Widener Leadership Works

7th Annual Food and Drug Law CLE

Botox®, Opiates, and Other Matters FDA—Year in Review, Top Notables, and Looking Forward

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

Wednesday, March 22, 2017

1:00–4:30 p.m.

Delaware Law School

delawarelaw.widener.edu

Food and Drug Law CLE
Wednesday, March 22, 2017
Agenda

12:00 noon **REGISTRATION CHECK-IN**

1:00 p.m. **PROGRAM SPEAKERS:**

Karyn M. Campbell
Director, Food & Drug Administration
Investigations Branch, Philadelphia District

Mary E. Crawley, Esquire
Assistant U.S. Attorney and Chief, Healthcare and Government Fraud,
Eastern District of Pennsylvania

Rebecca Glenn-Dinwoodie, Esquire
Director of Humane Litigation
Pennsylvania Society for the Prevention of Cruelty to Animals

Laurie Lenkel, Esquire
Office of the Commissioner
Food & Drug Administration

Matthew R. Noonan
Food Specialist/Investigator
Food & Drug Administration

Don Sapatkin
Deputy Health & Science Editor and Public Health Reporter
The Philadelphia Inquirer

Roseann B. Termini, Esquire
Food and Drug Law Legal Scholar
Adjunct Professor in FDA Law, Widener University Delaware Law School

4:30 p.m. **Refreshments**

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WIRELESS ACCESS INFORMATION AS A "WIDENER GUEST"

WIDENER UNIVERSITY DELAWARE LAW SCHOOL
BARRISTERS' CLUB
WEDNESDAY, MARCH 22, 2017

Username: FDLA
Password: cle2017

BIOGRAPHIES

Karyn M. Campbell

Karyn Campbell is the Director of Investigations Branch for FDA's Philadelphia District Office. Karyn has been with FDA in Philadelphia for 33 years. She is responsible for managing planned and unplanned inspections, investigations, examinations, and sample collections of the regulated industry in Pennsylvania and Delaware; coordinating Branch responses to emergencies; implementing training efforts; and maintaining Investigations Branch's quality assurance program. She is also a member of several FDA committees and working groups pertaining to human drugs and foods. Prior to her current position, she held the positions of Assistant Investigations Branch Director, Pre-Approval Inspection Manager, Compliance Officer, and Investigator. Karyn provides training in FDA law, evidence development, pharmaceutical inspections, and compliance issues internally at FDA and to industry. She has been a guest lecturer at several academic institutions including Temple University, Dickinson School of Law, and Widener University School of Law. She is currently an Adjunct Associate Professor at Temple University's School of Pharmacy, where she co-teaches a course in Pre-Approval Inspections in the Regulatory Affairs/Quality Assurance graduate degree program. She holds a B.S. in Biology from Gwynedd-Mercy College.

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Mary E. Crawley

EXPERIENCE

United States Attorney's Office, Eastern District of Pennsylvania, Philadelphia, PA
Assistant United States Attorney, Criminal Division: 1989 - Present.
Senior Litigation Counsel: 2011– March 2014
Chief, Healthcare Fraud and Government Fraud Section: April 2014 - Present.

Supervise all criminal prosecutions in the subject areas of health care fraud, procurement and program fraud affecting U.S. government agencies, environmental crimes, and crimes over which the Food and Drug Administration has jurisdiction, including off-label promotion of pharmaceutical products, and adulterated and misbranded drugs and food products.

- 2013: *Director's Award for Superior Performance*, as lead counsel in United States v. Synthes, Inc., et al.

- 1995: *John Marshall Award for Outstanding Legal Achievement.*

Paul, Weiss, Rifkind, Wharton & Garrison, New York, NY
Associate, Litigation Department: June 1986 - May 1989.

The Honorable Joe Eaton, United States District Judge, Southern District of Florida, Miami, FL
Law Clerk: June 1984 - May 1986.

EDUCATION

Columbia University School of Law, New York, NY J.D., 1984.
Harlan Fiske Stone Scholar 1983. Staff Member, Human Rights Law Review.

Barnard College, New York, NY A.B. magna cum laude 1981.

BAR ADMISSIONS

New York and Florida; Southern District of New York; Third Circuit Court of Appeals.

