16th Annual Pharmaceutical Regulatory and Compliance Congress and Best Practices Forum

Mergers & Acquisitions: Post-Deal Due Diligence and Integration Challenges

October 22, 2015

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Explanatory Notes

- All the information discussed is based on publicly available information
- None of the information we share today reflects non-public or "inside" information
- The contents of this presentation and related commentary reflect only the views of the respective speakers. The opinions presented here are not endorsed by any company, firm, government agency or other organization.

Topics for Discussion

I. **Introduction: M&A Frenzy**

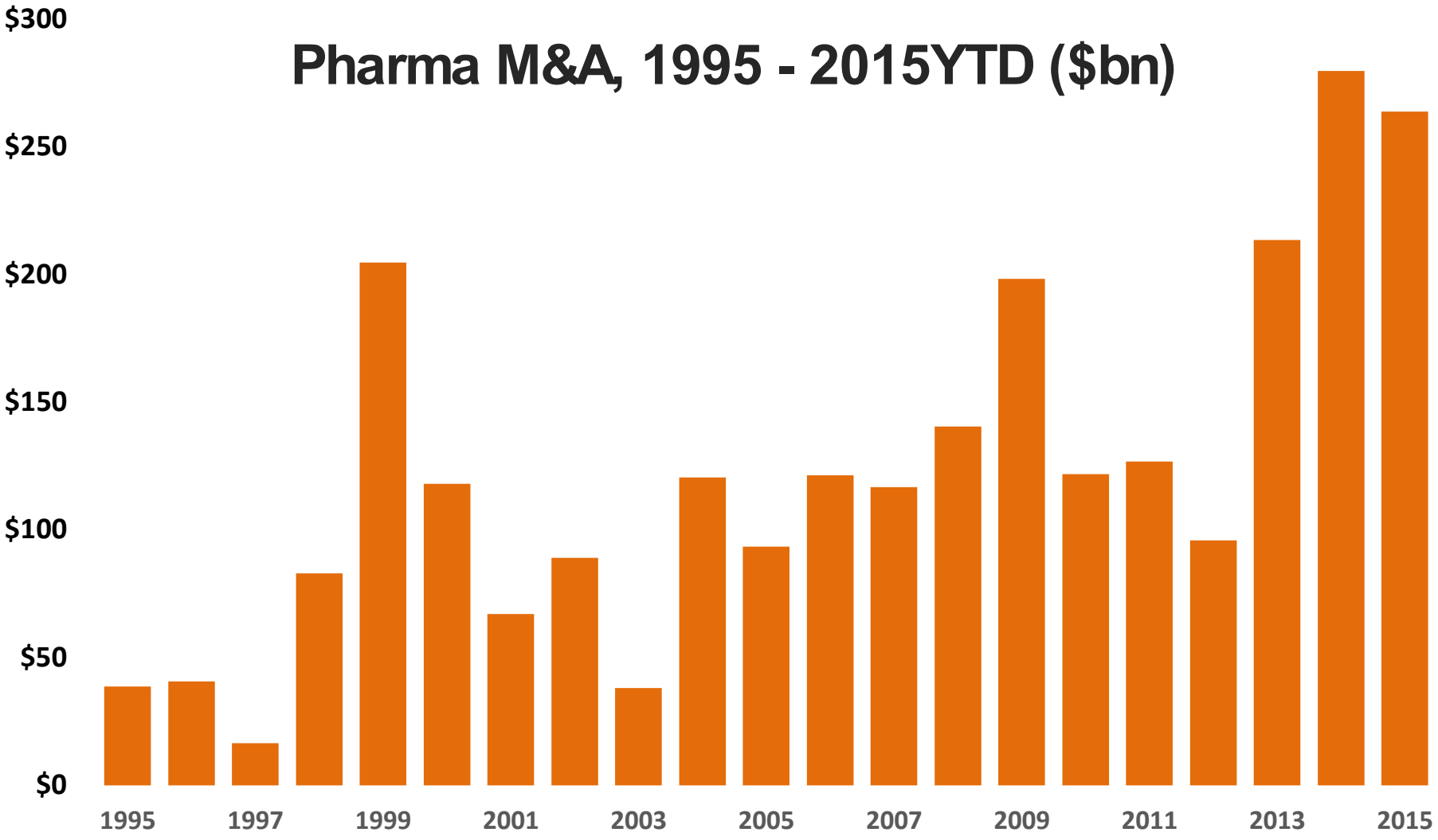
II. Post-Deal Integration Challenges & Issues

