§ 10.03 Liability for Setting and Reporting Prices

Manufacturers may face liability under the federal False Claims Act or other federal or state fraud or deceptive trade practice statutes for making false claims or false statements in connection with each of the various reimbursement mechanisms described above.

[1]—Inflated AWP

Both federal and state prosecutors have taken the position that AWPs that are significantly in excess of the price at which products are actually sold to providers may be "false" or "fraudulent" and hence actionable under the FCA or its state counterparts.[1] To date, this theory of liability has not been tested in the courts and, as a result, the courts have not ruled on any potential defenses, such as the defense that the government knew that AWP does not accurately reflect selling price.[2]

Class action plaintiffs and various state attorneys general who purport to represent classes of Medicare beneficiaries and private third-party payers who claim to base their reimbursement for drugs on AWP

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[1] See, e.g., Settlement Agreement between the United States and TAP Pharmaceutical Products, Inc. (Sept. 28, 2001) ("TAP Settlement Agreement") (as part of an approximately $875 million global criminal and civil settlement. TAP Pharmaceuticals agreed to pay approximately $600 million to settle charges that, *inter alia*, it set AWPs for one of its products, Lupron, at levels far higher than the price the majority of its physician customers paid for the drug. See § 10.05[5] N. 30 *infra.*); Settlement Agreement between the United States and Bayer Corporation (January 23, 2001) (Bayer Corporation paid $14 million to the federal and state governments to settle allegations that, *inter alia*, it improperly inflated AWPs for six products). In connection with these settlements, both companies entered into Corporate Integrity Agreements obligating them not to lower their AWPs, but rather to disclose their "average sales prices" to the relevant federal health programs. See Corporate Integrity Agreement between the Department of Health and Human Services Office of Inspector General and TAP Pharmaceutical Products, Inc. (Sept. 28, 2001) (hereafter, "TAP CIA"); Corporate Integrity Agreement between the Department of Health and Human Services Office of Inspector General and the Bayer Corporation (Jan. 23, 2001) (hereafter, "Bayer CIA").

Prosecutors have also argued that creating a large "spread" between AWP and purchase price violates the Antikickback Statute. See § 10.05[1] *infra.* On a related note, Thomas Bliley, former Chairman of the House Commerce Committee, concluded in September 2000 that "Medicare reimburses health care providers at prices dramatically more than what they pay for certain drugs." Letter from Thomas Bliley to Nancy-Ann DeParle, September 25, 2000, at 4. He also charged that some manufacturers have increased the spread on certain drugs in a "calculated and deliberate effort to use the Medicare-funded windfall as a marketing tool." *Id.*

[2] See § 10.02[2][c] N. 19 *supra.*

have also asserted claims under RICO, antitrust laws, and state consumer fraud statutes against manufacturers for allegedly inflating AWP under the theory that the elevated AWP caused them to pay excessive reimbursement or co-pays for the product. Dozens of such suits are currently pending in state and federal courts throughout the country.[3]

The assertion by both government officials and private plaintiffs

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[3] See:

First Circuit: Citizens for Consumer Justice v. Abbott Laboratories, No. 01-12257 (D. Mass., filed December 19, 2001).

Second Circuit: Teamsters Health & Welfare Fund of Philadelphia v. Bristol Meyers Squibb Company, No. 01-CV-9968 (S.D.N.Y., filed November 9, 2001).

Third Circuit: Action Alliance of Senior Citizens of Greater Philadelphia v. Bayer Corp., No. 01CV5998 (E.D. Pa., filed November 30, 2001); United Food and Commercial Workers Unions and Employers Midwest Health Benefits Fund and Action Alliance of Senior Citizens of Greater Philadelphia v. Pharmacia Corp., No. 01-5427 (D. N.J., filed November 28, 2001); Teamsters Health & Welfare Fund of Philadelphia v. GlaxoSmith Kline PLC, No. 01CV5939 (E.D. Pa, filed November 28, 2001); Teamsters Health & Welfare Fund of Philadelphia v. GlaxoSmith Kline PLC, No. 01CV5940 (E.D. Pa., filed November 28, 2001); Action Alliance of Senior Citizens of Greater Philadelphia v. Aventis S.A., No. 01-5548 (D. N.J., filed November 28, 2001); Action Alliance of Senior Citizens of Greater Philadelphia v. GlaxoSmith Kline PLC, No. 01CV5790 (E.D. Pa, filed November 16, 2001).

Fifth Circuit: Mary Robinson and Maggie Hudson v. Abbott Laboratories, No. CV02-0498-S (W.D. La., filed March 13, 2002); Board of Trustees of Carpenters and Millwrights of Houston and Vicinity Welfare Trust Fund v. Abbott Laboratories, Inc., No. 5:01CV339 (E.D. Tex., filed December 24, 2001).

Seventh Circuit: Action Alliance of Senior Citizens of Greater Philadelphia v. Fujisawa Pharmaceuticals Co. Ltd., No. 02C0396 (N.D. Ill., filed January 17, 2002); United Food and Commercial Workers Unions and Employers Midwest Health Benefits Fund and Action Alliance of Senior Citizens of Greater Philadelphia v. Abbott Laboratories, No. 01C8827 (N.D. Ill., filed November 15, 2001); United Food and Commercial Workers Unions and Employers Midwest Health Benefits Fund and Action Alliance of Senior Citizens of Greater Philadelphia v. Baxter International, Inc., No. 01C8828 (N.D. Ill., filed November 15, 2001).

