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Enforcement, Litigation, and Compliance Conference

December 7-8, 2016
Washington, DC

# Trends in Litigation

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# TRENDS IN LITIGATION

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# FILING TRENDS


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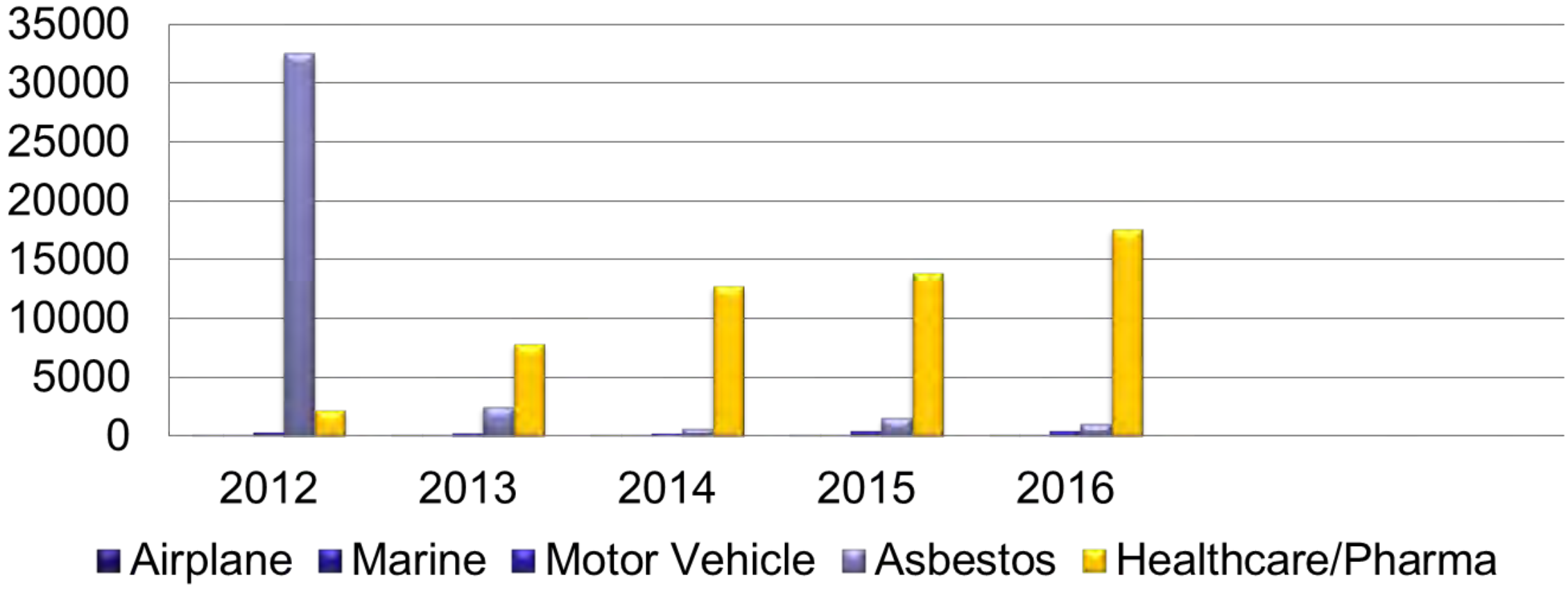
# Product Liability Cases in Federal Courts

