

**FOR IMMEDIATE RELEASE    CONTACT:**  
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## **NAMFCU ANNOUNCES MAJOR PRESCRIPTION DRUG SETTLEMENT**

The National Association of Medicaid Fraud Control Units (NAMFCU) announced on April 16 the largest Medicaid fraud settlement ever involving pharmaceutical manufacturers. Two major drug manufacturers, Bayer Corporation and GlaxoSmithKline failed to accurately report “best price” to the Center for Medicaid and Medicare Services (CMS, formerly HCFA) and failed to pay sufficient rebates to the state Medicaid programs in connection with their private labeling of certain drugs. Forty-nine states and the District of Columbia are participating in these settlements.

“Protecting the integrity of the Medicaid program continues to be a priority for my office and my colleagues throughout the country. This historic agreement goes a long way toward protecting the Medicaid programs and making them whole, by returning money to the Medicaid programs, most of which are severely strapped for resources,” Maryland Attorney General J. Joseph Curran, Jr. said.

The federal Medicaid drug rebate statute is designed to return money to the Medicaid program in the form of rebates from drug manufacturers. Under the statute, in order to have the pharmaceuticals eligible for Medicaid payment, all pharmaceutical manufacturers must provide “best price” information to CMS. “Best price” is the lowest price that a manufacturer offers its products for sale to commercial purchasers. CMS uses this “best price” information to calculate rebates payable to the state Medicaid programs under the statute.

Both Bayer and GlaxoSmithKline sold products to HMOs at deeply discounted prices, and then concealed and avoided their obligation to pay additional rebates to the Medicaid programs. This was accomplished by re-labeling or re-packaging these drugs under the HMO’s private label. This fraud scheme is referred to as “lick and stick.”

### **GlaxoSmithKline**

The U.S. Attorney’s Office for the District of Massachusetts conducted an investigation into alleged improprieties relating to the reported “best price” for Flonase, a nasal spray, and Paxil, an anti-depressant. Flonase was manufactured and sold by Glaxo Wellcome and Paxil was manufactured and sold by SmithKline Beecham. These two companies merged and became GlaxoSmithKline in December 2001.

The U.S. Attorney for the District of Massachusetts Michael J. Sullivan, stated, “Misconduct in the pharmaceutical industry significantly impacts our state and federal treasuries, as well as our citizens and taxpayers. This investigation was a model of cooperation and teamwork between the many interested agencies and federal prosecuting authorities. We believe

the result is an outstanding resolution of this matter.”

Through a private labeling agreement with Kaiser Permanente, an HMO in California, Glaxo Wellcome manufactured, packaged and shipped Flonase to Kaiser, but substituted the Kaiser unique identifying number for the Glaxo Wellcome unique identifying number on the label. The purpose of the private labeling arrangement was to provide Kaiser additional price discounts on Flonase without having to report the discounted price as Glaxo Wellcome’s “best price,” thereby avoiding the obligation to pay additional rebates to Medicaid under the Medicaid rebate program. Similarly, SmithKline began private labeling Paxil for Kaiser. Paxil was manufactured, packaged and shipped by SmithKline to Kaiser, but SmithKline substituted Kaiser’s unique identifying number for SmithKline’s unique identifying number on the label. SmithKline provided Kaiser additional price discounts on Paxil without reporting the newly discounted price to the Medicaid rebate program, thereby avoiding payment of additional rebates.

According to the agreements in principle, GSK has agreed to civil settlements of \$87,600,922 in damages and penalties to the federal and state governments. GSK will also enter into a Corporate Integrity Agreement (CIA) with the U.S. Department of Health and Human Services, Office of the Inspector General. At the insistence of NAMFCU, the CIA will require GSK to certify its “best price” methodology.

### **Bayer Corporation**

A qui tam complaint was filed in federal district court in Boston in February 2000 and the U.S. Attorney’s Office conducted an investigation into alleged improprieties relating to the reported “best price” for two of Bayer’s drugs, Cipro, an antibiotic, and Adalat CC, an anti-hypertensive. Bayer agreed to private label Cipro and Adalat CC for Kaiser and to sell these drugs to Kaiser at a discounted price. Bayer also agreed to private label Adalat CC for PacifiCare, also an HMO, and sell the private labeled Adalat CC to PacifiCare at a discounted price. Bayer has agreed to pay \$242,126,570 in damages and penalties to the federal and state governments for knowingly misreporting its “best price” to HCFA and underpaying its Medicaid rebates for Cipro and Adalat CC that was private labeled for Kaiser and PacifiCare from its determination of “best price.” Bayer will plead guilty to a charge of violating the Food, Drug and Cosmetics Act in federal district court in Boston. The government will recommend that Bayer pay a fine of \$5,590,800.

An addendum with new obligations will be added to Bayer’s current Corporate Integrity Agreement (CIA) with the U.S. Department of Health and Human Services, Office of the Inspector General. At the insistence of NAMFCU, Bayer will be required to certify its “best price” methodology. These certification processes will add a new responsibility which will enhance future state enforcement.

“My office, and all of the Attorneys General nationwide, will continue to join forces with our federal counterparts to determine whether pharmaceutical corporations are profiting illegally at the expense of the Medicaid programs,” said Massachusetts Attorney General Tom Reilly. “We will work tirelessly to recover state and federal dollars that are desperately needed to fund

health care services for our neediest citizens.”

“The state Attorneys General greatly appreciate the cooperation of the U.S. Attorney’s Office in Boston in pursuing these Medicaid rebate cases,” said E. Christopher Abruzzo, President of the National Association of Medicaid Fraud Control Units and Director, Pennsylvania MFCU. “More investigations like these are underway at the federal and state levels, and these practices of the pharmaceutical manufacturers will continue to be a focus for the states.”

“Over the past ten years, the multi-state efforts of the National Association of Medicaid Fraud Control Units have produced an impressive track record, with more than \$362 million returned to the state Medicaid programs, said NAMFCU Counsel Barbara Zelner. “Significantly, the funds recouped in these two rebate cases, together with the \$49 million recovery in the recently-concluded Pfizer/Lipitor case, surpass the total recoveries of all the Medicaid fraud global settlement cases of the past decade.”

The National Association of Medicaid Fraud Control Units represents the 48 federally certified Medicaid Fraud Control Units that are responsible for investigating and prosecuting providers that defraud the Medicaid program. The NAMFCU negotiating team for both cases was lead by the Directors of the Maryland, Pennsylvania and Washington State MFCUs.

“The expansion of the Medicaid program and the ever-increasing cost of prescription drugs have contributed to record budget deficits in many states,” Pennsylvania Attorney General Mike Fisher said. “These settlements will return much needed funds to the Medicaid programs, which will assist states in their efforts to continue to provide health care services to their most needy and vulnerable citizens.”