Ninth Circuit: State of Nevada v. Abbott Laboratories, No. CV-N-02-0080 (D. Nev., filed January 17, 2002); Action Alliance of Senior Citizens of Greater Philadelphia v. Immunex Corp., No. 01-1917 (W.D. Wash, filed November 27, 2001); Twin Cities Baker Workers Health & Welfare Fund and Action Alliance of Senior Citizens of Greater Philadelphia v. Dey, Inc., 01-4466 (N.D. Cal., filed November 26, 2001); United Food and Commercial Workers Unions and Employers Midwest Health Benefits Fund and Action Alliance of Senior Citizens of Greater Philadelphia v. Sicor, Inc., 01-1099 (C.D. Cal., filed November 19, 2001); United Food and Commercial Workers Unions and Employers Midwest Health Benefits Fund and Action Alliance of Senior Citizens of Greater Philadelphia v. Bristol-Meyers Squibb, Co., C014303WDB (N.D. Cal., filed November 19, 2001); Shirley Geller v. Abbott Labs, Inc., No. 02CV00553 DDP (C.D. Cal., filed October 26, 2001).

that "elevated" AWPs are actionable as fraud raises many questions:[4]

- *What does AWP really mean?* Although there is no statutory or regulatory definition of AWP, it has generally been understood to mean the manufacturer's suggested list price that a wholesaler charges a pharmacy for a drug.[5] This definition has commercial meaning in the context of the traditional model of distribution from manufacturers to wholesalers to retail pharmacies. However, the definition is nonsense for products such as drugs that are sold directly to patients or hospitals and that are therefore not distributed through wholesalers at all.[6]
- *How big an "AWP spread" is acceptable?* No government agency has offered any advice on how large a "spread" may be acceptable or even whether spreads in the traditional range of 16% to 20% above wholesale price are objectionable.
- *What is the proper measure of the "spread"?* For products that are sold through wholesalers, the best measure of the AWP spread—and the best way to gauge the reasonableness of AWP—would appear to be the difference between AWP and "wholesale" price. It is not clear, however, whether prosecutors would use the same measure where sales to wholesalers constitute only a small portion of overall sales, particularly if the manufacturer sells product to other customers at prices significantly below the wholesale price. Similarly, it is not entirely clear how to measure the "spread" where there are no wholesale sales.
- *If the "AWP spread" is measured by reference to wholesale price, should it be gross or net of chargebacks?* No government agency has provided guidance on this question.[7]

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[4] See Kalb, Bass & Fabrikant, "The Average Wholesale Price: It 'Ain't What the Government Wants to Pay,'" 12 BNA Medicare Rep. (Feb. 9, 2001).

[5] See OIG, "Cost Containment of Medicaid HIV/AIDS Drug Expenditures," OEI-05-99-00611, 3, 29 (July 2001); see also GAO, "Report on Medicaid Outpatient Drug Costs" (Mar. 18, 1992) ("Drug manufacturers suggest a list price that wholesalers charge pharmacies").

[6] In such cases, it is unclear how AWPs should be set. One approach would be to set AWP at some reasonable point *above* the highest price at which product is sold to any arms-length customer to account for the fact that both Medicare and most Medicaid programs reimburse based on a discount from AWP. However, neither the federal nor state governments have provided any guidance on this issue.

[7] The most sensible approach would be to measure by reference to gross wholesale price. The gross price represents the price that wholesalers pay for goods that they subsequently sell to the retail trade, rather than to providers who subsequently

• *How should AWPs be set for new products?* From a policy perspective, perhaps the most significant issue concerning AWPs relates to the pricing of new products. As a matter of economic reality, manufacturers that are seeking to introduce a new product generally must set AWP at a level at which, at a minimum, potential purchasers will not be financially *disadvantaged* by purchasing the product. Where the spreads for competitive products are large, manufacturers must set large spreads. Although one can argue that the federal health programs are generally no worse off if this occurs (because they would pay the large spread anyway), and in fact program beneficiaries are better off (because they have more choices), it is not likely that prosecutors will accept large spreads for new products any more readily than they do for old ones.

The assertion by private plaintiffs that, by allegedly inflating AWPs, manufacturers have violated antitrust laws by attempting to monopolize the market for certain drugs, also faces legal hurdles. For example, the plaintiffs' contention that each manufacturer has abused its "monopoly power" in the market for drugs that it manufactures by manipulating the AWP for its own drugs makes little economic sense. By definition, all manufacturers of products are "monopolists" of their own products. However, a relevant product market must include interchangeable or substitutable products. Just as a product market defined as all drugs manufactured by a single manufacturer is too broad because all of the drugs in a manufacturer's product line do not compete against each other, it is also too narrow because it fails to include competing drugs manufactured by other manufacturers. Ironically, plaintiffs contend that one reason manufacturers allegedly manipulate AWP is to more effectively compete against one another for market share.

[2]—False Medicaid Rebates

Liability under the FCA, its state analogues, or the Medicaid Rebate statute itself may arise in any situation in which a manufacturer knowingly underpays its Medicaid rebates. This liability can arise because of false statements to CMS or payment of invoices submitted by the states that manufacturers know do not properly reflect amounts actually due (i.e., are inaccurate). Liability under the latter theory could expose a manufacturer to enormous penalties because a single knowing misstatement of the Unit Rebate Amount could result in false

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purchase at prices determined by contract with a manufacturer.

claims being made to each of the various Medicaid programs.

In theory, manufacturers could underpay Medicaid Rebates either by intentionally lowering AMP or by intentionally failing to report true "best" prices. Little has been made of potential AMP fraud.[8] There are, however, at least three important theories of "best price" fraud:

[a]—Failure to Report Cash Discounts, Free Goods Contingent on Purchase, Volume Discounts, and Commercial Rebates

The term "Best Price" ("BP") is defined to include "all cash discounts, free goods that are contingent on any purchase requirement, volume discounts and commercial rebates."[9] Thus, manufacturers that knowingly fail to include the value of any such price concessions when determining BP face potential liability.