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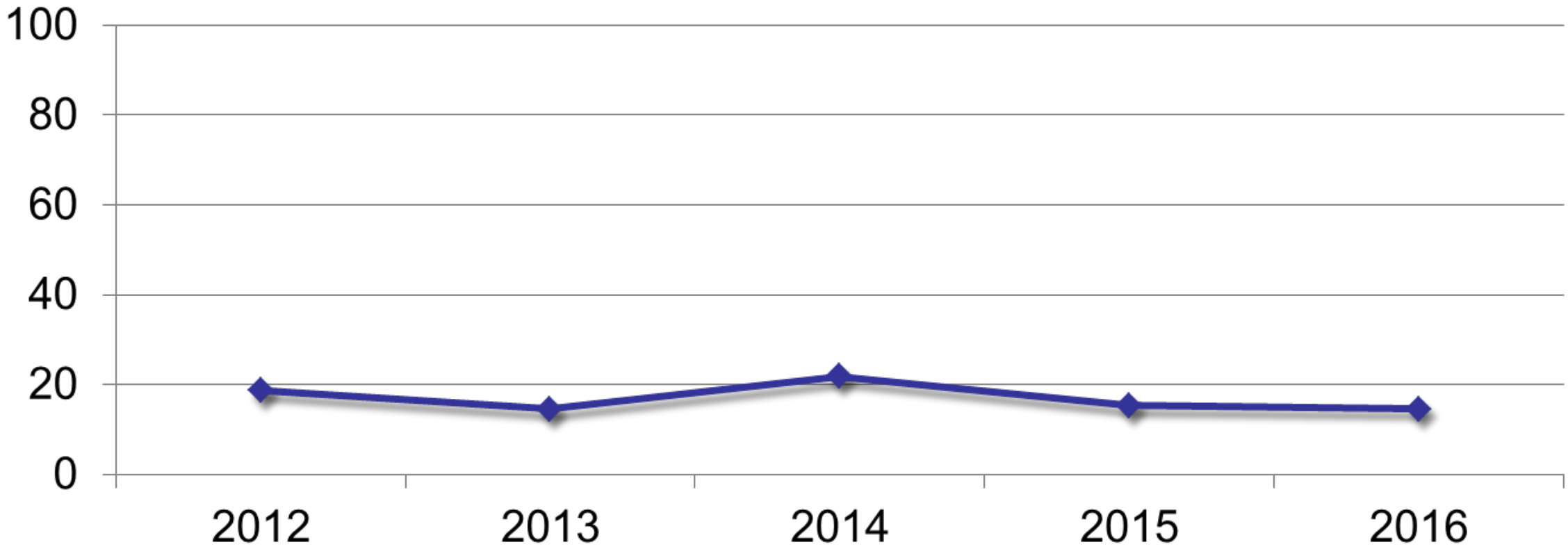
# Product Liability Cases as a Percentage of New Filings

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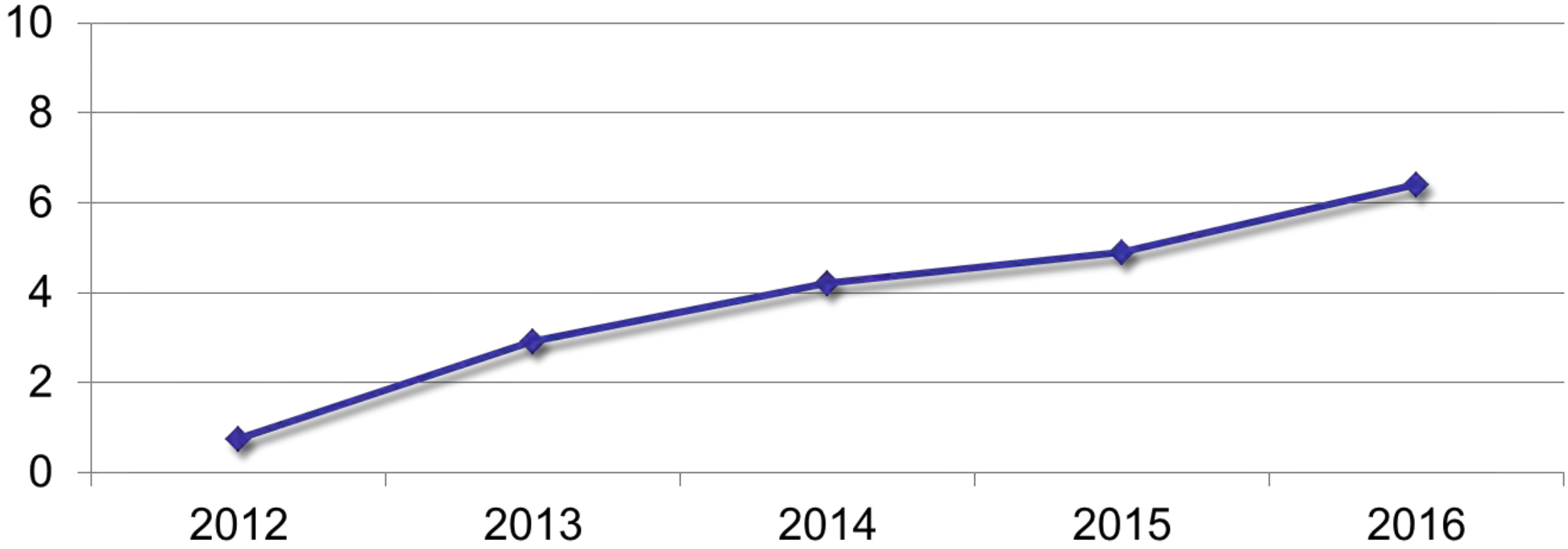
# Healthcare/Pharma as a Percentage of New Filings

