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Product Liability 2013

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Preface:

General Chapters:

Country Question and Answer Chapters:

Continued Overleaf →

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Country Question and Answer Chapters:

Chapter 6

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

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I. Introduction

On February 11, 2013, 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 $4.2 billion in taxpayer dollars in fiscal year 2012, the largest sum ever recovered in a single year. This record has been broken repeatedly over the past three years, and therefore it is a near certainty that the U.S. Food and Drug Administration ("FDA"), the U.S. Department of Justice ("DOJ"), other federal agencies, and individual state governments will continue to focus their attention in coming years to the pharmaceutical and medical device industry.

In particular, it is highly 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 investigation sand 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 chapter provides:

- an overview of federal and state government enforcement activities in 2012 related to pharmaceutical and medical device companies;
- a synopsis of government enforcement activities against company executives and counsel in 2012, 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 2012

Fiscal year 2012 was another banner year for the government's health care fraud prevention and enforcement efforts, with a record-breaking recovery of $4.2 billion.[i] For every one dollar spent on health care related-fraud and abuse investigations from 2009-2012, the government recovered $7.90.[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 the U.S. Department of Health and Human Services ("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 teams to assist in preventing fraud, waste and abuse in the Medicare and Medicaid programmes.[iii] Additionally, during FY 2012, DOJ and HHS increased their training of federal prosecutors, FBI agents and OIG agents.[iv]

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 Department of Justice, 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. In fiscal year 2012, DOJ recovered $1.5 billion in criminal fines and forfeitures under the FDCA.[v] Further, in fiscal year 2012, the DOJ obtained 14 criminal convictions for crimes under the FDCA.[vi]

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.[vii] In FY 2012, DOJ opened 1,131 new criminal health care fraud investigations involving 2,148 potential defendants, and convicted 826 defendants of health care fraud-related crimes.[viii] DOJ also opened 885 new civil investigations.[ix] The Departments of Justice and Health and Human Services recovered $3 billion through civil health care fraud cases brought under the FCA during fiscal year 2012.[x] Those matters included unlawful pricing by pharmaceutical manufacturers, illegal marketing of medical devices and pharmaceutical products for uses not approved by FDA, Medicare fraud by hospitals and other institutional providers, and violations of laws against self-referrals and kickbacks.[xi]

The following are representative of settlements negotiated by the Department of Justice and criminal fines imposed on pharmaceutical and/or medical device companies in 2012:

- February 2012 -
  - $11 million settlement with Dava Pharmaceuticals Inc. concerning FCA allegations;[xii]
- March 2012 -

- $180,000 settlement with EUSA Pharma (USA) Inc. concerning FCA allegations;[xiii]
- $2.8 million settlement with Cypress Pharmaceutical Inc. and Hawthorn Pharmaceuticals concerning FCA allegations;[xiv]

- April 2012 -
  - $322 million fine for Merck, Sharp & Dohme concerning claims of off-label promotion;[xv]
  - $190 million settlement with McKesson Corporation concerning FCA allegations;[xvi]
- May 2012 -
  - $1.5 billion payment including $700 million fine and $800 million settlement with Abbott Laboratories Inc. concerning claims of misbranding and off-label promotion;[xvii]
  - $3.65 million settlement with St. Jude Medical Inc. concerning FCA allegations;[xviii]
- June 2012 -
  - $41 million payment including $7 million fine and $34 million settlement with Orthofix Inc. concerning FCA allegations;[xix]
- July 2012 -
  - $3 billion payment including $1 billion fine and forfeiture and $2 billion settlement with GlaxoSmithKline LLC concerning failure to report safety data;[xx]
- October 2012 -
  - $95 million settlement with Boehringer Ingelheim Pharmaceuticals Inc. concerning FCA allegations;[xxi]
- November 2012 -
  - $30 million settlement with Orthofix International NV concerning FCA allegations and claims of payments to health care providers;[xxii]
- December 2012 -
  - $55 million settlement with Pfizer, Inc. concerning claims of off-label promotion;[xxiii]
  - $762 million payment including $136 million fine, $14 million forfeiture and $612 million settlement with Amgen Inc. concerning FCA allegations;[xxiv]
  - $109 million settlement with Sanofi-Aventis U.S. Inc. and Sanofi-Aventis U.S. LLC concerning FCA allegations and claims of payments to health care providers;[xxv] and
  - $11.4 million settlement with Victory Pharma Inc. concerning claims of payments to health care providers.[xxvi]

