

**Kratom, Opioids, Marijuana,
CBD, Whistleblower Actions,
Medical Device Safety, GMOs,
Dietary Supplements, E-
Cigarettes, Right-to-Try.....**

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Rules of Professional Conduct

- **Key Focus**
 - Communication
 - Competence
 - Diligence
 - Expediting Litigation
 - Zealous Advocacy

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Current Court Cases

- Talcum Powder- mixed results
- Mirena Birth Control-2018 Fed. Ct. issues with experts
- Zostavax- shingles Fed. Ct. 500 cases
- Xarelto- blood thinner- allegations excessive bleeding 24,700 individuals
- Taxotere- Failure to Warn- Permanent hair loss
- Essure-birth control- autoimmune 18,000 plaintiffs, U.S. sales halted

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Civil Lawsuits Veterinary Products

- **Hill's Pet Nutrition, Inc.**
- **Excessive levels of Vitamin D**
- **Allegations: breach of warranty, strict liability, failure to warn, deceptive trade practices**
- **Allegations: Delay in notification**

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Tobacco Products Regulation

Landmark Law

Signed into law: June 22, 2009

Family Smoking Prevention and Tobacco Control Act

This landmark legislation amended the FDCA.

What Does this Law Do?

- The FSPTCA granted the FDA new authority to regulate tobacco products to protect public health.

How did this Law amend the FDCA?

- Expressly permitting FDA regulatory authority
- Specific Center for Tobacco Products

New FDA Center

- Center for Tobacco Products

Key Element

- Graphic Warnings-
- Litigation Issue
- First Amendment Principles

Key Element

- Flavor Ban!
- Candy, Spice and Fruit Flavored Cigarettes

What About E-Cigarettes?

How to Regulate Drug and/or Device
or
Family Smoking Prevention and
Tobacco Control Act

Deeming Regulations

- **E-Cigarettes and Other Tobacco Products**
- **Rulemaking 2016**

What about Tobacco and Youth?

- Strategies
- Minimum Age
- FDA Continued Focus-Youth

Center Priorities

- 2017 Youth from 3.6 million in 2017 to
- 4.9 million inc. e-cigs. 2018
- Youth 78% High Sch. and 48 % Middle Sch.
- Tobacco product testing
- Promotion restrictions
- Modified risk evaluation
- Enforcement

Smoking Everywhere - *Soterra*

- Key Factor: How marketed

Therapeutic Use:

FDCA provision drug and/or device

Non Therapeutic Use:

FSPTCA- tobacco product

A Look to the Past to Understand the Present Law

Did FDA Even Want to Regulate Tobacco?

Who Created the Hawaiian Punch Mascot and the Kool-Aid Man?

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Big Tobacco

- Hawaiian Punch- 1960s R.J. Reynolds
- Kool-Aid-Philip Morris – applied same marketing as R.J. R. ex. Direct to children—colors, flavors and characters

Federal Court Order

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

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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 1, 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),
- MODIFIED by Order Dated Oct. 5, 2017
- Example N.Y. Times 9 (Jan. 7, 2018).

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Federal Court Order

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

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Graphic Warnings

- The *American Academy of Pediatrics et al. v. United States Food and Drug Administration*, 1:16-cv-11985, (D. C. Mass. 2016).

Graphic Warnings

- Court ordered the FDA to issue long overdue revamped warnings on an expedited schedule since several years elapsed.

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Graphic Warnings

- MEMORANDUM AND ORDER GRANTING INJUNCTIVE RELIEF (March 5, 2019)
- Proposed Rule submitted for Publication in the Federal Register by August 15, 2019
- Final Rule submitted for Publication in the Federal Register by March 15, 2020.

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Graphic Warnings

- https://www.tobaccocontrollaws.org/files/live/litigation/2631/US_American%20Academy%20of%20Pediatrics.pdf

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Opioid Crisis

- President Trump Public Health Emergency
- Support Act 2018– studies chronic administration

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Former FDA
Commissioner
Gottlieb

- Opioid Policy Steering Committee-
- Education for doctors i.e. Only when medically necessary.
- Risk Management expanded

OPIOID CRISIS

EXECUTIVE LIABILITY

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

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Opioid Crisis

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

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Opioid Crisis

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

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Opioid Crisis

- Gateway to Addiction
- Example Swimmer

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Settlement

- Oklahoma 270 million
- Resolves lawsuit filed by Oklahoma Attorney General
- Allegations deceptive marketing
- Spurred the opioid addiction crisis

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OPIOID CRISIS

- Bankruptcy Possible
- CHAPTER 11

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Drug Pricing

- **Gene Therapies Costs**
- **Disparity in Price**

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Orphan Drugs



Incentive for Product
Development



Decreased Tax Credit to 25 per cent.



PL 115-97, December 22, 2017, 131
Stat 2054, SEC. 13401.
MODIFICATION OF ORPHAN DRUG
CREDIT.

