



Enforcement,
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Food: Consumer Class – Actions and FDA Regulated Products

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Legal Standards

- Plaintiffs need not demonstrate the statement is actually false; “likely to mislead” is usually enough
- Most state consumer protection laws require causation; not all require reliance
- Challenged statements are judged under a “reasonable consumer” standard
- Economic injury is sufficient

Is That Slack Fill In Your Box?

Or Are You Unhappy to See Me?
(asks the plaintiffs' counsel)

What Is “Slack Fill?”

- **21 C.F.R. § 100.100(a)**: “Slack fill is the difference between the actual capacity of a container and the volume of product contained therein.”
- A container is “**misleading** if it contains nonfunctional slack fill.”
- Slack fill is “**nonfunctional**” unless the space is left (1) to protect package contents, (2) because the packaging equipment requires it; (3) because of settling, (4) because the package itself performs a disclosed function or is part of the product’s value, or (5) otherwise unavoidable for some valid reason.
- Certainly applies to **food**, should **not** apply to **drugs** or **cosmetics**.
 - See *Bimont v. Unilever* (S.D.N.Y. Sept. 9, 2015)

Slack Fill Consumer Fraud Claims

- *Ebner v. Fresh* (9th Cir. Sept. 27, 2016): Lip balm, where a screw mechanism keeps the last 25% from being usable.
 - Court: Unreasonable for consumers not to know how lip balm containers work or for them not to expect that some portion would be unusable as a result.
 - Packaging “is not false and deceptive merely because the remaining product quantity may be ‘unreasonably misunderstood by an insignificant and unrepresentative segment of the class of persons.’”
 - Bottom line: Regardless of whether a container includes “slack fill,” a consumer’s claim to have been “misled” still must be “reasonable” in order to survive dismissal

Slack Fill Consumer Fraud Claims

- *Izquierdo v. Mondelez Int'l, Inc.* (S.D.N.Y. Oct. 26, 2016)
 - “Sour Patch Kids” candy boxes, which allegedly contained slack fill.
 - Refused to hold that “a deceptively packaged product is immune from suit so long as the package accurately lists the product’s net weight and quantity.”
 - Also refused to hold, as a matter of law, that a “reasonable consumer” must “shake, squeeze, or manipulate” the box to determine if it is full.
 - But, nevertheless dismissed claims for lack of injury because the plaintiff received “the full value of her purchase.”
- Costco Premium Chunk Chicken Breast, labeled as 12.5 oz., but allegedly containing only 7 oz. of chicken and 5.5 oz. of water.

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 - Bottom line: Possible open door to claim that consumers bought Brand A vs. Brand B, not realizing that Brand A had slack fill.
 - Note: Same judge dismissed “shrimp tray” case vs. Costco, because a “reasonable consumer is one who reads the label.”

Slack Fill Consumer Fraud Claims

- *Fermin v. Pfizer* (E.D.N.Y. Oct. 18, 2016)
 - Bottles of Advil with clearly labeled pill counts but significant slack fill.
 - “This Court finds, as a matter of law, that it is not probable or even possible that Pfizer’s packaging could have mislead a reasonable consumer. The suggestion that [consumer fraud] laws should cover their failure to read an unambiguous tablet count does not pass the proverbial laugh test.”
- *Galanis v. Starbucks* (N.D. Ill. Oct. 14, 2016)
 - Claim that Starbucks misleads because “much of the volume” of cold drinks “is taken up by ice.”
 - “No reasonable consumer ordering an iced tea expects to receive a cup of tea with a side of ice.”

What's Still Out There on Slack Fill?

- Can of Chunk Chicken Breast, labeled as 12.5 oz., but allegedly containing only 7 oz. of chicken and 5.5 oz. of water.
 - Is that water content misleading?
 - Does it matter if a competing product has a lower water ratio?
- Two products sold next to each other by the same brand in the same size container, one containing X oz. of product and the other containing less.
 - Is the smaller package inherently misleading, even if it states the true weight?

Bet You Weren't Expecting an Herbicide Case

Glyphosate: The next wave of
consumer fraud claims

What Is Glyphosate?