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Rebecca Glenn-Dinwoodie

Rebecca Glenn-Dinwoodie, Esquire, is the Principal Attorney of Glenn-Dinwoodie Law. Her practice includes all phases of investigation and prosecution of criminal animal cruelty charges and related civil issues, as well as family and civil litigation. Her career has been dedicated to advocating for children, animals, and those who have been injured. She has lectured on legal topics relating to all facets of Pennsylvania animal cruelty and animal law, related civil litigation, as well as Pennsylvania criminal procedure. She has been a featured speaker at Humane Society Police Officer trainings throughout Pennsylvania. She is a member of the Pennsylvania Bar Association Criminal Justice and Animal Law Sections. She earned her J.D. from Temple University Beasley School of Law. She is admitted to the bars of the Commonwealth of Pennsylvania and the Eastern District of Pennsylvania in the Third Circuit.

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Laurie Lenkel

Laurie Lenkel is the Director of the FDA Office of the Ombudsman. In this role she is responsible for facilitating the resolution of disputes between FDA and the industries it regulates. As FDA Ombudsman she works to ensure that companies are treated fairly and that their opinions and views are heard. Ms. Lenkel came to the Ombudsman position in 2003 after spending three years in FDA's Center for Drug Evaluation and Research in the Division of Drug Marketing, Advertising, and Communication. Prior to joining FDA, Ms. Lenkel worked in the pharmaceutical and medical device industries. Her current professional activities include Chair of the Editorial Advisory Board of the *Food and Drug Law Journal*, member of the Executive Committee of the Food, Drug and Cosmetic Section of the New

York State Bar Association, and past Chair of the Federal Chapter of the United States Ombudsman Association. In addition to being a trained mediator, Ms. Lenkel is both a licensed pharmacist and attorney.

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Matthew R. Noonan

Matthew Noonan is a Compliance Officer with FDA's Office of Regulatory Affairs (ORA), Philadelphia District. He follows up on potentially violative establishment inspections and pursues voluntary correction or court action as appropriate. Matt also develops and presents district 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 to the district. He achieved ORA Level II Certification in Low Acid Canned Food, Acidified Food, and Seafood. Matt participated in Incident Management Team task forces for the 2015 Papal Visit and the 2016 Democratic National Convention.

After years of being inactive, Matt re-established the district's Food Cadre where he organizes, coordinates, and leads periodic meetings. He is also a member of the ORA Instructor/Inspector 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.

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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Don Sapatkin

Don Sapatkin is a health reporter and deputy health & science editor at *The Philadelphia Inquirer*. His public health beat runs the alphabet from asthma to vaccination, with a focus that comes in waves. HIV once was the biggest story, then (briefly) H1N1 and (very briefly, at least so far) Zika. For the last few years, opioid addiction has dominated. Don is most interested in examining how culture, behavior, and demographics converge to influence health — a combination of non-"medical" factors that play a big role in addiction. His work appears daily and in the newspaper's Sunday Health section, and at www.Philly.com/health.

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Roseann B. Termini

Roseann B. Termini, B.S., Ed. M., J.D. has extensive experience in food and drug law. Throughout her legal experience, which spans over 30 years, and even prior to her law career, she has pursued her food and drug law passion. Recently, Ms. Termini published a new comprehensive print edition of *Food and Drug Law: Federal Regulation of Drugs, Biologics, Medical Devices, Foods, Dietary Supplements, Personal Care, Veterinary and Tobacco Products,* 8^{th} ed. (2015). The reason for the recent 8^{th} edition is because it is critical to impart the latest law. Food, drugs, biologics, medical devices, foods, dietary supplements, personal care, veterinary and tobacco products regulation is constantly evolving with new cases and new regulations. The new edition provides a concise roadmap for the reader of a complex area of law. This edition contains a separate subject specific volume so the reader can choose the area of most interest. Professional considerations, ethical issues, enforcement including criminal corporate liability and politics are all covered.

Additionally, she decided to publish 12 stand-alone Ebooks of *Food and Drug Law: Federal Regulation of Drugs, Biologics, Medical Devices, Foods, Dietary Supplements, Personal Care, Veterinary and Tobacco Products,* 8^{th} ed. (2015). All of the 12 stand-alone e book volumes are contained in the new eighth edition print book and each volume is available as a separate Ebook.

Frequently, Ms. Termini presents food and drug law topics as a featured speaker at international and national conferences including the Central Atlantic Association of Food and Drug Law Officials (CASA), the Pennsylvania Bar Institute and the Food and Drug Law Institute Annual conferences. Further, she has published a broad array of specialized food and drug law subjects such as the "Why" of the United States Food and Drug Administration, corporate accountability, the Foreign Corrupt Practices Act, criminal liability, enforcement, health claims, supplements, safety, duty to warn, issues involved in prescription to over-the-counter drugs, preemption, regulation, promotion, tobacco, stem cells, risk assessment and globalization. Upcoming presentations include: *Who Really Regulates Your Pizza, Are "Smart Labels" Really Smart* and the *recently published regulations under the Food Safety and Modernization Act*. She is in charge of a legal education program at Delaware Law of Widener University that addresses "hot topics" such as controversial medical devices, tobacco regulation of e-cigarettes and dietary supplement enforcement.