Although it is easy to state, it is complicated to apply this rule for two reasons. First, neither the statute nor the MRA specifically defines the terms "cash discounts" or "commercial rebates." Moreover, neither specifically requires the inclusion in BP of *all* transactions that may reduce price.[10] That suggests that there are some forms of price concessions—i.e., those that are not "cash discounts," "free goods that are contingent on any purchase requirement," "volume discounts," or

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[8] As noted in § 10.02[3][b] N. 25 *supra* and accompanying text, manufacturers can lower their AMP by avoiding the CPIU penalty. In 1999, the HHS Inspector General, in response to an inquiry by Congressman Henry Waxman, looked into the question of whether manufacturers were intentionally seeking to avoid the CPI-U penalty by obtaining new NDC numbers for old products and thereby resetting the baseline AMP for their products. She concluded that "[t]he potential exists for manufacturers to be gaming the inflation rebate." Letter from June Gibbs Brown to Hon. Henry A. Waxman, November 22, 1999, at 3 (hereafter, "Brown Letter"). She further concluded that "[o]ne solution would be to decrease the base AMP for any new version of a drug by an amount equal to the percentage increase above the CPI-U for the earliest version of the drug. This would, of course, require a legislative change." *Id.* On a related note, HCFA has made clear that when innovator drugs are purchased for resale, "[b]aseline information, such as Market Date and Baseline AMP MUST follow the NDA of the product. It does NOT follow the NDC of the product." Medicaid Drug Rebate Program Release No. 26 at 2-3 (Nov. 24, 1992) (emphasis in original).

[9] See § 10.02[3][b] Ns. 29, 30 *supra* and accompanying text.

[10] This omission stands in stark contrast to the definition of AMP, which states that "AMP includes cash discounts allowed *and all other price reductions* . . . which reduce the actual price paid." Medicaid Rebate Agreement ("MRA") § I(a) (emphasis added).

"commercial rebates"—that need not be included in BP.[11]

CMS has not adopted this view. More specifically, relying on the language of the MRA which requires manufacturers retroactively to adjust their best prices "if cumulative discounts, rebates or *other arrangements* subsequently adjust the prices actually realized,"[12] it has stated that:

> "We consider administrative fees, incentives, promotional fees, chargebacks and all discounts or rebates, other than rebates under the Medicaid drug program, to be included in the calculation of AMP, if those sales are to an entity included in the calculation of AMP, and best price.
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> "Except for the explicitly listed exclusions in the rebate agreement and in section 1927 of the Social Security Act, and, in accordance with sections I(a) and I(d) of the rebate agreement, AMP and best price data '. . . must be adjusted by the Manufacturer if . . . other arrangements subsequently adjust the prices actually realized.' Thus, we consider *any* price adjustment which ultimately affects the price actually realized by the manufacturer as 'other arrangements' and, as required by the rebate agreement, included in the calculation of AMP and best price."[13]

In light of this, and given that all items and services can ultimately be monetized, prosecutors may take the view that the value of *all* items or services provided to a customer—or at least those that, under the circumstances, appear to be price terms—must be included in the determination of BP.

Second, even where the existence of commercial rebates is plain, the value of certain types of rebates may be impossible to calculate at the time of a quarterly Best Price report. For example, manufacturers generally do not know the value of rebates they will owe to customers who have "market share" or similar rebating arrangements. In those circumstances, manufacturers must report prices in the face of uncertainty about how they must ultimately be adjusted.[14]

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[11] "Value added programs" for which customers do not pay fair market value, even if acknowledged to be of value to customers, are an example of a service that may fall into this category.

[12] MRA § I(d) (emphasis added); see also § 10.02[3][b] N. 30 *supra* and accompanying text.

[13] Medicaid Drug Rebate Program Release No. 14, at 1 (1991) (emphasis added).

[14] Manufacturers appear to have several options. First, they can attempt to link

[b]—Nominal Price Manipulation

Manufacturers may also face liability for knowingly manipulating the "nominal price" exception to the definition of Best Price. As noted, both the Medicaid Rebate statute and the MRA states that Best

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rebates, when they are paid, to initial sales and retroactively adjust their BPs. This is the approach that appears to be required by the MRA (see MRA § I(d)), and which is favored by HCFA/CMS, which has stated that, by way of example, "a discount applied at the end of a calendar year to sales made throughout that past year may not be assigned only to the fourth quarter of the year. . . . Rather, the retroactive discount must be distributed to the four quarters of the year to which it is applied. . . ." Medicaid Drug Rebate Program Release No. 2, at 2 (1991). However, as a practical matter, retroactively allocating discounts is often extremely difficult, if not impossible. As an alternative, manufacturers may—although this is uncertain—also be able to accrue for the impact of future rebates. Finally, manufacturers can make the conservative assumption that customers will achieve the maximum rebates possible under the relevant contracts. This approach will likely result in overpayment of rebates, but it has the advantage of being administratively simple.

Along the same lines, it is generally difficult, if not impossible, for manufacturers accurately to calculate the impact of rebates paid to pharmacy benefit managers. HCFA has instructed manufacturers that:

> "Where PBM's subsequently adjust drug prices by applying discounts, chargebacks or rebates, these price adjustments should be included within the best price calculations. In other words, where the effect on the manufacturer for using the PBM is to adjust actual drug prices at the wholesale or retail level of trade, such adjustments need to be recognized in best price calculations. . . . However, we do acknowledge that there are many PBM/manufacturer arrangements and that only those that adjust actual drug prices will be captured in best price calculations."

HCFA, Medicaid Drug Rebate Program Release No. 29, at 1-2 (1995); see also Medicaid Drug Rebate Program Release No. 28, at 1 (1995). This instruction, however, is incomplete in critical respects. First, it is not clear whether PBM plan members (which generally reimburse retail pharmacies for drugs used by their beneficiaries) operate at either the "wholesale" or "retail" level. Second, even assuming that manufacturers know the operation level of PBM plan members, the manufacturers generally do not know what percentage of the rebates they pay to PBMs are passed through to plan members, nor do they know what those plans pay for product. Thus, manufacturers generally do not have sufficient information from which they can accurately determine whether rebates paid to PBMs are setting a new BP. Perhaps because of these uncertainties, HCFA indicated in 1997 that it was "currently re-examining the issue and hope[d] to clarify [its] position in the near future." Medicaid Drug Rebate Program Release No. 30, at 2 (1995).

