The Impact of Recent Court Decisions: Deference, Precedent, Preemption And the Impact on Marketing of Food and Dietary Supplements

Moderator:
Amy E Hancock
General Counsel, American Beverage Association

Panelists:
Anthony Anscombe, Steptoe & Johnson
Matthew Ball, K&L Gates

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Agenda

- Introduction To The Panel

- Impact of Recent Cases on Food & Dietary Supplements Marketing

- Compelled Speech/First Amendment
  - *NFILA v. Bacerra; American Beverage Association v. San Francisco*
- Article III Standing in Class Actions
  - *Frank v. Gaos*
- FDA Deference
  - *Buckman v. Plaintiff Legal Committee*

Industry Is Increasingly Being Targeted By Laws Compelling Speech About Their Products

- Industry is increasingly battling local, state, and national regulations implicating their First Amendment rights.
    - In 2015, San Francisco enacted an ordinance requiring the inclusion of health warnings on advertisements for sugar-sweetened beverages.
    - Over last 5 years, New York City and Philadelphia have enacted laws or regulations requiring restaurants to warn about the salt content of certain menu items.
    - California has applied Proposition 65 to require warnings with respect to a wide range of products from coffee to French fries to wine.
    - On May 8, 2019, HHS announced a final rule requiring all DTC television ads for prescription drugs to disclose the drug's "list price."

The Legal Framework Governing Such Laws Is Evolving.

- First Amendment challenges to compelled commercial speech historically have been evaluated under *Zauderer*.
    - *Zauderer* held that reduced First Amendment scrutiny is appropriate to regulations compelling the disclosure of "purely factual and uncontroversial" information "reasonably related to the State's interest in preventing deception of consumers"
    - Many courts expanded *Zauderer* to cover compelled disclosure of any "factual" and "accurate" information, regardless of whether it is designed to prevent deception.
- *Zauderer* left many questions unanswered.
    - Does reduced scrutiny really apply when law not designed to prevent deception? What does "factual and uncontroversial" mean? Are they distinct tests?

In *NIFLA*, The Supreme Court Clarified And Strengthened *Zauderer*'s Framework… But With A Caveat.

- *NIFLA* limited the context in which *Zauderer*'s reduced scrutiny applies.
  - Made clear that *Zauderer*'s scrutiny applies only to (1) purely factual *and* (2) uncontroversial disclosures (3) "about the terms under which … services [or products] will be available."
- *NIFLA* suggested that *Zauderer*'s scrutiny has teeth, even when it applies.
  - Held *the government* has burden to show disclosure is not unjustified / unduly burdensome.
  - Suggested the government must show disclosure is tailored to a real, rather than hypothetical justification, and may not chill speech or drown out speaker's intended message.

However, the Court drops an important caveat: "[W]e do not question the legality of health and safety warnings long considered permissible, or purely factual and uncontroversial disclosures about commercial products."

Changes To The Judiciary Are Likely To Impact The Evolution Of The Legal Framework Going Forward

- The appellate judiciary is rapidly changing.
    - Only 55 circuit judges were appointed during the entire Obama administration; in two years, the Trump administration has confirmed 39.
- Justice Kavanaugh may support further narrowing of *Zauderer*'s application.
    - In *American Meat Institute v. Dep't of Agriculture*, then-Judge Kavanaugh explained that he saw *Zauderer* simply as an application of *Central Hudson* applicable only in narrow circumstances.
    - However, Judge Kavanaugh indicated the government's interests in "consumer health or safety" are sufficient to "explain and justify the compelled commercial disclosures that are common and familiar to American consumers, such as nutrition labels and health warnings"

ABA v. San Francisco

- On June 25, 2015, San Francisco enacted ordinances targeting beverages; ABA, CRA & CSOAA challenge in N.D. Cal. :
  - (1) Speech Ban - bans certain beverage ads and names of beverage producers from appearing on city property (but expressly allow anti-beverage ads);
  - (2) Warning Mandate – compels inclusion of a warning on certain beverage ads appearing in San Francisco.

Warning text

WARNING: Drinking beverages with added sugar(s) contributes to obesity, diabetes, and tooth decay. This is a message from the City and County of San Francisco.

Size, placement, etc.

- Must occupy at least 20% of the space of an advertisement;
- Contrasting typography, layout, color vis-à-vis advertisement, and oriented with each advertisement;
- Must be offset by rectangular border, same color as warning text, width equal to first downstroke of capital “W” in “WARNING”;
- Word “WARNING” must be in capital letters;
- “Clearly legible,” & indelibly printed on or permanently affixed to ad.

Example…


REFRESHING!
COLA
WARNING
Drinking beverages with added sugar(s) contributes to obesity, diabetes and tooth decay. This is a message from the City and County of San Francisco.

