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Botox Settlement Adds More Frown Lines To Industry

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Law360, New York (September 28, 2010) -- On Sept. 1, the U.S. Department of Justice announced the resolution of an investigation into alleged off-label marketing of Botox by Allergan Inc.

While Botox, an injectable botulinum toxin, is best known for smoothing facial frown lines, it is also indicated for treatment of "non-cosmetic" indications, such as strabismus, cervical dystonia and excess sweating. Allergan pled guilty to a one-count information charging the company with distribution of a misbranded drug pursuant to 21 U.S.C. § 331(a) and 352(f)(1), and paid fines and forfeiture totaling $375 million.

Allergan also paid $225 million and entered into a settlement agreement to resolve civil False Claims Act suits brought by several qui tam relators that were consolidated following government intervention.[1]

As part of the civil resolution, Allergan entered into a five-year corporate integrity agreement imposing, inter alia, detailed oversight and auditing requirements relating to numerous activities including reimbursement assistance, managed care interactions and compendia communications.

Notably, the settlement agreement also requires Allergan to file a stipulation of dismissal with prejudice to withdraw its pending First Amendment-based declaratory judgment action against the U.S. Food and Drug Administration within seven days of payment of the civil settlement amount.[2]

As discussed more fully in this advisory, the Allergan settlement may signal an important development in the government's enforcement of federal health care laws against medical product manufacturers who fail to adequately control the actions of managed care functions and third-party vendors.

The case suggests that the government may view the activities of managed-care functions, and their vendors, as potential evidence of a company's intent to promote a product for a particular use, as well as a possible basis for alleging violations of the False Claims Act.

Reimbursement Services as Evidence of Unlawful Intended Use

Allergan pled guilty to a one-count information charging the company with misdemeanor distribution of a misbranded drug. The information charges the company with unlawful promotion of Botox for unapproved (off-label) uses including spasticity, migraine and various types of pain.

In particular, the government focused on a variety of alleged behaviors including use of off-label promotional materials, "sham" continuing medical education and third-party websites, sales targeting of known off-label product prescribers and unlawful activities related to reimbursement support and managed care interactions.

While many of the alleged activities in the information are similar to those charged in past off-label cases, the Botox information is unique in its focus on the activities of the managed care and reimbursement support functions.

The Federal Food Drug and Cosmetic Act and the FDA's implementing regulations do not specifically address reimbursement support activities; rather the clearest statement made by regulators regarding the parameters of reimbursement support services has come from the U.S. Department of Health and Human Services' Office of Inspector General, which is charged with preventing fraud, abuse and waste in the Medicare and Medicaid programs.[3]

Unsurprisingly, most enforcement actions involving allegations of the provision of unlawful reimbursement assistance have generally been resolved as anti-kickback statute violations or violations of federal drug price reporting laws, making the government's focus on these activities in the FDCA context unique.[4]

To support its criminal case, the government cited evidence that reimbursement support and managed care activities were knowingly undertaken with the express purpose of increasing off-label sales. For example, the information claims that the company used "value-added reimbursement support services to grow off-label sales" and noted that, although "government and private health care payers covered Botox for every FDA-approved indication," the company doubled the size of its reimbursement support team in 2003.[5]

According to the government, "the Botox reimbursement team was an extension of the sales force" and its "express goal" was to "improve injector economics by selling more Botox".[6]

Further, the government refers to documents that allegedly described these reimbursement support services (collectively part of a Botox Advantage Program) as "saving time and effort."[7] According to the information, internal company statements cited "reimbursement" as the "Number 1 reason limiting M.D. Botox use."[8]

In addition to the provision of reimbursement assistance, Allergan was alleged to have funded and controlled patient advocacy groups and paid remuneration to health care providers in exchange for these entities petitioning Medicare and Medicaid to reimburse off-label uses by influencing local coverage determinations and allegedly misleading administrators responsible for making those determinations pursuant to Centers for Medicare & Medicaid Services guidelines.[9]

The specific goal of these activities was purportedly to "expand Botox coverage for off-label uses" and to "eliminate any payer-imposed limitation on the amount of Botox injected" (known as "dosing caps").[10]

According to the government (and the relators' complaints in the civil case), off-label managed care and reimbursement efforts were coordinated through a formal strategy and planning process, known as "customer team units," through which managed care and reimbursement functions were allegedly used to support and supplement off-label sales and marketing tactics.

