



# War Over Words: Plant-Based, Cellular, and Novel "Meats" and "Dairy" Products

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# War Over Words: Plant-Based, Cellular, and Novel "Meats" and "Dairy" Products

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# Labeling Plant-Based and Cell-Cultured Dairy and Meat: Legal Uncertainty



# Plant-Based Meat

## Beyond Burger



## Impossible Burger



Medical  
Science  
.....

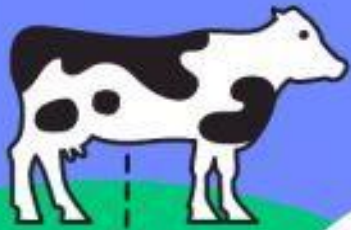


Food  
Science  
.....

# “Flora-Based” Milk

Old

New



# Animal-Free Dairy





Vegan gelatin  
by 2020?



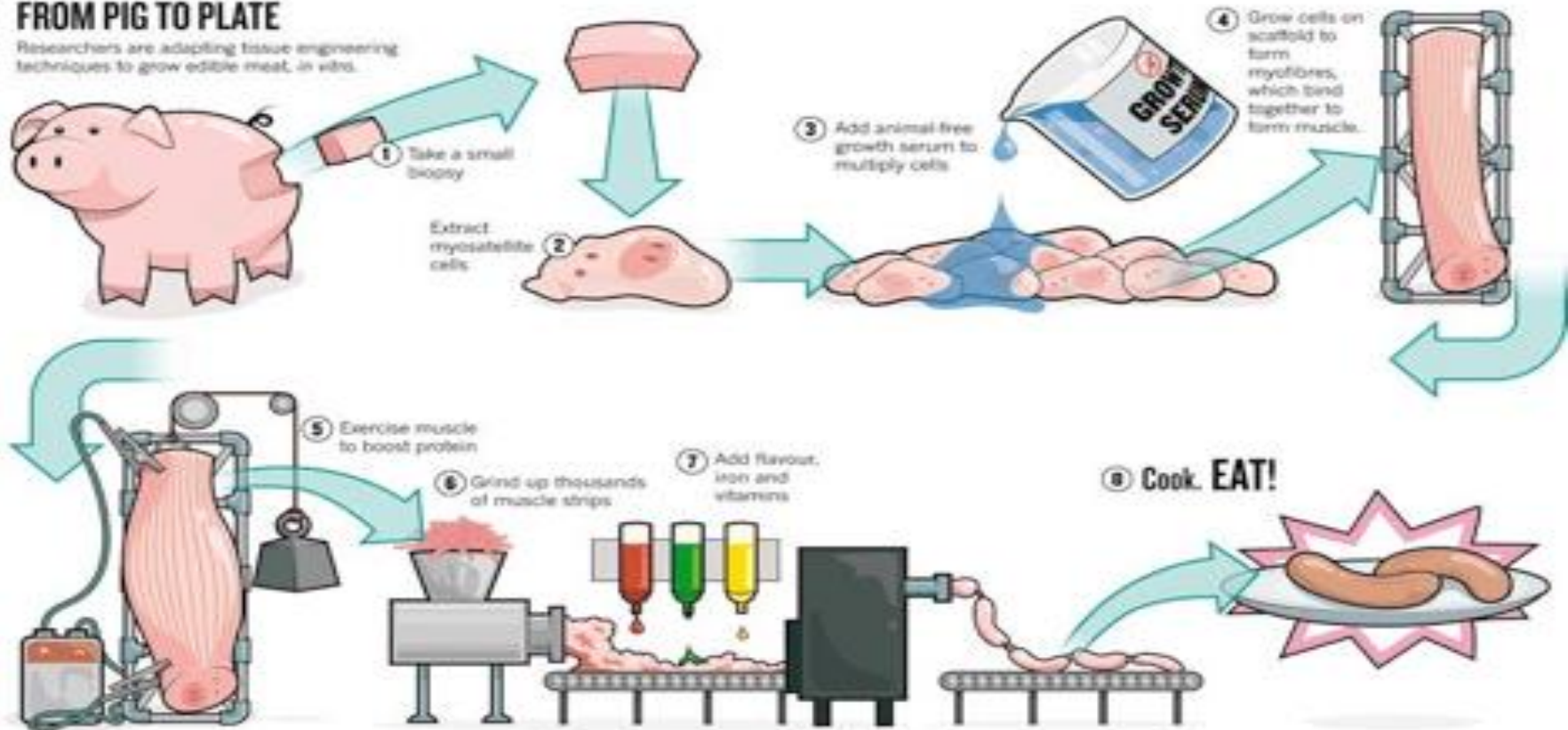
**Clara Foods**



# Cell-Cultured Meat

## FROM PIG TO PLATE

Researchers are adapting tissue engineering techniques to grow edible meat, *in vitro*.





BlueNalu

NEW AGE  
MEATS



SuperMeat



Integriculture

J  
U  
S  
T

Hs

Higher Steaks



mosameat

THE MEAT REVOLUTION



MEMPHIS  
MEATS



ALEPH FARMS

CLEAN MEAT GROWERS

# Standards of Identity

TITLE 21--FOOD AND DRUGS  
CHAPTER I--FOOD AND DRUG ADMINISTRATION  
DEPARTMENT OF HEALTH AND HUMAN SERVICES  
SUBCHAPTER B--FOOD FOR HUMAN CONSUMPTION  
PART 131 MILK AND CREAM

## Subpart A--General Provisions

§ 131.3 - Definitions.

§ 131.25 - Whipped cream products containing flavoring or sweetening.

## Subpart B--Requirements for Specific Standardized Milk and Cream

§ 131.110 - Milk.

§ 131.111 - Acidified milk.

§ 131.112 - Cultured milk.

§ 131.115 - Concentrated milk.

§ 131.120 - Sweetened condensed milk.

§ 131.125 - Nonfat dry milk.

§ 131.127 - Nonfat dry milk fortified with vitamins A and D.

