ICLG

The International Comparative Legal Guide to:

# Product Liability 2014

**12th Edition**

A practical cross-border insight into product liability work

Published by Global Legal Group, in association with CDR, with contributions from:

Ali Budiardjo, Nugroho, Reksodiputro
Allen & Gledhill LLP
Arnold & Porter (UK) LLP
Bahas, Gramatidis & Partners
BOPS Law Firm
Brandão Couto, Wigderowitz & Pessoa Advogados
Bulló – Tassi – Estebenet – Lipera – Torassa – Abogados
Carroll, Burdick & McDonough LLP
Clayton Utz
Clyde & Co LLP
Crown Office Chambers
Drinker Biddle & Reath LLP
Eversheds
Faus & Moliner
Fiebinger Polak Leon & Partner Rechtsanwälte GmbH
Freshfields Bruckhaus Deringer LLP
Gianni, Origoni, Grippo, Cappelli & Partners
Gowling Lafleur Henderson LLP
Greenberg Traurig, LLP
Herbert Smith Freehills LLP
Kleyr Grasso
Lee and Li, Attorneys-at-Law
Liedekerke Wolters Waelbroeck Kirkpatrick
Mannheimer Swartling Advokatbyrå AB
Matheson
McConnell Valdes LLC
Pachiu and Associates
Portilla, Ruy-Díaz y Aguilar, S.C.
Segal McCambridge Singer & Mahoney Ltd.
Seth Associates
Sidley Austin LLP
Tapia Elorza y Cia. Abogados
Taylor English Duma LLP
Taylor Wessing
White & Case LLP

CDR Commercial Dispute Resolution
GLG Global Legal Group

# The International Comparative Legal Guide to: Product Liability 2014

GLG
Global Legal Group

**Contributing Editors**
Ian Dodds-Smith, Arnold & Porter (UK) LLP and Michael Spencer QC, Crown Office Chambers

**Account Managers**
Edmond Atta, Beth Bassett, Antony Dine, Susan Glinska, Dror Levy, Maria Lopez, Florjan Osmani, Paul Regan, Gordon Sambrooks, Oliver Smith, Rory Smith

**Sales Support Manager**
Toni Wyatt

**Sub Editors**
Nicholas Catlin
Amy Hirst

**Editors**
Beatriz Arroyo
Gemma Bridge

**Senior Editor**
Suzie Kidd

**Global Head of Sales**
Simon Lemos

**Group Consulting Editor**
Alan Falach

**Group Publisher**
Richard Firth

**Published by**
Global Legal Group Ltd.
59 Tanner Street
London SE1 3PL, UK
Tel: +44 20 7367 0720
Fax: +44 20 7407 5255
Email: info@glgroup.co.uk
URL: www.glgroup.co.uk

**GLG Cover Design**
F&F Studio Design

**GLG Cover Image Source**
iStockphoto

**Printed by**
Ashford Colour Press Ltd.
May 2014



**ISBN** 978-1-908070-99-9
**ISSN** 1740-1887

**Strategic Partners**

MIX
Paper from responsible sources
FSC® C011748

## General Chapters:



## Country Question and Answer Chapters:

Chapter 5

# Update on Implications of Recent U.S. Governmental Enforcement Activities on Pharmaceutical and Medical Device Products Liability Actions


Lori G. Cohen

Christiana C. Jacxsens

Greenberg Traurig, LLP


## I. Introduction

On February 26, 2014, the Attorney General Eric Holder and the Department of Health and Human Services ("HHS") Secretary Kathleen Sebelius released a report showing that the U.S. government's health care fraud prevention and enforcement efforts recovered nearly $4.3 billion in taxpayer dollars in fiscal year 2013, the largest sum ever recovered in a single year. Over the past five years, the U.S. government has recovered $19.2 billion, up from $9.4 billion in the past five-year period, and therefore the U.S. Food and Drug Administration ("FDA"), the U.S. Department of Justice ("DOJ"), other federal agencies, and individual state governments will certainly continue to focus their attention in coming years on the pharmaceutical and medical device industry.

It also is likely that the federal government will continue to target individual executives for criminal liability in an attempt to change the behaviour of companies. Governmental investigations of executives of pharmaceutical and medical device companies exert a unique pressure on current and future civil products liability actions. It is thus important for medical device and pharmaceutical companies and their defence counsel to understand the current landscape of government investigations and to understand the impact of government enforcement actions on a company's civil products liability litigation.

In order to aid medical device and pharmaceutical companies and their defence counsel, this article provides:

- an overview of federal and state government enforcement activities in 2013 related to pharmaceutical and medical device companies;
- a synopsis of government enforcement activities against company executives and counsel in 2013, including the basis for corporate liability and recent case studies;
- a summary of hot topics in products liability cases based on governmental enforcement actions; and
- suggested defence strategies for best avoiding liability.

## II. Overview of Federal and State Government Enforcement Activities in 2013

Fiscal year 2013 was another banner year for the government's health care fraud prevention and enforcement efforts.[i] For every one dollar spent on health care related-fraud and abuse investigations from 2010-2013, the government recovered $8.10.[ii] Various governmental entities on both the federal and state levels coordinated in order to achieve that recovery, including, but not limited to, Offices of the State Attorneys General, U.S. Attorneys' Offices, DOJ, the Office of Inspector General ("OIG") for HHS, Congress, FDA, and the Veterans Administration. Through the Health Care Fraud Prevention and Enforcement Action Team ("HEAT"), DOJ and HHS created additional Medicare Fraud Strike Force teams to assist in preventing fraud, waste and abuse in the Medicare and Medicaid programmes.[iii] The Medicare Fraud Strike Force teams use data analysis techniques to identify high-billing levels in health care fraud hot spots so that DOJ can better target emerging and chronic fraud.[iv] New authority under the Affordable Care Act granted to HHS and the Center for Medicare and Medicaid Services ("CMS") allowed HHS and CMS to further root out fraud by revalidating all Medicare enrolled providers and suppliers and blocking enrollments in three fraud hot spots.[v] Also during FY 2013, the Office of Criminal Investigations for FDA increased its efforts to combat the online sale and distribution of potentially counterfeit and illegal medical products.[vi] In June 2013, FDA seized and shut down 1,677 illegal pharmacy websites.[vii]

Generally, governmental legal authority for criminal and civil investigations of pharmaceutical and medical device companies is derived from several separate statutes and regulations. First, government indictments may be based on provisions and related regulations of the Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 331 *et seq*. The DOJ, through its Civil Division's Office of Consumer Litigation and partners in U.S. Attorneys' Offices located throughout the country, brings civil and criminal actions for violations of the FDCA. Violations often include the unlawful marketing of drugs and devices, fraud on FDA, and the distribution of adulterated products.