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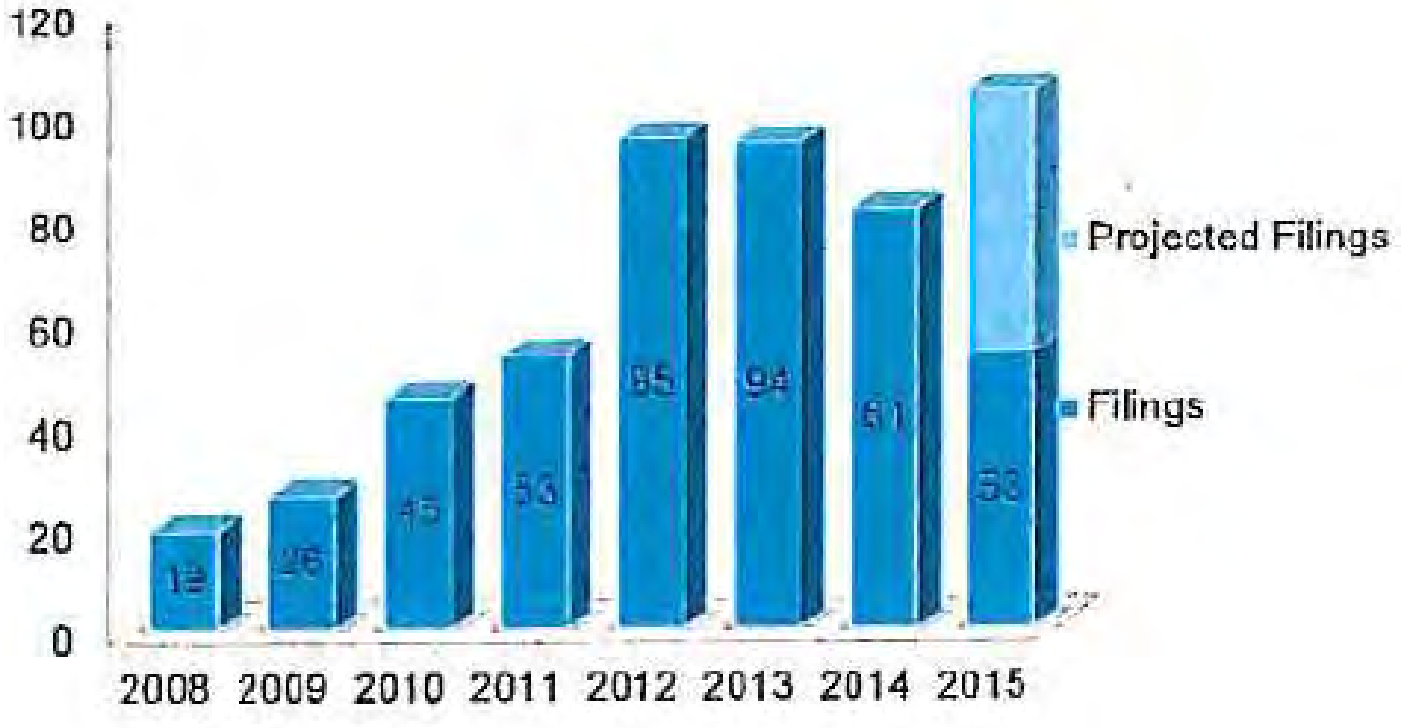
# Food and Beverage Class Actions

## Number of Filings




**2015 FILINGS AS OF AUGUST**

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# Outcomes So Far

**Multi-million dollar settlements, pre and post certification**

- **$35 million settlement (Dannon Yogurt, Activia)**
- **$8.5 million settlement (*Johnson v. General Mills Inc.*)**
- **$6.1 million settlement, $1.83 million to Plaintiff counsel (Cargill, stevia processing claim)**