Here again, manufacturers appear to have several options. First, they could take the position that PBM rebates do not impact the "wholesale" or "retail" level. Second, they could assert that they do not have information concerning the rebate amounts paid to those levels of trade. Third, and most conservatively, they can build in assumptions concerning the amounts passed through to PBM plan members in rebates and the amounts paid by those plan members to retail pharmacies.

Price shall "not take into account prices that are merely nominal in amount."[15]

On its face, this language appears to permit manufacturers to exclude from Best Price *all* nominal price sales. Where, however, nominal price sales are tied to sales at non-nominal prices of either the same product or a different product, the nominal price sales may be viewed as "discounts" or "rebates" within the meaning of the statute and the MRA. Thus, for example, a deal involving the sale of five units at $1.00 (non-nominal) and five units at $0.01 (nominal) is likely to be viewed as a deal at a blended price, and manufacturers that knowingly structure a blended transaction including "nominal" prices rather than more obvious discounts or commercial rebates may be deemed to have circumvented their statutory and contractual obligations.

Moreover, nominal price sales to commercial entities may be viewed as contrary to the spirit of the exception. At least one excerpt from the statute's legislative history, for example, suggests that the "nominal price" exception was intended to protect eleemosynary activities, such as the sale of birth control pills for $0.01 a pack to Planned Parenthood.[16] The Department of Veterans Affairs, interpreting the "nominal price" provision of the Veterans' Health Care Act,[17] has strongly endorsed this view.[18]

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[15] 42 U.S.C. § 1396r-8(c)(1)(C)(ii); MRA § I(d).

[16] 136 Cong. Rec. E2813-02, * E2815 (1990) (Sept. 12, 1990) (statement of Cong. Wyden); see also McElroy, "The Medicaid Rebate Program and Pharmaceutical Marketing Strategies: Avoiding Medicaid Drug Rebate Fraud" at 8 (unpublished, 2000) ("Historically, Congress crafted this exception to encourage manufacturers to continue to offer drugs at reduced prices to worthwhile causes.").

[17] See § 10.02[5] *supra*.

[18] In 1996, the Department stated that "[t]he 'nominal' pricing exclusion in the Act was not intended to protect incentive use schemes by eliminating from non-FAMP calculations all below-cost sales of a covered drug that result from customers' purchases of sizable quantities of packages at a standard commercial price." Department of Veterans Affairs, "Dear Manufacturer" Letter (Oct. 7, 1996). The Department went on to state that nominal pricing should be restricted to specific circumstances generally involving not-for-profit enterprises:

> "[The] VA views 'nominal' pricing as being pricing, usually below cost, designed to benefit the public by financially aiding disadvantaged, not-for-profit covered drug dispensaries or researchers using a drug for an experimental or non-standard purpose. Accordingly, low-price sales that do not fit this description may not be excluded from non-FAMP as sales made at a nominal price."

Id.

[c]—Private Labeling, Repackaging, and Relabeling Arrangements

Manufacturers may also face liability in connection with "private label" or "repackaging/relabeling" sales. For purposes of this treatise, we define private label sales as those in which a manufacturer ships product to a customer labeled with the *purchaser's* label and, generally, NDC number. By contrast, repackaging/relabeling involves the repackaging and relabeling by the *purchaser* of products that are initially shipped under the *seller's* label and NDC number.[19]

These types of sales are often made at very low prices, particularly to HMOs.[20] Some manufacturers have taken the position that they may be excluded from BP. That position is controversial.

In June 2000, HCFA/CMS stated that:

> "Section 1927(c)(1)(C)(i) of the Social Security Act specifies that best price is the lowest price available from the manufacturer to any wholesaler, retailer, provider, HMO, nonprofit entity, or governmental entity within the United States. Further, sections 1927(c)(1)(C)(i)(I)-(IV) and 1927(j) of the Act list specific exclusions from the best price calculation. Under these provisions, the sales to organized health care settings such as HMOs must be included in best price. While the entity may be engaged in the production, preparation, propagation, compounding, conversion or

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[19] The MRA generally excludes such sales from AMP but does not address the issue of Best Price. MRA § I(a) (AMP excludes sales to "wholesalers where the drug is relabeled under the distributor's national drug code number").

[20] In 1999, the HHS Inspector General found that HMO repackagers were able to purchase product as much as 34% below reported best price. Letter from HSS Inspector General June Gibbs Brown to Hon. Henry A. Waxman, at 1 (Nov. 22, 1999). A follow-up report issued by the OIG in 2001 concluded that that seven out of fifty-three manufacturers surveyed excluded sales to eight repackagers, three of which were HMOs, from their Medicaid "best price" calculations. The prices for excluded sales to HMOs were as much as 46% below the "best price" that was otherwise reported. OIG calculated that if the prices of the excluded sales to HMOs had been used to set "best price," the Medicaid programs would have received at least an additional $108 million in rebate payments in FY 1998 and FY 1999 alone. OIG recommended that HCFA (1) "require drug manufacturers who excluded sales from HMOs from their best price determinations to repay the lost rebates," and (2) "evaluate the policy guidance relating to the exclusion of sales to other (non-HMO) repackagers from best price determinations, especially where those repackagers used the drugs for their own use and did not resell them." HCFA concurred in these recommendations. See OIG, "Medicaid Drug Rebates: Sales to Repackagers Excluded from Best Price Determinations," A-06-00056 (Mar. 2001) (hereafter, "Sales to Repackagers").

processing of prescription drug products, it is still an HMO and its sales are subject to inclusion in the best price calculation. The best price provisions in the statute contemplate the inclusion of sales to HMOs without regard to special packaging or labeling. Therefore, as required under the Medicaid Drug Rebate program, manufacturers should include all sales to any entity, such as HMOs, that purchase drugs for direct consumer sales or distribution in best price calculations except as excluded by section 1927 of the Act."[21]

This statement purported to clarify a 1997 memorandum in which HCFA stated that "sales to manufacturers who repackage/relabel under the purchaser's NDC" are exempt from BP.[22]

HCFA/CMS's position leaves open several critical issues:

[i]—Private Label Sales

In the case of private label sales, a good argument can be made that a manufacturer has no responsibility to report prices on drugs that are not labeled with its NDC number. That is, the language of the statute provides that "best price" means "with respect to a single source drug or innovator multiple source [covered outpatient] drug *of a manufac-*

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[21] Medicaid Drug Rebate Program Release No. 47, at 2-3 (July 13, 2000).

