Criminal Enforcement

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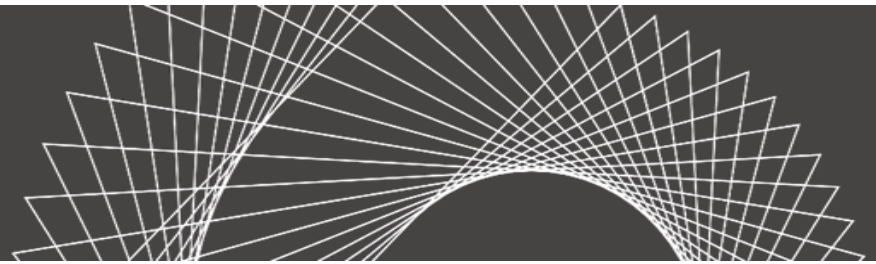
Food Cases and Factors:

Criminal Liability



Akin Gump
STRAUSS HAUER & FELD LLP

March 21, 2019

Howard Sklamberg
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Overview

- Park Doctrine Background
- Park Doctrine Criteria
- Recent Criminal Prosecutions in Food Industry
  - *Peanut Corporation of America* (2013)
  - *ConAgra* (2013)
  - *Quality Egg* (2014)

Park Doctrine Background

- Government may prosecute corporate officials for alleged violations of the FDCA.
  - Does not require proof that the corporate official acted with intent or even negligence, and even if such corporate official did not have any actual knowledge of, or participation in, the specific offense.
  - Theory derived from United States v. Park, 421 U.S. 658 (1975).
  - Focus on deterring continued FDCA violations by holding individuals legally responsible. First-time misdemeanor prosecution, with subsequent felony prosecution possible
  - In some cases, misdemeanor conviction may serve as the basis for debarment by FDA.

- Open question as to whether it effectively renders FDCA violations strict liability crimes for corporate officials in positions of responsibility or authority.
  - 8th Circuit in *U.S. v. DeCoster* (2016): each judge on 3-judge panel wrote separate opinion hinging on this issue
  - Majority Opinion, Judge Murphy: Officer liability under the FDCA not the equivalent of vicarious liability
    - Officer not held accountable for acts/omissions of others, but for "his own failure to prevent or remedy the conditions which gave rise to the charges against him."
  - Concurring, Judge Gruedner: Not vicarious liability; defendants negligent and thus responsible for own failures to exercise reasonable care to prevent introduction of adulterated food into interstate commerce.
  - Dissent, Judge Beam: Would have required defendants to have mens rea; negligence is insufficient.

Park Doctrine Referral Factors

- FDA has identified several criteria for referral of a case for prosecution under the Park Doctrine.
- In addition to considering the ***individual's position in the company*** and ***relationship to the violation***, and ***whether the official had authority to correct/prevent the violation***, FDA considers:
  1. whether the violation involves ***actual or potential harm to the public***;
  2. whether the violation is ***obvious***;
  3. whether the violation reflects a ***pattern of illegal behavior*** and/or ***failure to heed prior warnings***;
  4. whether the violation is ***widespread***;
  5. whether the violation is ***serious***;
  6. the quality of the ***legal and factual support*** for the proposed prosecution; and
  7. whether the proposed prosecution is a ***prudent use of agency resources***.

Park Doctrine Cases in Food Sphere

Peanut Corporation of America

- Peanut Corporate of America executives indicted in 2013.
- What Happened:
  - Federal investigation into Peanut Corporate of America (PCA) began in 2008, seeking to identify source of Salmonella outbreak
  - Nationwide salmonella outbreak traced back to PCA, leading to extensive recall of company's products
  - More than 700 people reported salmonella poisoning; at least 9 deaths
- Willfulness
  - Intent to defraud or mislead (deliberate, coordinated food safety process violations, misrepresentations to customer about safety of products, falsifying microbiological test results)
  - Obstruction of justice (lying to federal investigators, concealing relevant information)
- Result
  - Most severe criminal sentence imposed to date in food safety case (e.g., president sentenced to 28 yea in prison)
  - Sentences upheld by 11th Circuit in 2018

ConAgra

- Criminal charges brought against ConAgra in 2014.
- What Happened
  - Salmonella outbreak in 2006-2007, due to contaminated peanut butter distributed by ConAgra subsidiary
  - Sickened approximately 700 people
- Willfulness
  - Falsifying records, lying to FDA, knowingly putting consumers at risk
  - Aware of some risk of contamination, and after testing destroyed contaminated product in facility
  - Did not fully correct conditions in facility until after 2007 outbreak
- Result
  - Guilty plea by ConAgra subsidiary to misdemeanor FDCA violation
  - $8 million criminal fine; forfeit assets of $3.2 million (largest fine at that time paid in a food safety case)

Quality Egg

- Criminal charges brought against Quality Egg and corporate officers in 2014.
- What Happened:
  - 2010 Salmonella outbreak traced to Quality Egg
  - Approximately 56,000 people sickened
  - Company recalled hundreds of millions of shell eggs produced at Quality Egg facilities

- Willfulness
  - Bribery of public official
  - Introducing misbranded food into interstate commerce with intent to defraud or mislead
- Result
  - Company pleaded guilty to FDCA violations
  - Executives charged (and pleaded guilty) despite the fact that they did **not** have knowledge of contamination.
    - 3-month sentence, upheld by 8th Circuit
    - Supreme court denied certiorari.

