

# Healthcare Enforcement & Litigation

*Contributing editors*

Michael K Loucks, Jennifer L Bragg and Alexandra M Gorman



2018

GETTING THE  
DEAL THROUGH 

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Skadden, Arps, Slate, Meagher & Flom LLP

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# Global overview

Michael K Loucks, Jennifer L Bragg and Alexandra M Gorman

Skadden, Arps, Slate, Meagher & Flom LLP

Getting the Deal Through's *Healthcare Enforcement & Litigation* is a practitioner's guide to how government agencies around the world regulate and investigate the healthcare industry, and the unique legal issues presented in the jurisdictions discussed in this edition. The management of cross-border healthcare investigations poses myriad challenges for today's global healthcare corporations. Understanding how the healthcare industry is regulated in different jurisdictions, as well as knowing how such investigations are likely to play out, is crucial to successfully managing business operations in those countries. This book aims to address, on a jurisdiction-by-jurisdiction basis, the questions that arise regarding the way healthcare companies are regulated and the manner in which enforcement of the industry is carried out. In addition, for companies considering cross-border transactions, this book can serve as a resource to better understand the healthcare enforcement and regulatory landscape in the countries potentially covered by those transactions.

Continued prosecutions of large international healthcare companies underscore the importance of these issues to corporations operating globally today. For more than a decade, the United States Department of Justice has taken an aggressive enforcement stance towards the healthcare industry, and has vowed to continue its zealous enforcement when presented with evidence of wrongdoing. This has resulted in billions of dollars in fines and penalties being paid by healthcare companies, criminal liability and follow-on litigation. Such fines are frequently split between the various law enforcement and regulatory agencies that participate in the investigation. Remedial measures imposed are likewise significant, with companies often required to enter into corporate integrity agreements or, in some cases, to divest the business that engaged in wrongdoing. As the amount of money the federal government spends on healthcare continues to increase, one can expect that government enforcement of the industry will likewise increase. Indeed, in 2016, the US Congress allocated nearly \$1 billion for federal healthcare enforcement efforts.

The cases brought by the Department of Justice have received widespread international attention, and have prompted law enforcement authorities around the world to increase their own scrutiny of the healthcare industry. In addition, the Department of Justice's recent guidance

to its criminal and civil prosecutors was designed to strengthen the Department's pursuit of individual corporate wrongdoing in corporate investigations. We have not seen a significant impact of that guidance yet in the United States, but we expect that trend to extend internationally. Indeed, because the government is a primary payer for healthcare in many countries, there is particular interest in trying to detect and punish perceived misconduct. Towards this end, law enforcement entities around the world are increasingly working collaboratively with one another on these investigations. For example, over the course of six years, Siemens AG reached settlements with government entities in Germany, Greece, Italy, Nigeria and the United States, and the World Bank, concerning allegations of bribery and corruption. Moreover, the United States and Germany not only coordinated their investigations but also simultaneously announced their separate settlements with Siemens. The recent settlement of nearly \$520 million with Teva Pharmaceutical Industries Ltd suggests that the Department of Justice continues to expand its healthcare investigations to conduct that occurred outside the United States. The *Teva* settlement resolved charges concerning a scheme to increase sales and influence product registration by paying kickbacks to government officials (including physicians) in Mexico, Russia and Ukraine in violation of the Foreign Corrupt Practices Act. The Department of Justice's press release specifically noted that Teva did not receive full cooperation credit because of delays in the early stages of the investigation, including 'overbroad assertions of attorney-client privilege' and failing to produce documents on a timely basis.

There is every reason to expect aggressive law enforcement and regulatory investigation to continue in the United States for the foreseeable future, as well as for collaboration among international law enforcement entities to continue and to increase. Healthcare entities suspected of wrongdoing, regardless of their size or global reach – and perhaps because of it – are likely to face multiple inquiries from law enforcement and regulatory agencies in different countries. Such investigations are expensive, time-consuming and challenging for management, employees and counsel alike. We hope that this edition of *Healthcare Enforcement & Litigation* will serve as a valuable introduction to the unique features of law and practice that shape civil and criminal healthcare investigations across multiple jurisdictions.

## Getting the Deal Through

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Restructuring & Insolvency  
Right of Publicity  
Securities Finance  
Securities Litigation  
Shareholder Activism & Engagement  
Ship Finance  
Shipbuilding  
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