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MCKESSON
Empowering Healthcare

November 3, 2003

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

RE: Anti-Counterfeit Drug Initiative (68FR51270)
[Docket No. 2003N-0361]

Dear Sir or Madam:

On behalf of McKesson Corporation (hereafter McKesson), I am pleased to submit comments to the Food and Drug Administration (FDA) concerning the anti-counterfeit drug initiative and the agency's Counterfeit Drug Task Force Interim Report, issued October 2003. McKesson commends the agency for its important work to enhance pharmaceutical product safety throughout the pharmaceutical supply channel and its ongoing support of public and private sector collaboration to address this significant issue.

McKesson is the world's largest pharmaceutical supply management and health information technology company. As the nation's largest healthcare services corporation, we do business with over 5,000 hospitals, 35,000 physician practices, 10,000 extended care facilities, 700 home care agencies, 25,000 retail pharmacies, 600 payors, 450 pharmaceutical manufacturers and 2,000 medical-surgical manufacturers. We are the largest pharmaceutical distributor in North America, through our ownership of McKesson Canada and an equity holding in Nadro, a leading distributor in Mexico.

For the past 170 years, McKesson has led the industry in the delivery of medicines and health care products to drug stores. Today, a Fortune 20 corporation, McKesson delivers vital medicines, medical supplies, and health information technology solutions that touch the lives of more than 100 million patients each day in every health care setting. We understand the critical importance of medication safety and the need to protect the integrity of the pharmaceutical supply chain.

McKesson was the first drug distributor to fully automate our distribution process by implementing radio frequency and scanning technology throughout our entire warehouse and distribution network. Today, we are engaged in a joint innovative effort with Wal-Mart to beta-test RFID (radio frequency identification) technology for use in tracking inventory and assuring product safety.

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We are the industry leader and only single-source provider of drug distribution, automation, scanning and information technologies to help healthcare organizations reduce medication errors throughout the continuum of care. Over 10,000 hospitals, outpatient, and retail pharmacies utilize our bar code-based automation for pharmaceutical products. With the recent purchase of Sky Pharmaceuticals Packaging, Inc., a leading supplier of unit dose bar coded packaging solutions, McKesson now operates two GMP compliant packaging facilities for pharmaceutical products. Through these operations, we purchase pharmaceutical products in bulk quantities directly from the original manufacturer and repackage the tablets or capsules into smaller units, in FDA approved packaging, with a machine-readable bar code for our customers.

McKesson pioneered retail pharmacy automation with the Baker Cell pill counting technology with products in over 10,000 retail and outpatient pharmacies world-wide. We invented the first robotic dispensing system, which automates the dispensing of unit dose bar coded medications, and introduced the product to the hospital market in 1992. We also manufacture medication dispensing cabinets for nursing units that support bar code scanning for accurate drug restocking, and we have incorporated bar code scanning which utilizes a hand-held wireless scanner at the point of medication administration at the patient's bedside.

McKesson is working with our trading partners to develop and implement technology designed to improve electronic tracking for healthcare product distribution.

POTENTIAL OPTIONS FOR IMPROVING PRESCRIPTION DRUG SECURITY

Based on our long history and expertise in the distribution business and our commitment to a safe and secure drug supply, we welcome the opportunity to share our unique insights on issues surrounding the safe distribution of pharmaceutical products. To that end, we have focused our comments on questions concerning Technology and Packaging, Secure Business Practices and a Rapid Response and Alert System.

A) Technology and Packaging

Unit of use and unit dose packaging

Unit of use and unit dose packaging are important delivery solutions for certain health care settings, and both can provide increased security and protection for the product and the patient. To ensure integrity of the product, we offer the following recommendations:

1) all repackagers must source product directly from manufacturers or wholesalers;
2) wholesalers should purchase all pharmaceuticals intended for repackaging directly from the manufacturer;
3) a bar code should be applied to all unit dose packaged products.

Barcoding of unit dose medications further complements safety measures under implementation by the drug manufacturing and distribution industries to assure accurate drug delivery to patients in hospitals and other institutional settings. Our experience in providing unit dose services for hospitals, nursing homes and other institutional health care settings has shown that combining barcoding requirements with packaging technologies will also facilitate the adoption of pharmacy robotic fill and dispensing systems and enable point-of-care bar code scanning. Expanding the use of these automated, electronic solutions will improve the effectiveness of tracking solutions and help prevent counterfeiting.

McKesson supports packaging technologies that will improve the safety, security, and authenticity of manufacturers' products. However, as a repackager and a distributor, we believe that any *requirement* for the manufacturer to package pharmaceuticals for unit of use or unit dose dispensing should be balanced against the increased economic costs to the distribution and supply channel and, ultimately, to the consumer.

We encourage the FDA to continue to work with manufacturers and wholesalers to strengthen and enforce existing standards and good manufacturing practices (GMPs) to protect against counterfeiting of repackaged product.

