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PROMOTIONAL COMPLIANCE AND LIABILITY RISKS BEYOND THE FDA

Food & Drug Law Institute's Annual Advertising and Promotion for Medical Products Conference

October 16-17, 2018
Washington, D.C.

James N. Czaban, DLA Piper
Richard Cleland, Federal Trade Commission
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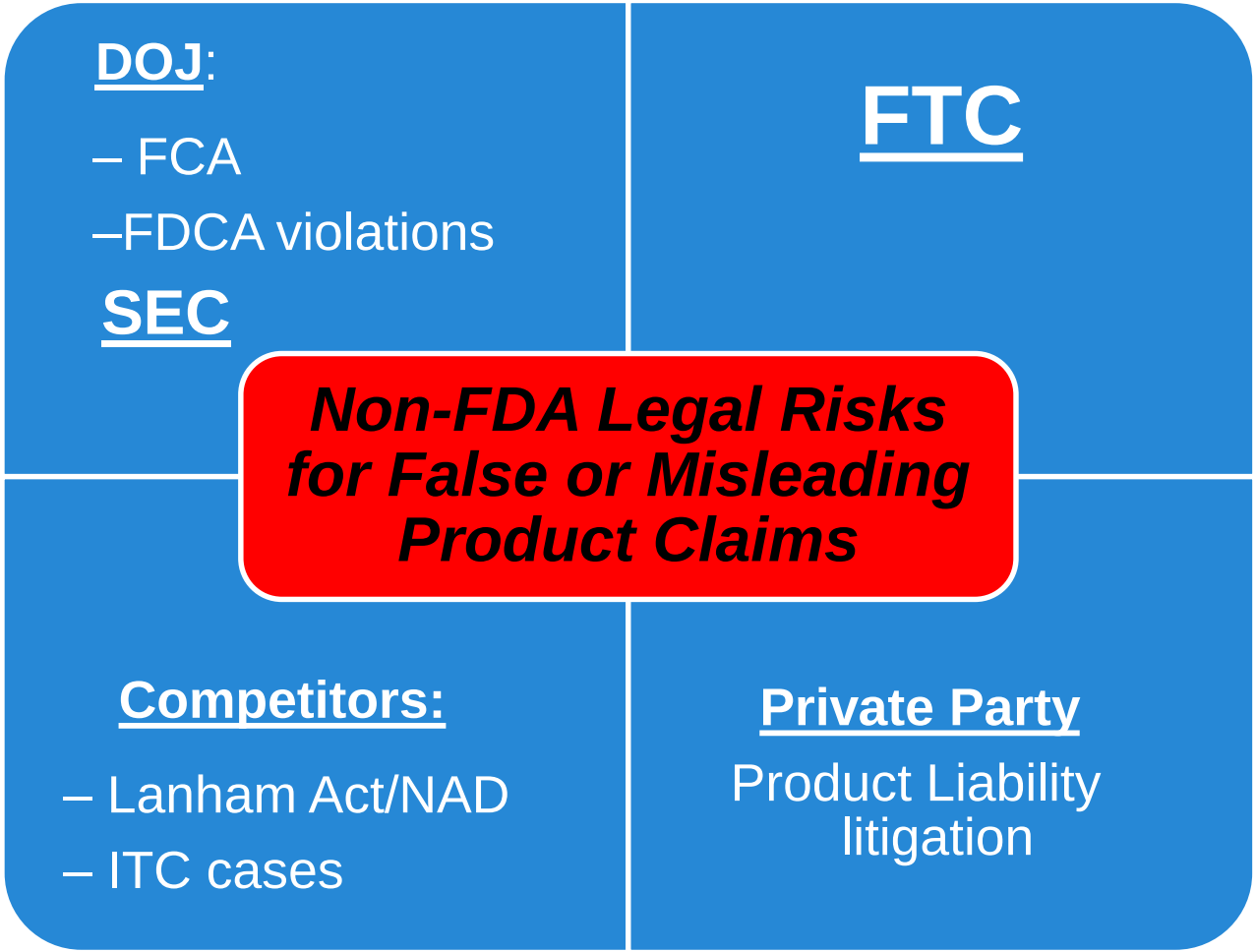
DOJ:
– FCA
–FDCA violations
SEC
FTC
Non-FDA Legal Risks for False or Misleading Product Claims
Competitors:
– Lanham Act/NAD
– ITC cases
Private Party
Product Liability litigation

Promotional Compliance and Liability Risks Beyond FDA

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Advertising and Promotion for Medical Products Conference

Washington, D.C.

