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Comparative Advertising in the United States

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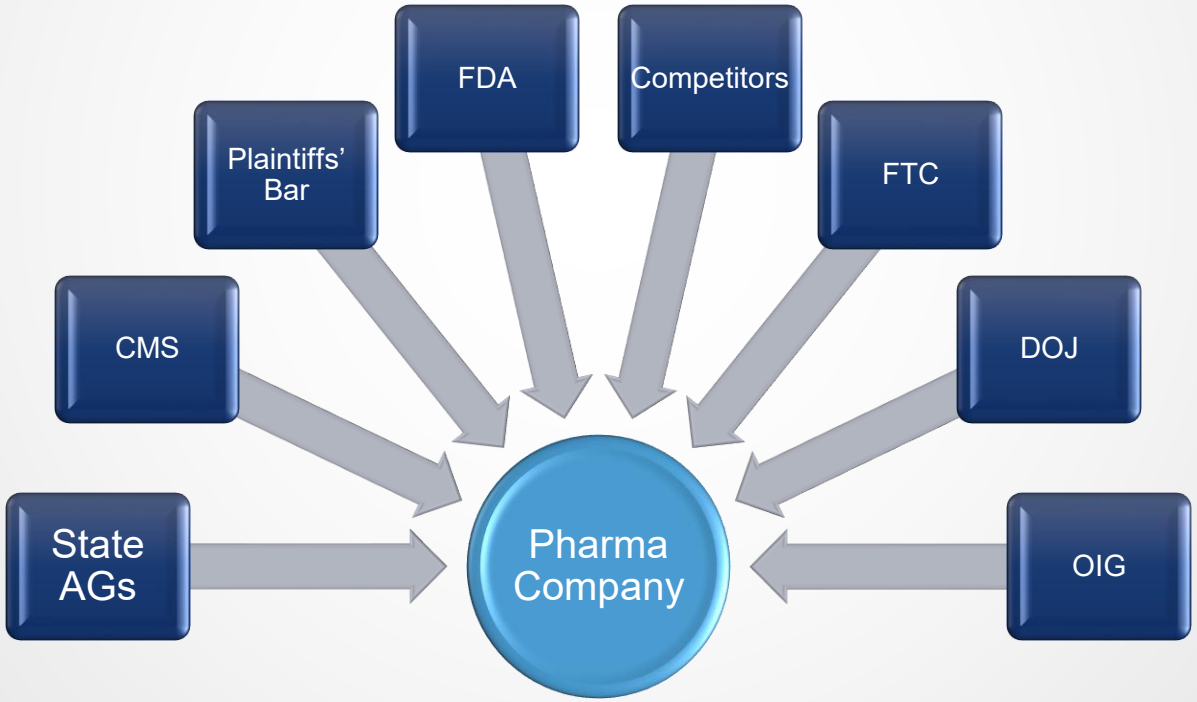
Agenda

- Overview of legislative framework and governing bodies
  - Key Federal Agencies and Others:
    - Food & Drug Administration,
    - Federal Trade Commission
    - National Advertising Division
  - Lanham Act False Advertising Claims and Comparative Advertising

Pharma Advertising in US Is to Everyone – Doctors, Patients, General Public

Many Sources of Advertising Challenges in US:



FDA and FTC Share Regulatory Responsibility for Medical Product Advertising and Promotion

- FDA enforces laws and creates and enforces regulations and guidance related to the development, promotion, and distribution of products by pharmaceutical companies
- FDA has primary jurisdiction over labeling of OTC drugs, and over labeling and advertising for prescription drugs
- FTC protects US consumers from deceptive or unfair business practices, including false or deceptive advertising, and from unfair methods of competition
- FTC has primary jurisdiction over advertising for OTC drugs

Primary Jurisdiction by Product Type

Product Type	Labeling	Advertising
OTC Drugs	FDA	FTC
Rx Drugs	FDA	FDA

Food & Drug Administration (FDA)

- **General Principles**
- **Food, Drug & Cosmetic Act prohibits distribution of misbranded products in interstate commerce**
  - "Labeling" (which includes advertising) must not be false or misleading in any particular (FDCA § 502(a))
  - Misbranding can include labeling or advertising that, for example:
    - makes claims without adequate substantiation
    - omits or minimizes safety information
    - promotes unapproved uses
    - is based on poorly designed, inadequate, or outdated studies
- **Burden is on the advertiser to substantiate advertising claims**

