



Tom McPhillips
Vice President
U.S. Trade Group

February 24, 2006

Dockets Management Branch
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

**Re: Anti-Counterfeit Drug Initiative Workshop and Vendor Display
(Docket No. 2005N-0510)**

Dear Dockets Management:

On behalf of Pfizer Inc, I respectfully submit these comments to Docket No. 2005N-0510.

EXECUTIVE SUMMARY

As the world's leading pharmaceutical manufacturer, Pfizer remains strongly committed to providing patients with safe and effective medications of the highest quality. We share the FDA's concern for the risk to patient health posed by counterfeit drugs, and welcome the opportunity to work with the FDA and other stakeholders to develop effective mechanisms for preventing the insinuation of counterfeit drug products into the U.S. drug distribution system.

Pfizer believes that counterfeiting issues must be addressed on many fronts, including enhanced business practices, regulatory and legislative solutions, heightened enforcement, and employment of technology. Pfizer has undertaken initiatives in all of these areas.

On the technology front, electronic track-and-trace systems, such as radio-frequency identification ("RFID") and electronic product codes ("EPCs"), represent a particularly promising means for enhancing the security of the medication distribution system. To learn more about how to implement such an approach in the United States, Pfizer has undertaken an RFID/EPC pilot program for Viagra. Under this program, great insights have been gained into the potential for RFID. This pilot program also continues to provide a much greater appreciation of the issues yet to be resolved.

More specifically, the Viagra pilot program has taught us that a fully integrated pharmaceutical track-and-trace system that relies on mass serialization of all items is not likely to

be widely available in the near term. The industry must first determine whether a track-and-trace system can or should be implemented for select or all medicines. The role that mass serialization will play in this process must also be determined. Pfizer believes that a timetable for widespread adoption of technology such as RFID cannot be established until these and other critical issues are addressed.

However, because of the paramount concern over patient safety, the battle against counterfeits cannot wait. Pfizer therefore continues to support the implementation of pedigree (chain of custody) requirements. To this end, Pfizer has and will continue to be a staunch supporter of model wholesale licensing and pedigree legislation being enacted in the states. This model legislation requires the use and authentication of pedigrees for medicines that leave the “normal distribution channel.” The model legislation supports the use of electronic pedigrees (“e-pedigrees”) when the widespread adoption of e-pedigrees becomes technologically viable.

Pfizer’s near-term vision for an e-pedigree is one that does not depend on the mass serialization of individual items. Rather, at least in the near-term, the e-pedigree would create an electronic file of a medicine’s movement through the distribution system. Such an approach would provide for the tracking of pharmaceuticals by lot. The approach would also address concerns about the burden of passing paper pedigrees, and may ultimately provide additional protection against counterfeiting of the electronic document itself through the use of digital signatures. In theory, when tracing a medicine’s history, this electronic information would be more readily retrievable than today’s process. Pfizer believes that there would be merit for pharmaceutical manufacturers to initiate the pedigree when such an electronic process is fully viable.

Pfizer also supports Federal efforts to combat counterfeiting. Pfizer recognizes that the implementation of a “universal” pedigree could help alleviate concerns over potential conflicting state requirements. And because any available weapon against counterfeits should be deployed, Pfizer supports lifting the stay of the Prescription Drug Marketing Act (“PDMA”) regulations.

Pfizer notes, however, that the PDMA broadly exempts authorized distributors of record (“ADRs”) from passing pedigrees to customers. This is a concern given the past history of counterfeits entering at the ADR level. The PDMA and implementing regulations should be amended to address this broad ADR exemption. And ultimately the PDMA and regulations should be updated as the widespread adoption of e-pedigrees and electronic track-and-trace technologies become feasible.

Finally, Pfizer supports the adoption on both the Federal and state level of stiff penalties for counterfeiting. It is also critical that the Federal government and state governments have dual authority to rigorously enforce those penalties.

