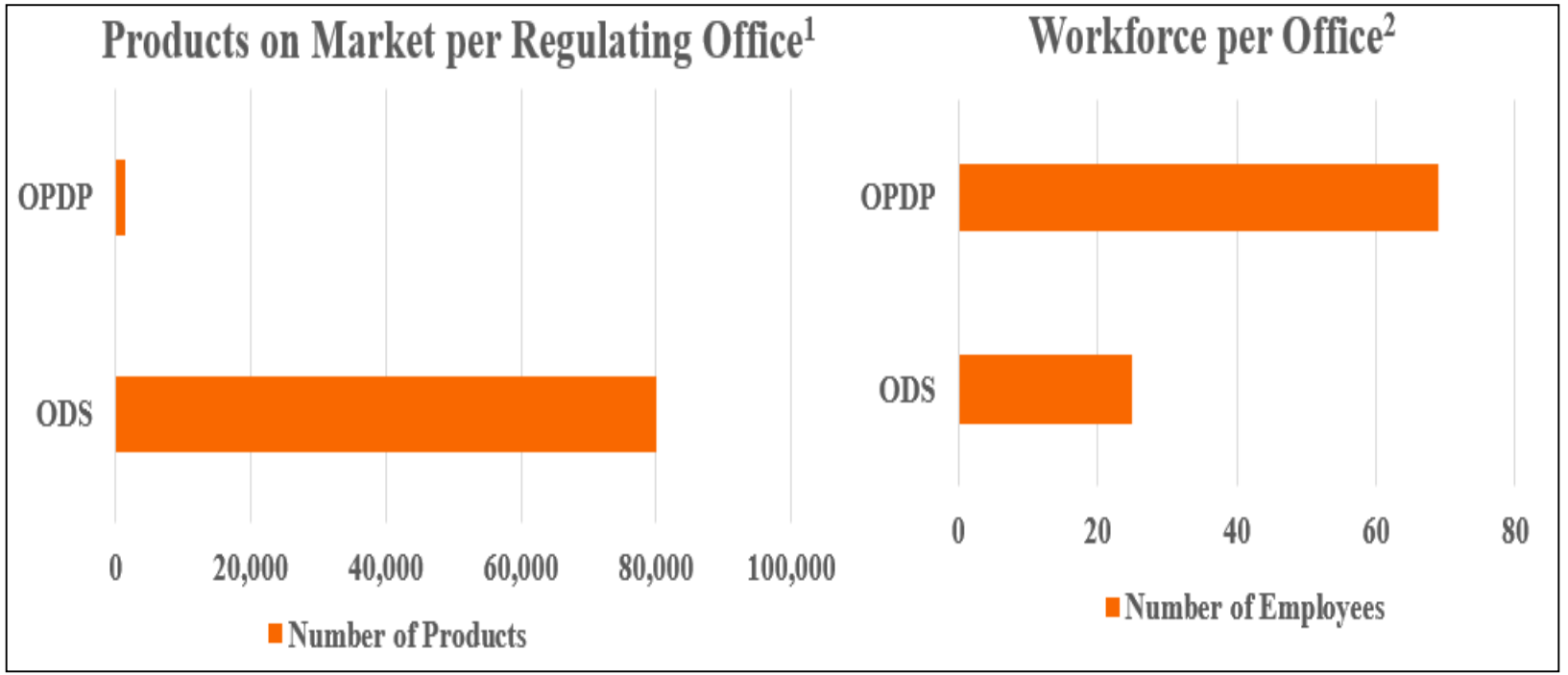
POTENTIAL LITIGATION SOLUTIONS

LANHAM ACT

UNFAIR TRADE PRACTICE STATUTES

Dietary Supplements: More Resources Imperative



POM Wonderful v. Coca-Cola Co.