Additionally, many of the federal criminal investigations and actions involving pharmaceutical and medical device manufacturers are based on the federal False Claims Act ("FCA"), 31 U.S.C. §§ 3729-33. The FCA prohibits knowingly presenting, causing to be presented, and/or conspiring to present a false or fraudulent claim for payment and other similar acts.[viii] In FY 2013, DOJ opened 1,013 new criminal health care fraud investigations involving 1,910 potential defendants, and convicted 826 defendants of health care fraud-related crimes.[ix] DOJ also opened 1,083 new civil investigations in FY 2013[x], significantly higher than the 885 new civil investigations it opened in FY 2012.[xi] DOJ obtained $3.8 billion through civil health care fraud cases brought under the FCA during fiscal year 2013.[xii]

The following are representative of settlements negotiated by the DOJ with pharmaceutical and/or medical device companies in 2013:

- March 2013 –
  - $45 million payment including $22.5 million fine and forfeiture and $22.5 million settlement with Par Pharmaceutical Companies Inc. concerning claims of off-label promotion;[xiii]

- April 2013 –
  - $24.9 million settlement with Amgen Inc. concerning FCA allegations;[xiv]
- May 2013 –
  - $500 million payment including $150 million fine and forfeiture, and $350 million settlement with Ranbaxy USA Inc. concerning claims of manufacture and distribution of adulterated drugs and making false statements to FDA;[xv]
  - $48.26 million settlement with C. R. Bard, Inc. concerning FCA allegations;[xvi] and
  - $33.5 million settlement with ISTA Pharmaceuticals Inc. concerning FCA allegations;[xvii]
- July 2013 –
  - $490.9 million payment including $233.5 million fine and forfeiture and $257.4 million settlement with Wyeth Pharmaceuticals, Inc. concerning claims of off-label promotion;[xviii]
- October 2013 –
  - $30 million settlement with Boston Scientific Corp., Guidant LLC, Guidant Sales LLC and Cardiac Pacemakers, Inc. concerning claims of sales of defective devices;[xix]
- November 2013 –
  - $2.2 billion payment including $485 million fine and forfeiture and $1.72 billion settlement with Johnson & Johnson concerning claims of off-label promotions and claims of payments to healthcare providers and pharmacy provider;[xx]
- December 2013 –
  - $22.28 million settlement with Genzyme Corp. concerning FCA allegations;[xxi] and
  - $5.475 million settlement with Abbott Laboratories concerning claims of payments to healthcare providers.[xxii]

Additionally, states have their own False Claims Act statutes and consumer protection laws. States that acquire drugs for their Medicaid programmes through federal contracts may also have the right to sue drug companies that overcharge for drugs. Various states obtained settlements for alleged violations of their False Claims Act statutes or consumer protection laws in 2013, including the following:

- January 2013 –
  - $5 million settlement between Pfizer, Inc., Endo Pharmaceuticals Inc., and Texas concerning claims of alleged over-charging;[xxiii]
- February 2013 –
  - $10.9 million settlement between Upsher-Smith Laboratories, Forest Laboratories, and Texas concerning claims of alleged over-charging;[xxiv]
- August 2013 –
  - $8.5 million settlement between Watson Pharmaceuticals, Inc. and Louisiana concerning claims of alleged over-charging;[xxv] and
  - $617,000 settlement between Sanofi-Aventis U.S. Inc. and Maryland concerning claims of payments to healthcare providers;[xxvi]
- September 2013 –
  - $5 million settlement between Major Pharmaceuticals Inc., The Harvard Drug Group LLC and Texas concerning claims of alleged over-charging;[xxvii]
- October 2013 –
  - $37 million settlement between McKesson Corp. and Virginia concerning claims of alleged over-charging;[xxviii]
- November 2013 –
  - $14 million settlement between McKesson Corp. and Wisconsin concerning claims of alleged over-charging;[xxix] and
  - $88.4 million settlement between Abbott Laboratories, Alcon, Apotex, Astellas Pharma Inc., Bayer AG, Biovail Corporation, Brenn Distribution, Inc., Eisai Co., Ltd., Eli Lilly and Company, Forest Laboratories, Inc., Gilead Sciences, Johnson & Johnson, Lupin Pharmaceuticals, Inc., Novartis AG, Otsuka Pharmaceutical, Par Pharmaceutical, Pernix Therapuetics, Perrigo Company, Ranbaxy Laboratories, Sanofi-Aventis, Sandoz Inc., Shire Plc, Takeda Pharmaceutical Company Limited, Taro Pharmaceutical Industries, UCB and Louisiana concerning claims of alleged over-charging.[xxx]

## III. Government Enforcement Activities against Company Executives and Counsel

### A. Basis for Corporate Liability: The Park Doctrine

Responsible corporate officers ("RCO") can be prosecuted for a violation of the United States Federal Food, Drug, and Cosmetic Act ("FDCA"). Such violations often include unlawful marketing of drugs and devices, fraud on FDA, and distribution of adulterated products. The RCO doctrine was developed in the Supreme Court decision, *United States v. Park*, 421 U.S. 658 (1975).[xxxi] In *Park*, Acme Markets President, John Park, was informed by FDA of poor conditions in his company's warehouses in Philadelphia, but the problems persisted.[xxxii] The government prosecuted Acme and Park for misdemeanour violations of food adulteration.[xxxiii] Park was convicted and was fined $250.[xxxiv] His conviction was reversed by the appellate court, but the Supreme Court reversed the appellate court and ordered Park's conviction be reinstated.[xxxv] The Supreme Court found in *Park* that the focus of RCO liability lies not in where a corporate defendant's position is within the corporate hierarchy, but rather if the corporate defendant had, "by reason of his position in the corporation, responsibility and authority either to prevent in the first instance, or promptly to correct, the violation complained of, and that he failed to do so".[xxxvi]

The "Park Doctrine" as it has evolved, provides that a responsible corporate officer can be held liable for a first time misdemeanour and a possible subsequent felony based on a violation of the FDCA without proof that the corporate officer acted with intent or even negligence, and even if such corporate officer did not have any actual knowledge of, or participation in, the specific offence.[xxxvii] The prosecution of a responsible corporate officer for a misdemeanour violation of the FDCA, a "Park Doctrine prosecution", is handled by the DOJ.[xxxviii] FDA has found that a Park Doctrine prosecution has a strong deterrent effect on pharmaceutical and medical device companies and other regulated entities.[xxxix]

