The Medicaid/340B Program "Best Price" Enforcement Landscape[1]

Kirsten V. Mayer[2]

Under the Medicaid Rebate Program, pharmaceutical manufacturers are required to report certain key price terms to CMS for each of their drugs. These include Average Manufacturer Price ("AMP") and Best Price.[3] AMP and Best Price are then used to calculate the rebate owed by a manufacturer to the states under the Medicaid Rebate Program.[4] But Medicaid is not the only program to make use of AMP and Best Price. Under the 340B Program, manufacturers are required to use Best Price and AMP to calculate the maximum price that a manufacturer may charge when it sells drugs to "covered entities" that participate in the 340B Program.[5] As a result, if a manufacturer has overstated the Best Price that it reported to CMS under the Medicaid Rebate Program, it may also have overcharged 340B Program covered entities for those same drugs.

For several years, manufacturers' Best Price reporting has received close scrutiny by both federal and state law enforcement. Investigations into the Best Prices reported by several manufacturers to CMS have led to significant settlements with recoveries for both the Medicaid

---

[1] Prepared for American Conference Institute, *"Big Four" Pharma Pricing Boot Camp* (May 2007).

[2] Attorney at Ropes & Gray LLP; J.D. *magna cum laude* Harvard Law School, 1998. Ms. Mayer represents corporate and individual clients in criminal and civil matters involving federal and state law enforcement agencies. She also advises clients in the context of internal investigations and strategic transactions in the health care industry.

[3] 42 U.S.C. §§ 1396r-8(k)(1) (definition of AMP), 1396r-8(c)(1)(C) (definition of Best Price), 1396r-8(b)(3) (manufacturer price reporting); Medicaid Rebate Agreement ("MRA") §§ I(a),(d); II(e),(f).

[4] *Id.*; Best price is used to calculate the rebate for single-source and innovator multiple-source drugs. 42 U.S.C. § 1396r-8(c)(1). It is not used to calculate the rebate for non-innovator multiple-source drugs. 42 U.S.C. § 1396r-8(c)(3).

[5] The 340B Program ceiling price is the maximum amount that a "covered entity" can be charged for a drug purchased through the 340B program. The ceiling price is calculated as Average Manufacturer's Price ("AMP") – Unit Rebate Amount. The Unit Rebate Amount is the lower of 15.1% of AMP, or AMP – Best Price for single-source and innovator multiple-source drugs. It is 11% of AMP for (non-innovator) multiple-source and over the counter drugs. The statutory and contractual definitions of each of these terms (AMP, Best Price, Unit Rebate Amount) link the 340B Program with the Medicaid Rebate Program, and the meanings of the terms have historically been the same for both programs. *See generally*, Section 602, Veterans Health Care Act of 1992, P.L. No. 102-585; 340B Program Pharmaceutical Pricing Agreement ("PPA"), § II(a)-(b).

More recently, the Director of the Office of Pharmacy Affairs for HHS-HSB-HRSA issued a "Dear Pharmaceutical Manufacturer" letter to clarify whether recent amendments to the statutory definition of AMP for purposes of Medicaid should be applied to the AMP used to calculate the 340B Program ceiling price. *See* Mitchell Letter, Jan. 30, 2007, *available at* http://www.hrsa.gov/opa/pharm-mfg-ltr013007.htm. The letter stated that the recent amendment to remove the deduction for customary prompt pay discounts from the calculation of AMP for Medicaid should not be applied to the calculation of AMP for calculation of 340B ceiling prices.

Program and 340B covered entities. This paper reviews these settlements and recent litigation in this area, and discusses briefly risks that they reveal. Because Best Price is one of the important pieces of pricing information used by the Medicaid and 340B Programs to address the cost of pharmaceutical products, the industry can expect DOJ, HHS-OIG and state law enforcement to continue to police it carefully.[6]