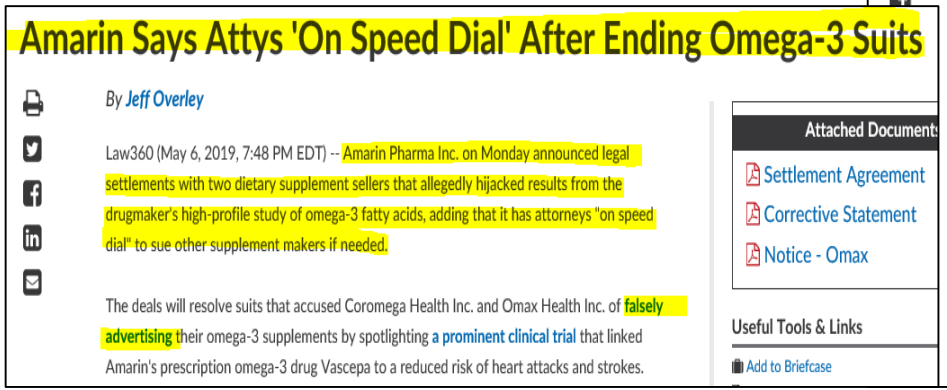
- Holding:
  - FDCA does not preclude a private party from bringing a Lanham Act claim in district court challenging a misleading food label regulated under the FDCA. *POM Wonderful LLC v. Coca-Cola Co.*, 134 S.Ct. 2228, 2241 (2014)
- Impact:
  - Lanham Act challenges are now being brought for more than just false/ misleading statements about competitor's products

Competitors Are Taking Matters Into Their Own Hands

Amarin Seeks ITC Action Against Products 'Cloaked' As Dietary Supplements

Going After Those Whose Don't 'Play By The Rules'

30 Aug 2017 | NEWS



Amarin Says Attys 'On Speed Dial' After Ending Omega-3 Suits

By *Jeff Overley*

Law360 (May 6, 2019, 7:48 PM EDT) -- Amarin Pharma Inc. on Monday announced legal settlements with two dietary supplement sellers that allegedly hijacked results from the drugmaker's high-profile study of omega-3 fatty acids, adding that it has attorneys "on speed dial" to sue other supplement makers if needed.

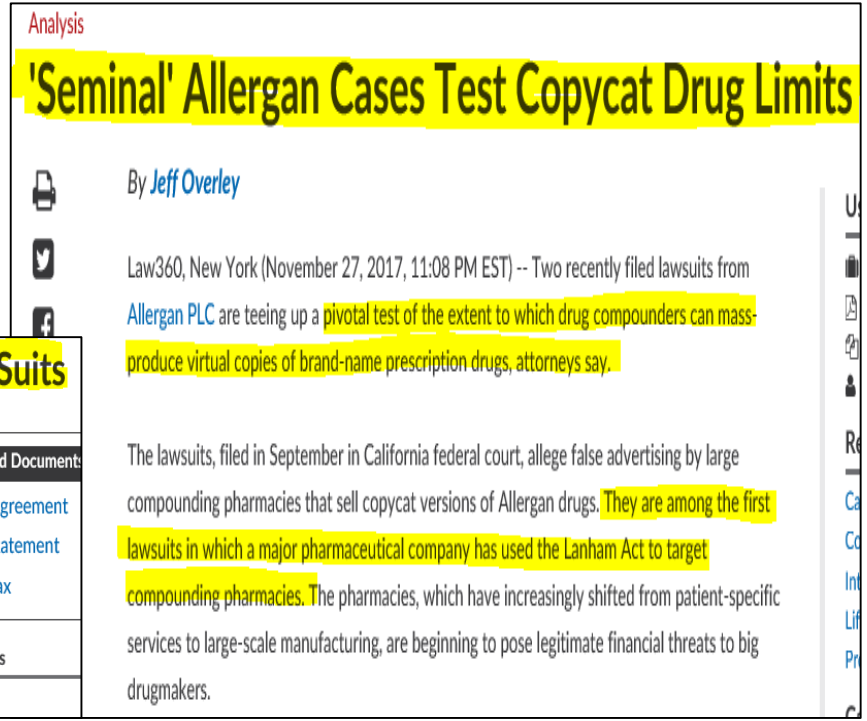
The deals will resolve suits that accused Coromega Health Inc. and Omax Health Inc. of falsely advertising their omega-3 supplements by spotlighting a prominent clinical trial that linked Amarin's prescription omega-3 drug Vascepa to a reduced risk of heart attacks and strokes.

