Cooley

PHARMACEUTICAL, BIOTECHNOLOGY, AND MEDICAL DEVICE MANUFACTURERS

SELECT PUBLIC GOVERNMENT INVESTIGATIONS

Current as of February 2017

PHARMACEUTICAL, BIOTECHNOLOGY AND MEDICAL DEVICE MANUFACTURERS
SELECT PUBLIC INVESTIGATIONS

Current as of 2/7/2017

NAME OF COMPANY	DATE	SOURCE	BRIEF DESCRIPTION
Biogen MA Inc.	12/16	SEC Form 10-K	On December 5, 2016, Biogen received a subpoena from the federal government for documents relating to government price reporting, rebate payments and Biogen's co-pay assistance programs for AVONEX, TECFIDERA, TYSABRI, and PLEGRIDY. On December 29, 2016, Biogen received a civil investigative demand from the federal government for documents and information relating to the company's relationships with entities providing clinical education and reimbursement support levels. They are cooperating with the government.
Maquet Getinge Group	12/16	Complaint (Borrero v. Maquet Getinge Group and David Rose, case no. L-8433-16, SC of NJ)	A qui tam Complaint alleges that Maquet acted in blatant and purposeful retaliatory treatment of compliance supervisors for their protests and objections to Maquet's failure to adhere to FDA rules, regulations and laws. Plaintiff maintains that Defendant is in direct violation of New Jersey Conscientious Employee Protection Act, which protects whistleblowing-type conduct.
Grifols SA	12/16	Complaint (U.S. ex rel et al v. Grifols USA LLC et al., case no. 8:16-cv-00226, M.D.Fl.)	A qui tam Complaint alleges that Grifols had undertaken a blatant and purposeful course of action to push its anti-thrombin concentrate drug, Thrombate III, into markets for which it has not been approved for use. The Complain contends that Grifols developed a plan to promote Thrombate III in markets beyond the drug's approved uses - using its sales force to improperly target pediatric patients and patients with acquired anti-thrombin III deficiency.
Valeant Pharmaceuticals International Inc.	10/16	Company Press Release dated 10/31/16	As Valeant previously stated in response to a prior, similar press report, the Company previously disclosed in October 2015 that the United States Attorney's Office for the Southern District of New York commenced an investigation involving Valeant. We have been fully cooperating with the authorities throughout the investigation, and we are in frequent contact and continue to cooperate with the U.S. Attorney's Office for the Southern District of New York. We do not comment on rumors about investigations, and cannot comment on or speculate about the possible course of any ongoing investigation. Valeant takes these matters seriously and intends to uphold the highest standards of ethical conduct as we move forward with our mission to improve people's lives with our healthcare products.

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Insys Therapeutics, Inc.	8/16	AG Press Release dated 8/25/16	Attorney General Lisa Madigan today filed a lawsuit against the pharmaceutical company Insys Therapeutics, Inc. for deceptively marketing and selling Subsys, a highly addictive opioid drug significantly more powerful than morphine and intended exclusively for the treatment of breakthrough cancer pain, to physicians treating non-cancer patients for off-label uses like back and neck pain in an effort to rake in high profits.
Mylan N.V.	8/16	U.S. Senator Press Release dated 8/22/16	According to news reports, despite stable manufacturing costs, Mylan Pharmaceuticals has increased the price for a two-pack of EpiPens from $100 in 2008 to $500 today, with some reports of consumers paying $600 or more; Not only is this alarming price increase unjustified, it puts life-saving treatment out of reach to the consumers who need it most. In a letter to the Federal Trade Commission (FTC), Senator Klobuchar urges an investigation into whether Mylan Pharmaceuticals has engaged in activities, such as using incentives or exclusionary contracts with insurers, distributors, or pharmacies, to deny an alternative product access to the market; Klobuchar has also called on the Senate Judiciary Committee to hold a hearing to investigate the enormous increase in the price of EpiPens
Eli Lilly & Company	8/16	SEC Form 10-Q	The Company has received a civil investigative demand from the U.S. Attorney's Office for the Southern District of New York requesting documents and information relating to our contracts with, services performed by and payments to pharmacy benefit managers. They are cooperating with this investigation.

