ICLG

The International Comparative Legal Guide to:

# Product Liability 2015

**13th Edition**

A practical cross-border insight into product liability work

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

Advokatfirma Ræder DA
Advokatfirman NorelidHolm
Ali Budiardjo, Nugroho, Reksodiputro
Allen & Gledhill LLP
Andreas Neocleous & Co LLC
Arnold & Porter (UK) LLP
Bahas, Gramatidis & Partners
Bennett Jones LLP
Bloomfield Law Practice
BOPS
Bufete Ocampo, Salcedo, Navarro y Ocampo, S. C.
Bulló – Tassi – Estebenet – Lipera – Torassa – Abogados
Carroll Burdick
Clayton Utz
Crown Office Chambers
DLA Piper Rus Limited
Drinker Biddle & Reath LLP
Eversheds
Faus & Moliner
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
Matheson
McConnell Valdés LLC
Nagashima Ohno & Tsunematsu
Pachiu and Associates
Pinheiro Neto – Advogados
Seth Associates
Sidley Austin LLP
Taylor Wessing

CDR Commercial Dispute Resolution
GLG Global Legal Group

GLG
Global Legal Group

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

**Head of Business Development**
Dror Levy

**Sales Director**
Florjan Osmani

**Commercial Director**
Antony Dine

**Account Directors**
Oliver Smith, Rory Smith

**Senior Account Manager**
Maria Lopez

**Sales Support Manager**
Toni Hayward

**Senior Editor**
Suzie Levy

**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 2015

Copyright © 2015
Global Legal Group Ltd.
All rights reserved
No photocopying

**ISBN** 978-1-910083-46-8
**ISSN** 1740-1887

**Strategic Partners**

MIX
Paper from responsible sources
FSC® C011748

## General Chapters:



## Country Question and Answer Chapters:



**Further copies of this book and others in the series can be ordered from the publisher. Please call +44 20 7367 0720**

**Disclaimer**
This publication is for general information purposes only. It does not purport to provide comprehensive full legal or other advice.
Global Legal Group Ltd. and the contributors accept no responsibility for losses that may arise from reliance upon information contained in this publication.
This publication is intended to give an indication of legal issues upon which you may need advice. Full legal advice should be taken from a qualified professional when dealing with specific situations.

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

Christiana C. Jacxsens

Marcella C. Ducca

Greenberg Traurig, LLP

## I. Introduction

On March 19, 2015, the Attorney General Eric Holder and the Department of Health and Human Services ("HHS") Secretary Sylvia M. Burwell released a report showing that the U.S. government's health care fraud prevention and enforcement efforts recovered nearly $3.3 billion in taxpayer dollars in fiscal year 2014, $1 billion less than it recovered in fiscal year 2013.[1] While financial recovery dipped this year, the U.S. government has recovered $27.8 billion over the past seventeen years, since the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") established a national Health Care Fraud and Abuse Control Program ("HCFAC").[2] 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 to the pharmaceutical and medical device industry.[3]

The federal government this year has increased its focus on targeting individual executives for criminal liability in an attempt to change the behaviour of companies, rather than simply fining companies. Governmental investigations and the threat of prosecution 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 2014 related to pharmaceutical and medical device companies;
- a synopsis of government enforcement activities against company executives and counsel in 2014, 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 2014

Fiscal year 2014 was a significant year for the government's health care fraud prevention and enforcement efforts.[4] For every one dollar spent on health care-related fraud and abuse investigations from 2012-2014, the government recovered $7.70.[5] 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.

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.[6] In FY 2014, DOJ opened 924 new criminal health care fraud investigations involving 805 potential defendants, and convicted 734 defendants of health care fraud-related crimes.[7] DOJ also opened 782 new civil health care fraud investigations in FY 2014.[8]

DOJ obtained a record $5.69 billion through civil health care fraud cases brought under the FCA during fiscal year 2014.[9] Of the $5.69 billion recovered in FY 2014, nearly $3 billion related to lawsuits filed under the whistleblower, or *qui tam*, provisions of the FCA.[10] The *qui tam* provisions of the FCA allow individuals to file lawsuits alleging false claims on behalf of the government.[11] If the government prevails in the action, the whistleblower receives up to 30 percent of the recovery.[12] There were over 700 *qui tam* suits filed in FY 2014.[13] Of the total recovery from *qui tam* cases during FY 2014, whistleblowers received $435 million.[14]

The following are representative of settlements negotiated by the DOJ with pharmaceutical and medical device companies in 2014:

- January 2014 –
  - $40.1 million settlement with CareFusion Corp. concerning FCA allegations.[15]
- February 2014 –
  - $5.25 million settlement with EndoGastric Solutions Inc. concerning FCA allegations.[16]
  - $192.7 million payment including $20.8 million in penalties and forfeiture and $171.9 million settlement



© Published and reproduced with kind permission by Global Legal Group Ltd, London

with Endo Pharmaceuticals and Endo Health Solutions concerning claims of misbranding.[17]

- March 2014 –
  - $27.6 million settlement with Teva Pharmaceuticals USA Inc. and its subsidiary, IVAX LLC, concerning FCA allegations.[18]
- April 2014 –
  - $7.3 million settlement with Astellas Pharma US Inc. concerning FCA allegations.[19]
- May 2014 –
  - $9.9 million settlement with Medtronic, Inc. concerning claims of payments to healthcare providers.[20]
- June 2014 –
  - $124 million settlement with Omnicare, Inc. concerning claims of payments to healthcare providers.[21]
- July 2014 –
  - $520,000 settlement with Vascular Solutions Inc. concerning FCA allegations.[22]
- August 2014 –
  - $18 million settlement with McKesson Corporation concerning FCA allegations.[23]
  - $2.6 million settlement with Omni Surgical L.P., doing business as Spine 360, concerning claims of payments to healthcare providers.[24]
- September 2014 –
  - $56.5 million settlement with Shire Pharmaceuticals LLC concerning FCA allegations.[25]
- October 2014 –
  - $6.07 million settlement with Biomet Spine and Bone Healing Technologies and Biomet Inc. concerning claims of payments to healthcare providers.[26]
- November 2014 –
  - $4.9 million settlement with Biotronik Inc. concerning claims of payments to healthcare providers.[27]
- December 2014 –
  - $80 million payment including $34.4 million in fines, $5.16 million in criminal forfeiture, and $40 million in civil settlement with OtisMed Corp. concerning distributing adulterated medical devices.[28]

