8th Annual Food and Drug Law CLE

All Matters FDA:

Opioids, Whistleblower Actions, Medical Device Safety, Food Defense, Personal Care Products Regulation, Dietary Supplement Regulation, Top Notables, and Other Matters FDA

Presented by the Widener University Delaware Law School Food and Drug Law Association

Wednesday, April 4, 2018

12:30–5:00 p.m.

Delaware Law School

delawarelaw.widener.edu

Food and Drug Law CLE
Wednesday, April 4, 2018
Agenda

12:00 noon	**REGISTRATION CHECK-IN**
12:30 – 1:00 p.m.	**Robert J. Durkin, Esquire, M.S., R.Ph.** Deputy Director Office of Dietary Supplement Programs, Center for Food Safety and Applied Nutrition, Food and Drug Administration (FDA)
1:00 – 2:00 p.m.	**Kevin M. Bosch** Special Agent, Federal Bureau of Investigation (FBI), Philadelphia Division **Kevin Spradlin** Intelligence Analyst, Federal Bureau of Investigation (FBI), Washington, DC **Matthew R. Noonan** Compliance Officer FDA Human & Animal Food Division
2:15 – 2:45 p.m.	**Stanley R. Milstein, Ph.D.** Former Acting Deputy Director (retired), FDA Office of Cosmetics and Colors
2:45 – 3:15 p.m.	**Break**
3:15 – 3:45 p.m.	**Roseann B. Termini, Esquire** Food and Drug Law Legal Scholar; National Speaker, Online FDA Law Courses, Widener University Delaware Law School
3:45 – 4:15 p.m.	**Charlene Fullmer, Esquire** Deputy Chief for Affirmative Litigation, Civil Division, United States Attorney's Office, Eastern District of Pennsylvania
4:15 – 4:45 p.m.	**Hooman Noorchashm, M.D.** Cardiac Surgeon, Philadelphia, PA
4:45 – 5:00 p.m.	**Q & A**

WIRELESS ACCESS INFORMATION AS A "WIDENER GUEST"

WIDENER UNIVERSITY DELAWARE LAW SCHOOL
Ruby R. Vale Moot Courtroom
WEDNESDAY, APRIL 4, 2018

Username: fdla
Password: cle2018

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COURSE MATERIALS

Course materials are available for download as a pdf at delawarelaw.widener.edu/fdacle

BIOGRAPHIES

KEVIN M. BOSCH

Special Agent, Philadelphia Division of the Federal Bureau of Investigation (FBI)

Special Agent **Kevin M. Bosch** has been with the Philadelphia Division of the Federal Bureau of Investigation (FBI) for twenty-two years. He is currently the Philadelphia Division Weapons of Mass Destruction (WMD) Coordinator, a member of the FBI's Hazardous Evidence Response Team (HERT) and a HAZMAT Technician. He has investigated a variety of Eurasian Organized Crime cases to include extortions, drug investigations, complex money laundering and fraud cases and a number of undercover operations. Immediately after the events of September 11, 2001, he was part of a contingent of Philadelphia Special Agents who were dispatched to assist in the recovery efforts in Staten Island, NY. In October 2001 he was assigned to the AMERITHRAX investigation where he conducted HERT operations at the AMI building in Boca Raton, Florida, and at several of the contaminated postal facilities in the Trenton, New Jersey, area. Special Agent Bosch is a 1992 graduate of West Chester University with a Bachelor Degree in Accounting and holds a CPA.

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ROBERT J. DURKIN, ESQUIRE, M.S., R.Ph

Deputy Director Office of Dietary Supplement Programs, Center for Food Safety and Applied Nutrition, Food and Drug Administration (FDA)

Bob Durkin is the Deputy Director of the Office of Dietary Supplement Programs (ODSP) in FDA's Center for Food Safety and Applied Nutrition (CFSAN). He has been in this role since July, 2016; prior to this serving as the first acting Office Director of ODSP.

Before joining ODSP, he served as Acting Director of the Food Defense and Emergency Coordination Staff (FDECS) at CFSAN. Bob joined the FDA in 2008 as a consumer safety officer with the Center for Drug Evaluation & Research's (CDER) - Office of Compliance where he worked on regulatory actions with respect to misbranded and unapproved new drugs, including compounded drugs, fraudulent drugs, marketed unapproved drugs, and over-the-counter drugs.

Prior to joining FDA, he served as a Commissioned Officer in the US Army where he completed a residency in Nuclear Pharmacy Practice at Walter Reed Army Medical Center and obtained status as Board Certified Nuclear Pharmacist.

Bob received his pharmacy degree from Philadelphia College of Pharmacy and Science, his master's degree in cell-molecular-biology from the University of Hawaii at Manoa, and his law degree from Widener University. He is licensed to practice pharmacy in Pennsylvania and Maryland and is a member of the Pennsylvania Bar.

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CHARLENE FULLMER, ESQUIRE

Deputy Chief for Affirmative Litigation, Civil Division,
United States Attorney's Office, Eastern District of Pennsylvania

Assistant United States Attorney **Charlene Keller Fullmer** is the Deputy Chief for Affirmative Litigation in the Civil Division of the United States Attorney's Office in the Eastern District of Pennsylvania, where she supervises and prosecutes health care and affirmative fraud matters. In October 2010, Attorney General Eric Holder presented her with the Attorney General Award for Exceptional Service, the Department of Justice's highest commendation.

She is a 1993 graduate of Lehigh University, cum laude, and a 1996 graduate of Temple University School of Law, cum laude, where she served on the Law Review.

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STANLEY R. MILSTEIN, Ph.D.

Former Acting Deputy Director (retired), FDA Office of Cosmetics and Colors

Stanley R. Milstein, Ph.D. retired in February 2017 as Acting Deputy Director in FDA's Office of Cosmetics and Colors at the FDA Center for Food Safety and Applied Nutrition (CFSAN) in Washington, D.C. Prior to joining the Agency, Dr. Milstein held several senior scientific and regulatory affairs positions in the R&D Division of the Andrew Jergens Company (Cincinnati, OH). He represented, FDA (until 2017) as a member of the U.S. delegation to the International Cooperation on Cosmetics Regulation (ICCR) and as the agency's non-voting liaison to the Personal Care Product Council (PCPC) International Nomenclature Committee (INC) from 1991-2017. He is currently a member of the FDA Alumni Association (FDAAA) - Activities Committee (http://www.fdaaa.org).

Professionally, Dr. Milstein is a Fellow of the Society of Cosmetic Chemists (SCC) and served the SCC in several local, regional, and national elected capacities over the past 35+ years. He served as Chair, Ohio Valley Chapter (OVCSCC) in 1984, Area II Director (1985), and also a term as President of the National SCC in 1992. He served as 2014 Chair, Mid-Atlantic Chapter SCC (MACSCC) and is currently the Senior SCC Area IV Director (Mid-Atlantic, Southeast, Florida, and Carolinas Chapters). He has been an active member of ACS since 1968 and of the Cincinnati Section (CINTACS) and the Chemical Society of Washington (ACS-CSW). He has held several visiting and adjunct faculty appointments in general and organic chemistry, as well as in cosmetic science in the Departments of Chemistry at Adelphi University (Garden City, NY) and the University of Cincinnati, respectively. Dr. Milstein has frequently addressed foreign regulatory delegations to FDA-CFSAN and has also spoken to audiences at CTFA, PCPC and ICMAD industry conferences. He also has been an annual invited presenter at the FDA Office of Regulatory Affairs University course on Import Operations and Entry Review and has made presentations at the Regulatory Affairs Program of Temple University. Most recently, he organized and co-Chaired a session on "*Cosmetic Chemistry*" at ACS-MARM 2017 (Hershey, PA, June 5, 2017).