Procedural Overview

- PI Denied; injunction pending appeal granted;
- Ninth Circuit (panel) rules in favor of plaintiffs;
- Ninth Circuit grants en banc review;
- NIFLA prompts request for additional briefing;
- Ninth Circuit (en banc) rules unanimously in favor of plaintiffs; majority + 3 concurring opinions.

En banc rationale

- Majority
- Ikuta
- Christen & Thomas
- Nguyen

- Primary legal issue: what standard applies?
  - *Zauderer v. Office of Discipl. Counsel*:
    - "purely factual and uncontroversial";
    - Not unduly burden protected commercial speech.

Article III Standing in Class Actions

Frank v. Gaos, 586 U.S. ____, 139 S. Ct. 1041 (2019)

Frank v. Gaos

- Class action vs. Google for alleged violations of the Stored Communications Act, i.e., Google's use of "referrer" headers

- After unsuccessfully challenging Article III standing in the District Court and the Ninth Circuit, Google and Plaintiffs entered into a settlement consisting of *cy pres* award and attorneys' fees

- Case reached U.S. Supreme Court on the question of whether *cy pres*-only settlements satisfied FRCP 23.

Frank v. Gaos

- During appellate process, Supreme Court punted on *Edwards v. First American Corp.*, 610 F.3d 514 (9th Cir. 2010), and decided *Spokeo, Inc. v. Robins*, 578 U.S. ___, 136 S.Ct. 1540 (2016)

- *Spokeo* holding: Article III standing requires a concrete injury even in the context of a statutory violation

- Solicitor General urged the Court to vacate and remand the case in light of *Spokeo*, which the Court did

Frank v. Gaos

- Holding:
  - Court has independent obligation to analyze standing in the contexts of class action settlements.
  - Court is powerless to approve settlement if no named plaintiff has standing.
  - No court had analyzed the whether Stored Communications Act violations were sufficiently particularlized to support standing

Impact of Frank v. Gaos on Food & Bev Class Actions

FDA/Private Enforcement

Authority, Deference, and Preemption

Anthony Anscombe, Steptoe

FDLI

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
- Flexible approach for minor violations. 21 U.S.C. §336
- Gvt. Enforcement: Focus on health and safety; FDA subject matter expertise, enforcement discretion, even-handed application, cooperative approach toward industry.

Reality

- FDCA, regulations, FDA guidance, warning letters fuel tidal wave of class action lawsuits seeking money.
- Will Supreme Court decisions affect the weight given to FDA regulations and interpretations in civil litigation?
- What limits have/will Courts of Appeal and the Supreme Court put on civil rights of recovery based on alleged violations of the FDCA?

Standards of Deference

- *Chevron v NRDC*, 467 U.S. 837 (1984): High measure of deference to formal agency interpretations of statutes they enforce.
- *Auer v. Robbins*, 519 U.S. 452 (1997) Deference to agency interpretations of own ambiguous regulations.
- *Skidmore v. Swift & Co.*, 323 U.S. 134 (1944): “Respect” given to agency actions commensurate with their persuasive force.

Reigning in *Chevron*

- **Criticism**: Can Congress delegate authority to executive branch to construe statutes in a way that judicial branch must follow?
- *PDR Network v. Carlton & Harris Chiropractic*, 588 U.S. __(2019) (TCPA/Hobbs Act/Chevron); Kavanaugh concurrence.
- *Smith v. Berryhill*, 587 U.S. __(2019) (Judicial review of final determinations by SSA.)

Neutralizing *Auer*.

- *Kisor v. Wilkie*, 588 U.S. __(2019)(Involved disability benefits from VA, and whether court should defer to agency's interpretation of its retroactivity rules)
- Narrow decision not to overrule *Auer*, but majority cabins application to very narrow circumstances.
- Concurrences of Roberts, Gorsuch and Kavanaugh highlight limitations.

Implications of deference decisions for civil litigation

- Greater ability for litigants to diminish the relevance of non-binding agency interpretations, guidance.
- Greater ability to make as applied challenges to formal agency actions.

Exclusivity of Agency Enforcement

- 21 U.S.C. §337 – vests enforcement authority in the United States, with limited authority given to States.
- *Buckman v. Plaintiff's Legal Committee*, 531 U.S. 341 (2001) (states "fraud on the FDA" claim impliedly preempted on "conflict" grounds – private enforcement would interfere with how FDA regulates medical devices.)

State Adoption of FDCA

- *In re Farm Raised Salmon Cases*, 42 Cal. 4th 1077 (2008): "[W]hile allowing private remedies based on violations of state laws identical to the FDCA ***may arguably result in actions that the FDA itself might not have pursued***, Congress appears to have made a conscious choice not to preclude such actions." (Emphasis added for purpose of irony.)

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)

Anthony Anscombe

Partner

aanscombe@steptoe.com

- Chicago:
  +1 312 577 1265
- San Francisco:
  +1 415 365 6700