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Food and Drug Law Institute
Food Enforcement and Compliance Conference

"The Criminalization of Dietary Supplement Enforcement"

March 21, 2019

Washington, D.C.

Jack Wenik, Esq.
Member of the Firm
Epstein, Becker & Green

The Regulation of Dietary Supplements/Ingredients

- Old Regulatory Structure Mimicked that for Drugs Requiring Pre-market FDA Approval of Products and Labels.[1]
- Passage in 1994 of the Dietary Supplement Health and Education Act ("DSHEA") Dramatically Curtailed Regulatory Oversight of Dietary Supplements/Ingredients.
- Dietary Supplements are "Foods" and are Presumed Safe.[2]
- To Take Action Against a Dietary Supplement, the Government Must Show it Presents an "Unreasonable Risk of Illness or Injury."[3]

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[1] See 21 C.F.R. § § 101.13-14; 101.70; 21 U.S.C. § 355.

[2] See 21 U.S.C. § 350b(a); 21 U.S.C. § 342(f)(1).

[3] See 21 U.S.C. § 342(f)(1)(A).

What is a Dietary Supplement/Ingredient?

- (ff) The Term "dietary supplement" –

  (1) means a product (other than tobacco) intended to supplement the diet that bears or contains one or more of the following dietary ingredients:

  (A) a vitamin;
  (B) a mineral;
  (C) an herb or other botanical;
  (D) an amino acid;
  (E) a dietary substance for use by man to supplement the diet by increasing the total dietary intake; or
  (F) a concentrate, metabolite, constituent, extract, or combination of any ingredient described in clause (A), (B), (C), (D), or (E); [1]

- To Avoid Being considered a "New Dietary Ingredient," Subject to Stricter Regulation, The Substance in Question Must Meet the Above Criteria and Have Been in the Food Supply before October 15, 1994.

[1] See 21 U.S.C. § 321(ff).

Government Strategies Against Dietary Supplements

- Government Often Claims a Dietary Ingredient is an Unapproved Food Additive.
- Government Often Claims a Dietary Supplement's Labeling or Advertising has made a Disease Claim, thereby Making it An Unapproved Drug.[1]
- Government Often Claims a Dietary Supplement is "Misbranded" or "Adulterated."

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[1] Dietary Supplements Can Make "Structure/Function Claims" 21 U.S.C. § 343(r)(6).

Criminal Statutes Used Against Dietary Supplements

- Criminal Cases Will Often Allege a Mail or Wire Fraud Scheme Involving the Sale of Dietary Supplements.[1]
- Government Cases will Sometimes Allege that a Dietary Supplement/Ingredient is Actually a Misbranded Drug.[2]
- It is Also Frequently a Tactic of the Government that it Will Allege that a Dietary Supplement or Ingredient is Misbranded or Adulterated.[2]
- In Many of These Cases the Government's Theory is that the Dietary Supplement Product has been "Spiked" with an Illicit Drug of Some Sort.

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[1] 18 U.S.C. § § 1341; 1343.

[2] 21 U.S.C. § 352(a).

[3] 21 U.S.C. § § 331(a); 333(a)(1); 331(a)(2); 342(a)(1).

The Myth of the "Dangers" of Dietary Supplements

- The FDA has Resented the Enactment of DSHEA and the Curtailment of its Regulatory Oversight of Dietary Supplements.
- The Agency has, at Times, Implied that "Unregulated" Dietary Supplements Present a Danger to the Public.
- Scientific Data Do Not Support This Assertion. For Example, in a Study Which Looked at 2.5 Years' Worth of Dietary Supplements' Adverse Event Reports, Only 203 of 41,121 Reports Were Found to be "Severe."[1]
- Compare, For Example, Acetaminophen, Which Accounts for 78,414 Emergency Room Visits Per Year.[2]

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[1] *Schmitz*, et. al, *Serious Adverse Events Reported with Dietary Supplement Use in the United States; A 2.5 Year Experience*, Journal of Dietary Supplements, December, 2018.

[2] *Bunitz*, et. al, *Emergency Visits for Overdoses of Acetaminophen-containing Products,* American Journal of Preventive Medicine, June 2011.

The Government's Periodic "Crackdowns" on Dietary Supplements

- The Government Occasionally Trumpets its Enforcement Actions Against the Dietary Supplement Industry.
- For Example, On November 17, 2015, the Department of Justice Widely Publicized Criminal/Civil Actions Against 100 Dietary Supplement Companies.
- More Recently, In a February 11, 2019 Statement, FDA Commissioner Gottlieb Stressed the Need to "Modernize" the Regulatory Oversight of Dietary Supplement Companies Since DSHEA, While Simultaneously Announcing Actions Against 17 Dietary Supplement Companies.