- **True Battlefield – Class Certification**

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# Recent Targeted Claims

- 100% Natural/ GMOs
- Trans Fat/ PHOs
- Health Claims
- Slack Fill
- Processing
- Premium
- Made with
- Made in USA
- Nutrient Content Claims
- Product Testing
- Added Sugar
- Competitor Suits







# What's Next?

## Use Undefined terms with Caution:

Original
Classic
Authentic
Traditional
Wholesome
Green
Pure
Smart Choice
Added Sugar


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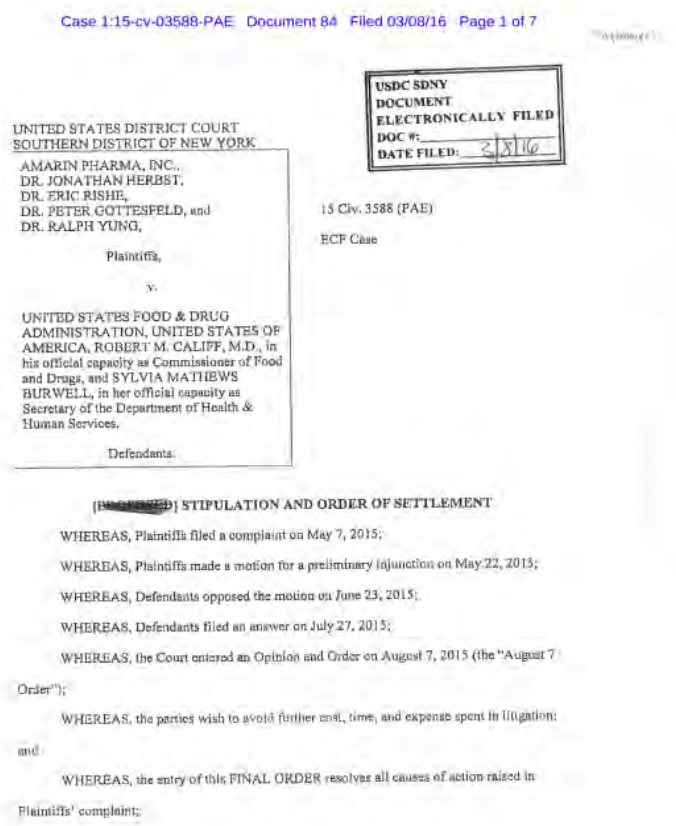
# SELECTED TRENDS IN ADVERTISING AND PROMOTION OFF-LABEL PROMOTION – THE *AMARIN* SETTLEMENT



Case 1:15-cv-03588-PAE Document 84 Filed 03/08/16 Page 1 of 7

USDC SDNY
DOCUMENT
ELECTRONICALLY FILED
DOC #:
DATE FILED: 3/8/16

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

AMARIN PHARMA, INC.,
DR. JONATHAN HERBST,
DR. ERIC RISHE,
DR. PETER GOTTESFELD, and
DR. RALPH YUNG,

Plaintiffs,

v.

UNITED STATES FOOD & DRUG ADMINISTRATION, UNITED STATES OF AMERICA, ROBERT M. CALIFF, M.D., in his official capacity as Commissioner of Food and Drugs, and SYLVIA MATHEWS BURWELL, in her official capacity as Secretary of the Department of Health & Human Services,

Defendants.

15 Civ. 3588 (PAE)

ECF Case

[PROPOSED] STIPULATION AND ORDER OF SETTLEMENT

WHEREAS, Plaintiffs filed a complaint on May 7, 2015;

WHEREAS, Plaintiffs made a motion for a preliminary injunction on May 22, 2015;

WHEREAS, Defendants opposed the motion on June 23, 2015;

WHEREAS, Defendants filed an answer on July 27, 2015;

WHEREAS, the Court entered an Opinion and Order on August 7, 2015 (the "August 7 Order");

WHEREAS, the parties wish to avoid further cost, time, and expense spent in litigation; and

WHEREAS, the entry of this FINAL ORDER resolves all causes of action raised in Plaintiffs' complaint;

# SELECTED TRENDS IN ADVERTISING AND PROMOTION OFF-LABEL PROMOTION – THE *AMARIN* SETTLEMENT (cont'd.)

- Vascepa approved to treat "very high" triglycerides
- Amarin sought to disclose truthful, non-misleading information to doctors that Vascepa could also be used to treat patients with "high" triglycerides
- August 17, 2016 – PI prohibiting FDA from taking action against Amarin over truthful, non-misleading "off-label" statements about its prescription drug Vascepa
- March 8, 2016 – Parties filed proposed settlement, subsequently approved by court

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# SELECTED TRENDS IN ADVERTISING AND PROMOTION OFF-LABEL PROMOTION – THE *AMARIN* SETTLEMENT (cont'd.)

