McKesson Corporation
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March 31, 2004

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

RE: Task Force on Importation (21 CFR Chapter I)
[Docket No. 2004N-0115]

Dear Sir or Madam:

On behalf of McKesson Corporation, we are pleased to submit comments to the U.S. Department of Health and Human Services for the Task Force on Importation. McKesson commends the agency for undertaking a study of drug importation and we appreciate the opportunity to share our perspective.

McKesson is the largest pharmaceutical supply management and health information technology company in the world. We are also the largest pharmaceutical distributor in North America, through our ownership of McKesson Canada, the leading wholesale distributor in Canada, and our equity holding in Nadro, a leading distributor in Mexico. We provide a broad array of products and services to 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. McKesson also repackages over 1.5 billion doses of drugs annually and provides analytical testing services in support of these operations.

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 16 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 has strict policies and procedures in place that both ensure the safety of the products we distribute and exceed the safety requirements of the countries in which we operate. We source 99.5% of our products in the U.S. and 100% of our products in Canada directly from the manufacturers.

We also understand that many people do not have adequate access to the pharmaceuticals they need. As the administrator of the Together Rx™ card, McKesson has actively promoted a safe and workable solution to high drug prices for low-income seniors. As of

March 28, 2004, over 1.2 million seniors are enrolled in the Together Rx™ drug savings card and have obtained demonstrated savings of over $318 million.

McKesson has also been an industry leader in the development and application of technology in health care supply management, in pharmacy automation, and in bedside barcode scanning of pharmaceuticals to assure patient safety. We were 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.

Evaluation of Drug Importation

Our long history and expertise in the pharmaceutical distribution business in both the U.S. and in Canada, combined with our steadfast commitment to a safe and cost effective drug supply, provide us with unique insights on many of the questions that have been raised concerning the importation of pharmaceutical products.

McKesson has serious concerns that a broad-based importation system may not assure both product safety and cost savings to the American consumer. However, it is possible that the safety and cost savings issues could be addressed through a narrower "closed distribution" system. Under such a system, pharmaceutical distributors with the appropriate technology, experience, and distribution networks on both sides of the border could safely transfer products between their distribution centers in Canada and their distribution centers in the U.S. To assure safety, these distributors must source 100% of their products directly from the manufacturers. Clearly, such a system would depend on the availability of product in Canada, the cooperation of key members of the supply chain, and the development of an allocation system to ensure equitable distribution to the American public.

It is important to recognize that U.S. demand for lower-priced pharmaceuticals will always exceed the available supply from Canada or from any other exporting country. The U.S. pharmaceutical market is the largest in the world, amounting to almost half of the world's pharmaceutical spending. In comparison, the Canadian market is less than 1/20th of the size of the U.S. market. This imbalance in demand will require an allocation system to ensure equitable distribution of the available imported pharmaceutical products. McKesson recognizes that any allocation policy will be highly controversial and will require government intervention.

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If an importation system is devised, we believe there are significant challenges that may make it difficult to safely provide an adequate supply of lower priced product. Addressing these challenges will add costs that could negate any potential savings. To ensure a secure and cost-effective supply chain, the Task Force must address the following issues of product safety and costs.

Safety

The preservation of a safe pharmaceutical supply chain is essential. There are several factors affecting the safety of imported products that merit particular attention.

1) Regulatory Oversight

As we have previously noted, demand in the U.S. will far outstrip the available foreign supply of pharmaceuticals. This disproportionate demand may create financial incentives for legitimate and illegitimate operators to seek alternate sources for prescription drugs and increases the threat of a gray market for vital medicines.

While Canada has strict policies in place to ensure the safety of pharmaceuticals for its citizens, the Canadian government has stated that it cannot guarantee the safety of drugs shipped to the U.S. At the same time, the U.S. lacks the resources to adequately monitor products shipped directly to patients over the border. Actual or alleged trans-shipment of product through Canada could result in the development of a gray market that is difficult to monitor. Adequate regulations and supporting resources are needed to prevent the shipment, through Canada, of pharmaceutical products that are improperly stored or handled, sub-potent, expired, adulterated, or counterfeit. Additionally, the institution and enforcement of severe criminal penalties are needed to deter those who knowingly distribute compromised pharmaceutical products.

Internet and international mail order pharmacies provide another channel for the importation of foreign product which is unregulated by U.S. authorities. McKesson believes that the lack of international, federal and state regulations has left consumers vulnerable to unsafe drugs. We have previously recommended that the FDA ban domestic and international prescription drug sales via the Internet unless those transactions and businesses are held to the same regulatory and licensing standards established by the Prescription Drug Marketing Act, state Boards of Pharmacy, and Departments of Health, and currently applied to U.S. distributors and pharmacies.

2) Product Testing, Packaging and Labeling

Appropriate testing of imported products may be required to ensure safety and potency. While resources exist at McKesson and elsewhere to test imported products, questions

remain as to the parameters of the testing, ability to access patented information to assure adequate testing, liability and costs associated with the testing.

