

What Life Science Company Executives need to know about the Responsible Corporate Officer Doctrine and their Management Liability Insurance

The directors and officers of a life science company are aware that they have personal exposure to civil liability - and criminal prosecution - for actions taken by their company in violation of the Federal Food, Drug and Cosmetic Act of 1938 (FDCA), even if they did not know about the company's wrongful acts. They also are aware that such exposure stems from the application of the *Responsible Corporate Officer Doctrine*, which has been increasingly cited by the government in pursuing life science company executives regardless of whether they had knowledge of company or employee wrongdoing.

What directors and officers may not realize is that their management liability insurance more than likely does not affirmatively address the *Responsible Corporate Officer Doctrine*, leaving them potentially bare when confronted with the enormous costs of defending a governmental action for violating the FDCA. This jarring realization has most recently been brought to light with a new appellate court decision upholding the convictions and prison terms of two corporate officers, including the company's chief operating officer, for violations of the FDCA, even though the officers were not found to have the *mens rea* - i.e, the criminal intent - to commit a crime. See [U.S. v. DeCoster](#), U.S. Court of Appeals for the Eighth Circuit, No. 15-1890 and 15-1891, filed July 6, 2016.

Commenting on the implications of this case in his well respected D&O blog, management liability expert Kevin LaCroix states: "It is worth noting in closing that responsible corporate officer enforcement actions or prosecutions may raise D&O insurance coverage issues.... One question that might be asked in many of these types of cases is whether or not the proceedings involve an alleged 'Wrongful Act' as is required to trigger coverage. Should these questions arise, these executives will want to be able to argue that the applicable D&O policy in any event covers them for allegations against them in their capacities as directors and officers 'by reason of their status as such.'" It will be difficult for executives to make this argument if their insurance does not affirmatively address coverage for the executive's culpability under the *Responsible Corporate Officer Doctrine*.

Although this potential gap in coverage is of interest to executives across the business spectrum, it is of particular importance to those in the life science industry, where the government has come down hard on holding individuals in positions of authority accountable for violations by the company of the FDCA and other applicable laws. Pharmaceuticals, medical devices and other life science products all have side effects:

accordingly, the laws are designed to ensure that life science firms and their officers comport with regulations enacted to protect the public. In recent years, the government has aggressively enforced these laws and has incorporated the prosecution of individuals under the *Responsible Corporate Officer Doctrine* into its enforcement arsenal.

Berkley Life Sciences has designed a management liability policy to affirmatively include coverage for the defense of directors and officers prosecuted based upon their position with the corporation – even in those instances where they have not been personally accused of engaging in wrongful acts. While the utmost due diligence in conducting business operations is the key to avoiding liability, insurance protection for the defense of governmental actions based upon the *Responsible Corporate Officer Doctrine* is an essential component of any management liability policy. An affirmative recognition of this protection in the policy will provide officers and directors with the peace of mind necessary to focus on the business of creating lifesaving medical products.

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