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Fourth annual food law tele-summit

Managing risk in the food industry

Norton Rose Fulbright US LLP
Thursday, November 17, 2016

Administrative information

- Everything we say today is opinion. We are not dispensing legal advice, and listening does not establish an attorney-client relationship. This discussion is off the record. You may not quote the speakers without our express written permission. If the press is listening, you may contact us, and we may be able to speak on the record.
- Today's program will be conducted in a listen-only mode. To ask an online question at any time throughout the program, click on the question mark icon located on the toolbar in the bottom right side of your screen. Time permitting, we will answer your question during the session.

Continuing education information

- We have applied for 2.0 hours of California and Texas CLE credit and 2.0 hours of New York transitional CLE credit. For attendees outside of these states, we will supply a certificate of attendance which may be used to apply for CLE credit in the applicable bar or other accrediting agencies.
- Norton Rose Fulbright will supply a certificate of attendance to all participants who:
  - Participate in the web seminar by phone and via the web
  - Complete our online evaluation that we will send to you by email within a day after the event has taken place

Speakers

Jane Caskey

Global Head of Risk Advisory

Toronto

Cori Annapolen Goldberg

Sr. Associate

New York

Rick Robinson

Global Co-Head of Life Sciences and Healthcare

Washington, DC

Randy Sutton

Partner

Toronto

Sara Zborovski

Partner

Toronto

Dr. Daniel Fabricant

Executive Director and CEO, Natural Products Association (NPA)

Washington, DC

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Today's program

- Insightful risk management – being "risk ready" (including general trends)
- US election watch 2016: What happens next?
- "Risk ready" for the food industry – the importance of your recall plan
- Dealing with a non-compliance (conducting a recall)
- Enforcement & litigation update – US and Canada
- Accountability in the food industry: avoiding a character of harms
- Q&A

Insightful risk management – being “risk ready”

Jane Caskey

Global Head of Risk Advisory

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Market Dynamics

The evolving risk landscape

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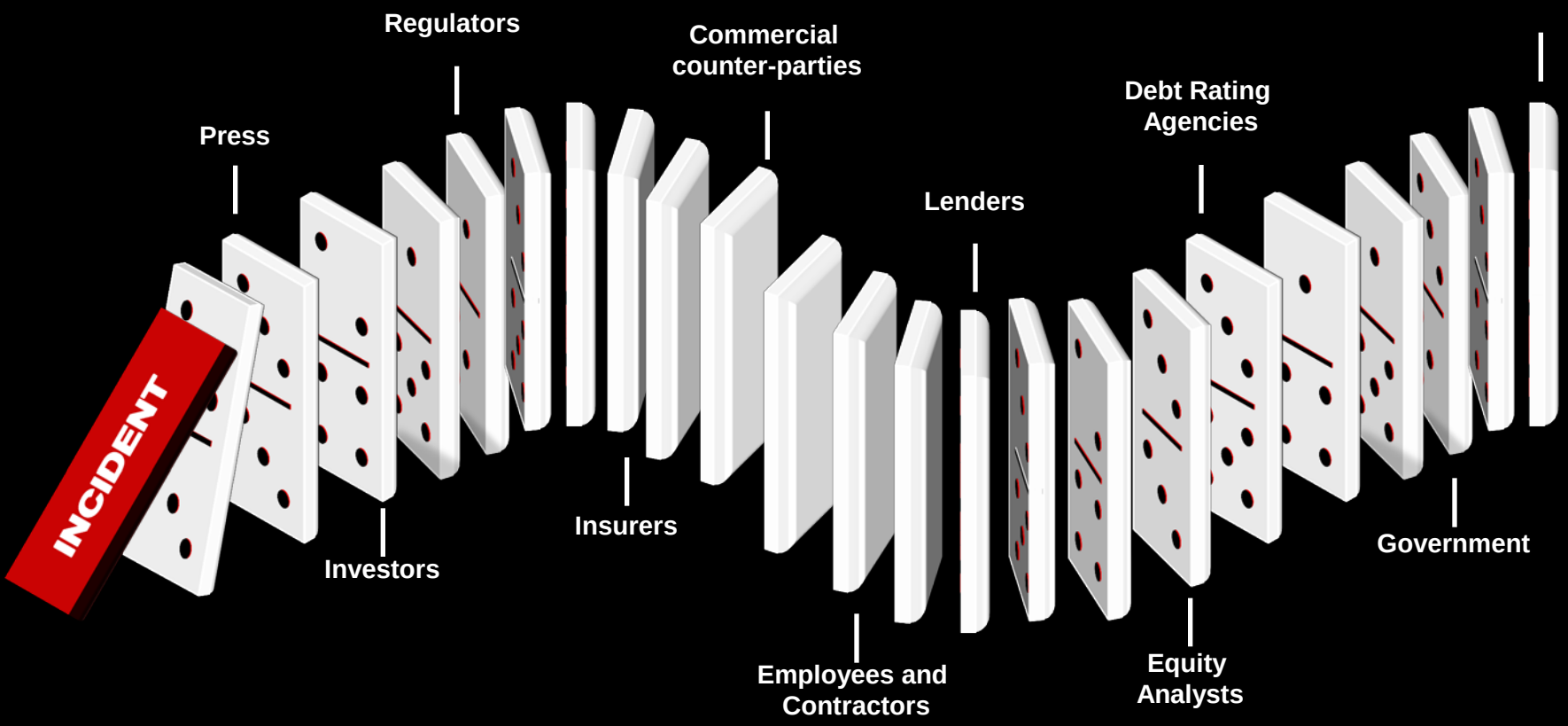
Global and Holistic

Risks Are interconnected – the domino effect

One incident can lead to follow-on consequences and loss of confidence across multiple issues and parties:



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Strategic & holistic risk management

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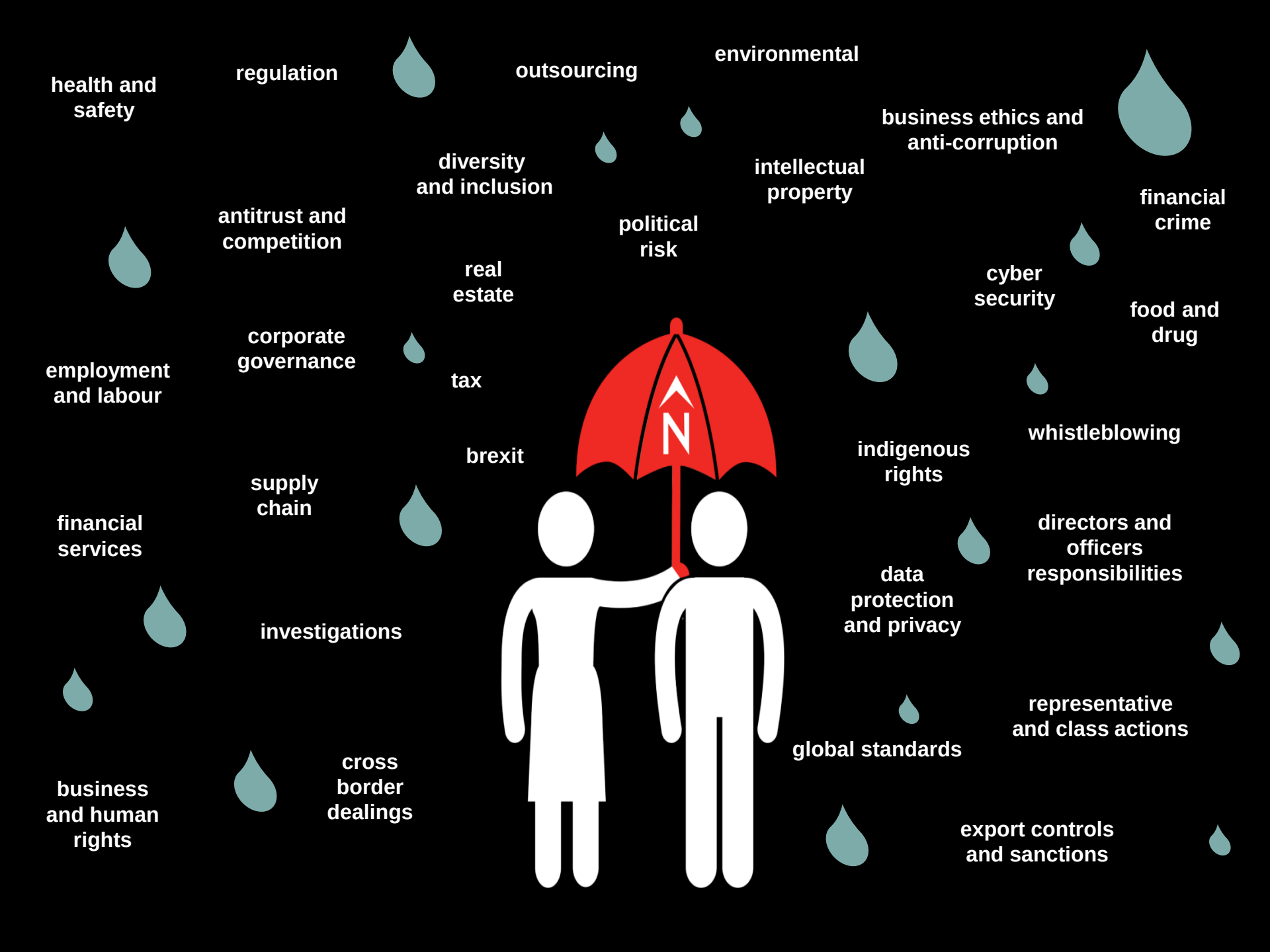
health and safety
regulation
outsourcing
environmental
business ethics and anti-corruption
diversity and inclusion
intellectual property
financial crime
antitrust and competition
political risk
real estate
cyber security
food and drug
corporate governance
employment and labour
tax
whistleblowing
brexit
indigenous rights
supply chain
financial services
directors and officers responsibilities
data protection and privacy
investigations
representative and class actions
global standards
cross border dealings
business and human rights
export controls and sanctions

Disruption to Regulations

The overlap between ethics and law

- Law often represents a minimum expectation
- Ethics often represents a standard that exceeds the legal minimum
- Companies need to know where to draw the line on what they "should" do versus what they "must" do to be risk ready

Traditional regulations and emerging risks

- Part of corporate governance strategy/legal compliance – i.e. food safety

- New and emerging regulatory requirements on non-traditional issues - supply chain human rights (*Modern Slavery Act* and *California Supply Chain transparency Act*)

- Creates legal and regulatory risk and exposure – i.e. litigation risks regarding disclosure, management of suppliers, meeting voluntary standards

Disruption to regulation

- Standardization of due diligence and benchmarks
  - HAACP – Food Safety/Quality Assurance (Traditional Standards Based Risk Management)
  - Sustainable Coffee Certifications (Voluntary industry standard)
  - Sustainable Palm Oil (best practices)
- Contractual requirements, pre-condition to supplier relationships (major retailers, restaurants, purchasers) – market driven standards of conduct
- Self-governance and self-auditing of supply chain and operations
- Also creates legal risk → disrupting regulatory context, new litigation risks