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Alere Inc.	7/16	SEC Form 10-K	The Company received a U.S. Department of Justice criminal subpoena addressed to Alere Toxicology Services, Inc. on July 1, 2016 which seeks records related to Medicare, Medicaid and Tricare billings dating back to 2010 for specific patient samples tested at our Austin, Texas pain management laboratory and payments made to physicians. They are cooperating with these investigations and are providing documents in response to both subpoenas. They and their subsidiary, Arriva Medical, LLC, are also in the process of responding to Civil Investigative Demands, or CIDs, the most recent CID which was received in July 2016, from the United States Attorney for the Middle District of Tennessee in connection with an investigation of possible improper claims submitted to Medicare and Medicaid. The CIDs request patient and billing records and records related to interactions with third parties. They are cooperating with the investigation of the United States Attorney for the Middle District of Tennessee and are providing documents responsive to the CIDs. They cannot predict what effect, if any, these investigations, or any resulting claims, could have on Alere or its subsidiaries.
Purdue Pharma LP	6/16	Renewed Petition to Enforce Administrative Subpoena (State of New Hampshire v. Purdue Pharma, LP, case no. 217-2016-cv-00322)	The OAG originally subpoenaed Purdue in August of 2015 seeking documents and information related to the company's opioid sales volume in the state, as well as the nature and scope of Purdue's plans and efforts to market the chronic pain pills OxyContin. Purdue argued that the contractual arrangement between the OAG and the assisting privatized law firm, Cohen Milstein Sellers & Toll PLLC, excused Purdue from complying with the subpoena because Cohen Milstein Sellers & Toll PLLC would be compensated on a contingent fee basis and therefore has an improper financial interest in the case. These objections were rejected by the court, thus resulting in a Summons in Civil Action by the New Hampshire State Judge in June of 2016.
Jazz Pharmaceuticals	5/16	SEC Form 10-Q	In May 2016, Jazz received a subpoena from the U.S. Attorney's Office for the District of Massachusetts requesting documents related to their support of 501(c)(3) organizations that provide financial assistance to Medicare patients, and, for Xyrem, documents concerning their provision of financial assistance to Medicare patients. Other companies have disclosed similar inquiries. Jazz intends to cooperate with this subpoena.

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Gilead Sciences Inc.	5/16	SEC Form 10-Q	In February 2016, Gilead received a subpoena from the U.S. Attorney's Office for the District of Massachusetts requesting documents related to their support of 501(c)(3) organizations that provide financial assistance to patients, and for their HCV products, documents concerning our provision of financial assistance to patients. Other companies have disclosed similar inquiries. They are cooperating with this inquiry.
Johnson & Johnson	4/16	SEC Form 10-Q	In March 2016, Janssen Pharmaceuticals, Inc. (JPI) received a Civil Investigative Demand from the United States Attorney's Office for the Southern District of New York related to JPI's contractual relationships with pharmacy benefit managers over the period from January 1, 2006 to the present with regard to certain of JPI's pharmaceutical products. The demand was issued in connection with an investigation under the False Claims Act.
Horizon Pharma PLC	4/16	SEC Form 10-K	In November 2015, the Company received a subpoena from the U.S. Attorney's Office for the Southern District of New York requesting documents and information related to its patient assistance programs and other aspects of its marketing and commercialization activities.
Merck & Co.	3/16	SEC Form 10-Q	The Company has received a civil investigative demand from the U.S. Attorney's Office for the Southern District of New York that requests information relating to the Company's contracts with, services from and payments to pharmacy benefit managers with respect to Maxalt and Levitra from January 1, 2006 to the present. The Company is cooperating with the investigation.