- **Glyphosate** is the active ingredient in Monsanto's "Roundup," the world's most popular herbicide.
- The EPA has approved Roundup and its labeling, but in 2015, the International Agency for Research on Cancer classified glyphosate as "**probably carcinogenic to humans.**"
- Plaintiffs have begun to attack foods labeled "all natural" if they contain glyphosate residues.

Glyphosate Consumer Fraud Claims

- Makers of “all natural” honey: Claim is that bees pick up glyphosate in flower nectar and transport it to their hives, inadvertently causing trace amounts to appear in honey. Can the honey be sold as “all natural” if it contains glyphosate, even if the manufacturer didn’t add it?
- Makers of “100% Natural Oats” granola products allegedly containing glyphosate because oat crops were sprayed with it.
- Makers of “all natural” and “100% whole grain” dry pastas allegedly containing glyphosate because the wheat was sprayed with it.

Born in the U.S.A.

Or, at least made here

When Is a Good “Made in the U.S.A.”?

- **FTC 1997 guidance:** “Unqualified U.S. origin claims should be substantiated by evidence that the product is all or virtually all made in the United States.”
- “All significant parts and processing that go into the product are of U.S. origin”; may contain “only a *de minimis*, or negligible, amount of foreign content,” and “final processing must take place in the U.S.”
- FTC also will look to “how far removed from the finished product the foreign content is,” and charge a manufacturer with knowing its suppliers’ sources.

Country of Origin Consumer Fraud Claims

- Consumers cannot enforce FTC guidance standing alone; they need to show some kind of damage from a false statement about country of origin.
- Claim is that “Made in X” commands a premium.
 - “Made in the USA” may connote greater safety or cause consumers to purchase in order to support domestic workers or industries.
 - “Made in Russia,” in connection with vodka, or “Made in Italy,” in connection with olive oil, may connote a desirable quality
- As in other cases alleging misleading statements, key question is “could I have purchased an equivalent good, sold without the false representation, for less?”

Natural Claims

(the perfect storm)

Regulatory Guidance

- FDA informal policy:
 - “[T]hat nothing artificial or synthetic. . . has been included in, or has been added to, a food that would not normally be expected to be in the food”
- Multiple Citizens Petitions filed, asking FDA to define “natural” or ban it from labeling
- FDA solicited public comments on the term “natural” in November 2015; comments closed May 10, 2016

The Current Landscape

- No final rule yet
- Consumer confusion
- Plaintiffs' attorneys fill the gap, resulting in hundreds of consumer class actions filed in federal and state courts

“Natural” Litigation

Attacks on means of production or ingredients; allegations of implied health benefit

- Snapple juices (high-fructose corn syrup)
- Tropicana orange juice (scientifically engineered)
- Ben & Jerry’s ice cream (alkalized cocoa)
- Kraft cheese (artificial food coloring)
- Hormel meats (GMO ingredients, including cultured celery powder, baking powder and maltodextrin)

Mixed Results

- Most survive a motion to dismiss
- Settlements
- Many stayed under primary jurisdiction doctrine

Brazil v. Dole Packaged Foods

- Putative class action filed in N.D. Cal (*i.e.*, Food Court)
- Alleging violations of CA consumer protection laws
- Product contained synthetic citric and ascorbic acid
- District court granted summary judgment and motion for decertification (damages class)
- Ninth Circuit reversed in part (non-precedential)
 - advertising could mislead a reasonable consumer (triable issue)
 - decertification ruling upheld because plaintiff could not calculate restitution with common proof

Other “natural” cases to watch

- **Briseno v. ConAgra (C.D. Cal)**
 - Claims that Wesson oil contains GMO ingredients
 - District court granted certification of eleven statewide classes
 - Case on appeal to the Ninth Circuit; oral argument held in September
 - Ascertainability and hybrid damages model are key issues
- **Jones v. ConAgra (N.D. Cal)**
 - Attacking “natural” labeling for several ConAgra products
 - District court denied certification, finding class members could not be identified through objective evidence (e.g., receipts)
 - Case on appeal to the Ninth Circuit; stayed pending Supreme Court’s decision in *Microsoft Corp. v. Baker*

Healthy Claims

(the next natural?)

