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Critical Legal Issues: WORKING PAPER SERIES

USING LITIGATION TO REGULATE DRUG PRICES: THE ASSAULT ON "AWP"

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INTRODUCTION

For the past several years, federal health care agencies have been engaged in a smoldering dispute over whether the Average Wholesale Price ("AWP") or "sticker" price for pharmaceutical products should be used in reimbursement formulas under Medicare Part B. In the late 1990's, health care reformers sought to replace AWP-based reimbursement with alternative formulae tied more directly to actual acquisition costs. President Clinton's 1998 budget contained that specific proposal. However, Congress rejected the President's proposal, electing to maintain AWP-based reimbursement, although at a reduced (95%) rate.

Yet the campaign against AWP-based reimbursement for Medicare at the Department of Health and Human Services ("HHS") continues unabated. In the Fall of 2001, the stakes in the dispute were raised considerably in the settlement of a

defending multi-million dollar lawsuits in which they are charged with committing fraud.

This WORKING PAPER explores these issues and demonstrates that the broad theory of AWP-based liability articulated in the *TAP* settlement is unfounded in law and fact. It will also briefly review the flurry of cases filed in the wake of the flawed *TAP* settlement to demonstrate how this broad theory of AWP liability exposes the pharmaceutical industry to billions of dollars of potential liability and threatens to erode HHS's and Congress's authority to set policy in this critical area.

I. "AWP" – THE "STICKER PRICE" FOR PHARMACEUTICALS

Although the federal Medicare program does not normally pay the cost for prescription pharmaceutical products, Medicare Part B allows for payment for certain "covered drugs" that are administered by a physician or HMO or certain self-administered drugs relating to cancer or immunosuppressant therapy. Under currently applicable federal regulations, physicians and HMOs are typically reimbursed at the rate of 95% of the "average wholesale price" or "AWP" for drugs that they prescribe and dispense to their patients.[2]

For more than thirty years, AWP has been viewed by both industry and government not as an actual price for any product but, like the "sticker price" for automobiles, as an "asking" price for pharmaceutical products. Periodically, each

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[2] 42 C.F.R. § 405.517(b).

excess of actual acquisition cost."[4] In December 1977, the Health Care Financing Administration ("HCFA") admonished states as they were setting reimbursement rates not to rely on AWP as an accurate reflection of actual cost, observing that "the Department is not convinced that those states which continue to reimburse at *average wholesale price* or wholesale invoice cost have made a real effort to approach actual acquisition cost."[5] Thus, almost twenty-five years ago, HHS was disabusing states of the notion that AWP approximated or even "approached" actual transaction costs.

Indeed, by the 1990's, the fact that AWP exceeded actual transaction costs was so much a part of the system that HCFA warned states that they could not rely upon AWP to calculate the Estimated Acquisition Cost — the estimate of the price generally and currently paid by pharmacists for the drug product — of pharmaceuticals for Medicaid reimbursement unless AWP was significantly discounted.[6] Indeed, OIG itself compared AWPs and actual costs to physicians of chemotherapy drugs in 1992 and concluded that the difference or "spread" between

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[4]39 Fed. Reg. 41,480 (Nov. 27, 1974); *see* 40 Fed. Reg. 34,516 (Aug. 16, 1975) (final rule).

[5]"Title XIX Social Security Act: Limitation on Payment Reimbursement for Drugs: Estimated Acquisition Cost (EAC)," HCFA Action Transmittal 77-13 (MMB) (Dec. 13, 1977)(emphasis added), *reprinted in* Medicare & Medicaid Guide (CCH) ¶ 28,714.

[6]"Medicaid Pharmacy – Actual Acquisition Cost of Generic Prescription Drug Products," Report of DHHS, OIG, Office of Audit Services, A-06-97-00011, *reprinted in* Medicare & Medicaid Guide (CCH) ¶ 45,559.

price – the so-called *sticker price* – for drugs. Few doctors, however, actually pay the full sticker price. In fact, some pay just one tenth of the published price.[9]

II. HHS TRIES TO ABANDON AWP — CONGRESS THINKS DIFFERENTLY

President Clinton's remarks reflected that his administration had sided with the reformers in believing that reimbursement based upon actual costs was preferable to reimbursement calculated from AWP. Specifically, HHS proposed in the President's 1998 budget that physicians be required to bill Medicare the actual acquisition cost for drugs.[10] The HHS also proposed that it be allowed to define AWP.[11]

Congress rejected the President's proposal. Rather than abandon AWP, the Balanced Budged Act of 1997[12] set Medicare reimbursement at the lesser of the billed charge or 95 percent of AWP.[13] While HCFA officials recognized that Congress had opted for a different solution, HHS remained convinced that a move

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[9]White House Office of Press Secretary, Remarks by the President in Radio Address to the Nation (Dec. 13, 1997) (emphasis added).

[10]"Excessive Medicare Payments for Prescription Drugs." Report of DHHS, OIG, Office of Evaluation and Inspections, OEI-03-97-00290 (1997).

[11]*See* S. 947, 105th Cong., 143 Cong. Rec. S6198, S6250 (1997); H.R. 2015, 105th Cong., 143 Cong. Rec. H6233 (1997).

[12]Pub. L. 105-33, 111 Stat. 251.

[13]*See* 42 U.S.C. § 1395u(o)(1).

patients to the lower-priced Zoladex. Reluctant to reduce the price of Lupron, the Justice Department's complaint alleged, TAP had its sales force provide incentives to physicians and HMOs, including unrestricted "educational grants" of tens of thousands of dollars, if they would continue their clinical use of Lupron. The Justice Department also alleged that TAP sales personnel had provided individual physicians with dozens of free dosages of Lupron, on the assumption that the physician would nonetheless claim reimbursement and thereby net a windfall profit from the federal government.