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Endo International PLC	3/16	SEC Form 10-Q	In March 2016, EPI received a CID from the U.S. Attorney's Office for the Southern District of New York. The CID requests documents and information regarding contracts with Pharmacy Benefit Managers regarding Frova®. We are currently cooperating with this investigation. We are unable to predict the outcome of these matters or the ultimate legal and financial liability, if any, and at this time cannot reasonably estimate the possible loss or range of loss, if any, for these matters but will explore all options as appropriate in our best interest.
Celgene Corp.	12/15	SEC Form 10-Q	In December 2015, Celgene received a subpoena from the U.S. Attorney's Office for the District of Massachusetts requesting documents related to their support of 501©(3) organizations that provide financial assistance to patients. They are cooperating with this request.
Mylan N.V.	12/15	12/2015 company SEC filings	The DoJ has subpoenaed Mylan regarding the marketing, pricing and sale of its generic doxycycline antibiotic products, as well as its communications with competitors about the antibiotics. The price for a bottle of 500 tablets of doxycycline hyclate went from $20 to $1,849, according to a 2014 study by the Healthcare Supply Chain Association. Several other companies were subpoenaed, including Lannett Company, Impax Laboratories, Par Pharmaceutical and Allergan PLC.
Merck & Co.	11/15	11/2015 company SEC filings	US Attorney's Office for the Eastern District of PA requested information on contracting and pricing with "certain pharmacy benefit managers and Medicare Part D plans" for Merck's asthma drug, Dulera.
Eli Lilly	11/15	11/2015 company SEC filings	US Attorney's Office for the Eastern District of PA and the DoJ (civil division) requested information on potential violations of the False Claims Act, focusing on its service agreements with wholesalers related to Medicaid rebates. Eli Lilly is responding, but maintains that "accounting practices related to average manufacturer prices and the Medicaid drug rebate program are correct".

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Bausch & Lomb (Valeant Subsidiary)	10/15	10/2015 company SEC filings	Valeant subsidiary Bausch & Lomb was subpoenaed as part of a criminal investigation by the DoJ regarding payments to medical professionals for certain surgical products.
Valeant Pharmaceuticals International Inc.	10/15	10/2015 company SEC filings	Valeant announced that two federal offices (Southern District of NY and MA) are investigating its patient assistance programs and significant price hike for two of its cardiac drugs, in response to an inquiry from Senator McCaskill (D-MO). The DOJ has subpoenaed documents relating to Valeant's patient assistance program, including requests for financial support, distribution of company products, information provided to CMS, and pricing decisions.
Biogen Idec Inc.	7/15	Second Amended Complaint (U.S. ex rel. Bawduniak v. Biogen Idec Inc., case no. 1:12-cv-10601, D.Ma.)	Sanofi announced that it is currently cooperating with a Department of Justice investigation of its FDA disclosures related to Plavix, an antiplatelet agent used to inhibit blood clots. The March 2013 SEC filing states that Sanofi learned of the investigation June 2012.
Pacira Pharmaceuticals Inc.	4/15	Company Press Release dated 4/16/15	Pacira announced in a press release that the company has received a subpoena from the U.S. DOJ requesting documents related to marketing and promotion of Exparel, a pain medication.
Teva Pharmaceuticals USA, Inc.	4/15	Second Amended Complaint (U.S. ex rel. et al v. Teva Pharmaceuticals USA, Inc. et al, case no. 13-cv-03702, S.D.NY)	A qui tam suit in the Southern District of New York alleges that Teva paid a number of kickbacks to physicians, including paying them for sham speaking events, in order to induce prescriptions of Copaxone and Azilect. According to a Teva spokesperson, the government has declined to participate further.
C.R. Bard, Inc.	10/14	First Amended Complaint (U.S. ex rel. et al v. C.R. Bard, Inc. and Bard Access Systems, Inc., case no. 2:11-cv-01250, E.D.La.)	A qui tam suit in the Eastern District of Louisiana alleges that C.R. Bard, a medical device manufacturer, fraudulently induced regulatory clearance of its intravascular catheters. The suit also claims that C.R. Bard employed a fraudulent scheme to bring about the medically unnecessary prescription and implantation of these devices, in violation of the False Claims Act.