October 17, 2018

Richard Cleland

Assistant Director

Division of Advertising Practices

Federal Trade Commission

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FTC Jurisdiction 1971 MOU

- With the exception of prescription drug, the Federal Trade Commission has primary responsibility with respect to the regulation of the truth or falsity of all advertising (other than labeling) of foods, drugs, device, and cosmetics. In the absence of express agreement between the two agencies to the contrary, the Commission will exercise primary jurisdiction over all matters regulating the truth or falsity of advertising of foods, drugs (with the exception of prescription drugs) devices, and cosmetics.

FDA Jurisdiction 1971 MOU

- The Food and Drug Administration has primary responsibility for preventing misbranding of foods, drug, devices, and cosmetics shipped in interstate commerce. The Food and Drug Administration has primary responsibility with respect to the regulation of the truth or falsity of prescription drug advertising. In the absence of express agreement between the two agencies to the contrary, the Food and Drug Administration will exercise primary jurisdiction over all matter regulating the labeling of food, drugs, devices, and cosmetics.

Won’t gang up -- mostly

The initiation of proceeding involving the same parties by both agencies shall be restricted to those highly unusual situations where it is clear that the public interest requires two separate proceedings. For the purpose of avoiding duplication of work and to promote uniformity and consistency of action in areas where both agencies have a concern and the actions of one agency may affect proceedings by the other, it is recognized that such liaison activity is required in instances where: (1) The came, or similar claims are found in both labeling and advertising, (2) Written, printed or graphic material may be construed as either advertising or as accompanying labeling or both, depending upon the circumstances of distribution; (3) The article is a drug or device and appear to be misbranded solely because of inadequacy of directions for use appearing in the labeling for conditions for which the article is offered in advertising generally disseminated to the public.

Statutory Restrictions

"no advertisement of a prescription drug, published after the effective date of regulations issued under this paragraph applicable to advertisements of prescription drugs, shall, with respect to the matters specified in this paragraph or covered under such regulations, be subject to the provisions of sections 12 through 17 of the Federal Trade Commission Act." 21 U.S.C. § 352 (n)(3)(B)

Matters specified

- True statement of established name, ingredients, & brief summary must appear in prescription drug advertising
- Similar provision for restricted medical devices

Summary

- Unlike the statutory exclusions, the MOU confers no rights on businesses
- FDA has jurisdiction over advertising and labeling for prescription drugs and restricted medical devices (which is exclusive as to items that are mandated to be included on the label or advertising by FDA).
- It’s an open question whether this exclusivity applies to other types of promotions, e.g., influencer marketing.

Summary continued

- FDA has jurisdiction over the labeling of non-prescription drugs, devices, foods, and cosmetics.
- FTC has primary authority over the advertising of non-prescription drugs, devices, foods, and cosmetics.
- Most importantly, recognize that some material may constitute both labeling and advertising.

False advertisements, and unfair and deceptive acts and practices

- Unfair methods of competition in or affecting commerce, and unfair or deceptive acts or practices in or affecting commerce, are hereby declared unlawful. 15 U.S.C. § 5(a)(1)
- It shall be unlawful for any person, partnership, or corporation to disseminate, or cause to be disseminated, any false advertisement . . . by any means, for the purpose of inducing, or which is likely to induce, directly or indirectly the purchase of food, drugs, devices, services, or cosmetics. 15 U.S.C. § 52

Definitions

- Deception means a representation or omission of fact that is likely to mislead a consumer acting reasonably under the circumstances, and that representation or omission is material to a consumer's purchasing decision.
- False Advertising means misleading in any material respect.

Drug defined

The term "drug" means (1) articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and (2) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (3) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (4) articles intended for use as a component of any article specified in clause (1), (2), or (3); but does not include devices or their components, parts, or accessories.

Reasonable Basis

- Failure to have a reasonable basis to support an objective claim constitutes a deceptive act and a false advertisement.
- Relevant factors include:
  - the type of claim (health or safety claim?)
  - the product (experience or credence claim?)
  - the consequences of a false claim
  - the benefits of a truthful claim
  - the cost of developing substantiation for the claim
  - the amount of substantiation experts in the field believe is reasonable

Competent and Reliable Scientific Evidence

- As a general principle, objective health benefit claims must be substantiated with Competent and Reliable Scientific Evidence at the time of dissemination.

- Establishment claims (e.g., clinically proven) require the level of evidence that experts in the field would require to demonstrate that the representation is true.

Unreliable and/or Not Competent

- Didn’t distinguish between cold prevention and cold treatment;
- Relied on cellular effects on the immune system (e.g., natural killer cells or t-lymphocytes);
- Relied on supplementation studies when products were not promoted for daily use;
- Relied on studies using different methods of administration;
- No statistical analysis and data not available;
- Failed to identify inclusion criteria;

- Relied on use under non-representative circumstances (ultra-marathon runners);
- Relied on studies not adequately blinded;
- Study enrolled wrong population;
- Relied on subjects' self-reported cold and flu experiences during the previous winter season as its baseline.
- No clinical evaluations to confirm the subjects' self-diagnosed reports; and
- Used invalidated measurements.