Most of these allegations, if proven true, would likely violate the anti-kickback provision of the Medicare and Medicaid Fraud and Abuse statute and the Prescription Drug Marketing Act of 1987.[15] Had the United States prevailed on these claims, HHS would have had the authority to exclude TAP from participation in Medicare and other federal health care programs, a result that would have imperiled the economic viability of the company.[16]

To settle the dispute and avoid the possibility of being excluded from continued participation in federal health care programs, TAP agreed to settle the matter, enter a single count guilty plea, and pay a substantial fine and civil penalty.[17]

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[15]42 U.S.C. § 1320a-7b(b)(2)(B); 21 U.S.C. §§ 333(b)(1)(B), 353(c)(1)("PDMA").

[16]*See* 42 U.S.C. §§ 1320a-7a, 7b(f)(1).

[17]Settlement Agreement and Release, *United States v. TAP Pharmaceutical Products Inc.*, 01-CR-10354-ALL (D. Mass. Sep. 28, 2001).

theory of fraud-based liability without any concomitant announcement of limiting factors or "safe-havens," the settlement effectively places the future of the AWP debate into the hands of unelected judges, juries and the plaintiffs' bar.

IV. THE FALSE CLAIMS ACT DOES NOT APPLY TO AWP PRICING

Given the federal government's long-standing acknowledgment that AWP is but a "sticker" price for pharmaceuticals and that the government persisted in using AWP as the basis for applying reimbursement formulas under Medicaid and Medicare, it would seem difficult, if not impossible, for the government to make out a credible FCA claim had the TAP case actually gone to litigation. To be entitled to damages under the FCA, the government must first demonstrate that: (1) the defendant submitted false information; (2) the defendant knew it to be false; and (3) the government relied upon the false information to its detriment.

In this case, to establish the "falsity" of the information submitted, the government would be required to demonstrate that its interpretation of AWP — that the AWP must bear some reasonable and yet undefined relationship to the actual transactional price — is correct and that any other potential interpretation of AWP is unreasonable.[19] Clearly when the President of the United States describes the

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[19] *See United States ex rel. Luckey v. Baxter Healthcare Corp.*, 2 F. Supp. 2d 1034, 1049 & n.9 (N.D. Ill. 1998) (government must prove that ambiguous terms are not subject to any reasonable alternative interpretation.), *aff'd*, 183 F.3d 730 (7th Cir.), *cert. denied*, 528 U.S. 1038 (1999).

While it might be difficult for the government to prevail in a False Claims Act case based upon this revised interpretation of AWP, the fact that HHS has the power to exclude pharmaceutical companies from Medicare and other health care programs in the event that it does prevail effectively precludes judicial review.[22] A responsibly-managed pharmaceutical company will simply not risk the destruction of its business in order to vindicate some abstract legal proposition, particularly where it might be vulnerable to an enforcement claim under some alternate and less questionable theory of culpability. Consequently, it is not likely that the issue of AWP liability will be resolved in litigation involving the federal government anytime soon.

V. DEFAULTING POLICYMAKING TO THE PLAINTIFFS' BAR

The issue will instead be resolved in the cloud of private party and state attorney general litigation which has exploded in the wake of the *TAP* settlement. Indeed, having articulated a broad theory of fraud liability that potentially sweeps in every pharmaceutical company in the nation, it is not surprising that the *TAP* settlement has been followed by dozens of class action cases that parrot the claims set forth in the *TAP* settlement — that the maintenance of AWP above and beyond actual transaction prices constitutes a fraud. The Justice Department and HHS lawyers have tried to articulate limits to the theory of AWP liability reflected in the

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[22] *See* 42 U.S.C. §§ 1320a-7a, 7b(f)(1).

constituting an pattern of racketeering."[24]

The future of these cases may be best represented by the Complaint filed in *Board of Trustees of Carpenters and Millwrights of Houston v. Abbott Laboratories, Inc.*[25] There, a statutorily defined employee benefit plan representing a group of class action plaintiffs brought fraud and RICO claims against all "engaged in the business of manufacturing, marketing and selling prescription pharmaceuticals throughout the United States."[26] The class includes any entity in the United States "who purchased a drug manufactured by any defendant when the purchase price of that drug was based in whole, or part, upon the published AWP during the period 1993 through the present."[27] The plaintiffs salt the now familiar charges regarding AWP with anecdotal snippets gleaned from government settlements and Congressional investigative reports and public documents, some of which relate questionable non-AWP related activities by certain manufacturers, to bolster their case against the industry.

The now ubiquitous state attorneys general have also climbed aboard the AWP bandwagon. Illustrative is the *State of Nevada v. Abbott Laboratories, Inc.*, a state law-based suit that purports to join as defendants companies that are or have

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[24]Complaint at ¶ 139.

[25]No. Civ. 5010 V 339, (E.D. Tex. Dec. 24, 2001).

[26]Complaint at ¶¶ 2, 80.

[27]*Id.*

illegal conduct. That theory of liability flies in the face of well-entrenched regulatory policies that were specifically described by the President of the Unites States as being both "legal" and "embedded" in the Medicare program and subsequently reaffirmed by Congress. Regardless of the outcome, these cases guarantee that the pharmaceutical industry will be required to pay millions to defend practices undertaken in good-faith reliance upon an established and unambiguous regulatory regime. And to the extent that the courts adopt any of the theories of AWP liability being advanced in these cases, the ability of HHS and the Congress to maintain control over this critical regulatory program will be substantially and forever compromised.