The USPLabs Case

- In November 2015, USPLabs and Several Owners/Officers were Indicted Regarding the Sales of two Widely Used Dietary Supplements, Jack3d and OxyElite Pro.
- The Government's Allegations Included that the Products Contained Dangerous Ingredients Which Purportedly Caused Liver Disease/Failure.
- As Part of its Recent Plea Agreement, USPLabs Agreed to Cease all Business Activities and Liquidate its Inventory.[1]
- As Part of Their Plea Agreements, USPLabs Owners Agreed to a Ten Year Ban from the Dietary Supplement Industry.[2]

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[1] *United States v. USPLabs, LLC*, No. 3:15-CR-00496-L, Doc. 694.

[2] *United States v. Jacobo Geissler*, No. 3:15-CR-00496-L, Doc. 670.

The Hi-Tech Pharmaceuticals, Inc. Case

- Company Indicted for, Among Other Things, Marketing a Product Produced from Red Yeast Rice.
- Government's Theory is That a Constituent of Red Yeast Rice, Monacolin K, is the Equivalent of the Prescription Cholesterol Medication Lovastatin, Thereby Making the Product a Misbranded Drug.
- There Have Been No Prior Criminal Prosecutions for the Sale of Red Yeast Rice.
- The Charges Also Include Allegations that Some Hi-Tech Pharmaceuticals, Inc.'s Products Contained Steroids, Thereby Making Them Misbranded Drugs.
- However, The FDA's Own Testing Only Detected Steroids in Trace Amounts

Strategies for Dietary Supplement Companies

- Enforcement Activity Against Dietary Supplement Companies is becoming as Aggressive as that in Healthcare.
- Accordingly, Dietary Supplement Companies Should follow what Most Healthcare Companies do:
  - Promulgate Written Compliance Policies
  - Hire a Compliance Officer
  - Conduct Regulatory/Compliance Training for Senior Management and Board Members
  - Purchase Appropriate Insurance: D&O; Investigation Coverage

Questions?

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DOJ Food and Supplement Safety Enforcement Priorities

John Claud
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Views and analysis expressed here are personal, and are not meant to impart any policy of the United States Department of Justice

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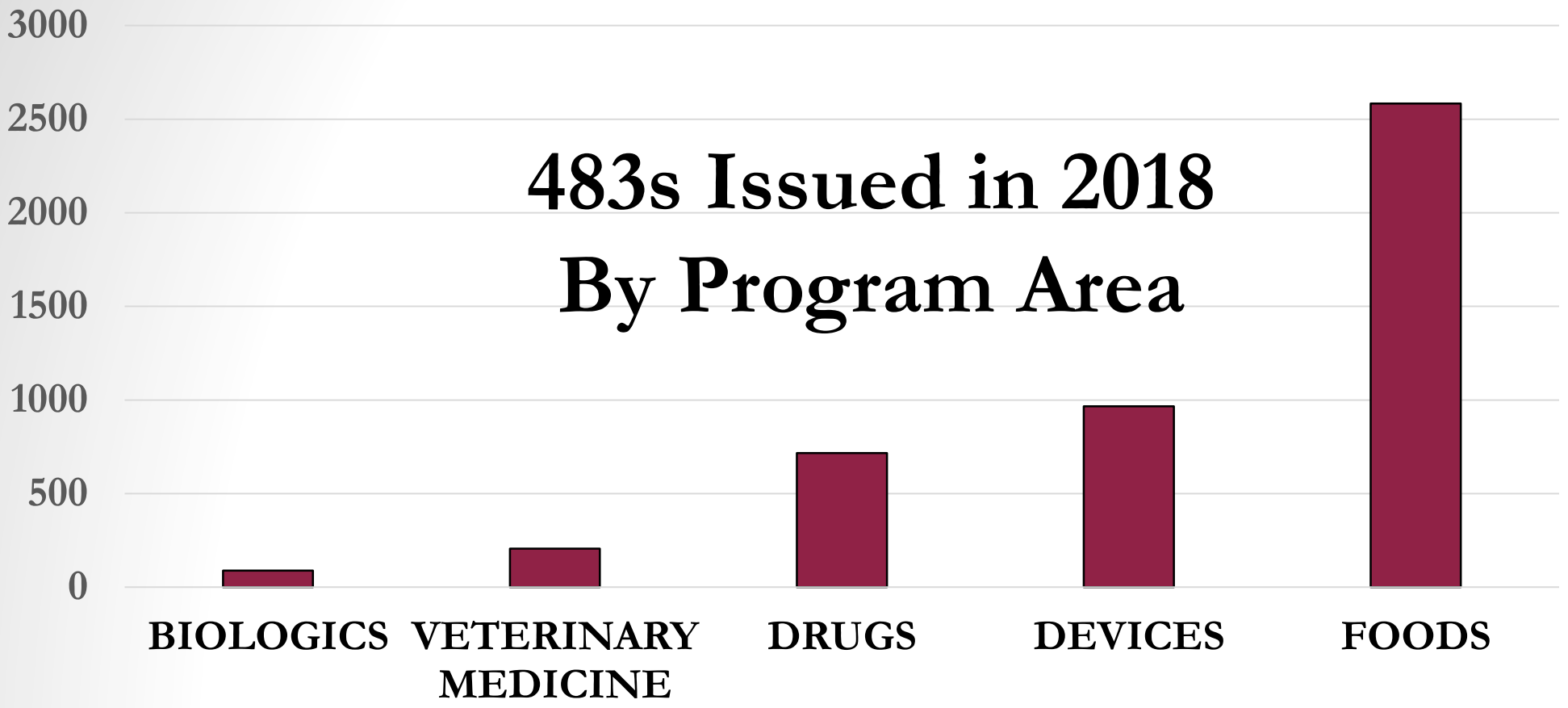
Prioritization and Management – Where to Expend Prosecutorial Resources?