SPECIFIC POINTS ADDRESSED IN PFIZER'S COMMENTS:

These comments will specifically address the following points:

- Pfizer's experience with the company's RFID/EPC Viagra pilot program.
- The obstacles to widespread adoption of RFID.
- The role FDA can play with the implementation of RFID.
- The timetable for RFID implementation.
- The setting of standards.
- Pfizer's continued support of the use of pedigrees.

Pfizer Viagra Pilot Program

Pfizer Pilot: Capabilities Created – Applied Technology Assessed

Program Announcement – A little more than a year ago, Pfizer announced the commitment that by the end of 2005 Pfizer would: (1) begin shipping Viagra in the United States with RFID/EPC tags; and (2) create an authentication capability for use by wholesalers and pharmacies.

As promised, on December 15, 2005, Pfizer's first RFID tagged Viagra was shipped to our U.S. customers. Pfizer's authentication capability was made available a few weeks later. All Viagra produced for sale in the United States now contains an RFID tag on its container.

Viagra was selected as it is Pfizer's most frequently counterfeited product and because it allowed Pfizer to minimize the number of teams, facilities, and packaging lines involved. A key objective of Pfizer's RFID pilot program is to learn more about the technology and the business processes that such an approach, including mass serialization and RFID technology, requires.

New Processes Developed – Pfizer's RFID pilot program for Viagra required the creation of many new capabilities. For example, Pfizer created a mass serialization process. This is a process that allows for the generation and assignment of a unique number (electronic product code) to each bottle, case, and pallet of Viagra.

Pfizer also decided to develop the ability to write and read EPC numbers at a high rate of speed. The capability was therefore established on existing packaging lines to write and read two bottles every second; this is the equivalent of over 7,000 package labels per hour. A backup system involving the application of a two dimensional ("2D") bar code to the label with the exact same EPC as the RFID tag was also created.

Once all of this was done, Pfizer equipped its logistics centers to capture the EPC information when product is shipped. Finally, Pfizer developed and implemented an authentication capability so that wholesalers, retailers, and pharmacists could authenticate the EPC.

Assessment – The Viagra RFID pilot was a complex project, involving over 70 Pfizer colleagues working thousands of hours and with costs approaching \$5 million to achieve Pfizer’s goal. Viagra consists of only five dosage/package combinations and is a very small percentage of our total units produced. Pfizer’s program was pursued in a way to be scalable, while maintaining productivity. Pfizer takes great pride in the fact that the company was able to maintain production throughput within 5% of prior rates, comply with GMP requirements, and not compromise quality.

Pfizer Pilot: Key Decisions

A number of key decisions needed to be made during Pfizer’s Viagra pilot program. The decisions ranged from the choice of frequency to efforts to ensure privacy.

NDC Number Not Used – Pfizer’s decision not to incorporate the NDC number into the EPC numbering scheme was based primarily on the absence of industry standards and patient confidentiality concerns. Pfizer understands that the decision not to include the NDC may create operational efficiency issues in the distribution channel. Pfizer also appreciates that encrypting the NDC may help address patient privacy concerns in the future. These are issues requiring further study.

Frequency Considerations – Pfizer chose to use 13.56 Mhz (High Frequency) tags on bottles and 915 Mhz (Ultra High Frequency) tags on cases and pallets based on the following:

- ***Analysis of the basic physics characteristics of HF and UHF.*** The primary belief here was that HF tags at the item level would address tag readability concerns with mixed tote shipments of Viagra along with other liquid formulation products and products packaged in foil.
- ***Benchmarking use of RFID across similar industries.***
- ***Existing knowledge of UHF deployment and the need to effectively manage the interference issues created by UHF read ranges.*** This was a concern in our Logistics Centers as well as on our packaging lines where tags were being written to, and read while, in close proximity to each other on high speed packaging lines.
- ***The types of hardware and tags available on the market to achieve tagging at each level.*** The issue here was primarily one of finding reliable tags small enough and suitable for tagging pharmaceuticals at the item level. Performance of item level and case level tags and the related hardware was also an important consideration.
- ***Input from others in the supply chain.***

Two Dimensional Bar Codes and Other Label Additions – Pfizer also decided to include a 2D bar code as redundant, back-up technology to the RFID tag. The 2D bar code was included in an effort to address potential RFID tag readability issues and minimize exception handling needs. In addition, the decision was made to disclose the use of RFID on the Viagra label. Pfizer consulted with FDA to determine the appropriate placement and content of the disclosure statement.