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 2014, including the following:

- March 2014 –
  - $5.9 million settlement between Janssen Ortho LLC and Janssen Pharmaceuticals, Inc. and Montana concerning claims of deceptive marketing.[29]
- June 2014 –
  - $105 million settlement between GlaxoSmithKline LLC and 45 states concerning claims of marketing drugs for unapproved uses.[30]
- August 2014 –
  - $19.5 million settlement between Taro Pharmaceuticals USA, Inc. and Texas concerning claims of misreporting drug prices.[31]
  - $35 million settlement between Wyeth Pharmaceuticals, Inc. and 42 states regarding off-label promotion.[32]
- October 2014 –
  - $31 million settlement between Organon International and 50 states concerning claims of misreporting drug prices, off-label promotion, and improper financial incentives.[33]
  - $39.75 million settlement between Pharmaceuticals, Inc., Ranbaxy Laboratories, Inc., Ranbaxy USA, Inc. and Ranbaxy, Inc. and Texas concerning claims of misreporting drug prices.[34]
- November 2014 –
  - $9.5 million settlement between Pfizer, Inc. and Nevada concerning claims of deceptive trade practices.[35]

## 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 the FDA, and distribution of adulterated products. The RCO doctrine was developed in the United States Supreme Court decision, *United States v. Park*, 421 U.S. 658 (1975).[36] 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.[37] The government prosecuted Acme and Park for misdemeanour violations of food adulteration.[38] Park was convicted and was fined $250.[39] His conviction was reversed by the appellate court, but the United States Supreme Court reversed the appellate court and ordered Park's conviction be reinstated.[40] 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".[41]

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.[42] The prosecution of a responsible corporate officer for a misdemeanour violation of the FDCA, a "Park Doctrine prosecution", is handled by the DOJ.[43] FDA has found that a Park Doctrine prosecution has a strong deterrent effect on pharmaceutical and medical device companies and other regulated entities.[44]

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".[45] 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.[46] 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.[47] 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;


© Published and reproduced with kind permission by Global Legal Group Ltd, London

(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.[48]

### 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 government-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.[49] 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.[50] If a pharmaceutical company does employ a debarred person, it can be fined up to $1 million and the debarred person can be fined up to $250,000.[51] As of April 2015, FDA has never debarred a company; however, it has permanently debarred 91 individuals.[52] Additionally, the OIG has the authority to individuals and entities from federally funded governmental programmes like Medicare and Medicaid as a consequence of felony or misdemeanour convictions for fraud and other misconduct. In 2014, the OIG excluded 3,754 individuals and entities from federally funded programmes.[53]

### 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 increased over the past year. A brief synopsis of these recent prosecutions follows.

On February 25, 2013, the United States Attorney for the Middle District of Georgia filed charges against four former officials of the Peanut Corporation of America ("PCA"), the President, Vice President, Operations Manager, and Office Manager/Quality Assurance Manager.[54] The government alleged the officials participated in a scheme to manufacture and ship salmonella-contaminated peanuts and peanut products.[55] The government relied on the Park Doctrine to support their allegations that the four officials defrauded PCA customers about the quality and purity of their peanut products and specifically misled PCA customers about the existence of foodborne pathogens in the peanut products PCA sold to them.[56] The charges were conspiracy, introduction of adulterated food into interstate commerce with intent to defraud or mislead in violation of 21 U.S.C. §§ 331(a) and 333(a)(2), introduction of misbranded food into interstate commerce with intent to defraud or mislead in violation of 21 U.S.C. §§ 331(a) and 333(a)(2), interstate shipments fraud, wire fraud, and obstruction of justice.[57] While initially all four officials pled not guilty, after a year of discovery, the Operations Manager pled guilty to several counts in exchange for a lesser sentence recommendation from the United States Attorney.[58] An additional fifth official, another Operations Manager, pled guilty to the same counts except for obstruction of justice prior to the charges being filed against the other four officials, in exchange for a lesser sentence recommendation from the United States Attorney.[59] On September 19, 2014, after a seven week trial, during which prosecutors presented the testimony of 45 witnesses (including the two Operation Mangers) and introduced 1,001 documents into evidence, a federal jury found the three remaining officials guilty.[60] The President and Vice President were convicted of conspiracy, mail and wire fraud, and the introduction of misbranded food into interstate commerce; the President was also convicted of the introduction of adulterated food, and the President and the Quality Assurance Manager were convicted of obstruction of justice.[61] As of the date of this publication, no date had been set for sentencing. The President, Vice-President, and Quality Assurance Manager have moved for a judgment of acquittal or, in the alternative, for a new trial on the basis that the jury improperly learned of nine deaths linked to the salmonella outbreak by performing their own research.[62]

On November 13, 2014, the United States Attorney for the Western District of Texas filed charges against Vascular Solutions, Inc. ("VSI") and its CEO.[63] VSI and the CEO were each charged with one count of conspiracy; four counts of introducing adulterated medical devices into interstate commerce in violation of 21 U.S.C. §§ 331(a), 351(f)(1)(B), and 331(a)(1); and four counts of introducing misbranded medical devices into interstate commerce in violation of 21 U.S.C. §§ 331(a), 352(o), 352(f)(1) and 331(a)(1).[64] VSI's Vari-Lase product line, a system designed to treat varicose veins by laser ablation, was cleared by the FDA only for the treatment of superficial veins; the government alleges the CEO and VSI sold and promoted the Vari-Lase products without clearance for the ablation of perforator veins, which is a more difficult and risky procedure because perforator veins connect the superficial vein system to the deep vein system.[65] The government alleges the CEO lead an illegal sales campaign which ignored specific warnings from the FDA not to sell Vari-Lase products for treatment of perforator veins, and then conspired with others to hide the campaign from the FDA.[66] The government further alleges that, with the CEO's approval, VSI continued to sell Vari-Lase for perforator vein treatment even after a company-sponsored clinical trial showed that the Vari-Lase system was less safe and effective than a competing device that the FDA had cleared for perforator vein treatment, after a whistleblower complained to the CEO, and after the government told the company about its investigation.[67] The government further alleges that the CEO urged the sales force to suggest to health care providers that Vari-Lase devices could be used to treat perforator veins.[68] Both VSI and the CEO have pled not guilty to all charges and discovery is ongoing as of the date of this publication.[69]