[22] Medicaid Drug Rebate Program Release No. 29 (June 5, 1997). The OIG has elaborated as follows:

> "Best price is defined by OBRA 90 to mean the lowest price available to any wholesaler, retailer, provider, HMO, nonprofit, or governmental entity with the only exclusions being certain government entities. The definition of best price thus specifically includes certain entities that are excluded from AMP, including HMOs.
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> "The HCFA periodically provides guidance to drug manufacturers concerning drug rebates through program releases. In Release No. 29, HCFA advised that sales to certain repackagers or relabelers should be excluded from best price as well as AMP. While sales to certain relabelers or repackagers are specifically excluded in the definition of AMP, these sales are not, however, mentioned in the definition of best price. Further, OBRA 90 specifically requires sales to HMOs to be included in the computation of best price. The HCFA issued Release No. 47 in July 2000 after it was alerted to a situation where drug sales to an HMO were omitted from a manufacturer's best price calculation because that purchaser was a repackager. In Release No. 47, HCFA reiterated that the statute requires sales to an HMO to be included in best price regardless of whether the HMO was repackaging the drug."

"Sales to Repackagers," N. 20 *supra* at 3.

turer, the lowest price available" to specific purchasers.[23] Similarly, the Rebate Agreement defines "best price" to mean "the lowest price at which the *manufacturer* sells the Covered Outpatient Drug. . . ."[24] The MRA makes clear that the term "manufacturer" has "the meaning set forth in [42 U.S.C. § 1396r-8(k)(5)] of the Act except, for purposes of this agreement, it shall also mean *the entity holding legal title to or possession of the NDC number for the Covered Outpatient Drug*,"[25] and it further makes clear that "[*f*]*or purposes of coverage under this agreement, all of those Covered Outpatient Drugs are identified by the Manufacturer's labeler code segment of the NDC number*."[26] Thus, where product is sold with the *customer's* label (including the NDC), the original seller, although technically a "manufacturer," is not the "manufacturer" of that drug for purposes of the MRA.[27] As such, the original seller of the drug has no statutory reporting or payment obligations with respect to that drug.[28]

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[23] 42 U.S.C. § 1396r-8(c)(1)(C)(i) (emphasis added); see also § 10.02[3][b] Nn. 29, 30 *supra*.

[24] MRA § I(d) (emphasis added); see also § 10.02[3][b] N. 30 *supra*.

[25] MRA § I(l) (emphasis added); see also § 10.02[3][b] N. 26 *supra*.

[26] MRA § I(g) (emphasis added); see also § 10.02[3][b] N. 26 *supra*.

[27] This analysis is underscored by the language of the statute and the MRA establishing the core reporting and payment obligations, which specify that manufacturers have obligations only with respect to *their* covered outpatient drugs. Specifically, the statute provides that:

> "A rebate agreement under this subsection shall require the manufacturer to provide, to each State plan approved under this subchapter, a rebate for a rebate period in an amount specified in subsection (c) of this section for covered outpatient drugs *of the manufacturer* . . . for which payment was made under the State plan for such period."

42 U.S.C. § 1396r-8(b)(1)(A) (emphasis added). The Rebate Agreement also stipulates that one of the "Manufacturer's Responsibilities" is "[t]o calculate and . . . to make a Rebate Payment to each State Medicaid Agency for the *Manufacturer's* Covered Outpatient Drugs paid for by the State Medicaid Agency during a quarter." MRA § II(a) (emphasis added). In addition, the Rebate Agreement requires each "manufacturer" to submit and periodically update a list of all of its "covered outpatient drugs." That list "is to include all new NDC numbers and continue to list those NDC numbers for drugs no longer marketed." MRA § II(a).

[28] This outcome does not contradict either Release 29 or Release 47. There is no conflict between the rule that manufacturers are not obligated to consider the price at which they sell drugs that are not their "covered outpatient drugs" to HMOs and the rule that they must consider the price at which they sell drugs which *are* labeled with their NDC numbers to HMOs.

[ii]—Repackaging/Relabeling

The repackaging/relabeling issue is somewhat more complicated. First, a strong argument can be made that under a variety of constitutional and administrative law principles, the government cannot retroactively recover monies from manufacturers that relied on HCFA's 1997 statement in Release 29 that "sales to manufacturers who repackage/relabel under the purchaser's NDC" are exempt from BP.