III. Corporate Integrity Agreement Implications

IV. Post-Deal Government Investigations (Buyer & Seller Implications)

V. Post-Deal Higher Risk Areas for Integration

Pharma M&A: Record Breaking Pace (Again)



Source: *Pharmaceutical and Life Sciences Deals Quarterly* (PwC); FactSet; public records

Pharma M&A: Select 2015 Deals

Announcement	Acquirer	Target	Value
January	Shire Plc	NPS Pharma	$5.1 billon
February	Valeant	Salix Pharma	$12.5 billon
March	Teva	Auspex Pharma	$3.1 billon
	Horizon	Hyperion Therapeutics	$866 million
	Mallinckrodt Plc.	Ikana Inc.	$2.3 billon
May	NantWorks	IgDraSol	$1.3 billon
	Alexion Pharmaceuticals	Synageva BioPharma	$8.4 billon
	Endo International	Par Pharmaceutical Companies	$8.1 billon
June	Allergan	KYTHERA Biopharmaceuticals	$2.1 billon
	Cardinal Health	The Harvard Drug Group	$1.1 billon
July	Teva	Allergan (Generic Business)	$40.5 billon
	Celgene	Receptos	$7.2 billon
	Hikma Pharma	Roxane Laboratories	$2.8 billon
	Valeant	Amoun Pharma	$800 million
August	Bristol-Myers Squibb	Promedior	$1.3 billon
	Valeant	Sprout Pharma	$1 billon
	Amicus Therapeutics	Scioderm	$900 million
September	Concordia Healthcare	Amdipharm Mercury Co.	$2.1 billon
	Amgen	Dezima Pharma	$1.6 billon
	Lannett Company	Kremers Urban Pharma	$1.2 billon

Source: *FactSet*; public records

Pharma M&A: Trillion Dollar Trend

- January 2014 – Today: Pharma companies have closed almost half a ***trillion*** dollars (more than $850 billion in announced deals).
- In 2014, there were eight pharma acquisitions valued at more than $1 billion. A dozen billion dollar deals have already closed in 2015 (and several more "ten digit" offers are on the table).

PharmExec.com

Pharma M&A and Financial Trends: The Frenzy and Risks Escalate

June 10, 2015

FINANCIAL TIMES

Big pieces of pharma M&A jigsaw have yet to be placed

October 14, 2015

- Pharma M&A activity distributed broadly across the market: big pharma, biotech, generic, specialty, U.S., ex-US.
- Variety of factors driving M&A activity in the pharma sector, including
  - Low interest rates
  - Patent expiration
  - Market positioning
  - R&D synergies
  - Scale efficiencies
  - Shareholder pressure
  - Tax inversion

THE WALL STREET JOURNAL. WSJ.com

Aug. 2, 2015

Pharma Execs Say To Expect More M&A

ROYAL SOCIETY OF CHEMISTRY

Merger fever sweeps pharma

10 September 2015 Katrina Megget

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V. Post-Deal Higher Risk Areas for Integration

II. Post-Deal Integration Challenges & Issues

"After we win the final takeover battle, what then?"

II. Post-Deal Integration Challenges & Issues

- Successor Liability (Merger vs. Asset Purchase)
- Limited Pre-Deal Transparency
- Systems Compatibility Challenges
- Cybersecurity Measures/Consideration
- Different/inconsistent policies and/or business approaches
- Early strategic calls: (i) fully integrate? (e.g., sales/marketing personnel); (ii) maintain acquired entity as stand-alone sub?
- Post-closing check-list for time sensitive issues (e.g., interviews/departures, document access/preservation, etc.)
- Other

