

## Key Compliance Concerns for the Generic Pharmaceutical Industry

By

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While the compliance pressures facing proprietary pharmaceutical companies have been well-documented, generic pharmaceutical companies typically face a less onerous set of compliance concerns because of the nature of their business model. Generic pharmaceutical companies compete based on their comparatively low cost and therefore do not mount sizable sales campaigns. Because these companies do not rely on sales representatives, heavy advertising, and relationships with referral sources (i.e., physicians), some of the most stringent compliance concerns in the pharmaceutical industry publicized over the past 10 years do not impact the generic pharmaceutical companies to the same extent as their proprietary competitors.

This does not mean, however, that generic pharmaceutical companies do not face regulatory and compliance constraints, nor have they been immune to enforcement actions. Generic pharmaceutical companies have been charged with pricing fraud, providing illegal kickbacks to pharmacies and wholesalers, anticompetitive behavior, and quality deficiencies. They are also susceptible to investigations and enforcement actions related to illegal bribes to foreign officials. This article outlines the major compliance issues that generic pharmaceutical companies face. Each section outlines the issue and governing laws and regulations and provides an example of enforcement actions involving generic pharmaceutical companies, if available.

### I. Pricing Fraud

There are several kinds of fraud associated with pricing pharmaceutical products and reporting pricing to relevant government authorities. Pricing

fraud implicates several laws and regulations including:

1. The Federal Anti-Kickback Statute. The federal Anti-Kickback Statute prohibits any person or entity from making or accepting remuneration to induce or reward any person for referring, recommending or arranging for the purchase of any item for which payment may be made under a federally funded health care program.<sup>2</sup> The Anti-Kickback Statute has been interpreted to prohibit pharmaceutical companies from offering inducements to customers to encourage the purchase of pharmaceutical products that will be reimbursed by the Medicare or Medicaid program.
2. State Anti-Kickback Statutes. A number of states have state anti-kickback statutes that parallel the federal statute. States increasingly pursue violations separately from the enforcement of the federal statute.
3. The False Claims Act. The False Claims Act provides that any person who presents or causes to be presented, false or fraudulent claims for payment or approval to the U.S. government or knowingly makes, uses or causes to be made or used, false records and statements to induce the government to pay or approve false and fraudulent claims, is liable for a civil penalty ranging from \$5,500 to \$11,000 per claim, plus three times the amount of damages sustained by the federal government.<sup>3</sup> Under the False Claims Act, a defendant can be held liable if it “knowingly presents, or causes to be presented . . . a false or fraudulent claim for payment or approval.”<sup>4</sup>

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<sup>2</sup> 42 U.S.C. § 1320a-7b(b).

<sup>3</sup> 31 U.S.C. § 3729.

<sup>4</sup> 31 U.S.C. § 3729(a)(1).

4. The Medicaid Best Prices Statute. The Best Prices Statute requires pharmaceutical companies to agree to charge Medicaid the lowest price at which it sells to private sector customers and enter into a rebate agreement order for federal matching funds to be available for covered outpatient drugs.<sup>5</sup> The manufacturer must submit a rebate to each state's Medicaid program based on the reported Average Manufacturer Price ("AMP"). For multiple source non-innovator drugs (most generics), the rebate is 11% of the AMP. Violation of this statute can also be a violation of the False Claims Act.

A number of scenarios can give rise to a charge of pricing fraud, including situations in which a generic pharmaceutical company:

- (a) engages in fraud by inflating the wholesale price of a product when reporting to a state for the purpose of increasing Medicaid reimbursement rate for that product;
- (b) inflates the wholesale price of a product with the intention of inducing pharmacy benefit managers and pharmacies to purchase and dispense the products by promising a relatively high government reimbursement relative to the actual cost of the product; or
- (c) misreports the "Best Price" and/or "Average Manufacturer Price" to avoid paying rebates under the Medicaid Rebate Law. Generic pharmaceutical companies have offered low prices to induce private insurers, wholesalers, pharmacists and businesses to purchase and prescribe their drugs, and to include them on their preferred formularies without reporting those discounts to the state Medicaid programs.

There have been many enforcement actions against generic and proprietary pharmaceutical companies for pricing fraud. The following cases provide a representative example of enforcement against generic pharmaceutical companies. In both cases, state or federal authorities alleged several kinds of pricing fraud along with violations of anti-kickback laws.

