

Developments in Pricing Fraud Litigation: *The Boston AWP Case and the FDB Settlement*

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Overview

- ❑ Background of AWP Litigation
- ❑ Trial Decision in the Boston AWP Case
- ❑ First DataBank Case and Settlement
- ❑ Concluding Thoughts

Background of AWP Litigation

What is AWP?

- "Average Wholesale Price" is a pricing benchmark used by industry participants and published in industry compendia.
 - Some trace its original use back to California Medicaid in 1960s.
 - Historically, AWP represented approximately 20% mark-up over WAC.
 - Adopted by Medicare and many state Medicaid programs as a reference point for pricing.
 - Also used in commercial contracts.

Background of AWP Litigation

Genesis of the Controversy

- Throughout the 1990s (and even earlier), numerous government reports noted that AWP did not represent acquisition cost of providers.
 - Some suggested adoption of different benchmarks to more closely approximate acquisition cost.
 - Most public and private payers continued using AWP, but periodically increased the percentage by which AWP was discounted to arrive at a reimbursement rate.
 - *Qui tam* suit filed alleging that manufacturers deliberately manipulated spread between AWP and providers' acquisition cost to market their products.

Background of AWP Litigation

Early Government Settlements

□ Bayer

- Late in 2000, DOJ announced \$14 million settlement with Bayer.
- Settled allegations that Bayer had inflated AWP and WAC, causing providers to submit inflated claims to Medicaid programs.
- 45 states joined and received a share of the recovery.

□ TAP

- In 2001, DOJ announced \$875 million settlement with TAP.
- Also a joint federal and state settlement.

Background of AWP Litigation

Early Case Chronology

□ **Late 2001**

- First class action suits filed in federal courts in Boston, Philadelphia, Chicago, Houston, and elsewhere.

□ **Early 2002**

- First suits filed by state attorneys general.

□ **April 2002**

- Judicial Panel on Multidistrict Litigation assigns the federal AWP suits to Judge Patti Saris in D. Mass. (Boston); all subsequent suits filed in or removed to federal court assigned to her.

□ **September 2002**

- Plaintiffs file first Master Consolidated Class Action Complaint.

Background of AWP Litigation

Plaintiffs' Core Allegations

- Plaintiffs allege that manufacturers report artificially high AWPs to create a spread between –
 - **Acquisition cost** - the price physicians and pharmacies pay to acquire the product, and
 - **Reimbursement amount** - the amount physicians and pharmacies receive from payors for dispensing the product.
- Manufacturers allegedly "market the spread" to physicians and pharmacies to induce them to select the manufacturers' drugs over competing products.

Background of AWP Litigation

Types of AWP Suits

- Private Class Actions
 - All federal class actions are combined in MDL 1456 before Judge Saris in D. Mass.
 - Two class actions now pending in state court.
- State Attorney General Actions
 - Approximately 25 states have initiated AWP suits.
 - Suits typically focus on alleged harm to the state's Medicaid program; some also include *parens patriae* claims.
 - Most are now in state court.
- New York City/County Actions
 - New York City and over 50 NY counties have filed AWP suits.
 - Most are in the MDL; some in state court.
- *Qui Tam* Actions
 - Three manufacturers are the subject of unsealed FCA claims brought on behalf of the U.S. government.

Background of AWP Litigation

Major Pretrial Developments in the MDL

- Established two tracks of defendants for pretrial management purposes
 - **Track One:** 5 companies on faster track for discovery and trial.
 - **Track Two:** All other companies (about a dozen).
- In 2005, court denied class certification as to self-administered drugs
 - However, as to physician administered drugs, court certified 3 classes of persons/entities who had allegedly made inflated payments based on AWP:
 - **Class One:** Medicare beneficiaries (nationwide)
 - **Class Two:** Medigap insurers (Mass. only); and
 - **Class Three:** Private payers and consumers (Mass. only)

Judge Saris's Trial Decision

The Trial

- In late 2006, Judge Saris presided over a 6-week bench trial involving 4 Track One defendants
 - Class One (Medicare beneficiaries) was not at issue in the trial; problems with nationwide notice resulted in delay
 - Classes Two and Three were at issue. Both classes had been certified for Massachusetts only, though without prejudice to later certification of other statewide or larger classes.
 - Class representatives were Blue Cross Blue Shield of Massachusetts and two multi-employer trust funds, Pipefitters and Sheet Metal Workers.

The Trial *(cont'd)*

- ❑ Only substantive claim at trial was that AWP inflation was an "unfair act or practice" under Mass. Gen. Laws. 93A.
- ❑ Forty witnesses testified, including economics and pharmaceutical pricing experts for both sides.
- ❑ Judge Saris issued findings of fact and conclusions of law on June 21, 2007.
- ❑ Court's opinion extends 183 pages and addresses each drug individually.

