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A National, Uniform Paper Trail for Drugs?

Pending "pedigree" requirements will bring new uncertainties.

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On Dec. 1, 2006, after a series of stays, the drug pedigree regulations of the Food and Drug Administration will go into effect.

Lifting the latest stay ends years of uncertainty about whether and when the FDA's pedigree requirements would take effect, but it also creates much uncertainty within the drug-distribution chain.

Such uncertainty includes concerns and questions about:

- Who qualifies as an "authorized distributor of record";
- Whether to focus on the implementation of a paper or electronic pedigree system; and
- Whether it is feasible for companies to comply with a labyrinth of state-by-state pedigree requirements in addition to the federal regulations.

Of these, the last issue appears to be the overarching concern among the FDA, state regulatory agencies, and industry. Thus, many advocate a uniform national approach to eliminate the nearly impossible task of identifying, tracking subsequent changes to, and complying with, the current patchwork of state pedigree requirements.

To date, that hasn't been accomplished, partly because the FDA doubts it has the statutory authority to require such an approach. Congress, however, is moving to remove the uncertainty, and such legislation is likely to be eagerly welcomed.

THROUGH THE CHAIN

Congress enacted the Prescription Drug Marketing Act of 1987 (PDMA) to combat drug counterfeiting and diversion. The statute established federal requirements for the wholesale distribution of prescription drugs. The regulations implementing the PDMA establish minimum federal guidelines for state licensure and for tracking drug products through the distribution chain. The tracking provisions are commonly referred to as "pedigree" requirements. They were initially scheduled to take effect in December 2000 but were delayed until recently.

Federal pedigree requirements are codified in Section 503 of the Federal Food, Drug, and Cosmetic Act. Section 503(e)(1)(A) requires anyone engaged in the wholesale distribution of a drug product, excluding the manufacturer and any authorized distributor of record, to provide to the recipient of the drug product, prior to distribution, a statement (i.e., a "pedigree") that identifies each prior transaction of the drug, including the dates and the names and addresses of all parties. The PDMA defines an authorized distributor of record as an entity with whom a manufacturer has established an "ongoing relationship" to distribute the manufacturer's products. Nowhere, however, does the statute define "ongoing relationship."

The focus of the FDA's regulations implementing the PDMA's pedigree provisions is twofold: (a) to flesh out the required content of a pedigree and (b) to further clarify who is an authorized distributor of record. The content requirements are relatively straightforward, and the FDA has specified what a pedigree statement must include.

Greater debate surrounds the provision about authorized distributors of record—and their exemption from the federal pedigree requirements. The PDMA defines an "authorized distributor of record" as one with whom a manufacturer has established an "ongoing relationship" to distribute the manufacturer's products.

But the FDA's final rule goes one step further. It defines "ongoing relationship" and does so in a way that potentially significantly limits which entities qualify as authorized distributors of record. Under the final rule, an "ongoing relationship" is that association that exists only when a manufacturer and a distributor "enter into a written agreement under which the distributor is authorized to distribute the manufacturer's products for a period of time or for a number of shipments." If a distributor is not authorized to distribute a manufacturer's entire product line, the written agreement must identify the specific drug product(s) that the distributor is authorized to distribute.

Under federal regulations, only nonauthorized distributors of record must follow the pedigree requirements. That is, the pedigree requirement applies to "secondary wholesalers" (wholesalers purchasing from another wholesaler, rather than from the manufacturer or authorized distributor of record). Manufacturers and authorized distributors of record are exempt.

Although the FDA has recommended that manufacturers and authorized distributors of record pass a pedigree to their distributor, they are not legally required to do so. The FDA has received complaints over the years that no legitimate business reason exists for exempting authorized distributors of record from the pedigree requirements. There have also been concerns that the distributor exemption may provide an opportunity for a pedigree to be "laundered" by distribution of a counterfeit product to an authorized distributor of record. Moreover, some fear that the current definition of an authorized distributor of record is vague and subjective, causing confusion among wholesale distributors about their status and their pedigree requirements.

Adding further confusion are the state laws that do not contain provisions about authorized distributors of record. Florida's state pedigree law, for example, was amended in July to provide for an abbreviated pedigree for "direct purchases." These are defined as a wholesale distributor's purchase of a drug directly from the manufacturer that is then sold directly to the pharmacy, clinic, or hospital where the drug is dispensed.