Risk areas

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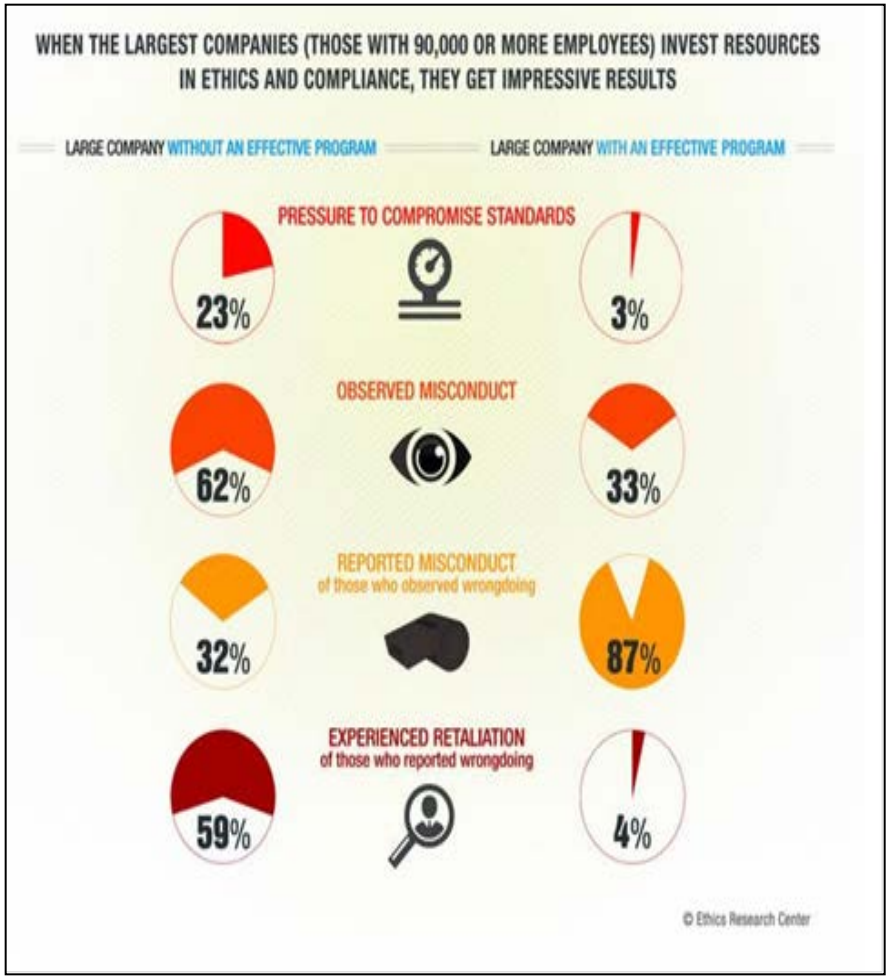
Conduct Risk and Ethics/Culture

Going beyond compliance = conduct/culture



Source: Ethics Research Center, "Research Report - The State of Ethics in Large Companies", 2015, online: www.ethics.org/nbes/large-companies.

- True insightful risk management must go beyond documenting compliance
- A recent study by the Ethics Research Centre shows that implementing effective ethics compliance programs (underpinned by strong risk culture) achieves significant results
- Not surprisingly, 75% of senior executives are increasingly focused on risk culture

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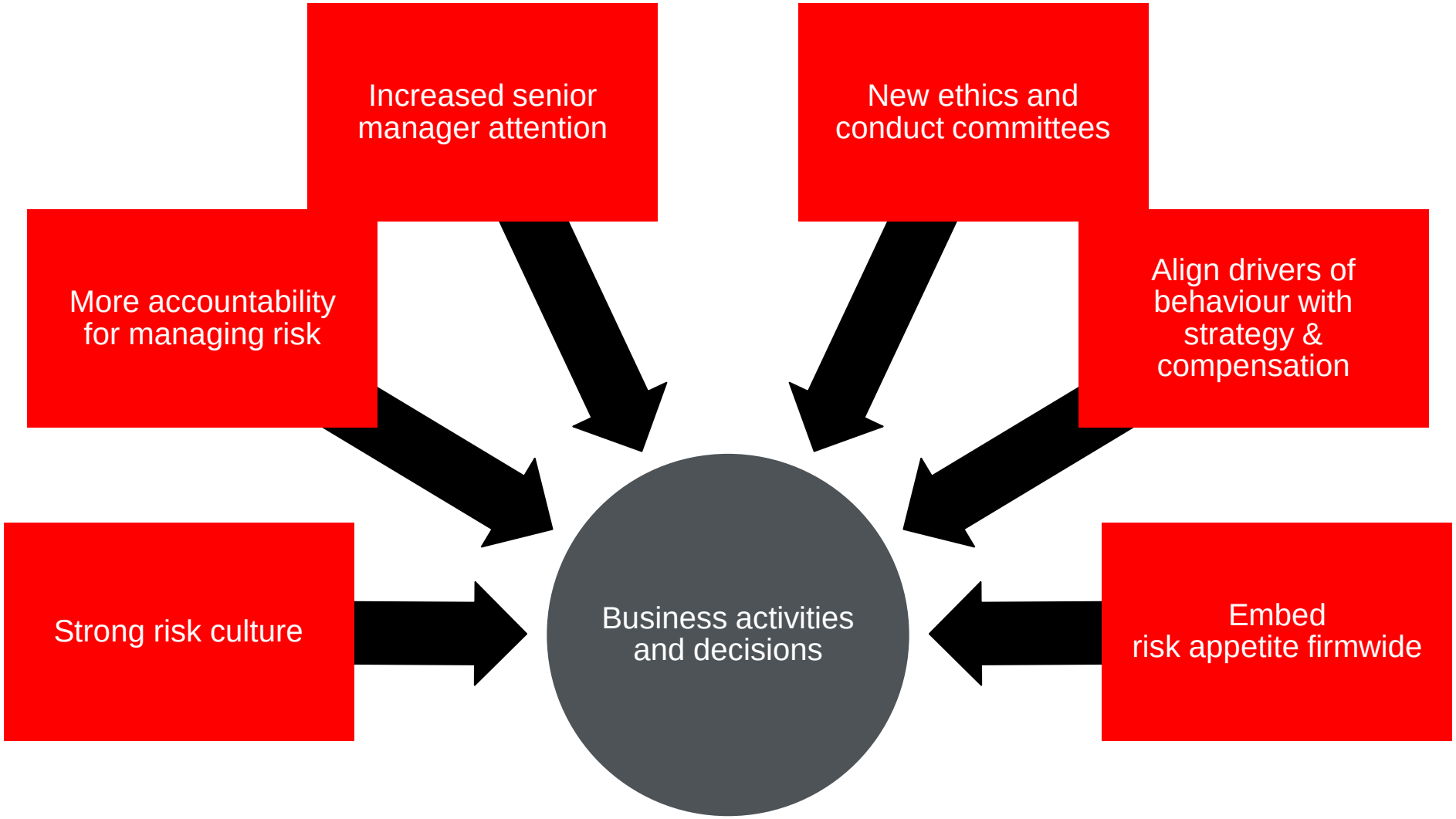
An increased focus on ethics and risk culture



Our approach – insightful risk management

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US election watch 2016: what happens next?

Cori Annapolen Goldberg

Norton Rose Fulbright US LLP

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President-elect Trump - impact on the food industry?

- Inauguration January 20, 2017
- New agency heads
- Elimination of “wasteful and unnecessary regulation”

Upcoming compliance deadlines

FSMA Deadlines

Rule	General Compliance Date[1]	Small Business Compliance Date (Fewer than 500 FTE employees company-wide, or as specified)	Very Small Business Compliance Date (business has annual food sales below applicable limit, or as specified)
Preventive Controls for Human Food	9-19-16	9-18-17	9-17-18 (<$1M)
Preventive Controls for Animal Feed	9-19-16	9-18-17	9-17-18 (<$2.5M)
Sanitary Transportation	4-6-17	4-6-18	4-6-17[2]
Foreign Supplier Verification Program	5-27-17		
3rd Party Accreditation and Certification	Upon Release of Model Accreditation Standards[3]		
Protection against Intentional Adulteration	7-26-17	7-26-18	7-26-19 (< $10M)
Produce Safety	1-25-18	1-25-19 (average annual monetary value of produce sold during the previous 3-year period is no more than $500,000.)	1-25-20 (average annual monetary value of produce sold during the previous 3-year period is no more than $250,000.)

[1] Please note that compliance date for retention of records supporting eligibility for non-general compliance dates begin anywhere from the effective date of the rule to one year before the compliance date. Please reach out to us for further assistance or refer to each final rule for these deadlines.

[2] No special time period is noted and therefore we follow the general compliance date.

[3] The provisions are effective immediately upon the rule being published but can be implemented only after publication of these standards, which have not yet been released.

Nutrition Facts Compliance

- Manufacturers will need to use the new label by July 26, 2018. However, manufacturers with less than $10 million in annual food sales will have an additional year to comply.

GMO Labeling Compliance

- National Bioengineered Food Disclosure Law passed in July 2016. USDA working group drafting rules to implement the measure.

“Risk ready” for the food industry: the importance of your recall plan & dealing with a non-compliance

Sara Zborovski

Norton Rose Fulbright Canada LLP

Cori Annapolen Goldberg

Norton Rose Fulbright US LLP

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Recall preparedness

- Prevention v. response
- Assume that a recall will be required
- Mistakes in response can cause problems
- Reputation and direct business impact
- Increased risk of regulatory scrutiny and litigation
- GOAL: reasonable incident response readiness

Recall plan requirements

- FSMA Preventive Controls for Human Food rule is final and in effect
- Written recall plans now required for foods with hazards requiring a preventive control
- The food recall plan must have procedures to perform the following actions:
  - Notification to consignees, with instructions
  - Public notification
  - Effectiveness checks
  - Proper disposal
- Recall Management Team Recommended

Recall plan requirements

- CFIA Recall Plans – guides for Manufacturers, Importers, Distributors and Retailers

- Basic elements of a recall plan:
  - Recall management team
  - Complaint file
  - Contact List – CFIA
  - Tracing
  - Production amounts
  - Distribution records
  - Recalled product records
  - Recall procedures
  - Recall effectiveness procedures
  - Testing

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Roadmap

Finding of Non-Compliance

- Food Safety Investigation
- Health Risk Assessment

The Decision to Recall

The Recall

Finding of Non-Compliance

- Health Hazard Evaluation

The Decision to Recall

The Recall

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Uh oh – a finding of non-compliance. Now what?

Finding of Non-Compliance	Food safety Investigation	Health Risk Assessment
Many possible triggers	Cooperate with CFIA	Prepare for Possible Recall

The decision to recall

- Consistent classifications across Canada and the US

Class I: High Risk

Class II: Moderate Risk

Class III: Low Risk

Uh oh – a finding of non-compliance. Now what?

