



Drug & Device Defense

Emerging Litigation & Regulatory Developments

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Insurance Coverage for Government Investigations



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Agenda

- Introduction
- Policies Available to Cover Government Investigations
- Major Coverage Issues Under D&O Policies
 - Notice of Claim
 - Advancement of Defense Costs
 - Key Exclusions
- Best Practices for Securing Coverage for Government Investigations

Available Policies – First, The Legal And Regulatory Minefield

- Government Agencies

- DOJ
- SEC
- FTC
- CFPB
- State AGs

The New York Times

BUSINESS DAY

Glaxo Agrees to Pay \$3 Billion in Fraud Settlement

By KATIE THOMAS and MICHAEL S. SCHMIDT JULY 2, 2012



- Violations

- FCA – Whistleblower/Qui Tam
- Anti-Kickback
- FCPA
- Other Federal and State Criminal Laws

- The numbers

- Average time to conclude FCPA claim, 7 years
- DOJ and private litigants recovered over \$19 billion from pharmaceutical and medical device companies for FCA violations
- Walmart spent over \$600 million and Siemens over \$1 billion in connection with FCPA investigations and lawsuits
- More than 700 whistleblower suits filed each year

THE WALL STREET JOURNAL.

11:38 am ET
Sep 2, 2009

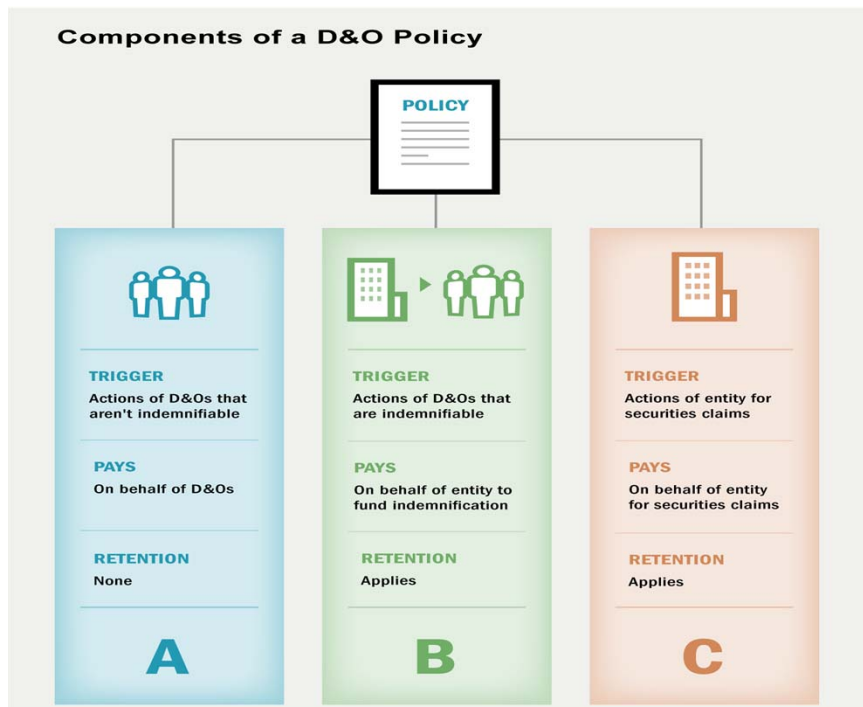
Pfizer Makes History With \$2.3B Fraud Settlement

Available Policies – Yes, There Is Coverage

- Directors & Officers
 - Private Company vs. Public Company D&O Policies
- Errors & Omissions
- Employment Practices Liability
- Fiduciary Liability
- Fidelity/Employee Theft



Overview of Public D&O Policies



Comments:

- **Personal Asset Protection:**
 - ✓ Side A
- **Balance Sheet Protection:**
 - ✓ Side B: Corporate Risk Transfer
 - ✓ Side C: Coverage for the Entity
- **Shared Limit**
 - ✓ Loss on one Insuring Agreement erodes limits available under the other Insuring Agreements
- **Compare with Private D&O Form:**
 - ✓ Entity is covered for all Claims, unless otherwise excluded (e.g., anti-trust)

Key Coverage Issues – Notice of Claim

- Policy Provisions
 - Claims-Made Policies
 - Sample Provisions
 - Definition of “Claim”
 - Claim Notification Requirements
- What triggers Claim Notification
 - Subpoena – even when your company is not the target
 - Search warrant
 - Formal document request – e.g., Civil Investigative Demand (CID)
 - Informal requests for information/documents by government agency
 - Request for witness interview