Moreover, HCFA/CMS's struggle with how to deal with drugs that are repackaged or relabeled reflects an important practical point—namely, where one "manufacturer" sells product to another "manufacturer," a determination must be made as to which manufacturer must report and pay rebates. As the system is currently designed, only one manufacturer can have such responsibilities. States obtain utilization data, by NDC number, and use that data to submit invoices to the manufacturer that is responsible for the rebate. The NDC numbers they receive are, by necessity, those of the manufacturer that actually distributed the drug at issue to pharmacies and patients.[29] The structure of the system thus requires that, as a general rule, the second or "receiving" manufacturer should be responsible for reporting and paying rebates.[30]

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[29] HCFA recognized this problem and its 1995 proposed regulations would have imposed obligations only on the second manufacturer. In the preamble to the proposed regulations, HCFA stated that "[u]se of incorrect NDC numbers could have a detrimental effect that would carry through the entire drug rebate process. . . . [F]lawed data would cause the States to invoice manufacturers for erroneous rebates, resulting in over and under billing for rebates." 60 Fed. Reg. 48,459 (Sept. 19, 1995) (emphasis added). To address this problem, the agency proposed to clarify that the term "manufacturer" referred to the "entity [that] possess[es] legal title to the National Drug Code (NDC) number for a covered outpatient drug, insulin, or biological product." 60 Fed. Reg. 48,442, 48,447. The agency specifically stated that "this clarification is necessary to permit a practical means of identifying the manufacturer of the drug to determine which manufacturer [where there is more than one candidate] is responsible for paying the rebate due under the statute to the State. This approach prevents duplicative manufacturer responsibilities for the drug." *Id.* (emphasis added).

[30] This rule runs into uncertainty where the second manufacturer is an HMO. HMOs clearly can be "manufacturers." See § 10.02[3][b] N. 26 *supra* and accompanying text (defining "manufacturer"). The Medicaid Rebate statute, however, specifically provides that "[c]overed outpatient drugs dispensed by health maintenance organizations, including Medicaid managed care organizations that contract under section 1396b(m) of this title [42], are not subject to the requirements of this section." 42 U.S.C. § 1396r-8(j)(1). Thus, HMOs that repackage or relabel do not pay rebates. Release 48 can be read as HCFA/CMS's view as to how manufacturers must deal with this specific situation—i.e., as a matter of policy, the

[3]—PHS Pricing

Manufacturers that sell to PHS entities at prices they know have been calculated incorrectly, may face liability for submitting false information or for filing false claims for payment. Although PHS pricing is determined by a statutory formula that relies on the AMP and BP numbers calculated under the Medicaid Rebate program,[31] failure to charge correct PHS prices can result in liability that is *in addition to* other liabilities under the Medicaid Rebate program.

Generally, PHS prices are equal to BP.[32] In those cases, manufacturers that knowingly inflate BP through any of the mechanisms described in connection with the Medicaid Rebate program[33]—such as failing to account for all price reductions in calculating BP or improperly using nominal pricing—may face liability for submitting false information or for filing a false claim for inflated PHS prices. In those cases where BP does not set the PHS price[34]—i.e., where PHS prices are fixed at either 11%[35] or 15.1% of AMP[36]—manufacturers that knowingly manipulate AMP may also face liability for charging incorrect PHS prices.

Drug manufacturers generally do not report AMP and BP under the PHS program, i.e., they generally make no statements directly to the government about AMP and BP in connection with the PHS program beyond the representation contained in the prices charged to PHS entities. Thus, manufacturers generally may face liability under the PHS program only with respect to the prices they charge to PHS entities. However, if a manufacturer does not report AMP or BP under the

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original seller must pay the rebates in that situation.

[31] See §10.02[3][b] *supra.*

under section 1396b(m) of this title [42], are not subject to the requirements of this section." 42 U.S.C. § 1396r-8(j)(1). Thus, HMOs that repackage or relabel do not pay rebates. Release 48 can be read as HCFA/CMS's view as to how manufacturers must deal with this specific situation—i.e., as a matter of policy, the original seller must pay the rebates in that situation.

[32] See § 10.02[4] N. 50 *supra* and accompanying text.

[33] See §10.03[2] *supra.*

[34] See §10.02[4] *supra.*

[35] 42 U.S.C. § 256b(a)(2)(B); Master Pharmaceutical Pricing Agreement § II(b) (hereafter, "PPA").

[36] 42 U.S.C. §§ 256b(a)(2)(A), 1396r-8(c)(1)(B); PPA § II(a).

Medicaid Report program, then those figures must be reported under the PHS program.[37] In such cases, manufacturers could face liability for any statements made about AMP or BP that are knowingly false.

Finally, because of the operation of the statutory formula in determining PHS prices, it is possible for manufacturers to use accurate prices while using incorrect data for either AMP or BP. For example, when BP is used as the PHS price, miscalculations of AMP generally will have no effect on PHS pricing.[38] Similarly, when AMP is used to determine the PHS price, errors in determining BP generally will have no effect on PHS prices.[39] In those cases, although a manufacturer may face liability under the Medicaid Rebate program for statements regarding BP or AMP, so long as PHS prices are accurate, manufacturers should not face additional liability under the PHS program for underlying, but irrelevant, miscalculations.

[4]—FSS Pricing

Under the Section 603 program that establishes favorable pricing for the Big Four Federal agencies, manufacturers report non-FAMP and Federal Ceiling Prices to the Department of Veterans Affairs. If

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[37] PPA § II(c).

[38] The equation AMP – ((AMP – BP)/AMP)% = BP holds true regardless of the value of AMP. For single source and innovator multiple source drugs, AMP helps determines whether the BP or AMP statutory formula will be used for calculating PHS prices. It is possible that an improperly inflated AMP might make a manufacturer select the BP formula because the difference between BP and the inflated AMP is greater than 15.1% of AMP. In that case—where the wrong formula is used to calculate PHS prices—the manufacturer would face liability for false price reporting even if BP itself was calculated correctly and the PHS entities were charged prices equal to BP. In such a case BP prices are the wrong prices to charge.

However, a manufacturer is unlikely deliberately to misreport a higher AMP. First, the inflated AMP will result in the charging of a PHS price that is lower than the price that would be determined under the AMP formula. Second, the inflated AMP will result in the payment of a higher rebate under the Medicaid Rebate program, since the rebate generally is the difference between AMP and BP.