I. "Lick and Stick" Arrangements – Who is the Manufacturer?

A manufacturer's obligation to report a Best Price for a particular drug is tied to that manufacturer's status as "the manufacturer" of the drug under the Medicaid Rebate Program. Under a straightforward reading of the applicable statute and Medicaid Rebate Agreement ("MRA"), "manufacturer" is defined broadly enough to include entities other than the pharmaceutical company that formulated and initially packaged the drug. Specifically, the MRA, interpreting the statute, defines "manufacturer" "also [to] mean the entity holding legal title to or possession of the NDC number" of the drug.[7] While wholesalers and retail pharmacies were specifically excluded from the definition of "manufacturer," health maintenance organizations were not.[8] This left open a door for pharmaceutical companies: an HMO customer with its own NDC number was apparently permitted to be "the manufacturer" of a drug for purposes of best price reporting requirements, even if that HMO didn't itself produce the drug, or have its own manufacturing facilities. As a result, certain pharmaceutical manufacturers entered into repackaging or private label agreements with certain HMO customers that shifted the status of "manufacturer" of the product – and, in theory, any best price reporting obligation -- to the HMO.

---

[6] *See e.g.*, Testimony of Lewis Morris, Chief Counsel to the Inspector General, HHS-OIG, before the House Oversight and Government Reform Committee, U.S. House Of Representatives "Allegations of Waste Fraud and Abuse in Pharmaceutical Pricing: Financial Impacts on Federal Health Programs and the Federal Taxpayer" at 3-4; 8 (February 9, 2007), *available at* http://www.oig.hhs.gov/testimony/docs/2007/020907tmy.pdf. State Attorneys General have also become increasingly active in pharmaceutical pricing enforcement. *See e.g., Nevada ex rel Steinke v. Merck & Co., Inc.*, No. 3:05-CV-00322-HDM-RA (D. Nev. 2005) (litigation pertains to whether certain nominal price transactions should have been included in defendant's calculation of Best Price); *Massachusetts v. Mylan Laboratories et al*, No. Civ. A. 03-11865-PBS (D. Mass. 2003)(litigation pertains to whether pharmaceutical manufacturer defendants reported accurate WAC or AMP prices).

[7] Rebate Agreement s I(1); 42 U.S.C. § 1396r-8(k)(5)(A)-(B) (A "manufacturer" is any entity "engaged in the production, preparation, propagation, compounding, conversion, or processing of prescription drug products...or in the packaging, repackaging, labeling, relabeling, or distribution of prescription drug products."). The 340B Pharmaceutical Pricing Agreement's definition of "manufacturer" is consistent with these. PPA § I(f).

[8] 42 U.S.C. § 1396r-8(k)(5)(A)-(B); PPA s. I(f) (incorporating the meaning set forth in section 1396r-8(k)(5)).

The U.S. Department of Justice ("DOJ") disagreed with this interpretation of the governing law. Relying principally on two CMS Releases and a March, 2001 HHS-OIG audit report, federal prosecutors have taken the position that a manufacturer's sales of a drug to an HMO must be included in the computation of that manufacturer's Best Price, regardless of whether the HMO was repackaging or purchasing a private labeled version of the drug.[9] Three settlements in this area illustrate the breadth and ultimate success of DOJ enforcement under this theory.

a. GlaxoSmithKline – Flonase and Paxil (2003)

In 2003, GlaxoSmith Kline ("GSK") entered into an $87 million civil settlement agreement to resolve its potential liability for reporting allegedly inaccurate best prices for two drugs: Flonase and Paxil. According to the government, Glaxo Wellcome had private labeled Flonase for an HMO customer for purchase at a discounted price and distribution by the HMO under a label that displayed the HMO's NDC number. SmithKline Beecham ("SKB"), on the other hand, had entered into a bulk repackaging agreement with the same HMO customer. Under that agreement, SKB had allegedly provided Paxil in bulk quantities that were not otherwise commercially available, for repackaging and relabeling by the HMO under its own NDC number. In both instances, Glaxo Wellcome and SKB chose not to include the private label or bulk sales for repackaging in their best price calculations for these products. The government's position was that these sales should have been treated as sales of Glaxo Wellcome- or SKB-labeled product, and thus should have been taken into account when the companies reported Best Price. GSK denied the government's allegations in this matter.