On December 8, 2014, the United States Attorney for the District of New Jersey filed charges against OtisMed Corporation and its founder and CEO.[70] OtisMed Corporation was charged with introduction of adulterated medical devices into interstate commerce with intent to defraud and mislead in violation of 21 U.S.C. §§ 331(a) and 333(a)(2) and the CEO was charged with three counts of introduction of adulterated medical devices into interstate commerce in violation of 21 U.S.C. §§ 331(a) and 333(a)(1).[71] The CEO founded OtisMed and conceived of its primary product, the OtisKnee orthopedic cutting guide, used by surgeons during knee replacement to ensure that surgical cuts were made at a precise angle, in order to aid in the success of the overall surgery.[72] None of OtisMed's claims regarding the OtisKnee device were evaluated by the FDA before the company used them in advertisements and promotional material.[73] Between May 2006 and September 2009, OtisMed sold more than 18,000 OtisKnee devices, generating revenue of approximately $27.1 million.[74] On October 2, 2008, OtisMed submitted a pre-market notification to the FDA seeking clearance to market the OtisKnee. OtisMed had not previously sought the FDA's clearance or approval and had falsely represented to physicians and other potential purchasers that the product was exempt from such pre-market requirements.[75] On September 2, 2009, the FDA informed OtisMed that its submission seeking clearance had been denied and warned OtisMed that any distribution prior to obtaining clearance would be an FDCA violation.[76] The CEO also received


© Published and reproduced with kind permission by Global Legal Group Ltd, London

advice from legal and regulatory counsel confirming it would be unlawful for OtisMed to continue distributing the OtisKnee.[77] Yet, the CEO directed OtisMed employees to organise a mass shipment of all OtisKnee devices that had been manufactured but had not yet been shipped and suggested ways for the employees to hide the shipments from FDA regulators. At the CEO's direction, OtisMed shipped additional OtisKnee guides per week after FDA denied OtisMed's request for clearance.[78] Both OtisMed and the CEO have pled guilty to the charges, but as of the date of this publication, the CEO has not been sentenced.[79] OtisMed was fined $34.4 million and ordered to pay $5.16 million in criminal forfeiture, as well as $40 million plus interest to resolve its civil liability.[80] OtisMed also agreed to be excluded from participating in all federal health care programmes for a period of 20 years.[81] OtisMed was a privately held company when OtisMed and the CEO committed the criminal conduct, but was later acquired by Stryker Corporation.[82] Stryker has agreed to a series of compliance measures aimed at preventing future misconduct.[83]

On December 16, 2014, the United States Attorney for the District of Massachusetts filed charges against 14 individuals who worked at or acted as owners of New England Compounding Center ("NECC"), the company who compounded preservative-free methylprednisolone acetate injections which were contaminated and led to a nationwide fungal meningitis outbreak in 2012 and many subsequent deaths.[84] The sealed indictment contained 131 counts, including racketeering, conspiracy, conspiracy, mail fraud, introduction of adulterated drugs into interstate commerce, introduction of misbranded drugs into interstate commerce, contempt and aiding and abetting.[85] NECC's owner and head pharmacist and NECC's supervisory pharmacist were charged second-degree murder of 25 individuals in Florida, Indiana, Maryland, Michigan, North Carolina, Tennessee and Virginia.[86] The other individuals charged were six NECC pharmacists, an NECC pharmacy technician, the NECC Director of Operations, the NECC National Sales Director, two of NECC's owners and directors, and the husband of NECC's majority shareholder.[87] Among other allegations, the government alleged the NECC employees were prioritising production over cleaning and disinfecting, were fraudulently completely cleaning logs, were aware of contamination and did not investigate the sources, failed to meet sterilisation requirements and ultimately knew they were producing medication in an unsafe manner and in unsanitary conditions, and authorised the medication to be shipped out anyway.[88] Many of the indictment's allegations use the various criminal defendants' internal emails to support allegations of conspiracy.[89] All 14 individuals have pled not guilty to all charges and discovery is ongoing as of the date of this publication.[90]

Appeals of convictions and sentences that are being imposed on responsible corporate officers are being upheld. On January 7, 2013, the former CEO of InterMune, Inc., sued HHS to vacate an order banning him from participating in federal health programmes stemming from a prior conviction.[91] In 2008, the former CEO 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.[92] According to the prosecution, the CEO made public statements regarding a new drug in a press release, promoting it off-label and overstating its effectiveness.[93] In 2009, a jury found the CEO 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.[94] In June 2011, the CEO appealed his conviction and sentence, which were affirmed in March 2013 by the Court of Appeals for the Ninth Circuit.[95] In August 2011, HHS informed the CEO 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).[96] The CEO 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.[97] The CEO then sued HHS, and the parties each moved for summary judgment.[98] 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.[99] The CEO has appealed this decision to the Ninth Circuit Court of Appeals where his case has been briefed and argued; the appeal remains pending as of the date of this publication.[100]

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

### A. The intersection of free speech and FCA claims

In 2012, the Second Circuit overturned the conviction of a pharmaceutical sales representative, convicted for criminal conspiracy to introduce misbranded drugs, finding he was improperly prosecuted for truthful speech about unapproved drug uses.[101] The sales representative was convicted of conspiring to promote the drug Xyrem, manufactured by Orphan Medical, for uses not approved by FDA. The Second Circuit held that the government cannot prosecute pharmaceutical manufacturers and their representatives under the FDCA for speech promoting the lawful, off-label use of an FDA-approved drug.[102] In the wake of *Caronia*, the government refined its tactics for FCA cases involving alleged improper marketing and promotion. As the government did in the recent VSI prosecution, the focus shifted from speech that promotes a product for off-label use to sales of a product for unapproved uses.[103] Yet, few cases have addressed this issue head-on, and the impact of *Caronia* remains unknown. In *Solis v. Millennium*, a former sales representative turned whistleblower at Schering-Plough (later Merck and Company) and Millennium Pharmaceuticals, alleged that the two manufacturers illegally marketed the heart medication Integrilin for unapproved off-label use and had the government known that the companies caused procurement for off-label use, it would not have provided reimbursement for such prescriptions.[104] The plaintiff alleged this conduct violated the FCA. The government declined to intervene in the case. Both defendant manufacturers moved to dismiss on various grounds and Millennium argued the plaintiff's claims should be dismissed because speech in aid of pharmaceutical marketing is a form of expression protected by the Free Speech Clause of the First Amendment and off-label speech is not a violation of the FCA.[105] *Amicus* briefs were filed in the case by both by PhRMA and DOJ.[106] PhRMA argued the defendant manufacturers were sued for their speech.[107] PhRMA argued further that for a party's speech to knowingly cause someone else to submit a false claim under the FCA, the First Amendment demands a direct causal nexus between the speech and the claim.[108] DOJ argued the speech was evidence and attempted to distinguish the speech from the actual act of inducing submission of false claims.[109] On March 26, 2015, the court granted Millennium's Motion to Dismiss, finding that prior federal lawsuits identified the same allegedly improper conduct by the whistleblower, that the whistleblower was not the original source of the FCA allegations, and therefore the court did not have jurisdiction under the FCA to proceed.[110] The Court did not address the free speech arguments in its Order.[111] On March 30, 2015, the court denied Merck and Schering-Plough's Joint Motion to Dismiss, however, Merck and Schering-Plough moved for reconsideration, arguing that the grounds to dismiss Millennium