§ 131.130 - Evaporated milk.

§ 131.147 - Dry whole milk.

§ 131.149 - Dry cream.

§ 131.150 - Heavy cream.

§ 131.155 - Light cream.

§ 131.157 - Light whipping cream.

§ 131.160 - Sour cream.

§ 131.162 - Acidified sour cream.

§ 131.170 - Eggnog.

§ 131.180 - Half-and-half.

§ 131.200 - Yogurt.

§ 131.203 - Lowfat yogurt.

§ 131.206 - Nonfat yogurt.



## “Hamburger” Standard of Identity

“Hamburger shall consist of chopped fresh and/or frozen beef with or without the addition of beef fat as such and/or seasoning, shall not contain more than 30 percent fat, and shall not contain added water, phosphates, binders, or extenders.”



WHOPPER Go on. Say it.

# U.S. Cattlemen's Association Petition to FSIS, 2018



- Limit the definition of “beef” to product from cattle born, raised, and harvested in the “traditional manner”
- Prohibit “beef” from coming from alternative sources – animal cells, plants, insects
- Limit definition of “meat” to tissue or flesh of animals that have been harvested in the “traditional manner”

# Enforcing Dairy SOI: *Dairy Pride Act*

- “Defending Against Imitations and Replacements of Yogurt, Milk, and Cheese To Promote Regular Intake of Dairy Everyday Act”
- “[P]rotect the integrity of dairy products by enforcing existing labeling requirements,” by preventing non-dairy products from being labeled with terms such as “milk,” “yogurt,” or “cheese.”
- Would amend Section 403 to emphasize that products marketed using terms for which a standard of identity exists, but that do not meet that standard, are “misbranded” and subject to FDA enforcement action.



