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

FDA Counterfeit Drug Task Force - Interim Report – October 2003
Response from T3C Incorporated
Docket Number 2003N-0361

Ladies and Gentlemen,

T3CI is a software technology company oriented towards providing software products and services for the large scale tracking and tracing of goods moving across enterprises in the supply chain. The principals of T3CI have provided sophisticated tracking solutions for manufacturing processes in the semiconductor and pharmaceuticals industries. Dr. Jon Golovin, President of T3CI received the prestigious annual Semiconductor Equipment and Materials International (SEMI) Award for North America in 2000 for breakthrough work on complex manufacturing execution systems.

My personal background is as an industry leader in the development of RFID based, Auto-ID software technology. In my role as Auto-ID Technology Director at SAP (world's largest enterprise software provider) I led the development of technology that uses RFID tags to better integrate the enterprise with the physical world. We developed an adaptive supply chain and item level cosmetic tracking pilot with Procter & Gamble and Wal*Mart. We also provided the core technology used in the widely publicized Metro Future Store pilot in Germany. I am an active participant and recognized leader in the MIT Auto-ID Center standards process. Responsibility is now transferring to EPC Global, which is a subsidiary of UCC/EAN. I am currently engaged in helping to define the fields and formats on the EPC tags, which will be used throughout the consumer packaged goods industry, and the protocol to be used between RFID readers and higher level software. My doctorate is from the Computer Science Department at Carnegie-Mellon University where I was also a faculty member.

T3CI is pleased to address a number of the many important questions raised by the FDA Counterfeit Drug Task Force – Interim Report, dated October 2003. This is a very important area of technical, social and economic policy to protect the health of Americans. The thrust of our response is to point out that much of the technology being developed and

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deployed for the consumer products area can be quickly adapted to meet the needs of reliably detecting counterfeit and diverted drugs. Utilizing this technology can both dramatically reduce the cost of deploying electronic tags and also make it much faster to deploy a system that can protect the US Pharmaceutical supply chain and consumers.

The costs of electronic tags and readers are very much driven by volume. The recent edict by Wal*Mart for case and pallet level tagging is expected to lead to a volume of 4 Billion EPC compliant tags. Considering the rest of the US retail industry, it is expected that this can grow to 20 Billion tags annually even before there is a transition to item level tagging. The anticipation of this volume has already reduced prices from several dollars to below 40 cents and towards about $0.15 in volume. It is expected that prices can come down close to 5 cents. Substantial creative energy and venture capital is going into developing technology to reduce the costs further. US Government statistics indicate that there are approximately 3 billion prescriptions dispensed in the US each year. With unit-of-use packaging and electronic tagging of every prescription, this would be an attractive market for some tag manufacturers but the overall costs for all participants in the industry will be substantially lower if combined with the significantly higher volumes in the consumer goods space. A single set of technology standards will benefit all participants.

I bring to your attention the detailed response attached. T3CI would be pleased to respond to any further enquiries concerning technical and regulatory matters in this important area. We would also appreciate notice of future reports and requests for comment in this area.

Sincerely

Richard Swan, Ph.D.
Chief Technical Officer

A. Questions Concerning Technology (Options 1-9)

11. Should a database, as described in Technology Option 5 be created? If so, who should develop the database? Where should it be housed? Who should have access to the data? Who should be responsible for updating and maintaining it?

EPC (Electronic Product Code) software standards promote the concept that each manufacturer can provide *EPC Information Service* sites on the public Internet, or other standards compliant networks. Unlike conventional web sites intended for browsing by humans, these EPC IS servers are designed to provide master data and other product and consumer information in a standard way for other software applications. Thus it would be possible for the FDA to adapt some EPC standards specifically for Drug Identification and Authentication processes and require each licensed manufacturer to maintain the information for each of their products. Yet, this information could be accessed by software used in the distribution chain in a uniform, coherent manner. Central repositories of information have obvious issues about maintenance, legal responsibility for the content, and other economic and technical issues. The EPC Global standards approach allows each manufacturer or other entity to be responsible for their own information while it is available in a uniform way for authorized participants.

12. Discuss the advantages and disadvantages and the role of track and trace technologies, in particular bar codes and RFID.

It is inexpensive (< $0.005) to print a barcode with a unique serial number on each pharmaceutical product. Using 2-dimensional barcodes, about a dime-sized circle of label area is needed. However, line-of-sight visibility is needed for a barcode reader to access the printed label. Also, except in very controlled conveyor-belt like environments, a human operator is needed to aim the laser reading device. This is typically the high cost part of barcode processes. The MIT Auto-ID Center has estimated that reading a barcode costs approximately 5 cents. [Kevin Ashton, MIT Auto-ID Center]

Passive, disposable RFID tags - those that do not require any associated power source such as a battery - cost $0.15 - $0.40 in high volume. This cost is modest relative to the average prescription cost of more than $50. However, the key advantage is that RFID tags can be read through many packing materials and from distances up to 3 meters (900 MHz EPC Class 1 tags). Other, closely related tags, such as those operating at 2.4 GHz have a shorter range but require a much smaller antenna. These style tags are being tested for application to small pharmaceutical doses in certain trials.

To effectively implement tracking and tracing through the pharmaceutical supply chain requires serialized identification at every level of packaging and shipment. Using EPC Global hardware and software standards established

technology and processes permit detailed tracking at the case and pallet level. Counterfeit detection and individual pedigrees and effective recall processes will require tracking at the unit-of-use level. Long term it will be best to use electronic technology at every level. However, it is technically feasible to combine electronic tags and barcodes for different levels of the shipment hierarchy.