Under current federal regulation, most foreign labels and packages do not comply with the Food, Drug & Cosmetic Act, as required for legal sale in the U.S. Lack of barcoding or NDC numbers on foreign products may require additional repackaging to enable rapid and efficient distribution of these products from wholesalers to pharmacists to patients. Country of origin labeling and language requirements for package inserts must also be considered. Should patient or product safety concerns necessitate relabeling or repackaging of imported products, additional costs will ensue.

3) Inventory Tracking

McKesson has been an advocate and leader in the adoption of technology to track and trace products through the supply chain. The use of electronic technology to track products from foreign countries would help to ensure that products are sourced in FDA-approved facilities and shipped through legitimate wholesale channels prior to sale in the U.S. The effective implementation of such a system for importation, however, poses significant challenges. Pharmaceutical manufacturers must agree to tag products globally at the time of manufacture, and approved foreign intermediaries must adopt the electronic reading technology. Despite wide spread support for such technology, harmonized standards to facilitate broad adoption of these technologies are still under development.

Tracking products without such electronic documentation could compromise the integrity and the efficiencies of the pharmaceutical distribution network. Paper pedigrees that are designed to document the source of the product and its movement through the distribution chain are subject to counterfeiting. McKesson has previously submitted comments to the FDA in opposition to the use of paper pedigrees, which can be easily forged and which cannot be effectively transmitted through our currently paperless and virtually automated distribution channel.

4) Recall Mechanism

Product recalls are currently initiated by the manufacturer and facilitated by wholesalers and pharmacies. Most recalls are national in scope, not global. It will be necessary to establish a process for recalls in the absence of a single governing body that has jurisdiction on both sides of the border. In order to execute a recall of foreign products, systems will have to be developed and instituted to monitor and track foreign-sourced products. It is also likely that segregated inventories of foreign-sourced and domestic-sourced product will have to be maintained at the wholesaler and pharmacy level. Questions will arise as to responsibility for initiating and overseeing the process and subsequent liability for such recalls.

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Costs

Ensuring the safety of the supply chain will add significant costs to imported product. Regulatory oversight, testing, repackaging/relabeling, tracking and recall mechanisms will reduce any available cost savings. In addition, other factors could further increase the cost of importation and reduce savings to U.S. consumers:

1) Proper Importation Documentation

Well executed importation has associated costs, including import/export licenses, customs broker fees, tariffs, bonds, and documentation fees.

2) Product Pricing

The economic principles of supply and demand, as well as currency fluctuations, will also impact any cost savings available through importation. In Canada, national and provincial bodies currently set and regulate prices for pharmaceutical products. These regulations apply only to products dispensed in Canada. Canadian price controls exist for Canadian citizens, not for the export market. In a legalized importation environment between the U.S. and Canada, we would expect the prices at which Canadian entities sell to the U.S. to rise as demand exceeds available supply. In fact, drugs exported from Canada are already sold at prices above domestic Canadian prices.

3) Generic Substitution

Generic pharmaceuticals are generally less expensive in the U.S. than in Canada and account for approximately 45% of the unit volume of drugs consumed in the U.S. American pharmacies today actively promote generic substitution. Under legalized importation, consumers may ultimately pay more to import a branded product than they would for a domestic generic product that is readily available.

4) Reimbursement

Reimbursement for pharmaceutical products by third party payors will need to be thoughtfully addressed in any importation system. Pharmacies and payors will need systems to track different channels of product acquisition in order to accurately reflect their average acquisition costs, upon which reimbursements by Medicaid are based. Foreign-sourced drugs will not have NDC numbers, which are the basis for most pharmacy management and reimbursement systems. Furthermore, it remains unclear as to what extent health insurers and government payors, including CMS, would reimburse pharmacies and patients for foreign-sourced products. Administrative complexities, and resulting costs, would increase as insurers implement systems to track and reimburse foreign-sourced products and provide adequate medication therapy management, drug utilization review, safety and counseling efforts for these products.

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5) Liability

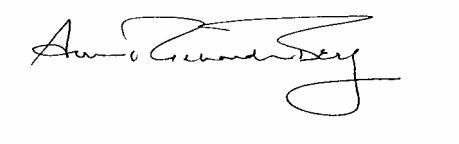
The importation of pharmaceutical products is also likely to entail the assumption of additional liability. Without regulations governing liability for imported product, it is unclear who (e.g. manufacturers, importers, government, payors) would bear liability for any adverse drug events associated with products sold outside their country of intended use. Additionally, since September 11, 2001, security concerns coupled with the rising cost of insurance have made it increasingly difficult for companies to attain adequate liability coverage. Liability insurance covering imported products is likely to be costly, thereby further reducing available cost savings.

Conclusion

Given our unique capabilities in Canada and the U.S., we stand ready to share our expertise to help the Task Force better understand safety and cost issues associated with drug importation. McKesson is committed to removing unnecessary costs from the health care system as we ensure the timely delivery of safe, cost-effective products. We remain concerned about the safety, cost and allocation issues which we believe could present significant barriers to the successful implementation of any importation system.

McKesson appreciates the opportunity to provide comments and recommendations based on our distribution experience within North America and the strict policies and procedures we have implemented to assure product safety. We applaud the FDA's commitment to providing a safe channel for lower cost drugs, and look forward to ongoing collaboration and cooperation to ensuring the safety, efficiency and effectiveness of the pharmaceutical distribution system.

Sincerely,



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