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 the following settlements for alleged violations of their False Claims Act statutes or consumer protection laws in 2012:

- February 2012 -
  - $57 million settlement between Mylan Inc. and California concerning claims of alleged over-charging;[xxvii]
- July 2012 -
  - $151 million settlement between McKesson Corporation and 29 states concerning claims of alleged over-charging;[xxviii]
  - $38 million settlement between Teva Pharmaceuticals, Barr Pharmaceuticals, AstraZeneca, Amgen, Inc., Fougera Pharmaceuticals, Baxter, Warner Chilcott, Wockhardt USA, Cypress Pharmaceutical, Inc. and Louisiana concerning claims of alleged over-charging;[xxix]
- August 2012 -
  - $181 million settlement between Janssen Pharmaceuticals, Inc. and 37 states concerning claims of deceptive and unfair trade practices in the marketing of Risperdal;[xxx]
- October 2012 -
  - $18.6 million settlement between Bristol Myers Squibb, Mylan Inc., Hoffman-LaRoche, Novo Nordisk Pharmaceuticals, Shionogi Inc. and Louisiana concerning claims of alleged over-charging;[xxxi] and
- November 2012 -
  - $90 million settlement between GlaxoSmithKline and 38 states concerning claims of unlawful promotion and misrepresentation of risks.[xxxii]

Increasingly, State Attorneys General have been hiring Plaintiffs' attorneys on a contingent-fee basis to pursue violations of False Claims Act statutes or consumer protection laws. Plaintiffs' attorneys can bring these actions on behalf of the State itself, or standing in the shoes of its citizens (*parens patriae* actions). However, States Attorneys General and Plaintiffs' contingency fee attorneys have inherently different motivations. Plaintiffs' contingency fee attorneys are incentivised to seek a maximum financial penalty, even if not appropriate for a company's conduct and not an appropriate "punishment". In contrast, States Attorneys General are ethically required to pursue justice and maximised financial penalties may not be a just result.

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).[xxxiii] 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.[xxxiv] The government prosecuted Acme and Park for misdemeanour violations of food adulteration.[xxxv] Park was convicted and was fined $250.[xxxvi] His conviction was reversed by the appellate court, but the Supreme Court reversed the appellate court and ordered Park's conviction be reinstated.[xxxvii] 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".[xxxviii]

The "Park Doctrine" as it has evolved and is in use today, 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.[xxxix] The prosecution of a responsible corporate officer for

a misdemeanour violation of the FDCA, a "Park Doctrine prosecution", is handled by the DOJ.[xl] FDA has found that a Park Doctrine prosecution has a strong deterrent effect on pharmaceutical and medical device companies and other regulated entities.[xli]

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".[xlii] 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.[xliii] 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.[xliv] 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.[xlv]

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.[xlvi] 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.[xlvii] 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.[xlviii] As of April 2013, FDA has never debarred a company; however, it has permanently debarred 91 individuals.[xlix] Additionally, the HHS Office of Inspector General 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.[l]

C. Recent Court Rulings Upholding Responsible Corporate Officer Prosecutions

Not only is the government prosecuting responsible corporate officers under the Park Doctrine, but appeals of these convictions and the sentences that are being imposed are largely being upheld.