[39] The calculations AMP – 15.1% AMP (for single source and innovator multiple source drugs) and AMP – 11% AMP (for other drugs) are not dependent on the value of BP. BP does help determine which statutory formula will be used for calculating PHS prices. It is possible that an incorrectly inflated BP might make a manufacturer select the AMP formula for a single source or innovator multiple source drug because the difference between the inflated BP and AMP is less than 15.1% or 11% of AMP. In that case, the manufacturer will use the wrong formula and may face liability for charging false PHS prices, even if the AMP calculation is done correctly and the PHS entities are charged that price. In such a case, prices based on AMP are the wrong prices to charge.

those figures are knowingly inaccurate, manufacturers may face liability for making false statements. Section 603 itself also provides that the Medicaid Rebate program penalties are applicable to Federal Ceiling Prices established in PPAs.[40] Additional liability may exist for false statements or for false claims in connection with the payment of inflated prices.

Manufacturers can overstate non-FAMP—which helps set the Federal Ceiling Price[41]—by:

(1) failing to include the value of discounts, rebates and other price concessions;
(2) improperly excluding direct sales from the calculation of non-FAMP,
(3) manipulating the inflation discount, or
(4) abusing nominal pricing.[42]

If manufacturers set FCP below the 24% discount mandated by Section 603, it would be possible—even if non-FAMP is miscalculated—for the Federal Ceiling Price to still be in compliance with Section 603.[43]

As noted, Section 603 also requires manufacturers to list their products on the Federal Supply Schedule.[44] In order to list drugs on the FSS, even if a manufacturer is only going to charge FCP to all Federal agencies,[45] manufacturers must submit Commercial Sales

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[40] 38 U.S.C. § 8126(e)(2). Section 603 adopts 42 U.S.C. § 1396r-8(b)(3)(B) and (C). Subsection (B) provides for a $100,000 penalty if a manufacturer refuses to provide information to the government about its charges or prices. See also PPA § IV.A. Subsection (C)(i) of the Medicaid Rebate statute provides a $10,000 penalty per day for the failure to provide timely information, and subsection (C)(ii) a $100,000 penalty for knowingly providing false information. See also Master Agreement § I.V.B. & C. Any notice or hearing requirements under these penalty provisions are handled by Veterans Affairs rather than by HHS. PPA § IV.D.

[41] FCP ≤ 76% of non-FAMP. See §10.02[3] *supra.*

[42] See § 10.03[2][b] N. 18 *supra* (detailing Veterans Affairs' view of proper use of nominal prices).

[43] For example, if FCP were 72% of a non-FAMP that was artificially inflated by 2%, the FCP would still be less than or equal to 76% of the properly calculated non-FAMP.

[44] See § 10.02[5] N. 64 *supra* and accompanying text.

[45] Manufacturers may also elect to file dual price lists, one charging FCP to the Big Four federal agencies, and one for all other agencies. See § 10.02[5] Nn. 76-78 *supra.*

Practice sheets and other information to the Department of Veterans Affairs in the course of negotiating a procurement contract. Misstatements to the Department can result in additional liability if they are knowingly false, and can lead to false claims for the payment of inflated prices. In addition, manufacturers that negotiate the listing of products on FSS are subject to pre-award audits[46] and to contractual provisions mandating price adjustments and reductions.[47]

[5]—Direct Price Reporting

Finally, manufacturers may face liability in the simplest of all situations—for knowingly misreporting prices when directly asked. Manufacturers report prices directly in a variety of contexts. Many, for example, report "wholesale" prices or "Wholesale Acquisition Cost" to the government or to reporting services on which the Medicaid programs rely. In addition, manufacturers are obligated to report an array of prices to the Texas Medicaid Program and, in certain circumstances, to other states as well.[48] And manufacturers must periodically respond to government audits and surveys concerning their prices. False statements or claims in these contexts can lead to liability.[49]

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[46] 48 C.F.R. § 515.408(4).

[47] 48 C.F.R. § 552.215-72.

[48] See § 10.02[3][a] Ns. 20, 21 *supra* and accompanying text.

[49] In 2000, for example, Texas sued three generic drug manufacturers under its false claims act for approximately $75 million for allegedly providing inflated prices to the state. Texas *ex rel.* Ven-A-Care of the Florida Keys, Inc. v. Dey, Inc., Roxane Laboratories, Inc. and Warrick Pharmaceuticals Corp., No. GV002327 (Travis Co. Dist. Ct.) (filed Sept. 29, 2000). The complaint alleged that the defendants failed to disclose decreases in their prices and failed also to include in their price calculations the value of discounts, rebates, free goods and other financial incentives. *Id.*

In 1998, Quantum Health Services agreed to pay $4.5 million to settle charges that it had overbilled the California, Oklahoma, and New York Medicaid programs by using invoices that did not disclose that the company received large amounts of free goods from the manufacturers of the product. Department of Justice press release, "Pharmaceutical Provider Agrees to Pay $4.5 Million" (Nov. 19, 1998).

In 1995, Rugby Laboratories agreed to pay $7.5 million to settle Justice Department charges that the company overcharged the Department of Veterans Affairs "by selling VA generic medications at discounts that were less than those given to other consumers." "Business Briefs: Two Companies Settle Fraud Charges," Am. Health Line (Nov. 1, 1995).

§ 10.04 False Claims Act Liability for Claims Relating to Drugs That Are Not Approved or That Should Not Have Been Approved

Manufacturers may also face liability for aiding, abetting, or causing false claims to be submitted if they are instrumental in the submission of claims for products that are not approved for a particular use or that they know should not ever have been approved by the FDA. This liability is entirely unrelated to the setting of AWP or reporting prices. We address these two related theories of liability in turn.