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Ranbaxy Laboratories Ltd.	9/14	Bombay Stock Exchange Announcement	In a filing with the Bombay Stock Exchange (BSE), Ranbaxy stated that it received a civil investigative demand (CID) from the US DOJ. According to BSE, the CID requests documents and information with respect to the pricing of certain Ranbaxy products reimbursed through Medicaid.
Reliance Medical Systems	9/14	DOJ Press Release dated 9/5/14	According to the U.S. Department of Justice, the U.S. has filed two complaints against Reliance Medical Systems, a spinal implant company. The complaints allege that Reliance used two distributorships, Apex Medical Technologies and Kronos Spinal Technologies, to make improper payments to physicians to induce them to use the company's spinal implants in surgeries.
Boston Scientific Corp.	5/14	SEC Form 10-Q	According to Form 10-Q filed on May 8, 2014, Boston Scientific received a subpoena from the U.S. Department of Health and Human Services' Office of the Inspector General on May 5, 2014. The subpoena requests information in connection with the launch and performance of the Cognis and Teligen line of devices, as well as information related to their Physician Guided Learning Program.
St. Jude Medical Inc.	5/14	SEC Form 10-Q	According to Form 10-Q filed on May 6, 2014, St. Jude received a civil investigative demand (CID) from the Civil Division of the DOJ in April 2014. The CID arises from allegations that St. Jude paid kickbacks to various health care facilities and providers in order to induce them to implant its cardiac devices.
Forest Laboratories, Inc.	4/14	Second Amended Complaint (U.S. ex rel. et al v. Forest Laboratories, Inc. and Forest Pharmaceuticals, Inc., case no. 12-CA-11354, D.Ma.)	An unsealed Second Amended Complaint claims that Forest illegally marketed Namenda, a drug approved only for the treatment of moderate to severe Alzheimer's Disease, for the treatment of mild Alzheimer's Disease. The suit was brought on by Timothy Leysock, a former Forest sales representative, who is acting on behalf of the US under the qui tam provisions of the False Claims Act.

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Ferry Machine Corp.	4/14	Complaint (Keriellen Mack v. Ferry Machine Corporation et al., case no. L-4050-14, Superior Court of NJ)	Keriellen Mack, a former Vice President of Sales at Ferry Machine Corp., is suing the company for allegedly selling uncertified medical device parts to Stryker Corp. and unfairly terminating her employment when she raised concerns over the scheme. The case is being handled by the Superior Court of the State of New Jersey, County of Bergen.
Endo Health Solutions Inc.	3/14	SEC Form 10-K	According to Form 10-K filed on March 3, 2014, Endo received a subpoena in November 2013 from the State of California related to its transvaginal surgical mesh products. The filing also stated that since then, Endo has received similar subpoenas from several other states.
Celgene Corp.	2/14	Complaint (U.S. ex rel. et al v. Celgene Corp., case no. 2:10-cv-03165, C.D.Ca.)	An unsealed Complaint filed in the Central District of California accuses Celgene of paying illegal kickbacks to doctors in order to induce them to prescribe its cancer drugs, Thalomid and Revlomid. In addition to paying illegal remuneration to physicians, the Complaint alleges that Celgene promoted these products for unapproved uses and hid some of the health risks associated with the use of Thalomid.
Novartis Pharmaceuticals Corp.	1/14	Second Amended Complaint (U.S. ex rel. et al v. Novartis Pharmaceutical Corp., Accredo Health Group Inc., BioScrip Corp., Curascript Inc. and CVS Caremark Corp., case no. 1:11-cv-08196, S.D.NY)	The Second Amended Complaint alleges that Novartis paid illegal kickbacks to specialty pharmacies BioScrip, Accredo, Curascript, and CVS Caremark in order to induce them to convince patients to order prescriptions for their products, including Exjade, Gleevec, Tasigna, Myfortic, and Tobramycin Inhalation Solution (TOBI). The amended complaint alleges that these kickbacks took the form of patient referrals, rebates, and other financial incentives. The suit was brought on by David Kester, a qui tam whistleblower and former Novartis employee acting on behalf of the US.
Pfizer, Inc.	1/14	Complaint (U.S. ex rel Health Support Awareness, Inc. v. Pfizer, Inc., case no. 1:13-cv-11917, D.Ma.)	An unsealed Complaint filed in the District of Massachusetts accuses Pfizer of engaging in deceptive marketing practices for its statin, Lipitor. The Complaint alleges that Pfizer's marketing campaigns deceived consumers into thinking they could not split their pills, thereby leading them (and, by extension, government health care programs) to spend more money than was necessary on Lipitor prescriptions.