Regulatory Guidance

- FDA regulations govern “heathy” as an implied nutrient content claim
 - used to suggest that a food may help maintain healthy dietary practices and
 - made in connection with an explicit claim (e.g. “healthy, contains 3 grams of fat”)
- Regulation requires that foods be low in fat, saturated fat, cholesterol and sodium, and that they contain at least 10% percent of one or more qualifying nutrients

Regulatory Guidance

- Citizens Petition filed by KIND LLC, requesting FDA revisit definition of “healthy”
- FDA solicited public comments in September 2016; comments close on January 26, 2017

2016 Guidance Document

- FDA issued non-binding guidance document in September 2016, pending new regulations on “healthy”
- Enforcement discretion towards products with disqualifying amounts of total fat, if the majority of total fat is unsaturated
- Enforcement discretion towards products with at least 10% of the DV of non-qualifying nutrients vitamin D or potassium

Current Landscape

- Unclear when or whether FDA will re-define “healthy”
- Consumer class actions filed in federal and state courts (not as numerous as “natural” claims)
- Many may be stayed under primary jurisdiction doctrine

KIND Bar Litigation

- MDL comprising several putative national and statewide class actions
- Triggered by Warning Letter concerning use of phrase “healthy and tasty” in product labeling
- Alleged that product is not “healthy” under FDA regulations because bars are high in fat
- Plaintiffs voluntarily dismissed “healthy” claims after FDA changed course, and allowed KIND to use “healthy and tasty” as a statement of corporate philosophy

Coconut Oil Litigation

- Handful of putative class actions in CA state and federal courts
- Triggered by FDA Warning Letter
- Plaintiffs allege coconut oil is marketed as a healthy alternative, despite having high levels of total fat and saturated fat

Coconut Oil Litigation

- California consumer protection claims survive motions to dismiss in two cases
 - *Hunter v. Nature's Way Prods.* (S.D. Cal. Aug. 12, 2016)
 - *Jones v. Nutiva* (N.D. Cal. Sept. 22, 2016)
- One case settled
 - *Cumming v. Betterbody Foods & Nutrition* (San Diego Cnty. Nov. 18, 2016) (Order scheduling approval hearing for \$1 million settlement)
- More cases on the way?
 - *Tracton v. Viva Labs* (S.D. Cal. Nov. 10, 2016) (recently-filed complaint by *Jones* counsel)

Evaporated Cane Juice Claims

(sounds like sugar to me...)

What is Evaporated Cane Juice?

- A sweetener derived directly from milled sugar cane using a single-crystallization process
- Does not go through the same process as refined sugar, which is made by heating the liquid into concentrated syrup, then refining it through repeated cycles of filtration and crystallization

2009 FDA Draft Guidance

- The term “ECJ” is misleading because the fluid used to make the sweetener does not meet the regulatory definition of “juice”
- FDA recommends the phrase “dried cane syrup” because cane syrup has a “standard of identity defined by regulation”

The Aftermath

- Class action litigation ensues, challenging use of ECJ on labels
 - consumers allege “ECJ” implies it is healthier than other sweeteners or hides the presence of “added sugars”
- FDA reopens comment period on its draft guidance (March 2014)
- Most courts stay or dismiss cases under primary jurisdiction doctrine

2016 FDA Final Guidance

- FDA withdraws “dried cane syrup” guidance and instead recommends the term “sugar”
- The term “ECJ” is still considered false and misleading