Attached Documents

- Settlement Agreement
- Corrective Statement
- Notice - Omax

Useful Tools & Links

Add to Briefcase



Analysis

'Seminal' Allergan Cases Test Copycat Drug Limits

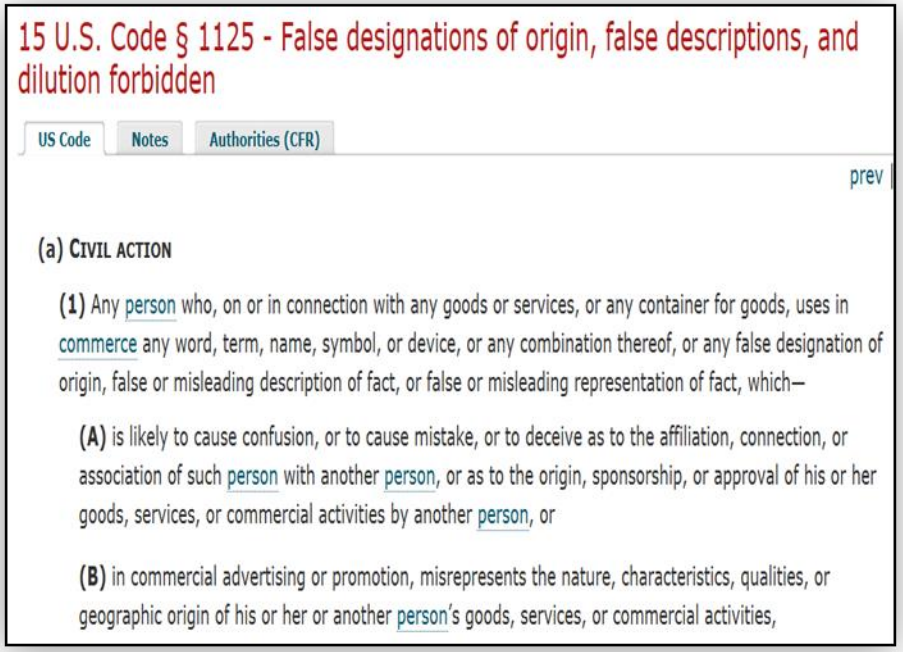
By *Jeff Overley*

Law360, New York (November 27, 2017, 11:08 PM EST) -- Two recently filed lawsuits from Allergan PLC are teeing up a pivotal test of the extent to which drug compounders can mass-produce virtual copies of brand-name prescription drugs, attorneys say.

The lawsuits, filed in September in California federal court, allege false advertising by large compounding pharmacies that sell copycat versions of Allergan drugs. They are among the first lawsuits in which a major pharmaceutical company has used the Lanham Act to target compounding pharmacies. The pharmacies, which have increasingly shifted from patient-specific services to large-scale manufacturing, are beginning to pose legitimate financial threats to big drugmakers.

Lanham Act

- 15 U.S.C. § 1125
  - Prohibits false/misleading advertising and unfair competition
  - Proving statement is misleading can require consumer survey (expensive)
  - Relief includes injunction, damages, and potentially attorneys fees



15 U.S. Code § 1125 - False designations of origin, false descriptions, and dilution forbidden

US Code | Notes | Authorities (CFR)

prev |

(a) CIVIL ACTION

(1) Any person who, on or in connection with any goods or services, or any container for goods, uses in commerce any word, term, name, symbol, or device, or any combination thereof, or any false designation of origin, false or misleading description of fact, or false or misleading representation of fact, which—

(A) is likely to cause confusion, or to cause mistake, or to deceive as to the affiliation, connection, or association of such person with another person, or as to the origin, sponsorship, or approval of his or her goods, services, or commercial activities by another person, or

(B) in commercial advertising or promotion, misrepresents the nature, characteristics, qualities, or geographic origin of his or her or another person's goods, services, or commercial activities,

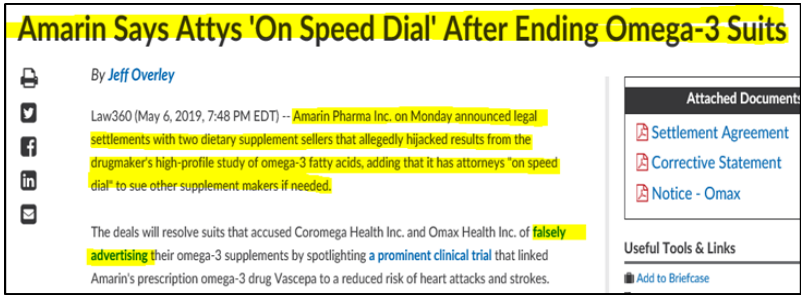
California

- Unfair Competition Law (UCL)
  - Remedy – injunctive relief (not damages)
  - Relief is limited to California
- Sherman Law
  - FDCA Analog
  - Similar Definition of "Drug"
  - Prohibits Marketing of Drugs that Have Not Been Approved by FDA (or CA)

"[The UCL] borrows violations of other laws and treats them as unlawful practices that the unfair competition law makes independently actionable."