Influencer Marketing

- An endorsement must reflect the honest opinions, findings, beliefs, or experience of the endorser.
- An endorsement may not convey any express or implied representation that would be deceptive if made directly by the advertiser.
- Advertisers are subject to liability for false or unsubstantiated statements made through endorsements, or for failing to disclose material connections between themselves and their endorsers.
- Endorsers also may be liable for false or misleading statements made in the course of their endorsements.
- Guides Concerning Use of Endorsements and Testimonials, 16 CFR Ch. 255, available at https://www.ftc.gov/sites/default/files/documents/federal_register_notices/guides-concerning-use-endorsements-and-testimonials-advertising-16-cfr-part-255/091015guidesconcerningtestimonials.pdf

Material Connections

- An unexpected relationship between an endorser and an advertiser that could affect the credibility of the endorsement from the perspective of the viewer must be disclosed.
  - Examples of such connections include:
  - Seller is compensating endorser;
  - Endorser is an employee or business associate of seller;
  - Endorser is related to seller;
  - Endorser is entered in sweepstakes;
  - Endorser gets free products.

Celebrity Endorsements

- In conventional ads, it's not necessary for an ad to disclose that a celebrity is being paid, because in that context payment would be understood.

- Outside of conventional ads (on talk shows, social networking sites): the relationship with the advertiser should be disclosed when a celebrity talks up a product because payment isn't obvious in that context.

Your Responsibility

- Ensure “influencers” receive guidance/training about need to ensure statements are truthful/substantiated; and

- Monitor “influencers” and take steps to halt continued publication of deceptive claims when discovered.

Contact Information

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Recent DOJ Enforcement Actions Involving Drug and Device Promotion

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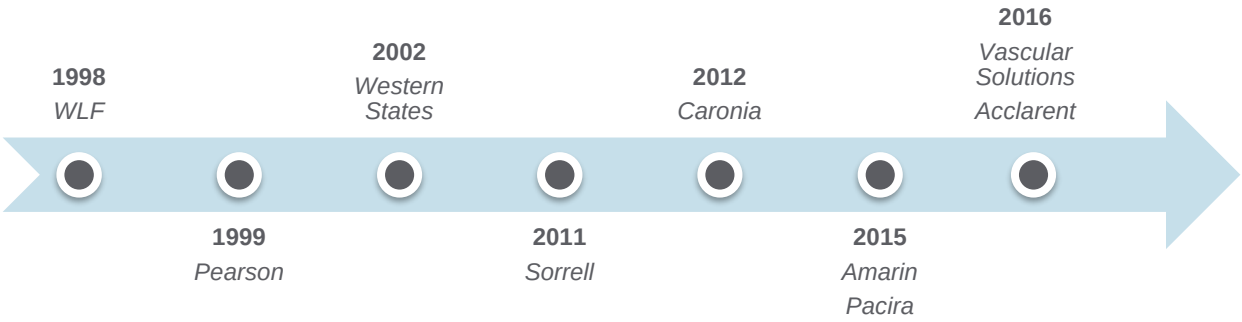
Major Developments Impacting DOJ Enforcement of FDA Promotional Rules

1st Amendment Cases – Over Time – Has Barred the Gov't from Prosecuting Truthful, Non-Misleading Speech



Amarin (2015)

Although the "First Amendment does not protect false or misleading commercial speech," when the "speech at issue consists of truthful and non-misleading speech promoting the off-label use of an FDA-approved drug, such speech … *cannot* be the act upon which an action for misbranding is based." Amarin Pharma Inc. v. FDA, 119 F.Supp.3d 196, 226-28 (S.D.N.Y 2015)

Vascular Solutions (2016)

"It is … not a crime for a … company or its representatives to give doctors wholly truthful and non-misleading information about the unapproved use of [its FDA-regulated product." Final Jury Instructions at 12, Vascular Solutions, No. 5:14-CR-00926-RCL, ECF 282

DOJ Policy Changes Impact Drug and Device Enforcement

Deputy Assistant Attorney General Ethan P. Davis Delivers Remarks to the Food and Drug Law Institute Enforcement, Litigation, and Compliance Conference

Washington, DC ~ Thursday, December 7, 2017

So when a new investigation or a potential indictment crosses my desk, I ask myself, and my team, a few questions: Is this a case where people got hurt, or where there was a clear threat of harm? Is this a case where people got defrauded? Is this a case where the target of the investigation acted knowingly or recklessly? If the answer to those questions is "yes," we will pursue the matter vigorously in the name of protecting the health, safety, and economic security of the American consumer.