FDA uses a set of non-binding criteria to evaluate RCO liability in connection with the Park Doctrine, referred to as the "Park Doctrine Criteria".[xl] When considering whether to recommend a misdemeanour prosecution against a corporate officer, FDA will consider the individual's position in the company and relationship to the violation, and whether the officer had the authority to correct

or prevent the violation.[xli] Further, FDA does not find knowledge of and actual participation in the violation to be prerequisites to a misdemeanour prosecution but does consider them factors that may be relevant when deciding whether to recommend charging a misdemeanour violation.[xlii] Other factors FDA will consider in determining whether to recommend a misdemeanour prosecution against a corporate officer include but are not limited to:

(1) whether the violation involves actual or potential harm to the public;

(2) whether the violation is obvious;

(3) whether the violation reflects a pattern of illegal behaviour and/or failure to heed prior warnings;

(4) whether the violation is widespread;

(5) whether the violation is serious;

(6) the quality of the legal and factual support for the proposed prosecution; and

(7) whether the proposed prosecution is a prudent use of agency resources.[xliii]

### B. Penalties for Park Doctrine Prosecutions

The penalties for responsible corporate officers prosecuted under the Park Doctrine include: fines; probation; jail time; FDA debarment; and exclusion from Medicare, Medicaid, or other governmentally-funded programmes. FDA can debar corporations or individuals, meaning it can prevent those corporations or individuals from having any involvement in the pharmaceutical or medical device industry.[xliv] For example, when a company applies for approval of a new drug, it must submit to FDA a signed statement that no debarred persons worked on the application.[xlv] If a pharmaceutical company does employ a debarred person, it can be fined up $1 million and the debarred person can be fined up to $250,000.[xlvi] As of April 2014, FDA has never debarred a company; however, it has permanently debarred 91 individuals.[xlvii] Additionally, the OIG has the authority to exclude individuals from federally-funded governmental programmes like Medicare and Medicaid as a consequence of felony or misdemeanour convictions for fraud and other misconduct.[xlviii]

### C. Recent Corporate Officer Prosecutions and Court Rulings Upholding Responsible Corporate Officer Prosecutions

Prosecutions of responsible corporate officers of pharmaceutical and medical device companies have continued over the past year. A brief synopsis of these recent prosecutions follows.

On March 27, 2013, the United States Attorney for the Eastern District of Virginia filed charges against Gallant Pharma International, Inc., its co-founders and co-owners, Talib Khan and Syed Huda, several sales representatives, and Gallant's office staff, supplier and shipper.[xlix] Khan and Huda were charged with conspiracy, importation contrary to law, introduction of misbranded drugs, and unlicensed medical wholesaling in violation of 21 U.S.C. §§ 331(a), 331(t), 371, and 545; Huda was additionally charged with wire fraud and making monetary transactions with criminally derived proceeds in violation of 18 U.S.C. §§ 1343 and 1957(a).[l] According to the prosecution, Gallant and its employees smuggled into the U.S. and sold non-FDA approved chemotherapy drugs and injectable cosmetic drugs and devices.[li] Many drugs also were required to carry an FDA "black box" warning and did not carry the warning or meet other FDA requirements.[lii] Khan pled guilty to a felony count of conspiracy and a felony count of introducing misbranded drugs into interstate commerce, and was sentenced to three years in prison, two years of supervised release, and to pay $3.4 million in forfeiture and restitution.[liii] Eight other defendants, including Huda, pled guilty to certain counts, and as of the date of this publication, are awaiting sentencing.[liv] As of the date of this publication, charges are still pending against two alleged co-conspirators who received the shipments of the drugs and devices.

On July 5, 2013, the United States Attorney for the Western District of Kentucky filed charges against National Respiratory Services, a medical device company, its owner and majority shareholder, Christopher Keegan, and its minority shareholder, James Rives.[lv] Keegan and Rives were charged with introducing a misbranded and adulterated drug into interstate commerce in violation of 21 U.S.C. §§ 331(a), 333(a)(1), 352(a) and 18 U.S.C. § 2.[lvi] Keegan and Rives both plead guilty to causing inhalation compounded medications to be sent to patients, through interstate commerce, which were sub-potent, super-potent, non-sterile, and therefore adulterated and misbranded in violation of the FDCA.[lvii] On October 18, 2013, Keegan was sentenced to one year of probation and to pay restitution of $2,030,343.[lviii] Rives was sentenced to one year of probation and to pay restitution of $75,985.[lix]

Not only is the government prosecuting responsible corporate officers, but appeals of these convictions and the sentences that are being imposed are continuing to be upheld. On January 7, 2013, the former CEO of InterMune, Inc., W. Scott Harkonen, sued HHS to vacate an order banning him from participating in federal health programmes stemming from a prior conviction.[lx] In 2008, Harkonen was indicted for wire fraud, aiding and abetting, and doing acts with intent to defraud and mislead, resulting in drugs being misbranded while held for sale after shipment in interstate commerce.[lxi] According to the prosecution, Harkonen made public statements regarding a new drug in a press release, promoting it off-label and overstating its effectiveness.[lxii] In 2009, a jury found Harkonen guilty of wire fraud and in April 2011, he was sentenced to six months home confinement, three years probation, 200 hours community service and a $20,000 fine.[lxiii] In June 2011, Harkonen appealed his conviction and sentence, which were affirmed in March 2013 by the Court of Appeals for the Ninth Circuit.[lxiv] In August 2011, HHS informed Harkonen that based on his felony conviction for wire fraud, he was excluded from participating in federal health programmes for five years under 42 U.S.C. §1320a-7(a)(3).[lxv] Harkonen requested review of his exclusion by an Administrative Law Judge, who affirmed the exclusion, and the HHS Appeals Board subsequently affirmed the Administrative Law Judge's decision.[lxvi] Harkonen then sued HHS, and the parties each moved for summary judgment.[lxvii] On October 22, 2013, Judge Phyllis Hamilton of the Northern District of California granted HHS's motion for summary judgment and entered judgment in favour of HHS.[lxviii] Harkonen has appealed this decision to the Ninth Circuit Court of Appeals, where the appeal remains pending as of the date of this publication.[lxix]