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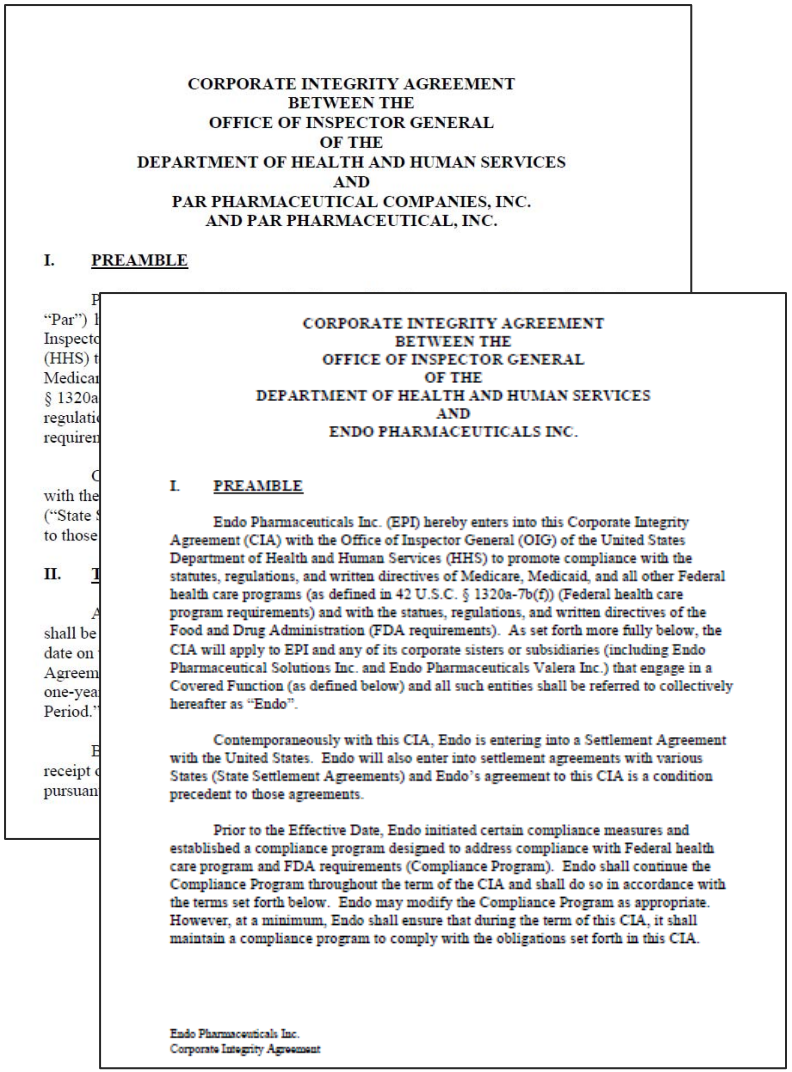

CORPORATE INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
PAR PHARMACEUTICAL COMPANIES, INC.
AND PAR PHARMACEUTICAL, INC.

I. PREAMBLE

CORPORATE INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
ENDO PHARMACEUTICALS INC.

I. PREAMBLE

Endo Pharmaceuticals Inc. (EPI) hereby enters into this Corporate Integrity Agreement (CIA) with the Office of Inspector General (OIG) of the United States Department of Health and Human Services (HHS) to promote compliance with the statutes, regulations, and written directives of Medicare, Medicaid, and all other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) (Federal health care program requirements) and with the statues, regulations, and written directives of the Food and Drug Administration (FDA requirements). As set forth more fully below, the CIA will apply to EPI and any of its corporate sisters or subsidiaries (including Endo Pharmaceutical Solutions Inc. and Endo Pharmaceuticals Valera Inc.) that engage in a Covered Function (as defined below) and all such entities shall be referred to collectively hereafter as "Endo".

Contemporaneously with this CIA, Endo is entering into a Settlement Agreement with the United States. Endo will also enter into settlement agreements with various States (State Settlement Agreements) and Endo's agreement to this CIA is a condition precedent to those agreements.

Prior to the Effective Date, Endo initiated certain compliance measures and established a compliance program designed to address compliance with Federal health care program and FDA requirements (Compliance Program). Endo shall continue the Compliance Program throughout the term of the CIA and shall do so in accordance with the terms set forth below. Endo may modify the Compliance Program as appropriate. However, at a minimum, Endo shall ensure that during the term of this CIA, it shall maintain a compliance program to comply with the obligations set forth in this CIA.