#### ***BMS Apothecon Settlement with the Department of Justice***

In September 2007, Bristol-Myers Squibb ("BMS") and its subsidiary Apothecon, a generic pharmaceutical

company, settled with the federal government for over \$515 million for various improper pricing and marketing practices, violating the anti-kickback laws, and causing the submission of false claims to federal health care programs. The Department of Justice described the company's illegal pricing activities:

[B]oth BMS and Apothecon set and maintained fraudulent and inflated prices for a wide assortment of oncology and generic drug products with the knowledge that federal health care programs established reimbursement rates based on those prices. By reporting false and fraudulent prices that were substantially higher than commonly and widely available prices in the marketplace, BMS and Apothecon created a "spread" between the reimbursement rates for federal health care providers and the actual prices for the drugs charged to its customers. The larger the spread on a drug, the larger the profit or return on investment for the provider. Because reimbursement from federal programs was based on the fraudulent, inflated prices, the United States alleged that BMS and Apothecon caused false and fraudulent claims to be submitted to federal health care programs.<sup>6</sup>

#### ***Massachusetts v. Mylan Labs***

In 2005, the District Court of Massachusetts declined to grant a motion to dismiss a complaint filed by the Commonwealth of Massachusetts against 13 defendant generic pharmaceutical companies for their alleged role in causing the state to overpay pharmacies and other providers for generic prescription drugs. The companies allegedly inflated their wholesale prices, thereby creating a discrepancy (or spread) between the price that providers paid the generic pharmaceutical company and the amount of reimbursement received from the Medicaid program.

The purpose of each defendant in creating the spread was to provide incentives or kickbacks for customers who buy and distribute its products, to increase the profits for such customers at the expense of the state Medicaid programs, and to increase its own profits by increasing its market share of particular drugs and classes of drugs.<sup>7</sup>

<sup>6</sup> Department of Justice, *Bristol-Myers Squibb to Pay More Than \$515 Million to Resolve Allegations of Illegal Drug Marketing and Pricing* (Press Release), September 28, 2007, [http://www.usdoj.gov/opa/pr/2007/September/07\\_civ\\_782.html](http://www.usdoj.gov/opa/pr/2007/September/07_civ_782.html).

<sup>7</sup> *Massachusetts v. Mylan Labs*, 357 F. Supp. 2d 314, 320-321 (D. Mass. 2005).

<sup>5</sup> 42 U.S.C. § 1396r-8.

The action is ongoing, but only six of the original defendants remain as defendants in the suit. Seven generic pharmaceutical manufacturers have entered into settlement agreements with the state, paying the Massachusetts Medicaid Program a combined total of \$14.76 million.<sup>8</sup>

## II. Anti-Kickback Violations

A pharmaceutical manufacturer may improperly pay a kickback to a wholesaler or health care plan to substitute a generic equivalent or use a specific generic product, implicating federal and state anti-kickback statutes and the False Claims Act.

### *BMS Apothecon Settlement with the Department of Justice*

In addition to the charges of pricing fraud described in the previous section, the government alleged that from 1994 through 2001, BMS and Apothecon “knowingly and willfully paid illegal remuneration such as stocking allowances, price protection payments, prebates, market share payments, and free goods in order to induce its retail pharmacy and wholesaler customers to purchase its products.” By paying this illegal remuneration to physicians and others, the companies knowingly caused the submission of false and fraudulent claims to the federal health care programs.<sup>9</sup> Apothecon also settled similar claims under various state anti-kickback statutes.

## III. Antitrust Violations

The FTC had been aggressively investigating proprietary pharmaceutical companies and tracking settlement agreements between proprietary and generic manufacturers. A generic pharmaceutical

company might agree (often as part of a patent dispute settlement) to delay entry into the market for a specific drug and accept payment for such delay. The FTC has brought claims against proprietary pharmaceutical companies under such circumstances alleging that such agreements are anticompetitive and violate the Sherman Act and the FTC Act.

### *FTC v. Watson Pharmaceuticals*

However, in February of this year, the FTC filed a complaint against Watson Pharmaceuticals, Par Pharmaceutical Companies, and Paddock Laboratories for entering into an agreement with Solvay Pharmaceuticals to delay entry into the market for the testosterone replacement drug AndroGel.<sup>10</sup> The complaint alleges that Solvay paid the generic pharmaceutical companies to abandon challenges to its AndroGel patent and to not bring a generic product to the market until 2015.<sup>11</sup> The complaint states that by delaying entry into the market, the defendants are cooperating on the sale of AndroGel and sharing the monopoly profits, rather than competing. The FTC claims that this is an unreasonable restraint of trade that violates Section I of the Sherman Act,<sup>12</sup> and an unfair method of competition that violates Section 5(a) of the FTC Act.<sup>13</sup>