Complaint Received

↓

1. Assemble Recall Team
2. Evaluate If Recall Is Necessary

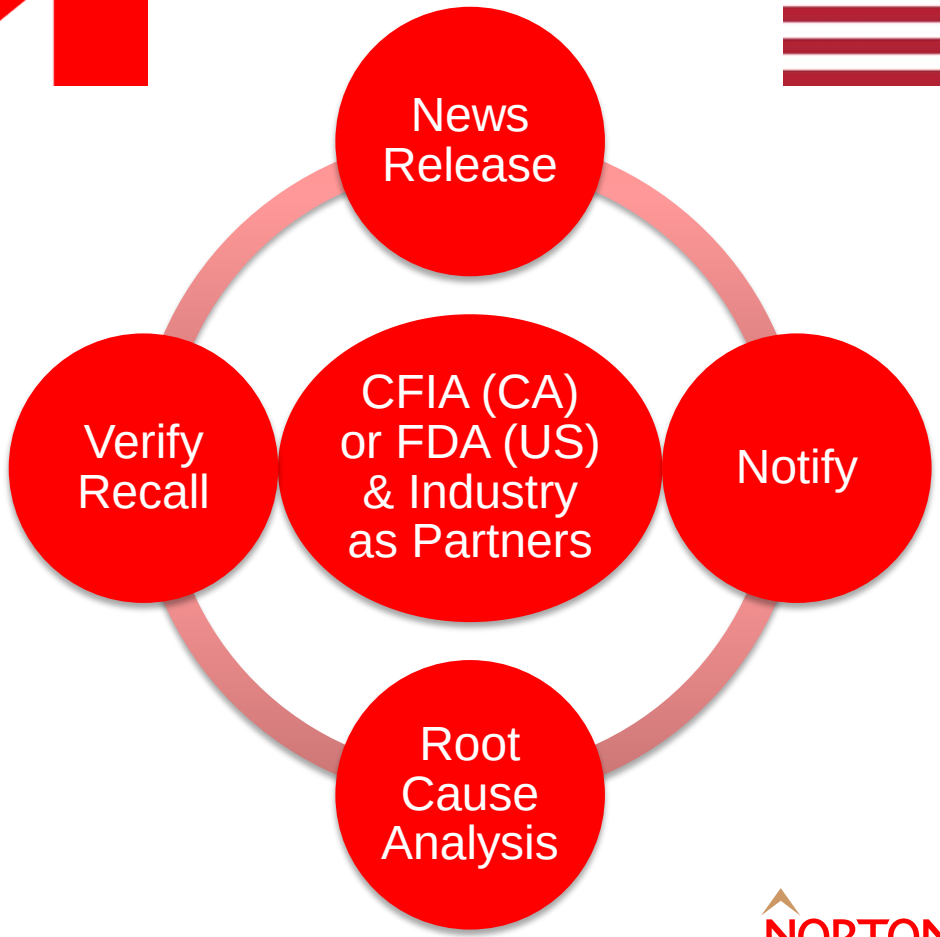
↓

If A Recall Is Necessary:

1. Determine the Depth of the Recall
2. Contact Appropriate Regulatory Agency
3. Initiate the Recall Plan:
   - Written Log of Actions/Dates
   - Implementing the Recall
   - Public & Media Statements
   - Monitoring Recall
   - Disposal of Products
   - Application for Recall Termination
   - Recall Aftermath & Debrief

The recall

- Similar recall life cycle across Canada and the US



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Business considerations – the importance of thinking globally

Don’t be like this guy!

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Powers in the face of non-compliance

- Letter of non-compliance (CA) /Warning Letter (US)
- Quarantine, seizure, detention
- Order to dispose / destroy
- Recall
- Action against licence, registration or permit

… and …

- Recommend prosecution

Enforcement & litigation - US

Rick Robinson
Global Co-Head of Life Sciences and Healthcare,
Norton Rose Fulbright

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US Government Criminal Investigations of the Food Industry

Overview

- Overview of a US (FDA/DOJ) investigation – how it comes about, what it looks like, how to handle
- The Yates Memo and what that means for companies and executives now
- Examples of recent enforcement action in the food space

Investigations

- Civil or criminal
- Civil remedies
  - Seizure of offending products
  - Injunction against operations and sales
- Criminal remedies
  - Misdemeanors – strict liability for introducing adulterated foods into interstate commerce; no proof of intent required
  - Felonies – intent to defraud or mislead FDA or consumers; usually reserved for most serious cases.

The “Yates Memo” focuses on individuals

“Six key steps to strengthen our pursuit of individual corporate wrongdoing”:

1) To qualify for any cooperation credit, corporations must provide the DOJ with “all relevant facts” relating to the individuals responsible for the misconduct;
2) Both criminal and civil corporate investigations should focus on individuals “from the inception of the investigation”;
3) Criminal and civil DOJ attorneys handling corporate investigations should be “in routine communication with one another”;

Overview of Yates Memo (cont'd)

4) Absent "extraordinary circumstances or approved departmental policy," DOJ will not provide criminal or civil immunity to culpable individuals when resolving a corporation's misconduct;
5) DOJ should not resolve matters with a corporation without a "clear plan" to resolve related individual cases; and
6) Civil attorneys should "consistently focus on individuals as well as the company," taking into account factors beyond an individual's ability to pay.

How does the Yates Memo change DOJ's enforcement priorities?

- Criminal and civil DOJ attorneys are instructed to focus on individual wrongdoing "from the very beginning of any investigation of corporate misconduct"
- Why?
  - "Because a corporation only acts through individuals"
  - Increases the likelihood that knowledgeable individuals will cooperate and provide information against higher-ups
  - Maximizes the chances that the resolution will include charges against both the corporation and culpable individuals

The “Park Doctrine”

- A responsible corporate official can be convicted of a misdemeanor based on a position of responsibility and authority to prevent and correct violations of the Food Drug and Cosmetic Act (FDCA).
- The corporate officer does not need to have acted with intent or even negligence, and the corporate officer does not need to have participated in – or even known about – the alleged violations.
- DOJ will consider whether the officer had the authority to correct and prevent the violation.
  - Knowledge of and actual participation in the violation are relevant factors.
  - DOJ will also consider whether the violation reflects a pattern of illegal behavior or failure to heed warnings.

Recent cases

- Chipotle – company announced that it received a federal grand jury subpoena in connection with a norovirus outbreak in California in 2015.
  - Focus on delay in reporting to local health authorities.
  - Second subpoena demanding company-wide documents back to 2013
- Parnell Appeal
  - Former PCA officers appealing felony convictions stemming from Salmonella outbreak at peanut butter plant.
  - Sentences ranged from 5 years to 28 years.
- ConAgra Restitution Hearing
  - Company pled guilty to a misdemeanor count of allowing adulterated food into interstate commerce and agreed to pay $11M in penalties.
  - Hearing next month on restitution for victims of tainted peanut butter.

Other trends

- The use of whole genome sequencing means that regulators will increasingly be able to link cases of human illness to a particular food or specific facility.
- Once that link is established, a criminal investigation is highly likely.

Key takeaways

- Corporate employees and management, particularly senior management, should be prepared to face higher scrutiny during and after investigations of corporate misconduct.
- It will be more difficult to enter into global settlements that resolve corporate liabilities and those of officers, directors, and employees all at the same time.
- Corporate officers may have exposure based on the Park Doctrine even in cases where they did not know the company was selling adulterated products.

Key takeaways (cont'd)

- Senior management can no longer delegate compliance to others.
  - Need to be able to demonstrate what you did personally to ensure that your company has an appropriate food safety culture.
  - Is there an adequate investment in employee food safety training?
  - How did you respond to prior food safety issues?
  - Has there been adequate investment in food safety infrastructure?

Enforcement & litigation - Canada

Randy Sutton

Partner, Norton Rose Fulbright

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Regulatory framework

Primary federal departments responsible for regulation and enforcement:

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Regulatory framework

- Health Canada pursuant to The Food and Drugs Act, establishes policies and sets standards relating to the sale of food and drugs.
- Canada Food Inspection Agency (CFIA) provides inspection services related to food and enforces food safety and nutritional quality standards established by Health Canada. The CFIA is involved in inspections, enforcement and providing guidance for the food industry.
- Competition Bureau deals with false or misleading advertising and anti-competitive conduct, but does not regulate food products per se.
- Patchwork of other federal and provincial legislation may also be relevant to risk, for example provincial consumer protection legislation.

Private litigation
consumer class actions

- Class action legislation throughout Canada.
- In addition to claims arising from recalls, consumer driven claims are advanced often based on consumer protection legislation and allege misleading advertising or false claims.
- Frequently copycat litigation based on similar claims in the United States, but simply transporting claims across the border has not always been successful.
- We see continued risk, but the Courts have established limits and we do not see the number of claims seen in the United States.
- Judges continue to view these cases (outside of the recall context) with some skepticism.


Trends

Private litigation
consumer class actions

- 2016 Litigation Trends Survey | Canada:
  - Class Actions are the third most common type of litigation matter respondents were facing – higher than their global counterparts.
  - Regulators are becoming more interventionist given new regulations and guidelines, greater enforcement and scrutiny.
  - “More class actions because that seems to be the activity of the current time – everything is going to be a class action.”

Trends

Canada Food Inspection Agency

- Stated priorities include more effective inspections, stronger more consistent rules and a modernized food safety program.
- Continued activity with food recall warnings and allergy alerts, with over 3000 food safety investigations annually and approximately 350 recalls per year:
  - CFIA continues to be proactive in issuing recalls and warnings with quick turn-around: target for 2016 is to ensure 100% of public warnings for class I recalls are issued within 24 hours of recall decision.
  - Recalls relating to undeclared allergens a recent trend.

Trends

Canada Food Inspection Agency Recent High Profile Mislabelling Prosecutions

- Mucci Pac Ltd.: Successful conviction earlier this year for falsely labelling imported vegetables a “Canadian.”
  - fined $1.5 million for offences under the *Food and Drugs Act*, the *Consumer Packaging and Labelling Act* and the *Canada Agricultural Products Act*.
  - charges were laid in June 2014 after a three year CFIA investigation uncovered over $1 million of tomatoes were labelled “Product of Canada” despite being imported from Mexico.
  - unique case because there was never a direct risk to individual consumers or public health; it was a matter of labelling.
- Cericola Farms: Charged with criminal fraud, offences under the Food and Drugs Act, the Consumer Packaging and Labelling Act and the Organic Products Regulations in relation to “organic” designation.
- Query if this is a new enforcement priority?

Trends: class actions

Maple Leaf Foods – Franchisee Claim for Supply Interruption

- Class Action certified in favour of Mr. Submarine franchisees for economic losses arising from the alleged breach of the duty to manufacture a product fit for human consumption etc. in relation to a significant food recall of ready to eat meats.
- Harm complained of was the non-supply of goods as a result of the recall to Mr. Sub, the intermediary, no evidence of injury to any customers.
- Acceptance that the claim could proceed as a class action even though it was solely for economic losses sustained as a result of the food recall.

Trends: class actions

Harrison v. Afexa Life Sciences Inc.

- Court accepts that the Food and Drugs Act legislation is a complete code and cannot ground a successful private claim by consumers in tort.
- Court finds that the Food and Drugs Act sets out enforcement in a comprehensive fashion through the regulatory rights of the inspector.
- No right of a consumer to advance a claim for civil or restitutionary relief for a breach of the Foods and Drugs Act.

Accountability in the Food Industry: Avoiding a Character of Harms

Dr. Daniel Fabricant (NPA)

Daniel Fabricant, PhD
CEO, Executive Director
Natural Products Association

Thursday

Roadmap

- **Harms/Hazards and Managing Risk**
- Regulatory Tools of FDA for Dietary Supplements
- Regulatory Action on Ingredients
- Legislative: What is NPA Doing?
- FDA on “Natural”
- NPA Tools to Assist Industry

What is a Hazard

A hazard or a hazard condition is a biological, chemical ,or physical agent in or condition of food with a potential to cause an adverse health effect such as injury or illness.