Current Landscape

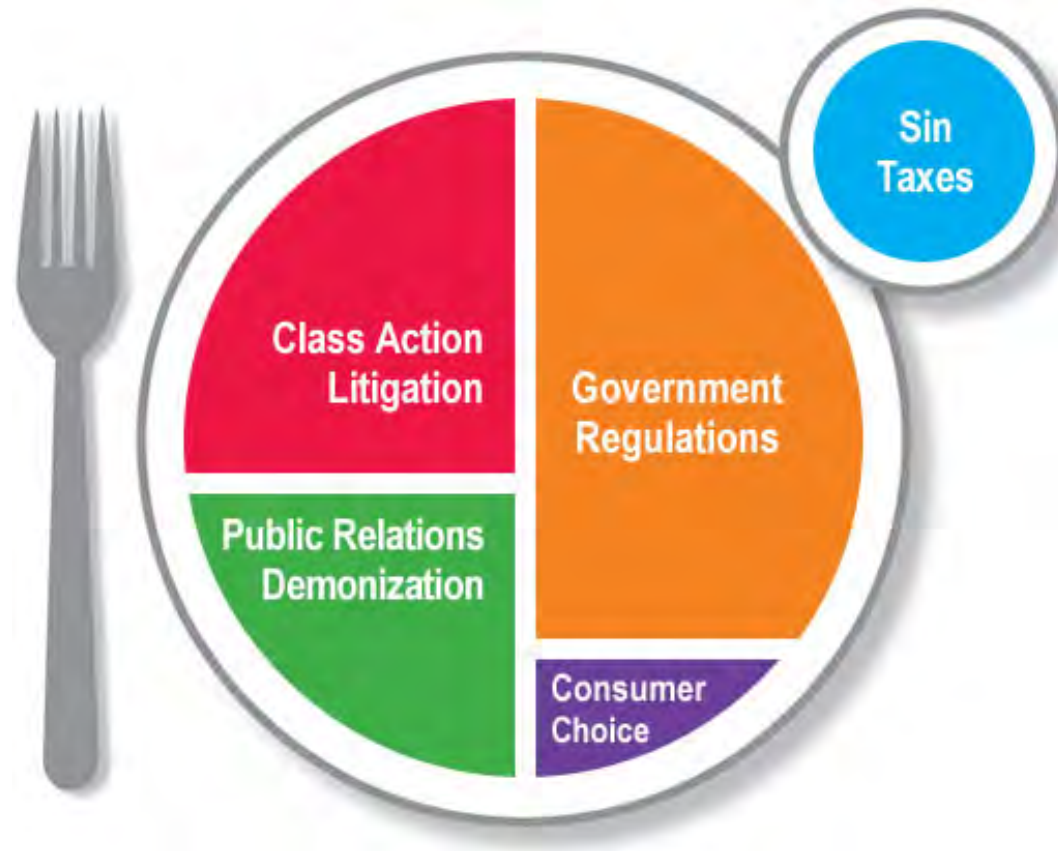
- Prior stays lifted
 - Swearingen v. Late July Snacks LLC (N.D. Cal.) (crackers, chips)
 - Swearingen v. Santa Cruz Natural Inc. (N.D. Cal.) (soda)
 - Reese v. Odwalla (N.D. Cal.) (juice)
- More cases have been filed

Swearingen v. Santa Cruz Natural Inc.

- Putative class action challenging use of ECJ on defendant's soda labels
- Claims under California consumer protection statutes, common law
- Plaintiffs allege they did not know ECJ was sugar and ECJ implies that product is healthier than it is
- Court denied in part motion to dismiss
 - rejects challenges to Article III standing and preemption arguments
 - rejects defendants' argument that a reasonable consumer is not likely to be deceived
 - dismisses some common law claims, but statutory claims remain

Better Nutrition Through Activism?

www.EatingAwayOurFreedom.org (a WLF Project)



“Added-Sugar” & Supply-Chain Suits

- Three-in-one opportunities (demonize + litigate + regulate)
- Seek business-conduct changes beyond what law/rules require
- Inspired in part by government action
- Ride wave of public attention/media scrutiny

“Added-Sugar” Class Actions



List of “Added-Sugar” Actions

- ***Hadley v. Kellogg*** (N.D. Cal., Aug. 29, 2016)
- ***Krommenhock v. Post Foods*** (N.D. Cal., Aug. 29, 2016)
- ***Truxel v. General Mills*** (N.D. Cal., Aug. 29, 2016)
- ***Amaya v. Dole Packaged Foods*** (N.D. Cal., Oct. 18, 2016)
- ***Lipkind v. Pepsico*** (E.D.N.Y., Oct. 4, 2016)

Class Actions in “Food Court”

- All filed by same firms; Hadley a class rep. in 3 of 4
- Four complaints, 568 pages (*Dole* slimmest at 56)
- Presence of “high” sugar content renders on-label health-related claims and verifiably truthful statements false or misleading
- Lengthy, identical indictments of sugar in each complaint
- Economic and increased risk of disease injury claims
- Injunctions, corrective ads, financial damages sought
- Claims under Calif. FRA, CLRA, and UCL

Class Actions in “Food Court” (cont.)