Endo Pharmaceuticals Inc.
Corporate Integrity Agreement

- Form of the transaction: Are you buying, selling or merging?
- Which party has a CIA: Buyer, seller or both?
- A recent example:
  - Par Pharmaceuticals entered into CIA in 2013
  - Endo Pharmaceuticals entered into CIA in 2014
  - Endo acquired Par Pharmaceuticals in May 2015

III. Corporate Integrity Agreement Implications

- Focus on CIA process
  - Notifications
  - Certifications
- Plan for early engagement with OIG monitor
  - Be realistic
- Systems, Processes, Policies & Procedures
  - Changes
  - Scope of covered activities
- Reportable events

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IV. Post-Deal Government Investigations (Buyer & Seller Implications)

"Don't anybody move: this is a merger."

IV. Post-Deal Government Investigations (Buyer & Seller Implications)

- Pending Investigations: of Buyer, of Seller
- Acquisition = unique opportunity for Buyer to demonstrate good faith
  - Changes in policy/practices, particularly key risk areas (e.g., incentive compensation)
  - Self-disclosures related to existing investigations
  - Culture change/enhancement
  - But, window of opportunity can close
  - And, delay/failure to act can backfire

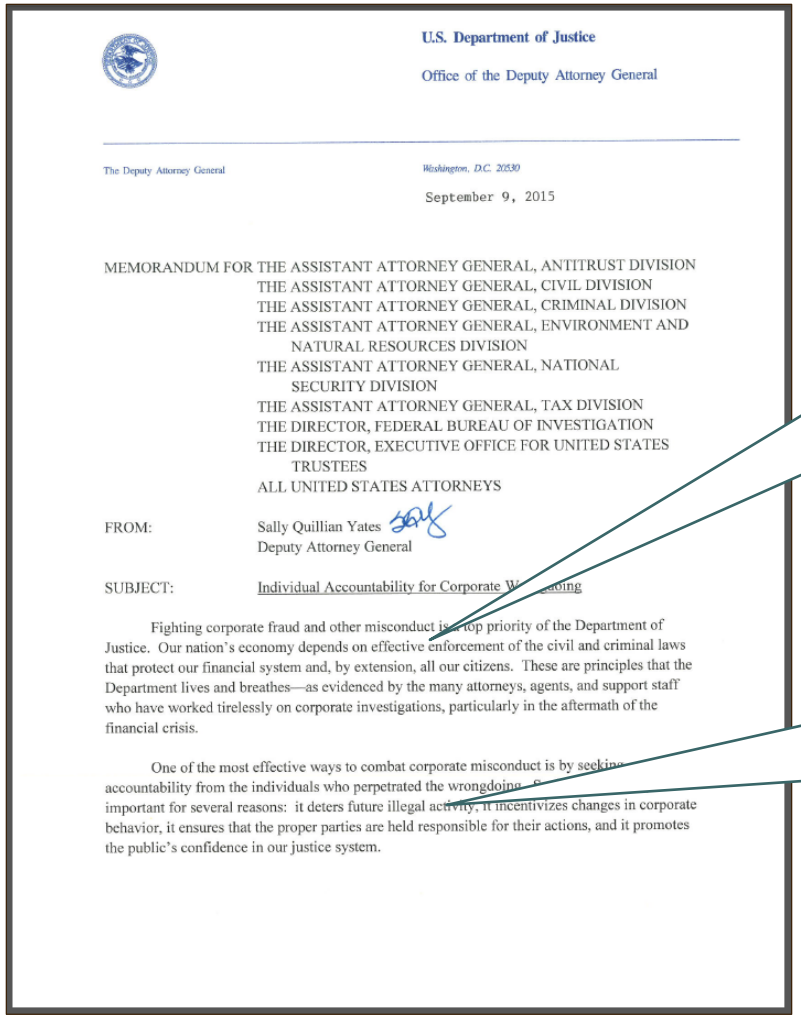
IV. Post-Deal Government Investigations (Buyer & Seller Implications)

"You're saying that because of the merger I have to admit both of you?"