### *Proposed Legislation*

In addition to advancing new theories such as in the Watson Pharmaceuticals complaint, the FTC is actively supporting legislation that will ban such “pay for delay” agreements. In March, H.R. 1706 was introduced; the bill would prohibit proprietary drug companies from compensating generic drug companies to delay the entry of a generic drug into the market.<sup>14</sup>

<sup>8</sup> Office of the Attorney General, *National Drug Company Pays \$7 Million to State's Medicaid Program to Settle Improper Drug Pricing Allegations* (Press Release), January 5, 2009, [http://www.mass.gov/?pageID=cagopressrelease&L=1&L0=Home&sid=Cago&b=pressrelease&f=2009\\_01\\_05\\_teva\\_settle&csid=Cago](http://www.mass.gov/?pageID=cagopressrelease&L=1&L0=Home&sid=Cago&b=pressrelease&f=2009_01_05_teva_settle&csid=Cago).

<sup>9</sup> Department of Justice, *Bristol-Myers Squibb to Pay More Than \$515 Million to Resolve Allegations of Illegal Drug Marketing and Pricing* (Press Release), September 28, 2007, [http://www.usdoj.gov/opa/pr/2007/September/07\\_civ\\_782.html](http://www.usdoj.gov/opa/pr/2007/September/07_civ_782.html).

<sup>10</sup> See Civil Complaint, *FTC v. Watson Pharmaceuticals*, No. CV-09-00598 (Jan. 27, 2009).

<sup>11</sup> See Civil Complaint, *FTC v. Watson Pharmaceuticals*, No. CV-09-00598 (Jan. 27, 2009).

<sup>12</sup> 15 U.S.C. § 1.

<sup>13</sup> 15 U.S.C. § 45(a).

<sup>14</sup> See FTC, *FTC Testifies in Support of Bill Banning “Pay-for-Delay” Settlements Between Brand and Generic Drug Companies* (Press Release), June 6, 2009, <http://www.ftc.gov/opa/2009/06/payforde lay.shtm>.

#### **IV. Quality and Manufacturing Processing Violations**

Generic pharmaceutical companies may experience quality problems, possibly after an FDA inspection uncovered issues with the company's manufacturing process. The FDA disseminates its expectations regarding current Good Manufacturing Practices ("cGMPs") through guidance documents and Warning Letters to individual entities. The cGMPs require the pharmaceutical industry to produce products using current manufacturing standards, specifications, and technologies.

In 2008 and 2009, many of the FDA Warning Letters were issued to domestic facilities, but an increase in personnel in foreign offices might predict more enforcement efforts against overseas facilities. In addition to focusing on production and manufacturing issues, cGMP Warning Letters may also incorporate other compliance issues such as misbranding. Some Warning Letters indicate that some pharmaceutical companies have failed to adequately address inspectional observations, suggesting that generic pharmaceutical companies should strive to provide high-quality responses to any FDA inspection or query.<sup>15</sup>

#### ***Caraco Pharmaceutical Laboratories***

Caraco Pharmaceutical Laboratories reportedly underwent a two-month FDA inspection ending May 12, 2009. The inspection was preceded by a Warning Letter in October 2008 in which the FDA expressed concerns with the failure of the company's Quality Control Unit to address manufacturing problems.<sup>16</sup> In March 2009, the company voluntarily recalled all manufactured tablets of Digoxin, a medicine used to treat heart problems, because of size and dosage variability.<sup>17</sup> The FDA reportedly has stalled government approvals of new drug products that the company plans to manufacture at its Detroit plant.

<sup>15</sup> The FDA makes available Warning Letters in a searchable format on its website at <http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/default.htm>.

<sup>16</sup> FDA, Warning Letter 2008-DT-05 to Caraco Pharmaceutical Laboratories, Ltd. (Oct. 31, 2008).

<sup>17</sup> FDA, *FDA's MedWatch Safety Alerts: April 2009*, <http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm152504.htm#carco>.

#### ***Ranbaxy Laboratories***

The FDA and Department of Justice investigated Ranbaxy Laboratories over quality issues with pharmaceuticals produced in its Indian facilities.<sup>18</sup> As a result of the investigations, the FDA imposed an import ban on 30 Ranbaxy drugs. The company has filed a corrective action plan, which the agency is currently reviewing.