The Boston U.S. Attorney's Office led the investigation. Of the $87 million recovered from GSK, $2,558,371 was recovered for 340B Program Covered Entities.[10]

b. Bayer – Cipro and Adalat CC (2003)

In 2003 Bayer pleaded guilty to a felony violation of the Drug Listing Act, 21 U.S.C. § 360. ("DLA") and entered into a civil settlement agreement to resolve its potential Best Price

[9] CMS Release No. 29 (1997); CMS Release No. 47 (2000); HHS-OIG Office of Audit Services, **Medicaid Drug Rebates – Sales to Repackagers Excluded From Best Price Determinations** (A-06-00-00056), *available at* http://www.oig.hhs.gov/oas/reports/region6/60000056.htm.

[10] The federal government received $46,773,403; the states received $38,269,148.

liability for Adalat CC and Cipro. According to the government, Bayer private labeled Cipro and Adalat CC for certain HMO customers by affixing a label that substituted the HMO customer's NDC number for Bayer's NDC number, but didn't otherwise alter or repackage the products. This allegedly led to inaccurate Best Prices when Bayer sold the private labeled product to the HMOs at significant discounts off regular prices without considering these discounted transactions in its calculation of the Best Price for its regular – non-private label – Cipro and Adalat. The government also alleged that Bayer omitted certain information and provided certain false information about the price of private labeled Cipro in connection with an HHS-OIG audit.

In addition to entering into a civil settlement, Bayer pleaded guilty to a violation of the DLA. Specifically, Bayer admitted that it had failed to list its private labeled Cipro with the FDA and failed to provide a copy of the labeling and NDC number for the private labeled Cipro to FDA in violation of 21 U.S.C. §§ 331(p), 333(a)(2), and 360(j). Other than what was admitted in connection with its criminal plea, Bayer denied the government's allegations in this matter.

The Bayer investigation was led by the Boston U.S. Attorney's office and was initiated, at least in part, by a whistleblower. The combined criminal fine and civil settlement amount totaled over $250 million. Of that, $9,482,620 was recovered for 340B Program Covered Entities.[11]

c. Schering-Plough – K-Dur (2006)

In 2006, Schering-Plough resolved its potential liability for a number of issues, including its potential liability for the Best Prices it had reported for Claritin Redi-Tabs and K-Dur. While the overall Schering resolution included both criminal and civil components, potential liability for the company's alleged private labeling of K-Dur was resolved with the civil settlement. As with Bayer and GSK, the government alleged that Schering had private labeled one of its products -- K-Dur -- for an HMO client, and had sold that private labeled product at a lower price than the Schering-labeled version of the product. The Best Price liability allegedly arose when Schering failed to consider the lower private label transaction prices when calculating its Best Price for the Schering-labeled product. Schering denied the government's allegations with respect to the Best Price of private labeled K-Dur.

[11] The federal government received $133,169,619. The states received $108,956,961.

The Schering investigation was led by the Boston U.S. Attorney's Office. Of the total civil settlement amount, which addressed several potential issues in addition to private labeled K-Dur, the 340B Program Covered Entities recovered $3,921,089.[12]

II. Data Fees, Educational Grants, Free Goods, Cash Payments, and Other Potential "Remuneration"

When a manufacturer calculates the Best Price for its drugs, it is required to take into account discounts that lower the price at which the drug was sold.[13] For several years, DOJ has looked closely at whether, under the facts and circumstances of a particular transaction, discounts or rebates provided on purchases of one drug may in fact be intended to achieve discounts or rebates on another drug -- or whether cash payments, data fees, free goods, or other services, like health management programs, may have been provided to discount or rebate a drug. If a manufacturer provides such things to achieve a specific discount off the purchase price of one of its drugs, the Best Price reported to CMS should include the value of that discount as well. [14]

Because transactions in this area may implicate both Best Price and Anti-kickback issues, manufacturers should expect DOJ to continue to scrutinize manufacturer conduct that includes elements that were present in the settlements discussed in this and the next section of this paper.

a. AstraZeneca – Zolodex (2003)

In 2003, AstraZeneca resolved its liability on a number of potential issues, including its Best Price reporting for Zolodex.[15] According to the government, AstraZeneca had provided certain price concessions to its customers, including cash discounts in the form of grants, services, and free goods contingent on a purchase requirement, and volume discounts and rebates that were not included in the company's invoice prices. The government argued that AstraZeneca reported inaccurate Best Prices for Zolodex when it failed to take these "off-

[12] In total, the 2006 civil settlement provided $159,502,000 to the federal government and $91,602,000 to the states.