Tracking technologies

We believe electronic tracking capabilities will significantly enhance counterfeit prevention efforts and will negate the need for an ineffective and potentially fraudulent pedigree paper trail. While paper pedigrees may provide some level of additional deterrence from counterfeiting, they themselves are subject to counterfeiting. Electronic tracking technology, such as RFID, would make it much more difficult for illegitimate and rogue operators to develop entry points within the distribution supply system. RFID has also demonstrated cost effectiveness by improving inventory control, expediting delivery shipments and reducing product waste and diversion. In order for this technology to be implemented, manufacturers must embrace RFID and assume the responsibility for placing electronic tags on their pharmaceutical products.

We support the use of RFID for all drugs and biologics to authenticate products, starting at the case level for products at "high risk of being counterfeited" and progressively moving to tracing capabilities for all products at the unit of sale level. Based on beta testing efforts with our trading partners, McKesson urges the FDA to endorse RFID tracking technology as the industry standard for pharmaceutical distribution.

As the agency addresses methods to prevent counterfeiting, we also encourage the FDA to promote the use of health information technology solutions to track pharmaceuticals through the healthcare system. We support the use of bar code "tracking" technology within the hospital setting to assure product distribution safety and efficiency. Proposed requirements should take into consideration the significant investments that many hospitals have made to date in barcoding technology and give them the flexibility to support and build upon these investments.

Product Shipments

Prescription drug distributors are a vital component in a dynamic health care delivery system. Leading pharmaceutical distributors save the health care system billions of dollars each year by maximizing economies of scale, creating efficiencies, reducing the number of transactions and simplifying product distribution. McKesson purchases products from more than 450 pharmaceutical manufacturers and supplies more than 75,000 customer sites. We offer our customers maximum access to thousands of products, delivery times and other value added services. At the same time, we comply with stringent storage, handling, safety and recordkeeping requirements from multiple federal and state regulatory bodies. Electronic track and trace technology will continue to enhance these efficiencies.

In contrast, direct manufacturer shipments to retail dispensers and other end users would increase transaction costs and complexities. Furthermore, expanding the number of shipments could increase the potential opportunities for diversion, thereby potentially compromising product and consumer safety. According to industry estimates, direct shipments from manufacturers to end-customers would add $50 billion in costs to the U.S. health care delivery system and redundancies to the current pharmaceutical distribution system (*Healthcare Distribution Management Association industry study, 2000*). A significant portion of these added costs would ultimately be borne by consumers and payers.

High risk drugs

Electronic tracking technologies will mitigate the need to develop "high risk" prescription drug lists for pharmaceutical products and will allow verification of a product's chain of custody. McKesson currently has a policy of purchasing 99.5% of all of its pharmaceuticals directly from the pharmaceutical manufacturer. This includes high-priced or break-through drugs, which we consider to be "high risk" for counterfeiting. To assure product safety prior to widespread adoption of electronic tracking technology, FDA could require all distributors to purchase "high risk" prescription drugs directly from the pharmaceutical manufacturer.

B) Regulatory Requirements and Secure Business Practices

McKesson strongly believes good business practices are the most effective deterrent to counterfeiting and enhance the security of the supply chain. Good business practices should include greater scrutiny in the purchasing process, background checks, and on-site inspections. Lack of due diligence and other screening procedures greatly exacerbates problems with rogue distributors. **We oppose the use of paper pedigrees, which can be easily forged and which cannot be effectively transmitted through the channel to ensure the integrity of the process. Electronic tracking technology offers the most secure way to police the drug distribution channel.**

Product safety

Based on our experience with the Florida Department of Health, we believe that better screening procedures prior to the issuance of a wholesale drug distributor license would greatly enhance product safety. We support the Healthcare Distribution Management Association's (HDMA) guidelines to assure the integrity of the pharmaceutical distribution system and enhance efforts to prevent counterfeiting of pharmaceutical products. The HDMA guidelines address the purchase of product by prescription drug distributors, and draw on best practices followed by its leading members. The new guidelines uniformly raise the standard of practice throughout the entire distribution system by recommending that distributors conduct rigorous due diligence, background checks, on-site inspections and ongoing reviews of suppliers and purchasers to ensure compliance with federal and state laws pertaining to prescription drugs.

The guidelines also recommend establishing systems and processes for reporting suspicious product and/or entities suspected of unlawful activity. Such practices adopted by industry and state regulators will go a long way toward identifying and excluding businesses that may engage in criminal activity.

McKesson's stringent business procedures

McKesson's unwavering commitment to product safety is reflected in the stringent processes and procedures we have instituted with our suppliers and throughout our pharmaceutical distribution network.