- Defendants’ motions to dismiss pending in 3 filed 8/29
- Preemption defense: Plaintiff can’t impose different “added sugar” disclosures or force labeling prior to June 2018 (new food label)
- No reasonable consumer would be misled
- Primary jurisdiction defense where “healthy” alleged to be misleading

Lipkind v. Pepsico

- Center for Science in the Public Interest-directed suit
- “No Added Sugar” front-of-label statement without qualifier preys on consumer confusion over sugar, implies “low in sugar”
- Product name, images, mislead consumers to think predominant ingredients are “super” foods
- “All sugars come from the fruit and/or vegetables, not a low calorie food” label statement too small and ambiguous in context
- Reliance & economic injury; NY and CA consumer-protection claims

Supply-Chain Class Actions



List of Supply-Chain Class Actions

- ***Sud v. Costco Wholesale***, No. 15-cv-03783 (N.D. Cal.), dismissed Jan. 15, 2016, consideration of amended complaint ongoing
- ***Barber v. Nestlé USA***, 154 F. Supp. 3d 954 (C.D. Cal. 2015), dismissed
- ***Hughes v. Big Heart Pet Brands***, No. 15-cv-08007 (C.D. Cal.), dismissed Jan. 15, 2016, 9th Cir. appeal, 16-55212
- ***DeRosa v. Tri-Union Seafoods***, No. 15-cv-07540 (C.D. Cal.), dismissed Jan. 15, 2016, 9th Cir. appeal, 16-55211
- ***Wirth v. Mars Inc.***, 2016 WL 471234 (C.D. Cal., Mar. 5, 2016), dismissed, 9th Cir. appeal, 16-55280
- ***Hodsdon v. Mars Inc.***, 162 F. Supp. 3d 1016 (N.D. Cal. 2016), 9th Cir. appeal, 16-15444
- ***Dana v. Hershey Co.***, 2016 WL 1213915 (N.D. Cal., Mar. 29, 2016), 9th Cir. appeal, 16-15789
- ***McCoy v. Nestlé USA***, 173 F.Supp.3d 954 (N.D. Cal., Mar. 29, 2016), 9th Cir. appeal, 16-15794

Nature of Supply-Chain Claims

- All allege failure to disclose likelihood of child or forced labor occurred in supply chain for product or ingredient violates FAL, CLRA, and UCL
- Four (*Sud, Barber, Hughes, DeRosa*) involve forced labor on fishing boats in Southeast Asia; four (*Wirth, Hodsdon, Dana, McCoy*) involve child labor in Ivory Coast cocoa fields
- All arose from media coverage, documentaries, activist campaigns
- Part of a larger corporate-disclosure movement—“significant but not essential” and “a nice gesture to bring awareness to the movement” according to activist quoted in *Corporate Counsel*

Status of Supply-Chain Actions

- All eight dismissed at trial court, six on appeal to 9th Circuit
- *Sud* dismissed for lack of standing, plaintiff amended complaint
- Courts in *McCoy*, *Wirth*, *Dana*, and *Hodsdon* found not “unfair” or “fraudulent” under UCL, no misrepresentation under FAL, and no duty to disclose under CLRA
- Courts in *Barber*, *Hughes*, and *DeRosa* held suits barred under “safe harbor” doctrine
 - Through State Supply Chains Act, legislature “delineated specific information that companies are required to disclose to consumers to aid their purchase”
 - Companies with \$100M+ in worldwide sales must disclose online whether they take steps to eradicate human trafficking and forced labor from supply chain

Debate over Safe Harbor

- Judges in *McCoy*, *Dana*, and *Hodsdon*, in dicta, questioned whether Supply Chains Act creates a broad safe harbor from state consumer-protection suits
- State attorney general filed *amicus* brief in *Hodsdon* appeal on September 26: Supply Chains Act does not provide safe harbor from point-of-sale omissions claims about use of slavery
- Notably, Supply Chains Act does not allow private enforcement
- Will private suits inspire California state AG to file actions under Supply Chains Act?

Defense Strategies

- Primary jurisdiction doctrine
- “Reasonable consumer” test
- Preemption
- Article III standing
- Ascertainability of the class
- Damage models applied on a class-wide basis