Top Cases in Food and Drug Law

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Eagle v. Azar

Erika Lietzan

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Legislative Branch

Executive Branch

Judicial Branch

- On the one hand, this is a dispute about one drug under a provision of the U.S. Code that has since been amended
- On the other hand, this dispute raises fundamental issues about
  - What it means to say that a statute is unambiguous or silent
  - Whether an agency's role is the same in both cases
  - What a court should consider when assessing whether the statute is ambiguous or silent
  - What it means when Congress then revises the statute on the same issue

One Simple (?) Provision

If the Secretary approves an application filed pursuant to section 355 of this title … for a drug designated under section 360bb of this title for a rare disease or condition, the Secretary may not approve another application … for such drug for such disease or condition for a person who is not the holder of such approved application … or of such license until the expiration of seven years from the date of the approval of the approved application …

FDCA § 527

Simpler

If FDA approves an NDA … for a drug designated under section 360bb … for a rare disease or condition,

it may not approve another application … for such drug for such disease or condition …

until the expiration of seven years from the date of the approval of the approved application …

Chevron

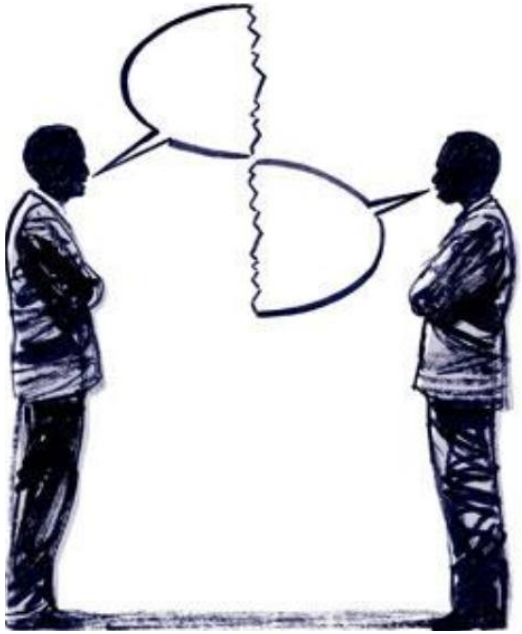
- First . . . is the question whether Congress has directly spoken to the precise question at issue. **If the intent of Congress is clear, that is the end of the matter**; for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress.
- If, however, the court **determines Congress has not directly addressed the precise question at issue, …** if the statute is **silent or ambiguous** with respect to the specific issue, the question for the court is **whether the agency's answer is based on a permissible construction** of the statute.

Eagle v. Azar

- Eagle: section 527 of the statute is unambiguous, and we win
- FDA: section 527 is ambiguous (silent?), our interpretation (policy?) is reasonable, and you lose
- District court: section 527 of the statute is unambiguous, and Eagle wins
- Court of appeals: to be determined

Talking Past Each Other

- Not entirely clear District Court understood the FDA argument



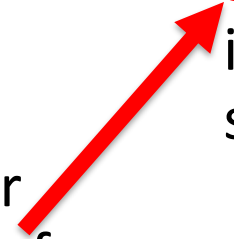
FDA Regulation

Statute:

If FDA approves an NDA … for a drug designated for a rare disease or condition,

it may not approve another application … for **such drug** for such disease or condition …

until the expiration of seven years from the date of the approval of the approved application …



