

# Square Peg in a Round Hole: Two Recent Cases Show Potential Limitations for States in AWP Litigation

Pharmaceutical Manufacturers and Providers Should Establish a System of Gathering and Maintaining Key Information



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Two recent state court cases in the series of litigation on reporting of average wholesale price (AWP) may provide a much-needed respite for pharmaceutical manufacturers who continue to be squarely within the sights of federal and, increasingly, state prosecutors, as well as *qui tam* plaintiffs. The cases also may demonstrate the limits states may face in pursuing litigation as a means to change industry practices.

First, in October 2009, the Alabama Supreme Court vacated jury verdicts against three pharmaceutical manufacturers in a case brought by the Alabama Medicaid Agency for alleged fraudulent reporting of inflated AWP for purposes of seeking Medicaid reimbursement.<sup>1</sup> More recently, in February 2010, a Utah state district court dismissed a lawsuit against a number of pharmaceutical manufacturers brought by the state of Utah on similar allegations with respect to the Utah Medicaid program.<sup>2</sup> Both cases demonstrate the limits of the states' AWP cases against pharmaceutical manufacturers and provide some lessons to the industry with respect to documentation of communications and other guidance from government agencies.

## HISTORY OF AWP LITIGATION

The AWP litigation began in 1995 with the filing of a *qui tam* action by Ven-A-Care, a Florida-based pharmacy, which alleged that pharmaceutical manufacturers were inflating AWP to the detriment of the Medicare and Medicaid programs.<sup>3</sup> This was followed by the 2001 Department of Justice settlements with Bayer Corporation<sup>4</sup> and TAP Pharmaceuticals.<sup>5</sup>

Following these settlements, multiple state attorneys general, on behalf of their respective state Medicaid programs, began pursuing lawsuits against pharmaceutical manufacturers for alleged fraudulent reporting of AWP (and wholesale acquisition cost (WAC)). The litigation also caught up with First DataBank and Medi-Span, which publish pharmaceutical pricing information, which settled in March 2009.<sup>6</sup> The Alabama and Utah cases below are two recent developments in the long history of AWP litigation, the outcomes of which may be indicative of pending actions in other states.

### **ALABAMA SUPREME COURT DECISION**

In overturning the jury verdicts against AstraZeneca, SmithKline Beecham, and Novartis, the Alabama Supreme Court found that the Alabama Medicaid Agency “failed to produce substantial evidence that it reasonably relied on the misrepresentation and/or fraudulent suppression” by the pharmaceutical manufacturers.<sup>7</sup> In doing so, the Alabama Court held that the trial court erred in denying the defendants’ motion for judgment as a matter of law, thereby signaling that the case never should have gone to trial.<sup>8</sup>

In its January 26, 2005, complaint against 73 pharmaceutical manufacturers, the Alabama Medicaid Agency alleged that (1) the manufacturers fraudulently “provided or caused to be provided false and inflated AWP [and] WAC...information for their drugs to...[First] DataBank;” (2) the reported AWPs and WACs “greatly exceeded the actual prices at which [the manufacturers] sold their drugs to retailers (physicians, hospitals, and pharmacies) and wholesalers” because they did not include “undisclosed discounts, rebates, and other inducements which had the effect of lowering the actual wholesale or sales prices charged to their customers as compared to the reported prices;” (3) the manufacturers “knew that the false and deceptive inflation of AWP [and] WAC...for their drugs would cause [the Alabama Medicaid Agency] to

pay excessive amounts for these drugs;” and (4) the Alabama Medicaid Agency “reasonably relied on the false pricing data in setting prescription drug reimbursement rates and making payment based on said rates.”<sup>9</sup>

It was with the “reasonable reliance” element that the Alabama Supreme Court took issue. The Court noted that the state’s case was based in part on the fact that the Medicaid Agency did not have knowledge that the AWP and WAC reported to First DataBank were list prices rather than actual prices.<sup>10</sup> The Alabama Supreme Court, however, found that “[t]his assertion is untenable in light of the correspondence and internal memoranda involved in the State’s formulation of its reimbursement methodology.”<sup>11</sup>

The Court found that the Medicaid Agency knew, as early as 1975, that AWP did not represent actual price.<sup>12</sup> The Court recited a lengthy list of documentation demonstrating the Agency’s knowledge, including a 1985 exchange between Faye Baggiano, then commissioner of the Alabama Medicaid Agency, and Richard Morris, associate regional administrator of the U.S. Department of Health and Human Services (HHS) whereby HHS threatened to withdraw federal funding to the Alabama Medicaid program if it continued to reimburse for drugs based on 100 percent of AWP.<sup>13</sup>

