



Cross-Cutting Regulatory Spheres and State Spotlight

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Raqiyyah R. Pippins

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State Litigation Based on Product Names (USDA/FDA)



State Litigation Based on Unique State Laws



Cannabis & Food

Cannabis/CBD & Food – Commercial Interest

Bloomberg

Deals

Coca-Cola Is Eyeing the Cannabis Market

HEALTH | HEALTH & WELLNESS

Cannabis Comes to Your Coffee and Candy—But Is It Legal?

Marketers are selling products containing cannabidiol, or CBD, a chemical found in hemp, claiming benefits such as pain relief and stress reduction. But the actual effects are unclear, as is the legal landscape.

Product	Ingredients
Cannabis	
	77.5% full-cream milk 18% Arabica highland coffee Sugar Natural Swiss hemp essential oil (13 mg)
100 ml contains:	
Energy value	290 kJ / 69 kcal
Fat	2.7 g
Carbohydrate	8.3 g
Protein	2.5 g
Elevated caffeine content - 40 mg/100 ml	





Interagency Collaboration and Enforcement



Questions?



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Cross Cutting State-Federal Issues

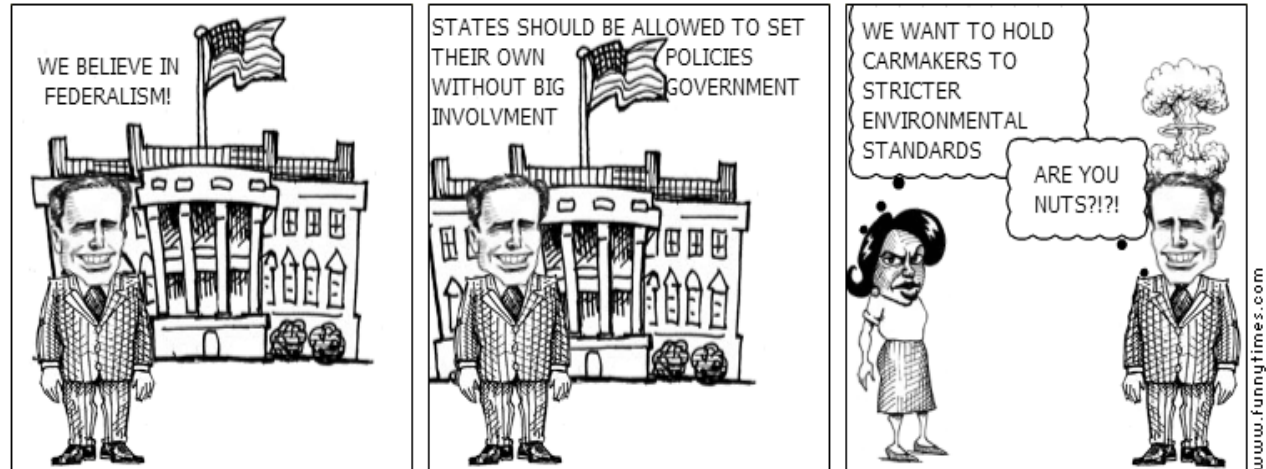
Laurie J. Beyranevand
Director, Center for Agriculture
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Federalism and the FDA

Generally speaking, the Food, Drug, and Cosmetic Act does not explicitly preempt the states from regulating food with the exception of the Nutrition Labeling Education Act.

Federalism by A. Ellis





What Does That Mean for the States?



Does Regulatory Inaction Allow Room for State Action?

Areas Ripe for State Regulation and Litigation





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Food Advertising, Labeling, and Litigation Conference

September 27, 2018

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Jensen Farms

- Recall:
 - Listeria outbreak associated with cantaloupes
 - 33 deaths and 143 hospitalizations
- Criminal charges against the brothers who owned and operated the company
- A pure *Park* case?