The point of this exercise is to weed out technical regulatory violations in order to focus our enforcement resources on practices that threaten consumer health or safety. These considerations mirror the principles governing all Department of Justice enforcement actions, which require us to evaluate the nature and seriousness of an offense and the deterrent effect of an enforcement action.

DOJ Policy Changes (cont'd)

Skadden

MEMORANDUM FOR: HEADS OF CIVIL LITIGATING COMPONENTS
UNITED STATES ATTORNEYS

CC: REGULATORY REFORM TASK FORCE

January 25, 2018

FROM: THE ASSOCIATE ATTORNEY GENERAL RBG

SUBJECT: Limiting Use of Agency Guidance Documents
In Affirmative Civil Enforcement Cases

The Guidance Policy also prohibits the Department from using its guidance documents to coerce regulated parties into taking any action or refraining from taking any action beyond what is required by the terms of the applicable statute or lawful regulation. And when the Department issues a guidance document setting out voluntary standards, the Guidance Policy requires a clear statement that noncompliance will not in itself result in any enforcement action.

The principles from the Guidance Policy are relevant to more than just the Department's own publication of guidance documents. These principles also should guide Department litigators in determining the legal relevance of other agencies' guidance documents in affirmative civil enforcement ("ACE").[1]

"Affirmative civil enforcement" refers to the Department's filing of civil lawsuits on behalf of the United States to recover government money lost to fraud or other misconduct or to impose penalties for violations of Federal health, safety, civil rights or environmental laws. For example, this memorandum applies when the Department is enforcing the False Claims Act, alleging that a party knowingly submitted a false claim for payment by falsely certifying compliance with material statutory or regulatory requirements.

Recent DOJ Enforcement Actions Reflecting These Trends

Promotional Enforcement Now Focused on Patient Health and Safety Issues

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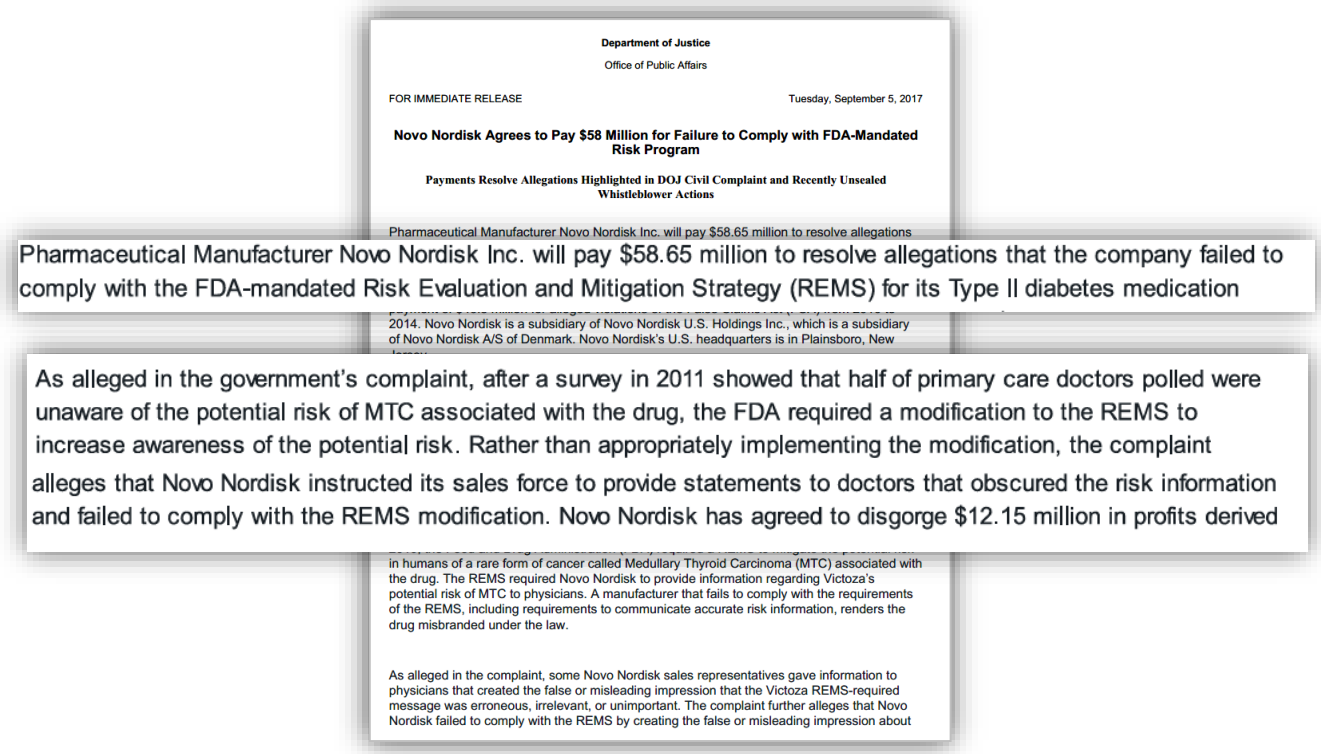
Novo Nordisk Agrees to Pay $58 Million for Failure to Comply with FDA-Mandated Risk Program