Dr. Milstein has published in the peer review literature of organic and medicinal chemistry, cosmetic science, and regulatory affairs, most recently as principal co-author of two chapters on cosmetic regulation in the *Handbook of Cosmetic Science and Technology* (Marcel Dekker/

Taylor-Francis, 2001, 2006) and co-author of a chapter on the analysis and regulatory aspects of color additives in cosmetics in *Analysis of Cosmetic Products* (Elsevier, 2007, 2017).

Dr. Milstein holds a B.S. degree in Biology from Rensselaer Polytechnic Institute, an M.S. degree in Pharmaceutical Sciences (Cosmetic Science) from the University of Cincinnati College of Pharmacy, and a Ph.D. in Organic Chemistry from Adelphi University (Garden City, NY). He also completed two post-doctoral research fellowships in medicinal chemistry and QSAR at Pomona College (Claremont, CA) and at the University of Cincinnati College of Pharmacy (Cincinnati, OH).

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MATTHEW R. NOONAN, ESQUIRE

Compliance Officer, FDA Human & Animal Food Division

Matthew Noonan is a Compliance Officer with FDA's Office of Regulatory Affairs (ORA), Human and Animal Food Division 2 East. He follows up on potentially violative establishment inspections and pursues voluntary correction or court action as appropriate. Matt also develops and presents agency training and industry presentations, and fields industry inquiries.

Previously, Matt served as a Field Investigator in program areas such as food, drugs, and bioresearch monitoring. He was a lead trainer of novice investigators across these areas. As a Food Specialist, Matt conducted complex high-risk inspections and served as a subject matter expert. He achieved ORA Level II Certification in Low Acid Canned Food, Acidified Food, and Seafood. Matt is also a member of the ORA Instructor Cadre for Preventive Controls for Human Food, the ORA Certification Board for Seafood, and the Certified Seafood Trainer Group under the Association of Food and Drug Officials.

Matt is an Assistant Adjunct Professor in the Temple University School of Pharmacy, Regulatory Affairs and Quality Assurance Graduate Program. He teaches separate courses in Good Manufacturing Practices for Food and for Drugs, and will soon begin teaching Food Law and Food Labeling and Regulatory Affairs.

Matt graduated cum laude from St. Joseph's University (Philadelphia, PA) with a BS in Chemistry and a Minor in Secondary Education, and from The George Washington University Law School (Washington, DC) with a JD. He is also a graduate of the inaugural ORA Potential Supervisors Program.

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HOOMAN NOORCHASHM, M.D.

Cardiac Surgeon, Philadelphia, PA

Dr. Hooman Noorchashm is a cardiothoracic surgeon in Philadelphia, Pennsylvania. He trained at Hospital of University of Pennsylvania and Harvard Medical School's Brigham and Women's Hospital. Dr. Noorchashm is a devoted patient advocate, author, speaker and father of six children.

Dr. Noorchashm met his wife, Amy Reed, in Medical School at the University of Pennsylvania. Amy was an anesthesiologist and surgical intensive care physician.

In October, 2013, Amy, underwent surgery to remove uterine fibroids through a laparoscopic procedure. The surgery involved the use of a medical device known as the Power Morcellator. Shortly thereafter it was discovered that Amy's fibroid was, in fact cancerous. The morcellation of the fibroid caused the cancer to spread throughout her abdomen, leading to Amy's untimely death in May of 2017.

Amy's diagnosis of leiomyosarcoma served as the beginning of Amy and Hooman's extensive research on power morcellation. As a result of their research, Hooman and Amy began a quest to educate companies, lawmakers, the medical community and the public about the dangers of power morcellation. They also lead, and Hooman continues to pursue regulatory reform efforts relating to FDA approved medical devices.

Hooman and I will present to you today in an interview/conversational format. We welcome interjection of questions throughout the presentation, so please feel free to raise your hand at any time and we will address your questions.

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KEVIN SPRADLIN

Intelligence Analyst, FBI, Washington, D.C.

Kevin Spradlin is an intelligence analyst in the FBI's Weapons of Mass Destruction Directorate (WMDD) in Washington, DC. As an analyst in the Critical Infrastructure Fusion Cell (CIFC), he identifies WMD threats and vulnerabilities associated with the food, water, energy, and transportation sectors. He joined the FBI in 2004 and was assigned to the Oklahoma City Field Office where he worked gang and violent crime matters, served on the Joint Terrorism Task Force, and was the WMD analyst. In 2010 Mr. Spradlin transferred to the FBI Academy at Quantico, Virginia as an instructor for newly hired analysts. He joined the CIFC in 2016.

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ROSEANN B. TERMINI, ESQUIRE

Food and Drug Law Legal Scholar; National Speaker, Online FDA Law Courses, Widener University Delaware Law School

Roseann B. Termini, B.S., Ed. M., J.D. has extensive experience in food, drug, medical devices, personal care, dietary supplement, tobacco and veterinary products regulation. Ms. Termini recently published a new comprehensive edition both in print and E-book formats of *Food and Drug Law: Federal Regulation of Drugs, Biologics, Medical Devices, Foods, Dietary Supplements, Personal Care, Veterinary and Tobacco Products* (2017). She published the new edition because of evolving law, novel cases and latest regulations and an E-book that mirrors the print book as well as 12 stand-alone separate subject specific E-books. Professional considerations, ethical issues, enforcement, criminal corporate liability and politics are covered. See: *www.fortipublications.com*

Frequently, Ms. Termini is a featured speaker at international and national conferences and webinars including the Central Atlantic Association of Food and Drug Law Officials, the Pennsylvania Bar Institute, FDANews and the Food and Drug Law Institute. Recently, she was selected to present at the Center for Ethics and Rule of Law Opioid Conference, was the sole speaker at a national opioid webinar and has been interviewed about this crisis. Ms. Termini is the faculty conference head of the annual "All Matters FDA" conference at Delaware Law, Widener University that addresses "hot topics" such as the Opioid Crisis, Foreign Corrupt Practices Act, Biosimilars, Intended Use, Tobacco Products Regulation, e-cigarettes, Dietary Supplements, and Corporate Accountability. Presentations have included: *Opioids, Botox, Personal Care Product Classification, Medical Marijuana, Right-to-Ask, Criminal Enforcement, Who Really Regulates Your Pizza, Are "Smart Labels" Really Smart, Terminology such as Healthy and Natural, and regulations under the Food Safety and Modernization Act*. Other publications span a broad array of topics such as: corporate criminal liability and accountability, the Foreign Corrupt Practices Act, health claims, supplements, product classification, personal care products safety, duty to warn, preemption, promotion, tobacco, stem cells, risk assessment and globalization.

Her writing expertise led her to an appellate clerkship, position as sole corporate pharmaceutical counsel, regulatory affairs attorney and senior deputy attorney general at the Pennsylvania Office of Attorney General (OAG) where she prosecuted cases at the trial and appellate levels and spearheaded the implementation procedures for the Pennsylvania Plain Language Act. She was the first recipient of the "Plain English" Award by the Pennsylvania Bar Association. Who's Who recognized Ms. Termini's excellence in the field with the Lifetime Achievement Award in 2017.

Ms. Termini has been actively involved in committees of several professional associations for many years, including her service as Chair of a Food and Drug Law Institute Committee. She is Vice Chair of the Pennsylvania Bar Association Disability Rights and Health Law Committees. She served on the President's Council at Immaculata University and as Vice Chair of the Justinian Association. Ms. Termini was appointed to the Board membership of the St. Thomas More Law Society and is a member of the Central Atlantic Association of Food and Drug Law Officials. Her publications are available for download on the SSRN Author page link below.