Peanut Corporation of America

- Recall:
 - Salmonella outbreak associated with peanut products
 - Nine deaths and an estimated 22,000 illnesses
- Longest prison sentences ever for individuals involved in a foodborne illness outbreak
- Focus on “garden variety” fraud

Quality Egg

- Recall:
 - Salmonella outbreak associated with eggs
 - Over 1,900 reported illnesses
- Prison sentences for strict liability crimes

Trends?

- “Bread and butter” cases
- FDA’s stated preference
- Scientific advances
- Changes in eating patterns
- High profile recalls/investigations
 - Will there be prosecutions?

A Telling Comparison

- Roos Foods (2016)
 - Listeria outbreak associated with cheese
 - One death and eight illnesses (per CDC)
 - Roof leaks, rust, product residue
 - Criminal charges against company
 - Civil injunction
- Vulto Creamery (2018)
 - Listeria outbreak associated with cheese
 - Two deaths and eight illnesses (per CDC)
 - Company testing continually found listeria, but failed to eradicate it
 - No criminal charges
 - Civil injunction



Michael S. Blume
Partner, Regulatory Practice
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Mike Blume focuses his practice on compliance, consumer fraud, and corporate liability for clients in the pharmaceutical, life sciences, food, dietary supplements, medical device, consumer products, and financial services industries. He has significant experience with the Federal Food, Drug, and Cosmetic Act; the Financial Institutions Reform, Recovery, and Enforcement Act (FIRREA); the False Claims Act; the Federal Trade Commission Act; and the Consumer Product Safety Act, among others. Mike has tried a variety of civil and criminal matters in federal court, and has managed investigations involving a variety of state and federal civil and criminal agencies, including the FBI, United States Postal Inspection Service, FDA, FTC, and state attorneys general.

Prior to joining Venable, Mike served as Director of the Consumer Protection Branch at the U.S. Department of Justice. As the leader of a proactive, innovative prosecuting arm of the DOJ, he gained considerable experience investigating and prosecuting an array of business crimes, primarily focusing on food, drug, and medical device safety; financial fraud; and consumer product safety.

During his tenure, he prioritized financial fraud, food safety, and mass marketing cases leading to precedent-setting prosecutions, and he worked to strengthen partnerships with consumer protection regulators worldwide and nationwide. Mike worked with leaders across multiple components of the DOJ and at numerous government agencies, including U.S. Attorneys' Offices nationwide, the FDA, FTC, CSPC, and state attorneys general.

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What Do Centers Do?

- Provide Policy/Guidance for Oversight of Regulated Products
- Program Development
- Program Priorities
- Enforcement Action where appropriate

What Does ORA Do?

- Consumer Safety Officers (i.e. Investigators, Compliance Officers)
 - Inspections/Investigations
 - Field Exams
 - Sample Collections
- Lab Analysts
 - Sample Analyses
- Enforcement Action where appropriate

FSMA & IFSS

Food Safety Modernization Act (FSMA) mandates building the National Integrated Food Safety System (IFSS)

- IFSS- Interagency Partnership
 - Partnership for Food Protection (PFP) promotes the development and advancement of the National IFSS.

FSMA & IFFS

- FY 17/18 – 130 State Contracts = 25.3M
- FY 17/18 – 290 Cooperative Agreements & Grants= 85.5M
 - Human Food Preventive Controls
 - Animal Food Preventive Controls
 - Produce Safety Rule

FSMA & IFFS

- Regular and frequent work planning sessions
 - Improve information sharing
 - Reduction in duplication of inspections
 - Cost savings
 - Efficient resource allocation (e.g., sample collection)
 - Compliance and enforcement (e.g. unapproved, filth-insanitary conditions)

FSMA & IFFS

- Joint Inspection Planning Check list tool
- Food Laboratory (e.g., validated methods, Chain of Custody)
- National Food Safety Data Exchange- to share data electronically
- Developing data definitions for the common data for ORA internal and States data sharing
- Produce Safety Farm Inventory Initiative

Moving Forward OCAR

- Observation
- Corrective
- Action
- Report

Thank You

- Questions?