Summary of Findings

Overview of Key Issues

- ❑ Class period/statute of limitations
- ❑ Two-Step Analysis
 - Liability screens
 - Multi-factor test
- ❑ Multi-Source drugs
- ❑ Damages

Summary of Findings

Class Period

- ❑ Class period covers six years, from 1998 to 2003
- ❑ Claims arising **before 1998** barred by four-year statute of limitations
 - Balanced Budget Act of 1997, which lowered Part B reimbursement to 95% of AWP, put large third-party payors on "inquiry notice" of "mega-spreads."
- ❑ No claims **after December 2003**, the effective date of the Medicare Prescription Drug Improvement and Modernization Act of 2003 (MMA).
 - MMA substituted "average sale price" for AWP as reference price for Part B reimbursement.

Summary of Findings

Two-Step Analysis

- Judge Saris identified several factors relevant to the determination of liability
 - The size and duration of a product's "spreads."
 - "Spread" = the difference between AWP and average sale price ("ASP")
 - ASP = "the actual average acquisition cost of providers, taking into account rebates, discounts, chargebacks, free samples, and the like"
 - Whether a product's list price is "real list price" at which "substantial sales" are made;
 - How the spreads are created; and
 - Whether the manufacturer engages in a "proactive scheme" to market the spread.

Summary of Findings

Two-Step Analysis (cont'd)

- Although not stated as such, the Court's analysis proceeds in two steps
- Step One: Potential Liability Screens
 - No liability if spreads within the 30% "speed limit"
 - No liability if "substantial" sales at WAC
 - Possible liability *per se* for "Mega-Spreads"
- Step Two: Multi-Factor Test

Summary of Findings

Step One: Liability Screens

- 30% "speed limit"
 - Spreads always under 30% are not sufficiently "egregious" to impose liability under the Massachusetts Act.
 - Evidence of spread marketing is "troubling" but does not necessarily result in liability when spread itself is within expected range of 30% or less.
- No liability if "substantial" percentage of sales are made within 5% of list price.
 - Judge Saris defined "substantial" to mean more than 50% of sales.

Summary of Findings

Step One: Liability Screens (cont'd)

- Liability for "mega-spreads"
 - Liability likely if spreads routinely reach percentages in the hundreds (and the 50% of sales screen does not apply).
 - With "mega-spreads," no need to show "proactive spread marketing or increase in the published AWP."
 - "Price manipulation" alone can, in the Court's view, constitute sufficient basis for liability under the Act.

Summary of Findings

Step Two: Multi-Factor Test

- If none of the liability screens applies, the Court considers a drug's "spreads" and its sales at WAC along with the remaining factors:
 - How "spread" is created
 - Judge Saris likens spread to a "pair of scissors: the spread could be increased by raising the top blade (the AWP) or lowering the bottom (the acquisition cost), or both."
 - Raising AWP to create spread is "strong evidence of unethical conduct."
 - Discounting to create a spread can also be the basis for liability.
 - Evidence of spread marketing
 - Comparative spread analysis used in pricing discussions is considered evidence of pricing on the spread.

Summary of Findings

Analysis Drug-by-drug and Year-by-year

- ❑ The Court applies its two-part test on a drug-by-drug and year-by-year basis.
- ❑ There can be liability for a drug for certain years and not for others.
- ❑ Liability, therefore, is potentially a reflection of a perceived pattern or of more isolated conduct.

Summary of Findings

Application of Court's Test

Drug	Spreads	Sales w/in 5% of WAC or equivalent?	Spread Marketing?	AWP Increased?	Liability
Procrit	Always < 30%	—	Y	Y	N
Cytosan (Inj.)	Regularly over 100%; high 676%	Virtually none	N	N	Y
Cytosan (Tab)	Sporadically over 30%; high of 39%	Overwhelming majority	Limited evidence	Y	N
Paraplatin	Sporadically > 30%; as high as 67%	83-99%	Y	Y	N
Proventil (2002)	1 NDC > 160%	83% over class period	N	Y	N*

* Although a "close question," Judge Saris excused the single spread above 30% as an "isolated, anomalous occurrence."

Summary of Findings

Application of Court's Test (cont'd)

Drug/Year	Spreads	Sales w/in 5% of WAC or equivalent?	Spread Marketing?	AWP Increased?	Liability
Vepesid (Inj.) (2000)	1 NDC > 750%	55% (only one year)	Limited evidence	N	N
Vepesid (Inj.) (1998-1999; 2001-2002)	Regularly over 30%; highs over 1000%	Almost none	Limited Evidence	N	Y
Rubex (2001)	Lowest spread 55%	62% (only one year)	N	N	N
Rubex (1998-2000; 2002)	Consistently over 30%; high of 438%	Almost none	N	N	Y

Summary of Findings

Multi-Source Drugs

- Multi-source drugs require additional analysis because reimbursement is not necessarily based on an individual defendant's AWP.
- In the class period, multi-source drugs covered by Medicare Part B were reimbursed at 95% of the lower of the lowest branded AWP or the median generic AWP.
- Plaintiffs can show legal causation only if they would have paid less had the defendant reported its "true" AWP.
 - In the Medicare context, this can occur only if the defendant's published AWP was above the median AWP used to set the reimbursement rate.
 - Outside Medicare, TPPs pay based on MACs, not AWP; therefore, the Court found no liability for Class 3 as to multi-source drugs.