Her enjoyment of writing expertise led her to an appellate clerkship, position as sole corporate counsel, regulatory attorney and senior deputy attorney general at the Pennsylvania Office of Attorney General (OAG). While at the OAG, she prosecuted cases at the trial and appellate levels and was in charge of writing the implementation procedures for the Pennsylvania Plain Language Act. She was the first recipient of the Plain English Award by the Pennsylvania Bar Association.

Ms. Termini designed and developed the inaugural online food and drug law courses at Widener University School of Law, Johns Hopkins University, the University of Georgia,

Drexel University and a direct to consumer promotion course at St. Joseph's University's Executive Program. Ms. Termini has also taught food and drug law courses at Temple University in the Quality and Regulatory Affairs Graduate Program and Penn State-Dickinson School of Law. She serves as faculty advisor to the Widener Law Food and Drug Law Association. Ms. Termini has been active on the committees of several professional associations for many years, including her service as Chair of a Food and Drug Law Institute Committee. She served on the President's Council at Immaculata University and Vice Chair of the Justinian Association. Ms. Termini is a member of the Central Atlantic Association of Food and Drug Law Officials and was appointed Vice Chair of the Pennsylvania Bar Association Health Law Committee.

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

COURSE MATERIALS

Botox, Opiates and Other Matters FDA

Roseann B. Termini

Rules of Professional Conduct

- Key Rules
- Communication
- Competence

Botox

- Are there really 100 Approved Uses for Botox?
- Off-Label
- Practice of Medicine

Executive Liability Foods

- *Corporate Executive Liability Food Safety—Peanut Corp., Jensen, and Quality Egg*
- *Peanut Corporation of America*—**Felony Convictions**
- *Jensen—Misdemeanor-Cantaloupes, 3rd party reliance*
- *Quality Egg—Guilty Pleas, "Cruel and Unusual Punishment"* 8th Cir. Court of Appeals affirmed three-month term of imprisonment

Corporate Accountability Recent Case Example

- ***United States v. Quality Egg***
- 2,000 cases of *Salmonella*
- Prison sentences (three months each)
- $100,000 criminal fine
- Restitution and
- Probation
- 8th Cir. Appeal

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)

Opium

Opiates – from opium

Opioids- man-made ex.

Oxycodone=OxyContin

Hydrocodone

Historical Background

- Victorian Era Popularity
- Laudanum-Beverage of Choice- Alcohol and Opium
- Elixirs
- Miracle Cures
- Gateway to 1906 Food and Drugs Act

Opioid Crisis

- Several Players- for example:
- Health Care Providers—Dentists, Physicians, Insurers, Drug Companies, Patients
- FDA Opioid Action Plan

Abuse-Deterrent

Long-term painkiller -Egalet Corp.

- Morphine sulfate- Arymo ER extended release
- Abuse Deterrent
- Cutting, breaking, crushing, chewing, or dissolving the tablets result in uncontrolled delivery of morphine that could lead to overdose and death.
- Advisory panel in August (2016) voted 18-1 to recommend approval
- https://www.fda.gov/Drugs/DrugSafety/ucm535708.htm

Drug Approvals

- 45 in 2015
- 22 in 2016
- 6 (March 13, 2017)
- http://bit.ly/2mpEBTM

Drugs: Off-Label

- Off-Label Enforcement
- *Caronia* and *Amarin—First Amendment Protections*
- *Speech-Must be Truthful and Non-Misleading*
- *Amarin-settlement*

  Key Points: optional preclearance provision – up to 2 submissions to FDA and 60 day response from FDA

Off-Label

- Federal Off-Label Settlements
- Multistate and State Off-Label Settlements

Marketplace Delay

- ***FTC v. Shire Viropharma, Inc. Case 1:17-cv-00131-*** (Filed 02/07/17)
- Brand-name antibiotic Vancocin
- FTC Characterization: 24 sham Citizen Petitions to delay generic versions

Marketplace Delay

- ***FTC v. Endo Settlement 2017*** *https://www.ftc.gov/news-events/press-releases/2017/01/endo-pharmaceuticals-inc-agrees-abandon-anticompetitive-pay-delay* (settlement)
- *Complaint Refiling-Other Pharmaceutical Companies*