Contact Details

rbtermini@widener.edu www.fortipublications.com
SSRN Author page: http://ssrn.com/author=944614
http://fortipublications.com/blog/ (All Topics Food and Drug Law Blog)
https://twitter.com/RoseannTermini
www.linkedin.com/in/roseanntermini/

COURSE MATERIALS

An Overview of FDA's Regulation of Dietary Supplements

Bob Durkin, Deputy Director, CFSAN/ODSP

"All Matters FDA"

Widener University Delaware Law School

April 4, 2018

Dietary Supplement Authority

- Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 301 et. seq.)
  - Dietary Supplement Health and Education Act
    - Laid out the major framework for dietary supplements
  - Public Health Security and Bioterrorism Preparedness and Response Act
    - Requirement for facilities to register with FDA
  - Food Allergen Labeling and Consumer Protection Act
    - Allergen labeling requirement

Dietary Supplement Authority

- Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 301 et. seq.)
  - Dietary Supplement and Nonprescription Drug Consumer Protection Act
    - Requirement for dietary supplement firms to submit serious adverse events to FDA
  - FDA Food Safety Modernization Act
    - Major overhaul of framework for food facilities

Dietary Supplement Authority

- Dietary Supplement Health and Education Act of 1994
  - Defined the term dietary supplement
  - Established requirements for new dietary ingredient premarket review
  - Established requirements for current good manufacturing practices
  - Included dietary supplements under the adulteration provisions

Definition of Dietary Supplement

- Product (other than tobacco) that is intended to supplement the diet
- Product that is intended for ingestion
- Contains one or more dietary ingredients
  - Vitamin
  - Mineral
  - Herb or other botanical
  - Amino acid
  - Dietary substance for use by man to supplement the diet by increasing the total dietary intake
  - A concentrate, metabolite, constituent, extract, or combination of any of the above dietary ingredients

Definition of Dietary Supplement

- It does not include
  - an article that is approved as a new drug, certified as an antibiotic, or licensed as a biologic
  - an article authorized for investigation as a new drug, antibiotic, or biological for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public

  (unless such article was first marketed as a dietary supplement or food)

Regulatory Responsibilities

- Facility Registration
- New Dietary Ingredient Notification
- Good Manufacturing Practices
- Dietary Supplement Labeling
- Structure/Function Claim Notification
- Adverse Event Reporting

Facility Registration

- All food facilities must register with FDA
  - Domestic and foreign
  - Basic information: name, address, type of activity conducted at the facility for each food product category, responsible party
  - FDA inspection acknowledgement
- Renewal of information every even numbered year

New Dietary Ingredients

- Dietary ingredients not marketed in a dietary supplement prior to October 15, 1994
- Manufacturers must submit a safety notification to FDA at least 75 days prior to marketing
- FDA has 75 days to respond
  - Acknowledgement – not approval
  - Objection (generally based on identity or safety)
- Notification is made public after 90 days

New Dietary Ingredients

- Notification must include
  - Name and address
  - Signature of responsible party
  - Name of the ingredient
  - Description of the product(s) containing the NDI
  - Amount of the NDI in product(s)
  - Conditions of use
  - History of use or other evidence of safety establishing the NDI "will reasonably be expected to be safe"

New Dietary Ingredients

- While the requirement has been in place for 20+ years, FDA has only received ~1000 NDINs
- Important that firms know:
  - When to submit a premarket notification
  - How to prepare a premarket notification

Current Good Manufacturing Practices

- FDA published the CGMP Rule in 2007
  - 21 CFR 111
- To help ensure dietary supplement product quality, purity, consistency, and safety
  - Production and process controls
  - Testing requirements for raw materials and finished products

Current Good Manufacturing Practices

- Applies to all firms who manufacture, package, label or hold dietary supplements
  - Domestic and foreign
- Compliance confirmed by periodic inspections
  - ORA investigators

Dietary Supplement Labeling

- Dietary supplements must follow food labeling requirements (21 CFR 101)
  - Must be labeled as a “dietary supplement”
  - Must list all ingredients
    - Properly formatted Supplement Fact label
  - Name/location of manufacturer
  - Domestic contact information for submission of adverse events

Dietary Supplement Labeling

- Allowed claims
  - Nutrient content claims
    - Characterizes the level of a nutrient
  - Structure/function claims
    - Describes the role of a nutrient or dietary ingredient intended to affect the structure or function in humans
  - Health claims/qualified health claims
    - Characterizes the relationship of any substance to reducing risk of a disease

Structure/Function Claims

- Claims made in accordance with section 403(r)(6) of the FD&C Act
  - nutrient deficiency disease claim
  - general well-being claim
  - structure/function claim
- Cannot claim to treat, cure, prevent disease
  - Disease = damage to an organ, part, structure, or system of the body such that it does not function properly, or a state of health leading to such dysfunction

Structure/Function Notification

- Firms need to
  - have substantiation that the claim is truthful and not misleading
  - notify FDA of the text of the claim no later than 30 days after marketing the product containing the claim
  - include the FDA disclaimer language
- Firms do not need to
  - provide the entire label/labeling with their notification
  - provide the substantiation

Disease Claims

- Context is CRITICAL
  - Not always possible to draw a clear line
  - Need to consider all information in labeling and elsewhere
  - No claim is likely to be always or never appropriate
- Factors to take into account
  - Guidance for Industry: Structure/Function Claims, Small Entity Compliance Guide

Adverse Event Reporting

- FDA's MedWatch program receives dietary supplement adverse events
  - Electronic portal, email, phone calls, letters
- Consumers and health care providers are encouraged to submit adverse events
- Manufacturers are required by law to submit serious adverse events to FDA within 15 business days