FDA: Comparative / Superiority Claims

- FDA often cites superiority claims in enforcement where companies claim, directly or indirectly, that a product is safer or more effective than another product.
- Competitors also often complain about comparative or superiority claims and share their concerns with FDA.
- Generally, FDA requires at least two adequate and well-controlled head-to-head studies to support comparative or superior efficacy and safety claims.
- Frequent issues in comparative studies / claims:
  - Appropriate doses and dose regimens for the compared products
  - Appropriate patient population
  - Selection and timing of endpoints
- Burden on advertiser to substantiate claims

Federal Trade Commission (FTC): General Principles

- Advertisements must be truthful and not misleading
- All objective product claims, both express and implied, must have a reasonable basis and must be substantiated before they are made
- If there are several interpretations of a specific claim (even if unintended) that a consumer may take away, substantiation is required
- In determining what message is being conveyed, FTC considers the overall impression of the advertisement and how a “reasonable consumer” would interpret ad

FTC: Claim Substantiation

- Claims (including comparative claims) regarding product attributes, performance, or preference must be substantiated with appropriate research showing reasonable basis
  - Required amount of substantiation is that which experts in the field believe is reasonable
- The level and type of substantiation required will vary depending on the claim
  - type of product
  - type of claim
  - consequences of a false claim
  - benefits of truthful claim vs. cost of developing substantiation
- Unqualified superiority/parity claims (e.g., “Nothing works faster”)
  - Must be supported by testing against a significant portion of the market — “85% Rule”

National Advertising Division

- Private, informal forum for resolution of advertising disputes
- Handles disputes when the challenged advertiser is a member of Council of Better Business Bureaus, or otherwise consents to resolution by NAD
- NAD review can be prompted by competitor or consumer complaint or by NAD's own monitoring
- NAD requires the advertiser to substantiate advertising
- Comparative claims must be truthful, accurate, and substantiated by competent and reliable evidence; head-to-head testing preferred

Lanham Act Section 43(a) False Advertising Claims

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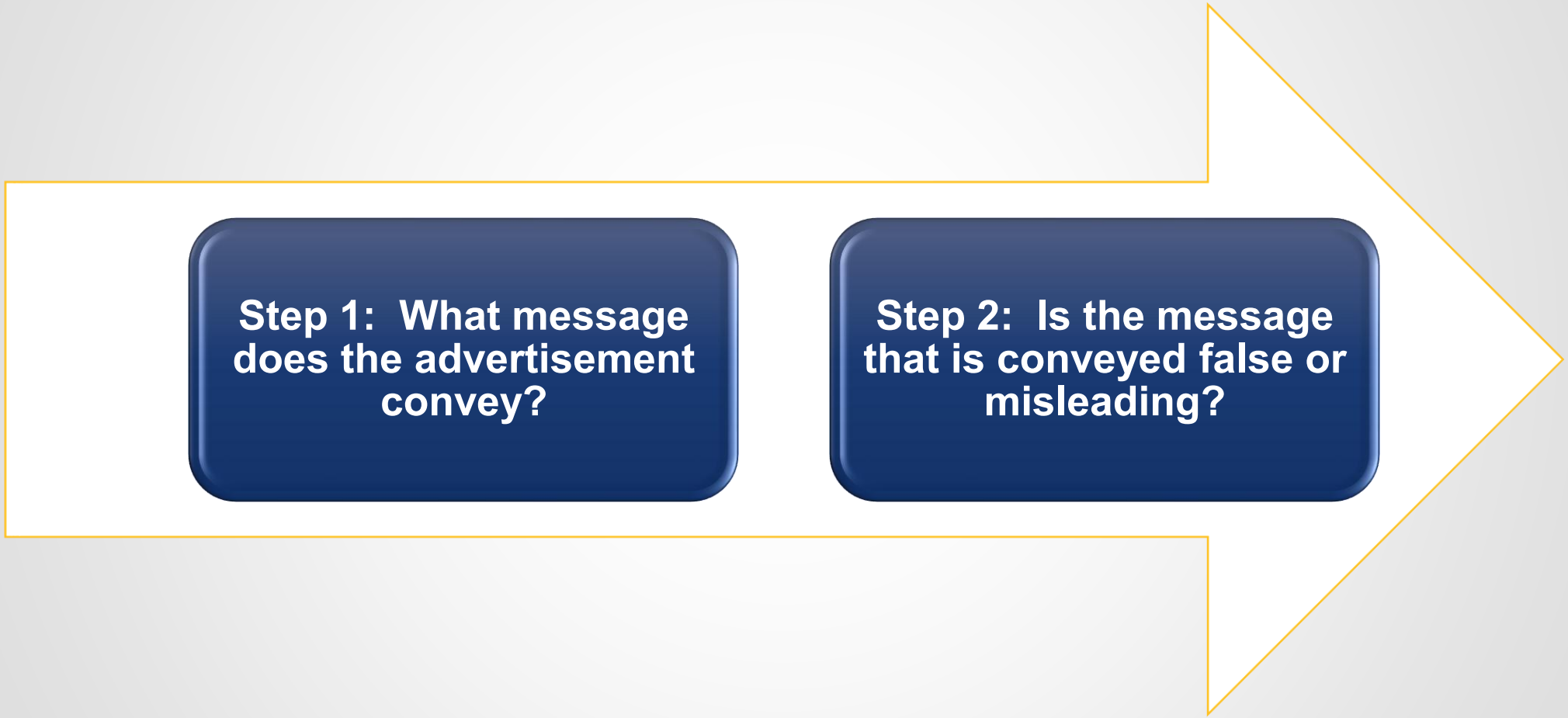
Lanham Act: Private Right of Action