Payments Resolve Allegations Highlighted in DOJ Civil Complaint and Recently Unsealed Whistleblower Actions

Pharmaceutical Manufacturer Novo Nordisk Inc. will pay $58.65 million to resolve allegations that the company failed to comply with the FDA-mandated Risk Evaluation and Mitigation Strategy (REMS) for its Type II diabetes medication Victoza, the Justice Department announced today. The resolution includes disgorgement of $12.15 million for alleged violations of the Federal Food, Drug, and Cosmetic Act (FDCA) from 2010 to 2012 and a payment of $46.5 million for alleged violations of the False Claims Act (FCA) from 2010 to 2014. Novo Nordisk is a subsidiary of Novo Nordisk U.S. Holdings Inc., which is a subsidiary of Novo Nordisk A/S of Denmark. Novo Nordisk's U.S. headquarters is in Plainsboro, New Jersey.

As alleged in the government's complaint, after a survey in 2011 showed that half of primary care doctors polled were unaware of the potential risk of MTC associated with the drug, the FDA required a modification to the REMS to increase awareness of the potential risk. Rather than appropriately implementing the modification, the complaint alleges that Novo Nordisk instructed its sales force to provide statements to doctors that obscured the risk information and failed to comply with the REMS modification. Novo Nordisk has agreed to disgorge $12.15 million in profits derived from its unlawful conduct in violation of the FDCA.

Promotional Focus (cont'd)



Department of Justice

Office of Public Affairs

FOR IMMEDIATE RELEASE Tuesday, September 5, 2017

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in humans of a rare form of cancer called Medullary Thyroid Carcinoma (MTC) associated with the drug. The REMS required Novo Nordisk to provide information regarding Victoza's potential risk of MTC to physicians. A manufacturer that fails to comply with the requirements of the REMS, including requirements to communicate accurate risk information, renders the drug misbranded under the law.

As alleged in the complaint, some Novo Nordisk sales representatives gave information to physicians that created the false or misleading impression that the Victoza REMS-required message was erroneous, irrelevant, or unimportant. The complaint further alleges that Novo Nordisk failed to comply with the REMS by creating the false or misleading impression about