The HHS “cautioned against the use of AWPs as estimates of drug ingredient costs [because]...published wholesale prices are not closely related to prices actually paid by providers.”<sup>14</sup> Following this exchange with HHS, the Agency conducted its own survey of wholesalers and found that the average percentage markup from WAC that pharmacies in Alabama were paying was 7.45 percent.<sup>15</sup> As a result, the Alabama Medicaid Agency sent a notice to providers on September 6, 1985, noting that “published AWPs...are inflated and that AWP is not the [Medicaid Agency’s] ‘best estimate of what price providers generally are paying for a drug.’”<sup>16</sup> The Court noted that the exchange

with HHS “set in motion the process culminating in the [Alabama Medicaid Agency’s] current reimbursement methodology.”<sup>17</sup>

As further evidence of the Agency’s knowledge, the Alabama Supreme Court cited the fact that in 1987, Carol Hermann, then an official at the Centers for Medicare & Medicaid Services (CMS), received an internal memorandum titled “Initiative on Lowering Drug Acquisition Cost and the State of Alabama,” which stated in relevant part that AWP listings “are usually about 20 percent higher than acquisition costs.”<sup>18</sup> This is notable because Ms. Hermann subsequently became the Alabama Medicaid Agency commissioner in 1989.<sup>19</sup> The state argued that because the CMS memorandum “was not addressed or sent to the [Agency],” the Agency did not have notice of it, despite Ms. Hermann’s knowledge of the letter.<sup>20</sup>

The Alabama Supreme Court “reject[ed] this argument out of hand” pointing out that in 1992, while Ms. Hermann was “actually serving as [the Agency’s] Commissioner, she was acquainted with that portion of the Medicaid manual stating that ‘AWP levels overstate the prices that pharmacists actually pay for drug products by as much as 10-20% because *they do not reflect discounts, premiums, special offers or incentives, etc.*’”<sup>21</sup> Thus, the Court concluded that “by 1992 at the very latest,” the Agency had actual knowledge.<sup>22</sup>

The Alabama Supreme Court also found that contrary to the state’s assertion, the Alabama Medicaid Agency had not relied on the reported AWP price to establish reimbursement levels and that, in fact, the Agency “determined for itself the appropriate reimbursement formulas based on its own surveys and calculations” and, therefore, could not claim reliance on the alleged misrepresentation.<sup>23</sup> The Court surmised that if the state did, in fact, rely on AWP, then the state could merely continue to reimburse based on AWP – 0 percent, as it did before 1985, instead of taking a discount from AWP.<sup>24</sup>

The Court, however, noted that “[o]n the contrary, it is clear beyond cavil that the

reimbursement methodology adopted by the [Agency] is the product of a conscious and deliberate policy decision, which seeks to ‘balance (i) the amount [it] reimburse[s] pharmacies that dispense drugs to Medicaid patients, and (ii) the requirement – established by federal law – to set reimbursement sufficiently high to ensure participation in the Medicaid program by retail pharmacies.’”<sup>25</sup>

Finally, the Alabama Supreme Court agreed with AstraZeneca’s assertion that the litigation was essentially an “attempt to use tort law to re-define [the Agency’s] Medicaid reimbursement obligations.”<sup>26</sup> Here, the Court noted that “[a]lthough the State does not explain when, or how, it first began to take issue with the pharmaceutical manufacturers’ methods of reporting, it is undisputed that the relevant reimbursement methodology has not changed since 1987;...[i]n other words, the State has *never altered its course of conduct* since taking issue with the reporting methodology.”<sup>27</sup> As such, the Court concluded that “given the State’s particularized knowledge of the challenged reporting practices, a claim of common-law fraud – with its element of reasonable reliance – is, like the proverbial ‘square peg in a round hole,’ particularly ill-suited for the task to which it was put in this dispute.”<sup>28</sup>

### UTAH DISTRICT COURT DISMISSAL

Perhaps taking notice of the Alabama Supreme Court’s decision in AstraZeneca, in February 2010, the District Court for the Third Judicial District for Salt Lake County in Utah dismissed with prejudice a Utah False Claims Act action against pharmaceutical manufacturers on similar grounds.<sup>29</sup> The dismissal arose from an action brought by the Utah attorney general against more than 30 pharmaceutical manufacturers alleging that the manufacturers fraudulently inflated the AWP of their drugs in order to overcharge the state’s Medicaid program. The District Court, however, held that the state’s complaint “failed to identify each

defendant's allegedly fraudulent misrepresentations and False Claims Act violations with particularity."<sup>30</sup>

Specifically, the Court agreed with the defendants that the state "failed to allege specific facts indicating that the defendants communicated directly with the State, let alone submitted a claim to the State" and "[y]et, the actual submission of a false claim is an essential element to any complaint seeking relief under Utah's False Claims Act."<sup>31</sup> The Court also noted that "[e]qually significant is the lack of allegations concerning the benefit which the defendants derived directly from the State."<sup>32</sup> Instead, the Court found that the state "merely concludes that a benefit must have been derived and 'ultimately ended up in the pockets of the defendants.'"<sup>33</sup>