© Published and reproduced with kind permission by Global Legal Group Ltd, London

were equally applicable to Merck and Schering-Plough.[112] This case remains pending as of the date of this publication, but significantly, the implications of *Caronia* and free speech on FCA claims remain untested as the court's ruling did not address these matters.

### B. New and anticipated FDA guidances and their implications on enforcement actions

In June 2014, the FDA released two long-anticipated draft guidances to address promotional labelling and advertising on the internet and social media platforms.[113] One guidance, "Internet/Social Media Platforms with Character Space Limitations — Presenting Risk and Benefit Information for Prescription Drugs and Medical Devices" provides recommendations for the presentation of risk and benefit information for prescription drugs or medical devices using Internet/social media sources with character space limitations, such as Twitter and the paid search result links on Google.[114] The draft guidance recommended that manufacturers include a drug's brand name, active ingredient, benefits and serious risks, as well as a hyperlink to complete risk information, within any character space limitation.[115] The draft guidance acknowledged that manufacturers will not always be able to satisfy that recommendation given some platforms like Twitter have a 140 character limit per tweet and given the need for some lengthier risk information; in those cases, FDA recommends the manufacturer reconsider using that platform.[116] However, in comment letters by Pharmaceutical Research and Manufacturers of America ("PhRMA") and the Medical Information Working Group, concerns were raised that this draft guidance would violate the First Amendment and FDA's own prior Twitter posts regarding pharmaceutical approvals.[117] It is not clear when a final guidance will be released, but if the final guidance mirrors the draft, companies should be cautious regarding their Twitter, Facebook and other social media posts, as such posts could be used against them in future enforcement actions or civil actions.

In its draft guidance "Internet/Social Media Platforms: Correcting Independent Third-Party Misinformation about Prescription Drugs and Medical Devices", FDA provides recommendations on the correction of misinformation from independent third parties on the Internet and through social media sites.[118] The draft guidance does not require a company to correct such third party misinformation; rather, if a company decides to voluntarily correct misinformation about its own product that is created or disseminated by an independent third party who is not under the firm's control or influence, a company can do so by providing appropriate truthful and non-misleading corrective information or, alternatively, by providing a reputable source from which to obtain the correct information.[119] While the draft guidance states FDA does not expect a company not expected to correct each piece of misinformation in an entire forum, but if and when a company chooses to do so, it should identify the misinformation it is correcting, define the portion of the forum it is correcting, and correct all the misinformation that appears in that clearly defined portion, including negative information and overly positive information which misstates the benefits of a product.[120] Companies need to be aware that cherry-picking of correcting certain misinformation and the failure to correct misinformation (particularly overly positive misinformation that overstates a product's benefits) could be used as fodder in future civil actions.

Additionally, FDA is expected to finalise a rule in September 2015, first proposed in 2012, that would allow generic-drug manufacturers to unilaterally change their warning labels based on new safety information, similar to brand-drug manufacturers. If finalised, the rule could result in liability for generic manufacturers if they fail to warn of their drugs' risks, even if that would means that their labelling is different from the brand manufacturers.[121] Aside from civil liability, generic manufacturers could face enforcement actions related to their drug labelling.

## V. Proactive Defence Strategies to Guard against Corporate Officer or General Counsel Liability

At a recent pharmaceutical compliance conference, Assistant Attorney General Stuart F. Delery (now Acting Associate Attorney General) reinforced the government's commitment to targeting health care fraud and abuse wherever they find it, but also emphasised the government's need to be "allies and partners" with industry.[122] Delery encouraged companies to design compliance programmes with "buy-in at all levels of the company", incentivising individuals to "see, report, and fix problems".[123] Delery cited an example of a generic drug manufacturer who ultimately pled guilty to felony charges after the manufacturer received early warnings of adulterated and misbranded drugs, hired auditors to investigate the issues, but never actually changed any practices or provided any additional training or resources.[124]

Given the government's recent remarks, recent prosecutions, and the RCO provisions for liability under the *Park* Doctrine, it is crucial for company executives to 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, and should not wait to do so until FDA or another governmental organisation brings an investigation into the company's practices.

DOJ has emphasised it would reward early disclosure of a serious problem, stating "the decision to come forward is the right one. When a company or individual acts responsibly by timely and voluntarily disclosing unlawful conduct, we will give serious consideration to that disclosure in deciding whether or how to charge or resolve the matter. Likewise, we will credit actions taken once the government has started to investigate".[125] Therefore, a company that recognises a serious issue is incentivised to disclose it to FDA or another governmental organisation, rather than wait for an investigation. Further, once FDA or another governmental organisation initiates 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, while continuing to be proactive and forthcoming with investigators.