Promotional Focus (cont'd

Skadden

Department of Justice

Office of Public Affairs

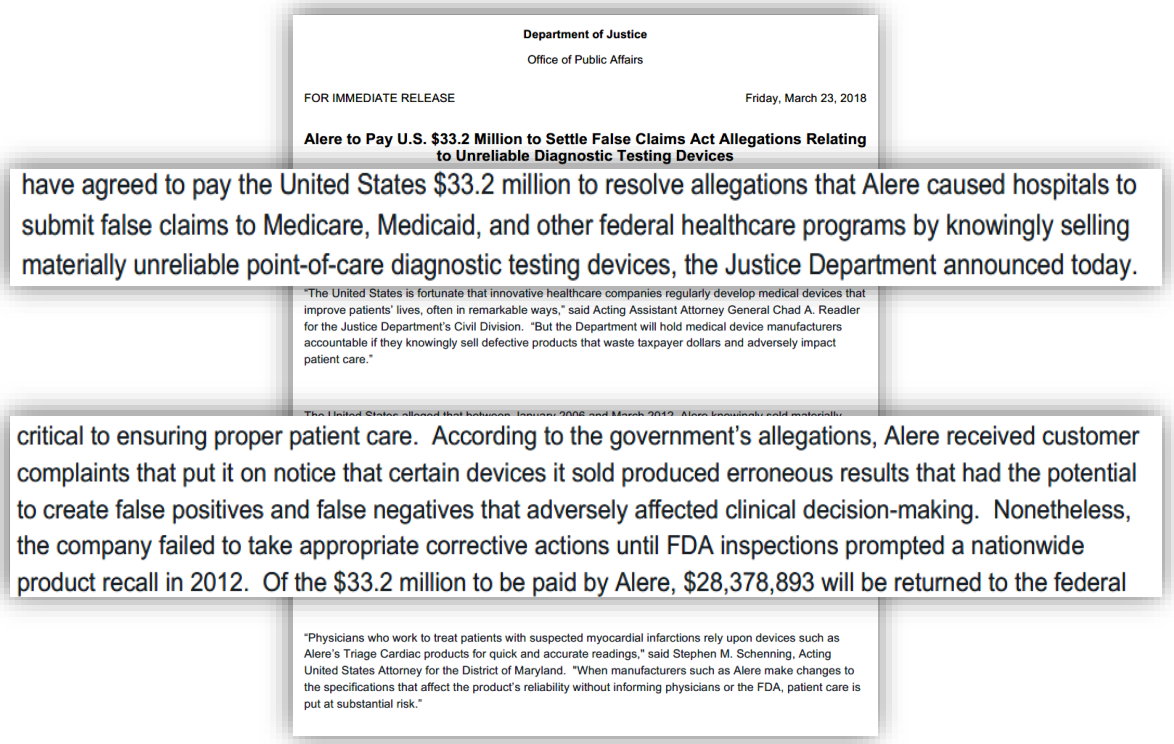
FOR IMMEDIATE RELEASE

Friday, September 22, 2017

Drug Maker Aegerion Agrees to Plead Guilty; Will Pay More Than $35 Million to Resolve Criminal Charges and Civil False Claims Allegations

As charged in a criminal information filed today, Aegerion introduced Juxtapid into interstate commerce that was misbranded because, among other things, Aegerion failed to comply with a Risk Evaluation and Mitigation Strategy (REMS). The resolution also includes a deferred prosecution agreement relating to criminal liability under the Health Insurance Portability and Accountability Act of 1996 (HIPAA). In addition, Aegerion has agreed to settle allegations that it caused false claims to be submitted to federal health care programs for Juxtapid. Aegerion has agreed to pay more than $35 million to resolve criminal and civil liability arising from these matters. Aegerion has also agreed to enter into a civil consent decree of permanent injunction aimed at preventing future violations of the Federal Food, Drug, and Cosmetic Act (FDCA).

Focus on Patient Health and Safety



Department of Justice

Office of Public Affairs

FOR IMMEDIATE RELEASE

Friday, March 23, 2018

Alere to Pay U.S. $33.2 Million to Settle False Claims Act Allegations Relating to Unreliable Diagnostic Testing Devices

have agreed to pay the United States $33.2 million to resolve allegations that Alere caused hospitals to submit false claims to Medicare, Medicaid, and other federal healthcare programs by knowingly selling materially unreliable point-of-care diagnostic testing devices, the Justice Department announced today.

"The United States is fortunate that innovative healthcare companies regularly develop medical devices that improve patients' lives, often in remarkable ways," said Acting Assistant Attorney General Chad A. Readler for the Justice Department's Civil Division. "But the Department will hold medical device manufacturers accountable if they knowingly sell defective products that waste taxpayer dollars and adversely impact patient care."

critical to ensuring proper patient care. According to the government's allegations, Alere received customer complaints that put it on notice that certain devices it sold produced erroneous results that had the potential to create false positives and false negatives that adversely affected clinical decision-making. Nonetheless, the company failed to take appropriate corrective actions until FDA inspections prompted a nationwide product recall in 2012. Of the $33.2 million to be paid by Alere, $28,378,893 will be returned to the federal

"Physicians who work to treat patients with suspected myocardial infarctions rely upon devices such as Alere's Triage Cardiac products for quick and accurate readings," said Stephen M. Schenning, Acting United States Attorney for the District of Maryland. "When manufacturers such as Alere make changes to the specifications that affect the product's reliability without informing physicians or the FDA, patient care is put at substantial risk."

Concluding Thoughts

Skadden

- Sweeping enforcement actions focused on general off-label promotion are unlikely absent a major DOJ win in the courts and/or changes in DOJ policy

- Current focus is on false and/or misleading statements where there is actual or patient for risk to patient health or safety

- Companies should pay particular attention to:
  - Compliance with REMS or similar obligations
  - Heightened attention to promotional messaging for products with boxed warnings or other significant risks (e.g., opioids, other controlled substances)
  - Adequate presentation of risk information

Speaker Biography

Skadden

John Bentivoglio is a Washington, DC, Partner with Skadden, Arps, Slate, Meagher & Flom LLP where represents pharmaceutical, medical device and biotechnology manufacturers in investigations by various U.S. attorney's offices, the Criminal and Civil Divisions of the U.S. Department of Justice, and state attorneys general and has negotiated several corporate integrity agreements. He also regularly advises life sciences companies on FDA and health care regulatory issues. Mr. Bentivoglio has extensive experience developing, implementing and assessing compliance programs in line with the U.S. Sentencing Commission and HHS OIG guidelines.

From 1997-2000, he served as Associate Deputy Attorney General and Special Counsel for Health Care Fraud at DOJ. From 1996-1997, he was a special assistant to the assistant attorney general, Criminal Division. Earlier in his career, Mr. Bentivoglio served as a professional staff member to Sen. Joseph R. Biden Jr., chairman, Committee on the Judiciary.