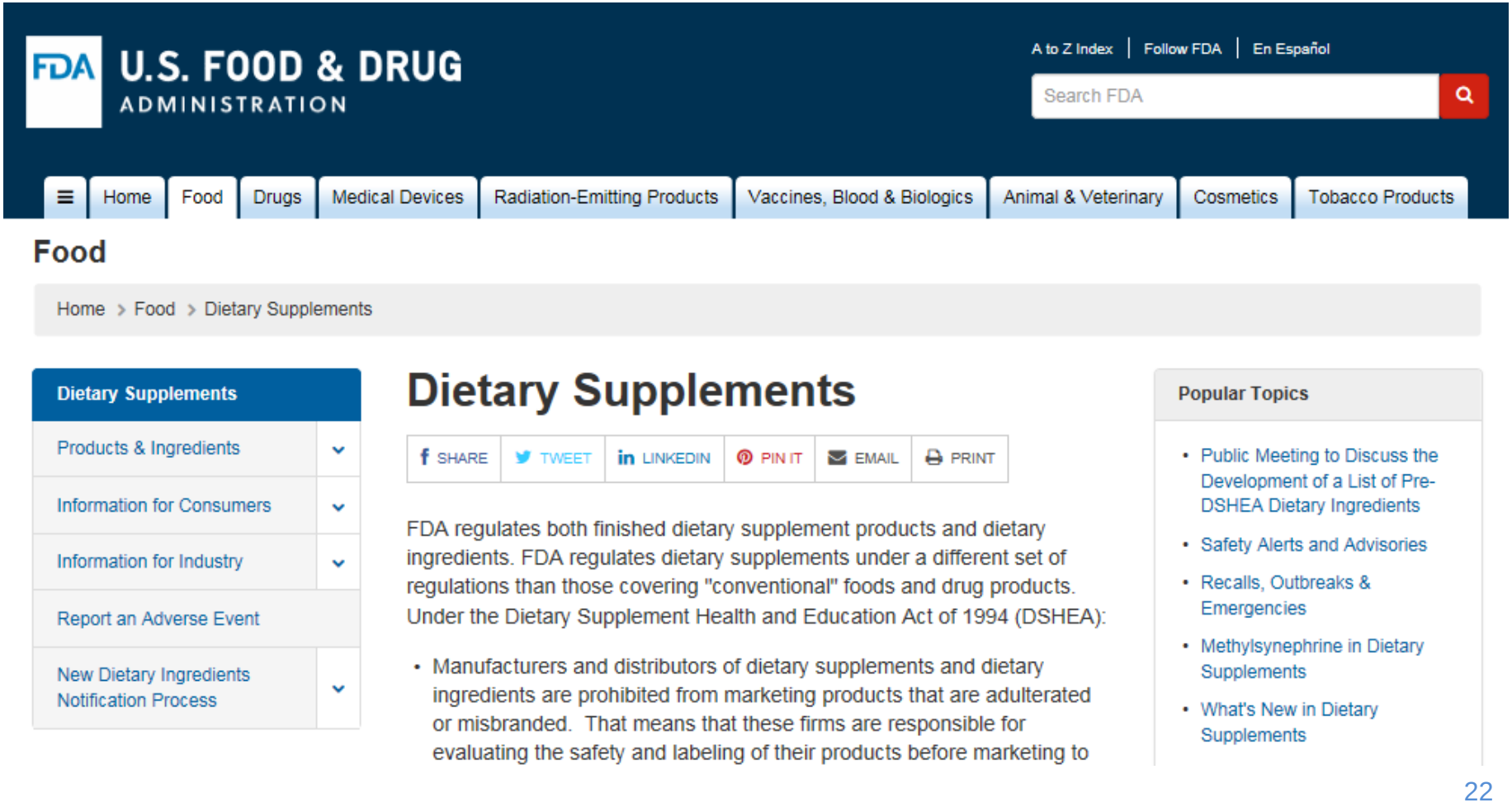
Adverse Event Reporting

- All dietary supplement adverse events are entered into the CFSAN Adverse Event Reporting System (CAERS) database
- Reviewer will evaluate cases
  - Identify any triggers with firms, products, ingredients
  - Determine if any follow-up information is necessary
    - Inspection, consumer warning, product recall

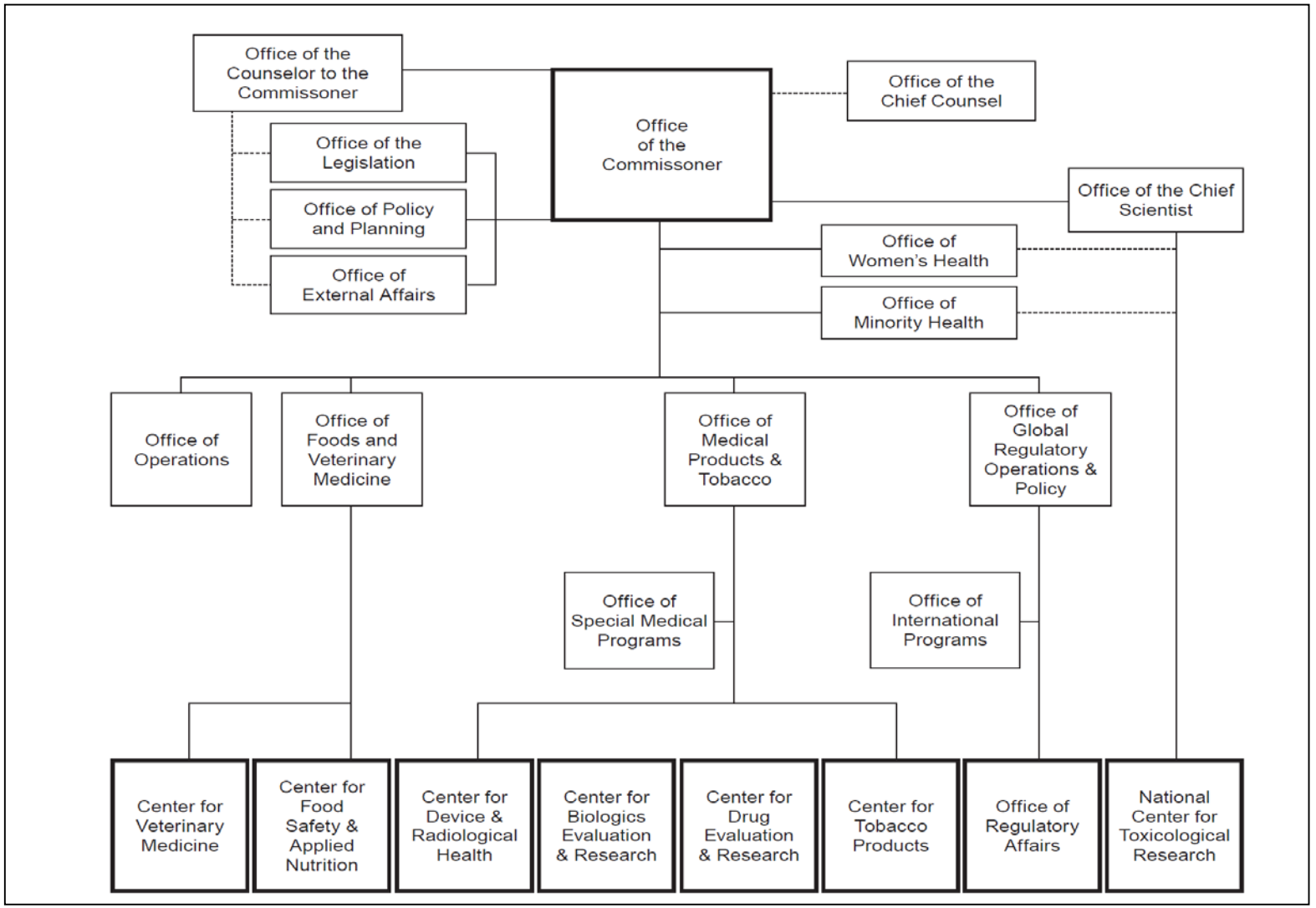
Regulatory Recap

- Facility (not product) Registration
- New Dietary Ingredient Notification (not approval)
- Good Manufacturing Practices
- Dietary Supplement Labeling
- Structure/Function Claim Notification (not approval)
- (Serious) Adverse Event Reporting

