



# The Monitor

The Inside Source on the Public Health Service 340B Drug Discount Program

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## BREAKING NEWS ALERT

### **9<sup>th</sup> Circuit Reverses Lower Court and Recognizes Covered Entity Right to Sue Manufacturers for 340B Overcharges**

*Federal Court Decision Could Have Dramatic Impact on Pricing Disputes*

A three-judge panel of the appeals court for the 9<sup>th</sup> federal circuit has unanimously reinstated a previously dismissed lawsuit brought by Santa Clara County, Calif., and a number of county-operated 340B entities to recover alleged prescription drug overcharges from 10 pharmaceutical manufacturers.

The panel, in an Aug. 27 opinion written by Judge Raymond Fisher, found that the covered entities had standing to bring the lawsuit because they are direct beneficiaries of the 340B pharmaceutical pricing agreements (PPAs) between the Health Resources and Services Administration (HRSA) and manufacturers. Evidence of an intended benefit is reinforced by federal statute, the panel said, returning the case to federal district court for a decision. The 9<sup>th</sup> Circuit also held that covered entities have the right to enforce discount pricing provisions under the PPA and to sue for reimbursement of payments in excess of the 340B ceiling prices.

Attorney Robert Litt, who represents AstraZeneca Pharmaceuticals and argued the case for the defendants, says his client and its co-defendants have not yet decided whether to appeal the case. However, Litt says the decision was wrong and that he is “pretty confident” his side will ultimately prevail because the pharmaceutical manufacturers engaged in no wrong-doing.

Because the decision was rendered by only three of the judges on the 28-judge appeals court, the manufacturers can appeal the ruling by the smaller panel to a limited full court review by a panel of 11 judges. An appeal could occur, because a plaintiffs’ victory could result in additional overcharge litigation being brought against the defendant drug manufacturers.

Besides AstraZeneca, the defendants include Aventis, Bayer, Bristol-Meyers Squibb, Pfizer, Schering-Plough, SmithKline Beecham, TAP, Wyeth, and ZLB Behring. If an appeal to the larger panel does not result in a decision favorable to the defendants, they could then appeal to the U.S. Supreme Court.

The appeals court decision reverses a decision by U.S. District Court Judge William Alsup of the Northern District of California, who had dismissed the case in a July 2006 ruling that rejected the plaintiffs’ false claims act allegations and contract claims. On the

contractual issue, the lower court held that a third party can sue on a contract only if the participants in the agreement in the case of a PPA – HRSA and the drug manufacturers – intended to give the third party a right to sue. Judge Alsup held that the PPA did not give 340B providers standing to sue on the contract.

Santa Clara originally brought the suit in 2005, citing reports by the Department of Health and Human Services’ Office of the Inspector General (OIG) that manufacturers were overcharging 340B entities. The District Court faulted the plaintiffs’ use of the OIG reports to substantiate overcharge claims, despite the plaintiffs’ contention that 340B providers have no access to confidential pricing information and needed to rely on the government studies.

The appeals court did not rule on the sufficiency of the plaintiffs’ evidence of overcharges, but focused its review on the providers’ standing under the contract. The appeals panel rejected the manufacturers’ position that the existence of HRSA’s dispute resolution procedure restricted providers’ access to the courts, noting that those procedures are voluntary. It also rejected the manufacturers’ argument that only HHS, rather than the federal court, has the authority to determine whether 340B providers have a private right to sue, and found that Santa Clara, as a county, has a federal common law right to sue.

More details on this matter will appear in the September issue of *The Monitor*, which will be published shortly.