Mr. Bentivoglio repeatedly has repeatedly been selected for inclusion in *Chambers USA: America's Leading Lawyers for Business* and *The Best Lawyers in America*.

In his spare time, John serves on the Board of Directors of the Children's Law Center and as a volunteer firefighter/EMT with the Bethesda-Chevy Chase Rescue Squad.

Liability Risks Beyond the FDA: Mass-Tort Litigation

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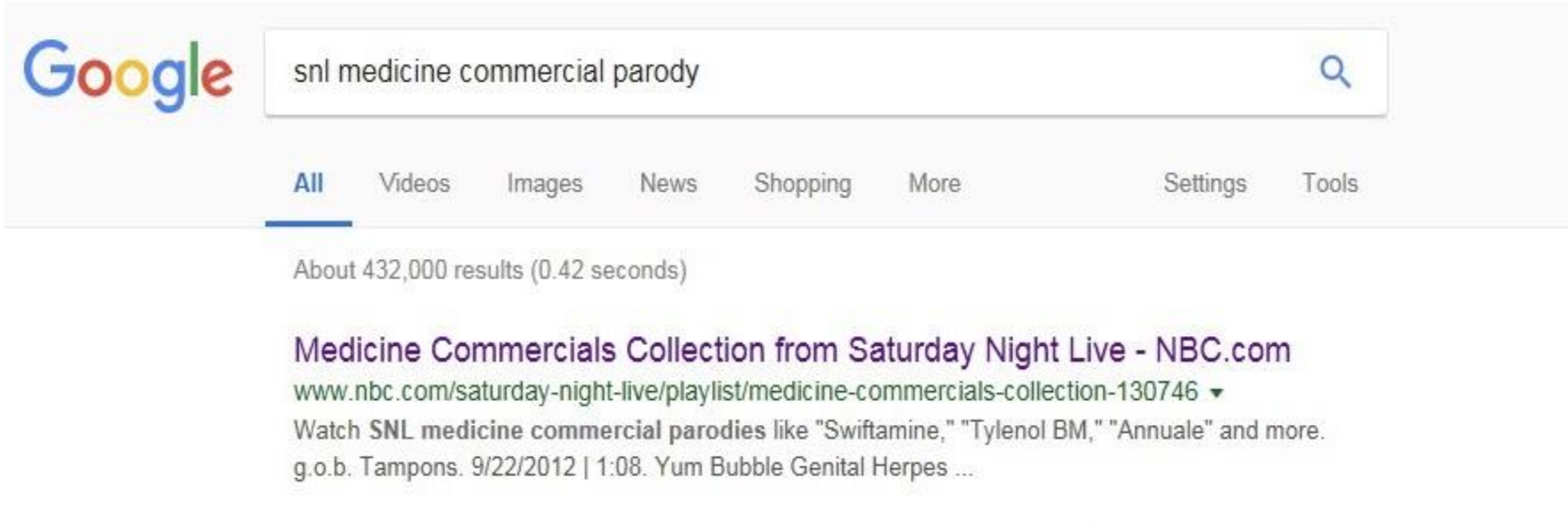
How Mainstream Is Promotional Activity?



Claims Related to Promotional Activity

- Failure to Warn
- Negligent / Fraudulent Misrepresentation
- Negligent / Fraudulent Concealment
- Consumer Protection / Deceptive Trade Practices

What are These Claims Saying?

- Led patients, physicians to believe the product was **safe and effective**
- Fraudulently promoted the products to increase user demand **without regard to risks**
- Hid or fraudulently **misrepresented the true risks** of using the product to patients, physicians
- Promoted off-label for **indications and usage not approved** by the FDA

The Story Plaintiffs Tell

Common Promotional Activities at Issue in Mass Torts

- Brochures for Physicians
- Sales Representative Education
  - Sales meeting minutes, instructions to sales rep trainers, guidance on verbatims
- Speaker Programs & Promotional Dinners
- Relationships with Medical Associations

How Does This Play Out in Litigation?

Sales Representative Training Guides

- “[Injury] is an obstacle to sales”
- “Only use the verbatim if a physician asks about [injury] and if not, Sell, Sell, Sell!”
- “[Company] has struggled with [injury] safety issues” and the medication was “misperceived to be the least safe” of its class

Off-Label Promotion

- FDA Untitled Letters
  - Informal, advisory warnings
  - Still can come into evidence if a plaintiff's usage was not entirely on-label
- Opens the door to other company documents about off-label promotion

Other Promotional Activity

- Speaker Programs
  - Cozy communications between company professional strategies personnel and KOLs
- Medical Associations
  - Financial support = favorable treatment

Takeaways

- Put your plaintiffs' counsel hat on
  - Does the promotional material make light of a serious condition in a way that could backfire?
  - Could the content be used to suggest profits over safety?
  - If an everyday person were to view the piece or the correspondence, how would they perceive the company?

