

# FDA Attacks Counterfeits

## Commissioner McClellan Moves to Block Counterfeits and Require Bar Codes Before Leaving FDA

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FDA relies on e-chips to thwart bogus products, and drops paper pedigrees and unit-of-use packaging.

**FDA** is proposing a multifaceted approach to halt the spread of counterfeit drugs in the United States. The main strategy is to establish an electronic tracking system that can ensure product integrity. At the same time, FDA is requiring drug manufacturers to add linear bar codes to containers and packages of drugs going to hospitals (see Sidebar, "FDA requires bar codes on hospital drugs"). The bar code initiative aims to promote patient safety but could complicate efforts to adopt e-chip tracking technology. Moreover, the voluntary nature of the anti-counterfeit initiative has raised complaints that it is inadequate to ensure the safety of the nation's drug supply. Ironically, successful implementation of this plan to identify and block distribution of bogus medicines could remove obstacles to broader importing of lower-cost prescription products.

### McClellan departs

The task of implementing these policies will fall to others at FDA, following the appointment of Commissioner Mark McClellan to administrator of the Centers for Medicare and Medicaid Services (CMS) in the Department of Health and Human Services (HHS). A top priority for the Bush administration has been to appoint a credible and knowledgeable individual to begin implementing the Medicare prescription drug benefit and quell complaints from seniors before the November elections. A physician and economist, McClellan knows a lot about drug pricing and reimbursement and their impact on biomedical innovation. He shaped health policy for the White House as a member of the Council of Economic Advisors before coming to FDA in late 2002 and advised the administration in crafting the Medicare bill.

In shifting McClellan to CMS, the administration also calculated that FDA could weather the

change. McClellan's replacement, Deputy Commissioner Lester Crawford, served as FDA's acting commissioner before McClellan's arrival, a period that saw him launch FDA programs to modernize good manufacturing practices (GMPs) and consolidate the regulation of biotech therapies with drugs. Recently he has been heading up food and animal safety and anti-bioterrorism initiatives, which are prime HHS concerns.

McClellan made the smart move last fall of assigning Janet Woodcock, director of the Center for Drug Evaluation and Research (CDER), to the Office of the Commissioner (OC) to help implement many of his risk management and strategic plan initiatives. Now Crawford has asked Woodcock to remain as one of three acting deputies instead of returning to CDER in April as planned. Woodcock will become deputy for operations; Murray Lumpkin, deputy for special programs; and Amit Sachdev, deputy for policy. Scott Gottlieb, director of medical policy development, will coordinate OC initiatives with CDER and the FDA centers for biologics and for medical devices.

Woodcock says she can extend her OC stay because CDER is in good hands under acting director Steven Galson. Key priorities for Galson are to continue integrating biologics staffers into CDER, to plan for the Center's move to new offices next year, and to deal with constant lawsuits related to generic drugs. Among many initiatives, Woodcock remains in charge of GMP modernization, developing guidance about protein characterization, and crafting a policy, which is expected this spring, regarding generic, or follow-on, biologics.

Although FDA will continue to function well, McClellan's departure leaves a big hole at the agency. An outspoken and highly visible commissioner, he advocated for policies to spur medical innovation and gain more-equitable global drug pricing. He did not shy away from controversial issues, as seen in his campaign to block drug importing and illegal Internet sales. He leaves FDA with a mountain of unfinished business, but with its drug approval and oversight systems in good shape. He also sets a high standard for future commissioners who want to leave a mark on FDA and the pharmaceutical industry.



## FDA requires bar codes on hospital drugs

A few days after unveiling its anti-counterfeiting plan, FDA published a 200-page final rule requiring manufacturers to print linear bar codes on most therapies dispensed in hospitals. The final rule varies little from a proposed rule issued in March 2003, which calls for bar codes on most drugs, vaccines, blood products, and some over-the-counter drugs used in hospitals. The rule states that all new products must carry bar codes within 60 days of approval, while existing products have two years to comply. The bar codes also must contain the NDC product code, but the expiration date and lot release numbers are voluntary. The rule does not require unit-of-use packaging, although demand from hospitals and other purchasers is prompting manufacturers to move in that direction.

HHS secretary Thompson has been a big fan of using bar codes to reduce medication errors in hospitals. By affixing bar codes to the drug unit, patient, and dispenser, the system ensures that the right patient receives the right dose at the right time. However, there are concerns that requiring manufacturers to revise production systems to print bar codes may interfere with efforts to incorporate RFID chips into packaging and labels. FDA officials acknowledge that chips may make bar codes obsolete within the next decade, but Thompson did not want to wait until then to begin establishing an electronic health information system able to track drugs through the distribution system, identify outliers and counterfeit products, facilitate recalls, detect prescribing errors, and ensure the safe and appropriate use of prescription drugs.