Promotion and Social Media

- Any FDA Guidance?
- Controversial
- Best Approach

Promotion Veterinary Products

- Direct-to-Consumer Promotion
- Rx Products

Shipper Liability

- ***United Parcel Service, Inc.* 2013**
- *Non-Prosecution Agreement*
- *Compliance Program*
- *$40 million forfeited*

https://www.justice.gov/usao-ndca/pr/ups-agrees-forfeit-40-million-payments-illicit-online-pharmacies-shipping-services

Shipper Liability

- ***United States v. FedEx Corp.,*** N.D. Cal., No. 3:14-cr-00380, (N.D. Cal. 7/17/14) (grand jury indictment regarding FedEx accepting shipments from illegal online "pharmacies");
- Charges Dismissed (June 17, 2016)

Biosimilars

- Biologics Price Competition and Innovation Act
- Case to Watch: *Sandoz Inc. v. Amgen Inc.*
  Oral Argument April 26, 2017

- Issue Concerns Notice of Commercial Marketing and 180 Day Rule

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 Device Symbols

- Final Rule: 81 FR 38911 (June 25, 2016)
- Permits use of Stand-Alone Symbols
- Prescription Device Labelling permits use of Rx only in labelling

Medical Devices-Progress

- Surgical Mesh
- Requirements Strengthened
- Example: Reclassified

Medical Devices-Progress

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

Corporate Counsel

- 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.

Looking Ahead

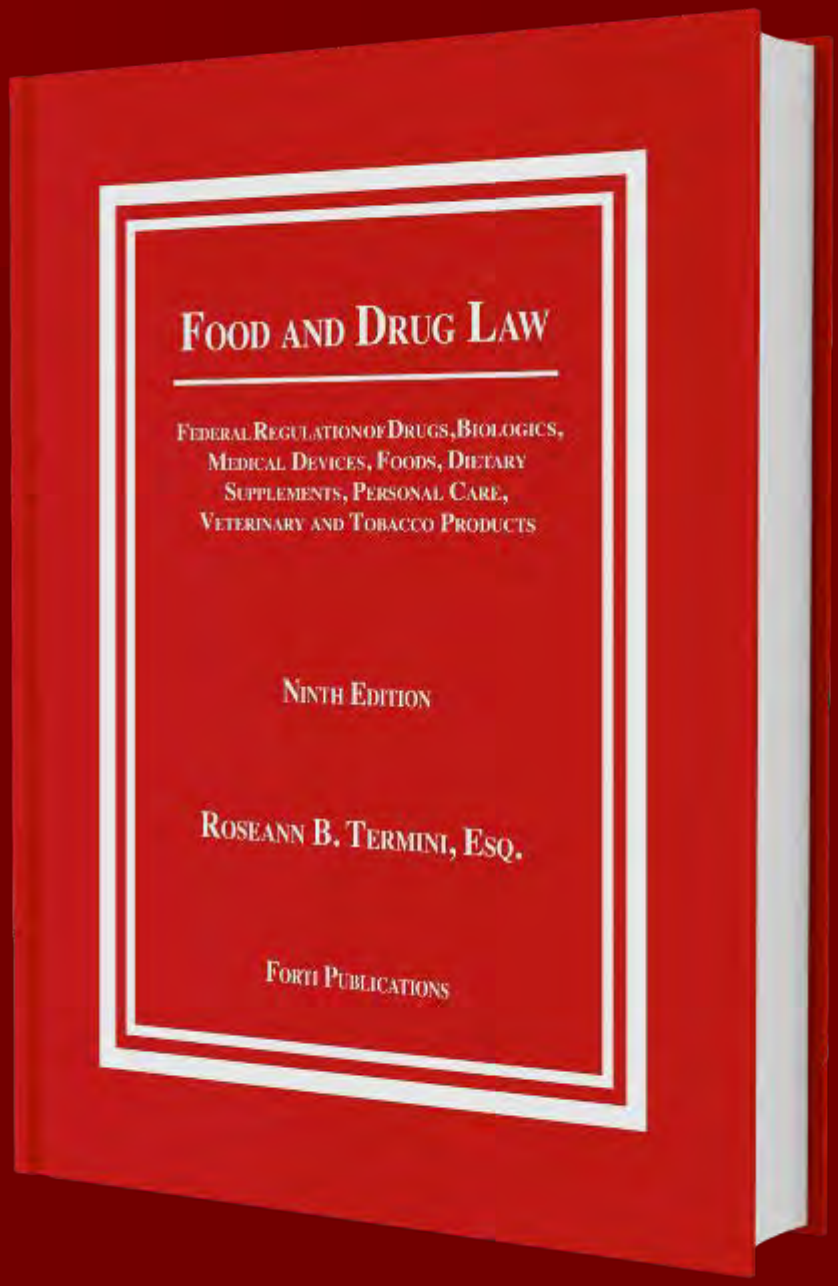
- Dumping Economic Harm "Honeygate"
- Jurisdiction Confusion—"Catfish"
- Cyber Security Concerns
- Resources and User Fees
- Drug Promotion and Social Media
- Lethal Injections ex. Arkansas