Amarin-UCL/Lanham Act

- "REDUCE-IT™
  - Vascepa® a highly potent FDA-approved drug *derived* from fish oil reduced the risk of major cardiovascular events by ~25% in *at-risk patients* taking *statin-therapy*
- Coromega/Omax *falsely* claimed results of REDUCE-IT showed their fish oil dietary supplements reduced major cardiovascular risk
- UCL/Sherman Law – *disease* claims render products unapproved drugs in violation of UCL/Sherman Law
- Lanham Act – disease claims unsupported (can't be extrapolated)/ contradicted by weight of evidence
- Favorable settlements – defendants stopped making statements/corrective advertising



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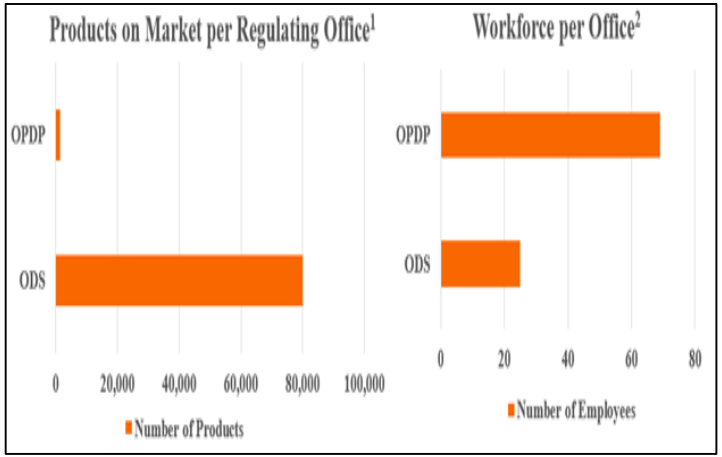

Common Defenses

- Preemption – FDCA preempts *UCL/Sherman Law* claims
  - Theory – plaintiffs are improperly seeking to enforce the FDCA, in violation of 21 U.S.C. § 337(a)
  - Typically Unsuccessful
    - Claims *not preempted* so long as claims under UCL/Sherman Law parallel the FDCA's
  - Defendants in Amarin cases did not bother

Common Defenses (cont.)

- Primary Jurisdiction Doctrine – Courts have *discretion* to dismiss/stay the case if they think FDA should decide issue
  - Theory – scientific/technical questions best left to FDA
  - Courts will find doctrine does *not* apply if:
    - Resolution of issue does not require scientific/technical expertise
    - FDA is not planning to decide the issue, such that the court decision is necessary to redress unfair competition
  - Equitable doctrine – courts have broad discretion to apply or not

Allergan-UCL/Lanham Act

- Typically, “drugs” subject to FDA approval
- Section 503A/503B provide narrow exemptions
  - 503A – can compound for identified individual who cannot tolerate commercial drug, pursuant to prescription
  - 503B – can compound drugs for healthcare facilities (without a prescription), so patients can be who have special medical needs can be treated quickly
- Defendants mass manufactured drugs that competed with Allergan’s w/o complying with 503A/503B
- Allergan favorably settled one case
- Allergan won other case (got injunctive relief, but small amount of damages)

