Morgan Lewis

Private Litigation Alleging False Claims Regarding Performance and Comparative Effectiveness

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Presentation Outline

- Potential Private Causes of Action Based on Comparative Effectiveness Claims
- What Communications are At-Risk?
- Case Studies
- Mitigating Risks

FDA Regulation Versus Private Litigation

- Historically, legal departments only needed to be concerned about compliance with FDA regulations regarding advertising and promotion.
- Now, legal departments need to be aware of potential private lawsuits brought by competitors.
- Raises new issues, including:
  - Difference standards and burdens of proof
  - Agency experts vs. lay judges and juries
  - Interplay between the FDCA and private civil claims

Recent Private Cases

- *ONY v. Cornerstone* (2011)
- *Genzyme v. Shire* (2012)
- *Endo v. Actavis* (2012)
- *Ferring v. Watson* (2012)
- *Millennium Laboratories v. Ameritox* (2012 and 2010)

Potential Private Causes of Action Based on Comparative Effectiveness Claims

- False Advertising Claims under the Lanham Act
- Unfair Competition and Deceptive Trade Practices Claims
- Defamation and Injurious Falsehood Claims
- Tortious Interference Claims
- False Claims Act Claims

Elements of a False Advertising Claims under the Lanham Act

- The defendant made a false or misleading statement of fact in a commercial advertisement about a product;
- The statement either deceived or had the capacity to deceive a substantial segment of potential consumers;
- The deception is material, in that it is likely to influence the consumer's purchasing decision;
- The product is in interstate commerce; and
- The plaintiff has been or is likely to be injured as a result of the statement

Elements of Unfair Competition and Deceptive Trade Practices Claims

- The defendant engaged in deceptive acts directed at consumers;
- The defendant's acts misled consumers in a material way;
- The defendant's deceptive acts caused harm to the plaintiff; and
- The defendant's deceptive acts caused injury or has the potential to cause injury to the public.

Elements of Defamation and Injurious Falsehood Claims

- The defendant made false statements;
- The defendant published the false statements to a third person;
- The defendant made the false statements with malice; and
- The defendant's false statement caused special damages to the plaintiff.

Elements of Tortious Interference Claims

- The plaintiff had a business relationship with a third party;
- The defendant knew of that relationship and intentionally interfered with it;
- The defendant acted solely out of malice, or used dishonest, unfair, or improper means; and
- The defendant's interference caused injury to the plaintiff's relationship.

What Communications are At-Risk?

- Publications in Peer-Reviewed Journals
- Scientific Presentations
- Press Releases
- Detailing Presentations
- Securities Filings
- Submissions to Insurers

Key Issues Arising in These Litigations

- When is a statement false or misleading?
- When is a communication an advertising or promotion under the Lanham Act?
- The interplay between the FDCA and these private causes of action

When is a statement false or misleading?

- Different standards and burden of proof than FDA
- Opinion or statement of fact?
- When are summaries of studies misleading?
- Statements can be literally true, but likely to mislead.

When is a communication advertising or promotion under the Lanham Act?

- Statements are advertising or promotion under the Lanham Act when:
  - They are commercial in nature;
  - Made for the purpose of influencing customers to buy the defendant's goods; and
  - Sufficiently disseminated to the relevant purchasing public.

- Application of test to various communications
  - Publications in academic journals
  - Press releases
  - Oral statements made by sales representatives

The Interplay Between the FDCA and Private Civil Actions

- Enforcement of the FDCA is placed exclusively with the federal government, and there is no private right of action for violations of the FDCA.
- Private plaintiffs cannot use false advertising or other claims as a backdoor means to enforce the FDCA.
- Therefore, it is not enough for a private plaintiff to prove that the defendant's claim of superiority is inconsistent with the FDCA (such as a requirement of two adequate and well-controlled clinical tests substantiating the claim).

The Interplay Between the FDCA and Private Civil Actions

- Permitting false advertising or similar claims would usurp the FDA's responsibility for interpreting and enforcing its regulations and indirectly create a private right of action for violation of the FDCA.

- Nevertheless, false advertising and similar claims may proceed when the truth or falsity of superiority claim may be determined without having to interpret or apply the FDCA.

CASE STUDY: *ONY v. Cornerstone*

- Involved two of the three animals derived surfactants used to treat premature infants with Respiratory Distress Syndrome.

- Chiesi sponsored an article that was authored by three neona-tologists and a clinical researcher that discussed the results of a retrospective study (not a clinical study) comparing the mortality rates associated with the use of ONY's and Chiesi's surfactants in over 14,000 infants based on data obtained from hospitals around the country.

- After the article was peer reviewed, it was published in the *Journal of Perinatology.*

CASE STUDY: *ONY v. Cornerstone*

- The article reported that, based on this data, ONY's product was associated with a 49.6% greater likelihood of deaths than Chiesi's product.
- Cornerstone issued a press release summarizing the article and study.
- After the article was published, ONY sought a retraction.
- The *Journal of Perinatology* refused to retract the article, but did agree to publish a letter to the editor explaining ONY's criticisms of the study.