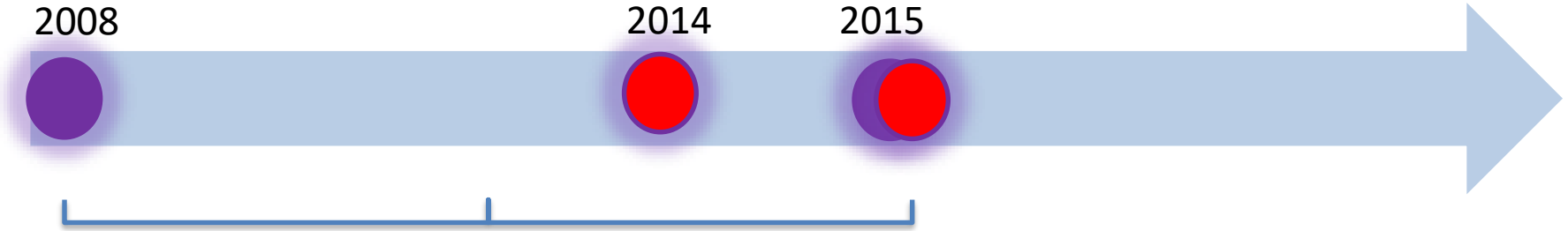
Regulations:

Such drug: same active ingredient, not clinically superior

Need-to-Know Facts

FDA gives Bendeka (bendustamine) OD designation for Cancer X.

And then denies Bendeka ODE.



Treanda (bendustamine)'s ODE for Cancer X.

The Controversy

Statute:

If FDA approves an NDA … for a drug designated for a rare disease or condition,

it may not approve another application … for **such drug** for such disease or condition …

until the expiration of seven years from the date of the approval of the approved application …

Options for Eagle?

1) Establish that Bendeka isn't "such drug" because it's superior
2) Convince Teva to waive ODE

FDA also says:

- Bendeka isn't entitled to its own ODE term if it's "such drug for such condition"; Eagle has to show clinical superiority for ODE

The World According to Eagle

If FDA **approves** an NDA … for **a drug designated** for a rare disease or condition,

it **may not approve** another application … for such drug for such disease or condition …

until the expiration of seven years from the date of the approval of the approved application …

1. Bendeka **was designated** for a rare disease (Cancer X)
2. FDA **approved** the Bendeka application
3. Therefore, **FDA cannot approve** another bendustamine for Cancer X for seven years

Simple. Clear.

FDA Sees Ambiguity

If FDA approves an NDA … for a drug designated for a rare disease or condition,

it may not approve another application … for such drug for such disease or condition …

until the expiration of seven years from the date of the approval of the approved application …

- We approved an NDA for bendustamine for Cancer X in 2008.
- We may not approve bendustamine for Cancer X until 2015?
- Orphan drug exclusivity for bendustamine for Cancer X ends in 2015?

Facing ambiguity . . . FDA reasons . . .

- There are quotes in the legislative history suggesting there is one exclusivity period for each such-drug-such-disease
- Allowing multiple exclusivity periods would allow companies to collaborate and stack it

The World According to FDA

If FDA approves an NDA … for a drug designated for a rare disease or condition,

it may not approve another application … for such drug for such disease or condition …

until the expiration of seven years from the date of the approval of the approved application …

FDA designated **Treanda** for Cancer X. FDA approved the Treanda NDA. FDA could not approve another application for bendustamine for Cancer X for 7 years.

After expiration of 7 years? The prohibition on approving bendustamine for X is over. Granting Bendeka ODE would reinstate it.

Different Understandings of the Case

- For Eagle, Treanda is irrelevant.
- This is just like the *Depomed* case, which FDA lost.

- For FDA, it's about Treanda: bendustamine already enjoyed 7 years of exclusivity for this disease.

The Sound of Silence

The statute says nothing explicit about what happens after expiration of Treanda's seven years.

- Eagle: *because it's irrelevant!!*
- FDA: silence is a gap for us to fill with a reasonable policy

Post Script

- Congress has revised the statute, which now expressly requires Company # 2 to show clinical superiority (whether or not # 1 had ODE)
- Changing the law? Ratifying FDA's approach?
- Court takes a pass . . .

The Big Picture: What's At Stake

Chevron Step 1. First . . . is the question whether Congress has directly spoken to the precise question at issue. **If the intent of Congress is clear, that is the end of the matter**; for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress.

