

Class Actions: The Next Phase

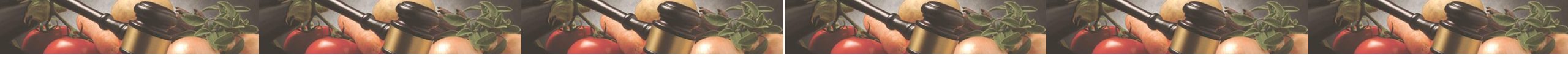
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Class Actions: The Next Phase

Public benefit or scourge?

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Private Enforcement of FDCA?

- “The FDCA statutory regime is designed primarily to protect the health and safety of the public at large.” *Pom Wonderful v. Coca Cola* (U.S. 2014)
- Limited remedies which focus on compliance; enforcement entrusted to FDA. 21 U.S.C. §337
- Benefits of Gvt. Enforcement: FDA subject matter expertise, enforcement discretion, even-handed application, cooperative approach toward industry.

Go forth and multiply

- CFSAN issued 305 warning letters in the last five years.
- Class actions lawsuits in that same time? 500-1000?
- CLRA letters/pre-litigation shake downs? Innumerable!

The Enforcers?

- NGOs: <https://cspinet.org/protecting-our-health/courts> - use courts to advance policy
- Everyone else:
<https://topclassactions.com/category/lawsuit-settlements/investigations/>
- Subject Matter Expertise: Little
- Objective: \$\$\$
- Enforcement discretion: no claim is too lame

Enforcement Tools

- B.&P.C. §17200: “Unfair competition shall mean and include any unlawful ...business act or practice.”
- Other states permit consumers to coopt statutory/regulatory violations into CFA laws either explicitly, or because such conduct is deceptive, unfair or unconscionable.

Common FDCA Hooks

- 21 U.S.C. §343(a) (“misbranded” = “labeling is false or misleading in any particular.”)
- 21 U.S.C. § 343(d) – prohibiting misleading containers.
- 21 U.S.C §355(a) - prohibiting unauthorized new drugs.

Plaintiff's formulae

- 1) Stat./Reg. violation + CFA Claim =
Liability
- 2) Price paid for "illegal product" = Damage
- 3) Damage x number of purchases = \$\$\$

Some of Plaintiffs' Favorite Cases

- *Franz v. Beiersdorf*, 745 F. App'x 47(9th Cir. 2018) (plaintiff had standing to bring UCL claim based on allegations she purchased an unapproved drug product that should not have been on the market)
- *Sandoval v PharmaCare US*, 730 F. App'x 417(9th Cir. 2018) (reviving UCL claim based on defendant's alleged failure to obtain FDA approval to market product as aphrodisiac)
- *Bruton v Gerber*, 703 Fed. Appx. 468 (9th Cir. 2017) (the reasonable consumer test is a requirement under the UCL's unlawful prong only when it is an element of the predicate violation)
- *Brazil v. Dole*, 660 F. App'x 531 (9th Cir. 2016)(FDA warning letters and non-binding policy were sufficient to create an issue of fact as to whether defendant's label was misleading to a reasonable consumer)

Liability: Proof of Actual Deception

Some violations require proof of deception – Ex. §343(a) (Misbranded label is false or misleading in any particular.)

- *Pratt v. Whole Foods*, No. 2014 WL 1324288, at *8 (N.D. Cal. Mar. 31, 2014) (under the “unlawful” prong of the UCL, a plaintiff must plead reliance when claims are premised on allegedly deceptive advertising)
- *Figy v. Amy's Kitchen*, No. CV 13-03816 SI, 2013 WL 6169503, at *3 (N.D. Cal. Nov. 25, 2013) (“[B]ecause the statutes plaintiff relies on prohibit specific types of misrepresentations on food labels—the listing of an ingredient by a name other than its common or usual name—the actual reliance requirement applies to plaintiff's claim even though it is brought under the unlawful prong of the UCL.”)

Remedy: Proof of loss and equitable right of restitution

Regardless of violation, did product have value? Plaintiff still must prove entitlement to restitution. Court can consider many factors...

- Equitable defenses: unclean hands, setoff, waiver/estoppel
 - *Cortez v. Purolator Air Filtration Products Co.*, 23 Cal.4th 163 (2000) (equitable considerations “may guide the court’s discretion” in fashioning a UCL remedy).
 - *Ticconi v. Blue Shield of California Life & Health Ins. Co.*, 160 Cal. App. 4th 528 (2008) (court has discretion to consider equitable defenses in creating the remedies authorized by the UCL, but not to defeat a UCL claim or prevent class certification)

Remedy: Injunctive relief?

- In class action context, consider whether Plaintiff has standing to enjoin conduct, and whether injunction serves interests of all class members?
- Or are plaintiffs merely trying to do FDA's job?

Constitutional Limits on FDA Authority

- Does agency have authority for the regulation or informal interpretation (i.e., warning letter, guidance document, etc.) underlying the class action?
- Does the defendant have a first amendment interest in truthful, non-deceptive advertising?