## IV. Hot Topics in Products Liability Cases Arising From Government Enforcement Actions

### A. New and Anticipated FDA Guidance and HHS Protocols and Their Implications on Enforcement Actions

#### 1. Anticipated Guidance on Public Unsolicited Requests for Off-Label Information

An ongoing issue for manufacturers is responding to unsolicited requests for off-label information on public forums and social media without running afoul of FDA regulations regarding promotional labelling and advertising. Specifically, companies may

encounter requests for off-label information through their product websites, discussion boards, chat rooms or other public electronic forums, and a company's response to such a request is often visible to users other than the original requester. Further, such a response can be posted for an indefinite period of time on the forum. In 2011, FDA released a draft Guidance on this issue, "Responding to Unsolicited Requests for Off-Label Information About Prescription Drugs and Medical Devices".[lxx] The draft Guidance explains FDA's view on the differences between solicited and unsolicited requests, and public versus non-public unsolicited requests.[lxxi] In response to an unsolicited public request for off-label information, such as a post on the company's Facebook page asking about an off-label use of a medication, in the draft Guidance, the FDA encourages companies to respond only when the request specifically mentions the company's named product, to identify itself as part of the company, to convey that the question pertains to an unapproved or uncleared use of the product and to contact the company further for additional information, and to ensure the response is not promotional in nature or tone.[lxxii] Provided a company follows these recommendations in responding to unsolicited requests for off-label information, the draft Guidance provides that the FDA will not use such responses as evidence of the company's intent to promote the product for an off-label use.[lxxiii] Because the draft Guidance has been viewed by some as narrow, a comprehensive guidance on this matter is expected by October 2014.[lxxiv]

### 2. New Final Guidance on Dear Health Care Provider Letters

FDA recently issued a final Guidance for pharmaceutical and medical device companies on Dear Health Care Provider Letters ("DHCP"), which update health care providers about additional warnings or new information about products.[lxxv] Among other recommendations, the Guidance recommends a DHCP letter contain a concise description of the issue that gave rise to the new warning or other change in prescribing information including the nature and severity of the issue, the population at risk, the degree of risk, whether the risk occurs with an approved or unapproved use of the drug, the rationale for the change, the recommended action, the course of patient counselling, how to report new cases of adverse reactions, company contact information and FDA contact information.[lxxvi] The Guidance includes specific formatting information including a two-page limit and minimum font type, and includes sample letters. The Guidance also specifically identifies information that should not be in a DHCP letter, including market information of a drug such as numbers of prescriptions, extensive details of the design of a clinical study, information about a safety review panel, plans to further investigate the problem if not specifically related to safety and promotional language or claims.[lxxvii] Provided a company follows the recommendations in this Guidance in their communications to physicians concerning updated warnings and information, the company will mitigate the risk of having a DHCP letter used against them by government entities for not completely and adequately warning a health care provider of a new risk or of new information.

### 3. New HHS Provider Self-Disclosure Protocol

On April 17, 2013, the OIG for HHS issued an update to its Provider Self-Disclosure Protocol ("SDP").[lxxviii] The SDP provides guidance to pharmaceutical and medical device companies who are subject to OIG's civil monetary penalty authorities on how to investigate possible fraudulent conduct involving Federal health programmes, quantify damages, and report the possible conduct to OIG.[lxxix] The SDP enables pharmaceutical and medical device companies to disclose potential violations of the Federal Anti-kickback Statute, among other violations. In making a disclosure pursuant to the SDP, among other things, a company must acknowledge that the conduct is a potential violation, explicitly identify the law(s) that were potentially violated, have performed an internal investigation concerning the conduct, and ensure that the conduct has ended or corrective action will be taken within 90 days of submission of the disclosure.[lxxx] Furthermore, the SDP has specific additional requirements for conduct involving false billing, conduct involving excluded persons, and conduct involving the anti-kickback statute and physician self-referral law.[lxxxi] While the requirements may appear rigid, making a disclosure pursuant to the SDP can be beneficial to a company. In cases involving a disclosure pursuant to the SDP, OIG has instituted a presumption against requiring corporate integrity agreement obligations.[lxxxii] Additionally, individuals or companies that use the SDP and cooperate with OIG pay a lower multiplier on single damages than would normally be required in resolving a government-initiated investigation.[lxxxiii] Aside from the enforcement action and penalties being reduced through the SDP process, the timeframe an investigation will last is reduced.[lxxxiv] While disclosures under the SDP process will not immunise a company from a government enforcement action, the benefits of an SDP can often outweigh the risks in not reporting. Companies should be mindful of their legal and ethical obligations to disclose conduct subject to investigation by OIG, and be thoughtful and thorough in any disclosures pursuant to the SDP.

## B. Parallel Civil Actions to Government Enforcement Actions

Given the high-profile nature of the government's recent prosecutions and the presumption that a guilty plea on behalf of a company or responsible corporate officer has, it is no surprise that the Plaintiffs' bar continues to file civil products liability lawsuits that parallel government enforcement actions. These parallel civil claims often reference the charges, plea and sentence from the criminal action. To the extent possible, companies should work to coordinate early and often between parallel civil and criminal litigation and their respective counsel, particularly as decisions made in the criminal litigation may expose the company to new or additional civil litigation, or force the company to make decisions it otherwise would not have in the civil litigation. As companies and responsible corporate officers continue to plead guilty to criminal charges, they can expect parallel civil actions like the following representative actions from 2013 to be filed against them:

On February 28, 2013, Plaintiff Daniel Luberda filed suit against Purdue Frederick Company and numerous of its executives alleging negligence, gross negligence, common law fraud, and violation of South Carolina Code of Laws related to an injury allegedly caused by Oxycontin.[lxxxv] The complaint references the guilty plea of several Purdue Frederick Company executives who plead guilty to the strict liability misdemeanour offence of misbranding a drug in violation of 21 U.S.C. 331(a) and 333(a)(1) related to Oxycontin.[lxxxvi] Judge R. Bryan Harwell of the District of South Carolina recently granted Motions to Dismiss of several of the executives, but the case is still proceeding against the company and other executives.[lxxxvii]

On April 30, 2013, Plaintiffs Judy Jarosch and Kai Jarosch, individually and as successors-in-interest to Marcus Jarosch, filed suit against Allergan, Inc., alleging strict liability, manufacturing defect, failure to warn, negligence, deceit by concealment, negligent misrepresentation and wrongful death related to an injury allegedly caused by Botox.[lxxxviii] The complaint references Allergan's guilty plea to off-label promotion of Botox and payment of $600 million.[lxxxix] On September 3, 2013, Plaintiffs Kevin and

Lori Drake, individually, and as next friend of J.D., filed a similar suit against Allergan, Inc., alleging strict liability, design defect, failure to warn, negligence, breach of implied warranties, breach of implied warranties, and violation of the Vermont Consumer Fraud Act related to an injury allegedly caused by Botox.[xc] Again, the complaint references Allergan's guilty plea to off-label promotion of Botox and payment of $600 million.[xci] Plaintiffs have specifically sought during discovery documents that Allergan produced to DOJ.[xcii] As of the date this article went to press, discovery is ongoing.