ONY's Lawsuit

- Dissatisfied with that response, ONY filed a lawsuit in the U.S. District Court for the Western District of New York against:
  - Chiesi, the manufacturer of the competitive product and the sponsor of the article;
  - Cornerstone, the exclusive distributor and the U.S. and the party that issued the press release in the U.S.;
  - Premier, the entity that provided the data used in the retrospective study;
  - Authors of the article (three neonatologists and a Premier employee);
  - Nature America (the publisher of the Journal) and its editor; and
  - The American Academy of Pediatrics (presumably because the Journal is the "official journal" of the AAP).

ONY's Lawsuit

- Asserted the following claims:
  - False advertising under the Lanham Act
  - Injurious Falsehood under NY Law
  - Tortious Interference with Contract
  - Violation of NY General Business Law § 349 "and similar statutes of other states" – which prohibit false, misleading, deceptive or unfair practices in trade or commerce.

Alleged Misrepresentations in *ONY v. Cornerstone*

- **"Result:** Calfactant [ONY's product] was associated with a 49.6% greater likelihood of death than poractant alfa [Chiesi's product].“
- **"Conclusion:** Poractant alfa treatment for RDS was associated with a significantly reduced likelihood of death when compared with calfactant."

Alleged Misrepresentations in *ONY v. Cornerstone*

- This study "show[ed] a significantly greater likelihood of death with calfactant than poractant alfa.“
- "This large retrospective study of preterm infants with RDS found lower mortality among infants who received poractant alfa, compared with infants who received either calfactant or beractant, even after adjusting for patient characteristics such as gestational age and [body weight], and after accounting for hospital characteristics and center effects.“
- ONY alleged that these conclusions "are unreliable, and therefore misleading" because the omission of length of stay data allowed the authors of the Article to postulate, promote and disseminate false conclusions.

Issues in *ONY v. Cornerstone*

- Are the statements regarding the study false or misleading statements of fact?
- Is the Journal article or the press release "commercial advertising or promotion" governed by the Lanham Act?
- Are these types of claims actionable under deceptive trade practices statutes?

District Court's Decision in *ONY v. Cornerstone*

- The district court granted the Defendants‘ Motion to Dismiss for failure to state a claim on all counts.
- The district court confirmed that statements of opinions are not statements of fact and cannot support any of the asserted claims.
- The district court recognized that statements must be viewed in context and the issue is whether a reasonable person would view them as expressing or implying any facts.
- Determination of whether a statement is an expression of fact or opinion is a threshold question of law for the court.

District Court's Decision in *ONY v. Cornerstone*

- “A proffered hypothesis that is offered after a full recitation of the facts on which it is based is readily understood by the audience as conjecture.”
- On the other hand, hypotheses may be actionable if they imply that the speaker's opinion is based on the speaker's knowledge of facts that are not disclosed to the reader.
- The reasonable reader of the article would have a well-developed understanding of issues in biomedical research.

District Court's Decision in *ONY v. Cornerstone*

- The reasonable reader of the article would have a well-developed understanding of issues in biomedical research.
- The article contained an initial section detailing the patient data and research methods utilized in the retrospective study and specifically listed what patient criteria was considered. By implication, the study confirmed that length of stay data was not considered.
- Therefore, the district court concluded that the article reflects the facts on which the author's conclusions are based and does not imply that undisclosed facts also exist supporting the authors' conclusions.

District Court's Decision in *ONY v. Cornerstone*

- Also, the context of the article confirmed that the average reader would perceive the challenged statements to be debatable hypothesis rather than assertions of unassailable facts.

- The Article acknowledged that the "study has certain limitations due to the retrospective nature of the database used," and that additional factors could likely affect the stated conclusions.

- Therefore, the district court held that the statements regarding the mortality rates were non-actionable hypothesis based upon limited and articulated facts" and any perceived faults in the methodology should be subjected to peer review rather than judicial review."

Unanswered Questions in *ONY v. Cornerstone*

- Because the district court dismissed all of ONY's claims based on its conclusion that there was no false or misleading statement of fact, it did not address several other issues raised by the case, including:
  - Whether the publication of the article or press release summarizing the article constituted "commercial advertising or promotion" under the Lanham Act
  - Whether ONY sufficiently alleged harm to consumers, as required by New York's deceptive trade practices statute

CASE STUDY: *Genzyme v. Shire*

- Involved the two main competitive drugs in the enzyme replacement therapy market for treatment of Gaucher disease.
- Shire issued a press release that purported to describe results in lumbar spine bone mass density ("BMD") at nine months from a "head-to-head" clinical trial of patients.
- Shire allegedly made superiority claims about BMD improvement based on clinical studies that were conducted for a different principal purpose.

CASE STUDY: *Genzyme v. Shire*

- Shire used an exploratory, retrospective, subgroup analysis of data collected by Shire during one of the initial Phase II clinical trials submitted to the FDA for approval of Shire's drug.

