



Department of Justice

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District of Massachusetts

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BRISTOL-MYERS SQUIBB TO PAY MORE THAN \$515 MILLION TO RESOLVE ILLEGAL DRUG MARKETING AND PRICING ALLEGATIONS

Boston, MA... Bristol-Myers Squibb Company (BMS) and its wholly owned subsidiary, Apothecan, Inc., have agreed to pay in excess of \$515 million to resolve a broad array of federal and state civil allegations involving their drug marketing and pricing practices, United States Attorney Michael J. Sullivan announced today.

Michael J. Sullivan, U.S. Attorney for the District of Massachusetts; R. Alexander Acosta, U.S. Attorney for the Southern District of Florida; Warren T. Bamford, Special Agent in Charge of the Federal Bureau of Investigation - New England Field Division; Mark Dragonetti, Resident Agent in Charge of the Food & Drug Administration - Office of Criminal Investigations; Joseph C. Moraski, Special Agent in Charge of Health and Human Services, Office of Investigations announced that today's civil 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. While BMS paid the remuneration in the form of consulting fees and expenses ostensibly in exchange for the providers' participation in various consulting programs, advisory boards, and preceptorships, the Government alleged that a purpose of the programs, some of which involved travel to luxurious resorts, was to influence the providers' prescribing habits. The Government also alleged that, from 1994 to 2001, Apothecan knowingly and willfully paid illegal remuneration such as stocking allowances, prebates, 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 Apothecan 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 is alleged to have 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. Because of the potential market benefit, BMS' long term care sales force promoted Abilify off-label for the treatment of dementia-related psychosis.

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.

"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," said Sullivan. "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."

BMS cooperated in aspects of the Government's investigation. For example, BMS voluntarily disclosed to the United States Attorney's Office in the District of Massachusetts its practices with respect to the remuneration paid to physicians in 2000-2003, and voluntarily provided to the government numerous documents detailing these practices. With respect to Abilify, prior to the government's investigation, BMS initiated steps to modify its physician

“call lists” to reduce the potential for off-label marketing. In addition, BMS made available to the government Frederick Lacey, a retired federal district court judge who had been serving as BMS' compliance monitor pursuant to a deferred prosecution agreement in the District of New Jersey. Judge Lacey and other senior BMS officials presented extensive evidence of the compliance practices under which BMS currently operates. The government took BMS's self-disclosure, its cooperation, and its current practices into account in agreeing to this civil resolution.

BMS has agreed to pay \$499,000,000 plus interest to resolve the federal and state civil claims. As of today, the interest owing is \$16,483,660.27, bringing the total payment owing to \$515,483,660.27. Of that amount, the federal recovery is approximately \$328 million; about \$25 million constitutes disgorgement of profits under the Food, Drug and Cosmetic Act resulting from BMS's illegal promotion of Abilify. That federal amount will be paid promptly. BMS has also agreed to settle the state civil claims (with payments to the affected stated Medicaid Programs). Final approval of the individual state settlements is pending, and the amount ultimately paid by BMS will include interest through the date of payment. As of today, and assuming final approval by all state Medicaid programs, the state share of the global civil settlement is approximately \$187 million. BMS has also agreed to pay \$124,000 to certain Public Health Service entities.

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.

This settlement resolves in whole or in part allegations made in six *qui tam* actions filed in the District of Massachusetts: *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. Apothecan, et al.*, Civil Action No. 00-10698-MEL (D. Mass.). The settlement also resolves one *qui tam* action filed in the Southern District of Florida: *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 False Claims 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 federal settlement amount, and an additional share of the state settlement amount.

This matter was investigated 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, and is being handled by District of Massachusetts Assistant U.S. Attorneys Gregg Shapiro and Susan Poswistilo and

Department of Justice Trial Attorney Andy Mao of the Fraud Section of the Civil Division. 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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