IV. Post-Deal Government Investigations (Buyer & Seller Implications)

- Newly-Discovered Issues in post-deal diligence
- Self-Disclosure Considerations and Interaction with the Gov't
  - Assess severity of risk (criminal, civil only/FCA, administrative?)
  - Assessment of "cooperation credit" difficult
  - DOJ Yates Memo, September 2015, raises the stakes (individual liability; extent of cooperation – all or nothing)
  - The unknown (e.g., potential whistleblowers; future issues)
- Litigation evaluation beyond DOJ (e.g., Reps/Warranties of Seller, Escrow considerations, etc.)

IV. Post-Deal Government Investigations (DOJ/Yates Memo)



U.S. Department of Justice

Office of the Deputy Attorney General

The Deputy Attorney General — Washington, D.C. 20530

September 9, 2015

MEMORANDUM FOR THE ASSISTANT ATTORNEY GENERAL, ANTITRUST DIVISION
THE ASSISTANT ATTORNEY GENERAL, CIVIL DIVISION
THE ASSISTANT ATTORNEY GENERAL, CRIMINAL DIVISION
THE ASSISTANT ATTORNEY GENERAL, ENVIRONMENT AND NATURAL RESOURCES DIVISION
THE ASSISTANT ATTORNEY GENERAL, NATIONAL SECURITY DIVISION
THE ASSISTANT ATTORNEY GENERAL, TAX DIVISION
THE DIRECTOR, FEDERAL BUREAU OF INVESTIGATION
THE DIRECTOR, EXECUTIVE OFFICE FOR UNITED STATES TRUSTEES
ALL UNITED STATES ATTORNEYS

FROM: Sally Quillian Yates
Deputy Attorney General

SUBJECT: Individual Accountability for Corporate W[illegible]doing

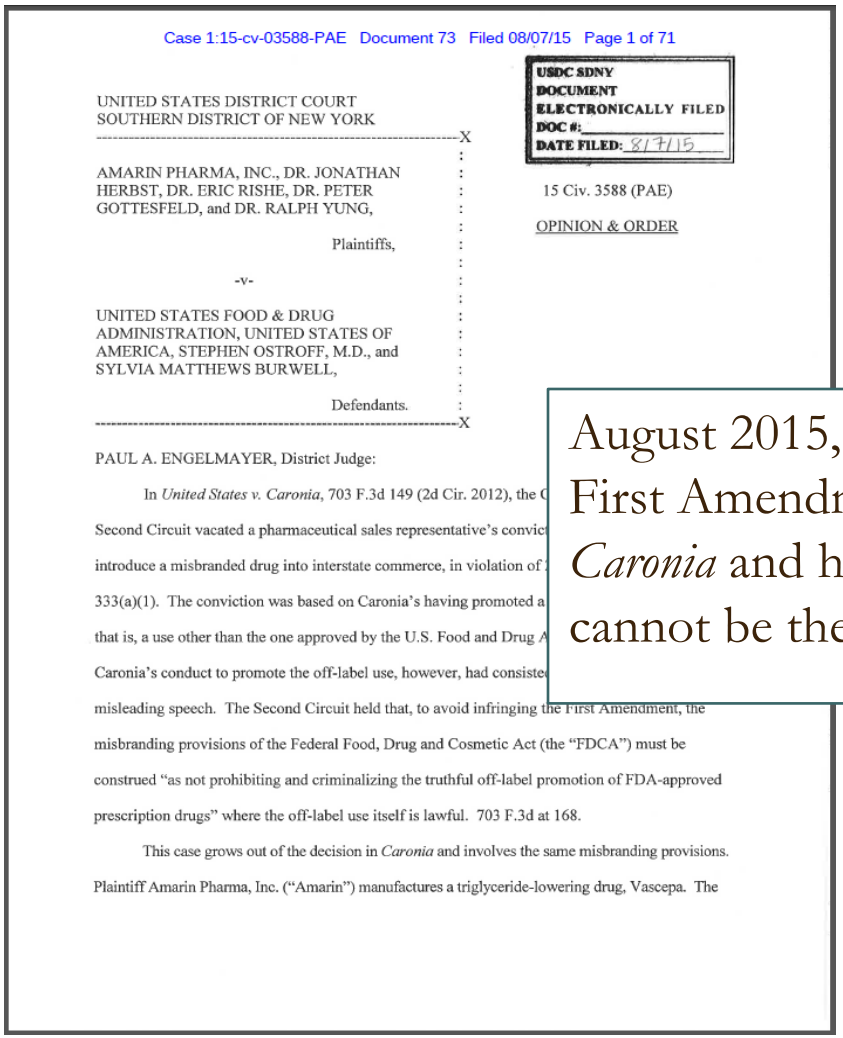
Fighting corporate fraud and other misconduct is a top priority of the Department of Justice. Our nation's economy depends on effective enforcement of the civil and criminal laws that protect our financial system and, by extension, all our citizens. These are principles that the Department lives and breathes—as evidenced by the many attorneys, agents, and support staff who have worked tirelessly on corporate investigations, particularly in the aftermath of the financial crisis.

