Pharmaceutical Pedigree

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Pedigree legislation, a part of an over-all anti-counterfeiting effort, is intended to cut down on counterfeit product from entering the supply chain. A "pharmaceutical pedigree" tracks the handling of product from the authorized wholesaler through to the dispensing pharmacist. While the concept is laudable there can be major issues with the way in which the industry is asked to comply, including the technology employed, the timelines expected, and the basic approach.

Federal Authority

In 1987, the Food & Drug Administration was granted authority to develop and enforce pedigree-tracking regulations under the Prescription Drug Marketing Act (PDMA). Enforcement has been delayed until December 1, 2006 [21 CFR 203.50]. In February 2004, the FDA established a Counterfeiting Drug Task Force that is considering a revised PDMA implementation date.

State Action

In the absence of federal activity, the states have acted. By 2003 three states had taken the lead on the issue (Florida, California and Nevada). Florida passed its law in 2003 (SB 2313) and was the first in the nation, many states have considered using this for a template for their own laws. Nevada followed suit close behind building upon an existing statutory framework. California passed its law in 2004 (SB 1307 - Figueroa).

In 2005, an additional 8 states adopted some sort of pedigree law (Arizona, Indiana, Iowa, New Jersey, New Mexico, Oklahoma, Texas and Virginia), while an additional 9 states (Arkansas, Illinois, Kansas, Maryland, Missouri, Nebraska, Oregon, and Utah) had considered, but ultimately failed to pass, similar legislation.[1]

In Florida, pedigrees are now required for the 34 top-selling drugs in Florida; all other drugs will come under that law as of July 1, 2006. Revisions are currently being considered that would delay implementation, especially as it pertains to Radio Frequency Identification (RFID) tracking (that technology is not anticipated to be commercially viable for two more years). The Florida Department of Health is in the process of revising its pedigree regulations.

California requires electronic pedigree tracking for all drugs sold in the state effective January 1, 2007. The rule-making process is currently underway, there is a possibility for a Pharmacy Board authorized extension to January 1, 2008 for implementation, and a further legislative extension is possible to January 1, 2009.

Nevada requires pedigrees for all drugs sold in the state, under legislation passed in 2003. And implemented the state's paper pedigree requirements for distributors other than those who are both an ADR and purchase product directly from its manufacturer. In 2005, the state enacted SB 37, which contained provisions for the implementation of electronic pedigree by January 1, 2007, but gave the Board of Pharmacy the ability to extend this date. The Nevada Board of Pharmacy has convened a stakeholders group to discuss the status and feasibility of implementing RFID technology.

The following states have since adopted Pedigree legislation:

State	Legislation
Arizona	HB 2193 of 2005, Ch. 290
Indiana	HB 1098 of 2005, P.L. 212
Iowa	HF 882 of 2005
New Jersey	SB 1753 of 2005, Ch. 206
New Mexico	SB 413 of 2005
Oklahoma	S 640 of 2005
Texas	HB 164 of 2005
Virginia	SB 1326 of 2005, Ch. 777

Currently, 11 states have pedigree laws, without federal action on this issue more states are likely to engage in passing their own pedigree standards. Compliance with these laws has the potential to be costly to many in the pharmaceutical industry, and they will face challenges at both the legislative and regulatory level.

National Standards

The National Association of Boards of Pharmacy (NABP) met in October of 2003 to develop model legislation for the states; among the provisions in their model act are anti-counterfeiting (pedigree) provisions. The NABP's intent was to take some of the best provisions in the Florida and Nevada statutes to include in its model law. In addition, both the HDMA and PhRMA/Pfizer each have model legislation on this issue. The HDMA proposal focuses on imposing stricter license standards for all distributors, with emphasis on due diligence, greater oversight,

increased penalties for those who traffic in counterfeit drugs, and focusing efforts on products most likely to be of interest to a criminal element.[2]

Technology

Discussion of pedigree implementation has circled around three different technologies. The first and easiest to implement is paper; in this system a case of drugs is accompanied by a paper document which traces its path through the distribution chain, being updated at each step. This approach can lead to a lot of paper files, and the potential for lost or torn documents. In an attempt to solve this problem and to make tracking of the package easier for all involved is the move toward electronic pedigree.

The electronic pedigree debate is where much of the current attention is focused. This electronic form can take two different paths, one is a barcode product – this enables a relatively easy collection of the needed information. This technology is already in use in Florida. Currently, the most talked about form of pedigree is called Radio Frequency Identification (RFID). This is a technology that most who are familiar with RFID admit will not be ready for broad commercial application until at least 2008. However, many involved in the discussion outside of the industry believe that this technology is currently available to manufacturers and wholesalers. The basic concept of this technology is that an electronic tag is applied to the product, when a scanner passes over the tag it is activated and a unique radio signal is sent out indicating the package contents to the reader. The costs involved with implementation, the distribution of the needed infrastructure in order to process the information are all barriers to those outside the industry that wish to push this technology. The Food and Drug Administration has stated that the "use of RFID technology is critical to ensuring the long-term safety and integrity of the U.S. drug supply."[3] There is a clear notice to industry to prepare for this eventuality.

Conclusion

In order to avoid a myriad of differing implementation strategies, the cleanest possible solution would be for the federal government to act under its authority granted by the PDMA, to create a single standard while simultaneously pre-empting state initiatives. If a state-by-state approach to pedigree is permitted to prevail, the result will be a "patchwork-quilt" of standards not to mention cross-jurisdictional enforcement issues that could be extremely problematic for a fast-moving and often complicated supply chain. In addition to variances in authorizing legislation those in industry will also have to comply with potential disparities in enacting regulation. The costs to any individual entity in the supply chain could be huge, and the technical requirements could be daunting. States, such as California, may prohibit manufacturers who fail to meet the standards from selling their product in the state.

1. 2005 Prescription Drug State Legislation, Natl. Council St. Legislatures, March 10, 2006.
2. HDMA Recommendations for Enhancing the Domestic Prescription Drug Supply Chain, www.healthcaredistribution.org, April 2004.
3. Radiofrequency Identification Feasibility Studies and Pilot Programs for Drugs, USFDA, November 2004.

NOTE: This Issue Brief was originally prepared by this author for a specific client, now out-of-business. Therefore, the content has been reclaimed by this author.