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November 4, 2003

U.S. Food and Drug Administration
Rockville, MD 20857

Re: Docket 2003N-0361
Counterfeit Drug Initiative

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On behalf of the employees of IntelliDOT Corporation I am pleased to offer the attached comments in response to the FDA invitation for comments on the Interim Report by the Counterfeit Drug Task Force. I offer apologies for the lateness of these comments and hope that the Task Force will find them sufficiently useful so as to include them in its evaluation.

We have limited our comments to those areas where we possess direct experience that might help the FDA Task Force in its deliberations. We have tried not to make this a commercial pitch for our own product, and have chosen to offer recommendations that we believe will assist in the creation of a national approach to solving this problem.

Thank you for the opportunity to participate.

Sincerely,

Gerald E. Forth
President & CEO

2003N-0361 C32

Comments related to Docket 2003N-0361
Interim Report by the Anti-Counterfeiting Task Force

Recognizing that we are in the minority, we would like to begin our comments by disagreeing with one of the interim conclusions reached by the Task Force. This relates to the belief that a multi-pronged approach will ultimately be less costly and more effective than a more comprehensive, but more focused solution. Although the multi-pronged approach will suit the vendors of the many types of counterfeiting countermeasures that are available in the market today, it will do little to provide a satisfactory solution to the problem of drug counterfeiting. There are many reasons for this belief, but the most compelling are the real-life experiences of organizations like the U.S Treasury, or industries like the music recording business as they have sought to prevent or control counterfeiting. Without exception, solutions that rely on what is "on the package" to prevent counterfeiting eventually fail. It is a simple matter of time, technology, and the great difficulty in training all users to identify legitimate countermeasures. But, is there a better solution set? We believe there is.

Before we respond directly to the questions posed by the Task Force, we would like to make a few more observations on the preliminary findings outlined in the report. First, we believe that the Task Force is correct in making the assumption that an adequate prevention system can be designed and implemented at no net cost to the consuming public. We believe, and will attempt to demonstrate in the following pages, that such a system will deliver a considerable increase in revenues to participating pharmaceutical manufacturers, and will also deliver significant savings and efficiencies to the remainder of the supply chain. Second, we believe that it is unrealistic to expect that visible countermeasures on packaging will ever provide a suitable solution. The sheer magnitude of the task of educating pharmacists and consumers on the number of possible technologies in use at any point in time is too large. The fact that such countermeasures must randomly change in order to remain effective makes the task impossible. In our research in the music industry, Vivendi International described to us how they would find both legitimate and counterfeit CD's side-by-side at retailers. One carried a seal with a hologram; the other had identical packaging, but no hologram. The store personnel hadn't even noticed the difference. This is a preview of what we can expect in pharmaceuticals, but with far more damaging consequences.

Our third observation is that the FDA needs to seek authority, or use existing authority to enforce a more disciplined and accountable supply chain for pharmaceutical products. While we are not in favor of regulations that will force further consolidation in the drug distribution business, it is apparent that the secondary market cannot be adequately regulated by the states alone. The fact that many medications pass through many hands on the way to the end user is a function of money to be made at each level, rather than an efficient means to deliver products at lower cost to hospitals and consumers. This is basic economic theory. If there is a profit to be made in each transaction, which there must be for these channels to exist, then streamlining the channels will not increase the costs to the end users. On the contrary, there is every reason to believe that costs will

actually decrease, and dangerous diversions will also decrease. While we agree that the supply chain has become very dependent on the use of secondary markets to balance short-term supply and demand, we also believe that this dependence is a zero-sum game that cannot yield any net benefit to the end users of the products, and may be discontinued in a relatively short period of time with no economic cost, but a great increase in consumer safety.

When the State of Florida undertook its investigation of drug diversion and counterfeiting, it found that 46% of all prescription drugs moved directly from manufacturer to either hospitals or chain drug warehouses. These drugs may then enter the secondary market through legal or illegal means, but we can assume that the vast majority arrived at their final destination safely. Of the remaining 54% of prescription drugs, approximately 90% flow through the "big three" drug wholesalers. These large distributors use less than 100 distribution centers to move all of this product to the dispensing pharmacies. This leaves a very small quantity flowing through regional or local distributors, most of whom are legitimate, quality-conscious businesses. A workable track and trace system, focused on these national and regional distributors, would provide reasonable security over at least 98% of the prescription drugs moving through the supply chain. If such a system were available, the authentication function could be concentrated at the distributor level rather than at the dispensing pharmacy level, greatly reducing the costs of such a system. Legitimate distributors, faced with the need to provide complete accountability for each product (pedigree), would soon move their business away from the secondary market distributors who refuse to participate. This would expand the coverage from 98% of the products to nearly 100% in a relatively short period of time.