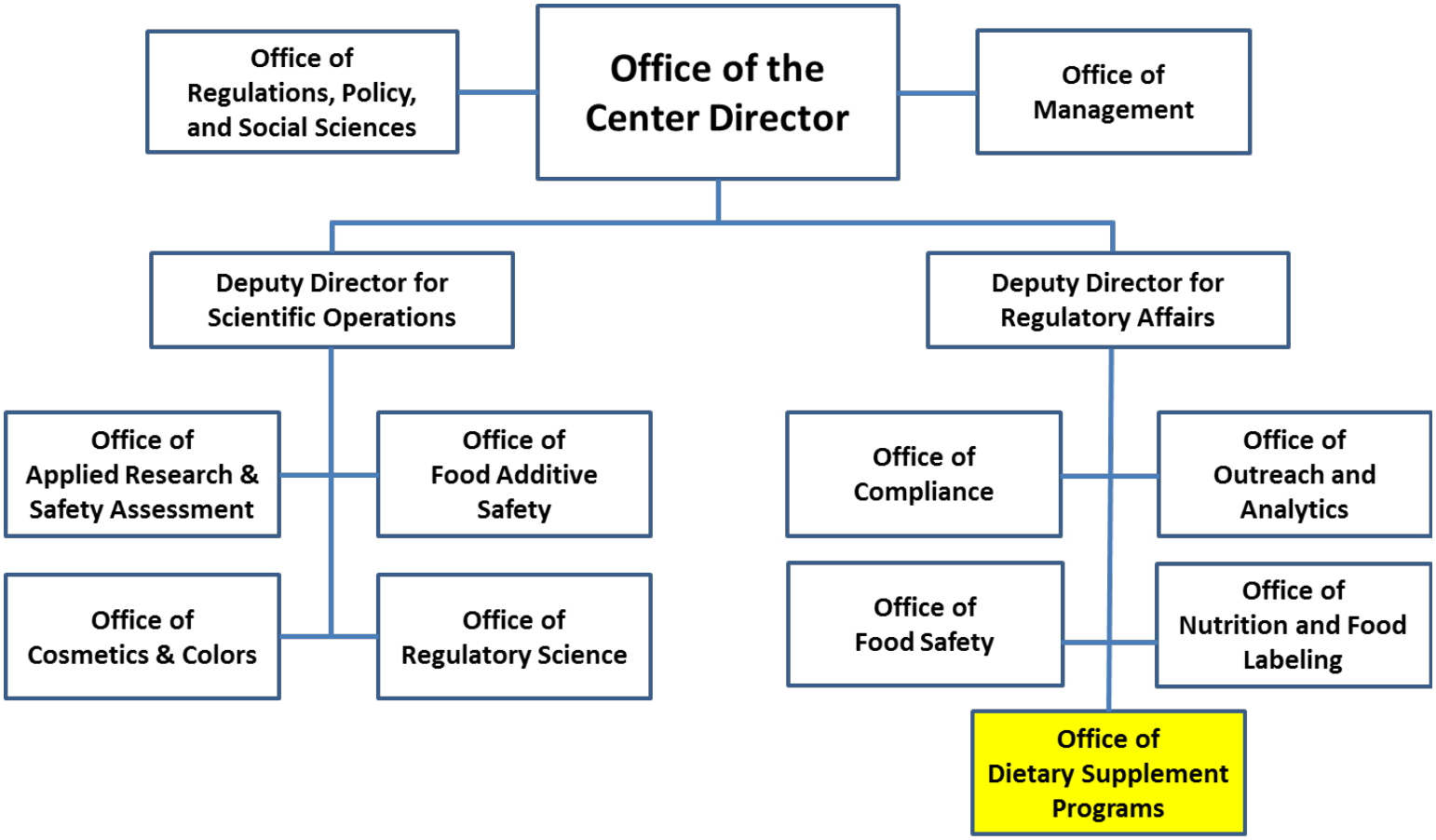
Dietary Supplements in FDA



FDA Organization



CFSAN Organization



CFSAN's ODSP

- 26 FTE's
- Program priorities
  - Protect consumers
    - Identifying and removing dangerous products
  - Ensure product integrity
    - Ensure products contain what they're supposed to contain
  - Promote informed decision-making

ODSP Priorities

- Protect consumers
  - Identifying and removing dangerous products
- Ensure product integrity
  - Enhance CGMP and NDIN compliance through education and enforcement
- Promote informed decision-making

Dietary Supplement Market Size

1994	Today
– 600 manufacturers	– 7,000 registered facilities
– 4,000 products	– 75,000+ products*
– $4 billion	– $40 billion*

*based on external data

U.S. FOOD & DRUG ADMINISTRATION

Thank you!

Office of Dietary Supplement Programs
Center for Food Safety and Applied Nutrition
Bob Durkin, Deputy Director
robert.durkin@fda.hhs.gov


FDA
U.S. FOOD & DRUG
ADMINISTRATION

FOOD DEFENSE THREAT OVERVIEW

4 April 2018

All Matters FDA Conference

Wilmington, DE

Federal Bureau of Investigation

Baltimore Field Office

Philadelphia Field Office

WMD Directorate

Protecting the Food Supply

Food Safety

unintentional
contamination

vs

Food Defense

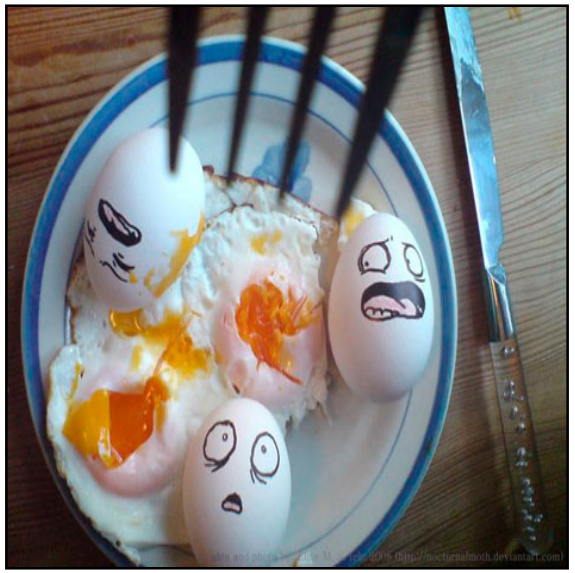
intentional
contamination

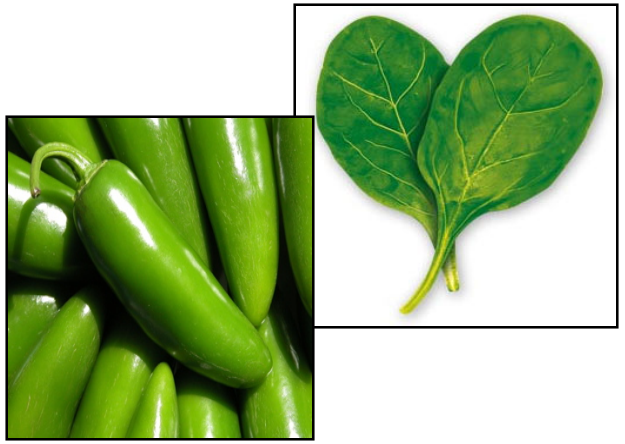
Food Sector Threat Overview

- No known, imminent threat to the US food sector.
- Insider threats are a concern.
- Terrorist groups have expressed interest in attacking the food sector with biological and chemical agents.