Intro/Background

FDA = Harm Removal Business

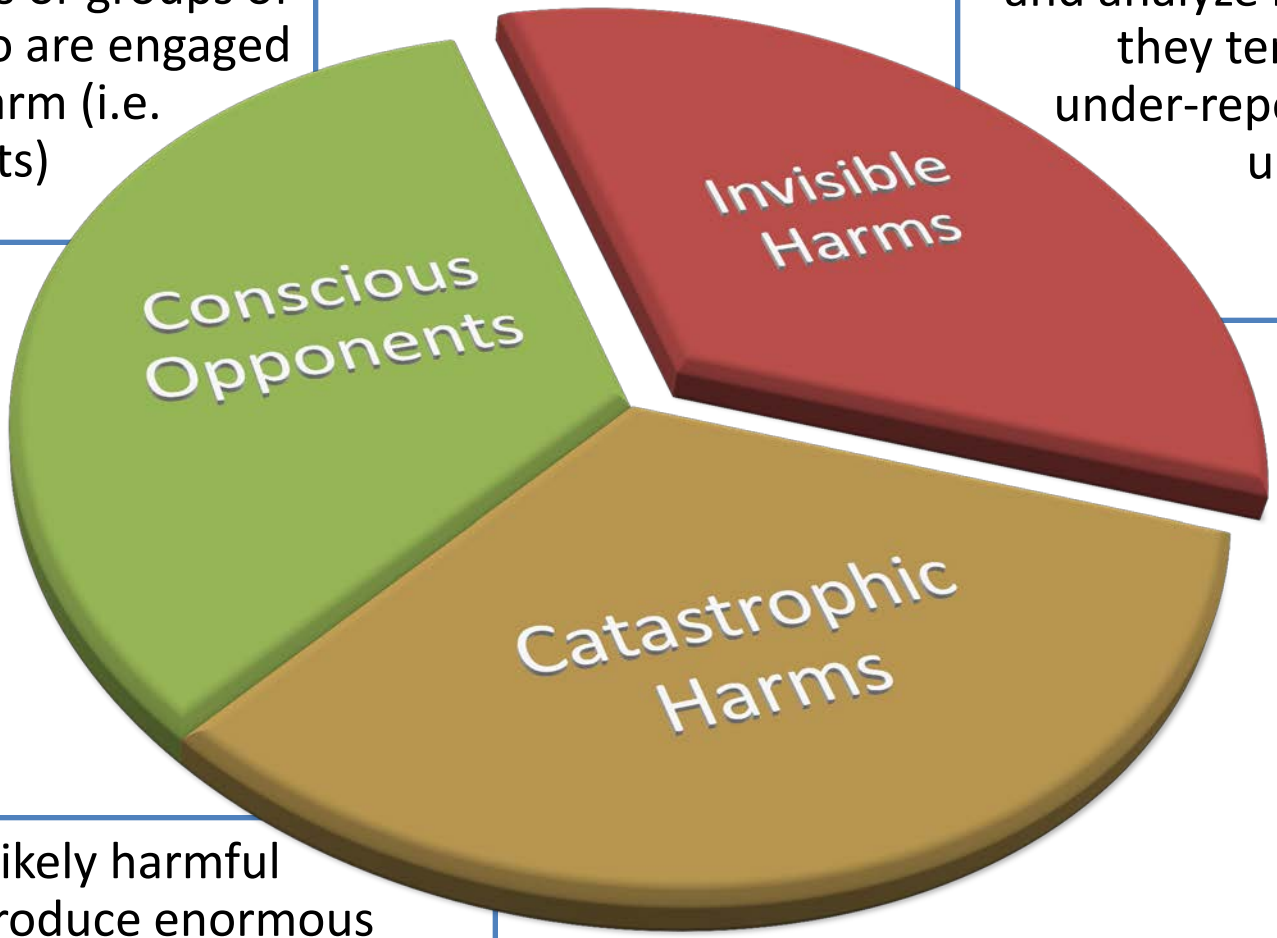
What are major non-compliance problems in the industry?

How does the agency address them?

Defining the Problem

- agencies are confronted with individuals or groups of individuals who are engaged in creating a harm (i.e. tainted products)

- are those which are difficult to discern and analyze because they tend to be under-reported or unknown



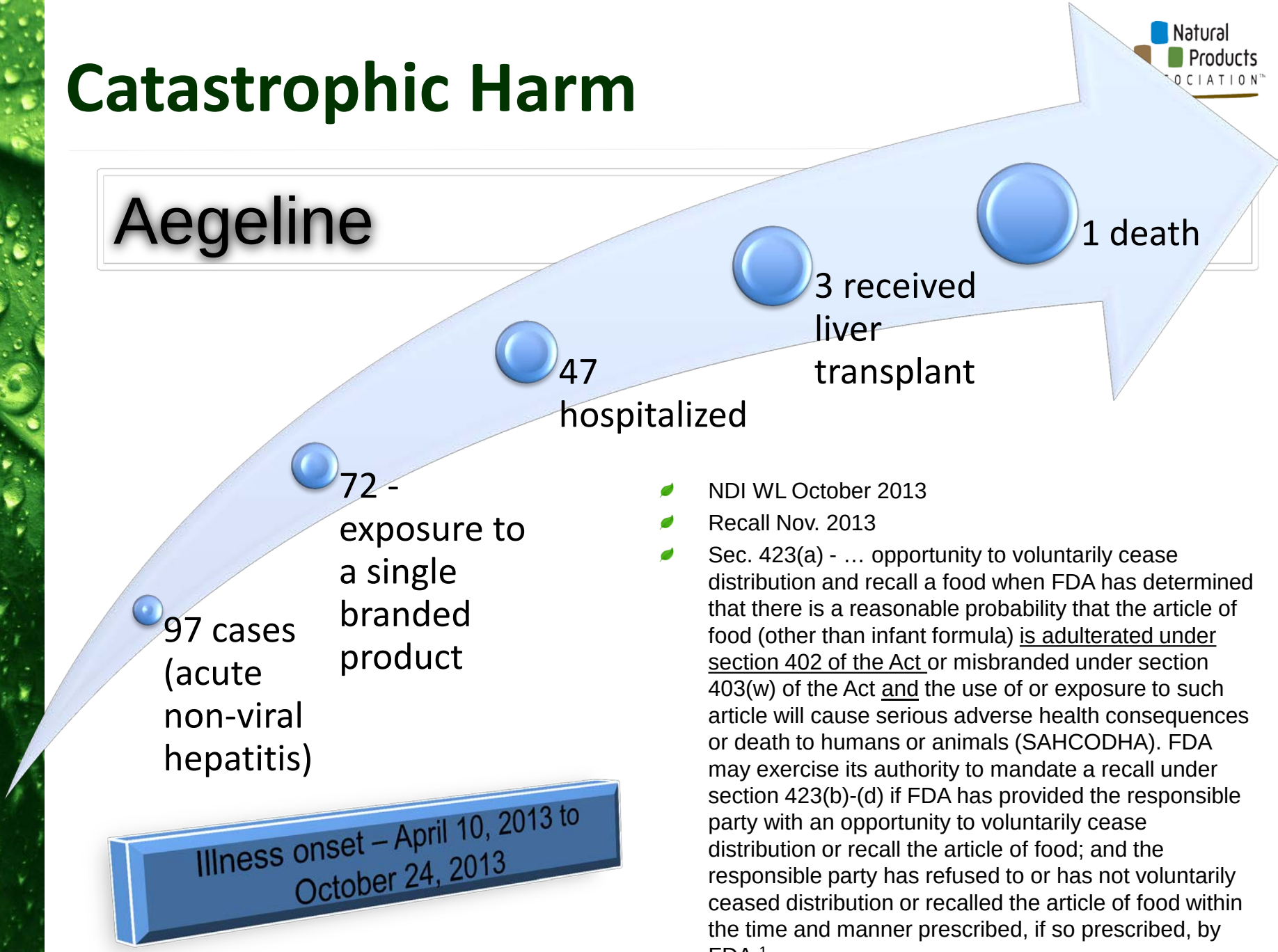
- relatively unlikely harmful events that produce enormous levels of victimization

FDA = Harm Removal Business

Conscious
Opponents

Catastrophic Harm

Aegeline



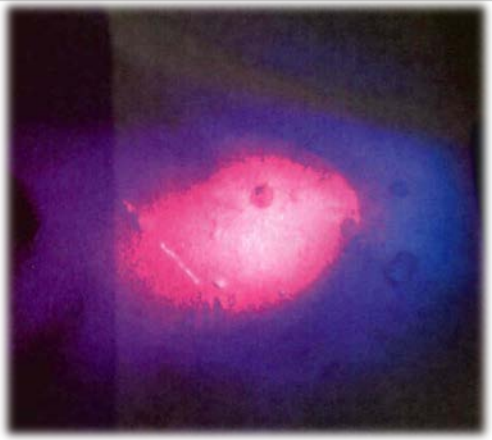
- NDI WL October 2013
- Recall Nov. 2013
- Sec. 423(a) - … opportunity to voluntarily cease distribution and recall a food when FDA has determined that there is a reasonable probability that the article of food (other than infant formula) is adulterated under section 402 of the Act or misbranded under section 403(w) of the Act and the use of or exposure to such article will cause serious adverse health consequences or death to humans or animals (SAHCODHA). FDA may exercise its authority to mandate a recall under section 423(b)-(d) if FDA has provided the responsible party with an opportunity to voluntarily cease distribution or recall the article of food; and the responsible party has refused to or has not voluntarily ceased distribution or recalled the article of food within the time and manner prescribed, if so prescribed, by FDA.[1]

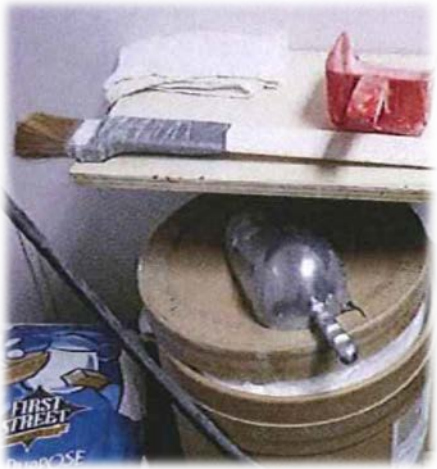
http://www.fda.gov/ICECI/ComplianceManuals/RegulatoryProceduresManual/ucm177309.htm

Invisible Harms

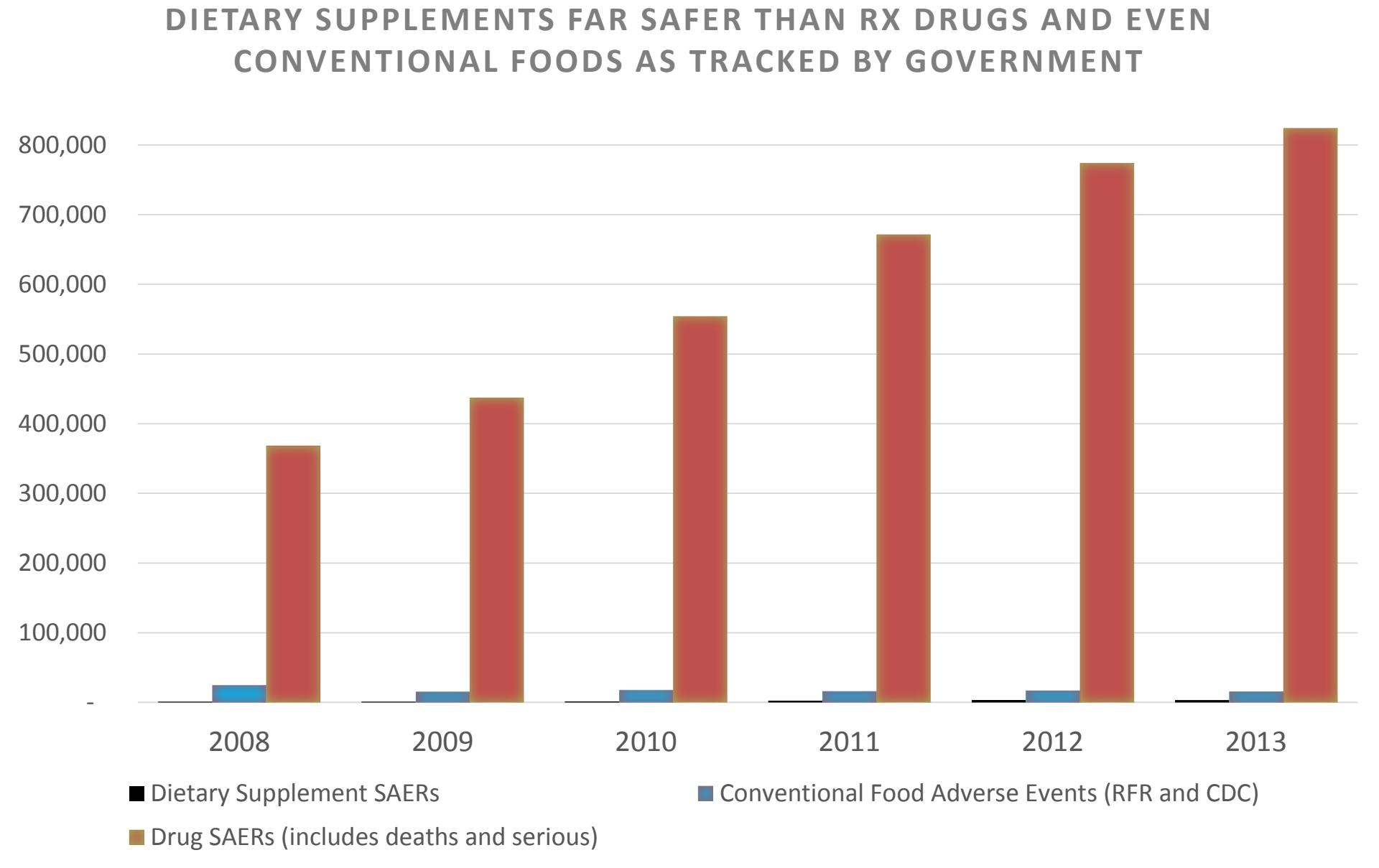
Poor GMPs (identity, purity, strength, composition, presence of contaminants)