Looking Ahead

- *Intended Use* and Tobacco Products Regulation
- Approval Disparity: Drug vs. Medical Device 510(k)
- State Court Remedies: Drugs vs. Medical Devices
- Right to Try Legislation—State vs. Federal

Looking Ahead

- FDA Oversight-Increased Self-Treatment
- Homeopathic Remedies
- Off-Label—Is *Amarin* the "law" now?
- Kind- Healthy and Natural
- Sell by, Use by, Best by.....
- FDA Communication



www.fortipublications.com

Contact Information

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

FDA U.S. FOOD & DRUG ADMINISTRATION
OFFICE OF REGULATORY AFFAIRS

FDA Overview

Karyn M. Campbell, Director
Investigations Branch
FDA/Philadelphia District

US Food and Drug Administration

- FDA Mission
  - Protect and promote the public health
- Statutes
  - Federal Food, Drug & Cosmetic (FD&C) Act
    - Title 21 United States Code (21 USC)
  - Public Health Service (PHS) Act
  - Bioterrorism (BT) Act

What We Regulate

- Human Foods
- Human Drugs
- Medical Devices
- Biologics
- Animal Feeds, Drugs, and Devices
- Infant Formulas
- Dietary Supplements
- Cosmetics
- Tobacco
- Radiation-Emitting Electronics
- Food and Color Additives

Field Activities

Domestic Operations

- Inspections
- Investigations
  - Emergency Response
  - Complaints
  - Surveillance
- Sample Collections
- Field Examinations
- Recall Audit Checks

Import Operations

- Entry Review
- Field Examinations
- Label Examinations
- Sample Collections
- Investigations
- Filer Evaluations

Inspection Authority

- Section 704 (21 USC § 374)
- Enter and inspect at reasonable times and in a reasonable manner
- Presentation of credentials and written Notice of Inspection (form FDA 482)
- Enter and inspect at reasonable times and in a reasonable manner

Factory Inspection

- Any factory, warehouse, facility, or vehicle
- Manufacturing, processing, packing, holding
- Before or after introduction into interstate commerce
- Equipment, finished and unfinished materials, containers, and labeling

Factory Inspection

- For prescription drugs, non-prescription human drugs, and restricted devices, extends to *all things therein* bearing on whether drugs or devices in violation of the Act are being manufactured, processed, packed, transported, or held
  - Records
  - Files
  - Papers
  - Processes
  - Controls
  - Facilities

Factory Inspection

- Exclusions
  - Financial data
  - Sales data other than shipment data
  - Pricing data
  - Personnel data other than qualifications of personnel to perform functions subject to the FD&C Act
  - Research data other than those relating to new drugs and devices


FDA
U.S. FOOD & DRUG
ADMINISTRATION

FDA Inspection Stories: Cheese

Matthew Noonan
FDA Compliance Officer
Office of Regulatory Affairs
Philadelphia District

Food Safety Statutes and Regulations

- Intended to ensure food is safe, sanitary, and appropriately labeled
- Minimize risk of foodborne illness and injury
- Evolve over time based on science and outbreaks

FD&C Act Prohibited Acts include:

- **Section 301 (21 USC § 331)**
  - a) Introduction of an adulterated or misbranded product into interstate commerce
  - dd) Failure to register with FDA as a food facility
    - If primarily wholesale
- **May result in judicial action**
  - Brought by DOJ