Indiana's pedigree law uses a different test: If the product has stayed within the "normal distribution channel," no pedigree is required. Indiana's statute lists the specific distribution chains that are deemed to fall within that channel. In essence, these transactions include manufacturers, authorized distributors of record, designated third-party logistics providers, chain-drugstore warehouses, and pharmacies.

Electronic or Paper?

Both the PDMA and the FDA's regulations appear to envision a paper (versus electronic) transaction. This is hardly surprising given technology in the late 1980s, when the PDMA was enacted. Now, nearly 20 years later, sophisticated electronic pedigree technologies are being tested by drug manufacturers.

The FDA intends to help move the industry in this direction, an intent that initially formed the basis for the agency's stay of its pedigree requirements until Dec. 1. The FDA had sought to give industry time to adopt electronic track-and-trace technologies that would allow an electronic pedigree of a drug from its manufacture to its final dispensing point. These technologies, however, are not yet widely available, and thus the FDA lifted its stay.

Many companies will have to create systems for paper pedigrees to ensure pedigree compliance by Dec. 1, and then later replace them with electronic technology. Yet the agency has concluded it can no longer stay the pedigree requirements because of concerns about increasing drug counterfeiting and diversion. The FDA has indicated it intends to focus its efforts on helping companies adopt electronic technology over the next few years.

There appears to be a consensus that a paper pedigree is far less desirable than an electronic one. A paper pedigree does not permit an automated, comprehensive chain of custody for a shipment of drugs. But these features are possible through radio-frequency identification and other track-and-trace technologies.

Many argue that paper-based systems are more time-consuming and more vulnerable to forgery. Radio-frequency identification and similar electronic technologies, on the other hand, can provide a de facto electronic pedigree that represents an effective tool for preventing counterfeiting and drug diversion.

Finally, although the federal pedigree requirements do not yet require an electronic pedigree, some state laws do. For example, once California's pedigree statute goes into effect, it will require electronic pedigree technology. Similarly, both Indiana and Nevada have enacted pedigree laws that, when fully implemented, call for electronic pedigrees.

State Patchwork

Although the FDA acknowledges that a national uniform regulatory scheme of electronic pedigree requirements is desirable, it claims it does not have the statutory authority to establish one.

Consequently, in addition to the federal pedigree requirements, a number of states have either already enacted, or are currently considering enacting, their own pedigree requirements. These requirements differ from, and are in addition to, the federal pedigree requirements.

Moreover, they can vary significantly from state to state. Some states require electronic pedigrees, others apply pedigree requirements to entities in the drug-supply chain not covered under the PDMA, and still others may require that the pedigrees contain information additional to that required under federal law. Complicating the situation further is that state laws also apply to out-of-state wholesalers distributing into a state.

The current patchwork of regulations and lack of uniformity render compliance extremely difficult, significantly increase the cost of doing business, and potentially impede the PDMA's goal of combating counterfeiting and diversion.

The FDA's Counterfeit Drug Task Force has acknowledged that national uniform pedigree requirements would better ensure the efficient distribution of effective medicine. The task force also has expressed concern that 50 different state pedigrees could create confusion in the marketplace and could stifle interstate drug distribution. The concern has also been raised that the current state-by-state approach could encourage counterfeiters to do business where requirements are easier to circumvent. Even those states with pedigree requirements currently in effect have urged the FDA to establish uniform pedigree standards.

In the end, there appears to be general consensus that it may be preferable to have in place a universal electronic pedigree used by all wholesalers, including authorized distributors of record, that would document the movement of every prescription drug from the manufacturer to the dispenser. But the FDA takes the position that it lacks the authority to create such a system under the PDMA. It has, though, offered to provide technical help if new federal legislation is enacted.

National Standards

To address the push for national uniform pedigree standards, this spring Reps. Dan Burton (R-Ind.) and Gil Gutknecht (R-Minn.) and Sen. David Vitter (R-La.) introduced legislation requiring electronic pedigrees for all drugs.

The Reducing Fraudulent and Imitation Drugs Act of 2006 would direct the secretary of Health and Human Services to require prescription-drug packaging to incorporate radio-frequency tagging technology or similar trace-and-track technologies; tamper-indicating technologies; and, to the extent possible, blister security packaging. It would further require that these technologies be used exclusively to authenticate the pedigree of prescription drugs.

This legislation is still in committee. Nevertheless, given the immense pressure, it is likely that Congress will be forced to address these issues in this or similar legislation at some point in the near future.

In sum, though the FDA has finally lifted its stay on its final pedigree rule, questions and concerns continue to loom large. They are likely to do so until a national uniform pedigree system is put in place.

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