FDA Still Balking At 1988 Drug Law
Tool To Fight Counterfeiting Of Medicine Still In Limbo

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WASHINGTON -- Despite its dire warnings about counterfeit prescription drugs flooding into the United States, the Food and Drug Administration has never used a "valuable tool" Congress gave it nearly 16 years ago to combat the problem.

A law passed in 1988 requires most drug wholesalers to provide sales histories, known as pedigrees, that would trace the movement of each prescription drug - from manufacturer to hospital, clinic or pharmacy.

The paper trail would establish an uninterrupted chain of custody as medicines make their way through the complex U.S. distribution system. The idea is that a drug that did not have a pedigree, or had a pedigree with gaps, would be subject to immediate suspicion.

But for 16 years the pedigree requirement, aimed at safeguarding the U.S. drug supply, has never been put into effect - even though drug manufacturers support it. Under pressure from drug distributors, the FDA has delayed enforcing it four times. Within the next several weeks the agency will make key decisions about the requirement.

In contrast to the federal government's repeated delays, Florida officials moved quickly last year to require the sales histories for high-use drugs. A state grand jury had concluded that "buying drugs with missing or forged pedigree papers is like buying an open bottle of medicine off the drugstore shelf."

Florida has had one of the worst counterfeiting problems in the nation. Gov. Jeb Bush, who signed legislation that includes a state pedigree requirement, said the measure would give patients confidence the drugs they are taking are "not diluted or relabeled or altered."

"I am very confident people will stop fooling around" if the federal pedigree requirement is put into effect, said J. Aaron Graham, vice president for security at Purdue Pharma, a Stamford-based drug manufacturer. He endorsed paper pedigrees as a temporary measure while experts work on a more sophisticated tracing technology.
Asked why his agency has not enforced the pedigree requirement, Dr. Mark B. McClellan, the FDA commissioner, said that although Congress passed the law, it also has expressed strong concerns about its feasibility as written.

"This was a law written 15 years ago in a different era of both counterfeiting technology and anti-counterfeiting technology," he said. "It didn't even extend to all parts of the drug distribution system."

"In contrast," McClellan said, "today we have the potential, perhaps, in the next few years, to come up with an electronic version of dealing with this problem more cheaply, more reliably, more securely in a way that can't be faked, like paper records."

Larry D. Sasich, a research analyst at the consumer group Public Citizen, said requiring pedigrees would help consumers now. In addition to slowing the flow of counterfeit drugs, Sasich said, pedigrees could make it easier to notify pharmacies and patients in the event of a drug recall.

Marvin Shepherd, director of the Center for Pharmacoeconomic Studies at the University of Texas, said the 1988 law was "a great law."

"But the wholesale [drug] industry came unglued," Shepherd said. "They just balked at it completely."

Another Delay

The FDA completed a final rule spelling out the details of the requirement in 1999 but has never allowed it to take effect. The latest delay will expire April 1, but a trade group representing prescription drug wholesalers has requested another one-year postponement. Wholesalers, who move prescription drugs from manufacturers to final users, argue the pedigree requirement would be costly and ineffective.

The Florida grand jury, which completed a comprehensive study of the counterfeiting problem, disagreed, contending that properly verified pedigrees are "the cheapest, easiest and most effective way" to prevent counterfeit drugs from entering the U.S. market.

The pedigree requirement has received much less attention than another provision of the 1988 law, one that prohibits the import of U.S.-made prescription drugs into the United States from other nations such as Canada.

The FDA has vigorously supported the import ban in the face of challenges from several cities and states seeking to bring in lower-cost drugs from abroad. Imports, even from Canada, could expose U.S. residents to the rising international tide of dangerous counterfeit drugs, the FDA says.

At least three factors contributed to the delays in putting the pedigree requirement into effect:

Wholesalers, especially smaller wholesalers, assert that thousands of their members might be forced out of business if they have to comply with the pedigree requirement. The Small Business Administration's Office of Advocacy backed them up in a February 2000 letter to the FDA that said the pedigree requirement could cause "serious disruption" in the nation's drug-distribution system. The wholesalers argue that new high-tech tracking methods would be more effective in identifying counterfeit drugs than paper pedigrees, which, they say, could be forged.

Members of Congress who control the FDA's budget have responded to the wholesalers' pleas. In 2000, the House Appropriations Committee supported the FDA's decision to delay putting the pedigree provision into effect. FDA records show that more than a dozen members of Congress took an interest in the issue. In a
letter to the FDA seeking a delay, Rep. Jo Ann H. Emerson, R-Mo., who serves on Appropriations, said the pedigree requirement would require most wholesalers "to liquidate their inventory and go out of business, none of which is of benefit to the industry, the FDA or consumers."

The FDA, like other federal agencies, can ill afford to ignore Congress. Responding to the House appropriators in 2001, the FDA called the drug pedigree system "a valuable tool ... [that] is a deterrent to the introduction and sale of substandard, ineffective and counterfeit drugs." But the FDA also reported that the pedigree requirement exempts a few large wholesalers, a loophole that it said only Congress could correct.