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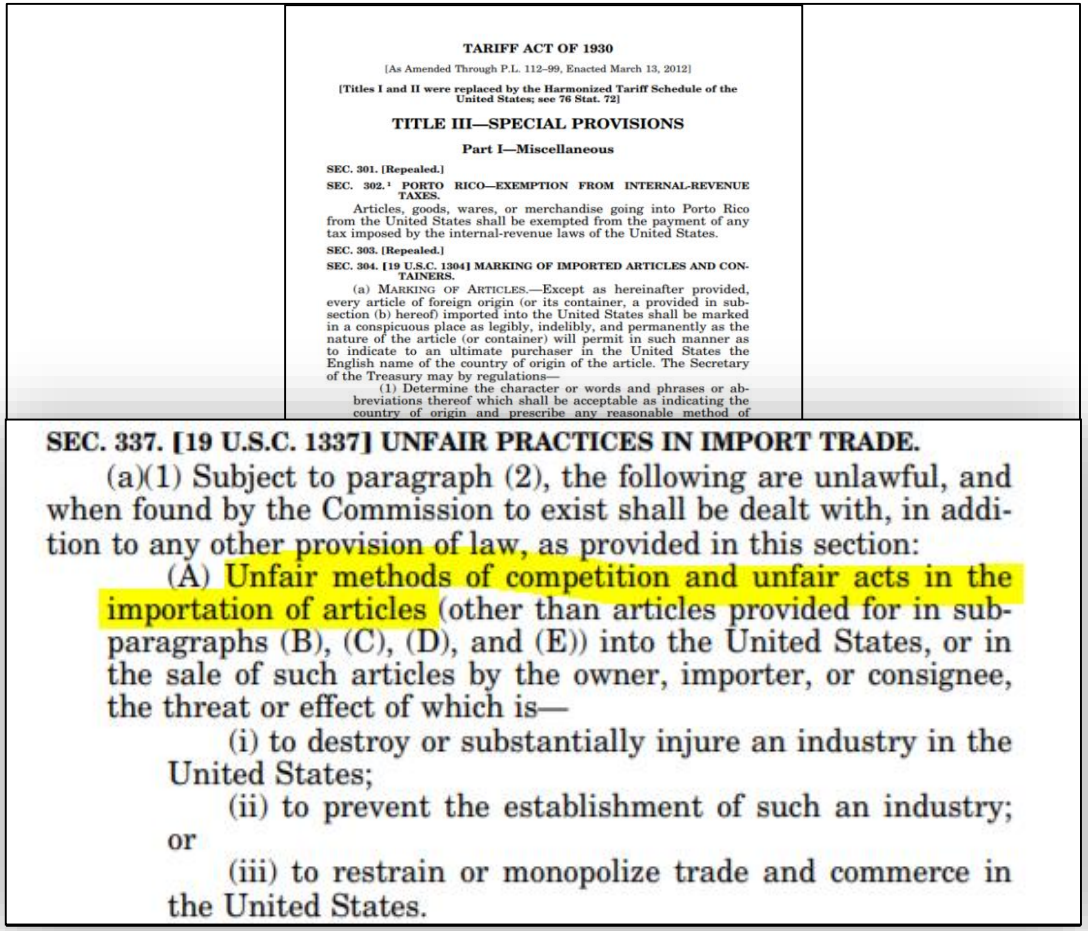
Section 337 of the Tariff Act

- **Similar strategy can be used to combat counterfeits/ unlawfully diverted foreign products**
- Prohibits unfair competition in the <u>importation</u> of goods into the United States



TARIFF ACT OF 1930

[As Amended Through P.L. 112–99, Enacted March 13, 2012]

[Titles I and II were replaced by the Harmonized Tariff Schedule of the United States; see 76 Stat. 72]

TITLE III—SPECIAL PROVISIONS

Part I—Miscellaneous

SEC. 301. [Repealed.]

SEC. 302.[1] PORTO RICO—EXEMPTION FROM INTERNAL-REVENUE TAXES.

Articles, goods, wares, or merchandise going into Porto Rico from the United States shall be exempted from the payment of any tax imposed by the internal-revenue laws of the United States.

SEC. 303. [Repealed.]

SEC. 304. [19 U.S.C. 1304] MARKING OF IMPORTED ARTICLES AND CONTAINERS.

(a) MARKING OF ARTICLES.—Except as hereinafter provided, every article of foreign origin (or its container, a provided in subsection (b) hereof) imported into the United States shall be marked in a conspicuous place as legibly, indelibly, and permanently as the nature of the article (or container) will permit in such manner as to indicate to an ultimate purchaser in the United States the English name of the country of origin of the article. The Secretary of the Treasury may by regulations—

(1) Determine the character or words and phrases or abbreviations thereof which shall be acceptable as indicating the country of origin and prescribe any reasonable method of

SEC. 337. [19 U.S.C. 1337] UNFAIR PRACTICES IN IMPORT TRADE.

(a)(1) Subject to paragraph (2), the following are unlawful, and when found by the Commission to exist shall be dealt with, in addition to any other provision of law, as provided in this section:

(A) Unfair methods of competition and unfair acts in the importation of articles (other than articles provided for in subparagraphs (B), (C), (D), and (E)) into the United States, or in the sale of such articles by the owner, importer, or consignee, the threat or effect of which is—

(i) to destroy or substantially injure an industry in the United States;

(ii) to prevent the establishment of such an industry; or

(iii) to restrain or monopolize trade and commerce in the United States.