[13] Medicaid Rebate Agreement § I(d); PPA § I(b).

[14] *See generally*, CMS Release No. 14 at 1 (1994).

[15] The settlement include a criminal plea to a violation of the Prescription Drug Marketing Act. The conduct at issue in connection with the plea was unrelated to the allegations relating to the company's Best Price reporting, which allegations were resolved with a civil settlement agreement.

invoice" price concessions into account in calculating the sales prices for these transactions. As a result, the reported Best Prices were allegedly too high.

The company resolved these and other allegations in a civil settlement agreement, without admitting any liability. The investigation was led by the U.S. Attorney's Office for the District of Delaware. The civil portion of the AstraZeneca agreement totaled $291 million, only a portion of which stemmed from the alleged Best Price issues.

b. Bayer – Adalat CC (2003)

The 2003 Bayer settlement discussed *supra* at 3-4 also involved allegations that Bayer had failed to take into account a $100,000 cash payment made to an HMO customer in connection with that customer's purchase of Adalat CC when Bayer calculated its Best Price for the drug. As a result, the government alleged that Bayer's Best Prices were inaccurate. This allegation was resolved as part of the civil settlement agreement in this matter.

c. Pfizer/Park-Davis – Lipitor (2002)

In 2002, Pfizer settled allegations that Parke-Davis Laboratories[16] had overstated the Best Price for Lipitor by concealing $250,000 in cash discounts to key managed care customers in exchange for favored status on the managed care organizations' formularies. The investigation was led by the U.S. Attorney's Office for the Eastern District of Texas and DOJ. It was initiated, at least in part, by a whistleblower. The government's position was that the $250,000 was a discount on goods sold that should have been, but was not, taken into account in calculating the Best Price for Lipitor. This conduct allegedly allowed Parke-Davis to retain over $20 million in Medicaid Rebates. The civil settlement agreement required Pfizer to pay $49 million to resolve its potential liability in this investigation.[17]

d. Schering-Plough - Claritin (2004, 2006)

In 2004 and 2006, Schering resolved its potential liability relating to its Best Price reporting for its Claritin products. The 2004 investigation focused on certain alleged price

[16] Parke-Davis Laboratories, at the time of the conduct at issue, was a subsidiary of Warner-Lambert. Pfizer acquired the company after the conduct at issue had occurred.

[17] The federal government received $27,915,300. The states shared $21,084,700.

concessions on Claritin that the government asserted Schering had provided to two managed care customers. According to the government, these concessions included cash incentives, deeply discounted products, pre-paid rebates, a risk-sharing arrangement, and health management programs that were, in the specific context of the customer relationships, targeted to reduce the customer's effective cost for Claritin. In 2006, the government focused on whether Schering had provided free Claritin Redi-Tabs to an HMO customer in connection with that customer's purchase of Redi-Tabs to achieve an overall reduction in price for the Redi-Tabs. The government's position was that this had occurred, and that the true transaction price of the Redi-Tabs (taking into account the value of the free product) should have been, but was not, reported by the company as the product's Best Price during the relevant quarters.

The 2004 investigation was led by the Philadelphia U.S. Attorney's Office and was initiated by three whistleblowers. The 2006 investigation was led by the Boston U.S. Attorney's Office. The company resolved its best price issues across both investigations with a combination of civil settlement agreements and a criminal plea. In 2004, Schering entered into a civil settlement agreement to resolve the issues in that investigation. The agreement provided for payments of $10,626,470 to 340B Program Covered Entities.[18] In 2006, Schering Sales pleaded guilty to a single count conspiracy to violate 18 U.S.C. § 1001 for concealing the fact that the company had reported false Best Prices for Redi-Tabs, and entered into a civil settlement agreement to resolve its Best Price and other issues. As discussed *supra* at 4-5, the 340B Covered Entities received $3,921,089 under this agreement.