"Value-Added Services," "Marketing-the-Spread" and Other Alleged Violations as Evidence of the Submission of False Claims

The government also adopted and built upon some of the relators' allegations that Allergan's provision of "value-added reimbursement services," fraudulent ICD-9 and other coding information caused the submission of false claims to state and federal health care programs.

The False Claims Act case focused both on Allergan's submission of claims allegedly caused by its off-label marketing scheme, and what is alleged to have been false certifications made to federal health care program providers regarding the company's compliance with federal health care laws, including the anti-kickback statute.

The settlement agreement between the parties sets forth the government's contention that the company: (1) promoted Botox off-label and for indications that were not medically accepted indications for which Medicaid provided coverage;

(2) made and/or disseminated false and misleading representations that Botox was effective for unapproved uses;

(3) instructed HCPs to use certain ICD-9 codes which were inapplicable for on-label diagnosis in order to ensure payment by state and federal health care programs; and

(4) offered and paid illegal remuneration to HCPs to induce them to promote and prescribe Botox.[11]

Allergan denies each of these allegations.

Botox is reimbursed as a "buy-and-bill" drug, meaning that prescribing physicians buy the product from Allergan and take the financial risk on the front end with the understanding that they will be made whole when they submit the bill for the drug and associated procedure, and are reimbursed by the patient's insurance program. This is in contrast to drugs that are reimbursed through an assignment of benefits process, under which the physician assigns the right to reimbursement to a third party.

According to the filings, state and federal health care programs generally did not cover the off-label uses of Botox, which often involved higher dosage forms and thus made the economics of off-label use impractical for most doctors. The relators and the government alleged that Allergan understood this and undertook a marketing scheme to remove the "barriers to access" for these off-label uses.

In describing Allergan's "illegal off-label marketing program," the plaintiffs alleged that Allergan managed-care employees worked with sales and marketing teams to target physicians and provide "in-kind consultation services … to maximize reimbursement associated with prescribing off-label Botox."[12]

This included reviewing physician claims, analyzing those payments and preparing Excel spreadsheets on how each target prescriber could maximize reimbursement.[13] Allergan employees also allegedly provided meals and other remuneration to physicians.

Allergan is further alleged to have coached HCPs on how to "disguise" off-label uses by using fraudulent ICD-9 codes when they submitted claims for reimbursement for Botox.[14]

The plaintiffs also alleged that Allergan contracted with a third party to provide a Botox reimbursement support hotline for the benefit of HCPs.[15] The third-party organization allegedly provided off-label billing assistance to HCPs, helped them fill out reimbursement paperwork and provided off-label clinical reprints to HCPs.

Another third party allegedly administered Botox promotional speaker programs, which also is alleged to have provided off-label reimbursement information and to have "enabled [Allergan] to pay physicians for prescriptions."

Finally, Allergan allegedly operated and funded a third-party patient's assistance program called Alliance for Patient Access, and a nonprofit known as "We MOVE," supposedly to disseminate off-label information about Botox.[16]

In addition to allegedly promoting Botox off-label and providing value-added reimbursement services, Allergan was accused of paying off-book discounts on Botox and marketing the drug based upon an artificially inflated spread between the cost reported to federal health care programs and the acquisition cost to HCPs.

In particular, the information asserts that Allergan created a "temporary price allowance program," under which the company allegedly guaranteed a six-month dated price to select physicians.[17]

Under the program as described, the price physicians would pay would be, in effect, average sales price plus 6 percent as set two quarters ago, therefore they were "always six months behind, minus any rebate, creating a spread."[18]

Another alleged tactic known as the "off-invoice discount strategy" gave targeted physicians an off-invoice discount of "at a minimum, the annual price increase for that year."[19]

According to plaintiffs, these discounts created a spread between the acquisition cost to HCPs and the reimbursement from Medicare and Medicaid because Allergan reported an artificially inflated average wholesale price and later an inflated ASP (the metrics by which government reimbursement for Botox was set).