Undercutting The Law

Last fall, the FDA adopted a much more critical position toward paper pedigrees than it had in 2001. In an unsigned preliminary report on plans to combat the rise in counterfeiting, the FDA said: "In addition to being costly, tracing a drug pedigree on paper, as envisioned by the [1988 law], is subject to multiple record-keeping failures, and may be subject to fraud."

McClellan, a Bush administration appointee, took over as FDA commissioner between the agency's two statements. But Bruce Levinson, director of the Pharmaceutical Policy Project at the Center for Regulatory Effectiveness, said he does not think partisan ideology influenced the FDA's shift in position.

Levinson noted that President Reagan, a conservative, signed the 1988 measure, but that most of the delays came during the more liberal Clinton administration. Indeed, while Clinton was in office, the Small Business Administration wrote the FDA to urge delaying the pedigree requirement. The center wants the requirement to take effect April 1 as scheduled.

William W. Vodra, a former associate FDA general counsel, said it was not unusual for members of Congress to vote for a measure that has broad public support and then use the appropriations process to undercut it. "When the failure to implement results in some public scandal, the Congress then excoriates the agency for failing to ask for the money needed," Vodra said. "It is all a game to the politicians."

Gerald F. Meyer, a former senior FDA official, said that in the early 1990s White House opposition and underfunding by Congress often hampered the FDA's attempts to put new rules into effect. In the mid-1990s, then-House Speaker Newt Gingrich, R-Ga., tried to dismantle the agency. But, like Vodra, Meyer could not recall the particulars of why the pedigree requirement was delayed.

Health And Safety Risks

The 1988 law emerged after a series of congressional hearings raised concerns about the safety and security of prescription drugs in the United States. Among other things, lawmakers found that imported drugs represented "a health and safety risk" to American consumers because those drugs could become sub-potent or adulterated during foreign handling and shipping.

The law said only U.S.-based manufacturers could bring drugs shipped to other nations back into the United States. It also set up the pedigree regime to trace the movements of prescription drugs. Congress changed some of the requirements in 1992, so it was not until 1994 that the FDA initially proposed a rule to put the pedigrees into effect. An agency chronology said the FDA received "very few comments reflecting concern" about the proposed rule.

It was another five years, in 1999, before the FDA issued a final pedigree rule. That set off the opposition, and the agency began to receive critical comments from wholesalers, trade groups and members of Congress objecting to certain provisions of the proposed rule, which was to take effect in 2000. The result was the first of the FDA's four decisions to delay the final rule.
Alan Goldhammer, associate vice president of the Pharmaceutical Research and Manufacturers of America, said his trade group wants the pedigree requirement to take effect immediately as part of a broader industry plan to combat counterfeiting.

Paper pedigrees "provide the most cost-effective currently available method for ensuring that counterfeit drugs do not enter the distribution system," Goldhammer said. He added that most of the information needed to produce pedigrees appears on invoices manufacturers include when they ship new drugs to wholesalers.

But Sal Riccardi, president of the Pharmaceutical Distributors Association, said the pedigree requirement would "effectively jeopardize the businesses of over 6,000 small wholesalers." The 1988 law puts small wholesalers at a disadvantage because they would have to provide pedigrees while a handful of very large wholesalers would be exempt, Riccardi said. Several industry officials said this issue has become more important in recent years as small wholesalers have proliferated.

"We all want to be part of the solution" to counterfeiting, said Anthony L. Young, counsel for the Pharmaceutical Distributors Association. But he added that wholesalers oppose any solution that would put them out of business.

Bar Codes And Chips

In place of paper pedigrees, the distributors association favors developing high-tech methods to track the movements of prescription drugs. This would include bar codes and small electronic chips that might be included in every package before it leaves a drug manufacturer.

FDA officials, including McClellan, have spoken hopefully about the prospects for this technology and said it might be put into effect "over time" as part of a broad anti-counterfeiting strategy the agency is expected to announce soon. The FDA invited several dozen companies to make proposals for so-called "track-and-trace" technology at a conference last fall, but some were cautious about the prospects, at least for the short term.

"Effective technology is many years away from implementation," said David W. Blois, a Merck & Co. vice president. "The scope of this technology would be far greater than any currently in operation."

Graham, the Purdue Pharma security chief, said the new technology will involve additional costs. But, he said, if progress continues at the current rate, the technology could be ready earlier than many skeptics predict. "It will be a good thing."

In Florida, meanwhile, officials began enforcing a new pedigree requirement in September that covers 30 prescription drugs selected because their high sales volume and high cost make them appealing to counterfeeters. In 2006, pedigrees will be required on even more drugs. Shepherd, the University of Texas expert, said Florida's decision was "a good pilot way" to put a pedigree requirement into effect.

Florida officials acted after the grand jury said it found the arguments against paper pedigrees "weak and unpersuasive." The grand jury added:

"In essence, the wholesale industry is fighting for the right to keep secret from their own customers the history of the drugs that they're being sold. We do not believe there is ever any good excuse to fail to disclose material information to buyers."

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