6th Annual Food and Drug Law CLE

All Matters FDA:
2016 Year in Review and Top Notables—Crimes, Misdemeanors and More

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

Wednesday, March 23, 2016
1:00–3:00 p.m.

delawarelaw.widener.edu
Food and Drug Law CLE
Wednesday, March 23, 2016
Agenda

12:00 noon  REGISTRATION CHECK-IN

1:00 p.m.  PROGRAM SPEAKERS:

Albert S. Glenn, Esquire
Assistant U. S. Attorney
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

Hooman Noorchashm, MD, PhD
Cardiac Surgeon
Philadelphia, Pennsylvania

Amy Reed, MD, PhD
Anesthesiologist and Surgical Intensive Care Physician
Philadelphia, PA

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

3:00 p.m.  Refreshments

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WIRELESS ACCESS INFORMATION AS A “WIDENER GUEST”

WIDENER UNIVERSITY DELAWARE LAW SCHOOL
BARRISTERS’ CLUB
WEDNESDAY, MARCH 23, 2016

Username:  FDL
Password:  cle2016
PRESENTATION SUMMARIES

Rebecca Glenn-Dinwoodie:

Animal products and animal testing are key components to our food and drug systems. Pennsylvania law criminalizes certain conduct related to the treatment of these animals through its Animal Cruelty Code, located at 18 Pa.C.S. § 5511. This presentation is intended to explicate what Pennsylvania criminal law dictates for treatment of these animals as well as give concreted cases that illustrate this law in practice.

Matthew R. Noonan:

Matthew Noonan’s “FDA Inspection Stories” will briefly describe various regulatory actions available to FDA for violations of the Food, Drug, and Cosmetic Act. Example cases will be presented to illustrate Judicial Action (e.g. Seizure, Injunction, and Prosecution), Administrative Action (e.g. Order of Need for Emergency Permit for Acidified Food), Advisory Action (e.g. Regulatory Meeting), and Import Action (e.g. Detention without Physical Examination). Multiple cases will show potential consequences of misrepresenting material facts to FDA officials.

Roseann B. Termini:

FDA Top Notables 2015-2016 —and Looking Ahead!

Year in Review—Top 5 (well more than 5) Highlights of FDA Accomplishments in 2015

Here are just a few top accomplishments in food and drug law in 2015 and in the first quarter of 2016. Although the FDA has across the board accomplishments, the following are standouts and all involve safety—Zika virus, Food Safety Modernization Act Final Rules, COOL Country of Origin Labeling, Innovation, Impact of Omnibus Appropriations Act, Corporate Executives-Criminal Liability, Postmarket-Surveillance of Specific Medical Devices, Power Morcellators, Cybersecurity and GMO….just to name a few.

Last year, the question posed was whether the United States really needs an “FDA”. The role and mission of FDA has been debated for years. The FDA role ranges from that of a regulator, watchdog and facilitator. Commentary ranges from overbearing federal regulation to lack of public protection. Yet, based on these selected accomplishments, FDA provides an important function in keeping with the mission of the Food, Drug and Cosmetic Act and the numerous amendments.

Food Safety Modernization Act Final Rules
Final Rule: Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food (2015)
Final Rule: Foreign Supplier Verification Programs (FSVP) for Importers of Food for Humans and Animals (2015)
Final Rule: Third Party Accreditation of Auditors or “Certification Bodies” (2015)

Country of Origin Labeling—COOL
In an ongoing clash primarily with Canada and Mexico, the revised U.S. "country of origin" labeling rules for packaged meat cuts including ribs and steaks were rejected by the WTO deeming it an unfair advantage to Mexican and Canadian livestock. (Oct. 20, 2014; May 18, 2015). Finally, part of the 2016 Consolidated Appropriations Act eliminated the country of origin labeling for beef and pork. H.R. 2029 114th (2015-2016).

Innovation Human Drugs—3-D Produced Drug
In 2015, FDA approved a drug that is manufactured using a 3-D printer. Aprecia Pharmaceuticals produces the drug Spritam and is intended to treat seizures in people who suffer from epilepsy. The benefits of using the 3-D printing technology allows the drug to dissolve more quickly and is easier to swallow. Further, the 3-D technology affords delivery of up to 1,000 mg in a single dose.