III. Nominal Pricing for Commercial Customers

In the Medicaid Rebate Program, and for purposes of calculating the 340B Program ceiling price, drugs sold at a "nominal price" -- defined as any price less than 10% of AMP -- should be excluded from a manufacturer's calculation of Best Price.[19] Until recently, this nominal price exclusion applied to any transaction at a nominal price without regard to the kind

[18] The total civil recovery in the 2004 settlement was $282,343,012. Of this, $165, 274,492 was provided to the federal government, and the states shared $117,068,520. These totals were reduced by amounts already paid by the company in connection with a prior Best Price re-filing for Claritin.

[19] 42 U.S.C. § 1396r-8(c)(1)(C)(ii); MRA § I(d),(s). Because "Best Price" is defined in the context of the 340B Program ceiling price to have the same meaning given to "Best Price" in the Medicaid Rebate Program, *see* PPA § I(b), the Medicaid Rebate Program's definition and use of "nominal price" applies in the 340B program context as well.

of customer involved in the transaction. Starting this year, however, the nominal sales that may be excluded from Best Price calculations are restricted to those sales made at nominal prices to (a) entities eligible for discounted prescription drug prices under Section 340(b) of the PHS Act; (b) intermediate care facilities for the mentally retarded, (c) state owned or operated nursing facilities; and (d) any other facility or entity determined by the Secretary of HHS to be a safety net provider.[20] Thus, while nominal sales to other customers now must be taken into account in a manufacturer's Best Price calculations, until this recent change in the law, a straightforward reading of the applicable law appeared to permit manufacturers to sell their products to commercial customers at a nominal price without being required to report that nominal price as the Best Price for that product for that quarter.

Federal and state law enforcement have taken a different view. The Best Price investigations that have focused on nominal price transactions have questioned why a manufacturer would offer a commercial customer a nominal price at all. The theory is that any nominal price offered to a commercial customer must be linked to the purchase of another product – otherwise the offer would not make commercial sense. Accordingly, the government has been quick to investigate whether an offer of nominal goods to a commercial customer was actually a disguised discount on other drugs, structured to enable the manufacturer to avoid reporting a lower Best Price.

In these investigations, DOJ and State Attorneys' General have relied on provisions of the MRA that define a "bundled sale," and describe how discounts provided for one drug within such an arrangement should be allocated across *all* the drugs contained in the arrangement.[21] Historically, in its nominal price investigations, the government has focused on whether a nominally priced product was (openly or implicitly) part of a bundled sale, and thus subject to

---

[20] Deficit Reduction Act of 2005, Pub. L. No. 109-171, § 6001(d)(2) (Feb. 8, 2006); *see also* 71 Fed. Reg. 77174 at 77184-85 (December 22, 2006) (proposed regulations implementing this provision). While OPA may ultimately choose not to accept certain DRA amendments to the calculation of AMP for the 340B program ceiling price, *see* note 4, *supra*, OPA does not appear to challenge the applicability to the 340B ceiling price of this change in the scope of the transactions that may be excluded from Best Price calculations. *See generally* Letter from BIO to Director of OPA (April 16, 2007) at 2, available at http://www.bio.org/healthcare/medicare/20070416.pdf.

[21] MRA § I (d)-(e) (the "packaging of drugs of different types, where the condition of rebate or discount is that more than one drug type is purchased, or where the resulting discount or rebate is greater than that which would have been received had the drug products been purchased separately."). "Bundled sale" is defined more succinctly in the PPA to refer to "the packaging of drugs of different types where the total price for the package is less than the purchase price of the drugs, if purchased separately. PPA § I(c). *See also*, 2001 Medicaid Drug Rebate Operational Training Guide, at F11a ("[t]he key to identifying a bundled sale is that the sale is *contingent* upon an additional purchase requirement(s) of the retail purchaser (e.g., pharmacies, beneficiaries, etc.)").

having its deep discount reallocated across one or more other drugs in the same transaction. Where the government can prevail in these investigations, the consequences can be severe for the manufacturer: not only may the manufacturer lose its ability to exclude its deeply discounted product from that product's best price calculations, but, depending on the impact of the reallocation of that discount, the manufacturer may also be looking at new Best Prices for the other drugs sold in the transaction as well.