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Recent DOJ Enforcement Actions – Civil vs. Criminal

CIVIL INJUNCTIONS

- Foo Yuan (E.D.N.Y.) – deficient cleanliness and hygienic
- Global Marketing (N.D.Ill.) – CGMP, drug claims
- Euroline Foods (E.D.N.Y.) - chronic insanitary conditions
- Meech Dairy Farm (D. Minn.) - above-tolerance drug residue

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Recent DOJ Enforcement Actions – Civil vs. Criminal

CIVIL INJUNCTIONS

- Blanchet (C.D.Cal.) – failing to adequately control risk of Listeria
- Vulto Creamery (N.D.N.Y.) – multistate listeriosis outbreak
- Riddhi (E.D.N.Y.) – CGMP
- Parrish (N.D.Ill.) – insanitary conditions
- Syfrett (S.D.Fl.) – did not list active drug ingredients
- EonNutra (D.Colo.) – drug claims

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Recent DOJ Enforcement Actions – Civil vs. Criminal

CRIMINAL

- **Zhang (N.D.Tex.) – mail fraud, smuggling of hidden synthetic stimulants**
- **Xu (N.D.Tex.) – wire fraud, hidden synthetic stimulants**
- **Gao (N.D.Tx.) – mail fraud, smuggling of hidden synthetic stimulants**
- **Parnell (M.D.Ga. / 11th Cir.) – fraud, distribution of contaminated peanuts**
- **Smith (E.D.Wa./9th Cir.) – drug claims for "mineral supplement"**
- **Wright County Egg (S.D. Ia./8th Cir.) – bribing inspector, selling adulterated eggs**

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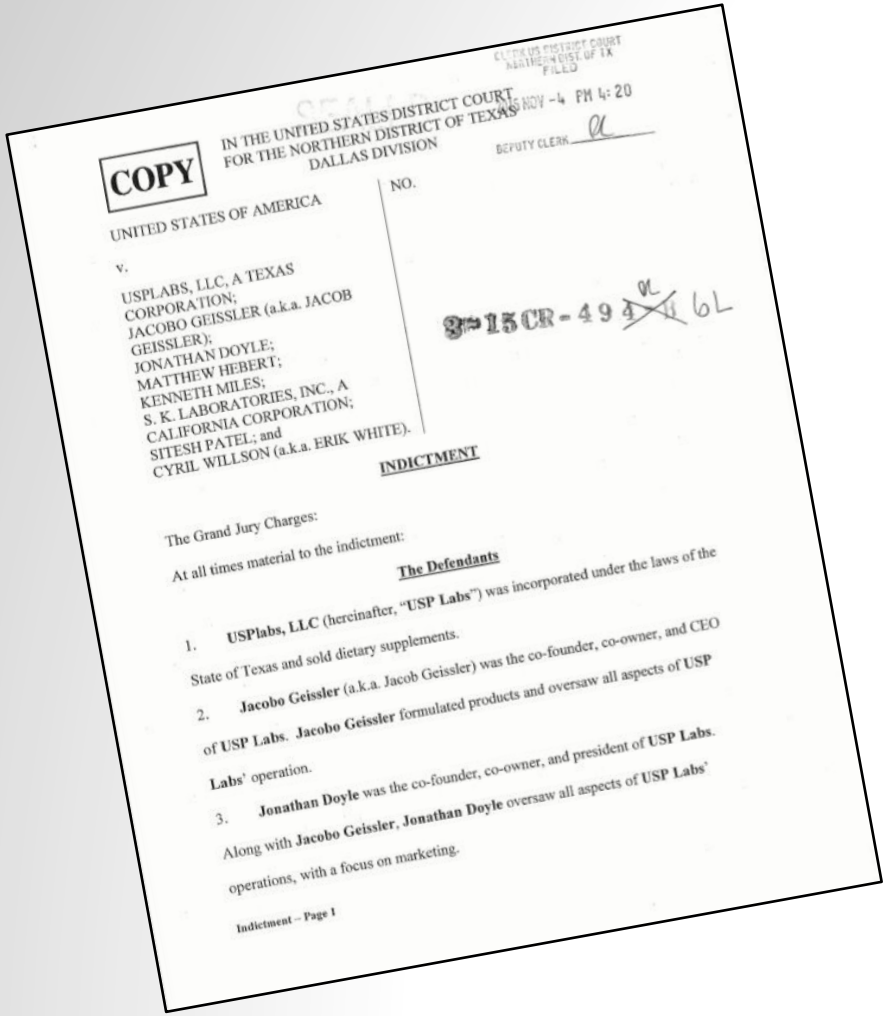
Recent DOJ Criminal Cases