### C. Pharmaceutical Drug Shortages and Expected Enforcement Actions

Pharmaceutical drug shortages have increased in frequency over the last few years, caused by alleged manufacturing/quality violations, facility shutdowns, production delays, shipping problems, ingredient shortages, and discontinuations.[xciii] Critics of the FDA argue that FDA's enforcement and compliance activities contribute to these shortages.[xciv]

Recognising that pharmaceutical drug shortages pose a serious risk to public health and in an attempt to reduce these shortages, on July 9, 2012, President Obama signed the Food and Drug Administration Safety and Innovation Act (FDASIA) of 2012.[xcv] FDASIA requires all manufacturers of certain drugs to notify FDA of potential discontinuances, regardless of whether they intend to discontinue the product permanently or are facing only a temporary interruption of supply.[xcvi] FDA will issue noncompliance letters to manufacturers who fail to comply with the notification requirements and will make the letter and the manufacturer's response to the letter available to the public. FDASIA also permits FDA to conduct expedited review of certain applications and inspections and requires FDA to evaluate the risks and benefits to patients of an enforcement action and any potential shortage it could create prior to issuing an enforcement action.[xcvii] Finally, FDASIA requires FDA to establish an internal Drug Shortages Task Force to develop and implement a strategic plan for enhancing its response to drug shortages.[xcviii]

In October 2013, FDA's Drug Shortage Task Force released its Strategic Plan.[xcix] Therein, FDA indicates it plans to use some flexibility before taking an enforcement action to mitigate a shortage.[c] As an example, FDA cited permitting the distribution of an injectable drug that was susceptible to a shortage and found to contain glass and metal particles, along with a letter warning health care professionals to use a filter when administering the drug.[ci] FDA noted, however, that this discretion was temporary and conditioned on the manufacturer's ability to demonstrate that the filter did not affect the way the drug works and could successfully remove the particles.[cii] Additionally, the Strategic Plan finalised a proposed rule on notifying FDA regarding a permanent discontinuance or interruption in the supply of a certain drug or biological product.[ciii] While the Drug Shortage Task Force's Strategic Plan does not include a penalty for failure to notify FDA of a discontinuance or interruption within a period of time, companies should expect the same and additional reporting requirements once the proposed rule is finalised.

## V. Pro-Active Defence Strategies to Guard against Corporate Officer or General Counsel Liability

Because RCO liability under the Park Doctrine necessarily will only apply to individuals who "have the responsibility and authority either to prevent in the first instance or to promptly correct certain conduct", company executives must maintain a hands-on approach and be fully aware of their potential liability under the FDCA. A company should have a risk management or compliance department with set policies for best practices, and should set forth certain mandatory compliance metrics to accompany those best practices. The compliance department should have a process in place to track and report on the compliance metrics. The compliance department should be intimately familiar with the FDCA and the standards and practices of FDA, and work with the business side of the company to ensure those standards and practices are maintained. Employees on all levels – from the CEO down – should be trained on the personal civil and criminal liability they could incur by falling below these standards. Aside from setting up and implementing compliance policies, a company should also identify its areas of compliance risk and set in place a specific plan to reduce risk in those areas.

Aside from internal policies, a company should consider obtaining insurance for its executives outside of a typical Directors and Officers ("D&O") policy. Insurance broker Marsh USA is one of the only insurance providers that has a specific insurance product called a RCO Corporate Response policy, which provides insurance coverage for pharmaceutical, life sciences, and health care corporate officers who may be held liable for their companies' actions under the RCO doctrine.[civ] Specifically, the policy provides coverage for defence costs incurred in the investigation or defence of any misdemeanour criminal proceeding, as well as administrative proceedings brought pursuant to the RCO doctrine, pays lost future compensation to insured persons resulting from exclusion/ debarment, and reimburses for the value of any compensation that must be returned or repaid by an insured person as a result of a judgment, decision, or settlement of an RCO claim. Of course, insurance only covers costs and will not affect other penalties like jail time, probation or exclusion.

Should FDA or another governmental organisation initiate an investigation into a company's practices, it is in a company's best interest to cooperate fully and early with the government, and to make best efforts to be precise and accurate in statements made to the governmental organisation. A company should also keep in mind that the outcome of any investigation, whether it be no action, a consent degree, a corporate integrity agreement, a fine, or other result, may have implications in its portfolio of civil products liability litigation, even if entirely unrelated to the pharmaceutical or medical device at issue in the civil products liability litigation. The company should take proactive steps to reduce the risk of civil products liability litigation arising from government enforcement actions including involving products liability counsel in drafting any responses or statements to FDA or other government entities.

## VI. Conclusion

Given the financial recovery involved, both federal and state governments are expected to remain aggressive in their recoveries from health-care based enforcement actions in 2014. Additionally the Park Doctrine will likely continue to be used as an enforcement tool against all companies governed by the FDCA and civil lawsuits related to enforcement actions are expected to continue. Companies should continue to monitor new FDA guidance and protocols and update their best practices accordingly.

## Endnotes

i Department of Justice News Release: "Departments of Justice and Health and Human Services Announce Record-Breaking Recoveries Resulting from Joint Efforts to Combat Health Care Fraud" (Feb. 26, 2014), available at http://www.justice.gov/opa/pr/2014/February/14-ag-206.html.

ii *Id.*

iii *Id.*

iv *Id.*

v *Id.*

vi Food and Drug Administration Press Release: "International Operation Pangea VI Combats Online Sale and Distribution of Unapproved Prescription Medicines" (Jun. 27, 2013), available at http://www.fda.gov/ICECI/CriminalInvestigations/ucm358837.htm.

vii *Id.*

viii 31 U.S.C. §§ 3729(a)(1)(A),(B),(C).

ix Department of Justice News Release: "Departments of Justice and Health and Human Services Announce Record-Breaking Recoveries Resulting from Joint Efforts to Combat Health Care Fraud" (Feb. 26, 2014), available at http://www.justice.gov/opa/pr/2014/February/14-ag-206.html.

x Id.; Department of Justice News Release: "Departments of Justice and Health and Human Services Announce Record-Breaking Recoveries Resulting from Joint Efforts to Combat Health Care Fraud" (Feb. 11, 2013), available at http://www.justice.gov/opa/pr/2013/February/13-ag-180.html.

xi *Id.*

xii Department of Justice News Release: "Justice Department Recovers $3.8 Billion from False Claims Act Cases in Fiscal Year 2013" (Dec. 20, 2013), available at http://www.justice.gov/opa/pr/2013/December/13-civ-1352.html.

xiii Department of Justice News Release: "Par Pharmaceuticals Pleads Guilty and Agrees to Pay $45 Million to Resolve Civil and Criminal Allegations Related to Off-Label Marketing" (Mar. 5, 2013), available at http://www.justice.gov/opa/pr/2013/March/13-civ-270.html.