# Milk.

**It doesn't have to come from a cow.**

VeganStreet.com

# SOYFOODS

ASSOCIATION OF AMERICA

## STANDARDS COMMITTEE

Peter Golbitz, Committee Chairperson

c/o Soyatech, Inc. • 318 Main Street • P.O. Box 84 • Bar Harbor, ME 04609 • USA  
Ph: 207.288.4969 • Fax: 207.288.5264 • E-mail: peter@soyatech.com

February 28, 1997

0581 97 FEB 28 AM 51

Dockets Management Branch  
U.S. Food and Drug Administration  
Department of Health and Human Services  
Room 1-23  
12420 Parklawn Drive  
Rockville, Maryland 20857

### CITIZEN PETITION

The undersigned submits this petition under sections 403(i)(1) and 701(a) of the Federal Food, Drug, and Cosmetic Act ("FDC Act"), 21 U.S.C. §§ 343(i)(1) and 371(a), and 21 C.F.R. § 10.30 and Part 102, to request the Commissioner of Food and Drugs to issue a "common or usual name regulation" in Part 102 of the U.S. Food and Drug Administration ("FDA") regulations to recognize the term "soymilk" as the established common or usual name to be used in labels and other labeling to identify a beverage of this nature (together with other refinements as described more fully below in this petition).

#### A. ACTION REQUESTED

The undersigned requests the Commissioner to issue a new regulation, to be included in Part 102 of the FDA's regulations, "Common or Usual Name for Nonstandardized Foods," Subpart B, "Requirements for Specific Nonstandardized Foods," to read as follows:

##### § 102. Soymilk

(a) The common or usual name of the liquid food that is obtained as a result of combining aqueous-extracted whole soybean solids and water, or, as a result of combining other edible-quality soy protein solids, soybean oil, and water, is "soymilk."

(b) Heat treatment is applied to inactivate trypsin inhibitors and to ensure safety by adequate pasteurization.

# Citizen Petition 1997

## Requests common or usual name regulation defining "soymilk"



[by electronic submission]  
Division of Dockets Management  
Food and Drug Administration  
Department of Health and Human Services  
5630 Fishers Lane, rm. 1061  
Rockville, MD 20852

#### CITIZEN PETITION

The Good Food Institute<sup>1</sup> (“GFI”) submits this petition under sections 403(i), 201(n), and 701(a) of the Federal Food, Drug, and Cosmetic Act (“FDCA” or “the Act”)<sup>2</sup> to request that the Commissioner of Food and Drugs issue regulations clarifying how foods may be named by reference to the names of other foods. Many products named in this fashion are already on the market, with many more likely to be developed in the future. The requested clarification would be consistent with current FDA regulations and policies, would reflect consumer understanding and the current realities of products in the marketplace, and would serve to foster continued innovation. Further, promulgating a general regulation regarding the nomenclature of these products will avert perceived regulatory uncertainty surrounding such product names, and will promote honesty and fair dealing in the interest of consumers.<sup>3</sup>

# GFI Citizens Petition, 2017

Requests FDA clarify that new foods may be named by reference to other “traditional” foods in a manner that makes clear to consumers their distinct origins or properties





# National Milk Producers Federation

## Citizens Petition, February 2019

1. Take enforcement action against misbranded non-dairy foods that substitute for and resemble reference standardized dairy food(s) but are nutritionally inferior to the reference food and include the name of the reference food in the statement of identity; and
2. Amend section 101.3(e) of FDA regulations to codify policies that permit use of standardized dairy terms for non-dairy substitutes that resemble and substitute for the same reference dairy food only under defined conditions.

# FDA Comment Period on Use of the Names of Dairy Foods in Labeling Plant-Based Products

- How do consumers use plant-based products and how do they understand terms such as, for example, “milk” or “yogurt” when included in the names of plant-based products?



**FEDERAL REGISTER**

The Daily Journal of the United States Government

# Consumer Attitudes About Plant-Based Dairy Labeling

October 2018 study conducted by the International Food Information Council (“IFIC”)

“When looking at front labels of cow’s milk and plant-based products, less than 1 in 10 believe that branded versions of soy milk, almond milk, cashew milk, and rice milk contain milk from cows.”

Research conducted by the Plant Based Foods Association found that 78% of cow’s-milk drinkers agree that “milk” is the most appropriate term for products such as soy milk and almond milk.