Chevron Step 1 & Role of Agencies

Is silence the same thing as ambiguity? Does one (silence) permit policy making but the other (ambiguity) only interpretation?

If one provision is clear on its face but another is arguably ambiguous, and a reasonable "policy" approach to the ambiguous provision leads to a different outcome under the clear provision, should the court stop at step 1?

Chevron Step 1 & The Role of Courts

- Does Step 1 analysis look at the broader statutory structure and Congressional purpose even when the statutory language on its face suggests a slam dunk reading? (*FDA v. Brown & Williamson* certainly suggests so.)
- Outcome in the Court of Appeals? FDA has a hard case to make. May depend on judges.

Hilsley v. Ocean Spray Cranberries

The Evolution of Damages Models in Consumer Class Actions

August T. Horvath, Partner, Foley Hoag LLP

The Case

- *Crystal Hilsley v. Ocean Spray Cranberries, Inc., et al.*, 17-cv-2335-GPC-MDD (S.D. Cal.).
- Class certification granted in part, Nov. 29, 2018.
- Plaintiffs allege that Ocean Spray's labeling claim of "no artificial flavors" for its Cran-Apple and Cran-Grape beverages is false because the beverages contain fumaric and/or malic acids.

Legal Background

- *Comcast v. Behrend*, 569 U.S. 27 (2013), held that a plaintiff moving for class certification must present a damages model that is both consistent with their damages theory and capable of calculating class-wide damages to establish "predominance" under Rule 23(b)(3).
- Damages under most state law statutes are limited to "restitution," i.e., extra money paid by consumers as a price premium charged for the falsely advertised feature.
- In effect, plaintiffs must show that the defendant increased its marketplace price, relative to the but-for world in which the feature was not claimed.

Possible Methods

1. Some type of regression analysis on observed market prices, isolating the feature of interest.

2. Asking consumers what they would be willing to pay for the product with and without the advertised feature (contingent valuation).

3. Conjoint analysis that asks consumers to choose among hypothetical products and prices, systematically varied so as to isolate the value of each feature.

Issues with Methods

- Each has been accepted by some courts.
- Market price regressions are great, if the data are available. But:
  - Marketplace does not always provide the feature mix necessary to isolate one feature.
  - Data may be proprietary, in the hands of third parties, difficult to obtain.
- Contingent valuation is:
  - a “willingness to pay” analysis that doesn’t assess what consumers actually paid.
  - considered to suffer from inherent statistical flaws.
- Conjoint analysis is:
  - considered a less biased measure of willingness to pay, but still willingness to pay.
  - Complex, demanding of respondents, and difficult to do well.

Legal Standard

- Not the same as *Daubert* standard for admission of expert witness testimony, which is relatively lenient.
- Focus is not the quality of the research, but the fit with plaintiff's theory of liability, injury, and damages.
- Willingness-to-pay analyses (CV and conjoint) have sometimes been rejected because they do not address whether an actual price premium was charged, therefore do not fit the market price premium theory.
- All three types of analysis have been rejected if the feature at issue is not properly operationalized and tested in an appropriate context.

Recent Pre-*Hilsley* Cases

- *In re NJOY, Inc. Consumer Class Action Litig.*, 2016 WL 787415, at *5-9 (C.D. Cal. Feb. 2, 2016). Conjoint analysis was rejected because it measured only willingness to pay and did not consider "supply side" market factors.
- *Zakaria v. Gerber Prod. Co.*, No. 15-CV-00200, 2017 WL 9512587 (C.D. Cal. Aug. 9, 2017), *aff'd*, No. 17-CV-56509, 2018 WL 5977897 (9th Cir. Nov. 14, 2018). Conjoint analysis was rejected because it measured only willingness to pay, and secondarily because prices tested may have been unrealistic.
- *Hadley v. Kellogg Sales Co.*, 324 F. Supp. 3d 1084 (N.D. Cal. 2018). Conjoint analysis was accepted despite measuring only willingness to pay because the expert stated assumptions that the court found reasonable about the relationship between willingness to pay and market price.

