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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

December 22, 2003

Docket No. 2003N-0361
Anti-Counterfeit Drug Initiative

Dear Sir/Madam:

The problem of counterfeit prescription drugs has been increasing in recent years and poses a serious threat to the public health of Americans. The best way to address this problem is for the private and public sectors to join forces and develop systems and processes to prevent counterfeiting, to identify counterfeit product that does enter the supply chain and to prosecute and punish those who are involved in this illegal activity.

Johnson & Johnson appreciates the opportunity to comment on the Food and Drug Administration's Counterfeit Drug Task Force Interim Report. We support FDA's goal of enhancing existing safeguards to protect the nation's drug supply from counterfeit drugs. We agree with the statements in the Interim Report that there is no single "magic bullet" against the growing number of sophisticated counterfeiters, and that a multi-pronged strategy is the most appropriate approach. We also agree that new technologies hold the promise of ensuring the integrity of these products in the future, when technologies are fully developed, tested and implemented. Through the FDA's thoughtful and open dialogue with the healthcare community on this and other important issues, Americans can continue to depend upon one of the safest prescription drug supply systems in the world. We support FDA's allocating sufficient resources to the effort and look forward to working closely with the agency and Congress in addressing these resource issues.

Johnson & Johnson is a comprehensive, broad based manufacturer of health care products and related services for the consumer, pharmaceutical, medical device and diagnostic markets. Johnson & Johnson has over 200 operating companies in 54 countries around the world, selling products in more than 175 countries.

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Unfortunately, like many other companies we have felt the impact of counterfeit drugs; our product PROCRIT has been the target of counterfeiters. Our comments are offered with the experience of having had to deal directly with the threat to the health and safety of the people who depend on the integrity of our products.

Although our company and others have taken important steps to combat counterfeiting, it is clear that more work needs to be done on many fronts, including improved control of the supply chain, stiffer penalties for counterfeiters, improved technology for product packaging and education for consumers, health care professionals and wholesalers/distributors.

With these objectives in mind, we respectfully submit the following comments that include our position on a number of important issues along with details on some of the anti-counterfeiting measures we have taken.

Distribution of Prescription Drugs

Johnson & Johnson believes that manufacturer-initiated policies to secure the integrity of the supply chain, coupled with FDA-mandated wholesaler and distributor certification requirements are the most effective and immediate steps that can be taken to reduce the potential for counterfeit product to enter the supply chain.

On December 10, 2003, our company issued a new policy to thwart counterfeiters' attempts to access the supply chain. This new anti-counterfeiting distribution policy requires direct purchasing wholesalers and distributors to obtain prescription medicines and devices directly from Johnson & Johnson companies (participating JOM wholesalers and distributors). We are also encouraging pharmacies, hospitals, and other customers to verify that their suppliers purchase all Johnson & Johnson pharmaceutical, biopharmaceutical, and medical device and diagnostic products direct from us, or participating JOM wholesalers and distributors. This new policy is in addition to our work to incorporate state-of-the-art anti-counterfeiting technology into product packaging. Just last week, another major pharmaceutical company adopted a policy similar to ours.

Close collaboration between all parties involved in the pharmaceutical supply chain is critical to prevent the introduction of counterfeit products into the market. Working together with our customers on this new distribution initiative sends a strong message that we will not tolerate activities that in any way compromise the health and well being of the patients that we serve.

In order to further strengthen the security of the supply chain, we recommend that the FDA certify wholesalers and distributors of prescription products. Criteria to standards similar to cGMP standards required of manufacturers the ability to immediately track and trace the source and destination of products using lot numbers, and background checks of employees who handle products.

Track and Trace /Pedigree

Ensuring the authenticity of pharmaceutical products will require that all parties involved in the U.S. prescription drug supply chain have access to documentation related to the origin of products and definitive verification that they arrived at the intended destination. Paper pedigree documents have proven to be ineffective in that they are costly to maintain and easier to counterfeit than the drugs themselves.

Johnson & Johnson agrees with the National Association of Chain Drug Stores recommendation that until a broad based, electronic track and trace system is implemented to ensure drug authenticity throughout the supply chain, the "one step forward, one-step back" model (e.g. knowing where a product came from and where it's going) should be adopted.

To ensure success, the FDA should work with all involved to define required standards on key components and business practices of a near-term, workable model. Further, the FDA should mandate industry-wide implementation of this model.