- The federal Lanham Act creates a private right of action against “any person” who in commercial advertising or promotion makes a “false or misleading representation of fact” about the “nature, characteristics, qualities or geographic origin” of his or her own “or another person’s” “goods, services, or commercial activities.”
- Generally limited to competitors (no consumer standing)
- Can apply to traditional and online advertising, detail pieces, press releases, continuing medical education, claims relying on scholarly articles, other statements in commercial advertising or promotions
- Injunctive relief and monetary remedies available
- Different burdens of proof and substantiation requirements than FDA/FTC/NAD – generally, burden on plaintiff to prove (a) the message conveyed; and (b) that the message is false or misleading

Lanham Act: Elements of a False Ad Claim

- Plaintiff must establish that:
  - The challenged ad makes **explicit** or **implicit representations of fact** about the plaintiff's or defendant's product;
  - The challenged ad has the **capacity to deceive** a not insubstantial segment of likely purchasers;
  - The deception is **material** in that it is likely to influence purchasing decisions; and
  - The plaintiff has been or is **likely to be injured** as a proximate result of the deception

Lanham Act: Two-Step Process to Determine Falsity



Step One: What Message is Conveyed?

- **Step 1: What message does the advertisement convey?**
  - Express (or literally false, false on its face) claim
    - Unambiguous factual statement susceptible to only one interpretation
  - False by necessary implications
    - Only reasonable inference of the advertisement is an allegedly false statement
  - Implied (or misleading) claim
    - Literally true claim that conveys an implied false message
  - Establishment claim (express or implied)
    - Claims that “studies show,” “tests prove,” etc. – can be express or implied
  - Puffery
    - Subjective claims that would not be reasonably relied upon as factual
- **Survey evidence often used to prove implied message conveyed**

Express or Implied Claim?

- Transplant detection rejection test is **"More sensitive and specific than current assessment tools across all types of rejection."**

Express or Implied Claim?

- Transplant detection rejection test is **"More sensitive and specific than current assessment tools across all types of rejection."**

Literally false: specificity rates measurable in clinical studies

Express or Implied Claim?

- Claim that antacid is "**the strongest antacid there is**"

Express or Implied Claim?

- Claim that antacid is "**the strongest antacid there is**"?

Implied claim: Product might be strongest antacid *chemically*, but extrinsic evidence required to show that the claim conveys a message of superior relief

Express or Implied Claim?

- Antacid product name "**Night Time Strength**"

Express or Implied Claim?

- Antacid product name "**Night Time Strength**"

False by necessary implication: Name necessarily implied false message that it was particularly effective for those suffering from heartburn at night.

Proving that an Ad Conveys an Implied Message

- Courts will not use their own judgment or experience to determine what implied messages are being conveyed
- Survey of target audience often used to prove message conveyed
- Surveys might also show that a disclaimer is not effective

Step Two: Is the message that is conveyed false or misleading?