Hilsley Expert Analysis

- Plaintiff's expert proffered a CV study.
  - Argued that CV was more appropriate than a conjoint analysis where only one product feature is of interest.
  - Defendants criticized the technique generally and also the representation of the product attributes in the study as executed.

- CV study found a 19% price premium for no-artificial-flavors claim.

Hilsley Court Rulings

- CV analysis was accepted. Willingness-to-pay shortcoming was addressed by joining it with a market analysis by another expert which applied its results to real-world price points.
- The same expert conducted a price survey of beverages with natural vs. artificial flavors, finding a price difference approximately similar to that of the CV analysis (29% difference). This analysis was rejected.
- On this basis, predominance under Rule 23(b)(3) was found and, other conditions also being met, a damages class was certified.

Implications

- Some courts have found that a willingness-to-pay analysis, without more, is not a good fit to a market price premium theory because market prices are not measured and assessed.
- However, in recent cases, the necessary "more" appears to be not much more. Recent cases have found the following "mores" as sufficient:
  - Use of real-world prices in the analysis – even though there is no way to measure the but-for price, thus begging the question whether there was any market price impact.
  - Stating assumptions about the defendant's marketplace behavior and/or supply curve, even if unsupported and unrealistic.

Where Do We Go from Here?

- Defense counsel need to do a better job of teaching judges about the deficiencies of these damages models.
- Retain competent expert witnesses trained in consumer decision making, the statistical techniques, and market analysis.
- Focus on the fit of the analysis to the legal theory, not its flaws in execution (i.e. *Daubert* issues).
- If the band-aids currently being applied to willingness-to-pay analysis to make them appear to fit market premium theories are not countered soon, we risk losing an important test of the appropriateness of class treatment.

Cases to Watch in 2019

Too Much of a Good Thing?

- Some ingredients, such as vitamins in vitamin supplements, are subject to variation in quantity.
  - Variations in handling, storage, etc.
  - Deterioration over time.
- FDA regulations require that supplements must contain a *minimum* of 100 percent of the amount claimed on the product label throughout shelf life. 21 CFR §101.9(g) and 21 CFR §101.36(f).
- There is no prohibition on there being *more* than the stated amount, so it is common to include more, to be sure that the minimum continues to be met, both initially and throughout the shelf life.

- *Chavez v. Church & Dwight*, 1:17-cv-01948 (N.D. Ill.), and *Palmer v. Whole Foods Market*, BC 713378 (Sup. Ct. Cal. LA) are two suits challenging this practice.
- They allege that excessive amounts of folic acid and vitamin B were included in supplements.
- The *Chavez* case has survived a Food, Drug & Cosmetic Act preemption challenge (May 16, 2018).
- These cases could establish whether this practice gives rise to a viable cause of action and, if so, what the limits are.

2018 Key Cases
The "Dormant Commerce Clause"

FDLI Annual Meeting

May 3, 2019

Ralph F. Hall
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Professor of Practice
University of Minnesota Law School

Principal, Leavitt Partners

Background

- Current
  - Professor of Practice - University of Minnesota Law School
  - Principal – Leavitt Partners
    - Complex health care policy and strategy work
    - Alliances
  - MR 3 Medical, LLC
- Past
  - General Counsel - Guidant CRM
  - Chief Compliance Officer – Guidant
  - Eli Lilly
  - Private practice

The Challenge

The United States is a republic with different levels of government.

- States have some powers and authority independent of the federal government
- Remember the 10th Amendment
  - "The powers not delegated to the United States by the Constitution, nor prohibited by it to the States, are reserved to the States respectively, or to the people.
- Health care often a local/state focus
  - Practice of medicine
  - Medicaid
  - Product liability
- Product regulation is usually federal
  - FDCA, Federal Meat Inspection Act, PPIA, etc.