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IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
DALLAS DIVISION

CLERK US DISTRICT COURT
NORTHERN DIST OF TX
FILED
2015 NOV -4 PM 4:20
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UNITED STATES OF AMERICA

v.

USPLABS, LLC, A TEXAS CORPORATION;
JACOBO GEISSLER (a.k.a. JACOB GEISSLER);
JONATHAN DOYLE;
MATTHEW HEBERT;
KENNETH MILES;
S. K. LABORATORIES, INC., A CALIFORNIA CORPORATION;
SITESH PATEL; and
CYRIL WILLSON (a.k.a. ERIK WHITE).

NO.

3-15CR-49

INDICTMENT

The Grand Jury Charges:

At all times material to the indictment:

The Defendants

1. **USPlabs, LLC** (hereinafter, "**USP Labs**") was incorporated under the laws of the State of Texas and sold dietary supplements.

2. **Jacobo Geissler** (a.k.a. Jacob Geissler) was the co-founder, co-owner, and CEO of **USP Labs**. **Jacobo Geissler** formulated products and oversaw all aspects of **USP Labs**' operation.

3. **Jonathan Doyle** was the co-founder, co-owner, and president of **USP Labs**. Along with **Jacobo Geissler**, **Jonathan Doyle** oversaw all aspects of **USP Labs**' operations, with a focus on marketing.

Indictment – Page 1

USPLabs

- Five individual defendants and two companies.
- Conspiracy, Introduction of Misbranded Food into Interstate Commerce.
- OxyElite Pro, recalled in 2013 after users suffered liver injuries
- Defendants imported substances with false and misleading labeling in part to avoid law enforcement and regulatory agency attention.

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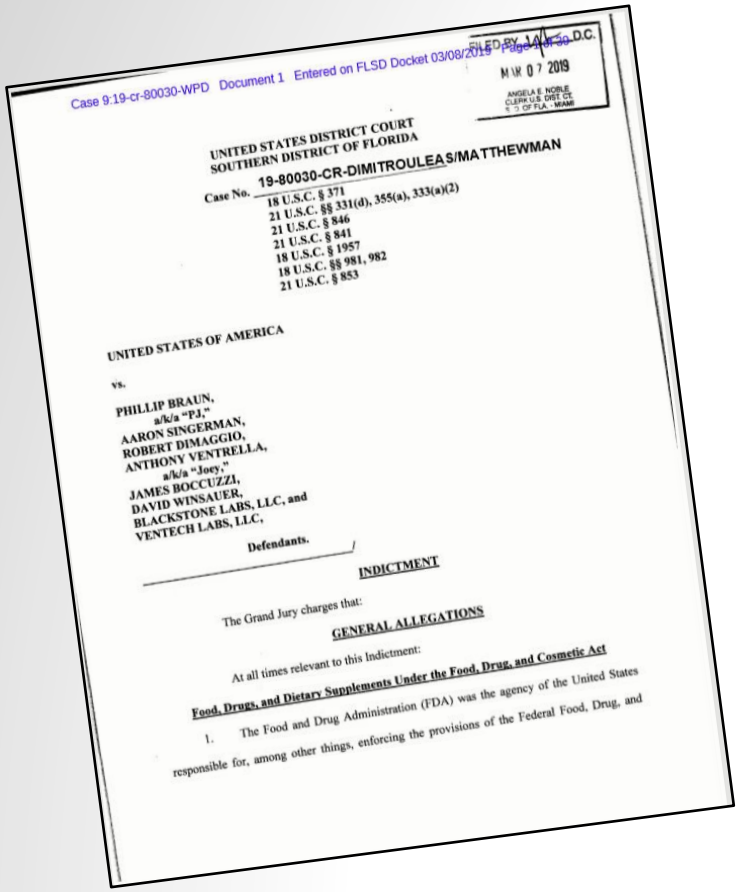
Recent DOJ Criminal Cases



Case 9:19-cr-80030-WPD Document 1 Entered on FLSD Docket 03/08/2019 Page 1 of 30

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ANGELA E. NOBLE
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UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA

Case No. 19-80030-CR-DIMITROULEAS/MATTHEWMAN

18 U.S.C. § 371
21 U.S.C. §§ 331(d), 355(a), 333(a)(2)
21 U.S.C. § 846
21 U.S.C. § 841
18 U.S.C. § 1957
18 U.S.C. §§ 981, 982
21 U.S.C. § 853

UNITED STATES OF AMERICA

vs.