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Controlled Substances Act

**Who declared "War on
Drugs"?**

Created DEA

Banned Hemp

**Hemp one of the oldest
domesticated crops**

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Farm Bill

- On December 20, 2018, President Donald Trump Agricultural Improvement Act of 2018
- Commonly known as " 2018 Farm Bill"

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Classification and Confusion

- CANNABIS- family of plants
- HEMP and MARIJUANA- 2 species
- HEMP vs. MARIJUANA
- Level of THC chemical compound induces psychoactive effects

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Product Classification and Confusion

- HEMP THC level 0.3 percent or less
- MARIJUANA THC level greater than 15 percent

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Terminology and Product Classification

- CBD Cannabidiol
- Product Proliferation
- Ex. Hemp Gummies
- Ex. Cannabis Drinks

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Remember

- Mission of FDA
- Regulations Needed

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Product Classification



"Poop" Cartel



Drug or.....

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Product Classification

- *United States v. Bacto-Unidisk*, 89 S. Ct. 1410 (1969)

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Product Classification

Poop Cartel

- *Physicians*
- *Patients*
- *Drug Companies*

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Fecal Microbiota

- Purpose: Cure C. diff
- Drug OR
- Organs, Tissues, Blood Products
- How: transfer
- Guidance –draft 2013
“Drug”

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Fecal Therapy

- Obesity
- Autism
- Ulcerative Colitis
- Alzheimer's
- Parkinson's

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Product Classification



Drug or Device



Line Away and Sudden Change



Intended Use



Representations



Fast forward to 2019



BORCHENKO v. L'ORÉAL USA, INC.

Sudden Change

- "FACE LIFT WITHOUT SURGERY"—"The Perfected Anti-Wrinkle Face Lift Acts in Minutes Lasts for Hours."

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- (a) "it gives a face lift without surgery"
- (b) "it lifts the skin"
- (c) "it firms the skin"
- (d) "it tones the skin"
- (e) "it smoothes the skin"
- (f) "it moisturizes the skin"

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- (g) “it provides a tingling sensation to indicate the article is working”
 - (h) “it lifts puffs under the eyes”
 - (i) “it provides the user with beneficial results for hours”
 - (j) “it is more effective if applied regularly”

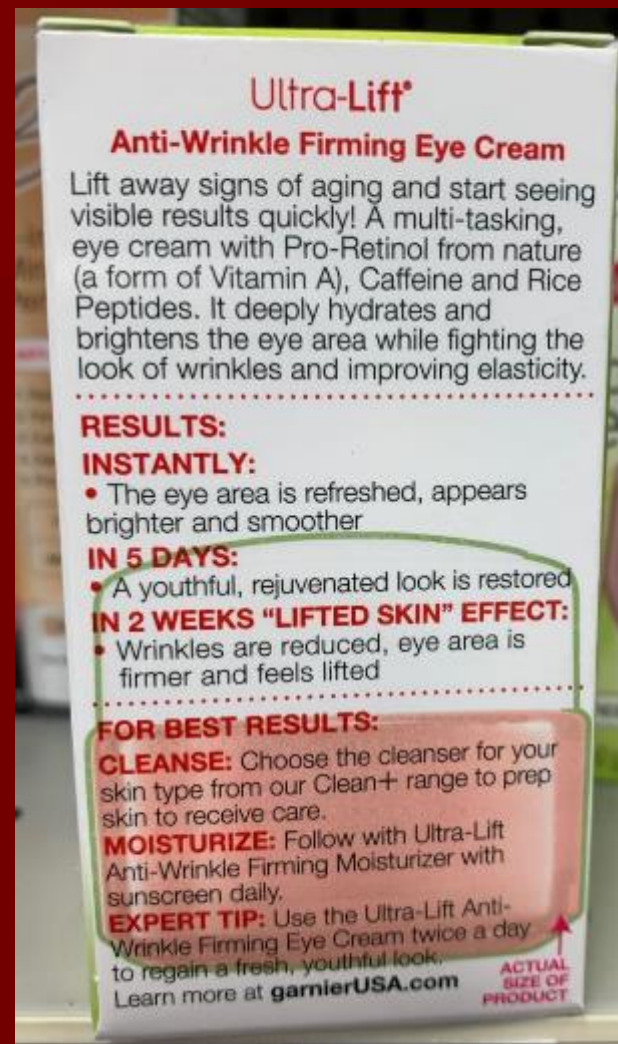


Cosmetic Safety

Makeover Needed



(Daily Moisturizer Front and Back)



(Eye Cream Front and Back)



(Night Cream Front, Back, and Side)

Sunscreen

- OTC
- SUNucate
- State legislation- permits students to possess and or use sunscreen products without written authorization from a parent, legal guardian or health care professional.

Dietary Supplements

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

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DSHEA

- 25 Years Later
- Proliferation in the marketplace
- How Regulated

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Gerber to Starbucks

- Gerber – fruits snacks pictures of real fruit
- Starbucks- sour gummy candies- names of fruit ex. Watermelon, tangerine, apple flavored candies
- *Sandra Brown v. Starbucks Corp.*, case number 3:18-cv-02286, U.S. D. Ct. Southern District California.