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Aegerion Pharmaceuticals, Inc.	1/14	Company Press Release dated 1/9/14	Aegerion announced that it received a subpoena from the District of Massachusetts requesting documents related to the marketing and sale of Juxtapid, a drug approved for the treatment of familial hypercholesterolemia.
Allergan, Inc.	12/13	Complaint (U.S. ex rel. Nevyas et al v. Allergan, Inc., case no. 2:09-cv-00432 E.D.Pa.)	An unsealed Complaint filed in the Eastern District of Pennsylvania claims that Allergan paid illegal kickbacks to eye doctors in order to induce them to prescribe Restasis, a prescription therapy for treating chronic dry eye. The False Claims Act suit alleges that Allergan offered free business consulting services and membership in its speakers bureau to doctors who prescribed Restasis, and as a result submitted thousands of fraudulent claims to both federal and state health care programs.
United Therapeutics Corporation	12/13	Company Press Release dated 12/9/13	United Therapeutics Corporation announced that it received a subpoena from OIG-HHS requesting documents related to the marketing of Remodulin Injection, Tyvaso Inhalation Solution, and Adcirca Tablets.
Janssen Pharmaceuticals, Inc. (subsidiary of Johnson & Johnson)	11/13	Petition for Order Enforcing Subpoena	On September 23, the City of Chicago filed a petition for an Order Enforcing the Subpoena for Janssen to produce documents that could substantiate false claims allegations that the pharmaceutical company deceptively marketed narcotic pain medications. The City contends that Janssen may have fraudulently promoted the safety and efficacy of its opioid drugs.
AstraZeneca PLC	10/13	Company Financial Report dated 10/31/13	In an October 2013 financial report, AstraZeneca announced that it received a subpoena in September 2013 from the U.S. Attorney's Office for the District of Massachusetts requesting documents pertaining to the safety of Seroquel, an atypical antipsychotic and antidepressant drug.
Abbott Laboratories, Inc. and 37 other companies	10/13	Complaint (State of Louisiana v. Abbott Laboratories, Inc. et al, case no. 3:13-cv-00681-BAJ-SCR, 19th Judicial District Court)	Louisiana brought suit against 38 pharmaceutical companies, accusing them of using false National Drug Codes (NDC). The Complaint alleges that these fraudulent NDCs were submitted to Medicaid for reimbursement, and as a result the State reimbursed the companies involved in the scheme for products that were not FDA-approved.

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Shire PLC, Shire LLC, and Shire U.S. Inc.	8/13	Notice of Removal from 19th Judicial District for the Parish of Baton Rouge to the U.S. District Court for the Middle District of Louisiana (case no. 13-cv-543, M.D.La.)	Louisiana alleges that Shire sold and promoted the drugs Adderall, Adderall XR, Daytrana, Vyvanse, and Intuniv for uses not approved by the FDA, caused the submission of false claims to government health care programs, and falsely reported the best price for certain products.
Novartis Pharmaceuticals Corp.	7/13	SEC Form 6-K	In July 2013, Novartis received a civil investigative demand (CID) from the U.S. Attorney's Office for the Southern District of New York requesting the production of documents and information relating to marketing practices for Gilenya, including the remuneration of healthcare providers in connection therewith.
Sage Pharmaceuticals, Inc.	6/13	DOJ Press Release dated 6/20/13	The DOJ announced that Acting Assistant Attorney General Stuart F. Delery filed a suit in the Western District of Louisiana against Sage and two of its senior employees. The Complaint alleges that Sage violated the FDCA by distributing misbranded and unapproved products, including over-the-counter cold and cough medications, wound cleansers, and prescription pain relievers.
Forest Laboratories, Inc.	5/13	SEC Form 10-K	In May 2013, Forest received a subpoena from the U.S. Attorney's Office for the Southern District of New York requesting documents related to Tudorza Pressair, an inhaler powder used in the treatment of bronchospasm associated with chronic obstructive pulmonary disease. The announcement in Forest's SEC filing does not further explain the nature of the investigation.
Janssen Pharmaceuticals, Inc.	5/13	SEC Form 10-Q	In May 2013, Janssen Pharmaceuticals, Inc. (JPI) received a subpoena from the Atlanta Regional Office of OIG-HHS, requesting documents and information regarding marketing practices, including remunerations paid to health care providers, for Nucynta IR and Nucynta ER, as well as any studies, reports and/or complaints regarding their safety and actual or possible side effects.