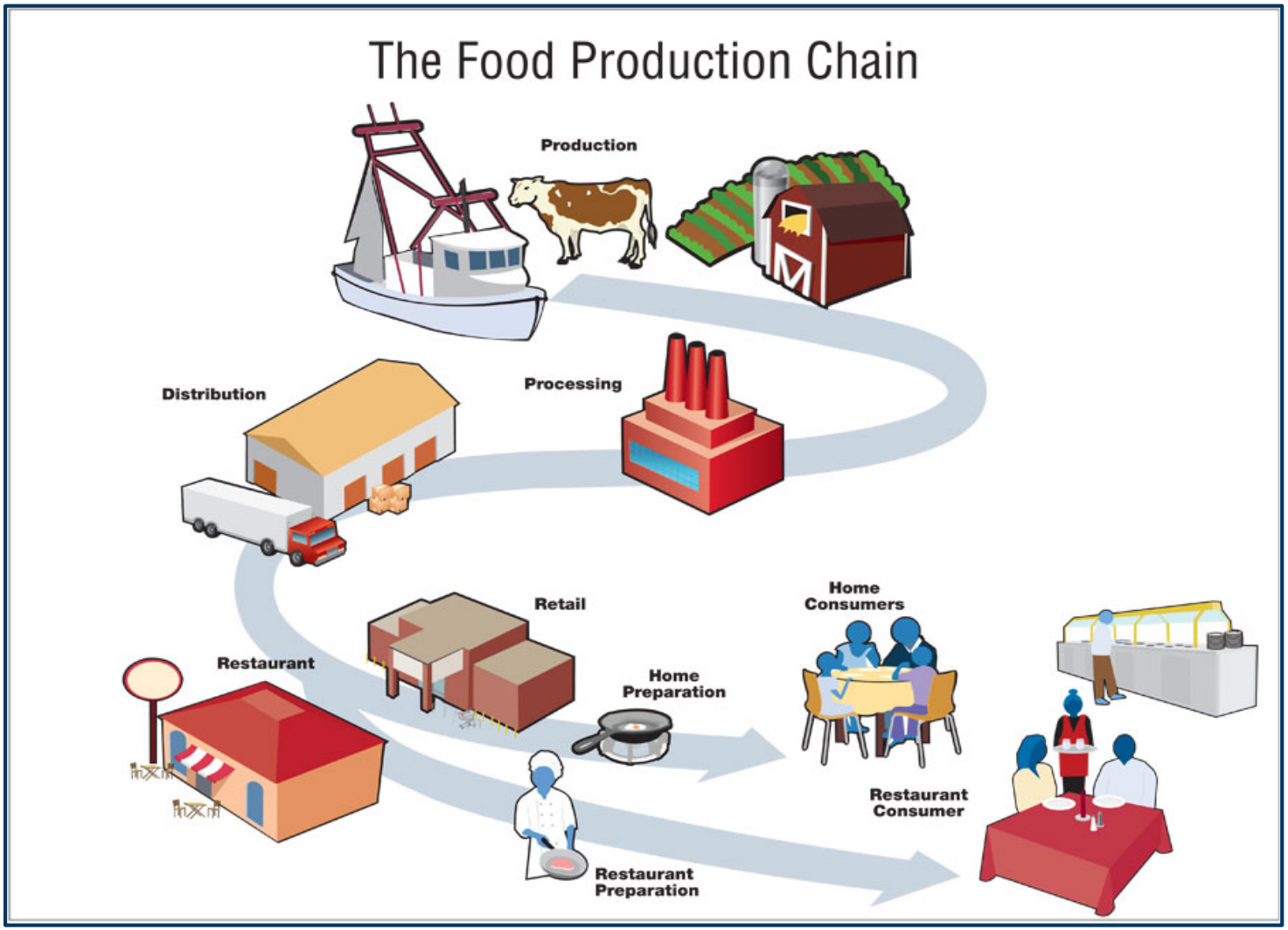
Why Target Food?

- Everyone eats
- Widespread publicity
- Short and long term impacts
- Difficult to distinguish deliberate, accidental, or natural outbreak
- Low cost to attack
- Little technical expertise required



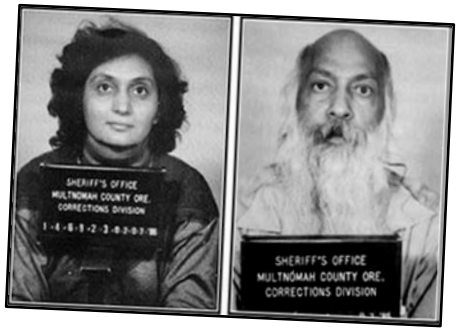


Potential Targets: From Farm to Fork



Potential Threat Actors

- Wide range of potential threat actors
  - Disgruntled employees
  - Foreign terrorist organizations
  - Homegrown violent extremists
  - Dissatisfied customers
  - Domestic extremist groups
  - Unaffiliated lone offenders



Assessing Threat Actors

- Intent
- Capability
- Access

Insider Threat

- What is the “Insider Threat”?
  - Individual who exploits his/her position to access a target in order to carry out a terrorist or criminal action.
- Difficult to protect against
- Difficult to detect

Disgruntled Employee: Oizumi, Japan

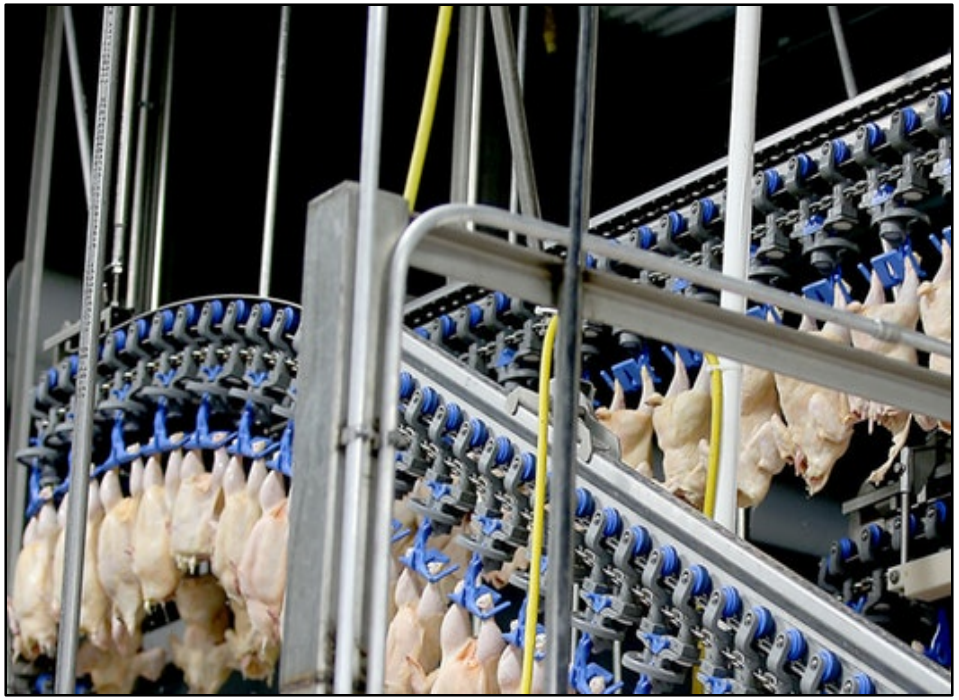
- January 2014 - Toshiki Abe arrested for lacing frozen foods with malathion.

- Contract worker for seafood company Maruha Nichiro Holdings Inc.

- Sickened more than 2,800 people

Disgruntled Employee: Cold Spring, MN

- June 2016- An employee adds sand and dirt from facility parking lot to vat in a poultry processing plant.



- Results in recall of 27 tons of chicken.

Islamic State of Iraq and ash-Sham (ISIS)

(U//FOUO) The 10 January video features a clip from a French-language, English-subtitled November 2014 ISIL video titled "What Are You Waiting For," specifically calling for lone offender attacks in France. A man speaking French says (according to the subtitles):

> (U//FOUO) "And if you are sincere to Allah in your worship and in your creed and are unable to make Hijra, then operate in France. Terrorize them and do not allow them to sleep due to fear and horror. There are weapons and cars available and targets ready to be hit. Even poison is available, so poison the water and food of at least one of the enemies of Allah. Kill them and spit in their faces and run over them with your cars. Do whatever you are able to do in order to humiliate them, for they deserve only this."

Pro-ISIS Social Media, Knights of Lone Jihad

ISIS Supporters: Derby, United Kingdom

- December 2016 – Munir Mohammed and Rowaida el-Hassan arrested for bomb plot in the UK.

- Mohammed was employed at a food plant that made ready-to-eat meals for grocery stores.

Contamination for a Cause: Athens, Greece

- December 2017 – An anarchist group in Greece announced it had obtained products from grocery stores near Athens, contaminated the products with chlorine and hydrochloric acid, and returned the tainted merchandise to store shelves.

- Intended to cause economic damage to major food companies.

Extortion Attempt: Friedrichshafen, Germany

- September 2017– An individual in Germany threatened to poison 20 different kinds of products if he did not receive $12 million.

- Police found five jars of baby food tainted with ethylene glycol in grocery store.

