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Bristol-Myers Squibb to Pay More Than $515 Million to Resolve Allegations of Illegal Drug Marketing and Pricing

WASHINGTON – Bristol-Myers Squibb Company (BMS) and its wholly owned subsidiary, Apothecon, Inc., have agreed to pay over $515 million to resolve a broad array of civil allegations involving their drug marketing and pricing practices, United States Attorney Michael J. Sullivan announced today.

The settlement was announced today by Assistant Attorney General for the Civil Division and Acting Attorney General Peter D. Keisler, United States Attorney for the District of Massachusetts Michael J. Sullivan, and United States Attorney for the Southern District of Florida R. Alexander Acosta.

"The integrity of our health care system rests on physicians being able to make decisions based on the best interests of their patients," said Keisler. "This settlement reflects the Justice Department's strong commitment to holding drug companies accountable for devising and implementing fraudulent marketing and pricing schemes that undermine that decision-making process at the expense of federal health care programs for the poor and the elderly."

Sullivan added: "Patients are entitled to unbiased decision-making from their physicians and should not have to worry that financial inducements or lavish entertainment have influenced their physicians' prescribing choices. Kickbacks are especially nefarious when they are used as part of a marketing effort to convince physicians to prescribe drugs for uses that the Food and Drug Administration has not determined to be safe and effective."

"The government alleges that Bristol-Myers Squibb, among other wrongdoing, fraudulently inflated the cost of a drug used primarily to reduce the side effects of cancer treatments and other generic drugs without regard to the increased costs borne by government health care programs or elderly and indigent patients," said U.S. Attorney R. Alexander Acosta of the Southern District of Florida. "Corporations cannot continue to mislead the government into paying vastly exaggerated prices by exploiting a health care system based on trust and fair play."

Today's settlement covers a wide assortment of illegal marketing and pricing practices.

First, the Government alleged that, from approximately 2000 through mid-2003, BMS knowingly and willfully paid illegal remuneration to physicians and other health care providers to induce them to purchase BMS drugs. BMS paid the illegal remuneration in the form of consulting fees and expenses to physicians and other health care providers to participate in various consulting programs, advisory boards, and preceptorships. Some of these programs involved travel to luxurious resorts. The Government also alleged that, from 1994 through 2001, 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. In both cases, the Government alleged that, by paying this illegal remuneration to physicians and others, BMS and Apothecon knowingly caused the submission of false and fraudulent claims to the federal health care programs.

Second, the Government alleged that, from 2002 through the end of 2005, BMS knowingly promoted the sale

and use of Abilify, an atypical antipsychotic drug, for pediatric use and to treat dementia-related psychosis, both "off-label" uses. The Food and Drug Administration has approved Abilify to treat adult schizophrenia and bi-polar disorder, but has not approved the use of Abilify for children and adolescents or for geriatric patients suffering from dementia-related psychosis. Indeed, the FDA has mandated that the package for Abilify carry a "black box" warning concerning its use in the treatment of dementia-related psychosis. Nonetheless, BMS directed its sales force to call on child psychiatrists and other pediatric specialists, and the sales force then urged physicians and others providers to prescribe Abilify for pediatric patients. BMS also created a specialized long term care sales force that called almost exclusively on nursing homes, where dementia-related psychosis is far more prevalent than schizophrenia or bipolar disorder.

Third, the Government alleged that both 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.

Finally, the Government alleged that BMS knowingly misreported its best price for the anti-depression drug, Serzone. Under the provisions of the Medicaid Drug Rebate Statute, BMS was required to report to Medicaid the lowest, or "best" price, for Serzone that it charged its commercial customers. In making its mandatory best price reports, BMS knowingly failed to include the low prices at which it sold "private-label" Serzone to Kaiser, a large commercial purchaser. As a result, BMS denied the Medicaid program and certain Public Health Service entities the benefit of the lowest price in the marketplace.

Out of the settlement amount, the federal recovery is over $328 million, of which over $25 million constitutes disgorgement of profits under the Food, Drug and Cosmetic Act resulting from BMS's illegal promotion of Abilify. BMS also will pay over $187 million to the Medicaid participating states, and $124,000 to certain Public Health Service entities.

This settlement resolves in whole or in part allegations made in seven qui tam actions brought under the False Claims Act. Those actions are: United States ex rel. Richardson v. Bristol Myers Squibb, Civil Action No. 06-11821-NG (D. Mass.); United States ex rel. Piacentile v. Bristol-Myers Squibb Co., Civil Action No. 05-10196-MLW (D. Mass.); United States ex rel. Forden v. Bristol-Myers Squibb Co., Civil Action No. 04-11216 -RGS (D. Mass.); United States ex rel. Cokus v. Bristol Myers Squibb, Civil Action No. 01-11627-RGS (D. Mass.); United States ex rel. Barlow v. Bristol-Myers Squibb, Civil Action No. 04-11540-MLW (D. Mass.); United States ex rel. Ven-A-Care of the Florida Keys, et al. v. Apothecon, et al., Civil Action No. 00-10698-MEL (D. Mass.); and United States ex rel. Ven-A-Care of the Florida Keys, Inc. v. Bristol Myers Squibb Co., Civil Action No. 95-1354 (S.D. Fla.). The Act allows for private persons to file a qui tam or whistleblower suit on behalf of the government. If the government is successful in resolving or litigating its claims, the whistleblower may receive a share of the recovery. The various relators will receive a total of approximately $50 million as their share of the settlement.

As part of today's settlement, Bristol-Myers Squibb entered into a Corporate Integrity Agreement with the Office of Inspector General of the Department of Health and Human Services that, among other things, requires the company to report accurate average sales prices and average manufacturer prices for its drugs covered by Medicare and other federal health care programs.

"Illegal drug marketing schemes and deceitful pricing by manufacturers will be vigorously pursued by OIG," said Daniel R. Levinson, HHS Inspector General. "We are committed to ensuring that beneficiaries participating in federal health care programs are not taken advantage of by those engaging in unscrupulous practices."

The investigation was conducted by the Boston offices of the Office of Inspector General for the Department

of Health and Human Services, the Federal Bureau of Investigation, and the Food and Drug Administration's Office of Criminal Investigations, along with Department of Justice Trial Attorney Andy Mao of the Fraud Section of the Civil Division, District of Massachusetts Assistant U.S. Attorneys Gregg Shapiro and Susan Poswistilo, and Southern District of Florida Assistant U.S. Attorney Mark Lavine. The National Association of Medicaid Fraud Control Units participated in the negotiation of the settlement, and the Corporate Integrity Agreement was negotiated by Mary Riordan of the Office of Inspector General at the Department of Health and Human Services.

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