© Published and reproduced with kind permission by Global Legal Group Ltd, London

## VI. Conclusion

Both federal and state governments are expected to remain aggressive in seeking financial recoveries from health-care based enforcement actions in 2015, and, given the financial incentives involved, whistleblower claims are expected to continue to rise. However, as Acting Associate Attorney General Delery recently explained, the government is not interested in "merely collecting a large fine and moving on to the next case".[126] The government has placed "a renewed emphasis on identifying non-monetary measures" that will help prevent the recurrence of misconduct and will "continue to seek criminal penalties, against both companies and individuals, under appropriate circumstances".[127]

## Endnotes

1. Department of Justice News Release: "Departments of Justice and Health and Human Services Announce Over $27.8 Billion in Returns from Joint Efforts to Combat Health Care Fraud" (Mar. 19, 2015), available at http://www.justice.gov/opa/pr/departments-justice-and-health-and-human-services-announce-over-278-billion-returns-joint.
2. *Id.*; Annual Report of the Departments of Health and Human Services and Justice, Justice, Health Care Fraud and Abuse Control Program FY 2014, available at https://oig.hhs.gov/publications/docs/hcfac/FY2014-hcfac.pdf.
3. *Id.*
4. Department of Justice News Release: "Departments of Justice and Health and Human Services Announce Over $27.8 Billion in Returns from Joint Efforts to Combat Health Care Fraud" (Mar. 19, 2015), available at http://www.justice.gov/opa/pr/departments-justice-and-health-and-human-services-announce-over-278-billion-returns-joint.
5. *Id.*
6. 31 U.S.C. §§ 3729(a)(1)(A),(B),(C).
7. Department of Justice News Release: "Departments of Justice and Health and Human Services Announce Over $27.8 Billion in Returns from Joint Efforts to Combat Health Care Fraud" (Mar. 19, 2015), available at http://www.justice.gov/opa/pr/departments-justice-and-health-and-human-services-announce-over-278-billion-returns-joint.
8. *Id.*
9. Department of Justice News Release: "Justice Department Recovers Nearly $6 Billion from False Claims Act Cases in Fiscal Year 2014; First Annual Recovery to Exceed $5 Billion; Over 700 Whistleblower Lawsuits for Second Consecutive Year" (Nov. 20, 2014), available at http://www.justice.gov/opa/pr/justice-department-recovers-nearly-6-billion-false-claims-act-cases-fiscal-year-2014.
10. *Id.*
11. *Id.*
12. *Id.*
13. *Id.*
14. *Id.*
15. Department of Justice News Release: "CareFusion to Pay the Government $40.1 Million to Resolve Allegations That Include More Than $11 Million in Kickbacks to One Doctor" (Jan. 9, 2014), available at http://www.justice.gov/opa/pr/carefusion-pay-government-401-million-resolve-allegations-include-more-11-million-kickbacks.
16. Department of Justice News Release: "Washington-Based Medical Device Manufacturer to Pay up to $5.25 Million to Settle Allegations of Causing False Billing of Federal Health Care Programs" (Feb. 19, 2014), available at http://www.justice.gov/opa/pr/washington-based-medical-device-manufacturer-pay-525-million-settle-allegations-causing-false.
17. Department of Justice News Release: "Endo Pharmaceuticals and Endo Health Solutions to Pay $192.7 Million to Resolve Criminal and Civil Liability Relating to Marketing of Prescription Drug Lidoderm for Unapproved Uses" (Feb. 21, 2014), available at http://www.justice.gov/opa/pr/endo-pharmaceuticals-and-endo-health-solutions-pay-1927-million-resolve-criminal-and-civil.
18. Department of Justice News Release: "Pharmaceutical Company to Pay $27.6 Million to Settle Allegations Involving False Billings to Federal Health Care Programs" (Mar. 11, 2014), available at http://www.justice.gov/opa/pr/pharmaceutical-company-pay-276-million-settle-allegations-involving-false-billings-federal.
19. Department of Justice News Release: "Astellas Pharma US Inc. to Pay $7.3 Million to Resolve False Claims Act Allegations Relating to Marketing of Drug Mycamine" (Apr. 16, 2014), available at http://www.justice.gov/opa/pr/astellas-pharma-us-inc-pay-73-million-resolve-false-claims-act-allegations-relating-marketing.
20. Department of Justice News Release: "Minnesota-Based Medtronic Inc. to Pay $9.9 Million to Resolve Claims That Company Paid Kickbacks to Physicians" (May 28, 2014), available at http://www.justice.gov/opa/pr/minnesota-based-medtronic-inc-pay-99-million-resolve-claims-company-paid-kickbacks-physicians.
21. Department of Justice News Release: "Nation's Largest Nursing Home Pharmacy Company to Pay $124 Million to Settle Allegations Involving False Billings to Federal Health Care Programs" (June 25, 2014), available at http://www.justice.gov/opa/pr/nation-s-largest-nursing-home-pharmacy-company-pay-124-million-settle-allegations-involving.
22. Department of Justice News Release: "Vascular Solutions Inc. to Pay $520,000 to Resolve False Claims Allegations Relating to Medical Device" (Jul. 28, 2014), available at http://www.justice.gov/opa/pr/vascular-solutions-inc-pay-520000-resolve-false-claims-allegations-relating-medical-device.
23. Department of Justice News Release: "McKesson Corp. to Pay $18 Million to Resolve False Claims Allegations Related to Shipping Services Provided Under Centers for Disease Control Vaccine Distribution Contract" (Aug. 8, 2014), available at http://www.justice.gov/opa/pr/mckesson-corp-pay-18-million-resolve-false-claims-allegations-related-shipping-services.
24. Department of Justice News Release: "Manufacturer of Spinal Devices and Surgeon to Pay United States $2.6 Million to Settle Alleged Kickback Scheme" (Aug. 29, 2014), available at http://www.justice.gov/opa/pr/manufacturer-spinal-devices-and-surgeon-pay-united-states-26-million-settle-alleged-kickback.
25. Department of Justice News Release: "Shire Pharmaceuticals LLC to Pay $56.5 Million to Resolve False Claims Act Allegations Relating to Drug Marketing and Promotion Practices" (Sept. 24, 2014), available at http://www.justice.gov/opa/pr/shire-pharmaceuticals-llc-pay-565-million-resolve-false-claims-act-allegations-relating-drug.
26. Department of Justice News Release: "Biomet Companies to Pay Over $6 Million to Resolve False Claims Act Allegations Concerning Bone Growth Stimulators" (Oct. 29, 2014), available at http://www.justice.gov/opa/pr/biomet-companies-pay-over-6-million-resolve-false-claims-act-allegations-concerning-bone.
27. Department of Justice News Release: "Biotronik Inc. to Pay $4.9 Million to Resolve Claims that Company Paid Kickbacks to Physicians" (Nov. 6, 2014), available at http://www.justice.gov/opa/pr/biotronik-inc-pay-49-million-resolve-claims-company-paid-kickbacks-physicians.