- A firm date should be set for industry adoption of the established model once a feasibility study has confirmed an agreed upon direction.
- Develop and adopt a minimum standard for implementation across all sectors of the U.S. pharmaceutical supply chain.

Increased Penalties for Counterfeiters

The current maximum penalty specified in the FD&C Act for counterfeiting prescription drugs is three years in prison. This is not tough enough to deter potential counterfeiters. Johnson & Johnson would support new legislation to increase the penalties for this crime to be more commensurate with the harm that these criminal acts can cause.

Education and Public Awareness/Rapid Alert System

There needs to be increased education of both consumers and healthcare professionals about how to detect counterfeit prescription medications. This needs to be done in a way that empowers people but does not cause undue alarm. A joint effort by the FDA and industry in this area would show that there is a true public/private partnership to protect the safety and health of all Americans taking prescription drugs.

Johnson & Johnson generally agrees with the proposal to use the MedWatch Alert System to distribute information about counterfeit prescription drugs. Although the system is not designed for this purpose, we believe that with cooperation between industry and regulators that this could prove to be a useful method of rapid alert.

Packaging Technology

Like many pharmaceutical companies, Johnson & Johnson is implementing a brand security program that includes the application of state-of-the-art anti-counterfeiting technologies to the packaging of our major products. We will continue to expand and modify these features over time.

We believe that the manufacturer is in the best position to select the most appropriate and effective anti-counterfeiting technologies based on the characteristics of the products, the costs of implementation, and the risks of counterfeiting. We suggest that FDA allow individual manufacturers to select the appropriate technologies for their products since they have the expertise in product development, manufacturing, and package design.

Medications considered by manufacturers and the FDA to be at "high risk" for counterfeiting should be the first to implement anti-counterfeiting technology. Further, we recommend that all newly launched products should include anti-counterfeiting features, and that all NDAs, BLA's and ANDAs include an assessment of the likelihood of counterfeiting, and the type of actions the firm will take to prevent it. This could be similar to the environmental assessment that is currently part of these submissions.

While radio frequency identification (RFID) has received much attention over the last several months in terms of a potential solution to the issue of counterfeit pharmaceuticals – and as a mechanism to gain better control of the distribution system – it should be noted that the uniform implementation of this technology is a long-term commitment. Interim steps using known technologies must be taken by all involved in the pharmaceutical supply chain to address the counterfeit issue.

Unit of Use Packaging

While the FDA has identified unit of use packaging as a potential anti-counterfeiting solution, Johnson & Johnson believes that the downsides, especially the ability of counterfeiters to duplicate unit of use dosing, outweigh the benefits.

The sophistication of counterfeiters is significant. Although the equipment required to duplicate unit of use dosing is costly, we believe it would just be a matter of time before this type of packaging becomes the target of counterfeiters.

Also, many prescription drug therapies do not easily lend themselves to unit-of-use packaging and standardized dispensing quantities. A number of medications require dosing based on specific details of a patient's condition. At the retail level, unit of use dosing would require significantly more space on pharmacy shelves for the same medication, and this could result in fewer products carried in pharmacies, an inconvenience for consumers. For pharmaceutical manufacturers, the significant retooling necessary to broadly institute unit-of-use packaging would be costly. From an environmental standpoint, far more material is required to package the same amount of medication, resulting in significantly more waste.

Repackaging for Resale

Johnson & Johnson believes that repackaging of prescription medications should meet all of the cGMP requirements of the originating manufacturer.

During repackaging, the manufacturer's original packaging is broken down to pill and vial levels destroying the original package integrity. This creates an opportunity for the entry of diverted and counterfeit drugs. In addition, the repackager may not have the appropriate controls based on the manufacture's approved process, product and packaging specifications. Once track and trace technology is adopted, repackaging should be required to apply lot numbers that enable the supply chain to track and trace lots from either end of the chain.

Conclusion

Johnson & Johnson is committed to working with the FDA, other government agencies and our colleagues in industry to protect the American public from the scourge of counterfeit drugs. It is the responsibility of all parties involved in the manufacture, distribution and sale of prescription drugs to take part in this effort.

Sincerely,

Patricia DeSantis
Senior Director, Regulatory Affairs
Johnson & Johnson PRD