Appropriations 2016-Alaskan Pollock
FDA updated its Seafood List to reflect a change for fish labeled as “Alaska Pollock.” As mandated by Congress in the Fiscal Year 2016 Omnibus Appropriations Act which was signed into law on December 18, 2015 (Public Law No: 114-113) and declared that only Gadus chalcogrammus caught in Alaskan waters or the exclusive economic zone (See: definition in section 3 of the Magnuson-Stevens Fishery Conservation and Management Act) adjacent to Alaska can be called Alaskan “Pollock” or Alaska “Pollock.” Previously, pollock harvested outside Alaskan waters or the exclusive economic zone were permitted to be labeled as “Alaska Pollock.” These fish can now be labeled only as “Pollock.”

Import Alert 99-40: Genetically Engineered Salmon
http://www.accessdata.fda.gov/CMS_IA/importalert_1152.html
The Fiscal Year (FY) 2016 Omnibus Appropriations Act was signed into law on December 18, 2015 (Public Law No: 114-113). The Omnibus Act directs that during FY16 the FDA shall not allow the introduction or delivery for introduction into interstate commerce of any food that contains genetically engineered salmon until FDA publishes final labeling guidelines for informing consumers of such content.

Corporate Accountability
United States v. Quality Egg, LLC—2,000 cases of Salmonella poisoning outbreak. The company fine amounted to $6.79 million and $7.8 million in compensation for damages caused by the contaminated eggs shipment. The two former executives, Jack DeCoster and Peter DeCoster, who pled guilty, received prison sentences (three months each and a $100,000 criminal fine, restitution and probation. Prison sentences deemed appropriate due to company’s prior problems of disregard for food safety standards and practices, bribery of a government inspector and disregarded high positive Salmonella test results. This case is an illustration of a “Park” prosecution.
Medical Devices
Postmarket Surveillance Investigation endoscopes and Studies Duodenoscopes
A Senate report (Report) titled Preventable Tragedies: Superbugs and How Ineffective Monitoring of Medical Device Safety Fails Patients faults FDA, medical devices manufacturers and hospital for the deadly superbugs connected to the use of endoscopes. According to the Report, several years elapsed until the safety concerns were revealed. For example, the Report details that hospitals failed to comply with mandatory requirements to report information to manufacturers.


Meanwhile, manufacturers of duodenoscopes must conduct postmarket surveillance studies to better ascertain how these devices are reprocessed. The reason for the FDA order is due to infection transmission associated with this device. FDA ordered the manufacturers to submit postmarket surveillance plans. There are no alternative devices for endoscopic retrograde cholangiopancreatography procedures (ERCP). Over 500,000 ERCP are performed annually and is the least invasive way of draining fluids from pancreatic and biliary ducts blocked by cancerous tumors, gallstones or other conditions. The outcome of the post market studies could entail label with different reprocessing instructions.

http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm465639.htm

Surgical Mesh
http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm479732.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery
FDA strengthened requirements for surgical mesh for the transvaginal repair of pelvic organ prolapse to address safety risks.
Case Examples: J&J unit Ethicon Inc. a $12.5 million jury verdict in 2015, including $7 million in punitive damages and in 2016, a $13.5 million verdict, which included $10 million in punitive damages over a transvaginal tape product.

Implantable Forms of Sterilization- Essure Permanent Birth Control
FDA Order: Bayer to conduct a postmarket surveillance study to obtain more data to better define and understand certain effects and events associated with Essure®, and issuing a Issuance of Draft guidance —manufacturers of all permanent hysteroscopically-placed tubal implants intended for sterilization include key information in patient and physician labeling.

Essure Permanent Birth Control

Weight Loss Bogus
Sale Slash LLC— agreed to pay over $43 million to settle the FTC's claims that it exaggerated weight loss pills' effectiveness as well as marketing by spamming consumers and using bogus celebrity endorsements. Sale Slash LLC agreed to pay the amount as part of a stipulation for a permanent injunction and monetary penalties against it. The settlement follows the FTC's restraining order against it in 2015.