© Published and reproduced with kind permission by Global Legal Group Ltd, London

28. Department of Justice News Release: "OtisMed Corporation and Former CEO Plead Guilty to Distributing FDA-Rejected Cutting Guides for Knee Replacement Surgeries" (Dec. 8, 2014), available at http://www.justice.gov/opa/pr/otismed-corporation-and-former-ceo-plead-guilty-distributing-fda-rejected-cutting-guides-knee.
29. Office of the Attorney General of Montana Press Release: "Attorney General Fox Announces $5.9 Million Pharmaceutical Settlement; Launches New Rx Drug Abuse Prevention Program" (Mar. 6, 2014), available at https://dojmt.gov/attorney-general-fox-announces-5-9-million-pharmaceutical-settlement-launches-new-rx-drug-abuse-prevention-program/.
30. Office of the Attorney General of Virginia News Release: "Attorney General Herring and 44 Other Attorneys General Reach $105 Million Settlement with GSK concerning Pharmaceutical Marketing" (June 4, 2014), available at http://www.oag.state.va.us/index.php/media-center/news-releases/132-attorney-general-herring-and-44-other-attorneys-general-reach-105-million-settlement-with-gsk-concerning-pharmaceutical-marketing-june-4-2014.
31. Office of the Attorney General of Texas Press Release: "Attorney General Abbott Recovers $19.5 Million for State of Texas, U.S." (Aug. 11, 2014), available at https://www.texasattorneygeneral.gov/oagnews/release.php?id=4814.
32. Office of the Attorney General of Ohio News Release: "Attorney General DeWine Announces $35 Million Multistate Consumer Settlement over Kidney Transplant Drug" (Aug. 6, 2014), available at http://www.ohioattorneygeneral.gov/Media/News-Releases/August-2014/Attorney-General-DeWine-Announces-$35-Million-Mult.
33. Office of the Attorney General of Florida Press Release: "Florida Obtains More than $483,000 from Organon in National Settlement" (Oct. 15, 2014), available at http://www.myfloridalegal.com/newsrel.nsf/newsreleases/6CDC6B259D0DB49B85257D72006B362F.
34. Office of the Attorney General of Texas Press Release: "Attorney General Abbott Recovers $39.75 Million for State of Texas, U.S. Medicaid Program" (Oct. 16, 2014), available at https://www.texasattorneygeneral.gov/oagnews/release.php?id=4874.
35. Office of the Attorney General of Nevada Press Release: "Attorney General Masto Announces an $8 Million Charitable Contribution as Part of a Settlement with Pfizer" (Nov. 3, 2014), available at http://ag.nv.gov/News/PR/2014/Consumer_Protection/Attorney_General_Masto_Announces_an_$8_Million_Charitable_Contribution_as_Part_of_a_Settlement_with_Pfizer/.
36. *United States v. Park*, 421 U.S. 658 (1975).
37. *Id.*
38. *Id.*
39. *Id.* at 665.
40. *Id.* at 678.
41. *Id.* at 673-674.
42. 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.
43. *Id.*
44. *Id.*
45. *Id.*
46. *Id.*
47. *Id.*
48. *Id.*
49. 21 U.S.C. § 335- 335a.
50. 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.
51. *Id.*
52. FDA Debarment List, available at http://www.fda.gov/ICECI/EnforcementActions/FDADebarmentList/default.htm.
53. Office of the Inspector General, List of Excluded Individuals and Entities Database, available at https://oig.hhs.gov/exclusions/exclusions_list.asp.
54. *USA v. Stewart Parnell, et al.*, 1:13-cr-00012-WLS-TQL, Indictment, ECF No. 1 (M.D. Ga. Feb. 13, 2013).
55. Department of Justice News Release: "Former Officials and Broker of Peanut Corporation of America Indicted Related to Salmonella-Tainted Peanut Products" (Feb. 21, 2013), available at http://www.justice.gov/opa/pr/former-officials-and-broker-peanut-corporation-america-indicted-related-salmonella-tainted.
56. *Id.*
57. Department of Justice News Release: "Former Officials and Broker of Peanut Corporation of America Indicted Related to Salmonella-Tainted Peanut Products" (Feb. 21, 2013), available at http://www.justice.gov/opa/pr/former-officials-and-broker-peanut-corporation-america-indicted-related-salmonella-tainted.
58. *USA v. Stewart Parnell, et al.*, 1:13-cr-00012-WLS-TQL, Plea Sheet, ECF Nos. 23, 24, 25, 26 (M.D. Ga. Feb. 28, 2013); Plea Agreement as to Samuel Lightsey, ECF No. 153 (M.D. Ga. May 7, 2014).
59. *USA v. Daniel Kilgore*, 1:13-cr-00007-WLS-TQL, Plea Agreement, ECF No. 6 (M.D. Ga. Feb. 11, 2013).
60. Department of Justice News Release: "Peanut Corporation of America Former Officials and Broker Convicted on Criminal Charges Related to Salmonella-Tainted Peanut Products" (Sept. 19, 2014), available at http://www.justice.gov/opa/pr/peanut-corporation-america-former-officials-and-broker-convicted-criminal-charges-related.
61. *Id.*
62. Jessica Corso, "Peanut CEO Wants Salmonella Poisoning Conviction Tossed" Law360 (Oct. 20, 2014), available at http://www.law360.com/articles/588551/peanut-ceo-wants-salmonella-poisoning-conviction-tossed.
63. *USA v. Vascular Solutions, Inc., et al.*, 5:14-cr-00926-FB, Indictment, ECF No. 1 (W.D. Tex. Nov. 13, 2014).
64. *Id.*
65. Department of Justice News Release: "Vascular Solutions Inc. and its CEO Charged with Selling Unapproved Medical Devices and Conspiring to Defraud the United States" (Nov. 13, 2014), available at http://www.justice.gov/opa/pr/vascular-solutions-inc-and-its-ceo-charged-selling-unapproved-medical-devices-and-conspiring.
66. *Id.*
67. *Id.*
68. *Id.*
69. *USA v. Vascular Solutions, Inc., et al.*, 5:14-cr-00926-FB, Order Accepting Waiver of Personal Appearance at Arraignment and Entry of Plea of Not Guilty by Vascular Solutions, Inc., ECF No. 24 (W.D. Tex. Dec. 10, 2014); Order Accepting Waiver of Personal Appearance at Arraignment and Entry of Plea of Not Guilty by Howard C. Root, ECF No. 26 (W.D. Tex. Dec. 10, 2014).