How Does Section 337 Work?

- Administered by the U.S. International Trade Commission (ITC)
- Proceeds based on Complaint
- ITC investigations are typically completed within 16 months

Remedies Under Section 337

- Cease/Desist (“C/D”) Orders for Product in U.S.
- Penalties for Failure to Comply with C/D Orders
- Border Remedies
  - Limited Exclusion Orders (LEOs)
  - General Exclusion Orders (GEOs)

Application of 337 to Stop Diversion

- *Certain Potassium Chloride Powder Products*

- Valeant argued that a Canadian company was engaging in false advertising by suggesting that its drug was FDA-approved by promoting the product with claims such as, “follow[s] strict FDA guidelines and procedures.”
- In July 2016, the ITC decided to institute an investigation into whether the Canadian company was engaged in “unfair methods of competition and unfair acts” in violation of Section 337.
- The Parties ultimately settled in the Fall of 2016.

Key Advantages of Utilizing Section 337

- A proactive strategy to protect the brand/business
- Federal remedy
- Border-exclusion remedies
- Expedited Relief (16-month clock)

Pros/Cons of Private Actions

- Pros
  - Tool to stop unfair practices
  - Injunction can minimize impact of defendant's unfair practice on business
  - Can send a strong message to other competitors
  - Can send a message to payors

- Cons
  - Litigation can be resource-intensive and protracted
  - May not be cost-effective to seek more than nominal damages
  - Not a silver bullet
  - May trigger counter-claims

IMPACT OF PRIVATE ACTIONS ON GOVERNMENT

FDA/HHS (Sometimes) Have Encouraged Lawsuits

FDA

Advertising Enforcement: US FDA Content To Let Competitors 'Duke It Out,' Woodcock Says

23 Sep 2018 | ANALYSIS

by Derrick Gingery

@dgingery | derrick.gingery@informa.com

Executive Summary

Office of Prescription Drug Promotion is focused on most egregious issues where human safety is at stake; CDER's Woodcock also says that First Amendment issues are affecting enforcement.

HHS

Trump Administration's Rx Drug Price Disclosure Reg Seen As Unworkable

21 Oct 2018 | ANALYSIS

by Brenda Sandburg

@brendasandburg | Brenda.Sandburg@informa.com

A striking feature of the proposed rule is the virtual absence of any penalty for non-compliance,

CMS says no other HHS-specific enforcement mechanism is proposed in the rule. "However, we anticipate that the primary enforcement mechanism will be the threat of private actions under the Lanham Act" for unfair competition in the form of false or misleading advertising, the rule says.

Effects on Enforcement?

- **FDA and DOJ work as partners**
- **Barrier to enlisting enforcement action: you need to convince us BOTH**

Effects on Enforcement?

- New nature of off-label enforcement after *Coronia*?
- FDA and DOJ are "very wary of wading into the First Amendment" unless perceived violations involve "egregious" behavior "where health and safety might be involved."
- Is the case solely one of commercial speech/First Amendment?
- Adequate Directions for Use → more modern focus: Data manipulation / cherry picking

Effects on Enforcement?

- **October Guidance on Guidance – no enforcement actions without clear statutory/regulatory violation**

- **Long-standing DOJ policy – we don't bring enforcement cases solely on guidance.**

Effects on Enforcement?

Enforcement touchstones:

- Consumer harm
- Undeclared ingredients
- Insanitary conditions
- Fraud

Effects on Enforcement?

- **Dietary Supplements – post-market regulation makes enforcement litigation expensive, resource intensive.**
  - **Assessment within those constraints**

- **Compounding Pharmacies – enforcement priorities are insanitary conditions, not commercial infringement**
  - **Adulteration v. misbranding**

Effects on Enforcement?

- A *de facto* referral system?
- How does government enforcement help the private case?
- Are there synergies with government enforcement priorities?
- Short term or long term?
- Confluence of conditions?

Effects on Enforcement?

- How does a private case dovetail with enforcement priorities?
- How fully formed is the civil case?
- How can government lawyers assess the merits of the case?
- How does it get before FDA and DOJ? What mechanism will best draw government attention?

Effects on Enforcement?

- **How does the False Claims Act model inform a private right of action under the FDCA?**

FDCA Private Right of Action

- **Questions?**