

## STATES' USE OF LAWSUITS TO REGULATE DRUG PRICING THREATENS PATIENTS' HEALTH

by

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On February 13, 2003, New York State Attorney General Eliot Spitzer announced the latest in a series of cases that his office has brought against the pharmaceutical industry. *New York v. GlaxoSmithKline, P.L.C.*, *New York v. Pharmacia Corp.* This time, the target of General Spitzer's ire is the manufacturers of several powerful cancer-fighting drugs and anti-nausea medications that are administered intravenously to patients by oncologists at chemotherapy clinics. At issue is the question of how price information for each of these drugs is reported by its manufacturer to commercial data publishers who list Average Wholesale Price ("AWP"). According to the Attorney General's press office, these manufacturers "are alleged to have reported an inflated average wholesale price in relation to the price charged doctors, pharmacists and other healthcare providers" and "as a result of such inflated prices, government health plans and consumers ... have grossly overpaid for drugs." Press Release, Office of New York State Attorney General Eliot Spitzer (Feb. 13, 2003).

While the Attorney General's lawsuit promises to "help bring health care costs under control," the facts suggests otherwise. Although the press kits accompanying the Attorney General's lawsuits decry the alleged deprecations of pharmaceutical manufacturers, the real targets of these actions are the oncologists who administer cancer-fighting drugs. In the event that the Attorney General is successful in these actions, it is the revenue of oncologists, not the profits of pharmaceutical companies, that will be cut.

From the consumer's perspective, the Attorney General's lawsuits fail to acknowledge that many cancer clinics cannot cover their expenses for drug-related services under existing reimbursement formulae. If physicians' reimbursement rates for clinically administered pharmaceuticals are reduced as a result of

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these lawsuits, some concomitant increase in the reimbursement rate for clinical fees and other charges will be required to keep the doors to many clinics open. As a result, any potential savings in terms of reduced pharmaceutical reimbursements will be most likely offset in large part by increased service and clinical charges. Of course, should Congress or the state legislatures fail to make such adjustments quickly, clinics will close and, as a result of the Attorney General's lawsuits, many elderly cancer patients may well find that some of the more modern and innovative cancer treatments are simply no longer available.

At bottom, these lawsuits represent a much larger trend in healthcare management where key coverage and reimbursement decisions are no longer being made by responsible healthcare officials but are rather the product of ad hoc solutions being imposed as the result of litigation or the threat of litigation. Because prosecutors have neither the responsibility nor competence to administer these programs on a system-wide basis, the courts should be wary of prosecutors and plaintiffs' lawyers who condemn long-standing and well-recognized practices as fraudulent or illegal, particularly where such practices have received the tacit or express approval of state and federal regulators. To do otherwise jeopardizes the health of at-risk patients.

***Reimbursement for Pharmaceuticals.*** The emergence of AWP as a basis for calculating drug reimbursement rates occurred many decades ago when private insurers needed a way to approximate the market prices of thousands of pharmaceutical products in a constantly evolving marketplace in which new products are regularly emerging and the prices paid in real transactions frequently vary. The confidential nature of the actual transaction prices made tracking actual sales and prices infeasible. Sensing a business opportunity, private publishing companies such as the *Red Book* and *Medispan* began publishing periodic compilations of product prices based on voluntary submissions by manufacturers. The publishers normally establish the AWP for any drug by taking the "wholesale acquisition cost" reported by manufacturers and adding a 20% to 25% increase to reach "average wholesale price" or AWP for each drug.

Both public and private health insurance programs understood that the published AWP's represented useful reference points, not actual prices. The actual wholesale markup for most pharmaceuticals falls far short of the 20% to 25% added by the data publishers. And manufacturers may offer discounts and rebates from wholesale acquisition cost, especially in the case of drugs where competitive alternatives exist. AWP has long been recognized by federal regulators and the healthcare industry as being a "sticker" price for drugs, in much the same way as automobile manufacturers post a Manufacturers Suggested Retail Price ("MSRP") for their products.<sup>1</sup> And like the MSRP, private insurers and government at all levels have long understood that AWP overstates the actual selling price of these drugs.