The Challenge

- On-going questions about the intersection of federal and state law
- Often arises in preemption cases
  - Constitutional basis (Supremacy Clause)
    - Statutory interpretation
  - Product liability
  - 21 U.S.C. § 360K
  - Usually private litigants
  - Usually some explicit federal statute in play
- Commerce Clause
  - Provides affirmative Congressional authority to act
  - Power of Congress to regulate interstate commerce
  - Basis for FDA authority
  - Impact on state power

Dormant Commerce Clause

But what if state acts in a way that impacts interstate commerce?

- May trigger the "dormant commerce clause"
  - How many of us even remember the "dormant commerce clause" from law school?
  - After all, it is "dormant"
  - It is not written in the Constitution
- Reciprocal concept to Commerce Clause
  - If Congress has the authority to regulate or impede interstate commerce, a state, logically, can't act to regulate interstate commerce
- Two recent cases have used the Dormant Commerce Clause to overturn state statutes

Dormant Commerce Clause

- Three primary lines of analysis
- "Extraterritorial application of state law"
  - Dormant commerce clause prohibits the "application of a state statute to commerce that takes place wholly outside of the state's borders." (Healy v. Beer Institute, 491 U.S. 324, 336 (1989))
- Discrimination against interstate commerce
  - Prohibits "economic protectionism" that burdens out-of-state competitors but not in-state competitors
- The "Pike" test
  - Burden on interstate commerce is different than the burden on in-state competitors in different and meaningful way
    - Pike assesses the actual impact of the statute, not its wisdom

Healthcare Distribution Alliance v. Zucker

- New York state statute (Opioid Stewardship Act or OSA)
  - Imposed a "tax" on manufacturers on sales of opioids
  - Tax could not be passed on to consumers or purchasers OSA failed dormant commerce clause
  - Regulated interstate commerce by preventing a company in Maine from increasing price to someone in New Mexico
  - If prohibition on pass through is limited to in-state purchasers, then New York purchasers would be subsidized by out-of-state purchasers

AAM v. Frosh

- Maryland statute prohibited "price gouging" by generic drug manufacturers
- Appellate court invalidated statute on dormant commerce clause grounds
  - Statute not limited to sales within Maryland
  - Statute focused on initial price charged by manufacturer – which could be an out-of-state transaction
  - Statute burdens interstate commerce

Importance of the Cases

- Address federal/state power relationship
- More states looking to address health care issues
  - Drug cost
  - Products capable of being abused
  - Access
  - Safety and effectiveness
  - Public reporting
- Dormant Commerce Clause limits ability of states to act
  - Reinforces importance of federal sphere
- States can still act
  - Practice of medicine
  - Medicaid
  - Rx controls

Case to Watch

- *Kisor v Wilke*
  - And its not an FDA case or even a health care case
  - Involves dispute over VA benefits
  - Pending before the Supreme Court
  - Decision expected this summer
- Challenges past cases such as *Auer*
- Under *Auer*, courts give great deference to an agency's interpretation of its (ambiguous) regulations
- Provides FDA with substantial leeway

Potential Impact of Kisor

If the Supreme Court upholds *Auer*

- FDA discretion remains as is
- Substantial latitude for FDA

If the Supreme Court rules for *Kisor*

- No deference to FDA interpretation of its regulations and guidances
- Harder to maintain "innovative" programs
  - Precert?
  - "Deeming" rule
- Enforcement risks for FDA
  - Another basis for challenges to enforcement

Questions?