In conclusion, we believe that the FDA should allow the pedigree requirements of the PDMA to go into effect within a reasonable time frame. The rules that define an acceptable pedigree should be amended to define this as an electronic record that is maintained from the point of manufacture, through any repackaging, to the point that the drug is delivered to the point of dispensing. Each manufacturer or repackager of pharmaceutical products should be required to initiate this electronic record and make it available to a global data base that may be accessed and updated by each participant in the supply chain. Any hospital or retail pharmacy should have sufficient access to this record so as to allow verification that the product in their possession has an unbroken, authentic electronic record. We further recommend that the FDA allow the pharmaceutical industry to construct this system and data base to their specifications and using such technologies that best meet their needs.

Specific responses to questions of the Task Force:

A.3

Tamper-evident packaging cannot be an effective deterrent by itself. Aside from the obvious ability of counterfeiters to copy most packaging, the ability of pharmacists or consumers to reliably authenticate such measures has been shown to be very low. On the

other hand, combining a tamper evident seal with a bar code or other carrier of a serial number can provide both package security and traceability. We believe that such a combination can provide the foundation of an affordable track and trace system. The cost of a suitable label that can carry either a bar code or later, a RFID chip, is very affordable.

A.5

We believe that the use of a tamper-evident seal that contains a machine-readable mark that holds a unique serial number is the foundation of an effective countermeasure. To be most effective, sealed pallets and cases, as well as individual packages most commonly delivered to the dispensing pharmacy should all carry a seal with a unique serial number. This will facilitate supply chain authentication of sealed packages and will provide a link between the individual package serial numbers and the over wrap serial number.

We believe it is possible to create an effective anti-counterfeiting system that will track only the 400 pharmaceutical products at highest risk. However, if an effective and easy to use track and trace system is installed, there are additional benefits to the industry that will move its use to all products. These benefits are not the concern of the FDA, but they include the ability to better manage inventories and reorders real-time, and the ability to gain access to marketing data that is part of a multi-billion dollar service industry.

A.6.

It is our recommendation that a bar code based track and trace system, using tamper-evident seals that contain the code that carries the unique serial number be utilized. It is the most financially attractive option. The central data base should include features that will allow this unique identifier to be either a multi-digit random number or the standard EPC that is proposed for use with RFID. This will facilitate any type of data entry on the supply chain side, and should relieve concerns about future transitions to newer technologies. In summary, the system should be able to accommodate all data capture technologies, but provide a standardized central data base.

It is critical, however, that the authentication logic not rely solely on information contained on the packaging. We recommend a "pitch and catch" process whereby a unique data element is forwarded by the central server to the expected destination. This will prevent exact copies of legitimate serial numbers from being authenticated by the system. This is a critical element of an effective system, whether it uses bar codes or RFID tags. We have a design for such a system and own some intellectual property rights that relate to this type of system.

A.10.

As mentioned in the response to A.6 a product may be authenticated or validated by reading the unique serial number on the container (pallet, case, or individual package) and verifying that such a serial number has been activated by a legitimate manufacturer or repackager. This information is also matched with a unique data element that does not reside on the package itself. In the IntelliDOT system, this element is the expected destination. Both the serial number and the destination must match for authentication to

be given. Exceptions to this authentication are set aside for further evaluation. This additional step will involve a query to the central server and to the manufacturer's server as to the validity of the serial number and destination. If the package is legitimate, but the destination was not scanned at the shipping point, there is a resolution process that allows the manufacturer to correct the error and still maintain the electronic pedigree.

The authentication should take place at each point in the supply chain where the product is received and shipped to another destination. It is accomplished by making a simple scan of the bar code containing the serial number on the package. If the Florida study is representative, more than 90% of all medications make one stop before being received and dispensed by a licensed pharmacy. If the distributor is willing to warrant the electronic pedigree of a product they sell, it would be unnecessary for the receiving pharmacy to also authenticate the product. However, we believe that many pharmacies would take this additional step for their own peace of mind.