But by using AWP as a reference point and by imposing reimbursement rates expressed as a fraction of the AWP, both public and private insurance programs found the published AWP's to be a useful tool to administer their programs. The Medicare program currently reimburses physicians for drugs administered in their offices based on 95% of AWP. 42 U.S.C. § 1395u(o)(1). Many private insurers also base reimbursement on AWP, with most offering a higher percentage of AWP than Medicare. Of course, in both public and private insurance systems, the system administrators ultimately have the authority to re-adjust reimbursement rates or use other reference points to fine-tune their systems and to meet changing conditions.

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<sup>1</sup>See, e.g., Department of Health and Human Services Office of Inspector General, "Limitation on Payment or Reimbursement for Drugs," Medicaid Action Transmittal, No. 84-12, 1984-2 Medicare & Medicaid Guide (CCH) ¶ 34, 157, at 10,191, 10,193 (Sep. 1984) ("Within the pharmaceutical industry, AWP means non-discounted list price. Pharmacies purchase drugs at prices that are discounted significantly below AWP or list price."). In a radio address in 1997, President Clinton made the same point: "Medicare reimburses doctors according to the published average wholesale price — the so-called sticker price — for the drugs. Few doctors, however, actually pay the full sticker price." White House Office of the Press Secretary, Remarks by the President in Radio Address to the Nation, 1997 WSL 767416, at \*1-2 (Dec. 13, 1997).

***Establishing Healthcare Policy Through Litigation.*** While over-reimbursing physicians for the cost of these drugs sounds counterintuitive in a period of constantly rising healthcare costs, it is generally understood that while oncologists are “over-reimbursed” for the drugs they administer, they are also “under-reimbursed” by Medicare in terms of the payments for the clinical services that they provide to their patients.<sup>2</sup> The current payments for drug administration services date from the 1980s when chemotherapy was largely a hospital procedure and office-based chemotherapy was limited to simple procedures. Current payment amounts for office procedures are still based on those limited procedures even though the large majority of cancer chemotherapy, including complex procedures, has now moved to physician offices. See American Society of Clinical Oncology, “Reform of the Medicare Payment Methods for Cancer Chemotherapy” (May 2001) (“ASCO White Paper”) at 16-18 (accessed at [www.asco.org/asco/downloads/general/ASCO%20White%20Paper%20on%20AWP.pdf](http://www.asco.org/asco/downloads/general/ASCO%20White%20Paper%20on%20AWP.pdf)). The rigidities of the Medicare payment system however, have kept reimbursement rates for services static and, as a consequence, the Medicare system has permitted over-reimbursement for pharmaceuticals in order to keep overall reimbursement rates in line.

Congress has recognized the need to simultaneously adjust the various components of the Medicare payments system but has yet to devise a workable and acceptable solution. *However, Congress has considered and rejected the very solution that the Attorney General would now impose as a consequence of his lawsuit.* Indeed, while the Administration and the Department of Health and Human Services have, from time to time, floated proposals to tie the Medicare drug reimbursement formula to rates more in keeping with the actual market prices of these drugs, Congress has resisted such moves.<sup>3</sup> Congress is again considering revising the Medicare drug payment methodology but, unlike the Attorney General, the current congressional proposals would couple reduced payments for drugs with increased payments for the related services. See, e.g., S. 1, 108<sup>th</sup> Cong. § 433; H.R. 1622, 108<sup>th</sup> Cong.; H.R. 2573, 108<sup>th</sup> Cong. §303.

***Consequences of Partial Reform.*** It is worth considering the consequences of Attorney General Spitzer’s success in these lawsuits. If AWP in its present formulation was eliminated and replaced by prices more in keeping with the actual market prices of these drugs, oncologists and cancer clinics would most likely no longer be able to treat Medicare patients with cancer unless reimbursement amounts for other cost elements are adjusted upwards. And nothing in Attorney General Spitzer’s lawsuit would increase these other reimbursement amounts.

Medicare patients with cancer will have no other feasible alternative if oncologists can no longer afford to treat them. Although hospital outpatient departments currently treat some patients — an estimated 20 % or so — they do not have the capacity to absorb the other 80 % if office-based treatment becomes financially impossible. See ASCO White Paper at 13-15.