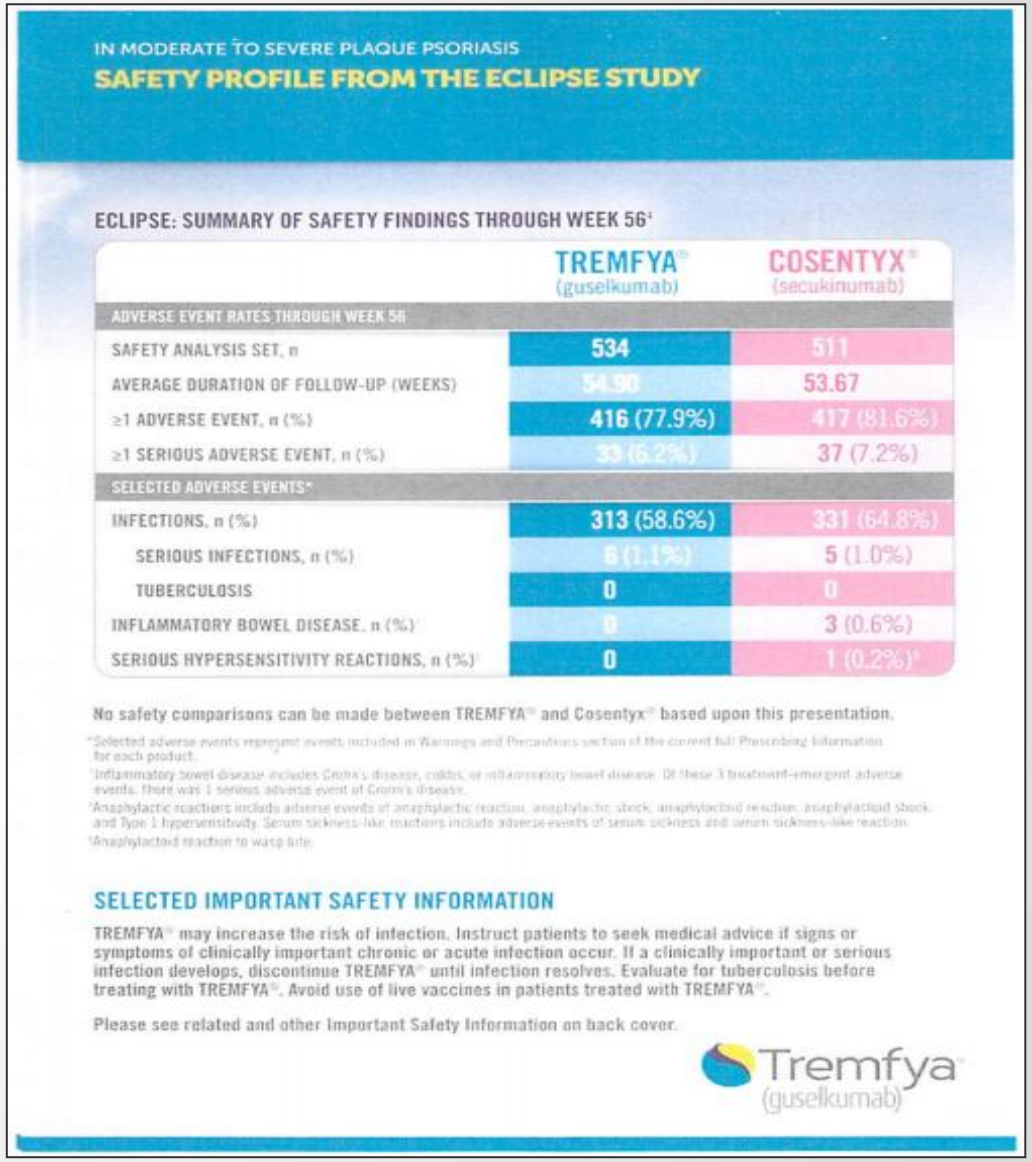
- **Determining truth or falsity**
  - Expert testimony
  - Plaintiff's tests and studies
  - Defendant's own tests and studies
  - Government guidelines
- **Lanham Act plaintiff has burden to prove that the challenged claim is false or misleading, not merely unsubstantiated**
- **When claim is an "establishment claim" (e.g. "tests show"), Plaintiff only needs to show that the advertiser's tests do not support the claim, or do not use a proper methodology**

Lanham Act: Common Types of Advertising Claims & Issues (Comparative or Monadic)

- Efficacy Claims
- Safety / AE Claims
- Dosing Claims
- Comparative Charts
- Cherry-Picking Data / Apples-to-Oranges Comparisons
- FDA Approval Claims
- Reimbursement / Coverage Claims

Comparative Claims: Cherry-Picking Data

- Janssen allegedly was misrepresenting safety profile of Tremfya as superior to Novartis's competing psoriasis drug Cosentyx by omitting "the most egregious adverse events" from the data
- Janssen allegedly made claims that its product was both superior and non-inferior to Cosentyx, but omitted "key safety information"
- "It chose to cherry pick among the adverse events recorded in the study."