GMO Mosquitoes
Intrexon Corp.'s Oxitec unit gained preliminary FDA backing to release its genetically modified mosquitoes and study their ability to slow or suppress the spread of Zika virus and other diseases carried by the blood-sucking insects.

Looking Ahead Outlook and Wish List
Laboratory-developed tests (LDTs)- how to regulate
Cybersecurity concerns
FDA user fees
Sterility Device Essure®
Drug Promotion and Social Media
Disparity- Drug vs. Med. Dev. Regulatory Approval Process
Disparity- Drug vs. Med. Dev. Harm ability to sue in state court
GMO — Federal vs. State
GMO— State “Trigger Clause” in nearby states. Vermont does not have trigger clause.
Right to Try—Why are states enacting their own legislation?
E-cigarettes
Smart Labelling—FOP
Tanning Booth for Beauty—“Warnings” and Cancer.
Sodium
Homeopathic Remedies and Oversight
Tanning Booth Federal Oversight
Off Label Marketing- Amarin

FDA Wish List—Congressional Authorization of more resources, so FDA can effectively fulfill the mission of the FDCA.
STAKEHOLDER Wish List—More Clarity from FDA!
RECOMMENDATIONS—The above accomplishment illustrate the necessity for “FDA” as well as an “FTC”. Further, hopefully Congress will revisit FDA regulatory authority for some products such as dietary supplements where FDA can only legally exercise post-enforcement authority. Stay tuned for further updates.
BIOGRAPHIES
Albert S. Glenn

Albert S. Glenn is an Assistant United States Attorney in the Eastern District of Pennsylvania. He joined the Philadelphia office in 1999, and is in the Criminal Division. Prior to Philadelphia, Mr. Glenn was an AUSA in San Francisco, and a criminal prosecutor in the U.S. Justice Department’s Civil Rights Division. Mr. Glenn has worked on criminal cases in a variety of subject areas, and among them are various cases involving prescription drugs. He is a 1979 graduate of UCLA School of Law.

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Rebecca Glenn-Dinwoodie

Rebecca Glenn-Dinwoodie is the Director of Humane Litigation at the Pennsylvania Society for the Prevention of Cruelty to Animals. Her practice includes all phases of investigation and prosecution of criminal animal cruelty charges and civil litigation related thereto. Her career has been dedicated to teaching or advocating for those most at risk, first as a public school teacher and child social worker, then as a family and civil litigation attorney, and now as in-house counsel for the largest animal non-profit organization in Pennsylvania.

She has lectured on legal topics relating to all facets of Pennsylvania animal cruelty and animal law, civil litigation related thereto, 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. in 2010 from Temple University Beasley School of Law. She is admitted to the bars of the Commonwealth of Pennsylvania and the Eastern District of 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. Dr. 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, Dr. Lenkel worked in the pharmaceutical and medical device industries. Her experience in regulatory affairs includes phase four clinical trial development, drug labeling, promotion and continuing medical education program review. Her current professional activities include serving on the Editorial Advisory Board of the *Food and Drug Law Journal* (including two terms as Chair), 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, Dr. Lenkel is both a licensed pharmacist and attorney. She also earned a doctorate in law and policy from Northeastern University.

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Matthew R. Noonan
CONDENSED VITAE

US Custom House, Room 900, 2nd & Chestnut Streets, Philadelphia, PA 19106
215-717-3720 (o)           matthew.noonan@fda.hhs.gov

EDUCATION
The George Washington University Law School, Washington, DC
J.D.
Saint Joseph's University, Philadelphia, PA
B.S. in Chemistry, Cum Laude
  • Minor: Secondary Education
  • Teaching Assistant, Department of Chemistry
  • Tutor, College of Arts and Science
  • Student Teacher, Ridley High School, Folsom, PA