a. Merck – Zocor and Vioxx (ongoing litigation)

In a 2005 Complaint filed in the District of Nevada, the State of Nevada and a relator have alleged that Merck failed to include the value of certain heavily discounted and free Zocor and Vioxx products in the company's calculation of Best Price for those products. The Zocor discounts allegedly were provided in connection with a Merck program that offered Zocor at a nominal price if a hospital maintained a 70% market share for Zocor, or established the product as the exclusive statin on its formulary. The Vioxx discounts allegedly were provided in connection with a program that offered Vioxx at a nominal price if a hospital committed to maintaining an 80% market share of the drug. The free goods were allegedly provided by Merck effectively to lower the price charged to purchasers of the products. The company moved to dismiss the complaint by arguing that the exclusion of nominal prices from a manufacturer's calculation of Best Price was absolute, and, thus, that Merck could not be liable for having failed to include these transactions in its calculation of Best Price for these drugs.

The Court disagreed and instead adopted the government's position. Drawing from a variety of sources, including the legislative history of the Medicaid rebate statute, a letter from then CMS Administrator Mark McClellan to the President and CEO of PhRMA, CMS Release No. 14, and the Oxford English Dictionary, the Court held that the statutory language – "prices that are merely nominal in amount" meant "all prices that are less than 10% of AMP, but without other qualifications" -- that is, "not tied to other conditions of performance or consideration in addition to the 'nominal prices'."[22] As a result, Merck's motion to dismiss was denied in May 2006. Currently, the case is stayed pending settlement discussions between the parties.

[22] *Nevada ex rel. Steinke v. Merck & Co., Inc.*, 432 F. Supp.2d 1082, 1086-87 (D. Nev. 2006).

b. Schering – Claritin (2004, 2006)

In the 2004 civil settlement discussed *supra* at 7, Schering also settled allegations that it had provided nominally priced products to certain HMO customers that should have been, but were not, taken into account when the transaction prices for other products provided to these customers was calculated. As a result, the government alleged, Schering had reported inaccurate Best Prices for Claritin during certain quarters. Specifically, the government alleged that Schering had provided a nominal price on one Claritin product knowing that its HMO customer would direct doctors in its staff model HMO to substitute the less expensive product, which was therapeutically equivalent to a more expensive product, thereby effectively providing the HMO a price concession on the more expensive Claritin product. Schering denied the government's allegations.

In the 2006 civil settlement discussed *supra* at 7, the government alleged that Schering had sold Claritin Redi-Tabs at a nominal price to a different HMO customer effectively to provide that customer with a discount on higher priced Redi-Tabs. The government argued that because the nominally priced sales were provided to achieve this discount on other product, the company was required to, but did not, take the nominally priced product into account when it calculated its Best Price for Redi-Tabs during the relevant quarters. Schering denied the government's allegations.

c. Wyeth – Protonix (ongoing investigation)

In March, 2005, Wyeth Pharmaceuticals announced that it had been served with a subpoena by the Boston U.S. Attorney's Office that sought documents relating to the company's AMP and Best Price calculations for its Protonix products. Wyeth has since reported that the subpoena appears to focus on issues relating to the exclusion of nominal prices from its Best Price calculations. According to the company, the investigation is ongoing and four current or former employees have been served with grand jury subpoenas seeking testimony on Protonix pricing and marketing.[23]

[23] *See* Wyeth 2006 Financial Report at 35-36.

IV. Miscalculation of AMP and BP

a. King Pharmaceuticals – entire product line (2005)

In 2005, King Pharmaceuticals resolved potential Best Price and AMP liability in a civil settlement with the federal government and participating states. According to the government, King had failed to report accurate AMP and Best Prices across its entire product line. This was allegedly the result of an absence of adequate internal systems or controls and the use of improper methodologies to calculate these price terms. Specifically, King allegedly failed to collect and analyze pricing information in a manner that ensured accurate calculations, did not adequately train personnel to calculate accurately, did not provide employees with appropriate tools, including specialized software to calculate rebate payments, and included inappropriate customers in its retail class of trade, thereby leading to inaccurate AMPs. King does not admit any liability in connection with this settlement.