- Don't assume drafts / emails won't see the light of day

Lanham Act and Related Issues

- **Lanham Act**: “Any person who…uses in commerce any…false or misleading description of fact, or false or misleading representation of fact, which…in commercial advertising or promotion, misrepresents the nature, characteristics, qualities, or geographic origin of his or her or another person’s goods, services, or commercial activities, shall be liable in a civil action by any person who believes that he or she is or is likely to be damaged by such act.” Lanham Act § 43(a) (15 U.S.C. § 1125(a)).
- **FDCA**: “A drug or device shall be deemed misbranded – if its labeling is false or misleading in any particular.” FDCA § 502(a) (21 U.S.C. § 352(a)).
- **State False Advertising Laws:** (e.g., California BPC § 17200): “unfair competition shall mean and include any unlawful, unfair or fraudulent business act or practice and unfair, deceptive, untrue or misleading advertising….”

Limitations on Alternative Causes of Action

- Lanham Act limited to use by competitors (*not* a consumer protection law)
  - For Rx branded/patented products, direct competitors may not exist
    - *Comparative advertising or advertising within a crowded product class more likely to face challenges*
  - Once genericized, branded drug advertising may cease, but generics would benefit from aggressive brand advertising anyway
- Courts/juries ill-suited to evaluate complex medical/scientific advertising claims
- State laws may be *preempted* by the FDCA
- Other causes of action may be *precluded* by the FDCA and FDA policy
- NAD proceedings are voluntary, non-binding, and unpredictable

Preemption/Preclusion of False Advertising Cases

- **FDCA, 21 U.S.C. § 337** "Except as provided in subsection (b), all…proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States…."
  - *["Subsection (b)" allows states to enforce some FDCA food violations]*
- **Supreme Court (2014)**:
  - "Neither the Lanham Act nor the FDCA, in express terms, forbids or limits Lanham Act claims challenging labels that are regulated by the FDCA."

BUT, food promotion may be different than drugs or devices:

  - "A holding that the FDCA precludes Lanham Act claims challenging food and beverage labels…would lead to a result that Congress likely did not intend. Unlike other types of labels regulated by the FDA, such as drug labels,…FDA does not preapprove food and beverage labels under its regulations and instead relies on enforcement actions, warning letters, and other measures."

Preemption/Preclusion of False Advertising Cases

- **Second Circuit (2016)**: for prescription drug advertising, "representations that are commensurate with information in an FDA label generally cannot form the basis for Lanham Act liability."

But….

- "Lanham Act liability might arise if an advertisement uses information contained in an FDA-approved label that does not correspond substantially to the label or otherwise renders the advertisement literally or implicitly false."

- **FDA CWL Guidance (2018)**: "if a firm communicates information that is not contained in its product's FDA-required labeling but that is determined to be consistent with the FDA-required labeling, FDA does not intend to rely on that communication to establish a new intended use."

Preemption/Preclusion of False Advertising Cases

- The courts' analyses of whether preclusion applies seemingly depend on whether, if a court were to rule on an advertising claim, it would create a potential conflict with FDA's regulatory role and its relevant "policy judgments" for the product or category.
- Lanham Act actions are available for food advertising because FDA does not pre-review or approve any performance claims (but does have baseline labeling requirements)
- Lanham Act actions may not be available for prescription drug advertising, even beyond the approved labeling, because FDA does pre-review and approve *some, but not all,* performance claims.
- *Is this basis of differentiation sustainable?*

International Trade Commission Cases

- The ITC has authority to ban importation of products under section 337 of the Tariff Act based on “[u]nfair methods of competition and unfair acts in the importation of articles.”
- Most ITC cases involve alleged patent infringement, but in at least 2 cases, complainants have sought exclusion orders based on allegedly violative advertising and/or labeling claims.
- The ITC has twice declined to institute an investigation on preclusion grounds – i.e., that to do so would usurp FDA’s regulatory authority. One denial still on appeal at Federal Circuit.
- While ITC jurisdiction is limited to imported products, its cases are highly expedited and its remedy is powerful. If a clear false advertising pathway is opened up, ITC may become a popular venue for some advertising challenges.

Securities Law Issues

- Public companies required to file annual, quarterly, and periodic reports
- SEC reports and IPO filings require extensive financial projections and regulatory risk factors
- Risk disclosures, descriptions of regulatory prospects, and financial projections based on false or misleading product claims may lead to securities law enforcement actions.

Q & A