PROFESSIONAL EXPERIENCE
Food and Drug Administration, Office of Regulatory Affairs, Philadelphia, PA
Food Specialist/Investigator, Philadelphia District
  • Conduct inspections primarily in food program area including HACCP, acidified food, low acid canned food, and dietary supplements
  • Consult on complex and potentially violative cases
  • Created and lead food cadre
  • Provide training regarding regulations, guidance, and technical information
  • Serve as head trainer for new investigators
  • Member of ORA Human Food Preventive Control Instructor Cadre
  • Member of ORA Seafood Certification Board
  • Completed food inspections as sole or lead investigator which resulted in the following regulatory actions:
    o Order for Need of Emergency Permit
    o Consent Decree of Permanent Injunction
    o 2 Seizures
    o 7 Warning Letters
    o Import Alert
    o 3 Regulatory Meetings
RECENT AWARDS
- Received Exceptional Rating during three of last four annual performance reviews
- Received Incentive Awards at 2014 and 2015 Philadelphia District Awards Ceremonies
- Received 2013 ORA Outstanding Service Team Award
- Nominated for Patrick J. Pouzar ORA Investigator of the Year Award in 2013

RECENT ACCOMPLISHMENTS
- Hosted FDA Associate Commissioner for Regulatory Affairs on inspection
- Earned ORA Level II Seafood Certification and Level II LACF/AF Certification
- Graduated from inaugural ORA Potential Supervisors Program
- Completed Better Process Control School Online, University of California at Davis
- Completed two state Department of Agriculture contract audits
- Assumed responsibility for district seafood export certificates
- Member of 2015 World Meeting of Families and Papal Visit Task Force. Inspected airport foodservice at function with Pope Francis.

RECENT PRESENTATIONS
FDA, ORA, Philadelphia, PA
“Food Sanitation Inspections”
“Filthy Warehouse”
“Overview of Food Microbiology”
“Controlling Growth Factors”
“Control by Refrigeration”
“Total QA Failure”
“Allergens”
“Aseptic Sampling”
“Environmental Sampling”
“HACCP Prerequisite Programs and Hazard Analyses”
“Seafood Warehouse Requirements”
“Seafood Hazard Analyses”
“GMP and Preventive Control Data Collection”
“*Clostridium botulinum* – The Most Potent Toxin Known to Man”

Central Atlantic States Association of Food and Drug Officials, Philadelphia chapter
“HACCP Plans and Regulations”
“Cooling and Refrigeration”

Pennsylvania Department of Agriculture
“Food Labeling and Allergen Control”
“Environmental Sampling”
“Food Safety Modernization Act”
“Juice HACCP”
Hooman Noorchashm, MD, PhD  
Amy J. Reed, MD, PhD

Hooman Noorchashm, MD, PhD is a cardiothoracic surgeon in Philadelphia, Pennsylvania. He trained at the Hospital of the University of Pennsylvania and Harvard Medical School's Brigham and Women's Hospital.

Amy J. Reed, MD, PhD is an anesthesiologist and surgical intensive care physician in Philadelphia, Pennsylvania. She trained at the Hospital of the University of Pennsylvania and previously held a faculty appointment at Harvard Medical School's Beth Israel Deaconess Medical Center.

They initially met in medical school at the University of Pennsylvania in Philadelphia, Pennsylvania and are married with 6 children, ages 3-14. Following a harrowing personal experience with a systemic error in surgical practice in October 2013, Drs. Reed and Noorchashm successfully campaigned against a gynecological practice known as "morcellation." They are now vocal advocates for patient safety, medical ethics and a reform to the FDA's legislation governing medical device clearance for marketing in the United States.

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*, 8th ed. (2015). The reason for the recent 8th 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.

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.