Allergan's ASP and AWP were alleged to be inflated since they did not reflect the actual prices at which Allergan was making its product available to HCPs through the off-invoice discounting scheme.

In furtherance of the effort, managed-care employees (known as "reimbursement business managers") allegedly provided "recovery analysis" spreadsheets and charts with detailed billing codes to HCPs and would explain the margins that they could pocket using particular codes and particular dosages.[20]

Because off-label uses of Botox generally require higher dosages of Botox, off-label usage and successful off-label reimbursement would mean higher profit margins for HCPs. Based upon the inflated ASP and AWP, reimbursement business managers were allegedly able to demonstrate a financial benefit to HCPs of 20 to 30 percent over acquisition cost for each patient vial/injection.[21]

Lessons for Industry

As scrutiny of managed care and reimbursement support-related functions continues, medical product manufacturers should seek to ensure that proper controls are in place. Maintaining a comprehensive framework to prevent, detect and correct potential violations of the FDCA and other federal health care laws may not only help mitigate enforcement risks but also may assist manufacturers in their defense of private litigation, which may accompany a settlement with the government.

For example, two days after the Botox settlement was publicly announced, a shareholder derivative action was filed in the Chancery Court of Delaware against Allergan and its board of directors, seeking to shift the cost of the settlement and related expenses to the board.

The complaint (brought on behalf of the company and its shareholders) alleges that Allergan's board was aware that misconduct was occurring and that board members breached their fiduciary duty to prevent it. The theory of the shareholder action builds upon the notion that the company allegedly

failed to put adequate controls in place to prevent functions such as sales, marketing and managed care from engaging in unlawful activities.[22]

Allergan noted in a Sept. 7 securities filing that the company is "investigating the action and expects to contest it vigorously".[23]

Medical product manufacturers should evaluate the extent to which the controls imposed by the U.S. Health and Human Services Office of Inspector General in the Allergan CIA could enhance oversight of their own managed-care activities. The Allergan CIA requires, inter alia, that the company develop policies, procedures and auditing mechanisms to ensure that managed care functions, compendia communications and third parties involved in managed care and reimbursement activities comply with federal health care laws.[24]

The following may help manufacturers better assess the extent to which their own managed care and reimbursement services activities pose legal and compliance risks:

— Training customer-facing managed care and reimbursement services functions on rules governing on-label promotion, the anti-kickback statute, the Prescription Drug Marketing Act and the Pharmaceutical Research and Manufacturers of America Code[25];

— Ensuring that product-specific materials distributed by customer-facing employees, including managed care personnel and third-party vendors, be approved by qualified personnel (such as through a promotional review committee) to ensure that materials comply with federal health care laws and are otherwise sound from a medical, legal and regulatory standpoint[26];

— Developing policies and procedures to mitigate the risk that employee activities (or those of third-party vendors) could be alleged to be unlawful "value-added services"[27];

— Requiring that third-party vendors, such as reimbursement services vendors, provide their personnel with a copy of the manufacturer's code of conduct and relevant compliance policies and train them accordingly, or otherwise be required to represent that they maintain and enforce a substantially similar policy, as part of the manufacturer's vendor selection and contracting process[28];

— Separating, in an appropriate manner, those functions which a manufacturer intends to be responsible for lawful dissemination of off-label information (such as in response to unsolicited requests from payors or HCPs), from commercial influence, including oversight and control by sales or marketing.[29]

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[1] The government chose to intervene in United States ex rel. Lang v. Allergan, Inc., Civ. No, 1:07-cv-1288-WSD (N.D. Ga. filed Jun. 5, 2007) and United States ex rel. Beilfuss v. Allergan, Inc, Civ. No. 1:08-ca-10305-RGS (D. Mass. filed Feb. 22, 2008) refiled as Civ. No. 1:08-cv-1883-WSD (N.D. Ga. filed Feb. 10, 2010). Cher Beilfuss was employed by Allergan as a Regional Health Policy Manager (RHPM); Kathleen O'Connor-Masse was employed as a Payor Reimbursement Account Manager and later as a Director of Western Area Reimbursement Account Managers. Both individuals' functions

provided reimbursement and managed care support to physicians and managed care customers. Dr. Amy M. Lang is a practicing pain specialist, and a one-time consultant and promotional speaker for Allergan; Charles J. Rushin was currently employed at Allergan at the time that his complaint was filed in a field sales function known as a Neuroscience Medical Consultant (NMC). The government chose not to intervene in a case brought by a third relator, Albert Edward Hallivis, who also has certain employment claims against Allergan.