DS vs. Conventional Foods vs. Rx



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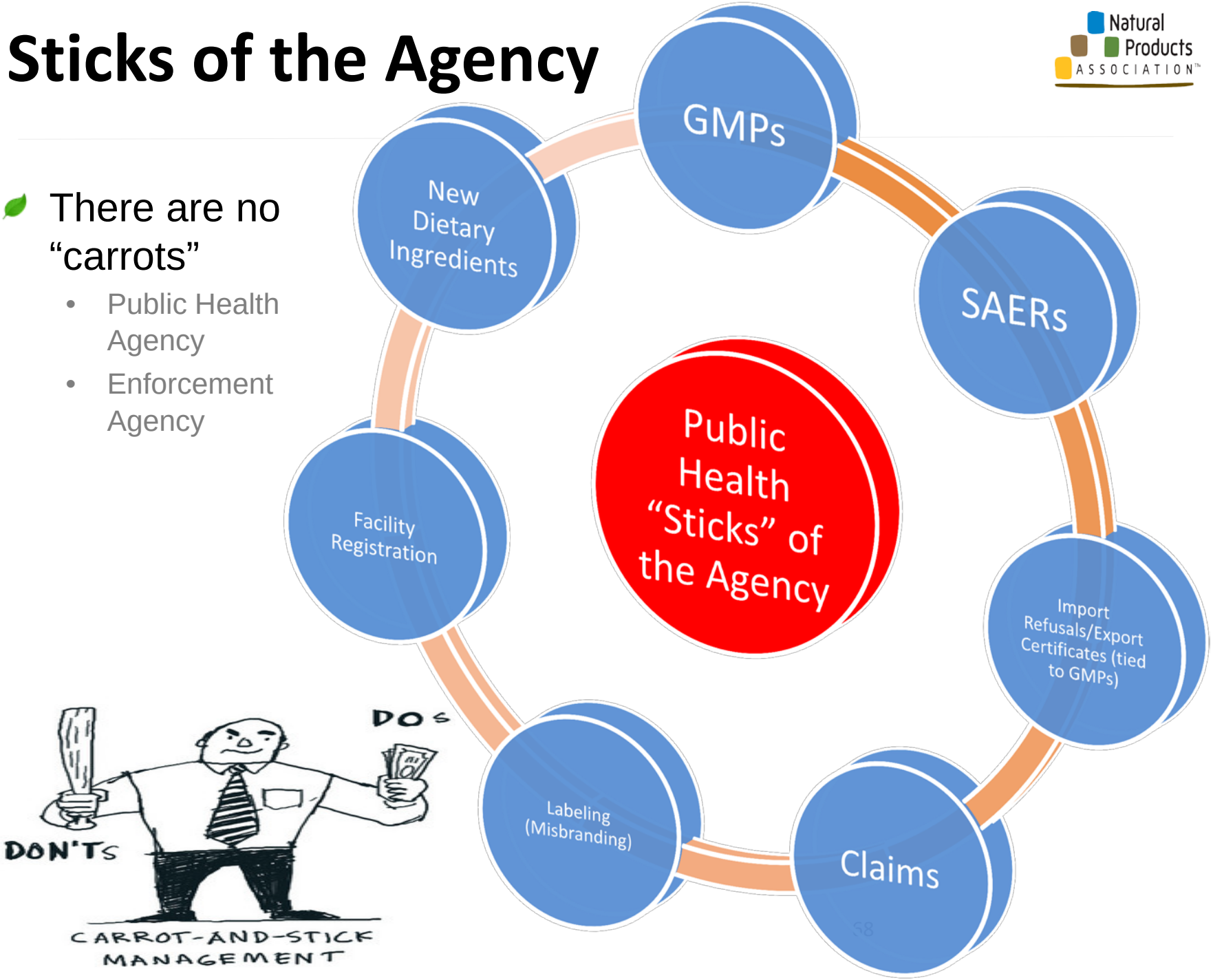
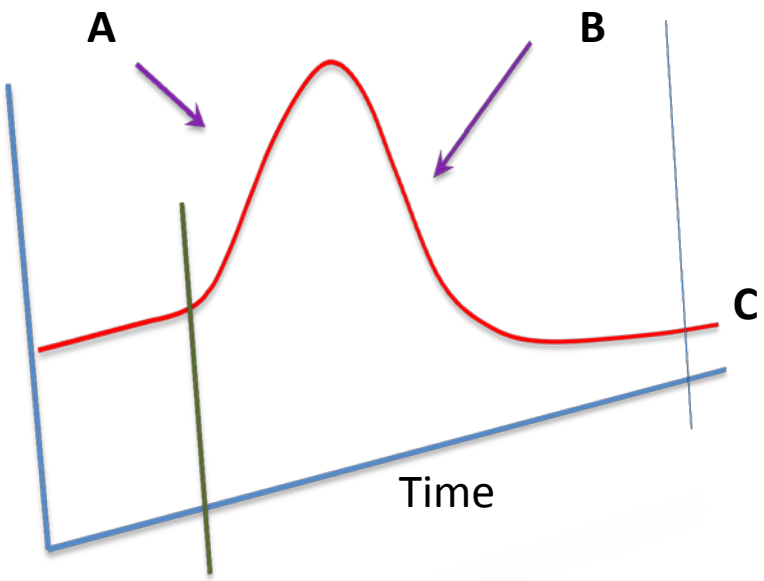
Sticks of the Agency

- There are no "carrots"
  - Public Health Agency
  - Enforcement Agency



Net Effect from Increased Inspections?



Are we at "A", "B" or "C" in terms of GMP Compliance?

Source: Malcolm K. Sparrow. The Character of Harms: *Operational Challenges in Control*. Cambridge Univ Press. 2008

Net Effect of Inspections

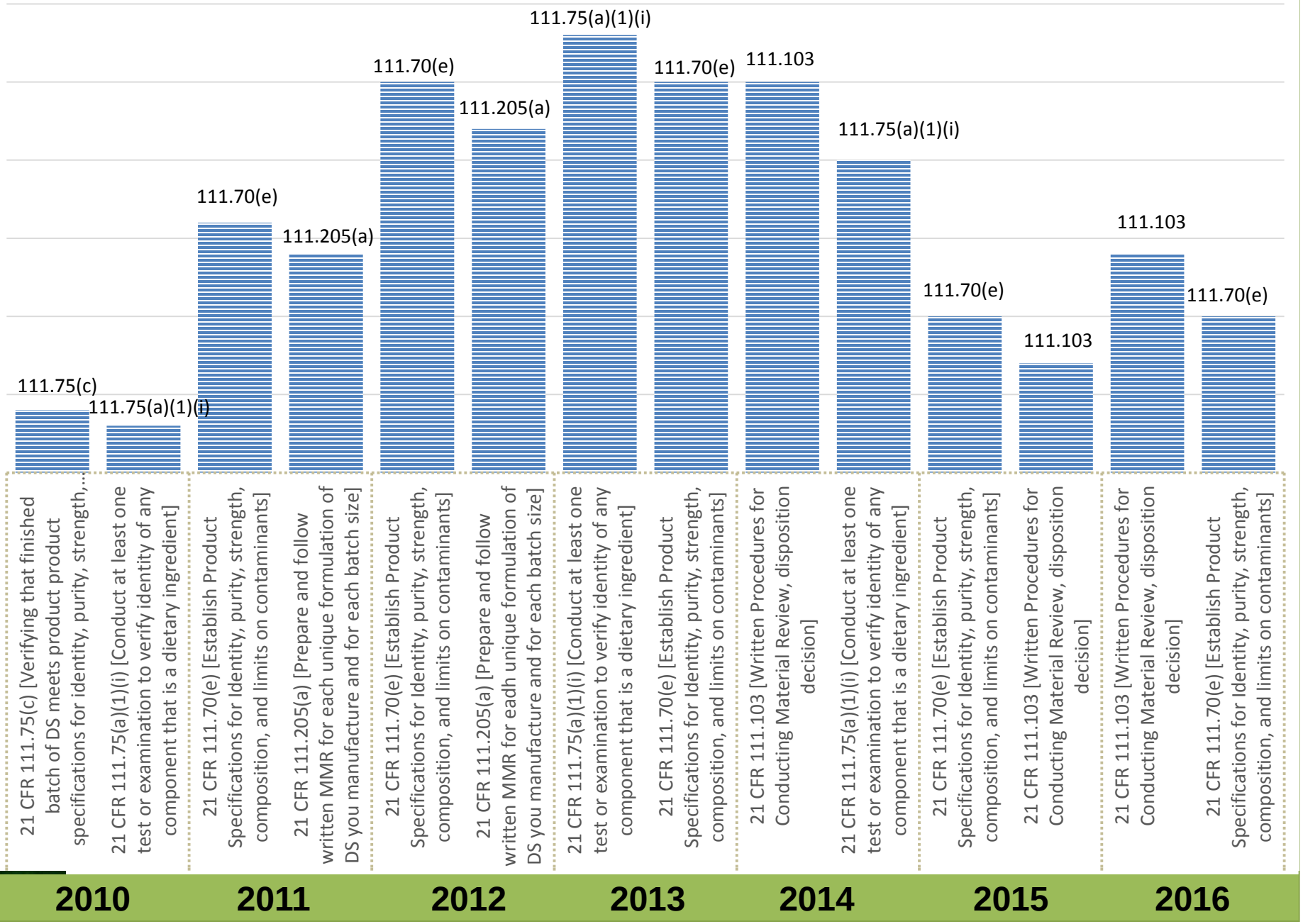
Without more data no one knows?

- We can't rely on 483's (inspector's observations) … FDA Headquarters may not agree that all evidence is sufficient to charge
- The top GMP charges from FDA WLs are changing
- Need for more self-regulatory initiatives like product testing to assess compliance
- slope "A" represents the firms having no GMPs in place?
- slope "B" represents the firms with some deficiencies noted on inspections but have some GMPs in place (have not implemented all of part 111)
- Fewer "easy" cases where no GMPs are in place (these cases are a quick turnaround for FDA)
  - You may need two or more inspections of a firm for a Warning Letter
    - ✓ More cases where the Agency needs more time to agree on what to charge
    - ✓ More cases that require additional evidence collection to support the charge?
    - ✓ Evidence considered "stale" after 6 months … strains resources of the Field
  - In the time the Agency has been evaluating the case evidence, the firm came into compliance, obviating the need to send a Warning Letter

Net Effect from Increased Inspections?