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Novartis Pharmaceuticals Corp.	4/13	DOJ Press Release dated 4/26/13	On April 26, 2013 the Justice Department announced that the United States filed a civil false claims lawsuit against Novartis involving alleged kickbacks paid by the company to health care providers. The lawsuit alleges that the payments violated the Anti-Kickback Statute and, as a result of Novartis's unlawful conduct, the government paid false claims for reimbursement for Lotrel, Valturna, Stalix, and other Novartis cardiovascular products.
Novartis Pharmaceuticals Corp.	4/13	DOJ Press Release dated 4/26/13	On April 23, 2013, the U.S. filed a complaint in the Southern District of New York against Novartis, alleging that the company gave kickbacks, in the form of rebates and discounts, to pharmacies in exchange for the pharmacies' agreement to switch transplant patients from competitor drugs to Exjade, a Novartis product.
Sanofi SA	3/13	SEC Form 20-F	Sanofi announced that it is currently cooperating with a Department of Justice investigation of its FDA disclosures related to Plavix, an antiplatelet agent used to inhibit blood clots. The March 2013 SEC filing states that Sanofi learned of the investigation in June 2012.
Warner Chilcott PLC	3/13	Complaint (U.S. ex rel. et al v. Warner Chilcott PLC et al, case no. 11-cv-10545-RGS, D.Ma.)	The qui tam Complaint alleges that Warner Chilcott paid kickbacks in order to induce doctors to prescribe nine of the company's drugs: osteoporosis treatments Actonel and Atelvia, ulcerative colitis treatments Asacol and Asacol HD, antibiotic Doryx, overactive bladder drug Enablex, hormone replacement drug Estrace, and contraceptives Loestrin and Lo Loestrin. In addition, the Complaint contends that Warner Chilcott misbranded drugs and violated patient privacy. As a result, the Complaint alleges that Warner Chilcott submitted false claims to government health care programs.
Warner Chilcott PLC	2/13	Complaint (U.S. ex rel. et al v. Warner Chilcott PLC et al, case no. 1:11-cv-11143, D.Ma.)	A qui tam suit was unsealed in the District of Massachusetts. The Complaint alleges that Warner Chilcott violated the False Claims Act through the promotion of Actonel and Atelvia, including making unsubstantiated claims concerning the drugs, providing illegal remunerations to health care providers, and engaging in improper conduct concerning prior authorizations.

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Walgreen Co.	1/13	Complaint (U.S. ex rel. et al v. Walgreen Co. et al, case no. 1:11-cv-07307-RWS, S.D.N.Y.)	A New York federal judge unsealed a whistleblower suit accusing Walgreen's drug infusion and home nursing units of paying doctors kickbacks in order to get them to prescribe high-cost specialty medications. The Complaint contends that the kickback scheme directed home nursing services to patients receiving higher-cost pharmaceutical infusions, and the drug infusion unit had become the preferred provider for the doctors prescribing the more expensive infusion drugs.
Stryker Corp., I-Flow Corp., Orthofix International, DJO Inc.	12/12	Complaint (U.S. ex rel Paulos v. Stryker, I-Flow, Orthofix, and DJO, case no. 11-cv-41, W.D.Mo.)	A Missouri federal judge unsealed a False Claims Act complaint brought by a former Stryker Corp. consultant accusing Stryker, I-Flow Corp., Orthofix, and DJO of marketing pain pumps for an off-label use specifically denied by the FDA.

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