# Comments Re: Public Health & Consumer Confusion

## **Organic Valley:**

“Allowing plant-based products to use standardized dairy definitions creates a high level of confusion for consumers. The rational expectation among consumers is that products labeled as “milk” are comparable in nutrition. In fact, plant-based products have become popular over the past two decades in part because of suggested health benefits and nutrition-related label claims, including nutritional superiority to milk. Sample label claims include . . . . ‘excellent source of calcium and Vitamin D,’ . . . ‘free of saturated fat, cholesterol or added sugar,’ and ‘1/4 the calories of lowfat milk.’”

## **American Academy of Pediatrics:**

“Given the importance of dairy products in the diet of children and the confusion that parents exhibit with regards to the nutrients contained in plant-based alternative products, the AAP recommends that FDA reserve the label of ‘milk’ solely for traditional dairy products to ensure that children receive optimal nutrition.”



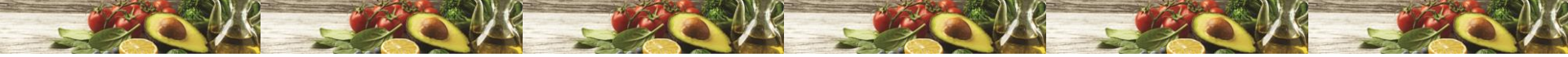
# Dairy Management Inc. and National Dairy Council 2018 Consumer Perceptions Survey

- The top reason consumers believe plant-based milks are labeled as “milk” is because the products are comparable on a nutrition front with more than half citing this as a reason.
- If plant-based “milks” were to be labeled as “drinks” or “beverages”, the majority of current plant-based milk buyers say they would be at least /more likely to purchase them.

# FDA Public Meeting on Horizontal Approaches to Food Standards of Identity Modernization

*September 27, 2019*





# **War Over Words: Plant-Based, Cellular and Novel “Meats” and “Dairy” Products**

Shelly Garg

Member & FDA Practice Group Leader

Sandler, Travis & Rosenberg PA

# Cell-Based Meat

- Questions in food technology: how we can address growing food population (9.7 billion people by 2050) and worsening climate crisis
  - Plant-based protein and Clean Meat!
- What is it?
  - Plant-based meat is meat made from plants
  - Clean meat – meat grown through cellular agriculture. No animal slaughter required.
- The problem: two main problems in agricultural technology are climate change and sustainability
  - UN scientists have written that animal agriculture contributes about 40 percent more to climate change than all of the planes, trucks, cars and other forms of transportation combined.
  - Eating chicken is worse for the climate than eating chickpeas



# FDA + USDA Agreement



USDA FSIS + DHHS/FDA announced a formal agreement to jointly oversee production of human food products derived from the cells of livestock and poultry on March 7, 2019

- Agreement discusses oversight roles and responsibilities for both agencies and how agencies will collaborate to regulate development and entry of products into commerce

# Joint Commitment

The agreement establishes both agencies shared commitment to:

- (1) cooperating to refining the details of the Parties' roles for comprehensive and coordinated oversight; and
- (2) a joint process by which the parties will identify any changes needed to statutory or regulatory authorities to effect the intended regulatory oversight.



# FDA

FDA responsible for implementing and enforcing FDCA, PHSa and FPLA.

- FDA broadly responsible for ensuring that food is not adulterated or misbranded
- HHS will inspect establishments that manufacture, process, pack or hold foods, with the exception of establishments regulated by USDA-FSIS.

# USDA

USDA-FSIS responsible for implementing and enforcing FMIA, PPIA, EPIA.

- FSIS places inspectors in meat and poultry slaughter and processing establishments and egg products processing plants.
- USDA-FSIS determines the equivalence of foreign inspection systems as a condition of eligibility to export meat, poultry and egg products to the US and reinspects 100 percent of imported meat, poultry and egg products.