© Published and reproduced with kind permission by Global Legal Group Ltd, London

70. *USA v. OtisMed Corporation*, 2:14-cr-00688-CCC, Information, ECF No. 1. (D. N.J. Dec. 8, 2014); *USA v. Charlie Chi*, 2:14-cr-00687-CCC, Information, ECF No. 1 (D. N.J. Dec. 8, 2014).
71. *Id.*
72. Department of Justice News Release: "OtisMed Corporation and Former CEO Plead Guilty to Distributing FDA-Rejected Cutting Guides for Knee Replacement Surgeries" (Dec. 8, 2014), available at http://www.justice.gov/opa/pr/otismed-corporation-and-former-ceo-plead-guilty-distributing-fda-rejected-cutting-guides-knee.
73. *Id.*
74. *Id.*
75. *Id.*
76. *Id.*
77. *Id.*
78. *Id.*
79. *Id.*; *USA v. Charlie Chi*, 2:14-cr-00687-CCC, Docket (D. N.J. Mar. 31, 2015).
80. Department of Justice News Release: "OtisMed Corporation and Former CEO Plead Guilty to Distributing FDA-Rejected Cutting Guides for Knee Replacement Surgeries" (Dec. 8, 2014), available at http://www.justice.gov/opa/pr/otismed-corporation-and-former-ceo-plead-guilty-distributing-fda-rejected-cutting-guides-knee.
81. *Id.*
82. *Id.*
83. *Id.*
84. Department of Justice News Release: "14 Indicted in Connection with New England Compounding Center and Nationwide Fungal Meningitis Outbreak" (Dec. 16, 2014), available at http://www.justice.gov/opa/pr/14-indicted-connection-new-england-compounding-center-and-nationwide-fungal-meningitis.
85. *USA v. Cadden, et al.*, 1:14-cr-10363-RGS, Indictment, ECF No. 1 (D. Mass. Dec. 16, 2014).
86. *Id.*
87. *Id.*
88. *Id.*
89. *Id.*
90. *USA v. Cadden, et al.*, 1:14-cr-10363-RGS, Initial Appearance and Arraignment, ECF No. 17 (D. Mass. Dec. 17, 2014); Initial Appearance and Arraignment, ECF No. 34 (D. Mass. Dec. 17, 2014); Initial Appearance and Arraignment, ECF No. 41 (D. Mass. Dec. 17, 2014); Initial Appearance and Arraignment, ECF No. 54 (D. Mass. Dec. 18, 2014); Initial Appearance and Arraignment, ECF No. 64 (D. Mass. Dec. 19, 2014).
91. *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).
92. *USA v. Harkonen*, 3:08-cr-00164-MHP, Indictment, ECF No. 1 (N.D. Cal. Mar. 18, 2008).
93. *Id.*
94. *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).
95. *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).
96. *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).
97. *Id.*
98. *Id.*
99. *Harkonen v. Sebelius, et al.*, 4:13-cv-00071-PJH, Judgment, ECF No. 36 (N.D. Cal. Oct. 22, 2013).
100. *Harkonen v. Sebelius, et al.*, 4:13-cv-00071-PJH, Notice of Appeal, ECF No. 37 (N.D. Cal. Dec. 23, 2013).
101. Jeff Overey, "2 Years On, FCA Battles Test Caronia Ruling's Reach," Law 360 (Nov. 26, 2014), available at http://www.law360.com/articles/596831/2-years-on-fca-battles-test-caronia-ruling-s-reach-.
102. *United States v. Caronia*, 703 F.3d 149, 168-69 (2d Cir. 2012).
103. Jeff Overey, "2 Years On, FCA Battles Test Caronia Ruling's Reach," Law 360 (Nov. 26, 2014), available at http://www.law360.com/articles/596831/2-years-on-fca-battles-test-caronia-ruling-s-reach-.
104. *Solis v. Millennium Pharmaceuticals, Inc., et al.*, 2:09-cv-03010-MCE-EFB, Complaint, ECF No. 1 (E. D. Cal. Nov. 4, 2009).
105. *Solis v. Millennium Pharmaceuticals, Inc., et al.*, 2:09-cv-03010-MCE-EFB, Motion to Dismiss, ECF Nos. 63 (E. D. Cal. May 30, 2013).
106. Jeff Overey, "Feds Rip PhRMA's Free Speech Claims In FCA Off-Label Suit," Law 360 (Aug. 29, 2014), available at http://www.law360.com/articles/572293/feds-rip-phrma-s-free-speech-claims-in-fca-off-label-suit.
107. *Id.*
108. *Solis v. Millennium Pharmaceuticals, Inc., et al.*, 2:09-cv-03010-MCE-EFB, PhRMA's Response to the United States' Opposition to PhRMA's Amicus Brief, ECF No. 144 (E. D. Cal. Sept. 9, 2014).
109. Jeff Overey, "Feds Rip PhRMA's Free Speech Claims In FCA Off-Label Suit," Law 360 (Aug. 29, 2014), available at http://www.law360.com/articles/572293/feds-rip-phrma-s-free-speech-claims-in-fca-off-label-suit; Jeff Overey, "FCA Free Speech Defense Tested In DOJ-PhRMA Fight," Law 360 (Sept. 19, 2014), available at http://www.law360.com/articles/576201/fca-free-speech-defense-tested-in-doj-phrma-fight.
110. *Solis v. Millennium Pharmaceuticals, Inc., et al.*, 2:09-cv-03010-MCE-EFB, Order, ECF No. 157 (E. D. Cal. Mar. 26, 2015).
111. *Id.*
112. *Solis v. Millennium Pharmaceuticals, Inc., et al.*, 2:09-cv-03010-MCE-EFB, Memorandum and Order, ECF No. 158 (E. D. Cal. Mar. 30, 2015); Motion for Reconsideration, ECF No. 159 (E. D. Cal. Apr. 3, 2015).
113. Draft Guidance for Industry: Internet/Social Media Platforms with Character Space Limitations—Presenting Risk and Benefit Information for Prescription Drugs and Medical Devices (Jun. 16, 2014), available at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM401087.pdf; Draft Guidance for Industry: Internet/Social Media Platforms: Correcting Independent Third-Party Misinformation About Prescription Drugs and Medical Devices (Jun. 16, 2014), available at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM401079.pdf.
114. Draft Guidance for Industry: Internet/Social Media Platforms with Character Space Limitations—Presenting Risk and Benefit Information for Prescription Drugs and Medical Devices (Jun. 16, 2014), available at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM401087.pdf.
115. *Id.*
116. *Id.*