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Publications SSRN Author page
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All Topics Food and Drug Law Blog
http://fortipublications.com/blog/
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www.linkedin.com/in/roseanntermini/
COURSE MATERIALS
Rebecca Glenn-Dinwoodie, Esq.
Director of Humane Litigation
March 23, 2016
Road Map for Today

• What the Pennsylvania SPCA does
• Brief outline of animal cruelty in Pennsylvania
• Animals destined to supply food
• Animals used for scientific testing
• The issues are real: cases in point
Pennsylvania SPCA

• Largest Humane Law Enforcement division in the state of Pennsylvania
  • Eleven (11) Humane Law Enforcement officers covering 22 counties across the Commonwealth of Pennsylvania
  • Full police powers to enforce the animal cruelty code
  • 100% donor funded: no funding from state or local governments
    • And, incidentally, no liability protection afforded state or local governments
Animal Cruelty in PA: 18 Pa.C.S. § 5511

• The Cruelty Code is organized not just by physical act or failure to act, or requisite mental state, but also by species and/or industry.
  • The same act committed on a zoo animal, police animal, owned animal, or farm animal can bring different penalties or exempt the perpetrator from charges entirely.
• Mental intent requirements often remain the same.
Penalties

- The same penalties apply as for other sections of the code. These include:
  - Jail time
  - Fines
  - Restitution
  - Forfeiture of the animals involved
  - Prohibition of animal ownership

“Normal Agricultural Operations”

Normal activities, practices and procedures that farmer’s adopt, use or engage in year after year in the production and preparation for market of poultry, livestock and their products in the production and harvesting of agricultural, agronomic, horticultural, silvicultural and aquicultural crop and commodities.
Cruelty to Agricultural Animals

- Applicable subsections:
  - 5511(a)(1) (if animal owned by another person)
  - 5511(b) (special considerations for bunnies, chicks)
Cruelty to Agricultural Animals

• Applicable subsections (con’t):
  • 5511(c) (with significant exception)
  • 5511(e) (transporting in a cruel manner)
  • 5511(g) (cruelty to cow to enhance appearance of utter)
  • 5511(h.1) (animal fighting with same significant exception)
  • 5511(q) (definition section)
Cases

  - “normal agriculture operations”
  - Arabian horse breeding versus horses for slaughter
  - Animal fighting and agricultural operation
Ag Gag Laws

- Laws aimed specifically to criminalize the actions of undercover investigations and investigators that often work to uncover animal abuse, labor violations, groundwater pollution and other unlawful activity within factory farms.
- Pennsylvania’s Ag Gag bill, shot down in 2013, would have included other industries as well, including fracking.
Animals in Scientific Testing

• Pennsylvania gives little to no protection under the cruelty code for animals in scientific testing.

• 5511(1) gives HSPOs the ability to apply for and execute search warrants. However:

  • “No search warrant shall be issued … which authorizes any … person to enter upon or search the premises where scientific research work is being conducted.” 5511(1)
Case in Point: Feeder Pigs

• Feeder pigs
  • Pigs were found in late December without appropriate shelter
  • They were standing in nearly frozen mud up to their ankles and chests.
Case in Point: Feeder Pigs

Vesta

Spot

Spidey Pig
Case in Point: Beef Cattle

- Centre County, Pennsylvania
- Early February of 2013: herd of beef cattle found emaciated; 9 cattle corpses found on scene
- Warning: some graphic pictures ahead
Case in Point: Beef Cattle
Case in Point: Beef Cattle

- Defendant was found guilty of animal cruelty on the summary level.
  - 30 days of jail per citation, maximum term of prohibition of animal ownership
  - Defendant appealed *de novo*, permissible under PA law for summary matters
  - Defendant was again found guilty and was sentenced to 360-1080 days in jail and prohibition of animal ownership for the maximum term (just under 5 years)
The Animals

• All five (5) of the feeder pigs went to barnyard animal rescues

• The 31 live cattle were too skinny to go far, so neighboring farmers split them up to join their herds
Questions?

Rebecca Glenn-Dinwoodie, Esq.
Director of Humane Litigation
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U.S. Food and Drug Administration

• FDA Mission
  o Protect and promote public health

• Regulated products include:
  o Foods, Cosmetics, and Dietary Supplements
  o Human Drugs
  o Medical Devices and Radiation-Emitting Electronics
  o Biologics
  o Animal Feeds, Drugs, and Devices
  o Tobacco Products
Food, Drug, & Cosmetic Act

- Primary statute
  - Food, Drug, & Cosmetic Act
    - Title 21 United States Code
    - Interstate commerce

FD&C Act by FDA (2014) (Public Domain)

hukum adalah segalanya by Rifqi Jamil (2012) (CC BY-SA 3.0)
Prohibited Acts

- **21 USC § 331**
  - Introduction into interstate commerce of an adulterated or misbranded product
  - Adulteration or misbranding of a product while held for sale after shipment in interstate commerce

- May result in judicial action
  - Brought by Department of Justice
Current Good Manufacturing Practices

- Minimum requirements for manufacturer to assure products are safe and of high quality
- Establish criteria for adulterated products under FD&C Act
- Title 21 Code of Federal Regulations
  - FDA issues cGMP regulations and enforces them through inspections.