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Navigating the Litigation Landscape

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The Litigation Landscape

- Continued upward trend for food and beverage class actions
- California remains the most active jurisdiction, with increased filings in New York
- Majority of cases target false labeling, slack fill, “natural” and health maintenance claims

Defense Tactics

- Attacking pleading deficiencies
- Failure to State a Claim pursuant to FRCP Rules 8, 12(b)(6), and 9
- Primary jurisdiction (FDA and FTC)
- Federal Preemption

Case Law Developments

- Motion to Dismiss in Class Action Cases
 - Personal Jurisdiction
 - Standing
 - Failure to State a Claim

Bristol-Myers Squibb Co. v. Superior Court of Cal., 137 S.Ct. 1773 (2017)

- Limitations on Nationwide Class Actions on Personal Jurisdiction Grounds?



-More than 600 Plaintiffs, California and non-California residents, brought mass tort action in California.

-BMS: headquartered in New York, incorporated in Delaware, and maintained substantial operations in New York and New Jersey.

Bristol-Myers Squibb

- Bristol-Myers had significant contacts with California, which the California Supreme Court found sufficient for jurisdiction.
- On appeal, the Supreme Court held that the mere fact that some plaintiffs were prescribed, obtained, and ingested Plavix in California was insufficient grounds for California to assert specific jurisdiction over the nonresidents' claims.
- In the absence of “a connection between the forum and the specific claims at issue”, California could not exert personal jurisdiction over Bristol-Myers.

Bristol-Myers Squibb

- Implication: companies can only be sued for a nationwide class action in their home forum?

Bristol-Myers Squibb

- Number of district courts have extend *Bristol-Myers* to class action context.
- So far, less successful in food and beverage cases, likely due to frequent CA form.



Injunctive Relief For False Labeling Claims

- A plaintiff seeking injunctive relief must demonstrate a "real or immediate threat that they will be wronged again—a likelihood of substantial and immediate irreparable injury."

Injunctive Relief: Circuit Split?

McNair v. Synapse Group, Inc., (3d Cir. 2012)



The court found that the plaintiffs lacked standing as they did not allege that they intended to subscribe in the future.

Accordingly, **“there is no reasonable likelihood that they will be injured by those techniques in the future”**.

Injunctive Relief: Circuit Split?

Davidson v. Kimberly-Clark Corp. (9th Cir. 2018)

“We hold that a previously deceived consumer may have standing to seek an injunction against false advertising or labeling, even though the consumer now knows or suspects that the advertising was false at the time of the original purchase, because the consumer may suffer an ‘actual and imminent, not conjectural or hypothetical’ threat of future harm Knowledge that the advertisement or label was false in the past does not equate to knowledge in the future.”



Injunctive Relief: Food and Beverage Cases



Fernandez v. Atkins Nutritionals, Inc., No. 3:17-cv-01628-GPC-WVG, 2018 U.S. Dist. LEXIS 1189, 2018 WL 280028 (S.D. Cal. Jan. 3, 2018) (plaintiff lacked standing to pursue injunctive relief where she knew how “net carbs” were calculated)



Rahman v. Mott's LLP, No. 13-cv-03482-SI, 2018 U.S. Dist. LEXIS 164620, at *10 (N.D. Cal. Sep. 25, 2018) (plaintiff lacked standing to pursue injunctive relief after he understood meaning of “No Sugar Added”)



Shank v. Presidio Brands, Inc., No. 17-cv-00232-DMR, 2018 U.S. Dist. LEXIS 70134, at *16 (N.D. Cal. Apr. 25, 2018) (plaintiff had standing to pursue injunctive relief where he would not know if product did not contain synthetic ingredients)

Failure to State a Claim Developments – The Rise of the Reasonable Consumer



Herbicides and Pesticides

“Given the widespread use of herbicides, the court finds it ‘implausible that a reasonable consumer would believe that a product labeled [Florida’s Natural] could not contain a trace amount of glyphosate that is far below the amount’ deemed tolerable by the FDA.”

Axon v. Citrus World, Inc., No. 18-cv-4162
(ARR)(RML), 2018 U.S. Dist. LEXIS 208006 (E.D.N.Y.
Dec. 10, 2018)

Failure to State a Claim Developments – The Rise of the Reasonable Consumer

Health Maintenance and “Diet” Claims



“Reasonable consumers would understand that Diet Coke merely deletes the calories usually present in regular Coke, and that the caloric reduction will lead to weight loss only as part of an overall sensible diet and exercise regimen dependent on individual metabolism.”

Becerra v. Coca-Cola Co., No. 17-cv-5916 (WHA), 2018 U.S. Dist. LEXIS 31870 (N.D. Cal. Feb. 27, 2018); *Becerra v. Dr. Pepper/Seven Up, Inc.*, No. 17-cv-5921 (WHO), 2018 U.S. Dist. LEXIS 54937 (N.D. Cal. Mar. 30, 2018)

Failure to State a Claim Developments – The Rise of the Reasonable Consumer



Slack Fill: “Given the prominence with which the Products’ weight appears on the front of the package, the ease with which consumers can calculate the number of candies contained therein, the consumers’ expectations of slack-fill, as well as plaintiffs’ conceded reliance on factors other than the Products’ packaging, we conclude as a matter of law that no reasonable consumer would be misled by the presence of slack fill, even assuming it were non-functional, in the Products’ packaging.”

Daniel v. Tootsie Roll Indus., LLC, 2018 U.S. Dist. LEXIS 129143, at *37 (S.D.N.Y. Aug. 1, 2018)