© Published and reproduced with kind permission by Global Legal Group Ltd, London

117. Jeff Overley, "FDA Twitter Rules Unconstitutional, Big Pharma Says," Law 360 (Sept. 22, 2014), available at http://www.law360.com/articles/579886/fda-twitter-rules-unconstitutional-big-pharma-says.
118. Draft Guidance for Industry: Internet/Social Media Platforms: Correcting Independent Third-Party Misinformation About Prescription Drugs and Medical Devices (Jun. 16, 2014), available at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM401079.pdf.
119. *Id.*
120. *Id.*
121. Sindhu Sundar, "Product Liability Legislation And Regulation To Watch In 2015," Law 360 (Jan. 2, 2015), available at http://www.law360.com/articles/603707/product-liability-legislation-and-regulation-to-watch-in-2015.
122. Department of Justice News Release: "Assistant Attorney General Stuart F. Delery Delivers the Keynote Address at the CBI Pharmaceutical Compliance Congress" (Jan. 29, 2014), available at http://www.justice.gov/opa/speech/assistant-attorney-general-stuart-f-delery-delivers-keynote-address-cbi-pharmaceutical.
123. *Id.*
124. *Id.*
125. Department of Justice News Release: "Assistant Attorney General Stuart F. Delery Delivers the Keynote Address at the CBI Pharmaceutical Compliance Congress" (Jan. 29, 2014), available at http://www.justice.gov/opa/speech/assistant-attorney-general-stuart-f-delery-delivers-keynote-address-cbi-pharmaceutical.
126. Department of Justice News Release: "Assistant Attorney General Stuart F. Delery Delivers the Keynote Address at the CBI Pharmaceutical Compliance Congress" (Jan. 29, 2014), available at http://www.justice.gov/opa/speech/assistant-attorney-general-stuart-f-delery-delivers-keynote-address-cbi-pharmaceutical.
127. *Id.*


© Published and reproduced with kind permission by Global Legal Group Ltd, London

**Christiana C. Jacxsens**
Greenberg Traurig, LLP
3333 Piedmont Road N.E., 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, LLP's Pharmaceutical, Medical Device & Health Care 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*, (2013-2015), *Georgia Super Lawyers* magazine as a "Rising Star" (2010-2015) and *Georgia Trend*'s "Legal Elite" (2012-2013). She is a frequent author and speaker on products liability and medical malpractice litigation issues.

Christiana received her J.D. from The George Washington University Law School, where she served as Notes Editor for *The Environmental Lawyer* and was a Deans Fellow with the Legal Writing and Research Program. She obtained an M.P.H. in Health Policy from George Washington University, and she received dual undergraduate degrees from Washington and Lee University consisting of a B.S., *magna cum laude*, in Chemistry, and a B.A., *magna cum laude*, in German Literature.

**Marcella C. Ducca**
Greenberg Traurig, LLP
3333 Piedmont Road N.E., Suite 2500
Atlanta, GA 30305
USA

*Tel:* +1 678 553 7375
*Fax:* +1 678 553 7376
*Email:* duccam@gtlaw.com
*URL:* www.gtlaw.com

Marcella Ducca is an associate with Greenberg Traurig, LLP's Pharmaceutical, Medical Device & Health Care Litigation Practice. She has experience litigating a variety of complex matters in both state and federal courts, including multidistrict litigation. Marcella is involved in the representation and defence of manufacturers in product liability cases pending across the country and has wide-ranging experience, particularly defending manufacturers of medical devices. In addition, Marcella has been involved in the defence of hospitals and physicians in claims alleging medical malpractice.

She is involved in a variety of organisations, including serving a Barrister of the Lamar Inn of Court, and as the Litigation Vice-Chair of the Young Lawyers Division of the American Bar Association. She has been listed by *Georgia Super Lawyers* as a "Rising Star", (2013-2015) and one of *Georgia Trend*'s "Legal Elite", (2012).

Marcella obtained her J.D. from Emory University School of Law, where she received numerous awards, served as Director-in-Chief and Special Teams Member of the Emory Moot Court Society, and was a member of the Order of Barristers. She received her B.A. from Emory University.

GT GreenbergTraurig

Greenberg Traurig, LLP is an international, multi-practice law firm with approximately 1,800 attorneys serving clients from 37 offices in the United States, Latin America, Europe, Asia, and the Middle East. The firm is among the "Power Elite" in the 2014 BTI Client Relationship Scorecard report, which assesses the nature and strength of law firms' client relationships. The firm's Pharmaceutical, Medical Device & Health Care Litigation Practice is an integral part of the firm's 600-plus member national Litigation Practice. The team is nationally recognised for its dynamic courtroom presence, responsiveness to clients and deep subject matter knowledge. Recent recognitions include national rankings for 2014 "Products Liability & Mass Torts" from *Chambers USA Guide*; national rankings for 2014 "Practice Liability & Mass Torts Defense: Pharmaceuticals and Medical Devices" from *The Legal 500 United States*; and a first-tier national ranking for "Litigation – Mass Tort Litigation and Class Actions – Defendants" from *U.S. News – Best Lawyers® 2015 Best Law Firms*. In addition, Greenberg Traurig is recognised as a "Product Liability Litigation Standout" in the *BTI Litigation Outlook 2015* published by BTI Consulting Group. For additional information, please visit www.gtlaw.com.


© Published and reproduced with kind permission by Global Legal Group Ltd, London

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
- Gambling
- Insurance & Reinsurance
- International Arbitration
- Litigation & Dispute Resolution
- Lending & Secured Finance
- Merger Control
- Mergers & Acquisitions
- Mining Law
- Oil & Gas Regulation
- Patents
- Pharmaceutical Advertising
- Private Client
- Private Equity
- 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