One of the most effective ways to combat corporate misconduct is by seeking accountability from the individuals who perpetrated the wrongdoing. S[illegible] important for several reasons: it deters future illegal activity, it incentivizes changes in corporate behavior, it ensures that the proper parties are held responsible for their actions, and it promotes the public's confidence in our justice system.

"Fundamentally, this memo is designed to ensure that all attorneys across the Department are consistent in our best efforts to hold to account the individuals responsible for illegal corporate conduct"

"In order for a company to receive <u>any</u> consideration for cooperation . . . the company must completely disclose to the Department all relevant facts about individual misconduct" (emphasis in original)

IV. Post-Deal, Inherited Legal Issues – Impacts Felt Years Later



Case 1:15-cv-03588-PAE Document 73 Filed 08/07/15 Page 1 of 71

USDC SDNY
DOCUMENT
ELECTRONICALLY FILED
DOC #:
DATE FILED: 8/7/15

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, STEPHEN OSTROFF, M.D., and SYLVIA MATTHEWS BURWELL,

Defendants.

15 Civ. 3588 (PAE)

OPINION & ORDER

PAUL A. ENGELMAYER, District Judge:

In *United States v. Caronia*, 703 F.3d 149 (2d Cir. 2012), the C
Second Circuit vacated a pharmaceutical sales representative's convict
introduce a misbranded drug into interstate commerce, in violation of
333(a)(1). The conviction was based on Caronia's having promoted a
that is, a use other than the one approved by the U.S. Food and Drug A
Caronia's conduct to promote the off-label use, however, had consiste
misleading speech. The Second Circuit held that, to avoid infringing the First Amendment, the
misbranding provisions of the Federal Food, Drug and Cosmetic Act (the "FDCA") must be
construed "as not prohibiting and criminalizing the truthful off-label promotion of FDA-approved
prescription drugs" where the off-label use itself is lawful. 703 F.3d at 168.

This case grows out of the decision in *Caronia* and involves the same misbranding provisions.
Plaintiff Amarin Pharma, Inc. ("Amarin") manufactures a triglyceride-lowering drug, Vascepa. The

August 2015, Amarin secures preliminary injunction in First Amendment/off-label dispute; court amplifies *Caronia* and holds that truthful and non-misleading speech cannot be the basis for a misbranding prosecution

IV. Post-Deal Government Investigations: Practical Tips for Gov't Interactions

- Build trust and credibility with other side
- Preservation of relevant documents and records
- Assume the other side knows more than you
- Apply law to the facts you have — not the facts you wish you had (and know the facts to maximize a defense and credibility)
- Careful selection and use of outside experts and consultants
- Remediation and Compliance (train and certify, monitor and test, punish and remediate, rinse and repeat)
- No one-size approach — be adaptable

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- AKS issues – commercial discount and service agreements, reimbursement support, patient assistance programs, etc.
- Government Drug Pricing & Reimbursement, including price increases following acquisition (e.g., recent subpoena)
- FCPA Diligence/O.U.S. Agent and Distributor Vetting
- Interaction/Disclosure with "Independent" Third Parties
- Clinical Activities
- Incentive Compensation
- Speaker Programs/Advisory Boards

" I called your doctor, Mr. Bennett . . he said to gobble up 2 companies and call him in the morning. "

END