13. What are the costs and challenges involved with setting up an infrastructure for utilizing various track and trace technologies?

The hardware cost of instrumenting a loading-dock door to capture case and pallet movements is approximately $5,000 in 2003. The cost will come down.

14. Tracking and tracing drugs and biologics throughout the drug distribution chain may result in the creation of a large database that includes tracking data from each entity that "handles" the product. Who should create and maintain such data? Where and how should the data be housed? Who should have access to the data? How can appropriate confidentiality be assured?

One approach is to establish that each manufacturer has responsibility for monitoring the flow of their own product and ensuring its safety. In that case, the information for each product movement can be funneled to a database for each manufacturer. A third party should operate the data collection process because goods shipments from distributors and within retailers will combine products from multiple manufacturers. This neutral, third party can ensure that each manufacturer only saw the movements of their own products. With appropriate interface standards there can be multiple, competing third parties along the lines of credit card clearing houses. Other arrangements are also possible. Patient usage information should not be collected in this system to avoid personal privacy issues.

15. Are there additional benefits beyond the ability to detect counterfeit product that anti-counterfeiting and track/trace technologies can provide for industry, (e.g., inventory control, facilitation of product recalls, and identification of theft and product diversion)? Give specific examples.

An effective electronic tagging process can provide the industry with many benefits. The core data provided is the current location, by serial number, of each item, plus a history of each movement. Based on this information, a key value is the ability to document a true pedigree of goods that have passed through legitimate channels and to detect, prior to use, goods that do not correspond to a legitimate chain of custody and hence may be counterfeit.

Beyond counterfeit detection, the tag on the product and the higher levels of container can give significant advantages:

- Improved automated handling with distribution centers.

- Improved product rotation.
- Improved, lower cost, targeted recall capability.
- Improved inventory tracking within each distributor or pharmacy.
- Improved drug billing and reimbursement procedures by reporting the unit-of-use serial numbers automatically.
- Improved control within hospitals and nursing homes through electronic recording.
- Reduced chance of mistaken drug administration, over or under administration in hospitals and nursing homes.
- Reduced "shrinkage" in the supply chain.
- Improved control of products that are withdrawn from the supply chain due to spoilage or shelf life expiry.
- Significant savings through better inventory management and optimized manufacturing and distribution.
- Better supervision of "trade promotion" and other payments made by manufacturers.
- Ability to provide patient level kiosks that can validate medicine and provided detailed product information. This can mitigate some of the regulatory compliance issues of Internet pharmacies.
- Ability to control drug diversion through institutional outlets.

17. For products that are shipped directly from manufacturers to retailers, would the use of track and trace technology on those products provide any additional benefits?

Some of these benefits are already listed in the response to Question 16 above:

- Improved automated handling with distribution centers.
- Improved product rotation.
- Improved, lower cost, targeted recall capability.
- Improved inventory tracking within each distributor or pharmacy.
- Improved drug billing and reimbursement procedures by reporting the unit-of-use serial numbers automatically.
- Reduced "shrinkage" in the supply chain.
- Improved control of products that are withdrawn from the supply chain due to spoilage or shelf life expiry.
- Significant savings through better inventory management and optimized manufacturing and distribution.
- Better supervision of "trade promotion" and other payments made by manufacturers.
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B. Questions Concerning Regulatory Requirements and Secure Business Practices (Options 10-13)

1. Discuss the most effective ways to achieve the goals of the wholesale distribution rule (21 CFR 203.3(u) and 203.50). Given recent or impending advances in technology, comment on the feasibility of using an electronic pedigree in lieu of a paper pedigree.

An electronic pedigree, that was uniformly required for all changes of custody of regulated products by all authorized handlers would be technically and economically feasible. By having a uniform requirement the applications of FDA regulations would be less subject to challenge and overall costs would be reduced.

5. Discuss the strengths and weaknesses of a pedigree as a means of tracking product integrity. Is there a deterrent value in having a pedigree? What is the most cost-effective approach to obtaining reliable pedigree information?

An electronic pedigree, required for all drug movements, would be cost-effective and provide supply-chain wide tracking and tracing capability. This would be a significant deterrent to regulated entities that contemplated accepting products from improper sources. The electronic chain of custody would clearly identify any entity that handled suspect goods and attempted to introduce them into the legitimate supply chain.

10. Comment on the need for FDA guidance dealing with site security and supply chain integrity in light of the importance of drug treatment for bioterrorism incidents.

One advantage of an electronic pedigree, reported dynamically through a distributed pharmaceutical track and trace system, is that there would be near-real time visibility of stocks of all drugs. This could facilitate the rapid transport of large quantities of drugs needed for bioterror incidents. It would reduce the needs to stockpile drugs and provide faster access to drugs that are local to the incident.

D. Questions Concerning Education and Public Awareness (Options 17-21)

5. Once a counterfeit drug is identified, what tools are available to the agency to notify potentially affected parties without inappropriately

scaring other consumers from taking their medications?

With electronically tagged medications and an effective electronic pedigree that can identify counterfeit drugs (even when the electronic tag is reproduced) immediate detection of suspect and recalled products is possible. Thus, it is feasible for each retail pharmacy and hospital to provide a kiosk where members of the public can validate their medications. This kiosk could be part of a medication information and education scheme for pharmacy clients and give the public reassurance about the quality of their medications. This would provide an outlet for public concern and save the industry large quantities of money when an alert occurred. Instead of patients either refusing to take their medication, or demanding replacement with fresh stock, the patient could personally and privately validate their existing packaged medicine at these kiosks. This also has the value of reducing the potential societal and economic havoc that could result from false alarms and rumors introduced by domestic or international terrorists.