Moreover, cancer patients could not buy their way out of this problem by making extra payments to their oncologists. Federal law prohibits any extra charges to Medicare patients for drugs and permits a maximum 15 % charge above the Medicare payment amount for services. 42 U.S.C. §§ 1395u(o)(3),

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<sup>2</sup>See, e.g., letter from Nancy-Ann DeParle, Administrator of the Health Care Financing Administration, to Members of Congress, dated Sept. 8, 2000 (“[W]e have concluded that Medicare payments for services related to the provision of chemotherapy drugs and clotting factors used to treat hemophilia and similar disorders are inadequate . . .”).

<sup>3</sup>In 1997, the Clinton Administration proposed legislation that would have based Medicare payment for drugs on physicians’ estimated acquisition cost. This proposal was rejected by Congress in the Balanced Budget Act of 1997, Pub. L. No. 105-33, which retained the AWP system but reduced payments from 100% to 95% of AWP. Subsequently, the Administration proposed a reduction of payments to 83% of AWP, but Congress did not enact that approach. In 2000, the Department of Health and Human Services distributed catalog prices of certain drugs to its Medicare carriers and suggested that they be used instead of AWP. Congress responded with section 429 of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000, Pub. L. No. 106-554, which placed a moratorium on administrative changes in payments for drugs pending completion of a study by the General Accounting Office.

1395w-4(g)(1)(A)(I), (2)(C)-(D). The law also effectively prohibits Medicare patients and doctors from making a private cash deal outside the Medicare program rules. *See* 42 U.S.C. § 1395a(b).

***The Limits of Litigation-Driven Healthcare Policy.*** It is noteworthy that the New York lawsuit includes no alternative explanation of what the manufacturers ought to have done. Companies that do not sell all their product at list price ordinarily sell at a variety of prices depending on the volume purchased, competitive conditions, and other factors. Since only one price is reportable, what is the price that New York contends is a non-fraudulent representation?

New York is not alone in its inability to go beyond allegations of fraud to a statement of what would constitute a non-fraudulent submission. Connecticut Attorney General Richard Blumenthal filed a comparable action against the same cancer drug manufacturers in the weeks following the New York lawsuits, and federal enforcement authorities, who are alleging similar improper conduct by pharmaceutical manufacturers, also decline to announce any rules on what constitutes an accurate statement of wholesale acquisition cost or AWP. *See* Business/Financial Desk, *Connecticut Says It Is Suing Seven Drug Makers*, N.Y. TIMES, Mar. 14, 2003. The federal government extracted settlements from TAP Pharmaceuticals and Bayer in which the companies were compelled to enter into corporate integrity agreements. Although the companies were accused of improper conduct with respect to AWP, the government did not attempt to define what would have been proper price submissions related to AWP but instead established a new requirement to submit information to the government on “average sales price” in the hope, not yet fulfilled, that Medicare and Medicaid could revise their payment methods to be based on those prices instead of AWP. *See* Corporate Integrity Agreement between the Office of Inspector General of the Department of Health and Human Services and TAP Pharmaceutical Products, Inc. (Sept. 28, 2001) at 8-11; Corporate Integrity Agreement between the Office of Inspector General of the Department of Health and Human Services and Bayer Corporation (Jan. 23, 2001) at 11-15.

Establishing rules on selecting a single published price to represent a potentially wide range of transaction prices and terms of sale is obviously a complex issue that can only be resolved through adoption of standard criteria by private and public insurers. Yet government litigators ignore congressional and regulatory standards and, unable to articulate what the rules for non-fraudulent price reporting might be, seem content to attack price reporting in particular cases and leave the rest.

***Conclusion.*** There is a truism that holds that if the only tool one has in one’s tool box is a hammer, then every problem starts looking a lot like a nail. So it is with state attorneys general. The problem is that lawsuits are particularly ill-suited instruments for fine-tuning the processes by which we compensate physicians for providing life-saving drugs to patients. While Attorney General Spitzer’s press release promises that the successful prosecution of these cases could “help bring healthcare costs under control,” a more likely result is that many elderly patients may well lose the access they currently have to clinical oncology services. Such are the limits of making policy through litigation.