In 2007, three Purdue Frederick Company executives were indicted for introducing a misbranded drug into interstate commerce for misbranding OxyContin.[li] The executives each 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).[lii] The executives were each sentenced to three years probation, 400 hours of community service and a $5,000 fine and were required to disgorge $19 million, $8 million, and $7.5 million, respectively.[liii] HHS then banned the executives from participating in Medicare, Medicaid, and other federal health care programmes for twenty years, due to their guilty pleas they served as "responsible corporate officers" who "had responsibility and authority either to prevent in the first instance or to promptly correct certain conduct resulting in the misbranding" of Oxycontin during a period in which the company admitted to marketing Oxycontin with the intent to defraud or mislead, in violation of the FDCA.[liv] The three executives appealed their exclusion through various administrative means, and ultimately had their exclusion reduced to twelve years before appealing to the District of Columbia, who upheld the length of the exclusion.[lv] The executives subsequently appealed to the United States Court of Appeals for the District of Columbia Circuit on the grounds that their exclusion was unauthorised because misdemeanour misbranding was not a misdemeanour relating to fraud and that the length of their exclusion period was arbitrary and capricious.[lvi] In 2012, the District of Columbia Circuit upheld their exclusion, finding that HHS was authorised to exclude them because their conduct was factually related to fraud in that their convictions were predicated upon the company they led having pleaded guilty to fraudulent misbranding and they admitted having "responsibility and authority either to prevent in the first instance or to promptly correct" that fraud.[lvii] The District of Columbia Circuit found the period of twelve years for exclusion was arbitrary and capricious and reversed and remanded it to the district court with instructions to remand it to the agency for further consideration consistent with its opinion.[lviii] The executives then moved for a rehearing *en banc*, which was denied.[lix] No additional information was available as of the date this chapter went to press as to whether HHS will further reduce their exclusion.

In 2008, the CEO of InterMune, Inc., W. Scott 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.[lx] According to the prosecution, Harkonen made public statements regarding a new drug in a press release, promoting it off-label and overstating its effectiveness.[lxi] After a jury trial, Harkonen was found guilty of wire fraud.[lxii] Harkonen was sentenced to six months home confinement, three years probation, 200 hours community service and a $20,000 fine.[lxiii] HHS then banned Harkonen from participating in federal health programmes for five years.[lxiv] Harkonen appealed his conviction.[lxv] In 2013, in an unpublished opinion, the U.S. Court of Appeals for the Ninth Circuit recently affirmed Harkonen's conviction and sentence.[lxvi] The Ninth Circuit held that Harkonen's public statements were not protected by the First Amendment because the First Amendment does not protect fraudulent speech.[lxvii] The Ninth Circuit further held that there was sufficient evidence to support the jury's finding that the statements were misleading, that Harkonen knew they were misleading and that Harkonen had the specific intent to defraud. Harkonen recently sued HHS to vacate his exclusion order and reinstate his privileges to participate in federal health programmes.[lxix] The government answered Harkonen's Complaint and Harkonen's suit against HHS remains pending as of the date this chapter went to press.[lxx] Notably, while the Ninth Circuit held Harkonen's statements were not protected by the First Amendment and upheld his conviction for wire fraud, the Second Circuit recently overturned the conviction of a sales representative convicted for conspiracy to introduce misbranded drugs.[lxxi] The Second Circuit held that the sales representative was convicted for his speech—for promoting an FDA-approved drug for off-label use—in violation of the First Amendment.[lxxii]

D. Recent 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 February 10, 2012, the United States Attorney for the Northern District of Texas filed charges against ApothéCure, Inc., a compounding pharmacy, and its owner, registered agent, President, sole director and pharmacist-in-charge, Gary Osborn.[lxxiii] Osborn was charged with two counts of introducing a misbranded drug into interstate commerce in violation of 21 U.S.C. 331(a).[lxxiv] ApothéCure processed, packed and held colchicine injections for intravenous use to treat back and neck pain.[lxxv] ApothéCure used pharmacy technicians to compound the injectable colchicine.[lxxvi] Three patients subsequently died after receiving the ApothéCure colchicine injections.[lxxvii] FDA tested the remaining colchicine injections and found several to be super potent (640% more than the level on the label) and some to be sub-potent.[lxxviii] The government alleged that, by virtue of his position, Osborn had the responsibility and authority to prevent the misbranding.[lxxix] The government further alleged Osborn instructed others on compounding, was responsible for the procedures and equipment in the labs, and that he was responsible for proper training and supervision of pharmacy technicians.[lxxx] Osborn and ApothéCure pled guilty to both counts.[lxxxi] In their plea agreements, Osborn and ApothéCure disputed that the misbranding resulted in death, and because of this dispute, the government agreed not to recommend an upward departure from the U.S. Sentencing Guidelines.[lxxxii] On October 18, 2012, Osborn was sentenced to ninety days of home confinement, one year of probation, 200 hours of community service, and a $100,000 fine.[lxxxiii]