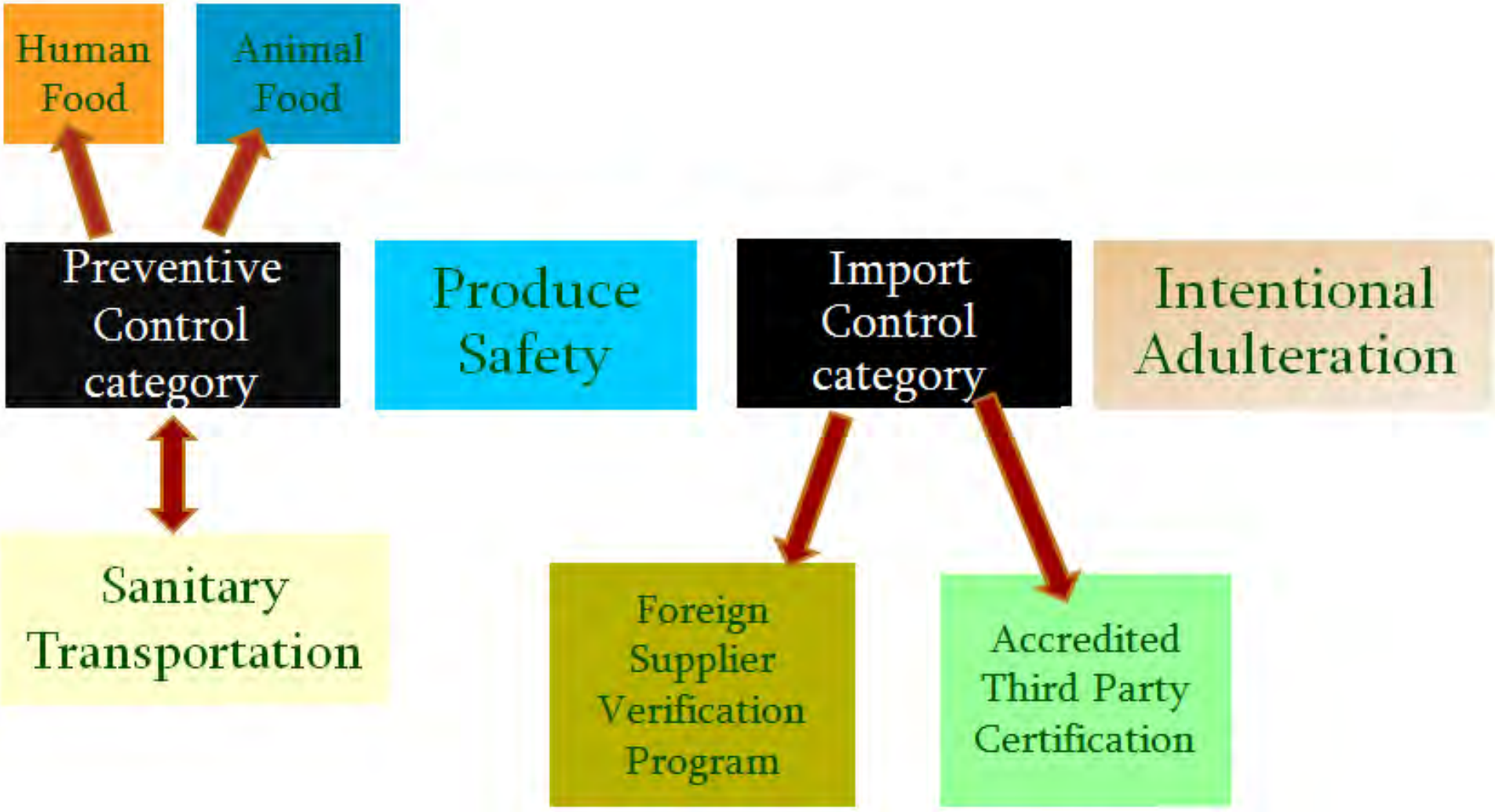
FD&C Act

- Per Section 402 (21 USC § 342), **adulteration** can include:
  - Insanitary food
  - Insanitary condition in food facility
- Per Section 403 (21 USC § 343), **misbranding** includes false and misleading labeling.

Food Safety Modernization Act

- Sweeping reform of food safety laws
- Directed FDA to issue new regulations and guidances
- Authorized new enforcement tools
  - E.g. suspension of food registration
- Emphasis on preventing illness and injury rather than reacting after-the-fact

7 New FSMA Rules



FSMA Roles

- **Food Industry: Prevention**
  - Primarily responsible for reducing risk of foodborne illness and injury
- **FDA: Standards**
  - Issues regulations
  - Provides industry with guidance to increase level of compliance
  - Performs inspections to assess compliance

Regulations

- **Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food**
  - **21 CFR 117**
  - **Establishes criteria for adulterated food**

- **Food Labeling**
  - **21 CFR 101**
  - **Establishes criteria for misbranded food**
    - **5 basic elements**

GMPs: 21 CFR 117, Subpart B

- Set of general **sanitation** standards to control contamination
- Minimum requirements for manufacturer to assure products are safe and of high quality

Subpart B—Current Good Manufacturing Practice

117.10	Personnel.
117.20	Plant and grounds.
117.35	Sanitary operations.
117.37	Sanitary facilities and controls.
117.40	Equipment and utensils.
117.80	Processes and controls.
117.93	Warehousing and distribution.
117.110	Defect action levels.