- How do you know if you are at slope “A” or slope “B”?
- Is the Agency still seeing firms with no GMPs?
  - (no GMPs = Not even establishing specifications to the kitchen sink)
- What are the top 10 or so GMP charges and are they changing?
- In the early days … no GMPs (establishing specs -- 111.70)
- Where is that charge today?
- Agency is writing more Warning Letters
- Agency Response Rate or “Efficiency Rate” is going down over the past few years
- For every VAI or OAI, an Agency action has not been taken

Top 2 cGMP Regulations Cited Each Year (2010 - 2016 YTD)



Enforcement in the Future

On the Rise

Other Ways to Enforce that are Less Resource Intensive?

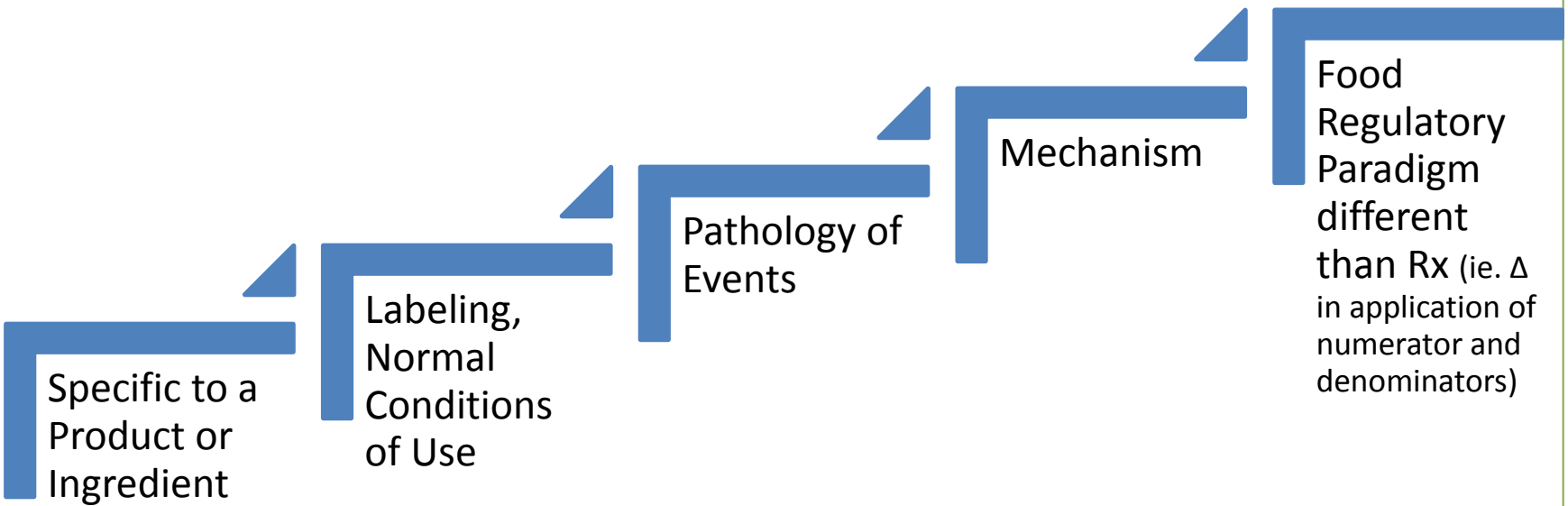
- Warning Letter Blitzes over similar claims
- NDI Enforcement for failure to file 402(f)(1)(B)
- Import Alert/Import Detention
- FSMA Inspections (Supply Chain)

DS GMP Inspections

- Lack of "bandwidth"
- Limited resources
- No Experts at FDA
- Commitment to re-inspect firms already inspected
- Downgrading WLs to Untitled Letters due to Time-In-Review
- Multiple inspections to achieve 1 Warning Letter
- Need to refresh as evidence grows stale
- Paperwork burden

On the Decline

Safety Triggers for Thought



Roadmap

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NDI: What is it?

- The term "new dietary ingredient" means a dietary ingredient that was not marketed in the United States in a dietary supplement before October 15, 1994. (See section 413(d) of the Federal Food, Drug, and Cosmetic Act (the act), 21 U.S.C. 350b(d)). At present, there is no authoritative list of dietary ingredients that were marketed in dietary supplements before October 15, 1994. Therefore, manufacturers and distributors (you) are responsible for determining if an ingredient is a "new dietary ingredient" and, if not, for documenting that a dietary supplement that contained the dietary ingredient was marketed before October 15, 1994.

Pre-DSHEA ingredients

- 413 (d) DEFINITION.—For purposes of this section, the term ‘‘new dietary ingredient’’ means a dietary ingredient that was not marketed in the United States before October 15, 1994 and does not include any dietary ingredient which was marketed in the United States before October 15, 1994.
- CRN in 1998* - *“The best policy is for any company to maintain its own records confirming long term use of an ingredient.”*

Accounting

- 85,000 products on the market.[1]
- We're on NDI # 1,000 at the agency
- FDA receives approximately 50 NDINs per year

1 - 85,000 figure is a count of dietary supplement UPCs using 2008 Nielsen Scantrack data. RTI International. "Model to Estimate Costs of Using Labeling as a Risk-Reduction Strategy for Consumer Products Regulated by the Food and Drug Administration". March 2011.

DS/DI/NDIs aren't FA's – Sec. 201(s)(6)

- (s) The term "food additive" means any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food (including any substance intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food; and including any source of radiation intended for any such use), if such substance is not generally recognized, among experts qualified by scientific as having been adequately shown through scientific procedures training and experience to evaluate its safety, (or, in the case of a substance used in food prior to January 1, 1958, through either scientific procedures or experience based on common use in food) to be safe under the conditions of its intended use; **except that such term does not include**—

  - **(6) an ingredient described in paragraph (ff) in, or intended for use in, a dietary supplement.**

Adulteration Prov. #1- 402(f)(1)(B)

A food shall be deemed to be adulterated—

(f) Dietary supplement or ingredient: safety.

- (1) If it is a dietary supplement or contains a dietary ingredient that—
- (B) is a new dietary ingredient for which there is inadequate information to provide reasonable assurance that such ingredient does not present a significant or unreasonable risk of illness or injury;

What is Adequate?

- Logistical information in 21 CFR 190.6
- Scientific Information in Responses To NDIs from the FDA
  - FDA responses at regulations.gov

    docket FDA-1995-S-0039

Adulteration Prov. #2 - 413(a)

- (a) IN GENERAL.—A dietary supplement which contains a new dietary ingredient shall be deemed adulterated under section 402(f) unless it meets one of the following requirements:
  - (1) The dietary supplement which contains only dietary ingredients which have been present as an article used for food in a form in which the food has not been chemically altered.
  - (2) There is a history of use or other evidence of safety establishing that the dietary ingredient when used under the conditions recommended or **suggested in the labeling of the dietary supplement** will reasonably be expected to be safe and, at least 75 days before being introduced or delivered for introduction into interstate commerce, the manufacturer or distributor of the dietary ingredient or dietary supplement provides the Secretary with information, including any citation to published articles, which is the basis **on which the manufacturer or distributor has concluded that a dietary supplement containing such dietary ingredient will reasonably be expected to be safe**.

- Lead (Pb), *E. coli*, etc. may occur in food but are not food by definition
- "The statute doesn't say "*present in the food supply in an article used for food*;" it states the NDI must be the article itself consumed as food."[1]
- A constituent of a botanical, then if not the article of the diet itself, would be considered new.

1- http://www.naturalproductsinsider.com/articles/2013/12/is-my-new-dietary-ingredient-really-new.aspx?pg=2

Focus of Enforcement in the Future

Enforcement Discretion

- **New Dietary Ingredients – What Will be the Charge?**
  - **402(f)(1)(B) - Food adulteration charge**
- **On What Grounds?**
  - **Failure to File NDI Notification**
- **FDA = Public Health Agency and Enforcement Agency**
  - **Show 'enforcement discretion'**
  - **Failure to File NDI Notification + Safety Concern**
- **Safety Concern??**
  - **Serious AER data from CAERS**
  - **known mechanism of action OR**
  - **no safety data on the ingredient**

Focus of Enforcement in the Future

New Dietary Ingredients

- **Defined in section 413 of the FFD&C Act**
- **How they fit under the Act is defined in 201(ff)**
- **Not marketed in the US before October 15, 199**[413 (d) DEFINITION]
- **Some require notifications before they can be lawfully marketed**
- **No authoritative list grandfathered dietary ingredients**

NNFA - National Nutritional Foods Association, NNFA List of Dietary Supplement Ingredients In Use Before October 15, 1994 (April 26, 1996). Docket No. FDA-2005-P-0259 [Document ID: FDA-2005-P-0259-0012].

Council for Responsible Nutrition, CRN List of Dietary Ingredients "Grandfathered" Under DSHEA (September 1998). Docket No. FDA-2005-P-0259 [Document ID: FDA-2005-P-0259-0010].

Focus of Enforcement in the Future

New Dietary Ingredient Notification

What Does it Buy You?

- By notifying the Agency, the burden is on FDA to show that it is unsafe
- Without Notifying the Agency, the DS can be adulterated for failure to submit an NDI notification + lack of safety data
- Just need to show “reasonable expectation of safety”

NDIs and Related Actions of Note

- Androstenedione – WL, seizures
- 6-Oxo – WLs, seizures
- DMAA – WLs, recalls, product destruction, Seizures
- Aegeline – WL, 423(a), product destruction
- Anatabine- WL
- Kratom – Seizures, Import Alert, Import Detentions

Other NDIs

- **Vinpocetine**
  - *Senator Claire McCaskill*
  - **October 6, 2015** – McCaskill letter to FDA (Stephen Ostroff)
  - http://www.mccaskill.senate.gov/imo/media/doc/FDALetterreVinpocetineandPicamilon.pdf

  - **Vinpocetine = 5 AKL NDIs filed**
    - NDI Rpt #12 (Amrion, Inc 7/8/1997) – AKL
    - NDI Rpt #34 (Leiner Health Products 10/20/1998) – AKL
    - NDI Rpt #46 (Leiner Health Products 3/24/1999) – AKL
    - NDI Rpt #47 (General Nutrition Corporation 4/16/1999) – AKL
    - NDI Rpt #48 (Pharmavite Corporation 5/12/1999) – AKL

- **Request for Common on Status of Vinpocetine (FDA) – attempt to ban a 5-time acknowledged DI**
- **October 25, 2016 – Senator Hatch Letter to Commissioner Califf**
- **NPA Comments on Vinpocetine – fits under 201(ff)(1)(F)**

NDIs and Related Actions of Note

WL to Star Scientific

- http://www.fda.gov/iceci/enforcementactions/warningletters/2013/ucm379639.htm
- Dx claims, tobacco, race-to-market provision and NDI.
- No NDI filed
- IND in 2011
- NDI never
- IND won the race
- Lawfully marketed
- Article of the diet