- FDA agree to be bound by the Court's decision
- Amarin may engage in truthful and non-misleading speech promoting off-label use of Vascepa
- Statements Amarin proposed to make to doctors are truthful and non-misleading
- Amarin bears the responsibility of assuring that its communications to doctors remain truthful and non-misleading
  - Optional preclearance procedures for new claims until 2020
  - Amarin may submit proposed communications to FDA
  - Settlement includes the timeline and procedure for resolving any dispute
  - FDA may contact doctors after the identification of a dispute

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# SELECTED TRENDS IN ADVERTISING AND PROMOTION OFF-LABEL PROMOTION – THE *AMARIN* SETTLEMENT (cont'd.)

- FDA now has agreed that a particular manufacturer may engage in truthful, non-misleading promotion about off-label uses
- Note FDA previously issued scientific and medical publications guidance
- Determining whether off-label promotion truthful and non-misleading poses challenges, so overall effect may be limited
- Special preclearance procedure has its challenges

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# SELECTED TRENDS IN ADVERTISING AND PROMOTION OFF-LABEL PROMOTION – THE *AMARIN* SETTLEMENT (cont'd.)

- Whether FDA has changed its position more generally remains to be seen
  - FDA has stated it accepts outcome only for this specific case
  - FDA has engaged in significant enforcement in the past
  - FDA likely would argue *Amarin* case limited to its facts (as they did about *Caronia*)
- But some attorneys have noted change in approach by DOJ
- Likely litigation approach now will be intense focus on facts of each
- Likely regulatory approach will be increased requests for preclearance of promotional materials
- Effect of New Administration

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# SELECTED TRENDS IN ADVERTISING AND PROMOTION NATIONAL ADVERTISING DIVISION OF THE BBB


- Advertising Self-Regulatory Council (ASRC) and Council of Better Business Bureaus (CBBB)
- NAD reviews complaints filed by competitors for substantiation
- NAD also monitors advertising
- NAD process involves briefing and formal meeting, but no discovery
- NAD process voluntary, but NAD can and will refer cases to agencies (FTC, FDA)
- NAD process confidential until publication of decision
- NAD created new procedure this year for case closure by settlement

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# SELECTED TRENDS IN ADVERTISING AND PROMOTION NATIONAL ADVERTISING DIVISION OF THE BBB (cont'd)

- NAD cases involve wide variety of industries
- Many cases involve more simple consumer claims ("How soft is the Charmin, really?)
- But many NAD cases often involve claims relating to food, dietary supplements, and medical devices
- Relatively few NAD cases involve complex therapeutics
- NAD decisions reported on NAD database and closely monitored by industry

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# SELECTED TRENDS IN ADVERTISING AND PROMOTION NATIONAL ADVERTISING DIVISION OF THE BBB (cont'd)

- NAD will review clinical claims and their substantiation by clinical studies
- "Establishment Claims" – Claims that a fact has been scientifically proven
- 2016 Case Example
  - "Clinically proven to be safe and effective" and Clinical trials showed … significant increases in joint comfort, mobility, and flexibility"
  - Single double-blind, placebo-controlled study, showed mixed scores by participants
  - Settlement includes the timeline and procedure for resolving any dispute
  - NAD recommended claims be narrowed, and "clinically proven" be removed

# SELECTED TRENDS IN ADVERTISING AND PROMOTION NATIONAL ADVERTISING DIVISION OF THE BBB (cont'd)

- "Comparison Claims" – Claims that one product achieves a better result than another
- 2016 Case Example
  - "superior comfort"
  - "keeps [product] moist for longer"
  - NAD found combination of clinical study and consumer preference study supported former, but not latter

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# SELECTED TRENDS IN ADVERTISING AND PROMOTION NATIONAL ADVERTISING DIVISION OF THE BBB (cont'd)

