

# U.S. Judge Issues Injunction Against Drug-Pedigree Rules

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By Beth Bacheldor

Dec. 8, 2006—A federal court has issued an injunction against requirements in the Prescription Drug Marketing Act (PDMA) of 1987, which had been set to take effect Jan. 1, 2007. Those requirements would have compelled certain drug distributors to document (via a pedigree, though not necessarily in electronic form) the chain of custody of drug products moving through the distribution system.

The injunction basically reinstates a stay on the PDMA regulations first put in place in 2000, several months after the U.S. Food and Drug Administration (FDA) issued its final rules based on the act. The agency had instituted the stay because of concerns that pedigrees would negatively impact small wholesalers. In June 2006, the FDA announced it would end the hold on the pedigree requirements on Dec. 1 in preparation for the January 2007 implementation of the PDMA (see FDA Issues New 'Counterfeit Drug Task Force' Report).

The federal court's ruling favors a group of smaller, independent wholesalers that argued, in a suit filed against the Department of Health and Human Services and the FDA on Sept. 20, that the implementation of the pedigree requirement was unconstitutional because it would be applied only to secondary wholesalers, not larger distributors. U.S. District Judge Joanna Seybert, in the Eastern District of New York, ruled in favor of the plaintiffs on Dec. 4, adopting an earlier report and recommendation from Magistrate-Judge A. Kathleen Tomlinson.

Robert Drucker, president and CEO of RxUSA Wholesale Inc.—one of the seven companies that jointly filed the suit in September—says the injunction is good news for secondary wholesalers. "There is a blatant power play by the big three pharmaceutical wholesalers, who are trying to kill all the secondary wholesalers," Drucker says. RxUSA and other secondary drug wholesalers, he explains, aren't against electronic pedigrees. . In fact, his company uses software from SupplyScape to create e-pedigrees and is currently compliant with the FDA's proposed pedigree requirements.

The problem with the pedigree requirements in the PDMA, Drucker says, is that they exempt larger distributors and require pedigrees only from secondary wholesalers. "Last year, I bought \$200 million worth of drugs from McKesson and sold them. Without this injunction, if I bought \$200 million more from McKesson, I wouldn't be able to sell them because McKesson wouldn't have to provide me with a pedigree that traces the chain all the way back to the supplier, and I wouldn't have a pedigree to pass on."

Drucker says he would fully support the PDMA's pedigree requirements if the larger wholesalers weren't exempt from complying. "If the exemption were removed, we'd be for the PDMA Act. We are not interested in striking down e-pedigrees. We support them," he says. "But if your competitor had a right to say whether you lived or died, would you allow that?"

The FDA has declined to comment on the court's ruling until the written order comes down, which Drucker expects to happen within the next few days.

"The U.S. District Court judge has issued only an oral opinion at this point," notes Crystal Rice, a spokeswoman with the FDA. "We are waiting for the written opinion. We will evaluate it and provide a statement regarding the PDMA pedigree provisions as soon as is practicable."

RELATED\_ARTICLES Douglas Farry, a managing director and chair of the RFID practice at McKenna Long & Aldridge, a nationwide law firm that focuses on the intersection of public policy and technology, says the secondary wholesalers' lawsuit and subsequent ruling in their favor highlights the fact that "there are a lot of unanswered questions about how to apply e-pedigrees."

Farry, who oversees McKenna Long's RFID Law Blog, says its important for RFID vendors to work with their customers to find public-policy solutions that work for everyone.

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