Preventive Controls: 21 CFR 117, Subpart C

[Illustration of loop for hazard analysis and risk-based PCs}. Retrieved from http://www.foodengineeringmag.com/articles/92826-fsma-harpc-update

- Requirement for food safety plan focusing on preventing hazards
  - Evaluate hazards in operation to determine which ones require a preventive control.
  - Specify preventive controls to prevent or minimize the hazards.
  - Specify actions to correct problems that arise.
  - Establish recordkeeping and verification procedures.

GMP Inspection: Roos Foods (Kenton, DE)

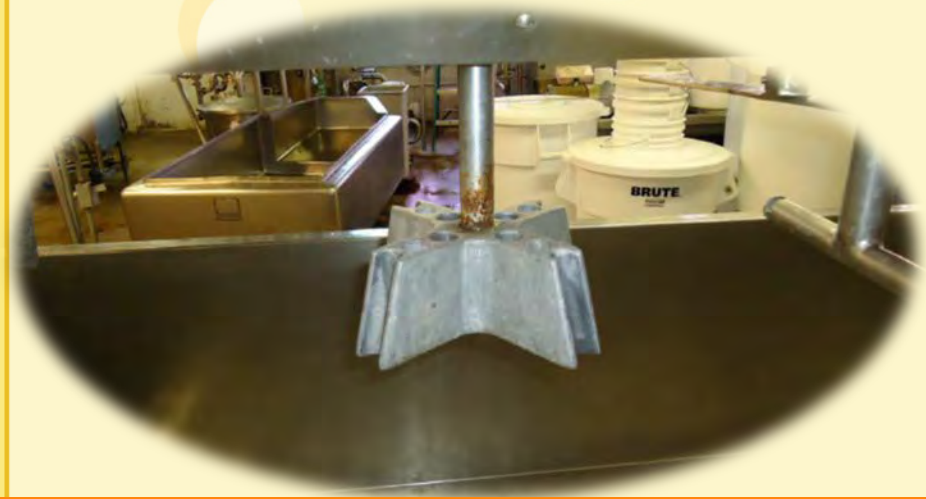
- February/March 2014 inspection of ready-to-eat soft or semi-soft Hispanic-style cheese (e.g. Queso Fresco) manufacturer found:
  - Roof leaking
    - Water was raining down into processing room.
      - ❖Including onto processing equipment and storage tanks
  - Rusty/flaking metal ceiling
  - Standing water on floor throughout processing room
  - Ineffective equipment cleaning (visible residue)

Filthy Conditions

Filthy Conditions

Filthy Conditions

Filthy Conditions



Filthy Conditions

Roos Foods: The Aftermath

- *Listeria monocytogenes*
  - 12 positive environmental subsamples
  - Positive finished product testing
  - Outbreak
    - 1 death in CA
    - 7 hospitalizations in MD
      - ❖Including 2 pregnant women and 1 newborn
    - Linked to Roos Foods by CDC
      - ❖Same strain as environmental samples
- **Massive voluntary recall**
- **But lack of commitment to discontinue production until corrections were made**

Roos Foods: Suspension of FDA Food Registration

- Barred firm from introducing food into interstate commerce
- Standard:
  - Reasonable probability of firm's food causing serious adverse health consequences or death to humans

Roos Foods: Legal Outcomes

- **Civil**
  - January 2016: Consent Decree of Permanent Injunction
    - If firm or owners want to begin producing and distributing food in the future, they can do so only if FDA confirms regulatory compliance first.
      - ❖So far a moot point
- **Criminal**
  - March 2016: Owners agreed to plead guilty.
    - To introduction of adulterated food into interstate commerce
    - Sentenced to $100,000 fine

Labeling Inspection: Castle Cheese (Slippery Rock, PA)

- November/December 2012 inspection of "real" Parmesan and Romano cheese manufacturer

- Major supplier to big-box retailers
  - Produced Target and WalMart store brands
    - Through an intermediary business
- Huge gross sales and apparent profits

Castle Cheese

- **Labeled name of food**
  - **"100% grated Parmesan" or "100% Romano"**
- **In actuality:**
  - **Often a mixture of imitation cheese, scraps of cheaper cheeses, and cut-rate additives**
    - **E.g. wood pulp (cellulose)**
    - **Not declared as ingredients**

[Photograph of wood pulp}. Retrieved from https://www.papnews.com/wood-pulp-exports-from-russia-up-10-per-cent-in-2015/

Castle Cheese: The Aftermath

- Post-inspection search warrant / raid
  - Owners had assault rifles registered in their name.
  - Led by FDA's Office of Criminal Investigations and the IRS
- Halted production soon after, but declined to voluntarily recall
- July 2013 FDA Warning Letter
- Production never resumed.