xiv Department of Justice News Release: "Amgen to Pay U.S. $24.9 Million to Resolve False Claims Act Allegations" (Apr. 16, 2013), available at http://www.justice.gov/opa/pr/2013/April/13-civ-438.html.

xv Department of Justice News Release: "Generic Drug Manufacturer Ranbaxy Pleads Guilty and Agrees to Pay $500 Million to Resolve False Claims Allegations, cGMP Violations and False Statements to the FDA" (May 13, 2013), available at http://www.justice.gov/opa/pr/2013/May/13-civ-542.html.

xvi Department of Justice News Release: "C.R. Bard Inc. to Pay U.S. $48.26 Million to Resolve False Claims Act Claims" (May 13, 2013), available at http://www.justice.gov/opa/pr/2013/May/13-civ-547.html.

xvii Department of Justice News Release: "ISTA Pharmaceuticals Inc. Pleads Guilty to Federal Felony Charges; Will Pay $33.5 Million to Resolve Criminal Liability and False Claims Act Allegations" (May 24, 2013), available at http://www.justice.gov/opa/pr/2013/May/13-civ-606.html.

xviii Department of Justice News Release: "Wyeth Pharmaceuticals Agrees to Pay $490.9 Million for Marketing the Prescription Drug Rapamune for Unapproved Uses" (Jul. 20, 2013), available at http://www.justice.gov/opa/pr/2013/July/13-civ-860.html.

xix Department of Justice News Release: "Boston Scientific and Subsidiaries to Pay $30 Million for Guidant's Sale of Defective Heart Devices for Use in Medicare Patients" (Oct. 17, 2013), available at http://www.justice.gov/opa/pr/2013/October/13-civ-1107.html.

xx Department of Justice News Release: "Johnson & Johnson to Pay More Than $2.2 Billion to Resolve Criminal and Civil Investigations" (Nov. 4, 2013), available at http://www.justice.gov/opa/pr/2013/November/13-ag-1170.html.

xxi Department of Justice News Release: "Genzyme Corp. to Pay $22.28 Million to Resolve False Claims Allegations Related to "Slurry" Used in Patients" (Dec. 20, 2013), available at http://www.justice.gov/opa/pr/2013/December/13-civ-1358.html.

xxii Department of Justice News Release: "Abbott Laboratories Pays U.S. $5.475 Million to Settle Claims That Company Paid Kickbacks to Physicians" (Dec. 27, 2013), available at http://www.justice.gov/opa/pr/2013/December/13-civ-1367.html.

xxiii Office of the Attorney General of Texas News Release: "Attorney General Abbott Recovers $36.34 Million for State of Texas, U.S." (Jan. 4, 2013), available https://www.oag.state.tx.us/oagnews/release.php?id=4262.

xxiv Office of the Attorney General of Texas News Release: "Attorney General Abbott Recovers $10.9 Million for State of Texas" (Feb. 13, 2013), available https://www.oag.state.tx.us/oagnews/release.php?id=4291.

xxv Office of the Attorney General of Louisiana News Release: "AG Caldwell Recovers $8.5 Million During Fraud Trial of Drug Company" (Aug. 15, 2013), available http://www.ag.state.la.us/Article.aspx?articleID=755&catID=2.

xxvi Office of the Attorney General of Maryland News Release: "AG Gansler: Sanofi US Pays $617,000 to Resolve Medicaid Kickback Allegations" (Aug. 22, 2013), available http://www.oag.state.md.us/Press/2013/082213.html.

xxvii Office of the Attorney General of Texas News Release: "State of Texas, U.S. to Share in $5 Million Recovery of Medicaid Funds" (Sept. 4, 2013), available https://www.oag.state.tx.us/oagnews/release.php?print=1&id=4511.

xxviii Office of the Attorney General of Virginia News Release: "Cuccinelli announces $37 million Virginia Medicaid fraud settlement with McKesson Corp. for inflating prices of 400+ drugs" (Oct. 18, 2013), available http://www.oag.state.va.us/Media%20and%20News%20Releases/News_Releases/Cuccinelli/101813_McKesson_Corp.html.

xxix Office of the Attorney General of Wisconsin News Release: "Attorney General J.B. Van Hollen Announces Settlement with McKesson and First Databank" (Nov. 5, 2013), available at http://www.doj.state.wi.us/media-center/2013-news-releases/november-5-2013.

xxx Office of the Attorney General of Louisiana News Release: "Attorney General Recovers $238 Million from Pharmaceutical Companies Engaged in Fraudulent Drug-Pricing Scheme" (Nov. 20, 2013), available at https://www.ag.state.la.us/Article.aspx?articleID=788&catID=5.

xxxi *United States v. Park*, 421 U.S. 658 (1975).

xxxii *Id.*

xxxiii *Id.*

xxxiv *Id.* at 665.

xxxv *Id.* at 678.

xxxvi *Id.* at 673-674.

xxxvii FDA Regulatory Procedures Manual, Section 6-5-3 - Special Procedures and Considerations for Park Doctrine Prosecutions (2011), available at http://www.fda.gov/ICECI/ComplianceManuals/RegulatoryProceduresManual/ucm176738.htm#SUB6-5-3.

xxxviii *Id.*

xxxix *Id.*

xl *Id.*

xli *Id.*

xlii *Id.*

xliii *Id.*

xliv 21 U.S.C. § 335-335a.

xlv Tamar Nordenberg, "Inside FDA: Barring People from the Drug Industry," FDA Consumer (Mar. 1997), available at http://www.fda.gov/ICECI/EnforcementActions/FDADebarmentList/ucm139627.htm.

xlvi *Id.*

xlvii FDA Debarment List, available at: http://www.fda.gov/ICECI/EnforcementActions/FDADebarmentList/default.htm.

xlviii 42 U.S.C. § 1320a-7.

xlix *USA v. Gallant Pharma International, Inc., et al.*, 1:13-cr-00130-CMH, Indictment, ECF No. 1 (E.D. Va. Mar. 27, 2013).

l *Id.*

li Department of Justice News Release: "Co-Leader of Illegal Drug Company Gallant Pharma Sentenced to 3 Years" (Mar. 7, 2014), available at http://www.justice.gov/usao/vae/news/2014/03/20140307khannr.html.

lii *Id.*

liii *Id.; USA v. Gallant Pharma International, Inc., et al.*, 1:13-cr-00130-CMH, Judgment, ECF No. 277 (E.D. Va. Mar. 11, 2014).

liv *Id.*

lv *USA v. National Respiratory Services, et al.*, 3:13-CR-00102-CRS-JDM, Information, ECF No. 1 (W.D. Ky. Jul. 5, 2013).