## No magic anti-counterfeit bullet

In response to multiple comments from parties involved in drug production, distribution, and healthcare, FDA's report, "Combating Counterfeit Drugs," combines incentives for adopting new product authentication and tracking technologies

with proposals to stiffen legal authorities and expand educational efforts to stem the flow of bogus drugs into the US supply system. The focus of the plan is to encourage manufacturers, distributors, and pharmacists to adopt a new drug "track-and-trace" system in four years. The envisioned sys-

tem would use embedded radiofrequency identification (RFID) chips that would record data on a drug product's movement from plant to pharmacist and ultimately to the patient. In addition to thwarting illegal operators, the e-tracking system could improve inventory control programs for all parties and make it easier to recall products that develop safety problems.

FDA sidesteps some of the more controversial issues that arose at its October 2003 open meeting about drug counterfeit proposals (see *Pharmaceutical Technology's* "Washington Report," December 2003). The agency most notably is not requiring manufacturers to put finished dosages in unit-of-use packaging, as advocated by some pharmacists and providers. FDA officials acknowledge that such a change could enhance patient safety, but decided that its effect on counterfeiting would not be sufficient to warrant the cost for manufacturers. For now, FDA is encouraging manufacturers to analyze the costs and benefits of unit-of-use packaging, starting with newly approved

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drugs, injectables, and products most likely to be counterfeited. FDA also supports independent efforts to develop standards for the size, shape, and organization of unit packaging that could reduce costs.

Similarly, FDA is not requiring manufacturers to adopt any specific antitampering packaging or product authentication systems such as holograms, colored labels, or chemical markers. Such approaches could be helpful in preventing counterfeiting, but FDA believes that there is no single “magic

bullet” able to foil illegal operators sufficiently to justify specific mandates. Moreover, agency officials fear that recommending any one product authentication technology would only alert counterfeiters to industry practices, and also could stifle further innovation. Manufacturers, instead, should explore the range of anti-counterfeiting technologies to determine which best fits the specific product and dosage form and the company’s capabilities.

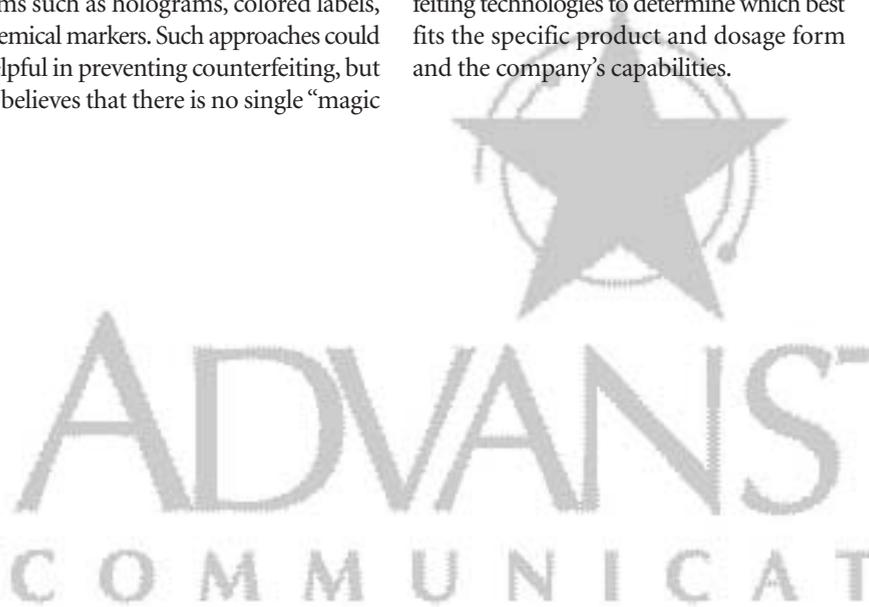
To spur the adoption of new technologies for existing products, FDA says it will review its policies on postapproval manufacturing changes. The agency plans to issue guidance about how companies can adopt anti-counterfeit packaging and labeling changes without the need to obtain prior FDA approval, possibly through a changes-being-effected supplement or notification in an annual report.

### **Chips, not paper**

The prospect of establishing a national electronic tracking system for all prescription drugs in four years is prompting FDA to once again postpone plans to implement the paper pedigree system that is required by the Prescription Drug Marketing Act (PDMA) of 1987. After several delays resulting from high costs and technical difficulties, FDA was scheduled to launch the paper pedigree system 1 April 2004, but decided that doing so now would be confusing and a waste of resources. Instead, the agency is backing the new electronic approach as a better way to meet PDMA objectives, but will reassess in 2006 whether the industry is progressing sufficiently to keep paper pedigrees on hold.

Manufacturers and wholesalers have begun feasibility studies of RFID systems, including a high-profile pilot test by wholesaler McKesson for Wal-Mart. RFID tracking involves inserting tiny electromagnetic chips, which contain unique mass serialization numbers that carry an electronic product code into drug labels and packages. When incorporated into systems with data readers and computer information bases, the chips automatically authenticate and track products moving through the distribution system, creating a de facto electronic drug pedigree. RFID chips can hold much more data than bar codes and do not have to be read manually by scanners.