McKesson buys 99.5% of its pharmaceutical products, including specialty, biotech, HIV and oncology drugs, directly from the pharmaceutical manufacturer. Such injectables as Serostim®, Epogen® and Procrit® and more than 200 additional products, including those considered to be at "high risk" for adulteration or counterfeiting, are sourced exclusively from the pharmaceutical manufacturers. This buying practice has been in place since 2000 and has enabled McKesson to enhance the safety of the product it delivers.

Our primary goal is to distribute product of the highest quality. While not required, McKesson has taken the initiative to establish a comprehensive review process for the limited number of alternate source vendors (ASVs) that supply less than 0.5% of our product. Before entering into a supplier arrangement with an ASV, McKesson completes a rigorous due diligence process for potential suppliers. The McKesson review includes a Dun & Bradstreet Report on the company and its owners, background and security checks, and assurance of appropriate licensing and insurance. Additionally, we conduct yearly site inspections, which include a review of the company's purchasing practices and a detailed check of the product.

Upon receipt at McKesson, the product is subjected to an extensive check-in and quality control process to verify packaging, dating and barcodes. Any product that does not pass these tests does not enter the McKesson distribution network. Once in the network, the products are carefully stored, controlled and tracked in accordance with the PDMA, FDA regulations, and individual state laws and regulations.

We recommend that FDA consider these procedures as examples of secure business practices which should be promoted on a widespread basis.

PDMA reforms

The minimum PDMA guidelines contained in 21USC353(e) et seq., and 21 CFR Part 205 should be strengthened to establish uniform national licensing standards and electronic tracking guidelines for qualified pharmaceutical distributors. The FDA should work closely with the state regulatory bodies to ensure implementation and enforcement of

these licensing requirements, which will limit opportunities for rogue distributors to operate within the distribution system. McKesson also recommends that PDMA revisions include stronger criminal and administrative penalties and enforcement actions against product counterfeiting. Severe penalties and tougher sentences are needed to deter and punish those responsible for counterfeiting/adulterating drugs as well as those who knowingly distribute such products. To that end, we recommend the following:

1) Establish fines that match the potential illicit financial gain;
2) Heighten and enforce criminal penalties for those who knowingly distribute adulterated or counterfeit product;
3) Establish lesser penalties for those who unknowingly distribute adulterated or counterfeit product due to negligence or poor business practices;
4) Support state action to quickly suspend/revoke licenses of those in violation of laws or regulations;
5) Work with states to inhibit rogue operators from receiving licenses in other states;
6) Establish fines for individuals who purchase prescription pharmaceuticals from "non-certified" internet pharmacies for their own personal use.

Pharmaceutical returns

As the FDA considers comprehensive solutions to prevent the proliferation of counterfeit drugs, McKesson believes that prescription drug returns must be addressed. Our company policy is to use the expertise of third party processors to handle unsaleable returned products safely and expeditiously. For drugs that are likely candidates for counterfeiting or adulteration, we will accept saleable returns of these products from our customers only within 48 hours if the chain of custody can be verified.

We encourage the agency to continue to work with the industry to develop a solution that is economically viable and will ensure that prescription returns are handled with appropriate security, safety and efficiency.

Internet pharmacy sales

Prescription drug sales via the Internet are increasing rapidly. Unfortunately, the lack of international, federal and state regulations governing these internet sales has left consumers vulnerable to counterfeit drugs. McKesson believes that the FDA should ban

domestic and international prescription drug sales via the Internet unless those transactions and businesses are held to the same regulatory standards established by the PDMA, state Boards of Pharmacy, and Departments of Health and currently applied to distributors and pharmacies, and that a monitoring effort is initiated. We encourage the FDA to work with the National Association of Boards of Pharmacy (NABP) and state attorneys general to ensure that internet pharmacy sites are certified and can provide chain of custody and electronic verification to validate the authenticity of their products.

C) Rapid Alert and Response Systems

McKesson supports FDA's efforts to improve rapid response systems to curtail and prevent counterfeit products from entering the domestic pharmaceutical product supply channels, and we advocate greater collaboration between the FDA and the DEA to protect the controlled substances market. Participation in a first response system by suppliers, distributors, providers, and dispensers is essential to protecting the public against counterfeit or adulterated product. Additionally, an electronic "alert" system could be helpful to other healthcare system improvements, such as HHS' efforts to develop a bioterrorism and emergency infrastructure response system.

Conclusion

It is unlikely that any single solution will be able to halt all counterfeit practices. However, the combination of electronic tracking technologies, secure repackaging procedures, direct manufacturer purchasing, and enhanced business practices by all members of the supply chain will greatly reduce potential entry points for counterfeiting.

McKesson appreciates the opportunity to provide its comments and recommendations based on our experience and current business practices. We welcome the FDA's commitment to enhancing public health and safety, and look forward to ongoing collaboration and cooperation to improve the safety, efficiency and effectiveness of the pharmaceutical distribution system through improved technology and regulatory reforms.

Sincerely,

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