PHILLIP BRAUN,
a/k/a "PJ,"
AARON SINGERMAN,
ROBERT DIMAGGIO,
ANTHONY VENTRELLA,
a/k/a "Joey,"
JAMES BOCCUZZI,
DAVID WINSAUER,
BLACKSTONE LABS, LLC, and
VENTECH LABS, LLC,

Defendants.

INDICTMENT

The Grand Jury charges that:

GENERAL ALLEGATIONS

At all times relevant to this Indictment:

Food, Drugs, and Dietary Supplements Under the Food, Drug, and Cosmetic Act

1. The Food and Drug Administration (FDA) was the agency of the United States responsible for, among other things, enforcing the provisions of the Federal Food, Drug, and

Blackstone/Ventech

- Six people and two Florida corporations were charged.
- Indictment: defendants sold hundreds of thousands of illegal products including anabolic steroids and fraudulently representing products were high-quality, legal dietary supplements.
- Defendants charged with creating illicit manufacturing company, routing sales of illegal products through trusted distributors.
- All defendants are presumed innocent until proven guilty beyond a reasonable doubt.

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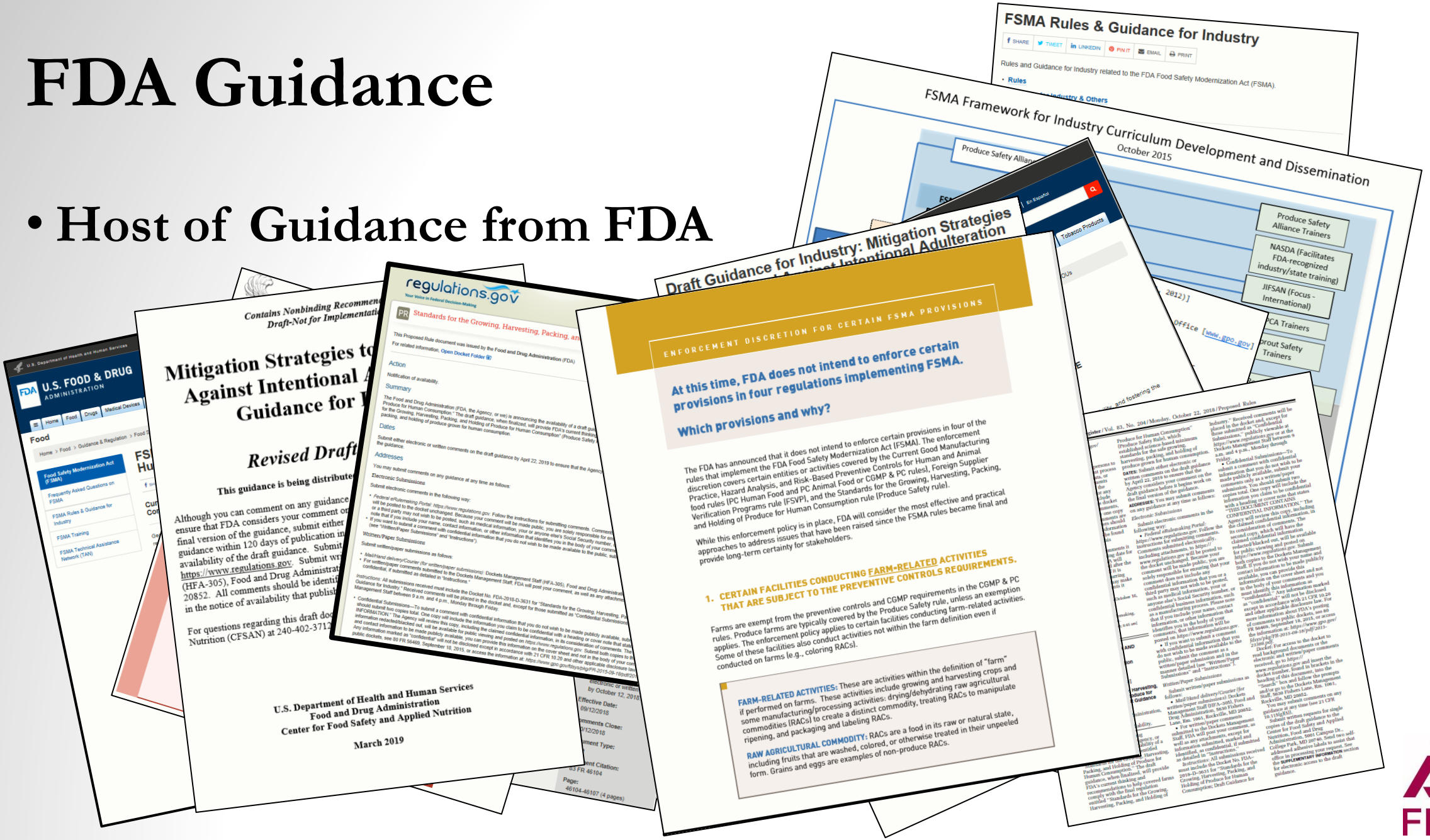
FDA Guidance