# FDA Responsibilities under Agreement

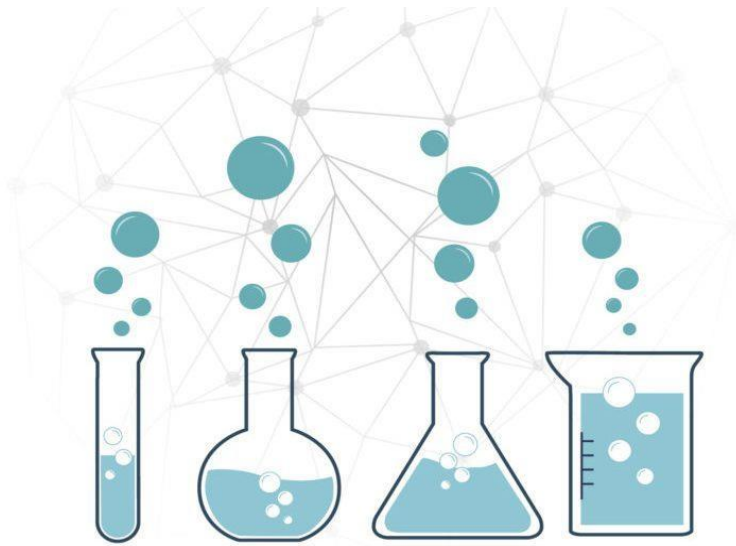


- Conduct premarket consultation processes to evaluate production materials/processes and manufacturing controls, to include oversight of tissue collection, cell lines and banks, all components and inputs.
  - Consult with USDA-FSIS, share results of premarket consultation processes with USDA FSIS, as authorized by law.
- Oversee initial cell collection and development and maintenance of qualified cell banks. Oversee proliferation and differentiation of cells through the time of harvest + at harvest, help coordinate transfer of regulatory oversight to USDA-FSIS
- Ensure covered entities comply with FDA requirements including facility registration, cGMPs and preventive controls regulation, requirements applicable to substances that become a component of food

# USDA Responsibilities under Agreement

- At harvest, help coordinate the transfer of regulatory oversight from FDA
- Require each establishment that harvests cells cultured from livestock or poultry subject to the FMIA or PPIA for purpose of producing human food required to bear USDA mark of inspection, processes those cells into such human food products, or packages and labels such products, to obtain a grant of inspection, as required by FSIS regulations.
- Conduct inspection in establishments where cells cultured from livestock and poultry subject to FMIA and PPIA are harvested, processed packaged or labeled.
- Require that labeling of human food products derived from cultured cells of livestock and poultry be preapproved and then verified through inspection, as required by FSIS regulations.

# Mutual Agreement



- Develop a more detailed joint framework or standard operating procedure for shared regulatory oversight RE harvest of biological material.
- Develop a joint process to identify any changes needed to statutory or regulatory authorities
- Collaborative working relationship at HQ and in the field
- Develop joint principles for product labeling and claims
- Cooperate in investigating food safety issues

# Moving Forward

- Agreement non-binding
- Can be changed as needed or based on personnel, resources and funding
- State “meat” labeling laws
- FDA Public Meeting on SOI – September 27, 2019







# **War Over Words: Plant-Based, Cellular and Novel “Meats” and “Dairy” Products**

Donnelly McDowell  
Kelley Drye & Warren LLP

# Implicated State Laws

- Little “FD&C Acts”
- State laws prohibiting unfair and deceptive acts and practices (“UDAP Laws”)
- State laws/legislation prohibiting use of meat and dairy terms for products without meat or dairy



# Little FD&C Acts & Food Standards

- Mirror provisions under the Federal Food, Drug & Cosmetic Act
  - “Any food is misbranded if it is offered for sale under the name of another food, or if it is an imitation of another food for which a definition and standard of identity has been established by regulation and its label does not bear, in type of uniform size and prominence the word ‘imitation,’ and immediately following, the name of the food imitated.” Cal. Health & Safety Code § 110685.

# State UDAP Laws

- A number of class actions have been filed challenging use of standardized terms for plant-based substitutes
- Claims have generally been unsuccessful but no consistent basis for courts' decisions:
  - Deference to FDA
  - Federal preemption
  - Implausibility of deception

# Do courts really understand FDA regulatory history?

- *Painter v. Blue Diamond Growers* (9th Cir. 2018):
  - “Notwithstanding any resemblance to dairy milk, almond milk is not a ‘substitute’ for dairy milk as contemplated by section 101.3(e)(1) because almond milk does not involve literally substituting inferior ingredients for those in dairy milk.”
  - “In addition, a reasonable jury could not conclude that almond milk is ‘nutritionally inferior’ to dairy milk within the meaning of 21 C.F.R. § 101.3(e)(4), as two distinct food products necessarily have different nutritional profiles.”