- NAD generally requires head-to-head comparison studies for comparison claims
- NAD has limited resources for highly scientific analyses
- NAD often tends to find implied claims
- NAD cases dot not include discovery or expert reports/testimony
- Unique strategic and tactical considerations for both the challenger and the competitor
  - May be quick inexpensive way to get competitor to change promotion
  - Although voluntary, potential consequences for not participating
  - Often even if challenger wins, relatively narrow changes can be made
  - If challenger wins, outcome is reported, but also with statement by competitor

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# *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001)

- State fraud-on-the-FDA claims are **impliedly preempted** by federal law
- Relationship between FDA and regulated entity is inherently federal because the relationship originates with, is governed by, and terminates according to federal law
- "The conflict stems from the fact that the federal statutory scheme amply empowers the FDA to punish and deter fraud against the agency, and that the authority is used by the Agency to achieve a somewhat delicate balance of statutory objectives."
- Concern that state tort law could upset that balance and fear of liability will drive content of submissions to FDA

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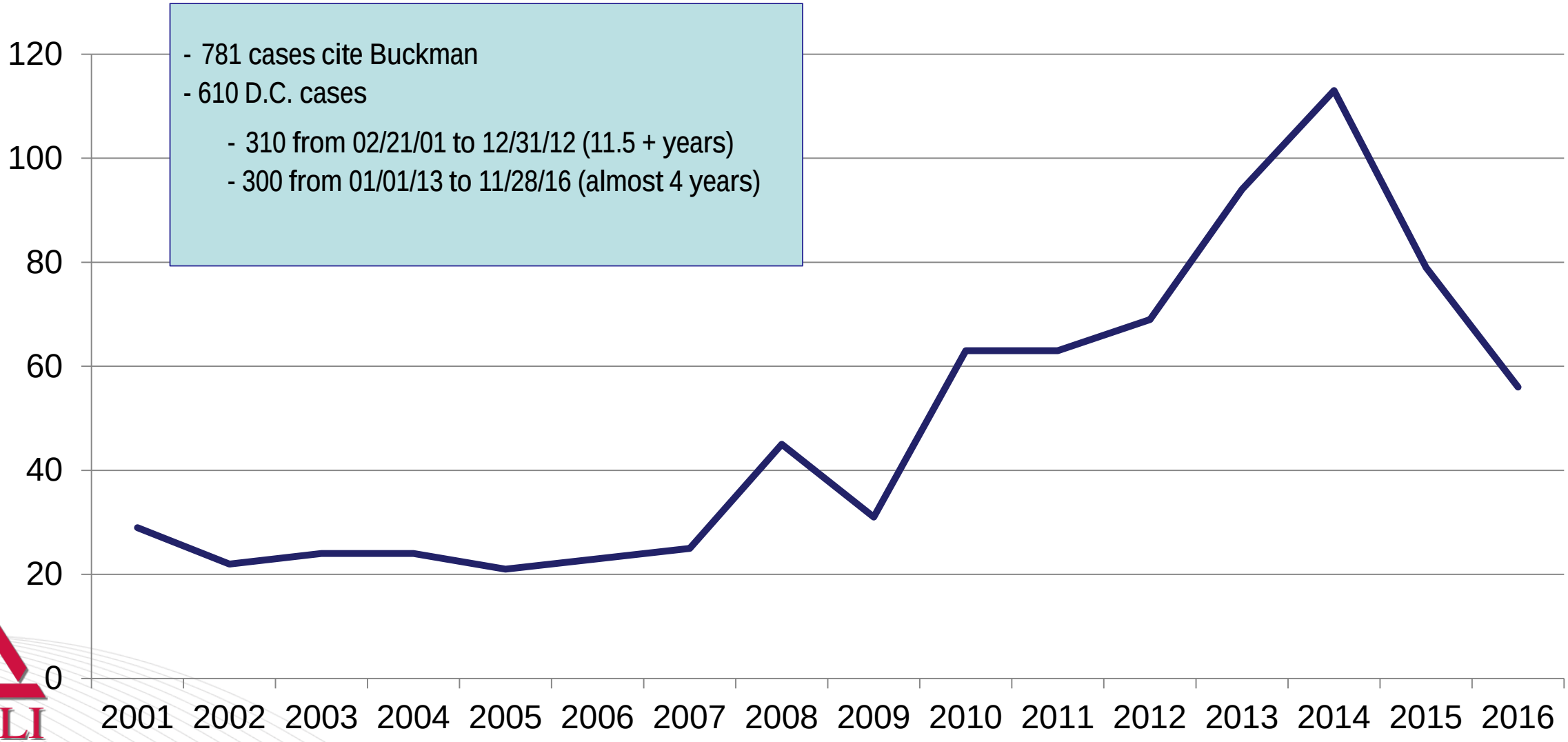
# *Buckman* Citations Over Time