- Host of Guidance from FDA



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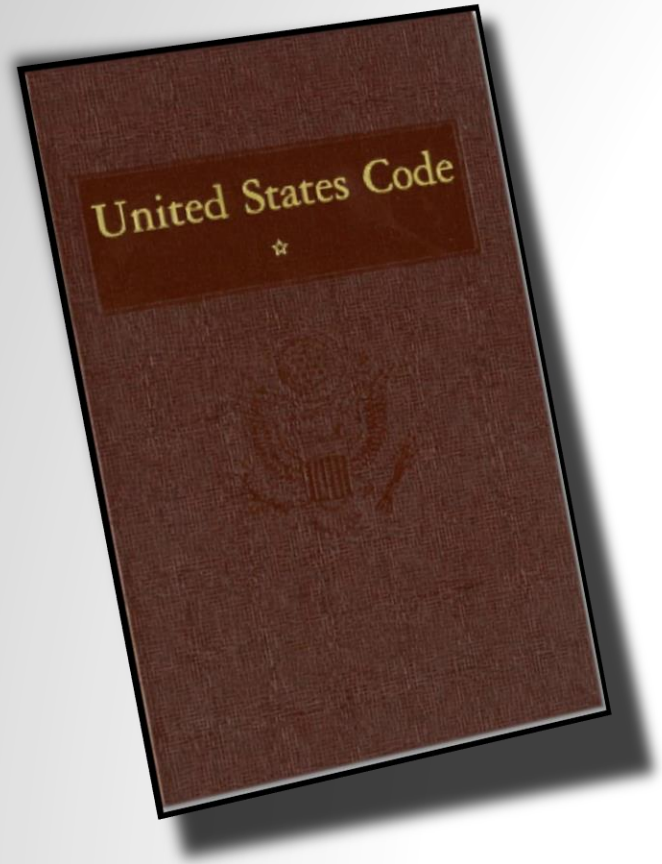
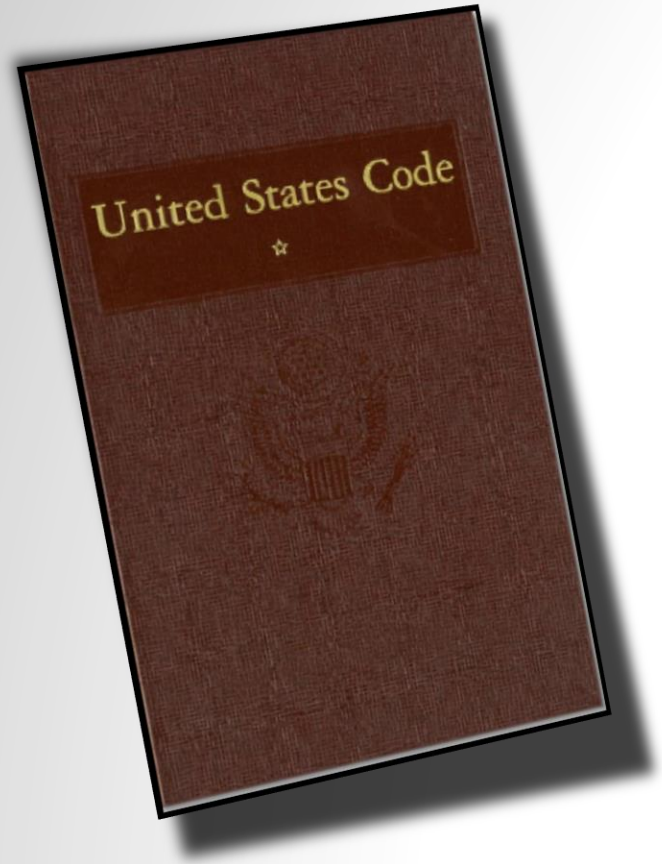
Enforcement Litigation



- **DOJ will litigate based on violations of federal law**

Enforcement Litigation



- Repeated Violations
- Failure to Take Corrective Action
- Contamination
- Mysterious Ingredients
- Drug Claims