Castle Cheese: Criminal Outcomes

- January 2017: Firm pled guilty
  - To introduction of misbranded food into interstate commerce
  - Sentenced to $1 million fine
  - President earlier pled guilty as a responsible corporate officer
    - To aiding and abetting
    - Sentenced to 3 years probation and $5000 fine

References

- FSMA Rule Fact Sheet for Preventive Controls for Human Food
- FDA Investigates presence of Listeria in some Hispanic-style Cheeses
- FDA resolves criminal and civil actions against cheese manufacturer
- FDA: Listeria found at cheese plant with mislabeled products
- The Parmesan Cheese You Sprinkle on Your Penne Could Be Wood
- Guilty pleas filed in federal criminal fake cheese cases
- Slippery Rock Cheese Companies Sentenced

Acknowledgements

- FDA ORA Philadelphia District
  - Steven Carter, Director of Compliance
  - Robin Rivers, Compliance Officer
  - Michael O'Meara, Supervisory Investigator (ret.)
  - Sean Duke, Investigator
  - Katelyn Staub-Zamperini, Investigator

FDA OMBUDSMAN

What's an Ombudsman?

Disclaimer

- *These views are my own and do not necessarily reflect those of the Agency or Department I work for*

Agenda

- Ombudsman:
  - Definition
  - History
  - Purpose
  - Role at FDA
    - Office of the Ombudsman
    - Ombudsman at the Center level
  - New and Noteworthy

FDA Ombudsman – Definition, History, Purpose

- A Swedish word loosely translated to “people’s representative”
- A person appointed to receive and investigate complaints about a government agency and attempt to resolve them via mediation or other dispute resolution mechanism

FDA Ombudsman

- First Ombudsman established at FDA 1989 after the generic drug scandal
- A place where people could go...
- Ombudsman in most FDA Centers

FDA Ombudsman – What we do

- Provide an impartial source of assistance
- Facilitate meetings to improve communication
- Provide feedback to the organization
- Negotiate, mediate, and offer options

Office of the Ombudsman – What We Do

- Established within the Office of the Commissioner to:
  - Resolve inter-center disputes
  - Coordinate appeals of Center decisions
  - Primary contact for issues in Centers without an ombudsman

Dispute Resolution Mandate

- FDAMA added section 562 to the Food, Drug, and Cosmetic Act (ACT)
  - Called for establishment of a more focused procedure for timely review of scientific disputes
  - 21 CFR 10.75 was amended to provide for review of a scientific controversy by an appropriate scientific advisory panel
  - Each Center was made responsible for developing and administering its own process for handling requests for review of scientific controversy

FDA Ombudsman – How we work

- Operate in a variety of manners
  - Resolve misunderstandings
  - Look into complaints
  - Listen to industry's issues and concerns
  - Respond to questions
  - Strategize options available to challenges or appeals

FDA Ombudsman

- What we do is to provide advice and guidance, in a neutral environment, on how best to resolve disputes

- What we don't do –
  - Make Decisions!

FDA Office of the Ombudsman

- Goals
  - Ensure that the agency fulfills its regulatory responsibilities
  - Provide an avenue for review of agency decisions
    - 21 CFR 10.75 “review up the chain of command”
  - Look at issues systematically to see how the process can be improved

FDA Office of the Ombudsman

- FDA liaison with the Small Business Administration on matters pertaining to Small Business Regulatory Enforcement Fairness Act (SBREFA)
  - The SBA National Ombudsman reviews issues brought by small business
  - FDA issues are forward to Ombudsman's office
  - Written comment is provided back to the National Ombudsman/small business

FDA Ombudsman

- Summary
  - We ensure that FDA policies and processes are fairly and evenly applied throughout the agency
  - We identify aspects of FDA policies, processes, or regulations that could be improved or may need re-evaluating or changing to ensure fundamental fairness

FDA Ombudsman

- Laurie Lenkel – OC
  301-796-8530
- Virginia Behr – CDER
  301-796-3436
- Abiy Desta – CDRH
  301-796-5699
- Marcia Larkins – CVM
  240-276-9015
- Sherry Lard (Whiteford) – CBER 240-402-7912
- Nathan Hurley – CTP
  301-796-9239
- Jessica Zeller – ORA
  1-844-871-4536