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# Recent FDA Activity & Reporting


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# What to Watch:  Online Reporting Tools


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# What to Watch: Online Reporting Tools


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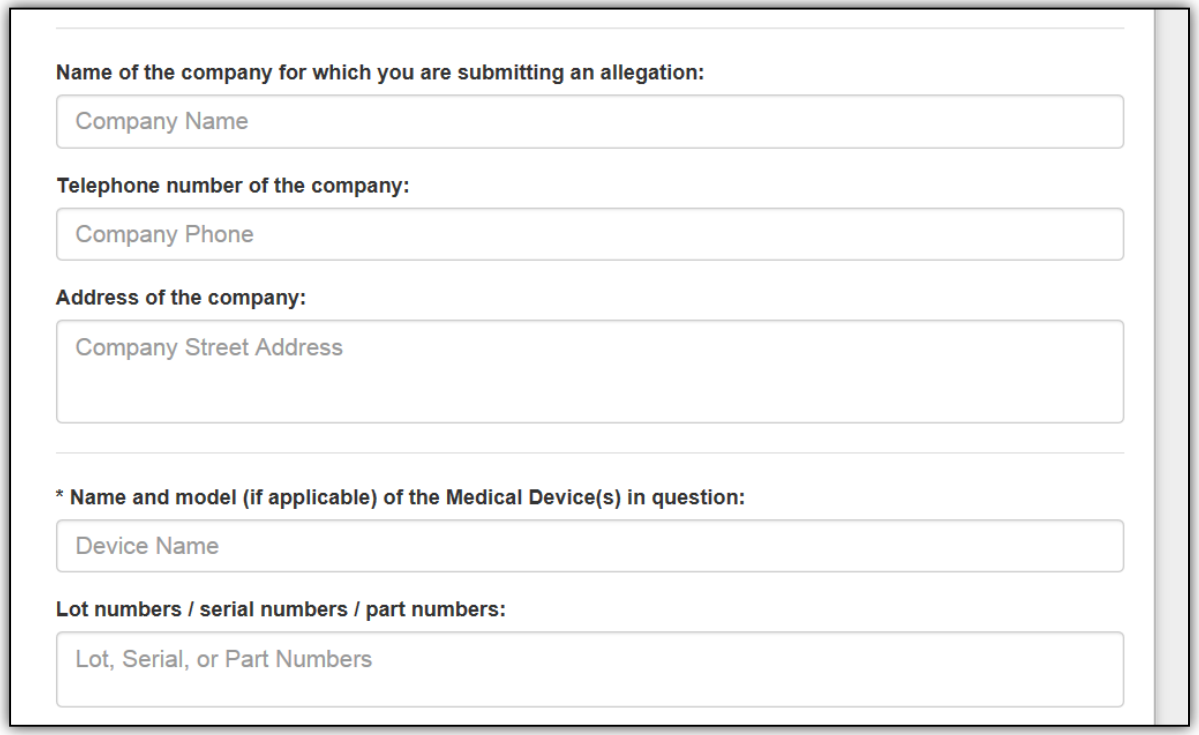
# What to Watch: Online Reporting Tools

## Allegations of Regulatory Misconduct Form





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# Food – FDA Reportable Food Registry

Responsible Parties Must Affirmatively Report:

- When there is “reasonable probability that use of/or exposure to an article of food will cause serious adverse health consequences to humans or animals.”
- Notify ASAP and within 24 hours
  - Through Electronic Portal (**http://www.safetyreportingpanel.hhs.gov/**)
  - 866-300-4374 = 24 hour “hotline”

Need not Report if:

- Condition originated with your facility
- Condition detected prior to transfer to any other person
  - Intra-company shipment is not a “transfer”
- Condition corrected or all affected food destroyed

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# Criminal Liability: 21 USC § 333




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