Summary of Findings

Multi-Source Drugs

- ❑ Often, there is no way of knowing which manufacturer produced the multi-source drug the plaintiff purchased.
- ❑ The Court concludes that this does not necessarily defeat causation.
 - Court finds that a defendant whose "true" AWP would have affected reimbursement "caused" plaintiffs to pay more for all versions of the drug.
- ❑ However, the Court apportioned damages for multi-source drugs based on each liable defendant's market share.

Summary of Findings

Damages

- Damages for single-source drugs are based on the difference between the "anticipated" spread and the actual spread, *i.e.*, $AWP - (1.30 * ASP)$.
- For multi-source drugs, a defendant's liability is based on the reimbursement rate that would have been set had that defendant reported its true AWP.
 - For branded multi-source drugs, this may be the same as for single-source drugs, since the "true" branded AWP (*i.e.*, its ASP) may well have set reimbursement under then-existing methodology.
 - But for generic multi-source drugs, reporting a "true" AWP may only lower reimbursement to the next highest reported AWP.
 - Damages in that case are based on the difference between actual median AWP and the "but-for" median AWP.

Possible Implications

- How broadly will the Court's framework apply?
 - The decision only directly concerns Massachusetts law.
 - Other state laws may have different legal standards.
 - Does Saris' framework apply in State Medicaid cases?
- What are companies supposed to do going forward?
 - Is the 30% "speed limit" a "safe harbor"?
 - Prior "plain meaning" decision.
- What will replace AWP as a reference price for contracting?

Next Steps

- Appeal
 - Judge Saris has indicated that she would certify an appeal of her Track 1 decision under Rule 54(b).
- Impact on Settlement
 - Two Track 1 companies settled with Class One.
 - Another settled with all three classes.
- Track Two
 - Court heard arguments in August on class certification as to three Track 2 defendants.
 - Court also ordered mediation of Track 2.
 - If mediation fails, trials for Track 2 companies are scheduled to begin in December 2007.

The First DataBank Settlement

Introduction

- Judge Saris, in addition to hearing AWP-related cases against manufacturers, has before her a case that alleges that First DataBank ("FDB"), a third-party publisher of AWP data, and wholesaler McKesson conspired to drive up the AWP of hundreds of drugs
- The case is New England Carpenters Health Benefits Fund v. First DataBank Inc., D. Mass., No. 1:05-CV-11148
- On October 6, 2006, First DataBank ("FDB") announced it would settle these claims

Introduction *(cont'd)*

- Under the terms of the Settlement (if approved) FDB will:
 - Lower the AWP of thousands of drugs (listed in an appendix to the settlement)
 - Likely discontinue publishing AWP within 2 years
 - Engage in mediation to identify a "sustainable benchmark for pharmaceutical reimbursement"

Summary of Allegations

- Plaintiffs are individuals and employee welfare benefit plans suing on behalf of a nationwide class of all third-party payors and consumers whose payments for hundreds of branded, self-administered drugs were based on AWP data supplied by FDB.
- Plaintiffs allege that FDB and McKesson engaged in a scheme to fraudulently inflate AWP in violation of:
 - Federal RICO statute;
 - California state consumer protection and anti-fraud laws; and
 - In the alternative, the consumer protection and anti-fraud laws of the fifty states

Summary of Allegations *(cont'd)*

- Three publishing companies compiled and reported AWP, but Plaintiffs allege that FDB "had a virtual monopoly as an electronic source for drug pricing information."
- Until March 15, 2005, FDB falsely represented that its AWP information was obtained through a survey of the three national wholesalers.
- In fact, FDB did not systematically survey wholesalers but typically set AWP by applying either a 20% or 25% markup, depending on the drug, to the drug's wholesale acquisition cost ("WAC").
 - Pharmacies typically buy drugs at WAC plus or minus a factor that generates a margin for wholesalers, and are reimbursed by third-party payors ("TPPs") on the basis of AWP.