FDA Inspector 2824 by FDA (2009) (Public Domain)
• 21 USC § 374

• Investigators are allowed to enter and inspect at reasonable times and in a reasonable manner.
  ○ Typically unannounced

• Inspections may cover personnel, facilities, equipment, materials, production, labeling, etc.
  ○ And records if applicable

• May include sample collections
FDA Advisory Actions

• Include:
  o Warning Letter
    ▪ Written letter advising of specific violations and warning of judicial action if corrections are not made
    ▪ Issued to achieve voluntary compliance and establish prior notice
  o Regulatory Meeting
    ▪ In-person meeting to stress seriousness of deficiencies and need for corrections
Drug Manufacturing Inspection

- Antimicrobial hand soaps and hand sanitizers
  - Also manufactures industrial chemical cleaners
- Responsible for following drug cGMPs including:
  - Prevention of cross-contamination
    - Especially with chemicals
  - Active ingredient concentration
    - E.g. labeled as 1%
- Drug operations led by QA Director
  - Reports to President, who is responsible for oversight

Drug cGMPs = 21 CFR 211
Cross-contamination

- Shared blending tanks between drugs and chemicals
- Mere water rinse in between
  - No detergent
- E.g. prior run: Foamy Acid Cleaner

[Illustration of blending tank]. Retrieved from https://www.cadcrowd.com/contest/156-mixer-tank-design

CAUTION
Causes Severe Skin Burns!

FDA Inspection Stories
### Active Ingredient Concentration

- Per testing summary sheet

#### Collected Tuesday

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<th>Result (%)</th>
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<td>0.96</td>
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#### Collected same document on Thursday

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</tr>
<tr>
<td>G</td>
<td>2/1/16</td>
<td>1.00</td>
</tr>
</tbody>
</table>
Testing Summary Manipulations During Inspection

• E.g. Batch G was 4440 lb.
  ○ 44.4 lbs. active ingredient were intended to be added.
  ○ By mistake, only 40 lbs. were actually added.
    ▪ \( \frac{40}{4440} = 0.90\% \) (approximate expected result)
  ○ Reported testing “result” was 1.00%.

• Repeated denials

• Restroom break

• “Forgot” changing lab summary sheets
  ○ Within past two days
Batch Record Manipulations During Inspection

- Repeated denials
- Handwritten results
  - “May have” whited out results, changed them, and photocopied the records
    - But “doesn’t remember”
- Typed master language
  - Cut out words from other documents, taped them onto batch records, and photocopied the records
    - “Because it looks better” to FDA
- QA Director cited lack of memory whenever painted into a corner.
Data Integrity Concerns

• When President was told of data integrity concerns, QA Director was rushed to hospital with chest pains.
  - “Could not handle stress” of inspection
    ▪ No longer participated
  - Relieved of drug responsibilities
    ▪ 30 year employee

• No gas chromatograph instrument for two years

• Regulatory action of choice → Regulatory meeting
  - Themes:
    ▪ Allocation of resources
    ▪ Oversight of QA personnel
    ▪ cGMP expertise
    ▪ Honesty

  - Rationale
FDA Administrative Action

• Such as Order of Need for Emergency Permit
  ○ 21 USC § 344
  ○ If FDA finds very significant microbiological non-compliance with acidified food or low acid canned food regulations:
    ▪ Further distribution in interstate commerce would be “permitted” only if FDA grants an Emergency Permit.
      ▪ Firm applies for permit based on evidence of corrections and regulatory compliance.
    ▪ Previously manufactured batches are evaluated by FDA on a batch-by-batch basis.
1. Establish scheduled process, as developed by a processing authority.

