

## **Covering the Costs of a Regulatory Investigation – the Berkley Life Sciences’ Solution**

Through its publication of a memorandum known as the “Yates Memo” entitled “Individual Accountability for Corporate Wrongdoing,” and other more recent public pronouncements, the U.S. Department of Justice has made no secret of its continuing mission to investigate and punish individual liability for corporate wrongdoing, particularly in the life science arena.

In light of the DOJ’s renewed corporate accountability efforts, many legal and insurance experts have examined whether language in standard D&O insurance policies adequately responds to a regulatory inquiry or investigation, and have found coverage under these policies to be deficient. In one recent article by the global law firm of Herbert Smith Freehills entitled “[The Push for Individual Accountability and D&O Insurance Coverage](#),”\* the authors, citing recent case law, discuss these potential coverage deficiencies in more detail. The authors conclude that finely tailored, comprehensive and effective investigation cover under a D&O policy is essential as the DOJ’s focus on rooting out and prosecuting corporate misconduct continues unabated.

### **A Uniquely Crafted Solution**

Berkley Life Sciences has carefully crafted its LS Prime® Corporate Safeguard Directors and Officers Liability policy to harmonize with the new reality of DOJ, SEC and other governmental investigations of alleged corporate or individual wrongdoing. The policy is specifically designed to respond to the types of inquiries life science companies and their executives may receive from regulators. An important feature of this policy is a coverage section for “First Response Costs” to address preliminary or “informal” requests for information directed to life science companies and their executives even in the absence of a formal “claim”. “First Response Costs” coverage includes a broad definition of “investigation” addressing informal communications from regulators investigating wrongdoing. It also addresses life science specific investigatory inquiries of corporate and individual wrongdoing, such as:

- A section 305 Notice under the Food Drug and Cosmetic Act;
- An investigation of a suspended clinical trial, or other health care study, due to death or a serious adverse event; or
- An investigation into the use of a misbranded or adulterated product.

Other important features include the following:

- Investigation coverage is distinct from a “claim,” thereby alleviating any reporting issues in the event an investigation is not reported, and subsequently becomes a claim.
- Policy exclusions do not apply to First Response Cost cover.
- Coverage extends to liability under the Responsible Corporate Officer Doctrine even in the absence of a formal allegation of corporate wrongdoing.
- Coverage extends to the entity while an insured person remains a target. This resolves any allocation disputes and helps facilitate a coordinated response to the investigation.
- Any deductible applicable to First Response Costs reduces the deductible applicable to a subsequent claim.

---

\* *Herbert Smith Freehills*. (2016, October 20). Retrieved from <http://hsfnotes.com/fsrandcorpcrime/2016/10/20/the-push-for-individual-accountability-and-do-insurance-coverage/#more-6447>

- If indemnification which is owed by the corporate entity to an insured person fails for any reason, the policy will advance such “loss” on a first dollar basis. This alleviates the indemnification dilemma created by the DOJ’s position on cooperation and advancement highlighted in the Yates Memo and the above-referenced article.
- In the event an investigation creates a conflict amongst insureds, for example, the corporation wants to seek full cooperation credit from the regulators and consequently refuses to indemnify insured persons, the policy will advance expense and loss payments without the application of a deductible.
- In the event of a conflict of interest between multiple insureds, the policy recognizes the potential need to retain separate counsel for each insured to ensure that each executive is protected.

### **The Berkley Life Sciences Answer**

In summary, the U.S. Department of Justice and other regulatory agencies are increasingly focused on pursuing claims against individual corporate executives as well as corporate entities. This often begins with an informal investigation. Life science companies are more likely than most to be the subject of an informal investigation: they provide goods and services in a highly regulated industry and often have international operations where ensuring compliance with all local laws may be complex. Accordingly, even an informal request for information from a regulator requires a thorough and complete response. It is essential to ensure that the unique risks faced by life science company executives, beginning with these informal investigations, are properly addressed. Berkley Life Sciences remains committed to providing the broadest protection available to life science companies and their executives in the marketplace and has developed a form specifically tailored to address the concerns of life science companies operating in a highly regulated and litigious environment.



**Simon Beynon**, Senior Vice President, Management Liability

Simon Beynon has over 25 years of underwriting, marketing and sales experience in the property and casualty insurance business, including more than 20 years specifically in the management liability insurance area.

Products and services are provided by one or more insurance company subsidiaries of W. R. Berkley Corporation. Not all products and services are available in every jurisdiction. Certain coverages may be provided through surplus lines insurance company subsidiaries of W. R. Berkley Corporation through licensed surplus lines brokers. Surplus lines insurers do not generally participate in state guaranty funds and insureds are therefore not protected by such funds. In California, Berkley Life Sciences conducts business as Berkley LS Insurance Solutions, LLC, a licensed surplus lines broker (License Number 0H44165).

Any reference to insurance is descriptive and presented for discussion purposes only. Coverage afforded under any insurance policy issued is subject to the individual terms and conditions of that policy as issued. Claims scenarios are hypothetical in nature and for illustrative purposes.