Pfizer Pilot: Next Phase

Pfizer's Viagra pilot program has provided initial lessons about the application of RFID/EPC tags within Pfizer's "four walls." The pilot program will also provide further insights into the viability of the widespread adoption of RFID.

Pfizer realizes this is not just about applying an RFID tag. There needs to be an exploration about how best to handle the data generated by RFID and about exception reporting. It is also essential to gain greater insight into the needs of distribution channel participants. The considerable costs associated with RFID must be further explored. The acceptance, performance, and utility of the tags in the market must also be assessed.

The next phase will require a high level of collaboration and feedback amongst trading partners. To this end, Pfizer has been engaged in discussions with several of our supply chain partners to understand their plans for authenticating Viagra. Pfizer is encouraged that, during the first quarter of 2006, many of our supply chain partners have plans in place to begin authenticating Viagra at select sites.

OBSTACLES TO WIDESPREAD IMPLEMENTATION OF RFID

There must be continued collaboration to obtain real world experience with RFID and mass serialization throughout the distribution channel. This will require time and a significant investment before RFID is ready for widespread implementation.

As Pfizer moves forward, the company will be seeking feedback on the performance and utility of RFID-tagged products under normal day-to-day use. Through this, Pfizer hopes to gain a greater understanding of the benefit and effect of the use of these new technologies with a select or total system usage.

Consensus must also be achieved on data access issues and sharing of information. In particular, access to data by manufacturers will be an essential element of tracking the distribution of medications. Research is also needed on the feasibility of tagging all pharmaceuticals such as biologics and liquids. Finally, and yet just as important, decisions must be made on RFID/EPC standards and the use of appropriate tags in a cost effective manner that provides robust information.

All these factors, along with credible marketplace data from our Viagra RFID pilot, will be considered when developing our future strategy for securing the supply chain and enhancing patient safety. And as we have consistently stated, technology alone will not address the issue of counterfeiting.

FDA'S ROLE IN IMPLEMENTING RFID

Pfizer believes that FDA should continue to actively participate and, where appropriate, facilitate the discussions on the feasibility of implementing RFID. FDA's February 8-9,

2006, Anti-Counterfeit Drug Initiative Workshop and Vendor Display is an excellent example of the vital role that FDA can play in this area.

We believe that it is premature to establish a firm deadline for the implementation of track-and-trace technologies until the experience of Pfizer and other companies conducting pilots can be fully assessed. To that end, we believe that industry should take the lead in determining how technology can be applied both in the near-term and the long-term. By participating in this dialog, FDA can help to assess RFID and provide future guidance on this issue.

TIMETABLE FOR RFID IMPLEMENTATION

As noted above, numerous issues must first be addressed before a specific timetable is set for the widespread adoption of RFID. Critical among these issues is the utility and performance of RFID tags under day-to-day use. Certain key questions such as how the data will be shared, and whether all pharmaceuticals will be tagged, must be resolved. Standards must also be established and the feasibility of tagging all pharmaceuticals such as liquids and biologics must be assessed. Costs represent another important issue that must be fully understood.

Pfizer anticipates that it may be possible to implement the tagging of a limited number of pharmaceuticals within three to five years. However, it will likely take several additional years beyond that to adopt RFID for all prescription medications. The required investment in this technology will be large for all distribution channel participants and especially the manufacturers.

THE SETTING OF STANDARDS

Pfizer supports the process used by EPCglobal to establish standards that are specific to the pharmaceutical industry and driven by business requirements. However, to be successful, there must also be broader participation by the retail and hospital pharmacy. While standards are under development, guidelines on critical issues such as privacy, EPC numbering, and frequency should be developed to assist others undertaking pilots.

UNIVERSAL PEDIGREES

Given that the widespread implementation of RFID may be many years off, Pfizer supports current efforts to require the implementation of pedigrees. Pfizer also recognizes that a “universal” pedigree is the ideal. But it must be a pedigree associated with strong rules that are enforceable and a system that is able to ensure that the medication distribution system is not breached.

