Legal Opinion Letter

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ALABAMA SUPREME COURT REJECTS PHARMACEUTICAL PRICING "REGULATION THROUGH LITIGATION"

by
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In one of 2009's most significant state court rulings, the Alabama Supreme Court reversed verdicts against three prescription drug makers totaling over a quarter billion dollars. The court's decision in *AstraZeneca LP v. State of Alabama*, 2009 WL 3335904 (Ala. Oct. 16, 2009), is "exemplary of litigation currently pending in state and federal courts" involving allegations that the nationwide pricing policies of pharmaceutical manufacturers caused states to overpay for Medicaid recipients' prescription drugs. The actions originated in 2005 when Alabama Attorney General Troy King, working with privately retained contingency fee lawyers, sued over 70 pharmaceutical manufacturers, including defendants AstraZeneca, Novartis, and GlaxoSmithKline. The Alabama Supreme Court ruled 8-1 that the defendant companies did not defraud the state.

Background. Over the past several years, states such as Alabama, represented by contingency fee lawyers, have sued virtually the entire pharmaceutical industry alleging fraud in the reporting of prices for drugs covered under Medicaid programs. State Medicaid agencies reimburse providers – typically treating physicians and retail pharmacies – for the costs of prescription drugs disbursed to individuals who cannot afford to pay their own medical bills. Medicaid reimbursements may be made on the basis of an estimated cost, such as the "average wholesale price" ("AWP") or "wholesale acquisition cost" ("WAC"), which is supplied by manufacturers to an independent price reporting service.

AstraZeneca and similar lawsuits involve claims that the states were unaware that pharmaceutical manufacturers reported "list prices," which did not include discounts, rebates or other price concessions. The lawsuits allege that providers were over-reimbursed because the states unwittingly used the reported list prices in their Medicaid reimbursement formulas.

The Alabama Supreme Court Decision. After careful and thorough review of the factual record, the Alabama Supreme Court concluded that state regulators could not have reasonably relied on the pharmaceutical manufacturers' published prices for prescription drugs. Numerous government publications and other public reports clearly demonstrated that Medicaid regulators understood that both AWP and WAC were undiscounted "list prices" for pharmaceutical products – like the sticker price on a

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new car or a grocery item subject to a coupon in the local paper. Alabama was not duped into paying the undiscounted price. Tellingly, notwithstanding the fact that the Alabama lawsuits were filed several years ago, the State has not changed its Medicaid reimbursement methodology and has continued to rely on the same reported prices it claimed to be fraudulent.

The Alabama Supreme Court concluded:

> the State's argument that it believed the published AWPs to represent actual AWPs is simply untenable. On the contrary, it is clear beyond cavil that the reimbursement methodology adopted by the [Alabama Medicaid 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.'

Regulation through Litigation Rejected. The Alabama Supreme Court appreciated that litigation such as *AstraZeneca* "is essentially an 'attempt to use tort law to re-define [state] Medicaid reimbursement obligations.' . . . Such regulation through litigation raises, of course, serious questions of federal preemption and supremacy." This practice challenges business conduct which legislators and regulators, who are properly charged with balancing often competing policy considerations, have permitted. Fairness concerns also come into play. *In re Zyprexa Prods. Liab. Litig.,* 2009 WL 4260857, *66 (E.D.N.Y. Dec. 1, 2009) (Weinstein, J.) ("this slash-and-burn-style of litigation would arguably constitute an abuse of the legal process.").

More broadly, the AWP litigation is part of a trend of government executive branch officials partnering with private contingency fee lawyers to sue lawful businesses. The trend began with the coordinated state attorneys general litigation against tobacco product manufacturers, which resulted in the roughly $246 billion Master Settlement Agreement in 1998. Since then, state and local government lawyers have been looking for their "next tobacco." They have filed actions against numerous product manufacturers, including gun makers for harms caused by gun violence, former manufacturers of lead pigment and paint for harms caused by deteriorated lead paint, and energy companies for carbon dioxide emissions that allegedly contribute to global warming, among other actions. Economic hardship and rising health care costs may be fueling efforts by state executives to use litigation as a way to control or recoup health care expenditures.

When attorneys general work with private attorneys – individuals with interests that may be different from the state – the overall benefit to the public becomes suspect at best. As former Clinton Administration Labor Secretary Robert Reich, who coined the phrase "regulation by litigation," observed: "This is faux legislation, which sacrifices democracy to the discretion of administration officials operating in secrecy."

Looking Ahead. *AstraZeneca* creates a significant hurdle for the state in related cases, such as a nearly $80 million judgment being appealed by generic drug manufacturer Sandoz, Inc. The reasoning of the Alabama Supreme Court also indicates that there will be significant proof problems for other states, particularly with respect to proving reasonable reliance.

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