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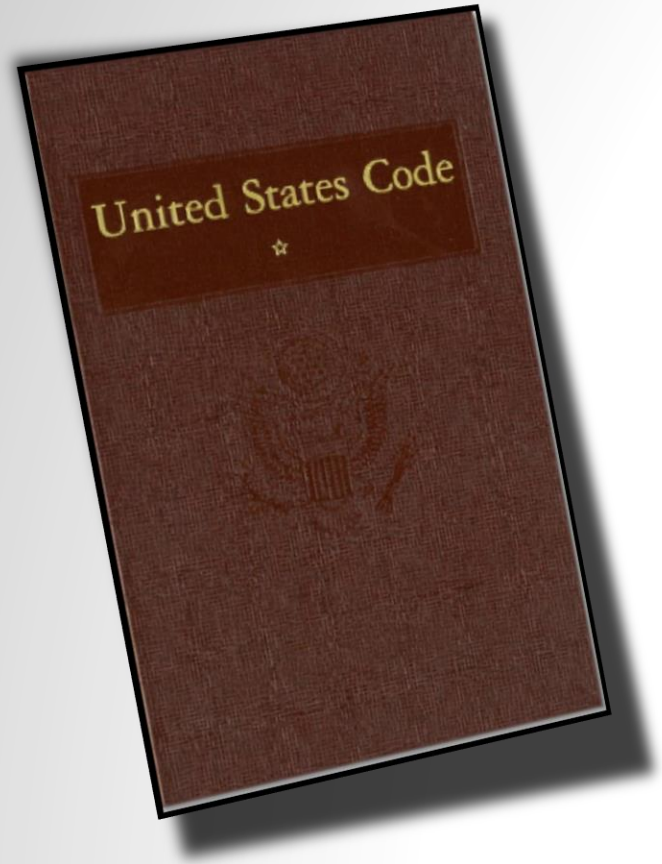
Enforcement Litigation



- Mail Fraud
- Wire Fraud
- Smuggling
- Conspiracy
- Bribery
- Adulteration
- Misbranding
- Intent to Defraud or Mislead

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Will Comm'r Gottlieb's Departure Affect DOJ's Enforcement Efforts?

- "FDA is committing to new priorities when it comes to our oversight of dietary supplements . . . . "

- Communication to public
- Reg framework to evaluate product safety
- Develop new enforcement strategies

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DOJ's Enforcement Efforts

- "The growth in the number of adulterated and misbranded products – including those spiked with drug ingredients not declared on their labels, misleading claims, and other risks – creates new potential dangers. "

- FSMA-like rollout of broader enforcement plan?
- Increased inspections?
- Referrals to DOJ?

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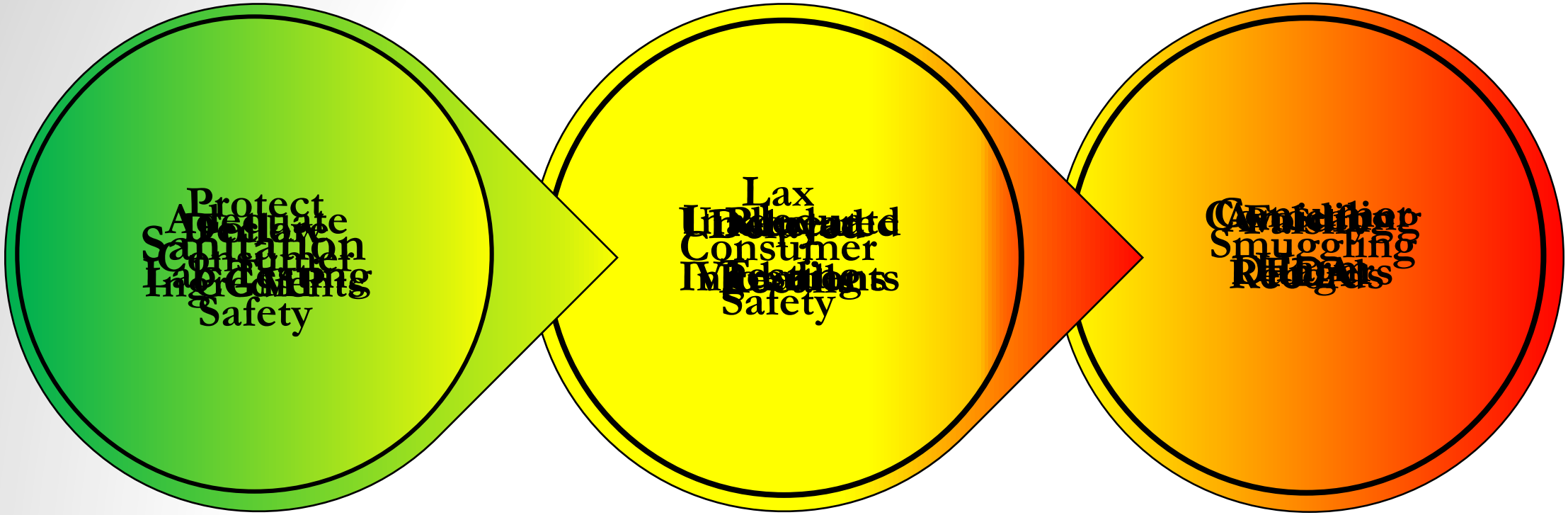
What Might Trigger Enforcement Action?



Good practices

Civil Injunction?

Grand Jury subpoena?

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