IN MODERATE TO SEVERE PLAQUE PSORIASIS

SAFETY PROFILE FROM THE ECLIPSE STUDY

ECLIPSE: SUMMARY OF SAFETY FINDINGS THROUGH WEEK 56[1]

	TREMFYA® (guselkumab)	COSENTYX® (secukinumab)
ADVERSE EVENT RATES THROUGH WEEK 56		
SAFETY ANALYSIS SET, n	534	511
AVERAGE DURATION OF FOLLOW-UP (WEEKS)	54.30	53.67
≥1 ADVERSE EVENT, n (%)	416 (77.9%)	417 (81.6%)
≥1 SERIOUS ADVERSE EVENT, n (%)	33 (6.2%)	37 (7.2%)
SELECTED ADVERSE EVENTS*		
INFECTIONS, n (%)	313 (58.6%)	331 (64.8%)
SERIOUS INFECTIONS, n (%)	6 (1.1%)	5 (1.0%)
TUBERCULOSIS	0	0
INFLAMMATORY BOWEL DISEASE, n (%)†	0	3 (0.6%)
SERIOUS HYPERSENSITIVITY REACTIONS, n (%)‡	0	1 (0.2%)§

No safety comparisons can be made between TREMFYA® and Cosentyx® based upon this presentation.

*Selected adverse events represent events included in Warnings and Precautions section of the current full Prescribing Information for each product.

†Inflammatory bowel disease includes Crohn's disease, colitis, or inflammatory bowel disease. Of these 3 treatment-emergent adverse events, there was 1 serious adverse event of Crohn's disease.

‡Anaphylactic reactions include adverse events of anaphylactic reaction, anaphylactic shock, anaphylactoid reaction, anaphylactoid shock and Type 1 hypersensitivity. Serum sickness-like reactions include adverse events of serum sickness and serum sickness-like reaction.

§Anaphylactoid reaction to wasp bite.

SELECTED IMPORTANT SAFETY INFORMATION

TREMFYA® may increase the risk of infection. Instruct patients to seek medical advice if signs or symptoms of clinically important chronic or acute infection occur. If a clinically important or serious infection develops, discontinue TREMFYA® until infection resolves. Evaluate for tuberculosis before treating with TREMFYA®. Avoid use of live vaccines in patients treated with TREMFYA®.

Please see related and other Important Safety Information on back cover.

Tremfya® (guselkumab)

Comparative Claims: Different Clinical Trials ("Apples-to-Oranges")

- Comparative chart combines information from separately conducted clinical studies with different methodologies, endpoints, etc., but presents them side-by-side, therefore suggesting a direct comparison

Pivotal Trial Data*	[redacted] U.S. Pivotal at 12 Months[4,5]	[redacted] U.S. Pivotal at 12 Months[6,7]
Screening IOP	18.5 mm Hg	18.7 mm Hg
Screening Medications	1.4†	1.6
Baseline IOP (after med washout)	24.4 mm Hg	25.4 mm Hg
Post-op IOP Results	16.7 mm Hg	17.0 mm Hg
Post-op IOP Results at 24 Months	17.0 mm Hg	17.1 mm Hg[5]
IOP Reduction from Screening	10%	9%
IOP Reduction from Baseline	32%	33%
Post-op Medications	0.2†	0.2

*A head-to-head study of [redacted] and [redacted] has not been conducted.
†The [redacted] pivotal trial included a large cohort of patients (18%) that were on no glaucoma medications preoperatively, whereas all [redacted] subjects were on 1-3 glaucoma medications preoperatively.

Key Considerations in Assessing Advertising Claims

- Does the advertising convey an express false claim or is it subject to multiple reasonable interpretations (and are any of those interpretations false)?
- Does the advertising use charts or comparisons that could be misleading?
- Does the advertising claim expressly or impliedly rely on tests that may not support every reasonable interpretation of the claim?

Comparative Advertising and Trademarks

- US trademark law generally permits “nominative fair use” of competitor marks in comparative advertising, i.e. use other than as a designation of source for the advertiser’s own goods
- “Nominative fair use” defense considers varying factors depending on the appellate circuit, but generally:
  - Is the advertisement using the competitor mark other than as a designation of source for its own goods, i.e., to refer to the competitor product?
  - Is the competitor product not readily identifiable without mark?
  - Does the advertisement use more of the competitor mark than is necessary?
  - Does the advertisement do anything to suggest a connection to the trademark owner?
- Ultimate question is likelihood of confusion