[2] Settlement Agreement between United States, et. al. and Allergan, Inc. ¶ 19 (Sept. 1, 2010).

[3]See, e.g. OIG-HHS, Adv. Op. No. 06-16 (Posted Oct. 10, 2006) (Finding that provision of reimbursement consulting services in conjunction with free advertising services, by a medical device manufacturer to a supplier, could constitute unlawful remuneration within the meaning of the Anti-Kickback Statute); OIG-HHS, Adv. Op. No. 10-04 (Posted May 6, 2010) (Finding that, coincident to a discussion of permissible services, that pre-authorization or other services which save a physician's office staff time, result in realization of savings, or which were designed to refer or induce the purchase of manufacturer's products could constitute unlawful remuneration within the meaning of the Anti-Kickback Statute).

[4] See, e.g. Settlement Agreement between United States, et al. and Kyphon Inc. (May 22, 2008) (Resolving civil Anti-Kickback and False Claims allegations that Kyphon fraudulently marketed its kyphoplasty procedure by providing fraudulent coding information and other unlawful reimbursement assistance to healthcare providers, to make use of the procedure and device more profitable); Settlement Agreement between United States et. al. and TAP Pharmaceutical Products, Inc. (Sept. 28, 2001) (Resolving civil Anti-Kickback and False Claims allegations that TAP provided unlawful reimbursement assistance to providers and marketed Lupron® based upon the spread between the acquisition cost to providers and the rate at which federal healthcare programs would reimburse the drug). Cf. Information, United States v. Orphan Medical, Inc., Crim. No. CR-07-531 -ENV, ¶ 13 (E.D.N.Y. filed July 2, 2007) (Supporting criminal charges against a manufacturer and an individual

consultant with evidence of unlawful promotion of Xyrem®, including some allegations that the manufacturer allowed or encouraged the consultant to discuss how to conceal off-label prescriptions from payors).

[5] Information. United States v. Allergan, Crim. No. 1:10-cr-00375-UNA, at ¶ 26 (N.D. Ga. Filed Sept. 1, 2010).

[6] Id.

[7] Id. at .27

[8] Id. at 28.

[9] Id. at 29-30.

[10] Id.

[11] Settlement Agreement, supra note ii., at ¶ G.

[12] First Amended Complaint, United States ex. rel. Beilfuss v. Allergan, Inc., Civ. No. 1:08-cv-01883-WSD, ¶¶ 34.c-e. (N.D. Ga. Filed Feb. 19, 2010).

[13] Id.

[14] Id. at 34, 69..

[15] Id. at 34.e..

[16] Id. at 34.l..

[17] Id. at 34.k..

[18] Id..

[19] Id. at¶ 83.

[20] Id. at 84-87.

[21] Id.

[22] Complaint. Louisiana Municipal Police Employees' Retirement System v. Pyott, No. 5795 (Del. Ch. filed Sept. 3, 2010).

[23] SEC Form 8-K. Alergan, Inc. (Sept. 3, 2010).

[24] Corporate Integrity Agreement between OIG-HHS and Allergan, Inc. (Aug. 30, 2010).

[25] Id. at III.B.3.f, j-k, s.

[26] Id. at III.B.3.q.

[27] See id. at III.B.3 (requiring generally that all product-related functions comply with the Anti-Kickback Statute and other federal healthcare laws and imposing specific requirements related to fee-for-service arrangements).

[28] Id. at III.B.2.

[29] See id. at III.B.3 (requiring generally that all product-related functions comply with the FDCA and imposing specific requirements on the unsolicited request and off-label information distribution processes within the company).