A.11.

We propose the creation of a pharmaceutical industry owned central data base, but one that is managed by an independent entity for several reasons. This data base, while potentially large in transaction volume, would not require any more sophistication that those currently in use in other high transaction industries. Existing security solutions, such as used in e-commerce today, will be sufficient to protect the integrity of the data. The software itself may be run on any number of Secure Applications Systems Providers (SASP's) such as EDS, IBM and others. These companies provide the hardware, system security and backup that such a system will require.

A properly designed system such as that offered by IntelliDOT is self-updating. Each manufacturing location and repackaging plant has a local server that transmits data to the central or global data base. The data base itself is subject to rules as to data retention and backup that can be configured to meet industry and FDA requirements. One disadvantage of the global RFID concept that has been circulated is that the proponents would like to use such a system for managing the global supply chain, which makes it very expensive and complex. The system we are proposing for supply chain security has one primary purpose: to protect the drug supply chain. While it will deliver additional informational benefits to manufacturers and distributors, that is not its primary mission.

A.12.

The only realistic methods for containing a unique identifier on a package are machine-readable technologies such as bar codes and RFID. Each has its advantages, and its costs. Bar codes require line of sight reading, and this is widely and easily used today. There is the added advantage of connecting the line of sight with a validated reading of the code, thus minimizing errors. RFID does not require line of sight for reading, but many materials interfere with RF signals, making the read not as automatic as many portray. Bar codes are printed at practically no cost on existing labels or packaging, while RFID chips still have a relatively significant cost.

Most bar codes, including 2-dimensional codes, have one additional defect. Public domain codes have many uses, yet no single registry to ensure that conflicts in numbering sequences will not happen. This presents a problem for a system that relies on every serial number being unique and never reused. This recommends the use of a proprietary symbol that can be appropriately managed for proper security. IntelliDOT owns such a symbol that is capable of carrying the GTIN or EPC, plus lot and expiration and a unique serial number. The company is prepared to put this symbol to use in an anti-counterfeiting system at no cost to users. IntelliDOT would assume responsibility for the integrity of the serial number system and the issuance of such to all legitimate users.

A.13.

The costs of establishing and maintaining a universal track and trace system are surprisingly affordable, if it uses a combination of tamper-evident seals and a protected bar code symbol to identify the product. We believe that such a system can be installed and maintained for all pharmaceutical products and deliver a net benefit of between $146 million and $446 million dollars to the supply chain as a whole. These benefits are concentrated at the manufacturer level, but it is our belief that a more thorough evaluation of the efficiencies to be gained, and losses avoided, at the distribution level will yield a similar net benefit. We have made no effort to quantify the financial benefits that will result to consumers and insurance companies from the substantial reduction in counterfeit medications.

If every manufacturer, repackager, retail pharmacy and hospital in the U.S. were to install scanners and authentication software, a project far more comprehensive than we consider necessary, the total implementation costs are estimated to be $96.4 million. The annual costs of operating the system, assuming the system would be run by a for-profit company such as IntelliDOT, would be $153.7 million. A ¼% increase in pharmaceutical revenues from the reduction in counterfeiting activities (the recent Lipitor event represented more than $15 million in revenues) would equal $300 million annually. Our research suggests that from ¼ % to ½% increase in revenues is likely.

We also believe that a small-scale pilot to demonstrate the real savings and the feasibility of the track and trace system may be done on a regional basis, involving one manufacturer and one national or regional distributor, for a total cost of about $350,000. It is almost inconceivable that such a small sum could stand in the way of such an important evaluation.

B.3. & B.5.

An electronic pedigree is the by-product of an effective track and trace system. The goal of the system is to squeeze illegitimate product from the marketplace within a relatively short period of time. As this happens, end users, primarily pharmacies will gain confidence that a quick scan of a product and the responding OK from the system will be sufficient. The system will still document every transaction and maintain a permanent record of its lifespan, but it is our opinion that the pedigree as we think of it today will cease to be important. It is there if needed, but the day-to-day user of the system will not even know it exists.

In our opinion, there is no stronger deterrent than the certainty that an illegitimate product will be identified at the moment it tries to enter the supply chain, and that the source of that product will immediately be called to account for the misstep. The uncertainty as to whose hands touched a suspect product that exists today will disappear. Those who depend on the shadows to operate will be exposed and prosecuted. This should not be delayed.