2. File same process with FDA.

3. Deliver same process to product.
   - Decrease pH to ≤ 4.6 by adding acid.
     ▪ To prevent *Clostridium botulinum* from producing toxin.
   - Subject product to thermal process.
     ▪ To destroy dangerous microorganisms such as *E. coli* O157:H7.
     ▪ And to treat headspace and interior cap.
### Acidified Protein/Energy Drink Inspection (Warning Letter Follow-up)

<table>
<thead>
<tr>
<th>Batch</th>
<th>pH</th>
<th>Processing temperature (F)</th>
</tr>
</thead>
<tbody>
<tr>
<td>C1</td>
<td>6.6</td>
<td>W1 52</td>
</tr>
<tr>
<td>C2</td>
<td>5.8</td>
<td>W2 55</td>
</tr>
<tr>
<td>C3</td>
<td>6.2</td>
<td>W3 50</td>
</tr>
<tr>
<td>C4</td>
<td>6.6</td>
<td>W4 59</td>
</tr>
<tr>
<td>C5</td>
<td>6.5</td>
<td>W5 60</td>
</tr>
<tr>
<td>C6</td>
<td>6.9</td>
<td>W6 49</td>
</tr>
<tr>
<td>C7</td>
<td>6.4</td>
<td>W7 54</td>
</tr>
</tbody>
</table>

**Cool as a Cucumber**

**In a Bad Whey**

**A Lime Out Da Door**

FDA issued Order of Need for Emergency Permit 8 business days after inspection.

- **Rationale**
  - Underprocessed products and batches were recalled.
  - FDA denied release of most previous batches.

- Firm eventually was granted an Emergency Permit based on correction plan.
  - But soon went out of business
Import Action

• Such as Detention without Physical Examination
  ○ 21 USC § 381 authorizes FDA to refuse admission into U.S. of products that appear to violate FD&C Act.
  ○ Can be based on:
    ▪ FDA analysis
    ▪ History of problems or potential problems with same or similar products
    ▪ Burden of demonstrating compliance rests with importer
Judicial Actions

- **Seizure**
  - 21 USC § 334 allows Government to remove specific violative products or batches from commerce.
    - In rem action
  - Complaint for Forfeiture filed with DOJ
  - U.S. Marshals “arrest” Defendant (violative articles)

- **Prosecution**
  - 21 USC § 333 provides for imprisonment and/or monetary fines for persons who commit a Prohibited Act.
• U.S. Marshalls seized 128 drums of imported honey
  o Adulterated with Chloramphenicol
    ▪ Animal antibiotic which is highly dangerous to humans
    ▪ Used to protect bees from bacterial infections
      ❖ But adequate withdrawal times before harvest must be implemented, or else the antibiotic can contaminate the honey.
  o Manufactured in China
  o FDA sample collection and analysis
  o FDA witnessed destruction.
  o Rationale
Detention without Physical Examination – Honey

- FDA published “Red List” of foreign honey manufacturers whose products will be detained due to antibiotic contamination.

Stop hand by Silsor (2005) (GFDL)
Prosecution – “Largest Food Fraud in U.S. History”

- Circumvented antidumping tariffs and increased FDA scrutiny on Chinese honey by laundering it through other countries and mislabeling the country of origin.
- **10 executives of importer were indicted for fraud.**
  - Two cooperating executives ultimately pled to reduced charges and received sentences that included substantial fines and, for one, a year in prison.
  - Other executives have avoided prosecution by remaining oversees.
Prosecution

• Injunction
  - Court Order preventing firm from violating the law or ordering it to do something
    - E.g. stop distributing products in interstate commerce
    - Per 21 USC § 332
  - Halts flow of violative products in interstate commerce and requires correction of conditions which caused violations
  - Can be settled via Consent Decree
This picture shows two cat-like animals lying atop cardboard boxes containing food packaging material, along the east wall of the warehouse.
This picture shows a small gray cat-like animal under a pallet containing YYY brand salt (batch 1234). The pallet was in the northeast section of the warehouse, stacked in the eighth pallet row from the north wall.
Cats