# Should UDAP decisions matter to FDA?

- Consumer confusion re product composition vs. nutritional profile
- Compare FDA mission to purpose of state UDAP laws



# State Laws Prohibiting Dairy Terms

- North Carolina passed a law requiring its Department of Agriculture and Consumer Services “to enforce FDA's standard of identity for milk as adopted in the North Carolina Administrative Code to prohibit the sale of plant-based products mislabeled as milk.”



1,538 views | Jun 18, 2018, 09:48am

# In North Carolina, Plant-based Milk Isn't Milk, But Only If Other Southern States Agree



**Legal Newsline** Former Contributor 

Policy

*We cover issues that affect businesses in state and federal courts*

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*Implementation of enforcement plan required when 11 states of listed nearby states implement similar law*



# Legislation Restricting Standardized Meat Terms Have Gained More Traction

- More than ten states have enacted laws aimed at restricting use of meat terms in substitute products that do not contain meat
- Many other states have proposed similar legislation

# Are Plant-Based Meats Covered?

- Compare:
  - Kentucky law: “A food shall be deemed to be misbranded. . . [i]f it purports to be or is represented as meat or a meat product and it contains cultured animal tissue produced from in vitro animal cell cultures outside of the organism from which it is derived.”
  - Mississippi law: “A plant-based or insect-based food product shall not be labeled as meat or a meat food product.”

# Court challenges ensue..





# **War Over Words: Novel Foods and Commercial Free Speech**

Nigel Barrella  
Barrella Law PLLC



# First Amendment protects "commercial speech" (ads, labels, solicitations, etc.)

*Va. Bd. of Pharmacy*, 425 U.S. 748 (1976)

- S.Ct. protects commercial speech for "first time"
- Can't ban pharmacists from advertising drug prices

Earlier? *Anderson & Co. v. Wash. Dept. Ag.*, 402 F.Supp. 1253 (1975)

- Invalidating state law banning "dairy terms" from oleomargarine labels or advertising (because 1A)