TOP TEN FOOD & DRUG CASES OF 2018

McNair *v.* Johnson & Johnson

Supreme Court of Appeals *of* West Virginia (May 2018)

PROF. WILLIAM M. JANSSEN
CHARLESTON SCHOOL OF LAW

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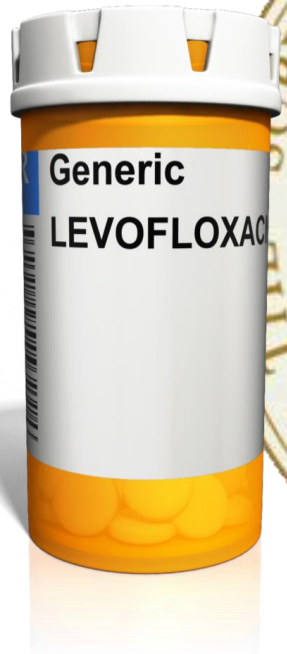

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"Innovator Liability"

Permit generic drug users to bring product liability claims against the brand manufacturer.

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"Innovator Liability"

Permit generic drug users to bring product liability claims against the brand manufacturer.

All U.S. CoA:
Predict "no".

Most U.S. DCt:
Predict "no"
except Vt., Ill., Miss.

UNITED STATES COURTS

Overturned *by* Statute (2015)

Alabama
2014

CALIFORNIA REPUBLIC

California
2017

Massachusetts
2018

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Drug & Device Law

"Scorecard:
Innovator Liability in Generic Drug Cases"

https://www.druganddevicelawblog.com/2009/11/scorecard-non-manufacturer-name-brand.html

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"Innovator Liability"

Permit generic drug users to bring product liability claims against the brand manufacturer.

McNair *v.* Johnson & Johnson

3-2 Decision: May 11, 2018

Why a Top-10 Case?

- ✓ Arrived late to "innovator liability"
- ✓ Comprehensive survey of case law
- ✓ Well-written majority + dissent
- ✓ Strongly-reasoned Plaintiff briefing:
  - Generic "foreseeability"
  - "Defective label" (not drug)
  - Remedy for every wrong

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Majority Opinion

No Strict Liability:

- Would be contrary to core S/L theory:
  - *Implied representation of fitness*
  - *Burden should be borne by who benefits from product on the market*
  - *Burden mitigated by cost-spread*

McNair *v.* Johnson & Johnson

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MAJORITY OPINION

No Strict Liability:

No Negligent Misrepresentation:

- No action "without a duty broken" :
  - *Generic injuries → not foreseeable result of brand mfrs' conduct but of laws over which mfrs have no control*
  - *Remedy lies with Congress / FDA*

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"Wrong," "Imprudent," "Appalling," "Injurious," "Short-Sighted," etc.:

- Foreseeability guides common law tort:
  - ➢ *Who is responsible for label content?*
  - ➢ *Likelihood of injury is foreseeable*
  - ➢ *Burden is minimal (already exists)*
  - ➢ *Consequences of liability are wise*

DISSENTING OPINION

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McNair *v.* Johnson & Johnson

3-2 Decision: May 11, 2018

MAJORITY OPINION

3 - 2

DISSENTING OPINION

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According to FDA:

90% of all prescription scripts written in the United States are filled by generic drugs

OPTION #1:
Federal law permits generic mfrs. to alter their labels when necessary.

OPTION #2:
Federal law removes preemption when generic mfrs. fail to petition FDA to alter their labels when necessary.

OPTION #3:
Federal law creates capped generic claim system (funded by sur-charges).

OPTION #4:
Federal law forbids mandatory generic substitution; consumers choose.

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Option #7:

Federal law does nothing.

Whether generic users can recover or not becomes a State-by-State dice roll.

Option #5:

Federal law codifies innovator liability (becomes a new cost borne by brand mfrs., absorbed by increase in pharma costs).

Option #6:

Federal law forecloses innovator liability (just an unfortunate consequence of the Hatch/Waxman balance).

Option #1:

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Azar v. Allina Health Services

U.S. Supreme Court – No. 17-1484
Orally Argued: January 15, 2019
(decision pending)

Escaping Notice-And-Comment

Can HHS alter the "Medicare fraction" formula applied to hospitals that serve a "significantly disproportionate number of low-income patients" without providing notice-and-comment?