- The clinical trial focused primarily on changes in hemoglobin concentration. Changes in BMD was neither a primary nor secondary endpoint of the original study. It was an exploratory endpoint.

Shire's Press Release

- Shire's press release stated:
  - "In a head-to-head trial between [Shire's product] and [Genzyme's product], only patients treated with [Shire's product] experience statistically significant improvement in lumbar spine bone mineral density at nine months."
  - The clinical study showed "clinically and statistically significant improvement from baseline in mean [lumbar spine] Z-score . . . At nine months of treatment with [Shire's product], but not in the cohort of patients treated with [Genzyme's product]."
- Genzyme demanded that it retract its press release and explain the scientific and medical reasons for the retraction.
- Shire denied that its press release was false or misleading.

Genzyme's Lawsuit

- Genzyme filed a Complaint alleging a single claim – False Advertising under the Lanham Act.
- Genzyme claimed that the retrospective analysis was biased and did not substantiate the advertising claims made by Shire that its product shows "clinically and statistically significant improvement" in BMD because, among other reasons:
  - The comparison of changes in BMD were done retrospectively and BMD was not a primary or secondary endpoint of the study and such analysis cannot be used to substantiate comparative efficacy claims.
  - There was no significant difference between the groups of patients for BMD and Shire failed to disclose that no conclusion regarding group-to-group comparisons can be made based on the data from the study.
  - The patients taking Shire's drug had a greater BMD deficiency than the patients taking Genzyme's drug; thus the patients receiving Shire's drug had significantly more room for improvement.

District Court's Decision in *Genzyme v. Shire*

- Shire filed a motion to dismiss raising three issues:
  - The press release is not commercial advertising or promotion under the Lanham Act.
  - The complaint did not adequately allege that the press release was false or misleading.
  - The complaint did not adequately allege that the press release will deceive physicians or injure Genzyme.

District Court's Decision in *Genzyme v. Shire*

- The district court denied the motion to dismiss.
  - The court held that although the original presentation of the comparative data at a medical conference was protected scientific expression, its secondary dissemination in a press release was not.
  - The press release selectively disseminated information favorable to shire and unflattering to Genzyme to an audience that included both physicians and patients (via the National Gaucher Foundation).

District Court's Decision in *Genzyme v. Shire*

- The court held that unless the complaint of speech is such that a court can say that no reasonable person could be misled, it is not appropriate to resolve the issue of truthfulness on a motion to dismiss. The court construed the complaint as alleging that the press release conveyed the literally false message that Shire's product outperforms Genzyme's product in improving BMD and determining "the veracity of this allegation involves a delving into murky scientific data an analysis" that is inappropriate on a motion to dismiss.
- The district court held that Genzyme was entitled to a presumption of consumer deception at the pleading stage, noting that patients were a segment of the relevant audience.

CASE STUDY: *Endo v. Actavis*

- Involved branded and generic versions of a prescription pain reliever that was occasionally abused by crushing the tablets in to a fine powder and inhaling them to product a high.
- In response, Endo developed a crush-resistant product oxymorophone hydrochloride extended-release tablets and discontinued the sale of the non-crush resistant formulation.
- Actavis manufactured a generic version of the non-crush resistant formulation and it continued to market its product as AB Rated to Endo's product.
- Endo alleged that Actavis's product was never AB Rated to its crush-resistant product, the only product sold by Endo in over six months.

Endo's Lawsuit

- Alleged three claims:
  - False advertising under the Lanham Act;
  - Unfair Competition under the New Jersey Fair Trade Act and the common law; and
  - Violation of the New Jersey Consumer Fraud Act.
- Actavis filed a motion to dismiss making three arguments:
  - Endo's claims are preempted by the FDCA;
  - The complained-of advertisements are not false; and
  - Endo does not have standing to bring the New Jersey Consumer Fraud Act claim because Endo is not a "consumer."

CASE STUDY: *Ferring v. Watson*

- Involved competitors with products used for in-vitro fertilization in a process referred to as assisted reproductive technology ("ART").
- Ferring alleged that one of Watson's paid consultants made false and misleading statements at presentations detailing Watson's product. The presentations were streamed over the Internet.
- It appears as though Watson concedes that its consultant inadvertently made several misstatements regarding Ferring's product, including that it was the subject of a Black Box warning.

CASE STUDY: *Ferring v. Watson*

- Ferring brought numerous claims, including:
  - False advertising under the Lanham Act;
  - Unfair Competition Under New Jersey Statute § 56:8-1 and the common law; and
  - Defamation.

Mitigating Risks of Private Actions

- In any scientific articles or presentations, disclose details regarding the data used and the methodology employed in any studies.
- Disclose any potential conflicts of interests or relationships between the authors and the relevant pharmaceutical companies.
- If you are going to issue any press releases or comparative data in promotional materials, consider distributing the entire article or study with the press release or promotional materials.
- Consider limiting circulation of any press releases or other comparative claims to sophisticated consumers (i.e., physicians and not patients)
- Closely script any oral presentations to ensure accuracy.

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