Summary of Allegations *(cont'd)*

- Beginning in late 2001, FDB and McKesson reached a secret agreement to raise the WAC-to-AWP markup for all drugs to a uniform 25%.
 - AWP's of drugs that had historically been marked up 20% thus increased by several percentage points.
- To conceal the scheme, FDB and McKesson agreed to increase a drug's spread only when some other WAC-based price announcement was made by a drug manufacturer.
 - When a manufacturer raised its WAC, McKesson communicated to FDB the new 25% WAC-to-AWP markups, which FDB then published.
- Plaintiffs allege that the scheme was very successful:
 - Before 2002 only 20% of the prescription drug manufacturers had AWP's with a 25% mark-up over WAC
 - By early 2002, 90% of the industry used the higher markup
 - By 2004, McKesson put the percentage at 99%

Summary of Allegations *(cont'd)*

- ❑ McKesson allegedly benefited from the increase in spread between AWP and WAC because its customers, large retail pharmacies, pay for drugs at WAC but are reimbursed by many payors based on AWP.
- ❑ FDB allegedly benefited by becoming McKesson's and drug manufacturers' preferred source of drug pricing information.

FDB Settlement

- ❑ In its settlement, filed on October 4, 2006, FDB did not admit wrongdoing or agree to compensate Plaintiffs for their alleged overpayments.
- ❑ However, FDB indicated in its statement that the case had raised "concerns with respect to the integrity of the pricing information that is provided to First DataBank for purposes of publishing AWP."
- ❑ Therefore, FDB had concluded that AWP could not be published by it or any other compendia "as a sustainable reimbursement benchmark."

FDB Settlement

Key Provisions

- Lower published AWP
 - Requires FDB to lower the AWP it publishes for thousands of NDCs so that their WAC-to-AWP markup is no greater than 20%.
 - Reduction must occur by March 2008.
- Identify new pricing benchmark
 - Calls for FDB to engage in a Court-approved mediation process with "major participants in the pharmaceutical industry ... to facilitate the establishment of a sustainable benchmark for pharmaceutical reimbursement."
- Cease publishing AWP
 - Within two years of the effective date of the agreement, FDB will cease publishing AWP information.
 - There are two caveats, however.

FDB Settlement

Key Provisions (cont'd)

- Cease publishing AWP—*Caveat #1*
 - If a competing service continues to publish AWP, FDB has the option of continuing or resuming publication of its own AWP data — provided that its AWP does not exceed WAC by more than 20%.
 - What is the likelihood that other publishing houses will continue to publish AWP?
 - On August 20, 2007, Judge Saris granted preliminary approval to the settlement of a separate suit against Medi-Span under which Medi-Span will cease publishing AWP within three years unless another publisher continues to publish AWP.
 - FDB offers its own assessment: AWP cannot be published by it or any other compendium "as a sustainable reimbursement benchmark."

FDB Settlement

Key Provisions (cont'd)

- Cease publishing AWP—*Caveat #2*
 - FDB may publish AWP information whenever, "as a result of changes in law, regulation or industry practice, verifiable pharmaceutical wholesale price information becomes available"
 - What does "verifiable" mean?

Court Approval

- On June 7, 2007, the Court granted preliminary approval to the terms of the proposed settlement.
- Judge Saris certified on a preliminary basis a settlement class of all individuals and entities who paid for prescription pharmaceuticals based on AWP disseminated by FDB that was "based on a FDB wholesale survey."
- The Court has scheduled a Fairness Hearing for January 22, 2008 to consider:
 - Whether to certify a final settlement class; and
 - The fairness, reasonableness, and adequacy of the settlement.

Next Steps in Litigation

- On August 27, Judge Saris certified two classes in the remaining case against McKesson. They are:
 - All individuals who paid a co-payment during the class period for one of the drugs whose AWP was "jacked up" by FDB/McKesson.
 - All TPPs that reimbursed for these drugs based on AWP supplied by FDB.
- The court declined (for now) to certify the TPP class for damages citing the role of PBMs in pharmaceutical reimbursement.
 - PBMs are the "800-pound gorillas of pharmaceutical reimbursement.
 - PBMs "knew about the dramatic bump in AWP pricing in 2002 and had the power and financial incentive to institute contract pricing mechanisms with pharmacies to bring reimbursement costs back to the status quo for client TPPs."

Potential Implications

- The practical impact of the FDB settlement (if approved) will be immediate and significant — particularly if other publishers of pharmaceutical pricing compendia follow FDB's lead.
- The demise of AWP will require substantial changes in government regulations and industry practice.
 - Without AWP, governmental and private commercial payors that calculate reimbursement as a percentage of AWP will need to find a substitute pricing benchmark.
 - Likewise, manufacturers with contracts based on AWP will need to transition those contracts to another reference price.
- Possible legal implications of an agreement to define a "sustainable benchmark for pharmaceutical reimbursement."

Concluding Thoughts

- End of AWP?
 - Medicare Modernization Act
 - Medicaid developments
 - Private contracting
- Have core issues been made moot by regulatory developments?
 - ASP
 - AMP

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