State Initiatives

Pfizer has been and will continue to be a staunch supporter of model wholesale licensing and pedigree legislation being enacted in the states. There are a number of key provisions in the model legislation that offer practical solutions to the immediate challenges of ensuring patient safety by combating counterfeits.

Strong Licensing and Bond Requirements – A key element of the model legislation is a strict licensing and bonding requirement for wholesale drug distributors. The goal is to make sure regulators know who is moving lifesaving medications that ultimately reach the patients who need them.

Electronic Pedigrees – The model also requires the study of e-pedigrees by the appropriate state regulatory body. Based on the findings of the study, and with input from key stakeholders, the implementation date for a mandated e-pedigree for all products would occur no sooner than December 31, 2007.

Normal Distribution Channel – Another key element of the model legislation is a requirement for creation of a pedigree only when a medication leaves the “normal distribution channel.” Generally speaking, the “normal distribution channel” involves the distribution from the manufacturer to the wholesaler or chain warehouse to the pharmacy to the patient. Pfizer regards this as important since medications that leave this “normal” system are most susceptible to the introduction of counterfeit medications.

Authorized Distributor of Record – The model recognizes that there should not be a broad exemption for authorized distributors of record. This is because, in certain cases, ADRs have been the entry point for counterfeits.

States Success – Pfizer is extremely pleased that a growing number of states have been successful in passing pedigree laws and applaud the efforts of those states actively engaged in efforts to pass similar legislation.

The Stay of the PDMA Regulations Should be Lifted

Pfizer is also a staunch supporter of Federal efforts to combat counterfeiting. A “universal” pedigree could help alleviate the worry over different or conflicting state requirements.

However, we are concerned that the currently stayed PDMA regulations broadly exempt ADRs from passing pedigrees to customers. We also recognize that e-pedigrees, and ultimately effective electronic track-and-trace technologies such as RFID, will be far more effective than the PDMA’s paper pedigree system at ensuring the integrity of the pharmaceutical supply chain.

Pfizer therefore supports amending the PDMA and PDMA regulations so that they are more fully aligned with the model pedigree legislation discussed above. Most notably, the broad ADR exemption should be addressed. The PDMA and regulations should also be updated as the widespread adoption of e-pedigrees and electronic track-and-trace technologies become feasible.

Nevertheless, Pfizer recognizes that the final PDMA regulations, issued in 1999, would be helpful to provide some stop-gap protection. The stay should thus be lifted. Although paper pedigrees are vulnerable to falsification and vulnerable to disuse, they aid in enforcing diligence in supply transactions. A pedigree reveals the number of times a drug product has changed hands, and the identities of those involved.

Given the limited amount of product meeting the requirement of PDMA for a pedigree, this information by itself may raise suspicions regarding authenticity or potential quality issues. Moreover, the pedigree requires the exercise of appropriate diligence to ensure the accuracy of its information, and to evaluate the circumstances of the drug’s distribution history. And of course, the pedigree can be helpful in facilitating investigations and recalls.

New and Enhanced State and Federal Penalties

Pfizer believes that enhancing the penalties for counterfeiting might achieve additional deterrence. Heightened penalties, and the ability to enforce the penalties, should be shared by the Federal and state authorities.

CONCLUSION

Pfizer believes that counterfeiting issues must be addressed on many fronts, including enhanced business practices, regulatory and legislative solutions, heightened enforcement, and employment of technology. In the long-term, and on the technology front, track-and-trace technologies have the potential to be an important part of the anti-counterfeiting and product integrity efforts. In the short-term, Pfizer supports the continued implementation of pedigree (chain of custody) requirements.

Pfizer is grateful for the opportunity to provide these comments to FDA, and looks forward to continuing to collaborate with FDA and other stakeholders on this important initiative.

Sincerely,

A handwritten signature in black ink, appearing to read "Tom McPhillips", with a long horizontal flourish extending to the left.

Tom McPhillips