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AUTONOMY

RIGHT TO REQUEST

- ❖ Right-to-Try State vs. Federal Legislation vs. Federal Compassionate Use
- ❖ States Right-to-Try impetus for Federal “streamlined” process and Federal Rt.-to-Try Law (2018).
- ❖ *Individual Patient Expanded Access Applications - Form FDA 3926 (June 2016)*

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.

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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.

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Wadler v. Bio-Rad

Corporate Counsel prevailed in retaliation
Vacated \$2.96 million doubling due to a
2018 decision Digital Trust, Inc. Dodd-Frank
does not apply to internal reports.

- <http://cdn.ca9.uscourts.gov/datastore/opinions/2019/02/26/17-16193.pdf>

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Wadler v. Bio-Rad

- SOX claim – protected activity, VACATED and REMAND for the district court to consider whether a new trial is warranted.
- <http://cdn.ca9.uscourts.gov/datastore/opinions/2019/02/26/17-16193.pdf>

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Innovation

- Post partum depression drug approval

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LOOKING AHEAD

- ◆ Cyber Security Concerns
- ◆ Resources and User Fees
- ◆ Lethal Injections

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

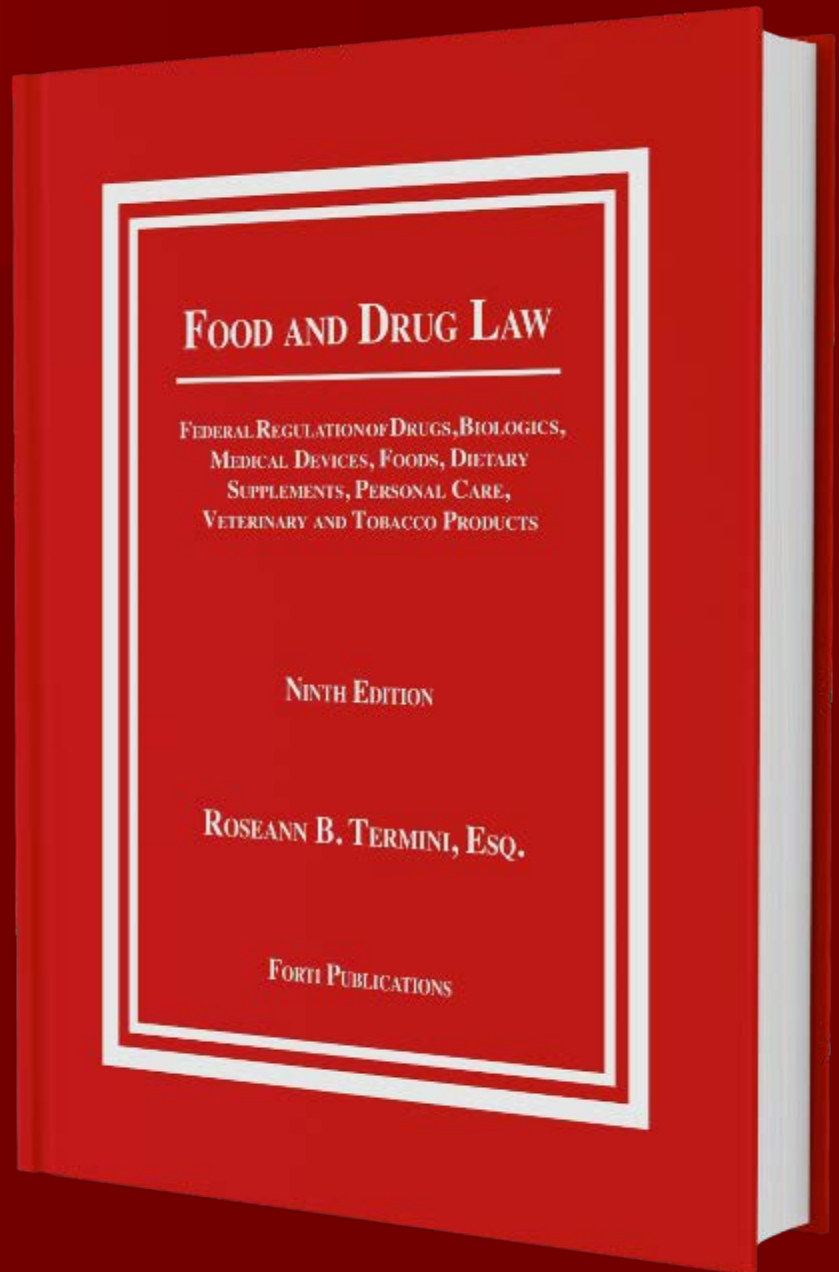


LOOKING AHEAD

- ◆ Federal Initiatives Opioids
- ◆ Federal Initiatives E-Cigarettes, Menthol, Flavors

Does FDA Really Regulate Love?

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