NDIs and Related Actions of Note

Aegeline

- Discussed Previously

NDIs and Related Actions of Note

Other NDIs

- **Kratom**
- **-Never been filed as NDI by anyone**
  - **February 28, 2014** – FDA issues Import Alert IA 54-15
  - **September 25, 2014** – U.S. Marshals seize 25,000 lb. raw kratom ($5M) from Rosefield Management in Van Nuys, California
  - December 18, 2015 - http://www.bevnet.com/news/2015/with-mounting-pressure-from-fda-vivazen-removes-kratom-in-product-reformulation
  - **January 6, 2016** – RelaKzpro (Administrative Detention) 402(f)(1)(B)
  - FDA – failure to file an NDI, safety concerns
  - http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm480344.htm
- **DEA – Attempted to ban Kratom as Schedule I drug (August 2016)**
- **DEA withdraws kratom ban, opens public comment period as per Congressional request**

Other NDIs

Picamilon

- **September 28, 2015** - FDA employee provides signed affidavit, notarized by state of MD
- http://www.npainfo.org/App_Themes/NPA/docs/press/PressReleases/Welch%20Affidavit%20Picamilon%20092815-signed-OR.PDF
- **October 22, 2015** – Oregon AG lawsuit over picamilon and BMPEA
- **November 9, 2015** – FDA inactivity on picamilon prompted Sen McCaskill to pull picamilon and vinpocetine supplements
- http://www.mccaskill.senate.gov/imo/media/doc/allletterspicamilon.pdf
- **Touhy regulations** – provide a procedure for centralized agency decisionmaking concerning how the agency will respond to a subpoena or other request for testimony or documents served
- Procedural error (Touhy v. Ragen, 340 U.S. 462, 468 (1951); 5 USC Section 301 (*Touhy* Regulations)
- **November 30, 2015** – FDA sends WL to 5 firms stating picamilon does not meet the statutory definition of a dietary ingredient
- **Prior to Nov 30, 2015**, FDA had never rendered a position on picamilon's NDI status
  - DBM Nutrition, ICF International, Top Secret Nutrition LLC, Applied Nutriceuticals Inc., SDC Nutrition, Inc.

Other NDIs

BM PEA

- *Beta-methylphenethylamine*
- **2012** – BMPEA was being detained upon import under 402(f)(1)(B) by FDA
- **April 22, 2015** – FDA sent WLs to 5 firms that BMPEA is not a legal ingredient
- **October 22, 2015** – Oregon AG lawsuit over picamilon and BMPEA

Other NDIs

Powdered Caffeine

- *Caffeine is GRAS and is a lawful food ingredient and dietary ingredient*
- Powdered caffeine should be regulated under the normal conditions of use as stated on the label (not under the conditions when people take inordinate amounts of it)
  - **Everything is toxic in high amounts**
  - High water consumption – hypervolemic hyponatremia
  - **September 1, 2015** – FDA sends letters to five companies stating powdered caffeine is dangerous and presents a significant or unreasonable risk of illness or injury to consumers.
  - They still make **1/16, 1/32** teaspoons for measuring **“drop”, “smidgen”, “pinch”, “dash” and “tad”** in cookbooks.
  - These terms and their corresponding amts have been around forever
  - **Products were labeled correctly**

Future of NDI Enforcement

- **Blue-Green Algae**
  - *Aphanizomenon flos aquae*
- **Kava?? - making a comeback**
  - http://www.fda.gov/Food/ResourcesForYou/Consumers/ucm085482.htmking a comeback
  - **http://www.fda.gov/Food/ResourcesForYou/Consumers/ucm085482.htm**
  - March 25, 2002 Consumer Advisory
- Re-evaluation of old NDIs (Vincamine/Vinpocetine)??

- **Other PEA variants** not found in plants (N,N dimethyl/diethyl, etc.)
- **1,4-Butanediol**
- **Tryptamines** (progenitors or variations of known psychedelic tryptamines)
- **Bee Venom**

Roadmap

- Harms/Hazards and Managing Risk
- Regulatory Tools of FDA for Dietary Supplements
- Regulatory Action on Ingredients
- **Legislative: What is NPA Doing?**
- FDA on “Natural”
- NPA Tools to Assist Industry

Legislative Issues – NPA Lead

Natural Products Association

Medical Foods
- FDA Guidance Issued
- Need to better define foods that fit this category

NFL
- Final Rule
- NPA Comments
- DS Labels look very similar to the way they used to (FDA lacked empirical data)

FSMA
- FDA never addressed DI for use in DS
- Request for special session
- Enforcement strategy??

GRAS
- Final Rule
- FDA wants voluntary submissions

WIC
- Expand WIC food packages
- Inclusion of multivitamins

FDA Redbook
- FDA planning a revision
- FDA announced inclusion of DS under FDA's Redbook
- Congress Push Back
- FDA apparently ha dropped

Puerto Rico
- Final Rule
- NPA Comments
- DS Labels look very similar to the way they used to (FDA lacked empirical data)

Massachusetts
- State legislation
- Bill to ban sale of wt. loss and muscle building to minors

Cosmetics Bill (Feinstein)
- Possible drop in 2017
- Address Ingredients
- GMPs
- SAERs
- Inspections

NDAA Defense Authorization
- Sen. Blumenthal
- Amendment to limit military access to DS at base commissaries and post exchanges

Roadmap

- Harms/Hazards and Managing Risk
- Regulatory Tools of FDA for Dietary Supplements
- Regulatory Action on Ingredients
- Legislative
- **FDA on “Natural”**
- NPA Tools to Assist Industry

Natural Comments - NPA

- FDA requested comments on use of ‘natural’ on human food labeling in December 2015
  - Whether appropriate to define ‘natural’
  - How the agency should define ‘natural’
  - How the agency should determine appropriate use of the term on food labels
  - USDA has defined “natural” for meat and poultry
    - not more than “minimally processed”
    - No artificial flavor or flavoring, coloring ingredient, chemical preservative or any other artificial/synthetic ingredient
- USDA - has defined “natural” for meat and poultry
  - not more than “minimally processed”
    - Smoking, roasting, freezing, drying, grinding, pressing, etc.
  - No artificial flavor or flavoring, coloring ingredient, chemical preservative or any other artificial/synthetic ingredient

Natural Comments - NPA

- The term “Natural” has more appeal to consumers in the U.S. than the term “organic” and therefore FDA should allow it
- NPA fought FDA for the rights of retailers and mfrs to include the term on products in the 1960s and 1970s
- NPA filed Comments May 10, 2016 in response to FDA’s call for stakeholder comment
  - Organic is non-GMO
  - “Natural” should be separate from “Organic”, which does not allow GMO ingredients
  - FDA should address/define “natural” through public rulemaking
  - NPA supports one overarching Federal standard to avoid patchwork regulations from states, commonwealths, and territories on ‘natural’ claims
  - NPA recommended harmonization of its future ‘natural’ definition with USDA’s FSIS definition of ‘natural’ (above)

Natural Comments - NPA

- Other highlights on ‘Natural’
  - NPA requested FDA incorporate its policies on foods developed from biotechnology in its definition of natural
  - ‘Natural’ should encompass both ingredient AND process
  - Illustrative List of Natural Processes
    - NPA supported the development of an illustrative list of accepted ‘natural’ processes
  - Illustrative List of Natural Ingredients
    - NPA requested the inclusion of natural preservatives, natural colors, incidental additives and some processing aids be included in the positive illustrative list of allowable natural ingredients
  - NPA supported a multi-tier approach, similar to USDA’s National Organic Program, which allows for 5% synthetics (if synthetic on their allowable list) for products seeking “organic” certification
  - Products with “100% natural” or “all natural” claims should have no synthetics
  - NPA’s “natural seal” standard for personal and home care products has been an industry standard as companies re-formulate with safer ingredients

Labeling category	Principal display panel	Information panel	Ingredient Statement	Other package panels
"100 percent natural" or "All natural" (Entirely natural; whole, raw or processed product)	"100 percent natural" or "All natural" (optional) FDA sea and certifying agent seal(s) (optional)	"100 percent natural" or "All natural" (optional) Certifying agent name (required); business/Internet address, telephone #, (optional)	If multi-ingredient product, identify each ingredient as "natural" (optional)	"100 percent natural" or "All natural" FDA seal and certifying agent seal(s) (optional)
"Natural" (95% or more natural ingredients)	"Natural" (plus product name) (optional) FDA seal and certifying agent seal(s) (optional)	"X % natural" for ≥ 95% (optional) Certifying agent name (required); business/Internet address, telephone number (optional)	Identify natural ingredients as "natural" (required if other natural labeling is shown)	"X% natural" (optional) FDA seal and certifying agent seal(s) (optional)
"Made with Natural Ingredients" (50 to 95% natural ingredients)†	"Made with natural (ingredients or food group(s))" (optional) "X % natural" if < 95% or ≥ 50% (optional) Certifying agent seal of final product handler (optional) Prohibited: FDA seal	"X % natural ingredients (optional) Certifying agent name (required); business/internet address, telephone number (optional) Prohibited: FDA seal	Identify natural ingredients as "natural" (required if other natural labeling is shown)	"made with natural (ingredients or food group(s))" (optional) "X % natural" (optional) Certifying agent seal of final product handler (optional) Prohibited: FDA seal
Less Than 50% natural ingredients (Allowable as long as the percent designated is truthful and not misleading)	"Made with X% natural (ingredients or food group(s))" (optional) "X % natural" if < 50% (optional) Certifying agent seal of final product handler (optional) Prohibited: FDA seal	"X % natural ingredients (optional) Certifying agent name (required); business/internet address, telephone number (optional) Prohibited: FDA seal	Identify natural ingredients as "natural" (required if other natural labeling is shown)	"made with X% natural (ingredients or food group(s))" (optional) "X % natural" (optional) Certifying agent seal of final product handler (optional) Prohibited: FDA seal

Roadmap

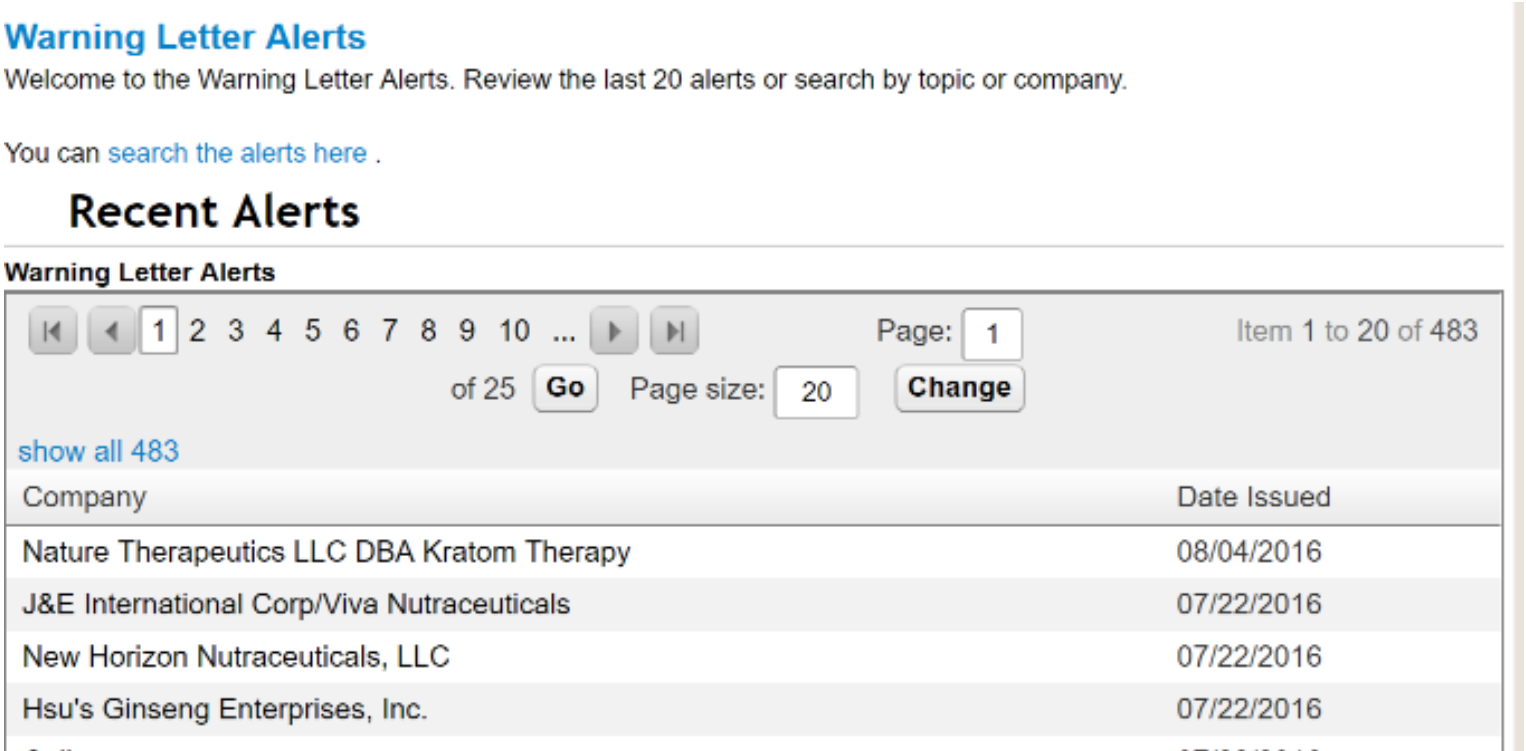
- Harms/Hazards and Managing Risk
- Regulatory Tools of FDA for Dietary Supplements
- Regulatory Action on Ingredients
- Legislative
- FDA on “Natural”
- **NPA Tools to Assist Industry**

