Drug Pedigree Systems

Helping eliminate counterfeit drugs and protect against drug errors

by Rolando DeCardenas

The Problems

Drug counterfeiting is a serious and growing problem—despite the efforts of pharmaceutical companies, distributors, healthcare providers, and the government. The term "counterfeit" encompasses many forms of illegitimate pharmaceuticals, such as those stolen, adulterated, inappropriately diverted, or blatantly fake medications—all of which have been found in this country's drug supply. Compounding the problem is the complexity of our country's drug supply chain.

The Solutions

To safeguard against counterfeiting and medical errors, the healthcare industry has developed two solutions: drug "pedigree" systems and certification programs. By tracing each step of a drug's journey through the supply chain—from manufacturer to distributor to provider to patient—drug pedigree systems authenticate drug safety. Certification programs, such as the National Association of Boards of Pharmacy's Verified-Accredited Wholesale Distributors™ (VAWD™) certification, ensure that a wholesaler has appropriate licensure, internal procedures, and employee background checks in place. To receive VAWD certification, a wholesaler must pass an intensive onsite survey of its processes and procedures, employee information, and business practices.

While the World Health Organization (WHO) estimates that only about one percent of drug sales in the United States market includes counterfeits, the U.S. Food and Drug Administration (FDA) acknowledges that the problem is real and growing. And, considering the FDA's estimate that four billion prescriptions were filled in the United States in 2005, one percent equates to a troubling 40 million prescriptions.[1]

State and federal reform to protect against counterfeiting and medical errors have produced uneven results. Some states, such as Nevada and Indiana, now *require* manufacturers, wholesaler distributors, retail pharmacies, and/or physicians' offices to produce pedigrees during audits. In other states, such as Florida and California, pedigree requirements were repealed, delayed, or scaled back due to pressure from wholesalers.

The outlook for a federal solution is just as murky. Congressional response to the growing drug counterfeit problem included H.R. 5156 that was introduced in April 2006. This bill, which has not made it out of committee, would amend the Food, Drug and Cosmetic Act to add prison time and fines for someone knowingly holding, selling, or dispensing counterfeit drugs. And on Dec. 1, 2006, the FDA had planned to begin full enforcement of pedigree requirements within the Prescription Drug Marketing Act (PDMA) of 1987, a positive step toward putting federal muscle behind anti-counterfeit measures. The PDMA requires minimum standards for state licensing of wholesale distributors of prescription drugs and, if enforced, would require wholesalers to provide purchasers with a pedigree identifying each prior sale of the drug. Then on December 4, a New York federal court issued a temporary injunction preventing the FDA from enforcing the federal pedigree requirements. The FDA appealed the case on February 2, and at press time the PDMA pedigree requirements remain inoperative.

What Oncology Providers Need to Know

In February 2004, the National Association of Boards of Pharmacy developed a National Specified List of Susceptible Products that highlighted drugs susceptible to counterfeiting. Included were seven drugs commonly used in cancer care: 1. Epogen® (epoetin alfa); 2. immune globulin; 3. Lupron® (leuprolide); 4. Neupogen® (filgrastim); 5. Procrit® (epoetin alfa); 6. Zofran® (ondansetron); and 7. Zoladex® (goserelin). The National Association of Boards of Pharmacy eliminated the list from its model legislation in December 2005, however, because of a lack of adoption into state laws. Instead, the organization now urges states to begin developing drug pedigree systems.

With the expensive price tags associated with many drugs used to fight cancer, oncology drugs may be at increased risk for counterfeiting. According to the FDA, the U.S. drug supply is increasingly vulnerable to a variety of increasingly sophisticated threats, including "a more sophisticated ability to introduce finished dosage form counterfeits into legitimate drug distribution channels."[2]

Drug counterfeiters use a wide array of techniques, including diluting or re-labeling drugs, manufacturing fake drugs, or selling "compromised drugs." Unfortunately, many of these drugs are hard to detect, because the more sophisticated counterfeiters use equipment that makes pills and bottles appear remarkably authentic. These drugs are then sold at steep discounts to "shady" secondary wholesalers.

What steps can an oncology practice take to safeguard providers and patients? The answer is two-fold: partner with a distributor that has implemented a drug pedigree system that can trace and authenticate each step of a drug's journey through the supply chain

Top Five Reasons Community Cancer Centers Need Drug Pedigree Systems

1. Drug pedigree systems provide a safeguard against counterfeit drugs.
2. Drug pedigree systems allow providers to quickly and accurately identify a drug's past should a question arise.
3. Drug pedigree systems establish a chain of custody from manufacturer to practice.
4. Drug pedigree systems protect patients from adulterated drugs.
5. Drug pedigree systems protect providers from possible legal action.

ILLUSTRATION/GETTY IMAGES

The FDA's proposed phased requirements for pedigree will use risk-based factors to initially focus on the drug products that are most vulnerable to counterfeiting.

and/or purchase drugs from a reputable, VAWD-certified wholesale distributor.

Drug Pedigree Systems

Drug pedigrees can be performed the old-fashioned way, using paper records, or they can be completed electronically. A number of technology companies, such as Axway, ePedigreeNet, Raining Data, SupplyScape, 3i Infotech, and Verisign, have developed electronic pedigree, or e-pedigree, systems. While e-pedigree systems require a commitment of money and resources, these systems offer many benefits:

- Speeding up the pedigree-checking and drug authentication process
- Improving wholesaler, retailer, and provider efforts to identify, quarantine, and report suspected counterfeit drugs
- Allowing wholesalers, retailers, and manufacturers to conduct efficient, targeted recalls.