# Main test: *Central Hudson*\* Four-Step

If commercial speech is

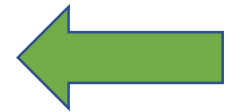
1. Lawful and not inherently misleading

**Then government can regulate only if**

2. Regulation serves substantial state interest

3. Regulation directly advances that interest

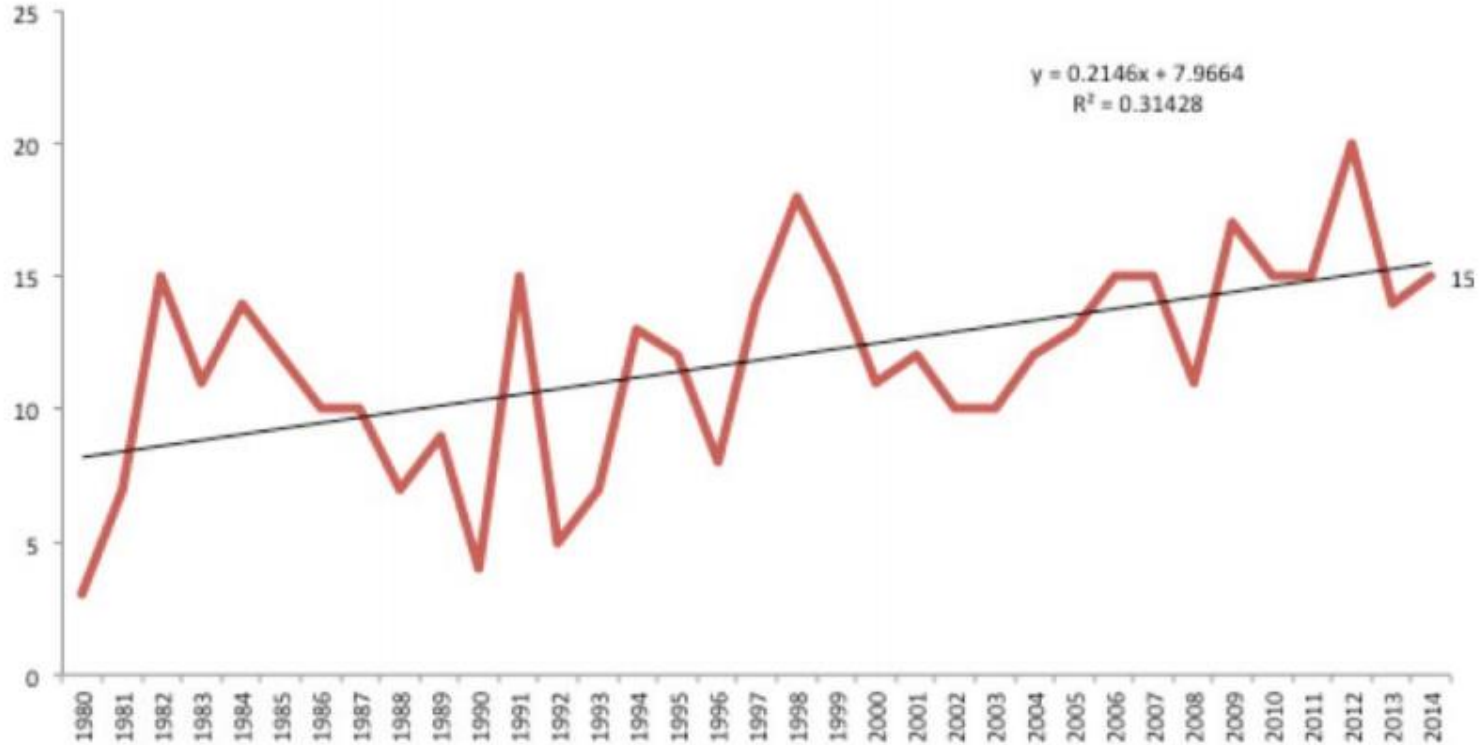
4. Regulation is no more extensive than  
necessary to serve that interest



(alternatives?)

\*447 U.S. 557 (1980)

## Appeals Court Citations to Central Hudson



\*Source: John C. Coates IV, *Corporate Speech and the First Amendment* 30 Const. Commentary 223 (2015).

## Beyond *Central Hudson*?

*Sorrell v. IMS Health*\* (2011)

- "Heightened scrutiny" for speaker-based or content-based restrictions on speech
- Prohibiting sale of prescription data to marketers ==> speaker- and content-based

Framework already having impacts:

*Caronia, Amarin, R.J. Reynolds, NIFLA, ABA v. SF*  
(some discussed in earlier panels)

\*564 U.S. 552



## Ways to Invoke First Amendment

- **Direct Challenge to Law/Regulation (facial/overbreadth or as-applied)**
- **Aid for Statutory Interpretation (constitutional avoidance canon)**
- **Statutory Interpretation Phase of *Chevron* (challenging regulation/policy)**

**Note: "Chilling effect" sometimes justifies earlier, vagueness-based challenges**

## Direct Challenge: Dairy

*Ocheesee Creamery v. Putnam*\* (2017)

- Fla. law: skim milk w/o vitamin A = "imitation milk product"
- 11th Cir: invalid under 1A, could do vit. A disclosure instead

Pending challenge to FDA equivalent

(18-cv-738 M.D. Penn., mot. to dismiss denied 3/31/19)



\*851 F.3d 1228

# Direct Challenges: State Laws

## *Turtle Island Foods v. Missouri*

- Pending challenge to criminal prohibition on "misrepresenting product as meat" if not derived from "harvested livestock"
- Prevents plant-based products from using meat terms, "content-based" restriction
- Also includes vagueness challenge – not clear what law actually prohibits?



# Direct Challenges: State Laws

## *Upton's Naturals v. Bryant*

- Pending challenge to Miss. law prohibiting cell-based, plant-based, and insect-based foods labeled as "meat" or "meat food product"; restricts speech in content- and speaker-based manner
- Possible settlement: proposed regulation exempts products with clear qualifying language like "plant-based," "meatless," "vegan," etc.
- Does not address cell- or insect-based...