This picture shows a small gray cat-like animal at the east wall of the warehouse, in the eighth pallet row from the north wall.
This picture shows apparent cat excreta stools on the floor adjacent to the south wall of the south walk-in refrigerator, between the first and second pallets from the entry to the refrigerator.
This picture shows a large gray cat-like animal lying on some of the same excreta as the previous slide.
This picture shows the first (top) layer box in the southwest section of the pallet, with five stains approximately 1x1, 0.5x0.5, 0.25x1.5, 0.25x1.5, and 0.5x0.5 inches.
Other Four Legged Friends

This picture shows two dog-like animals in the center-east section of the warehouse on the second-to-last day of the inspection.
This picture shows an employee leading three dog-like animals out of the facility after the inspection started.
This picture shows a dog-like animal moving freely in the center-east section of the warehouse on the second-to-last day of the inspection. The dog had just been rummaging through an open cardboard box on the floor containing discarded food, including fresh peas.
This picture shows a pile of very hard apparent animal excreta along the east wall of the warehouse, near the eighth pallet from the north wall.
• Regulatory action of choice ➔ Permanent Injunction
  ○ Rationale
  ○ Consent Decree
Thank you!
TOP FDA NOTABLES 2015-2016
And
Looking Ahead....

Roseann B. Termini

Food Safety Modernization Act Final Rules

- Administrative Detention (2013)
- Preventive Controls – Risk Based and CGMPs (2015)
- Produce Safety (2015)
- Foreign Supplier Verification for Importers - Animal and Human Food (2015)
FSMA Proposed Rule

- Focused Mitigation Strategies to Protect Food Against Intentional Adulteration
COOL

- Background
- Country of Origin Labelling (COOL)
- Farm Security and Rural Investment Act (2002 Farm Bill)
  Amended the Agricultural Marketing Act
- Suppliers provide information to Retailers
- Retailer notification for Shellfish and Fish: April 2005
Exemption: If Covered Commodity is an Ingredient in Processed Food Item
2008 Farm Bill expanded food commodities
Requires the retailers to notify consumers of the country of origin of beef, lamb, pork, chicken, goat meat, peanuts, pecans, macadamia nuts, fruits and vegetables, ginseng
Applies to domestically produced commodities
COOL Notification

- How to notify
  - label, sticker, twist tie
  - “Product of the United States”
  - “Grown in Mexico”
Who must keep COOL records?

- Suppliers
- Retailers
COOL and WTO


- Why?

- Trade Barrier
Innovation

- 3-D Technology
- FDA Approved Drug Spritam®
- Manufactured using 3-Dprinter
- Intended Use to Treat Seizures
Public Law No. 114-113
Labelling
Alaskan or Alaska Pollock only if...
Caught in Alaskan waters or
Exclusive economic zone
Import Alert 99-40

- What?
- Genetically Engineered Salmon
- Appropriations Act
- Importation Prohibited Until...
- Final Labeling Guidelines Published
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
Medical Devices

- Endoscopes
- Post Market Surveillance Studies
Medical Devices

- Surgical Mesh
- Requirements Strengthened
Medical Devices J&J Ethicon, Inc.

Case Example

Transvaginal Tape Product

- $12.5 million jury verdict Includes $7 million in Punitive Damages (2015)
- $13.5 million jury verdict- Includes $10 million in Punitive Damages (2016)
Medical Devices

- Implantable Forms of Sterilization
- Essure®
Looking Ahead

- Laboratory Tests-How to Regulate
- Cybersecurity Concerns
- Resources and User Fees
- Drug Promotion and Social Media
Looking Ahead

- Approval Process Disparity: Drug vs. Medical Device
- Disparity: Drug vs. Medical Device Ability to Institute Legal Proceedings in State Ct.
- Right to Try State Legislation
- GMO and State Laws ex. Vermont and Trigger Issues
Looking Ahead

- Federal Tanning Booth Legislation
- Homeopathic Remedies and FDA Oversight
- Off-Label—Is *Amarin* the law now?
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