[1]—"Off-Label" Promotion

There is little law on the issue of whether manufacturers can be held liable under the FCA for off-label promotion and, if so, under what factual circumstances. In *United States ex rel. Franklin v. Parke-Davis*,[1] the relator alleged that the defendant manufacturer had violated the FCA by promoting the "off-label" use of certain products reimbursed by Medicaid.[2] As noted, Medicaid covers only those "Covered Outpatient Drugs" which are approved by the FDA or which are included in certain specified compendia.[3] The drugs at issue did not satisfy either criterion.[4]

The district court rejected each of the defendant's legal defenses. First, it rejected the argument that the FCA could not be used "as an end-run around the enforcement provisions of the [Food, Drug and

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[1] United States *ex rel.* Franklin v. Parke-Davis, 147 F. Supp.2d 39 (D. Mass. 2001).

[2] More specifically, the amended complaint alleged that the defendant (whose liabilities allegedly were assumed by Pfizer, Inc.) promoted off-label uses of its product Neurontin by hiring non-physicians to ghost-write favorable articles for scientific journals and paying actual specialists to be the "authors," training "medical liaisons" to promote off-label, and "distributing payments" to physicians to interest them in off-label uses through "consultants'" meetings, "speakers' bureaus," medical education seminars, grants, "studies," "advisory boards," and teleconferences. United States *ex rel.* Franklin v. Pfizer, Inc., No. 96-11651 (D. Mass.) (Amended Complaint ¶¶ 21, 23-48, 51-59). The complaint alleges that, through its actions, the defendant violated the FCA both by promoting sales that were ineligible for Medicaid reimbursement (*id.* at ¶¶ 69-73) and by causing the submission of claims tainted by kickbacks (*id.* at ¶¶ 74-77).

[3] See § 10.02[3][b] N. 27 *supra.*

[4] *Parke-Davis*, N. 1 *supra*, 147 F. Supp.2d at 44.

Cosmetic Act] by creating a cause of action for money damages."[5] According to the court,

> "the failure of Congress to provide a cause of action for money damages against a pharmaceutical manufacturer for marketing off-label drugs does not preclude an FCA claim where the manufacturer has knowingly caused a false statement to be made to get a false claim paid or approved by the government in violation of 31 U.S.C. § 3729(a)."[6]

Second, under the facts alleged, the court rejected the argument that off-label promotion does not necessarily involve false statements or fraudulent conduct, finding that "the gravamen of Relator's claim is that [the defendant] engaged in an unlawful course of fraudulent conduct including knowingly making false statements to doctors that caused them to submit claims that were not eligible for payment by the" Medicaid program.[7] The court acknowledged that a "much closer question would be presented if the allegations involved only the unlawful—yet truthful—promotion of off-label uses to physicians . . . without any fraudulent representations by the manufacturer."[8]

Third, the court rejected the argument that the independent actions of physicians broke the chain of causation, holding that "[i]n this case, when all reasonable inferences are drawn in favor of the Relator, the participation of doctors and pharmacists in the submission of false Medicaid claims was not only foreseeable, it was an intended consequence of the alleged scheme of fraud."[9]

Finally, the court rejected the argument that the relator's claim failed because he had not alleged that the defendant's statements to physicians were material to the government's payment decision, holding that the relator had adequately alleged that the defendant had knowingly caused the submission of false claims through a fraudulent course of conduct.[10]

This case suggests that manufacturers may be liable under the FCA

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[5] *Id.* at 51.

[6] *Id.* at 52.

[7] *Id.* at 52. Specifically, the relator alleged that the company had encouraged its representatives to make "exaggerated and false claims about safety and efficacy." *Id.*

[8] *Id.*

[9] *Id.*

[10] *Id.*, 147 F. Supp.2d at 552-553.

for off-label promotion, at least when they make false statements to physicians. Whether the reasoning of this decision will be adopted by other courts, and whether this theory of liability will be expanded, remain to be seen.

[2]—Fraud in the FDA Approval Process

In *United States ex rel. Konrad v. Lifescan, Inc.*,[11] relators advanced a similar argument—namely, that the defendant violated the FCA by causing the submission of claims for a product that had been approved by the FDA but which would not have been approved absent the defendant's fraud against the agency in the approval process. Specifically, they alleged that the defendant concealed two important defects in its blood glucose monitoring system (by omitting material facts from its premarket notification and by failing to alert the FDA to adverse events related to the device post-approval), and that by concealing these defects it fraudulently induced the FDA to clear the product for marketing and fraudulently induced consumers to use it and insurers to pay for it. The company settled the case for approximately $30 million in civil damages,[12] also pled guilty to three misdemeanor counts of violating the FDCA, and paid approximately $30 million in criminal fines.[13]

The potential reach of this theory is far from clear. Plaintiffs, however, may rely on it to attempt to impose liability under the FCA on manufacturers for any actions which would have caused the FDA either to refuse to approve a product initially or to order the product withdrawn from the market following approval. Such actions could theoretically include fraud in the research process, failure to report material conflicts of interest, or, as the *Lifescan* case itself suggests, failure properly to report material adverse events.[14]

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[11] United States *ex rel.* Konrad v. Lifescan, Inc., Civ. No. 97-2569 (TFH) (D.D.C. 1997).

[12] Lifescan Settlement Agreement (Dec. 13, 2000).

[13] United States v. Lifescan, Inc., No. CR00-20356JF Plea Agreement (Dec. 15, 2000); see also "Circa Pays $2.7M to Settle False Claims Act Allegations," Andrews Pharm. Lit. Rep. (June 1996) (Circa Pharmaceuticals, Inc. agreed to pay $2.7 million to settle allegations stemming from the company's manufacture and sale of generic drugs. The agreement specifically alleges that the company's manufacture and sale of the untested generic drugs caused claims for payments to be submitted under the False Claims Act.).

[14] Ironically, in 2001 the Supreme Court held that a class of plaintiffs alleging that they were injured by pedicle screws used in their spinal surgeries could not sue the manufacturer under state law for defrauding the FDA into granting approval to market

the screws. Buckman Co. v. Plaintiffs' Legal Committee, 531 U.S. 341, 121 S.Ct. 1012, 148 L.Ed.2d 854 (2001).