Definition of Claim

ACE – Public D&O Policy Form - New - 5/15	ACE – Private D&O Policy Form - PF15193 (12/08)
<p>Claim means: * * *</p> <p>3. a civil, criminal, administrative or regulatory <u>investigation of an Insured Person</u> commenced:</p> <p>(i) by the service upon or other receipt by the Insured Person of a written notice, including a subpoena, target letter or Wells Notice, from the investigating authority identifying such Insured Person as an individual against whom a proceeding . . . [i.e., civil, criminal, arbitration, mediation, other alternative dispute resolution, administrative or regulatory proceedings] may be commenced;</p> <p>(ii) in the event of an investigation by the Securities and Exchange Commission . . . by the service of a subpoena (or, where applicable, the foreign equivalent) upon the Insured Person;</p> <p>* * *</p> <p>5. a Preliminary Investigation, if reported at the option of the Insureds . . .</p>	<p>Claim means: * * *</p> <p>g) a civil, criminal, administrative or regulatory <u>investigation</u> commenced by:</p> <p>(i) the service upon or other receipt by <u>any natural person Insured</u> of a written notice, investigative order, or subpoena; or</p> <p>(ii) the service upon or other receipt by <u>any Company</u> of a written notice or investigative order;</p> <p>from the investigating authority identifying such natural person Insured as an individual, or such Company as an entity, respectively, against whom a proceeding . . . [i.e., civil, criminal or regulatory proceedings] may be commenced;</p>

Comments:

- Public D&O Forms do **not** cover entity investigations
 - ✓ Exception by Endorsement: SEC investigations on a co-defendant basis (for an Additional Premium)
- Private D&O Forms may cover entity investigations
 - ✓ Beware of Exclusions
- *Note:* favorable commencement wording – i.e., “service upon or other receipt” vs. “filing of”



Definition of Preliminary Investigation

ACE – Public D&O Policy Form - New - 5/15

Preliminary Investigation means:

1. whether or not a **Wrongful Act** is alleged, a request or demand for an **Insured Person** to appear at a meeting, deposition or interview, or produce documents, relating to the business of the **Company** or the **Insured Person's** capacity as such, or by virtue of their status as such, where such request or demand is:
 - (i) by any federal, state, local or foreign law enforcement authority or other governmental investigative authority (including, but not limited to, the Department of Justice, the Securities and Exchange Commission and any attorney general);
 - (ii) by the enforcement organization of any securities or commodities exchange or other self-regulatory entity; or

Comments:

- No Wrongful Act requirement
- Broad scope of applicable authorities
- *Note:* Preliminary Investigations do not include any routine or regularly scheduled regulatory or internal supervision, inspection, compliance, review, examination, production or audit conducted in the normal review or compliance process of the Company

Notice Provision

ACE – Public D&O Policy Form - New - 5/15

The **Insureds** shall, with respect to any **Claim** other than a Preliminary Investigation, give to the **Insurer** written notice of any **Claim** made against the **Insureds** as soon as practicable after the Named Insured's general counsel or risk manager, or equivalent positions, first learn of the Claim, but in no event later than 60 days after termination of the Policy Period

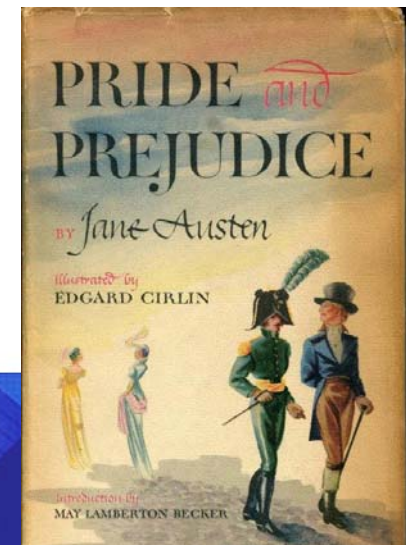
If the **Insureds** fail to provide notice of a **Claim** to the **Insurer** as specified above, the **Insurer** shall not be entitled to deny coverage for the **Claim** based solely upon late notice unless the **Insurer** can demonstrate its interests were materially prejudiced by reason of such late notice.