While no indictment had been filed as of the date this chapter went to press, the government may similarly charge individuals from New England Compounding, the company who compounded methylprednisolone acetate injections which led to a fungal meningitis outbreak and many subsequent deaths.[lxxxiv] A grand jury has been convened and the investigation into those responsible is ongoing.[lxxxv] Prosecutors are expected to focus on charges of fraud, selling tainted drugs in violation of the FDCA, and defrauding Medicare or Medicaid.[lxxxvi]

On March 27, 2012, the United States Attorney for the District of Idaho filed charges against Bodybuilding.com founder and CEO Ryan DeLuca.[lxxxvii] DeLuca was charged with five counts of introducing and delivery for introducing of misbranded drugs into interstate commerce in violation of 21 U.S.C. 331(a) and 331(a)(1).[lxxxviii] Bodybuilding.com sold five types of synthetic anabolic steroids as "dietary supplements" when they were actually drugs under the FDCA.[lxxxix] The government alleged that, by virtue of his position, DeLuca was strictly liable for the criminal misdemeanour of misbranding, regardless of the extent of his knowledge of the violations.[xc] DeLuca pled guilty to all five counts.[xci] In his plea agreement, DeLuca agreed that an FDA compliance officer at Bodybuilding.com informed him the products contained ingredients that did not qualify as dietary supplements, and that, as CEO, he is deemed responsible for Bodybuilding.com's sales of misbranded products.[xcii] On August 2, 2012, DeLuca was sentenced to three years of probation and a $500,000 fine.[xciii]

On May 14, 2012, the United States Attorney for the Middle District of Pennsylvania filed charges against Zinnanti Surgical Design, LLC ("Zinnanti Surgical") President and Owner William Joseph Zinnanti.[xciv] Zinnanti was charged with one felony count of introducing adulterated medical devices into interstate commerce.[xcv] Zinnanti Surgical manufactured Bayonet Electro-Surgical Pencils, used to cut and cauterise tissue surrounding a patient's thoracic vertebrae during back surgery.[xcvi] The devices were adulterated because the methods, facilities, and controls used for manufacture, packing, and storage did not comport with current good manufacturing practice.[xcvii] The government alleged Zinnanti acted with the intent to defraud and mislead the FDA with regard to the manufacturing procedures he had in place. Zinnanti pled guilty to the one felony count of introducing adulterated medical devices into interstate commerce.[xcix] On January 28, 2013, Zinnanti was sentenced to four months imprisonment and one year of supervised release.[c]

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

A. 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 CEO provides, it is no surprise that the Plaintiffs' bar has begun to file parallel civil litigation to 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, 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 previously discussed, a jury convicted the CEO of InterMune, Inc. of wire fraud for his involvement regarding the marketing of Acctimune.[ci] Representatives of a proposed nationwide class filed action filed a civil suit against Intermune, Inc., Harkonen and Genentech, Inc., alleging fraud and deceptive marketing of Actimmune and referencing in support of their claims the charges and ultimate conviction of Harkonen.[cii] The defendants moved to dismiss and the Court ultimately dismissed Plaintiffs' claims with prejudice.[ciii]

A similar parallel action was filed based on the conduct of four former Synthes executives who were indicted for conspiracy, false statements, introducing into interstate commerce adulterated and misbranded medical devices with intent to defraud, introducing into interstate commerce adulterated and misbranded medical devices, and aiding and abetting regarding marketing of bone cement for the treatment of vertebral compression fractures, even though the label specifically warned against such use.[civ] Three patients died and prosecutors alleged the four Synthes executives lied to FDA investigators.[cv] The executives were prosecuted, pled guilty, and received jail sentences of five to nine months each for their role in an alleged conspiracy to conduct unapproved clinical tests of bone cement.[cvi] Plaintiff Eva Sloan, individually and as executrix of Lois Eskind, filed a civil suit against Synthes, Inc. and Norian Corporation, alleging fraud, conspiracy to commit fraud, willful, wanton, malicious and reckless misconduct, failure to warn, gross negligence, negligence *per se*, fraudulent concealment, and wrongful death.[cvii] The civil suit is based on same conduct at issue as in the criminal action, that the alleged unapproved clinical trial of bone cement caused the death of Lois Eskind after a surgeon injected the bone cement into her spine.[cviii] Less than six months after the suit was filed, the Court entered an order dismissing the case with prejudice and noting that issues between the parties were settled.[cix]