# Direct Challenges: State Laws

## *Turtle Island Foods v. Soman*

- Pending challenge to Arkansas law
- Prohibits selling "under name of another food"
- Prohibits use of terms "similar to a term that has been used historically" re: another food
- ...and "meat" must be "harvested livestock"



(law was also meant to address "cauliflower rice")

- Complaint & motion for injunction follows *Central Hudson*, notes misleading labels already prohibited generally

# What about FDA?

## Statement from FDA Commissioner Scott Gottlieb, M.D., on the process FDA is undertaking for reviewing and modernizing the agency's standards of identity for dairy products

We also are actively looking at how we have been enforcing the FD&C Act with respect to food names and our own standard of identity for milk and what it means when milk is qualified with words like almond or soy. We recognize that, as a regulatory agency, it's not appropriate to unilaterally change our regulatory approach if we have a history of non-enforcement. We also need to closely consider the potential First Amendment issues related to the different uses of these terms.

# FDA: Relevant Law

- **FDCA § 403(i)** – (nonstandardized) food must bear the "common or usual name of the food, if any there be..."
- **FDCA § 401** – when promulgating standard for a food, Secretary must do so "under its common or usual name so far as practicable..."
- **FDCA § 403(a)** – food label cannot be "false or misleading in any particular"
- (?) **FDCA § 403(g)** – must follow standard if it "purports to be" a standardized food
- (??) **FDCA § 403(c)** – "imitation" foods must be labeled as "imitation \_\_\_\_\_"

# First Amendment Arguments to FDA

## GFI Citizen Petition (FDA-2017-P-1298)

- Argues ban on terms like "soy milk" or "almond milk" would not advance any interest, more extensive than necessary
- Ban on terms inconsistent with history, practice
- Statutory/*Chevron* analysis of FD&C Act in light of 1A
- Argues ban would be content-based and speaker-based restriction; powerful interests want to use gov. against "disfavored" speakers



# First Amendment Arguments to FDA

## Docket on Dairy Terms (FDA-2018-N-3522)

- 14,000+ comments, 500+ mention the First Amendment
- Including comments from:
  - Plant Based Foods Association
  - American Beverage Association
  - Soyfoods Association of North America
  - Upfield ("I Can't Believe It's Not Butter")
  - FreedomWorks Foundation
  - Institute for Justice
  - Good Food Institute

# First Amendment Arguments to FDA

## NMPF Citizen Petition (FDA-2019-P-0777)

- Proposes regulation of non-dairy alternative names through "imitation" provision of FD&C Act
- Argues names like "soy milk" and "almond milk" are false and misleading
- Argues proposed regulation would amount to mere "disclosure" requirement (lesser constitutional scrutiny under *Zauderer*), and is "factual and uncontroversial"

# Indirect/Defensive 1A: Stat. Interpretation

GFI amicus brief

- Almond milk not an "imitation milk" under FD&C Act
- Would raise serious constitutional Q's (Court affirmed dismissal of class action without invoking constitutional considerations)

No. 17-55901

IN THE  
UNITED STATES COURT OF APPEALS  
FOR THE NINTH CIRCUIT

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CYNTHIA CARDARELLI PAINTER, individually and on behalf of other  
members of the general public similarly situated,  
Plaintiff-Appellant,

v.

BLUE DIAMOND GROWERS,  
Defendant-Appellee.

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On Appeal from the United States District Court  
for the Central District of California  
No. 2:17-cv-02235-SVW-AJW  
Hon. Steven V. Wilson

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BRIEF OF THE GOOD FOOD INSTITUTE  
AS AMICUS CURIAE IN SUPPORT OF  
DEFENDANT-APPELLEE SEEKING AFFIRMANCE

# Closing Thoughts

- Regulation urged by conventional meat and dairy producers – could be viewed as "rent-seeking" (compare to concerns raised in *Sorrell*)
- WATCH the state challenges re: PB/cell-based
- WATCH doctrinal evolution, esp. Supreme Court
- All stakeholders should FORMULATE a position, and be prepared to invoke it!
- May have impact in our "War Over Words"