lvi Id.; Food and Drug Administration Press Release: "Former Owner of Louisville Pharmaceutical Company Pleads Guilty to FDA Violations" (Jul. 24, 2013), available at http://www.fda.gov/ICECI/CriminalInvestigations/ucm362572.htm.

lvii *USA v. National Respiratory Services, et al.*, 3:13-CR-00102-CRS-JDM, Plea Agreements, ECF Nos. 16, 17, 21, 22 (W.D. Ky. Jul. 23, 2013); Food and Drug Administration Press Release: "Former Owner of Louisville Pharmaceutical Company Pleads Guilty to FDA Violations" (Jul. 24, 2013), available at http://www.fda.gov/ICECI/CriminalInvestigations/ucm362572.htm.

lviii *USA v. National Respiratory Services, et al.*, 3:13-CR-00102-CRS-JDM, Judgment and Commitment Order, ECF No. 37 (W.D. Ky. Aug. 16, 2013).

lix *USA v. National Respiratory Services, et al.*, 3:13-CR-00102-CRS-JDM, Judgment and Commitment Order, ECF No. 38 (W.D. Ky. Aug. 16, 2013).

lx *Harkonen v. Sebelius, et al*., 4:13-cv-00071-PJH, Complaint for Declaratory, Injunctive and Other Relief, ECF No. 1 (N.D. Cal. Jan. 7, 2013).

lxi *USA v. Harkonen*, 3:08-cr-00164-MHP, Indictment, ECF No. 1 (N.D. Cal. Mar. 18, 2008).

lxii *Id.*

lxiii *USA v. Harkonen*, 3:08-cr-00164-MHP, Jury Verdict, ECF No. 240 (N.D. Cal. Sept. 29, 2009); Amended Judgment, ECF No. 382 (N.D. Cal. May 26, 2011).

lxiv *USA v. Harkonen*, 3:08-cr-00164-MHP, Amended Notice of Appeal, ECF No. 384 (N.D. Cal. Jun. 7, 2011) and USCA Memorandum, ECF No. 392 (N.D. Cal. Mar. 12, 2013); USA v. Harkonen, 11-10209, 2013 WL 782354 (9th Cir. Mar. 4, 2013).

lxv *Harkonen v. Sebelius, et al*., 4:13-cv-00071-PJH, Motion for Summary Judgment and Opposition to Plaintiff's Motion for Summary Judgment, ECF No. 30 (N.D. Cal. Jul. 12, 2013).

lxvi *Id.*

lxvii *Id.*

lxviii *Harkonen v. Sebelius, et al*., 4:13-cv-00071-PJH, Judgment, ECF No. 36 (N.D. Cal. Oct. 22, 2013).

lxix *Harkonen v. Sebelius, et al*., 4:13-cv-00071-PJH, Notice of Appeal, ECF No. 37 (N.D. Cal. Dec. 23, 2013).

lxx Food and Drug Administration Draft Guidance "Responding to Unsolicited Requests for Off-Label Information About Prescription Drugs and Medical Devices" (Dec. 27, 2011), available at http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm109905.htm.

lxxi *Id.*

lxxii *Id.*

lxxiii *Id.*

lxxiv Jeff Overley, "FDA Isn't Cracking Down On Social Media Ads, Report Says" Law360 (Apr. 8, 2013), available at http://www.law360.com/articles/430896/fda-isn-t-cracking-down-on-social-media-ads-report-says.

lxxv Food and Drug Administration Guidance "Dear Health Care Provider Letters: Improving Communication of Important Safety Information" (Jan. 23, 2014), available at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM233769.pdf?source=govdelivery&utm_medium=email&utm_source=govdelivery.

lxxvi *Id.*

lxxvii *Id.*

lxxviii Office of Inspector General for the U.S. Department of Health & Human Services: "Provider Self-Disclosure Protocol" (Apr. 17, 2013), available at http://oig.hhs.gov/compliance/self-disclosure-info/.

lxxix *Id.*

lxxx *Id.*

lxxxi *Id.*

lxxxii Office of Inspector General for the U.S. Department of Health & Human Services: "Provider Self-Disclosure Protocol" (Apr. 17, 2013), available at http://oig.hhs.gov/compliance/self-disclosure-info/.

lxxxiii Office of Inspector General for the U.S. Department of Health & Human Services: "Provider Self-Disclosure Protocol" (Apr. 17, 2013), available at http://oig.hhs.gov/compliance/self-disclosure-info/.

lxxxiv Office of Inspector General for the U.S. Department of Health & Human Services: "Provider Self-Disclosure Protocol" (Apr. 17, 2013), available at http://oig.hhs.gov/compliance/self-disclosure-info/.

lxxxv *Luberda v. Purdue Frederick Corp., et al*., 2013-CP-26-1221, Complaint (S.C. Cir. Feb. 28, 2013).

lxxxvi *Id.; USA v. The Purdue Frederick Company, Inc.*, 1:07-cr-00029-JPJ, Plea Agreements, ECF Nos. 7-9 (W.D. Va. May 10, 2007).

lxxxvii *Luberda v. Purdue Frederick Corp., et al.*, 4:13-CV-00897-RBH, Order, ECF No. 186 (D. S. C. Mar. 28, 2014).

lxxxviii *Jarosch, et al. v. Allergan, Inc*., No. 30-2013-00646924, Complaint for Damages and Demand for Jury Trial (Cal. Super. Apr. 30, 2013).

lxxxix *Id.*

xc *Drake, et al. v. Allergan, Inc*., 2:13-CV-00234-WKS, ECF No. 1, Complaint (D. Vt. Sept. 3, 2013).

xci *Id.*

xcii *Drake, et al. v. Allergan, Inc.*, 2:13-CV-00234-WKS, ECF No. 34, Complaint (D. Vt. Sept. 3, 2013).

xciii Patricia Anstett, "FDA: Prescription-drug Shortages Getting Worse," The Seattle Times (Jan. 21, 2012), available at http://seattletimes.nwsource.com/html/health/2017293495_drugshortage22.html; Katie Thomas "Drug Shortages Persist in U.S., Harming Care," The New York Times (Nov. 15, 2012), available at http://www.nytimes.com/2012/11/17/business/drug-shortages-are-becoming-persistent-in-us.html?pagewanted=all.

xciv Nadia Kounang, "Is the FDA to blame for drug shortages?," CNN (Jul. 25, 2012), available at http://www.cnn.com/2012/07/25/health/fda-drug-shortages.

xcv Food and Drug Administration Safety and Innovation Act (FDASIA) (Public Law 112-144); see also "Fact Sheet: Drug Products in Shortage in the United States" (Jul. 23, 2012) available at http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCAct/SignificantAmendmentstotheFDCAct/FDASIA/ucm313121.htm.