Finally, an executive and three sales managers of Stryker Biotech,

LLC were indicted for wire fraud, conspiracy, aiding and abetting, and distribution of a misbranded device related to the off-label promotion of the combined use of Calstrux, a bone void filler, and OP-1, a protein that promotes bone growth.[cx] Prosecutors further alleged patients reported adverse events, and after the executives were aware of these adverse events, they continued to promote off-label and did not warn physicians of the adverse events.[cxi] During the trial of three of the executives and the company, the company pled guilty to a misdemeanour and paid a $15 million fine.[cxii] Prosecutors subsequently dismissed all charges against all four executives after reviewing documents which showed the executives acted in good faith.[cxiii] Plaintiff April Cabana filed suit against Stryker Biotech, LLC, Stryker Corporation, Medtronic, Inc., Medtronic Sofamor Danek USA Inc., a physician and a hospital, alleging negligence, strict liability, breach of express and implied warranty, fraud, and negligence *per se* related to injury by bone void filler products.[cxiv] The Complaint references the indictments regarding the illegal promotion of the bone void filler products in violation of the FDCA.[cxv] The defendants have moved for summary judgment, which had not yet been heard as of the date this chapter went to press.[cxvi]

B. Food and Drug Administration Safety and Innovation Act (FDASIA) of 2012 and Claims Related to Pharmaceutical Drug Shortages

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

Drug shortages peaked in 2011, with 251 drug shortages reported to FDA, with the most critical shortages in drugs that treat cancer, nutrition and electrolyte-imbalances, neuromuscular conditions, and pain.[cxix] Recognising pharmaceutical drug shortages pose a serious risk to public health and attempting to reduce these shortages, on October 31, 2011, President Obama issued Executive Order 13588, requiring pharmaceutical companies to provide FDA with adequate advance notice of manufacturing discontinuances that could lead to shortages of certain drugs.[cxx] The Executive Order also gave FDA additional authority to help to avoid or mitigate existing or potential drug shortages.[cxxi]

As an additional step to help prevent and reduce drug shortages, on July 9, 2012, the president signed the Food and Drug Administration Safety and Innovation Act (FDASIA) of 2012.[cxxii] 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.[cxxiii] FDA will issue non-compliance 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.[cxxiv] Finally, FDASIA required FDA to establish an internal Drug Shortages Task Force to develop and implement a strategic plan for enhancing its response to drug shortages.[cxxv]

While drug shortages fell in 2012 to 177, likely as a result of the Executive Order, FDASIA, and FDA's efforts to reduce and prevent drug shortages, litigation regarding drug shortages continues.[cxxvi] FDASIA, in particular, may fuel more negligence *per se* claims. As FDASIA mandates a pharmaceutical company notify FDA of a potential discontinuance, any failure to do so may give rise to the statutory violation necessary for a successful negligence *per se* claim.