FDA expects that next year manufacturers will begin applying RFID chips to pallets, cases, and packages of the pharmaceuticals most likely to be counterfeited, and that wholesalers, chain drug stores, and some hospitals will begin acquiring and installing information systems that are able to read and use this tracking information. An FDA timeline calls for these actions to be extended in 2006 to more products and for more pharmacists and hospitals to have a full RFID tracking system in place by 2007.



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During this process, FDA will examine whether it needs to revise rules regarding labeling, electronic records, and adherence to GMPs to accommodate new technologies. Another task is to ensure that a fully electronic tracking system complies with patient privacy protection policies. FDA and manufacturers also are examining whether RFID systems present any safety issues for pharmaceuticals. Researchers are conducting stability tests on drugs with labels or containers that have chips and will test if frequency emissions from chips could affect sensitive biotech products.

In announcing the anti-counterfeit plan, McClellan noted that the private sector—and not FDA—should assume responsibility for establishing and maintaining the e-tracking database. FDA expects that all stakeholders will help develop standards for establishing unique mass serial numbers to identify a pallet, case, or package; protocols for reading tags; and compatible software requirements to ensure system interoperability. Manufacturers also should work with FDA and other members of the supply chain to address regulatory and economic

issues that could delay the adoption of the RFID tracking approach.

### **Sticks and carrots**

In addition to encouraging technological innovation, FDA is proposing other changes in laws and policies to further deter production and distribution of counterfeit products.

**Stiffer criminal penalties.** FDA is asking the United States Sentencing Commission to increase jail terms for drug counterfeiters. Under current rules, making a counterfeit drug brings only a three-year maximum sentence, compared with as many as ten years for counterfeiting a drug label.

**Stronger state wholesaler regulation.** The National Association of Boards of Pharmacy (NABP) has issued revised model rules for wholesalers that FDA would like states to adopt. The new NABP model establishes more-stringent licensing and disclosure requirements for drug wholesalers and calls for more-frequent inspections and stiffer penalties for distributing illegal products.

**Broader input on counterfeit activity.** A Counterfeit Alert Network will collect re-

ports on counterfeit incidents from national health organizations, consumer groups, and the industry and will disseminate FDA alerts to members and subscribers. FDA also is encouraging pharmacists, physicians, and other health professionals to use MedWatch, FDA's safety information and adverse reporting system, to report information about suspect counterfeit products, instead of establishing a separate reporting system.

**Identifying likely counterfeit targets.** Some states and organizations are developing lists of the high-priced, high-volume, and scarce products that are most likely to attract counterfeiters. Pharmacists and providers feel that such lists also should include therapies likely to cause the most harm if counterfeited such as injectables and treatments for AIDS and cancer. FDA supports the compilation of a national list by NABP and other stakeholders to avoid redundancies and to help the public identify suspect products, but prefers that private organizations lead this effort.

**Heightened security.** FDA is promoting secure business practices and expects to develop guidance for the industry about

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securing facilities and production sites. FDA also plans to increase site inspections of drug repackaging companies, which have served as an avenue for counterfeits to enter the supply chain. FDA advises firms to name a high-level individual or team to coordinate anti-counterfeiting activities and to check the legitimacy of suppliers and other business partners.

**International cooperation.** FDA also plans to collaborate with international organi-

zations to identify counterfeiters and establish tracking systems. The agency is supporting efforts headed by the World Health Organization and will work more closely with the Permanent Forum on International Pharmaceutical Crime and the Interpol Intellectual Property Crimes Action Group to implement worldwide anti-counterfeit drug strategies.

## Information and imports

Another FDA goal is to increase public information about the dangers of counterfeit drugs. The agency plans to issue more advisories about buying drugs safely through the Internet, an activity that also supports its campaign to halt Internet sales of illegally imported drugs.

Although illegal imports are not all counterfeits, Internet purchasing opens the door for bogus products to enter the US market. The surge in shipments of unauthorized drugs to United States customers has prompted an FDA crackdown. An FDA "sting" operation in January netted evidence of counterfeit and misbranded products being mailed to Americans and led to actions against importers in Texas. The tension heated up in February when several state and local governments launched new efforts to help citizens obtain drugs from Canada. Members of Congress threatened to block McClellan's appointment to CMS until he explained his anti-import stance.

Data from IMS Health show that sales of prescription drugs that were reimported from Canada to the United States topped \$1 billion in 2003 compared to \$500 million in the previous year. The growth trend may level off as manufacturers limit sales to Canadian mail-order pharmacies shipping products to the United States. Pfizer informed several Canadian firms in February that it would cut off supplies, similar to earlier action by GlaxoSmithKline.

While Congress debates drug import proposals, FDA analysts are examining what resources the federal government would need to make drug reimporting safe, as required by the new Medicare reform legislation. The department is taking this study "very seriously," says HHS Secretary Tommy Thompson, and will address the impact of an electronic track-and-trace system on import activities. A main argument against importing is that FDA has no way to ensure that a product from Canada is genuine and has been shipped and handled correctly, and an electronic tracking system could reduce this concern. **PT**