xcvi *Id.*

xcvii *Id.*

xcviii *Id.*; see also Valerie Jensen, "FDA is asking the public to send in ideas for combating drug shortages," FDA Voice (Feb. 13, 2013), available at http://blogs.fda.gov/fdavoice/index.php/2013/02/fda-is-asking-the-public-to-send-in-ideas-for-combating-drug-shortages/.

xcix Food and Drug Administration Strategic Plan for Preventing and Mitigating Drug Shortages (October 2013), available at http://www.fda.gov/downloads/drugs/drugsafety/drugshortages/ucm372566.pdf.

c *Id.*

ci *Id.*

cii *Id.*

ciii *Id.*; Food and Drug Administration Proposed Rule: Permanent Discontinuance or Interruption in Manufacturing of Certain Drug or Biological Products (November 4, 2013), available at https://www.federalregister.gov/articles/2013/11/04/2013-25956/permanent-discontinuance-or-interruption-in-manufacturing-of-certain-drug-or-biological-products.

civ Marsh USA RCO Corporate Response (Feb. 7, 2012), available at https://usa.marsh.com/ProductsServices/MarshSolutions/ID/19546/RCO-Corporate-Response.aspx; Judy Greenwald, "2013 Innovation Awards: RCO Corporate Response," Business Insurance (Mar. 10, 2013), available at http://www.businessinsurance.com/article/20130310/NEWS07/303109993#.

**Lori G. Cohen**

Greenberg Traurig, LLP
3333 Piedmont Road NE
Suite 2500
Atlanta, GA 30305
USA

*Tel:* +1 678 553 2385
*Fax:* +1 678 553 2386
*Email:* cohenl@gtlaw.com
*URL:* www.gtlaw.com

Lori G. Cohen chairs Greenberg Traurig's national Pharmaceutical, Medical Device & Health Care Litigation Practice Group and Trial Practice Group. She has a national litigation practice focusing on products liability litigation and specifically, medical device and pharmaceutical litigation. She serves as both National and Regional Counsel for multinational companies and has expertise in mass tort, multidistrict and class action litigation. Lori has obtained 56 defence verdicts at trial.

She has been profiled in Law360's 2012 "Top Female Trial Attorneys", the *Financial Times* and *The National Law Journal*'s "Winning- Successful Strategies From Some of the National's Top Litigators". *The National Law Journal* recognised her as one of "The 50 Most Influential Women Lawyers in America" and featured her as one of the "Top 40 Under 40", which highlights the 40 most successful U.S. litigators under the age of 40. The National Law Journal also recognised two of her trial victories as "Top Defense Wins". She is listed in *Best Lawyers in America, The Legal 500: United States*, *The Legal 500*'s "Leading Trial Lawyers", *Chambers and Partners USA Guide*, *Outstanding Lawyers in America, The International Who's Who of Business Lawyers, The International Who's Who of Life Science Lawyers, The International Who's Who of Products Liability Defense Lawyers*, *Georgia Trend's* "Legal Elite" and *Georgia Super Lawyers*, including "Top 10 Georgia Super Lawyers" (2013-2014), "Top 100 Georgia Super Lawyers" (2005-2014) and "Top 50 Female Georgia Super Lawyers" (2005-2014). Lori was one of a very small group of attorneys selected nationally for inclusion in the 2010-2013 editions of the Chambers and Partners USA Guide's National Pharmaceutical Industry Products Liability Table.

**Christiana C. Jacxsens**

Greenberg Traurig, LLP
3333 Piedmont Road NE
Suite 2500
Atlanta, GA 30305
USA

*Tel:* +1 678 553 2105
*Fax:* +1 678 553 2106
*Email:* jacxsensc@gtlaw.com
*URL:* www.gtlaw.com

Christiana C. Jacxsens is a shareholder in Greenberg Traurig's Products Liability Litigation Practice. She concentrates her practice on complex medical and products liability litigation, with a focus on pharmaceutical and medical device litigation. Christiana has experience managing litigation, including mass tort litigation, involving a variety of products and medical issues, such as pharmaceuticals, orthopedic and spinal medical devices, ICDs, sutures, surgical mesh devices and investigational products. She has served as second chair trial counsel in complex medical negligence cases and has assisted in the trials of medical device products liability and clinical trial cases. In addition, she advises hospitals, physician groups, pharmaceutical and medical device companies on regulatory and compliance matters, including informed consent issues, adverse event reporting, and HIPAA compliance.

She was selected by the *Daily Report* as one of 2010's 10 Atlanta attorneys "On the Rise," and is listed in *The Best Lawyers in America*, (2013-2014), *Georgia Super Lawyers* magazine as a "Rising Star" (2010-2014) and Georgia Trend's "Legal Elite" (2012-2013). She is a frequent author and speaker on products liability and medical malpractice litigation issues.

GT GreenbergTraurig

Greenberg Traurig, LLP is an international, multi-practice law firm with approximately 1,750 attorneys serving clients from 36 offices in the United States, Latin America, Europe, the Middle East and Asia. Greenberg Traurig is among the Top 10 law firms on *The National Law Journal*'s 2013 NLJ 350, an annual ranking of the largest firms in the U.S. Our Products Liability Practice was selected as a *Law360* 2011 "Practice Group of the Year". We offer clients a team of experienced trial attorneys, broad national coverage and sophistication in managing complex, high-profile cases. We help clients bridge diverse legal systems and cultures, with a focus on efficient and effective strategic advice and services. Our Products Liability team is supported by complementary resources in the areas of health care law and regulation, white collar litigation and governmental affairs. For additional information, please visit www.gtlaw.com.

Other titles in the ICLG series include:

- Alternative Investment Funds
- Aviation Law
- Business Crime
- Cartels & Leniency
- Class & Group Actions
- Competition Litigation
- Construction & Engineering Law
- Copyright
- Corporate Governance
- Corporate Immigration
- Corporate Recovery & Insolvency
- Corporate Tax
- Data Protection
- Employment & Labour Law
- Environment & Climate Change Law
- Franchise
- Insurance & Reinsurance
- International Arbitration
- Lending & Secured Finance
- Litigation & Dispute Resolution
- Merger Control
- Mergers & Acquisitions
- Mining Law
- Oil & Gas Regulation
- Patents
- Pharmaceutical Advertising
- Private Client
- Project Finance
- Public Procurement
- Real Estate
- Securitisation
- Shipping Law
- Telecoms, Media & Internet
- Trade Marks

GLG
Global Legal Group

59 Tanner Street, London SE1 3PL, United Kingdom
Tel: +44 20 7367 0720 / Fax: +44 20 7407 5255
Email: sales@glgroup.co.uk

www.iclg.co.uk