#### **V. Foreign Corrupt Practices Act ("FCPA")**

The FCPA makes it unlawful to bribe foreign government officials to obtain or retain business. A "foreign official" means any officer or employee of a foreign government, a public international organization, or any department or agency thereof, or any person acting in an official capacity.<sup>19</sup> The FCPA also contains accounting and recordkeeping provisions. Because of the structure of many countries' health services, doctors and hospital officers or managers may be considered "government officials" for the purposes of the statute.

The anti-bribery provisions apply to a large range of entities and individuals, including foreign-owned companies that register securities in the United States or otherwise are required to file reports with the SEC. The FCPA contains an exception for "grease" payments to facilitate "routine government action" but this exception does not apply to any action involving discretionary decision making.

#### ***Siemens AG***

Last year, the German company Siemens AG and three of its subsidiaries pled guilty to criminal charges under the FCPA.<sup>20</sup> Siemens also settled a related civil enforcement action with the SEC for

<sup>18</sup> See FDA, *Regulatory Action against Ranbaxy's Paonta Sahib Plant in India*, <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/ucm118411.htm>.

<sup>19</sup> 15 U.S.C. §§ 78dd-1(a), 78dd-2(a).

<sup>20</sup> Department of Justice, *Siemens AG and Three Subsidiaries Plead Guilty to Foreign Corrupt Practices Act Violations and Agree to Pay \$450 Million in Combined Criminal Fines* (Press Release), December 15, 2008, <http://www.usdoj.gov/opa/pr/2008/December/08-crm-1105.html>.

FCPA violations.<sup>21</sup> The company was specifically charged with bribing officials to sell medical devices in China, Russia, and Vietnam, improperly entering the payments onto its books, and failing to have adequate internal controls to detect and prevent the payments. While this company is not a pharmaceutical manufacturer, this landmark case is a good example of the risks involved in engaging in such practices. The company was subjected to a \$450 million criminal penalty and \$350 million disgorgement of profits from the illegal activity. The Siemens action was a landmark because of the size of the penalties and the scope of the wrongdoing. Several examples of pharmaceutical manufacturers that have been prosecuted for FCPA violations include:

#### *Schering-Plough Corporation*

In 2004, Schering-Plough entered a \$500,000 settlement with the SEC because its Polish subsidiary had given \$75,000 to a charitable organization headed by a Polish government official who directed a Polish government agency that influenced pharmaceutical purchasing decisions. The SEC alleged that payments were not accurately reflected on the subsidiary's books.<sup>22</sup>

#### *Akzo Nobel N.V.*

In December 2007, Akzo Nobel N.V., a Dutch pharmaceutical company, announced a settlement with the SEC and DOJ over actions taken by two of its

subsidiaries that were alleged to have made improper payments to Iraqi government officials to facilitate sales of pharmaceuticals to Iraq in conjunction with the United Nation's Oil for Food program. The payments were characterized as "after-sales service fees" but no additional services were performed. The company agreed to pay \$2.9 million in combined fees and penalties to the United States government.<sup>23</sup>

#### *Novo Nordisk A/S*

In May 2009, Danish pharmaceutical company Novo-Nordisk also agreed to pay \$9 million fines related to the Oil for Food Program. The company's agents made improper payments to the former Iraqi government in order to obtain contracts with the Iraqi ministry of health to provide insulin and other medicines.<sup>24</sup>

### **VI. Conclusion**

It is true that generic pharmaceutical companies do not face as many government enforcement actions as their proprietary counterparts, primarily because they do not have many of the same marketing and promotional programs. However, the compliance concerns facing the generic pharmaceutical industry are very real, and the liabilities can be high. Generic pharmaceutical companies subject to FDA, OIG, SEC, and FTC regulation must remain vigilant in order to avoid liability under the laws and regulations that govern the generic pharmaceutical industry.

<sup>21</sup> See U.S. Securities and Exchange Commission, *Litigation Release No. 28029* (December 15, 2008), <http://www.sec.gov/litigation/litreleases/2008/lr20829.htm>.

<sup>22</sup> See U.S. Securities and Exchange Commission, *Litigation Release No. 18740* (June 9, 2004), <http://www.sec.gov/litigation/litreleases/lr18740.htm>.

<sup>23</sup> See U.S. Securities and Exchange Commission, *Litigation Release No. 20410* (December 20, 2007), <http://www.sec.gov/litigation/litreleases/2007/lr20410.htm>.

<sup>24</sup> See U.S. Securities and Exchange Commission, *Litigation Release No. 21033* (May 11, 2009), <http://www.sec.gov/litigation/litreleases/2009/lr21033.htm>.