In the future, the implementation of radio frequency identification (RFID) for drugs will create a much more robust e-pedigree system. Briefly, here's how RFID would work. Manufacturers would put RFID tags on all of their drugs to provide the data needed to fill out a pedigree. These RFID tags could then be scanned electronically, allowing the current "owner" to see the entire chain of custody from manufacturer to wholesaler to physician, including the names and addresses of prior purchasers.

RFID tags and e-pedigrees are difficult—although not impossible—to counterfeit, so sophisticated tools, such as holograms and color-shifting inks, are likely to be used in conjunction with these systems.

The US Oncology Solution

US Oncology—an oncology services network affiliated with over 1,000 physicians practicing in more than 400 locations, including 78 comprehensive cancer centers and 13 freestanding radiation centers in 37 states—has implemented supply-chain safeguards for pharmaceutical distribution to its affiliated practices. Today US Oncology only distributes drugs that can be traced directly back to their manufacturers. This process requires that US Oncology purchase directly from manufacturers almost 100 percent of the time. US Oncology purchases most of the remaining drugs, primarily slow-moving or emergency products, from Morris & Dickson, a Louisiana-based distributor that is another early adopter of electronic pedigree technology and only buys from manufacturers.

To address drug safety and convenience concerns, US Oncology initiated an open dialog with its physicians and included their ideas in the design of its multimillion dollar drug distribution system. Several elements of the system, including the easy-to-use online ordering system, online accessibility to electronic pedigrees, and a 24-hour turn-around time from placing an order to delivery of product, were requested by physicians. US Oncology also implemented additional control measures to improve drug safety, including:

- A system for tracking the lot numbers and expiration dates for all drugs
- A strict return policy, which only allows a drug to be returned if its lot number or pedigree can be verified
- The quarantine of all suspected or tainted drugs
- Regular audits.

The Road Ahead

Consumer awareness is likely to grow as more states and the federal government adopt legislation calling for electronic pedigrees and as more counterfeit drugs are found in the supply chain and publicized in the media. Community cancer centers and providers can address these issues by developing consumer-friendly information about pedigree systems and other steps that are being taken to reduce the risk of counterfeiting and drug errors, and by being ready to answer questions that arise from cancer patients. (A list of educational resources can be found on page 41).

Despite the continued need for vigilance, the industry seems to be moving in the right direction. The FDA's proposed phased requirements for pedigree will use risk-based factors to initially focus on the drug products that are most vulnerable to counterfeiting. If the FDA is permitted to enforce those requirements, community cancer centers can expect wholesalers of most of the drugs used in cancer treatment to provide either electronic or paper pedigrees. Many in the healthcare industry believe that all wholesalers in the legitimate drug supply chain will provide electronic pedigrees to all customers by the end of 2007, if not sooner.

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References

[1]Lutter RW. Statement of Randall W. Lutter, PhD, Associate Commissioner for Policy and Planning, Food and Drug

ILLUSTRATION/GETTY IMAGES

Five Steps to Ensure Your Drugs Are Safe

Oncology practices need to know where their pharmaceuticals come from and ensure that they are buying from reputable distributors. Start by following these five, practical steps:

STEP 1

Ask your distributor who they buy from. Many wholesalers have already moved or are moving toward purchasing 100 percent of their products directly from the manufacturer, avoiding secondary wholesalers completely.

STEP 2

Know your distributor's return policy. Make sure your wholesaler only allows returns if a product's lot number or pedigree can be verified. Without this safeguard, you could be shipped tainted or counterfeit drugs.

STEP 3

Use a VAWD-certified distributor. The National Association of Boards of Pharmacy Verified-Accredited Wholesale Distributors (VAWD) certification program conducts on-site inspections and verifies that its extensive criteria are met by distributors. The VAWD program is becoming the national standard to safeguard the wholesale drug distribution chain from compromised or counterfeit drugs. Currently, there are 28 VAWD-certified distributors in the United States.

STEP 4

Choose a distributor with digital pedigree records. In states that have implemented pedigree requirements, you must be able to trace a drug's movement from the manufacturer to your practice. Digital records make this process much less time-consuming for your staff than having to compile the information manually.

STEP 5

Select a distributor with turn-key pedigree services. Some distributors provide practices with turn-key, electronic pedigree services, which shift the burden of record-keeping from the physician office to the distributor.

Additional Anti-Counterfeiting Resources

For Physicians

- *Dangerous Doses* by Katherine Eban. See *www.dangerousdoses.com* to learn more.
- A fact sheet from the World Health Organization can be found online at: *www.who.int/medicines/services/counterfeit/impact/ImpactF_S/en/index.html.*
- A presentation by John Agwunobi, MD, to the FDA's 2006 Counterfeit Drug Task Force Public Workshop is available online at: *www.fda.gov/oc/meetings/rfid/0209FDA1.pdf.*
- A presentation by Randall Lutter, MD, PhD, to the 2006 RFID World Conference can be found online at: *www.fda.gov/oc/speeches/2006/rfid0301.html.*

For Patients

- The FDA's counterfeit drugs website at: *www.fda.gov/counterfeit.*
- A practical article on the WebMD website can be found by following this link: *www.webmd.com/content/article/95/103346.htm.*
- The "Counterfeit Drugs Section" of the National Association of Boards of Pharmacy can be accessed at: *http://www.nabp.net/.*
- A fact sheet by the American Society of Health-System Pharmacists can be found online at: *www.safemedication.com/meds/medSafety.cfm#counterfeit.*

Administration. July 11, 2006. Available online at: *www.fda.gov/ola/2006/counterfeit0711.html.* Accessed January 31, 2007.
[2]United States Food and Drug Administration. *FDA Counterfeit Drug Task Force Report: 2006 Update*. Available online at: *www.fda.gov/oc/initiatives/counterfeit/report6_06.html.* Accessed January 31, 2007.