Comments:

- **Optional** notice of Preliminary Investigations
- **Mandatory** notice of all other Claims
- Timing elements:
 - ✓ As soon as practicable
 - ✓ Knowledge of Named Insured's GC or RM
 - ✓ But, even if the GC/RM are unaware of the Claim, notice is required within 60 days after end of Policy Period
- Savings Clause:
 - ✓ Material Prejudice standard

Key Coverage Issues – Notice of Claim

- Leading cases as to whether government investigation is a “claim”
 - *MBIA Inc. v. Federal Ins. Co.*, 652 F.3d 152 (2nd Cir. 2011)
 - *Polychron v. Crum & Forster Ins. Co.*, 916 F.2d 461 (8th Cir. 1990)
 - *Employers Fire Ins. Co. v. ProMedia Health Systems, Inc.*, 2013 WL 1798978 (6th Cir. April 30, 2010)
 - *BioChemicals, Inc. v. Axis Reinsurance Co.*, 2015 WL 71493 (D. Mass. Jan 6, 2015)
- Coverage for pre-tender/notice costs
- Role of prejudice in overcoming late notice defense



Key Coverage Issues – Defense Costs

- Defense costs key component of D&O policies given nature of FCA and FCPA claims
- Advancement and allocation provisions – insurer controls
- Billing rates – What is “reasonable and necessary”
- Insurer litigation guidelines
- Insurers’ reservation of rights for recoupment of defense costs



General Litigation
Management Guidelines
Effective April 2013

AIG Bring on tomorrow

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Advancement Provision

ACE – Public D&O Policy Form - New - 5/15

If the **Company**:

1. refuses to indemnify, advance or pay covered **Loss** of an **Insured Person**; or,
2. fails to indemnify, advance or pay covered **Loss** of an **Insured Person**, within 60 days after an **Insured Person** requests in writing such indemnification, advancement or payment,

and such covered **Loss** is within the Retention, then the **Insurer** shall advance such amounts on behalf of the **Insured Person** until either: (i) a **Company** has agreed to make such payments; or, (ii) the Retention has been satisfied. In no event shall any such advancement by the **Insurer** relieve any **Company** of any duty it may have to provide advancement, payment or indemnification to any **Insured Person**. Any payment or advancement by the **Insurer** within an applicable Retention shall apply towards the exhaustion of the Limit of Liability.

If the **Insurer** pays under this **Policy** any indemnification, advancement or payment owed to any **Insured Person** by any **Company** within an applicable Retention, then that **Company** shall reimburse the **Insurer** for such amounts and such amounts shall become immediately due and payable as a direct obligation of the **Company** to the **Insurer**.

Comments:

- “Advancement for Any Reason”
 - ✓ Provides Side A protection to Ds/Os for an otherwise Side B Loss



Key Coverage Issues – Exclusions

- Ill-Gotten Gains and Crime/Fraud exclusions
- Prior/Pending exclusion
 - Unique issues related to FCA whistleblower/qui tam actions
 - *Amerisource Bergen Corp. v. Ace Am. Ins. Co.*, 100 A.3d 283 (Pa. Super. 2014)



III-Gotten Gains and Crime/Fraud Exclusions

ACE – Public D&O Policy Form - New - 5/15

The **Insurer** shall not be liable for that portion of **Loss** on account of any **Claim**:

- A. alleging, based upon, arising out of, or attributable to the gaining of any personal profit, remuneration or financial advantage to which any **Insured** was not legally entitled. However, this exclusion shall not apply: (i) unless and until there is a final, non-appealable adjudication as to such conduct in the underlying action; or, (ii) in a **Securities Claim** alleging violations of Section 11, 12 or 15 of the Securities Act of 1933, as amended, to the portion of any **Loss** attributable to such violations.
- B. alleging, based upon, arising out of, or attributable to any deliberately fraudulent or deliberately criminal act or omission. However, this exclusion shall not apply unless and until there is a final, non-appealable adjudication as to such conduct in the underlying action. Notwithstanding anything in this exclusion to the contrary, for acts or omissions which are treated as a criminal violation in a **Foreign Jurisdiction** that are not treated as a criminal violation in the United States of America, the imposition of a criminal fine or other criminal sanction in such **Foreign Jurisdiction** will not, by itself, be conclusive proof that a deliberate criminal or deliberate fraudulent act occurred.

Comments:

- Favorable Trigger Wording
 - ✓ “final non-appealable adjudication . . . in the underlying action”
 - ✓ *SEC v. Harbinger Capital* (July 2013)



Prior or Pending Litigation Exclusion

ACE – Public D&O Policy Form - New - 5/15

The **Insurer** shall not be liable for that portion of **Loss** on account of any **Claim**:

* * *

G. alleging, based upon, arising out of, or attributable to any prior or pending litigation or administrative or regulatory proceeding which was filed against an **Insured**, and of which an **Insured** had notice, on or before the prior or pending proceeding date shown in Item 6 of the Declarations, or the same or substantially the same **Wrongful Act**, fact, circumstance or situation underlying or alleged therein.

Comments:

- Favorable Qualifiers:
 - ✓ “filed against an Insured”
 - Prevents insurer from relying on proceedings against 3rd parties
 - ✓ “of which an Insured had notice”
 - Qui Tam implications