Supermarket Salad Bar: Ann Arbor, MI

- April 2016 – Kyle Bessemer contaminated grocery store food bars with a mixture of rat poison and hand sanitizer

- Charged with two counts of poisoning food, drink, medicine, or water supply causing property damage

WMD Coordinators

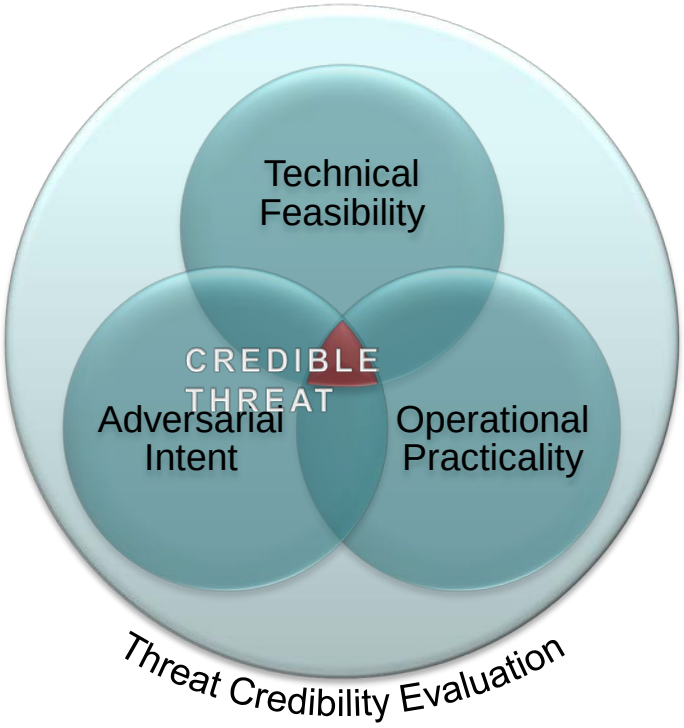
- Special agents
- At least one in each field office
- Conduct outreach
- Implement countermeasures
- Investigate WMD crimes and acts of terrorism
- Provide WMD training
- Coordinate FBI response to WMD incidents

Weapons of Mass Destruction Directorate

Vision: An enduring, integrated, and agile USG capability to prevent and neutralize all WMD

RESPONSE COORDINATION

- Lead and manage the **Threat Credibility Evaluation (TCE)**
- Recognized USG process to assess WMD threats



- WMDCs reach-back into WMDD to get real-time feedback from interagency **WMD Strategic Group**
- As the threat becomes relevant, teams deployed from HQ to support investigations

Key Takeaways

- Intentional contamination is a real threat to the food supply
- Possible to have significant public health and economic impact from intentional contamination
- Collaboration is required to implement food defense because the scale of the food sector means no agency can address the issue singlehandedly

tions?

SA Erik Negron
FBI Philadelphia
Email: ernegron@fbi.gov

IA Kevin Spradlin
FBI WMDD RNCIU
Email: kspradlin@fbi.gov

Opioids, Whistleblower Actions, Medical Device Safety, Food Defense, Personal Care Products, Dietary Supplement Regulation, Top Notables and Other Matters FDA .....

Roseann B. Termini

Rules of Professional Conduct

Key Focus

- Communication
- Competence
- Diligence
- Expediting Litigation
- Zealous Advocacy

Federal Court Order

- Altria, R.J. Reynolds Tobacco, Lorillard and Philip Morris USA
- Corrective Statements Remedy Newspapers and Television

United States v. Tobacco-Free Kids Action Fund v. Philip Morris USA Inc. and ITG Brands, LLC

- Corrective statements remedy Order #1015 (Dkt. No. 5733; Aug. 17, 2006), *United States v. Philip Morris USA Inc.,* 449 F. Supp. 2d I, 938-41 (D.D.C. 2006), *aff'd in part & vacated in part,* 566 F.3d 1095 (D.C. Cir. 2009) *(per curiam), Cert. Denied,* 561 U.S. 1025 (2010), is hereby MODIFIED by Order Dated Oct. 5, 2017
- Example N.Y. Times 9 (Jan. 7, 2018).

Federal Court Order

- A. Adverse Health Effects of Smoking

Federal Court Order

- B. Addictiveness of Smoking and Nicotine

Federal Court Order

- C. Lack of Significant Health Benefit from Smoking “Low Tar”, “Light”, “Ultra Light”, “Mild” and “Natural” Cigarettes

Federal Court Order

- D. Manipulation of Cigarette Design and Composition to Ensure Optimum Nicotine Delivery

Federal Court Order

- E. Adverse Health Effects of Exposure to Secondhand Smoke

Federal Court Order

- Court opinioned over a decade of litigation
- Where to draw the line? When does zealous advocacy become overzealous?

Pipeline Products

- E-cigarettes Heating Device
- Advisory Committee Determined Insufficient Evidence that heating device reduces risks of tobacco related disease. (Jan. 2018).

Drug Approvals

- Generics and Novel Therapies

Homeopathy

- **Originated in Germany**
- U. S. - Introduced by German Immigrants
- Flourished in 19th Century
- 2 Principles "law of similars" "let like cure like" and "law of infinitesimals"-the more dilute then the more powerful

Homeopathic Definition

- **Why in the FDCA?**
- Senator Royal Copeland (NY) was a physician trained in homeopathy and was a key sponsor of the 1938 FDCA.

Homeopathic Remedies

- Gain in popularity
- 2017 Guidance Issued
- Defined under (21 U.S.C. 321(g)(1))

Generic Litigation

- Barry Sherman- founder and former CEO of Apotex
- Company filed several lawsuits
- Lower prices
- Increased Generic Competition

Biotechnology

- Medical Advances
- FDA Approvals Increase
- Ex. Novel Gene Therapy Approval – Luxturna
- Treats Hereditary Retinal Disorder

Biotechnology

- Cell-based Gene Therapy- CAR T-cells
- Ex. Blood Cancers
- Cost –expensive

Biosimilars

- Biologics Price Competition and Innovation Act
- Case to Watch: *Sandoz Inc. v. Amgen Inc.*
- Issue Concerned Notice of Commercial Marketing and 180 Day Rule

Supreme Court Held- Notice Proper

Dietary Supplements

- Common Misnomer- Not regulated
- FDA Does Regulate- Issue is how Dietary Supplements are Regulated.

Opioid Crisis

- President Trump Public Health Emergency
- White House Summit “do some litigation against Pharmaceutical Companies” (March 1, 2018)
- Why- to combat opioid epidemi

FDA Commissioner Gottlieb

- Opioid Policy Steering Committee-
- Education for doctors i.e. Only when medically necessary.
- Risk Management expanded
- Fentanyl- Mail Facilities
- “Dark Web”-agents

Opioid Crisis
U. S. Department of Justice

- Federal government announcement
- Backing state and local litigation
- Intends to seek reimbursement from drug companies and distributors

Opioid Crisis

- DEA – federal policy concerning manufacturing and production
- Due Process- amend regulations
- Revolving Door

Opioid Crisis
Executive Liability

- *Purdue Pharma Revisited-*
- *Key Element- how the product promoted*

Opioid Crisis

- Landscape- counties, cities, towns, tribal territories, states……
- Why? One reason ex.–resources- drain on taxpayers
- Likelihood of success

Opioid Crisis

- Health Care Providers—Dentists- ages 10-19, Physicians, Insurers, Drug Companies, Hospitals, Nurses.
- Patients
- Victims ex. Infants

Opioid Crisis

- Gateway to Addiction
- Bogus Supplements – Kratom

Addiction Threat Gabapentinoids and Gabapentin

- FDA approved and not opioids
- Indications-neuralgia, fibromyalgia, and neuropathic pain associated with diabetes or spinal cord injuries
- Off-label potential as alternative to opioids
- Ex. Gabapentinoid —Lyrica
- Ex. Gabapentin—Neurontin
- NOTE: Neurontin- whistleblower started off-label litigation.