In 2011, twenty plaintiffs filed suit against Genzyme Corporation in the U.S. District Court for the District of Massachusetts related to a shortage of Genzyme's drug Fabrazyme, which is used to treat Fabry disease, a lethal genetic illness.[cxxvii] The plaintiffs allege Genzyme created a shortage of Fabrazyme by introducing adulterated injectable vials into interstate commerce, subsequently entering into a consent decree with the FDA and promulgating a rationing system, causing the plaintiffs to receive diluted doses of the drug.[cxxviii] The suit included claims for negligence, negligence *per se*, strict liability, breach of warranty, violation of the Bayh-Dole Act, violations of various state deceptive trade practices act, and loss of consortium and the plaintiffs sought, among other remedies, declaratory relief regarding drug rationing and an injunction to take drug licences away from Genzyme.[cxxix] Genzyme moved to dismiss for failure to meet minimum pleading standards and failure to state a claim upon which relief may be granted, and argued that the plaintiffs' suit alleged "Genzyme is not manufacturing the biologic treatment Fabrazyme quickly enough, well enough, or in sufficient quantities to meet demand" and is an attempt to shoehorn such allegations into products liability claims.[cxxx] Oral argument was held September 28, 2011, but no decision had been released as of the date this chapter went to press.[cxxxi]

In 2012, two plaintiffs filed suit against Hospira, Inc. in the U.S. District Court for the Middle District of Florida, related to a shortage of Hospira's drug Aquasol A (injectable vitamin A palmitate), used to treat Vitamin A deficiency, which can cause blindness.[cxxxii] The plaintiffs allege Hospira was able to meet market demand for Aquasol A until November 2010, when it closed a manufacturing site and had not stockpiled enough Aquasol A to create an inventory to mitigate against supply disruptions.[cxxxiii] The plaintiffs allege Hospira acted with reckless disregard for human life and health and created a global shortage which led to otherwise preventable injuries including causing her to lose her vision.[cxxxiv] Hospira moved to dismiss plaintiffs' claims based on failure to state a claim.[cxxxv] The court granted Hospira's Motion to Dismiss, dismissing the plaintiffs' complaint with prejudice.[cxxxvi] The plaintiffs appealed to the Eleventh Circuit, but no decision has been released as of the date this chapter went to press.[cxxxvii]

Also in 2012, several of the same Fabrazyme and Aquasol A plaintiffs filed suit against HHS, FDA, the United States National Institutes of Health ("NIH"), Mount Sinai School of Medicine, as well as several HHS, FDA, and NIH officials in their official capacity in the U.S. District Court for the District of Columbia.[cxxxviii] The plaintiffs allege the defendants illegally delegated unprecedented governmental authority to pharmaceutical companies, because, during drug shortages, a pharmaceutical company rather than the patient, physician, or FDA, determines whether a patient will be treated, what order patients will be treated, whether or not to dilute the medication, and how much information will be provided to the public regarding the medical consequences of removing the patient from a drug.[cxxxix] The suit included claims for violations of the doctrine of separation of powers, violations of the 10th Amendment, violations of the patent clause, violations of the 5th Amendment, and violations of the FDCA.[cxl] The plaintiffs seek, among other things, injunctive relief, invalidation of FDA licences, invalidation of patents, and disgorgement of profits.[cxli] All the defendants moved to dismiss and the plaintiffs voluntarily dismissed Mount Sinal School of Medicine, but no decision had been released as of the date this chapter went to press regarding the remaining defendants.[cxlii]

Products liability attorneys should monitor these suits as their outcome has the potential to either spur or discourage future similar suits, and potentially establish a new area of liability for manufacturers. Attorneys should also watch for developments and new policy from FDA's Drug Shortage Task Force as it is expected to finalise and release its Strategic Plan in mid-2013.[cxliii]

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

As 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 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 internal policies, a company should consider obtaining insurance for its executives outside of a typical D&O policy. Insurance broker Marsh USA has developed a unique 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.[cxliv] 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 and probation.

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

In its first *Park* doctrine prosecution of 2013, the government charged four former officials of a food company, Peanut Corporation of America, with mail and wire fraud, the introduction of adulterated and misbranded food into interstate commerce with the intent to defraud or mislead, and conspiracy related to salmonella-tainted peanuts and peanut products.[cxlv] This expansion of *Park* is likely to continue and all companies governed by the FDCA, not just pharmaceutical and medical device companies, should remain vigilant regarding best practices as prosecutions continue. Further, if the last several years are any indication, the government will remain aggressive in its recoveries from health care based fraud enforcement actions in 2013.

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- Product Liability
- Project Finance
- Public Procurement
- Real Estate
- Securitisation
- Shipping Law
- Telecoms, Media & Internet
- Trade Marks

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