The Utah District Court also concluded that the state "failed to allege fundamental elements of common law fraudulent misrepresentation and for relief under the Utah False Claims Act."<sup>34</sup> Specifically, the Court found that the state failed to plead how each individual defendant's alleged false reporting of AWP directly related to the state's reimbursement formula for the defendant's drugs.<sup>35</sup> More to the point, the Court found that the state did not plead "how it acted in *reasonable reliance* on the pricing information."<sup>36</sup>

Indeed, the Court hypothesized that the state's "inability to plead reasonable reliance may be explained by its public acknowledgement in 1999 that it understood that actual acquisition costs for generic drugs was 60.1% below AWP and that AWP does not in fact reflect market prices."<sup>37</sup> Given the state's knowledge that the published AWP's did not represent actual price averages, it could not meet two of the elements of the Utah False Claims Act, namely that the defendants "knowingly made a false claim and that the State was deceived by published AWP's in setting its Medicaid reimbursement formula."<sup>38</sup>

### LESSONS FOR COMPLIANCE OFFICERS

While the AWP litigation may continue in other states, the cases discussed above pro-

vide some useful lessons for the pharmaceutical industry and for health care providers generally. In both the Alabama and Utah cases, the courts cited historical documentation from each of the states' Medicaid agencies, including Medicaid manuals and provider communications. Given the significant amount of communication between Medicaid and other health care regulatory agencies and the health care industry, pharmaceutical manufacturers and providers should establish and implement a system of gathering and maintaining such information as part of an effective compliance program. Such a system can help ensure that manufacturers and providers have ready access to information and guidance provided by government agencies to address day-to-day compliance questions.

Additionally, given changes in programs over time, and indeed changes in personnel at the government agencies and in administrations, historical information may become more difficult to obtain, especially as manuals are revised, policies are changed, and Web sites are updated. This is particularly important in cases where a manufacturer or provider relies on communications from the agency or where the government is establishing a new policy or reimbursement methodology. As part of the system to maintain documentation, manufacturers and providers also should maintain any requests for information by a government agency and the information submitted in response to such request.

Note: Morgan Lewis represented Pfizer in the Utah District Court case, but the author of this article was not personally involved in the matter.

### Endnotes:

1. *AstraZeneca LP v. State*, Ala., No. 1071439 (Oct. 16, 2009).
2. *Utah v. Apotex Corporation*, et al., No. 080907678.
3. *United States ex rel. Ven-A-Care of the Florida Keys, Inc. v. Bristol Myers Squibb Co.*, Civil Action No. 95-1354 (S.D. Fla.).
4. See U.S. Department of Justice News Release, Bayer to Pay \$14 Million to Settle Claims for Causing Providers to

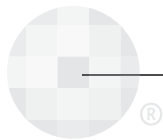
- Submit Fraudulent Claims to 45 State Medicaid Programs (Jan. 23, 2001), available at [www.justice.gov/opa/pr/2001/January/039civ.htm](http://www.justice.gov/opa/pr/2001/January/039civ.htm) (last visited on March 8, 2010).
5. See U.S. Department of Justice News Release, TAP Pharmaceutical Products Inc. and Seven Others Charged with Health Care Crimes; Company Agrees to Pay \$875 Million to Settle Charges (Oct. 3, 2001), available at [/www.justice.gov/opa/pr/2001/October/513civ.htm](http://www.justice.gov/opa/pr/2001/October/513civ.htm) (last visited on March 8, 2010).
6. *New England Carpenters Health Benefit Fund v. First Databank Inc.*, D. Mass., No. 05-11148-PBS, 3/17/09; *District Council 37 Health and Security Plan v. Medi-Span*, D. Mass., No. 07-10988-PBS, March 17, 2009.
7. *AstraZeneca* at 43.
8. *Id.*
9. *Id.* at 20-21.
10. *Id.* at 25 (emphasis in original).
11. *Id.* at 32.
12. *Id.*
13. *Id.* at 10.
14. *Id.* at 11.
15. *Id.* at 15.
16. *Id.* at 14.
17. *Id.* at 33.
18. *Id.* at 16.
19. *Id.*
20. *Id.* at 34.
21. *Id.* (emphasis in original).
22. *Id.*
23. *Id.* at 42.
24. *Id.* at 38.
25. *Id.* at 41.
26. *Id.*
27. *Id.* at 42.
28. *Id.*
29. *Utah v. Apotex Corporation, et al*, No. 080907678 (Feb. 26, 2010).
30. *Id.* at 6-7.
31. *Id.* at 9 (citing Utah Code Ann. §26-20-7).
32. *Id.*
33. *Id.*
34. *Id.* at 10.
35. *Id.*
36. *Id.* at 11 (emphasis added).
37. *Id.* (citing Utah Dep't of Health, Div. of Health Fin., Medicaid Pharmacy – Acquisition Cost of Generic Prescription Drug Products (Feb. 1999)).
38. *Id.* at 11.

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