The King investigation was the product of both a whistleblower and self-disclosure by the company, after it discovered certain issues during an internal review apparently prompted by the company's receipt of an SEC subpoena. Of the total settlement amount of $124 million, $73,420,225 was provided to the federal government and $50,637,093 to participating states. The 340B Program covered entities were to receive a portion of the federal recovery.

b. Private Litigation to Enforce 340B Ceiling Prices

In March 2003, HHS-OIG issued the first of a series of reports raising concerns about potential overcharges by manufacturers to 340B program covered entities.[24] While the initial reports expressed concern that manufacturers were overcharging the 340B Program covered entities, the report that expressed the most significant concerns in this regard was withdrawn four months after it issued, and subsequent reports focused instead on issues related to HRSA's oversight of the pricing used by the program. However, as a result of the early reports, two

[24] HHS-OIG OAS, **Pharmaceutical Manufacturers Overcharged 340B-Covered Entities** (A-06-01-00060) (March 2003), *available at* http://oig.hhs.gov/oas/reports/region6/60100060.htm; HHS-OIG-OEI, **Appropriateness of 340B Drug Prices** (OEI-05-02-00070)(June 2004), *withdrawn* October 21, 2004, http://oig.hhs.gov/oei/reports/oei-05-02-00070.pdf; HHS-OIG-OEI, **Deficiencies in the 340B Drug Discount Program's Database** (OEI-05-02-00071) (June 2004), *available at* http://oig.hhs.gov/oei/reports/oei-05-02-00071.pdf; HHS-OIG-OEI, **Deficiencies in the Oversight of the 340B Drug Pricing Program** (OEI-05-02-00072) (October 2005), *available at* http://oig.hhs.gov/oei/reports/oei-05-02-00072.pdf; HHS-OIG-OEI, **Review of 340B Prices** (OEI-05-02-00073)(July 2006), *available at* http://oig.hhs.gov/oei/reports/oei-05-02-00073.pdf.

private proposed class action suits were filed against dozens of manufacturers, alleging that the manufacturers had defrauded Covered Entities in California and nationwide, and seeking damages and an accounting to return monies presumed to owed and penalties for alleged misconduct.[25]

The first of these was filed in federal court in Alabama within a month of the issuance of the HHS-OIG report that was later withdrawn. This suit proposed a nationwide class of 340B Program covered entities, and sought an accounting and damages under breach of contract and unjust enrichment theories. Although defendants' motion to dismiss was denied, and the case appeared to be moving forward to discovery and other proceedings related to plaintiff's efforts to certify a class, in September 2006, plaintiffs voluntarily moved to dismiss the case without prejudice, stating that they no longer wished to pursue the action.[26] The court granted the motion, and judgment was entered for the defendants on September 26, 2006.

The second suit was filed in 2005 in state court in California, and proposed a class of California counties that fund California 340B Program covered entities. This suit sought an accounting disclosure, and damages and penalties under California's unfair competition law, false claims act, and for unjust enrichment. In this case, however, after defendants successfully removed the case to federal court, defendants' motion to dismiss the complaint was granted. The District Court's dismissal is currently on appeal with the Ninth Circuit.[27] The issues were fully briefed as of February 20, 2007.

Conclusion

As the settlements and ongoing litigation reviewed in this paper show, state and federal prosecutors have been and remain active in Best Price enforcement. While the efforts by 340B Program Covered Entities to initiate litigation on their own behalf have not been successful to date, these efforts have brought attention to the issues raised by the litigation. Manufacturers

[25] *See County of Santa Clara v. Astra USA, Inc. et al*, No. C 05-03740-WHA (N.D.Cal. 2005); *Central Alabama Comprehensive Healthcare, Inc. et al v. Aventis Pharmaceutical, Inc. et al.*, 3:04-CV-00673-MHT-VPM (M.D.Al. 2004)

[26] Plaintiff's Motion to Dismiss Without Prejudice, *Central Alabama Compr. Healthcare, Inc., supra* note 23, Dkt. No. 202 (September 20, 2006)

[27] *County of Santa Clara v. Astra USA, Inc. et al*, No. 06-1647 (9th Cir. 2006).

should expect continued attention from federal regulators and federal and state law enforcement in this area.