Safe Harbor List

- List of dietary ingredients marketed prior to DSHEA in 1994
- This list includes verified ingredients from media reports, advertising, and other public sources
- Verify that your ingredient is on this list before you submit a NDI submission
- Addresses evidence FDA is seeking for a company to prove it was a pre-DSHEA ingredient
- NO OTHER lists will be excepted by the FDA

Warning Letter Database

- View violations against the dietary supplement Good Manufacturing Practices (GMPs)
- Beneficial for those responsible for labeling compliance to avoid the introduction of misbranded product
- View FDA Trends and print reports



Warning Letter Alerts

Welcome to the Warning Letter Alerts. Review the last 20 alerts or search by topic or company.

You can search the alerts here .

Recent Alerts

Warning Letter Alerts

1 2 3 4 5 6 7 8 9 10 ... Page: 1 Item 1 to 20 of 483

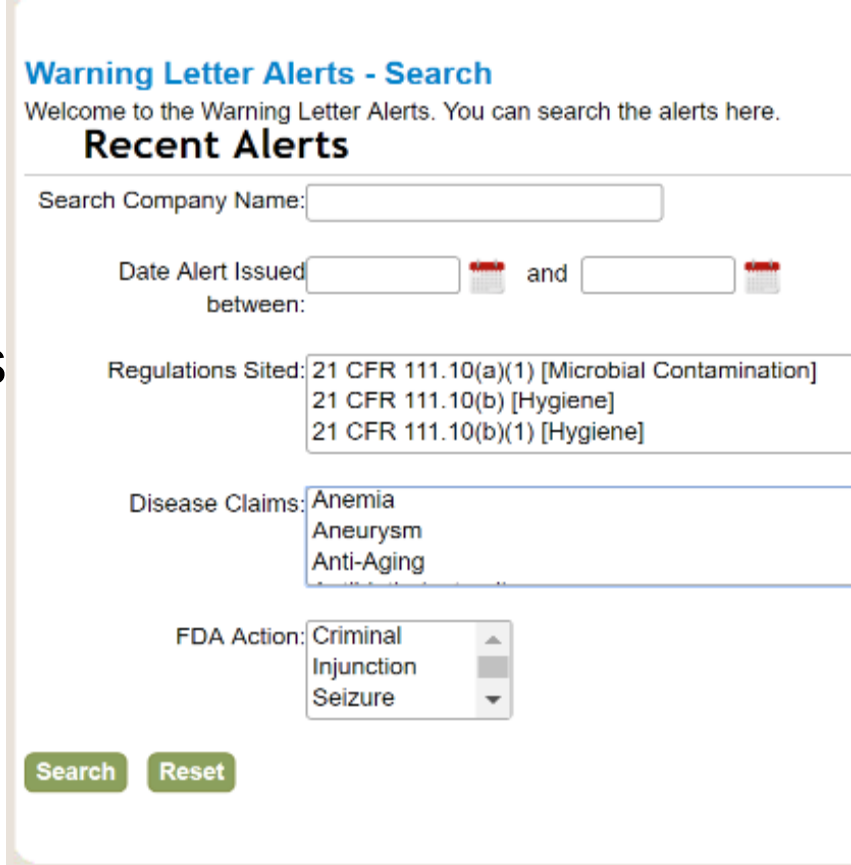
of 25 Go Page size: 20 Change

show all 483

Company	Date Issued
Nature Therapeutics LLC DBA Kratom Therapy	08/04/2016
J&E International Corp/Viva Nutraceuticals	07/22/2016
New Horizon Nutraceuticals, LLC	07/22/2016
Hsu's Ginseng Enterprises, Inc.	07/22/2016

Warning Letter Database

- Searchable
  - Company
  - Dates
  - Regulations Sited
  - Disease Claims
- More than just warning letters
  - Captures enforcement actions from all federal agencies
    - Seizures
    - Injunctions
    - Fortfeitures
    - Civil & Criminal
  - disease claims/claim categories
  - Includes supplements and cosmetics



TruLabel Database

Registration

- License Plate
- Lists Responsible Companies
- Label – publicly available
- No hiding from government

Testing

- Random Testing of Specific Categories of DS Products
- Assess Year-to-Year Compliance for Various Categories
- Sample size of categories – designed to detect a 2% change in compliance
- Is the Industry Improving?

Natural Products ASSOCIATION™

Any Questions?

Stay up-to-date on food law developments by subscribing to our blog:
http://www.thehealthlawpulse.com/category/food-safety/

Speaker

Jane Caskey

Global Head of Risk Advisory, Norton Rose Fulbright

Jane Caskey is global head of our risk advisory practice. She currently sits as a member of our global executive committee and our Canadian management committee.

Ms. Caskey practises intellectual property law, including all aspects of trade-mark and patent litigation including expertise in remedies and damages references, trade-mark prosecution, and opposition work. She is also involved in advising clients on strategy, branding issues, identifying and commercializing IP rights, IP support in corporate commercial transactions and trade-mark portfolio management and strategy. Ms. Caskey has particular expertise in the pharma/life sciences industry.

Ms. Caskey has extensive experience as an advocate at both the trial and appellate levels and appears regularly before the Federal Court of Canada and the Superior Court of Justice of Ontario. She also participates in resolving client issues through negotiation/alternative dispute resolution and has broad experience as an advocate on arbitrations and mediations. Ms. Caskey is a frequent lecturer at Insight, The Canadian Institute, Federated Press and the Advocates' Society, and has written articles on IP enforcement, counterfeiting, protection and licensing of IP rights.

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Speaker

Cori Annapolen Goldberg

Sr. Associate, Norton Rose Fulbright

Cori Annapolen Goldberg focuses her practice on FDA issues for the food, drug, and device industries; health law matters; government and internal investigations; and white collar criminal defense. Cori has both transactional and regulatory expertise. She has worked with clients including medical device manufacturers, pharmaceutical companies, food manufacturers, hospitals, academic medical centers, physicians, and other health care providers. Her practice includes the representation of clients in compliance matters, including internal investigations and self-disclosures.

Cori advises her clients on a broad array of topics including food and drug law issues, including FSMA implementation and food safety concerns; clinical research considerations; corporate compliance concerns; and fraud and abuse issues. She also represents large corporations in investigations by the US Department of Justice, the Department of Health and Human Services Office of Inspector General, the US Food and Drug Administration, and other federal and state agencies.

NORTON ROSE FULBRIGHT

Speaker

Rick Robinson

Global Co-Head of Life Sciences and Healthcare, Norton Rose Fulbright

Rick began his legal career representing a wide variety of corporations and their officers in government investigations and white-collar criminal cases. During this time, he participated in a number of high-profile public corruption cases.

In the late 1980s, the federal government publicly announced that the investigation and prosecution of health care fraud and abuse would be one of its top law enforcement priorities. Thereafter, healthcare clients began turning to Rick to counsel and defend them in this new environment of increased regulation and scrutiny.

Rick combines the skills he developed as a trial lawyer with a broad knowledge of administrative law and healthcare regulations to defend our healthcare clients in government audits and investigations. He helps clients avoid unwanted scrutiny by working with them to design regulatory compliance programs and by advising them on a multitude of voluntary disclosure issues. Rick also has represented many of our clients in litigation affirmatively challenging regulations and policies adopted by government agencies.

NORTON ROSE FULBRIGHT

Speaker

Randy Sutton

Partner, Norton Rose Fulbright

Randy Sutton practises in the area of dispute resolution. Mr. Sutton represents international and domestic clients in a variety of business sectors in court and administrative proceedings, mediations and arbitrations and has appeared in the provincial and federal courts throughout Canada.

Mr. Sutton has provided advice on commercial, contract, tort, product liability, product recall, insurance, defamation, intellectual property and franchise matters. He also provides ongoing risk management and insurance coverage advice. He has developed specific expertise in the area of class action litigation and has acted for a number of clients in class actions throughout Canada.

Mr. Sutton is a member of the British Columbia, Saskatchewan and Ontario bars and practises throughout Canada. He is co-chair of our national class actions team, the partner responsible for professional liability matters in Ontario, a member of our Canadian risk and audit committee and leads our life sciences and healthcare industry group in Canada.

NORTON ROSE FULBRIGHT

Speaker

Sara Zborovski

Partner, Norton Rose Fulbright

Sara Zborovski practises regulatory, commercial and intellectual property law in our Toronto office. She assists companies regulated by Health Canada in obtaining market access and in all areas of compliance. Ms. Zborovski has experience in a wide range of matters involving the innovative pharmaceutical and biotechnology, natural health product, medical device and food and beverage industries.

Ms. Zborovski advises clients on product classification, clinical trials, market authorization and market access strategies, including clinical trial applications and agreements, product licence strategies, market access strategies (including assistance with the Common Drug Review and formulary listings) and establishment licensing and GMP programs. She also assists companies regulated by the Patented Medicine Prices Review Board.

On the compliance side, Ms. Zborovski assists clients in developing SOPs and compliance policies, ensuring compliant packaging and labelling (including label reviews) and provides strategic advice on advertising and marketing programs (including assistance with pre-clearance agencies and representing companies in disputes before the Pharmaceutical Advertising Advisory Board and Advertising Standards Canada). She also advises clients on federal and provincial privacy laws, particularly as these relate to healthcare, and federal and provincial access to information and freedom of information matters.

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Speaker

Dr. Daniel Fabricant

Executive Director and CEO, Natural Products Association (NPA)

Daniel Fabricant, Ph.D. is Executive Director and CEO of the Natural Products Association (NPA), the nation's largest and oldest trade organization representing the natural products industry. Recently, he served as the Director of the Division of Dietary Supplement Programs at the U.S. Food and Drug Administration (FDA). Prior to the FDA, Dr. Fabricant was vice president, global government and scientific affairs, for NPA. He earned a Ph.D. in Pharmacognosy from the University of Illinois at Chicago, where he has served as an adjunct professor in the Department of Medicinal Chemistry and Pharmacognosy since 2009.

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