Food Safety Modernization Act Final Rules — FSMA

- *Administrative Detention* (2013)
- *Prior Notice-Imported Food (2013)*
- *Preventive Controls* –Risk Based and CGMPs (2015)
- *Produce Safety* (2015)
- *Foreign Supplier Verification* for Importers-Animal and Human Food (2015)
- *Accreditation-3rd Party* (2015)

FSMA Rules

- *Focused Mitigation Strategies to Protect Food Against Intentional Adulteration* (2016)
- *Final Rule—Sanitary Transportation* (2016)

Promotion- Social Media Off-Label

- Any FDA Guidance?
- Controversial
- Best Approach

Promotion Veterinary Products

- Direct-to-Consumer Promotion
- Rx Products

Autonomy
Right to Choose

- Right-to-Try State Legislation vs. Federal Compassionate Use
- Recent State Right-to-Try impetus for Federal "streamlined" process
- *Individual Patient Expanded Access Applications* - Form FDA 3926 (June 2016)

Medical Devices-Progress

- Surgical Mesh- lawsuits
- Requirements Strengthened
- Example: Reclassified

Medical Devices-Progress

- Implantable Forms of Sterilization
- Essure®
- Postmarket Studies Ordered by FDA
- Final Guidance Issued
- Boxed Warning

Corporate Counsel Obligations

- Foreign Corrupt Practices Act
- *Wadler v. Bio-Rad*
- Company allegations— corporate counsel terminated (2013) due to "abusive conduct"
- Corporate counsel—reported possible bribes under FCPA to Audit Committee.

Wadler v. Bio-Rad

- Outcome
- Corporate Counsel prevailed in retaliation lawsuit against Bio-Rad
- Jury Award— $2.96 million in back wages and $5 million in punitive damages.

Ex Chief Regulatory Affairs and CEO

- Apotex and Teva Pharmaceutical Industries
- Allegations of Trade Secret Disclosure about Tevs's Products in Development
- Lawsuit 2017 (July)– against Mr. Desai, (former) CEO of Apotex

Innovation

- FDA Approval- Digital Pill
- Monitors whether and when patient take medication
- Ex. Abilify- Otkusa Pharmaceutical-sensor in drug-sends signal to smartphone app.
- Extension to other products- perhaps alert physicians about patient abuse of opioids.

Innovation Coke Plus

- Popular in Japan-product has laxative effect
- Received “Gold” Stamp of Approval
- Japan-popular
- “Food for Specified Health Use”

Looking Ahead

- Cyber Security Concerns
- Resources and User Fees
- Drug Promotion and Social Media
- Lethal Injections ex. Arkansas

Looking Ahead

- FDA Oversight-Increased Self-Treatment
- Homeopathic Remedies
- Off-Label—Still in Flux Is *Amarin* the "law"? Greater Transparency
- FDA Communication

Looking Ahead

- *Intended Use* and Tobacco Products=Totality of Evidence Regulation- Partial Rule effective March 19, 2018- concerns product derived from tobacco and classification- device, drug, combination
- Portion of Rule on HOLD: discussion off-label uses- Application to drugs/biologics
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Looking Ahead

- Right-to-Ask or Right-to-Try Legislation—
- Federal Inititives

Looking Ahead

- Targeted Ex. Sleep Study
- GET THIN's pre-authorization requests for Lap-Band surgery normally elective.
- Falsified sleep study results

Looking Ahead

- Corporate Liability- Peanut Corp. of America
- Affirmed sentences of imprisonment
- President Stewart Parnell 28 years
- Peanut Broker Michael Parnell 20 years
- Quality Assurance Director 5 years

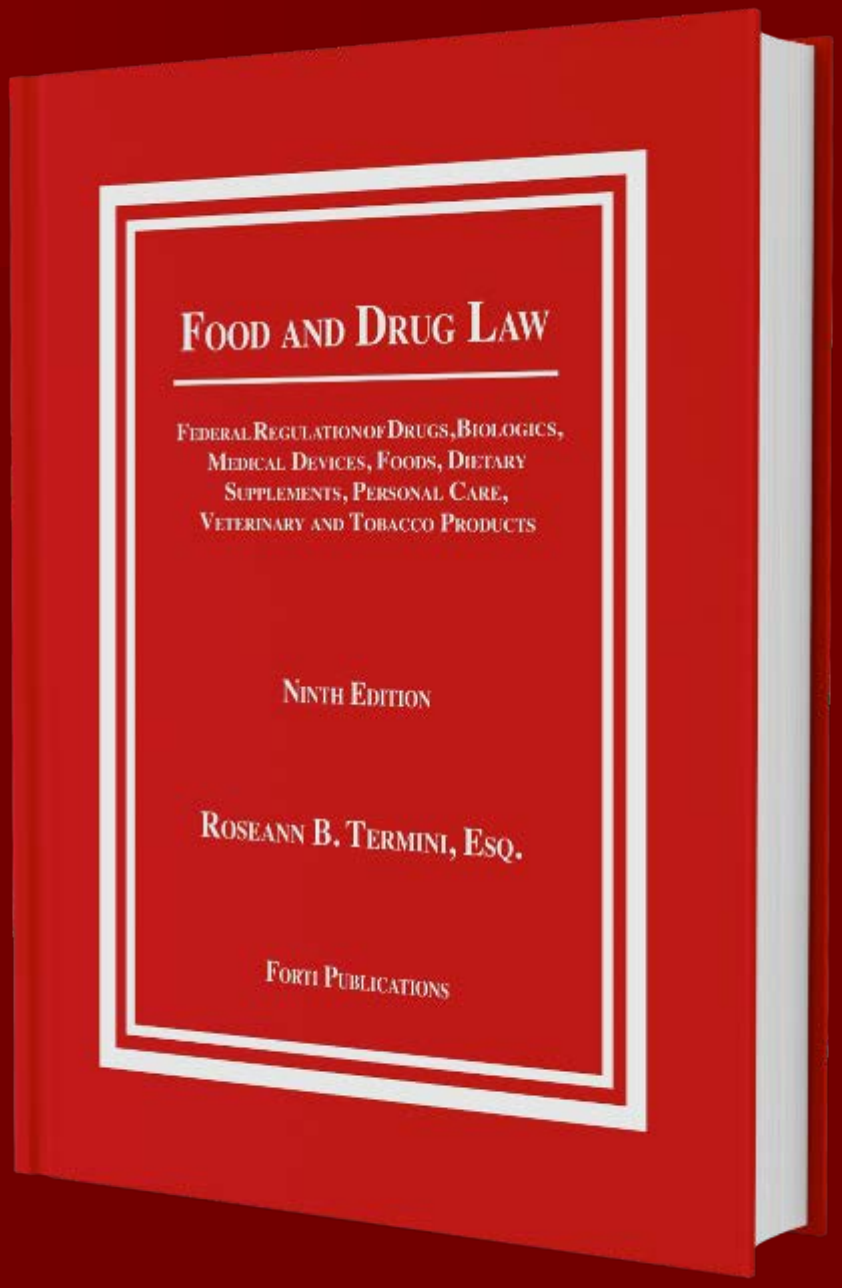
Does FDA Really Regulate Love?

- Yes- warning letter sent to food manufacturers for listing the word “love” as an ingredient.

- Warning Letter Issued Nashoba Brook Bakery, LLC. (9/22/2017)

Love Regulated

- Your Nashoba Granola label lists ingredient "Love". Ingredients required to be declared on the label or labeling of food must be listed by their common or usual name [21 CFR 101.4(a)(1). "Love" is not a common or usual name of an ingredient, and is considered to be intervening material because it is not part of the common or usual name of the ingredient.



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Contact Information

- rbtermini@widener.edu
- www.fortipublications.com
- Publications SSRN Author page
- http://ssrn.com/author=944614
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