February 24, 2006

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

Re: Submission of written comments to FDA Counterfeit Drug Task Force
Docket Number: 2005N-0510

Dear Sir or Madam:

On behalf of CVS/pharmacy, I respectfully submit the following comments to the FDA Counterfeit Drug Task Force (Docket Number: 2005N-0510).

Introduction

CVS is America's largest retail pharmacy, operating more than 5,400 retail and specialty pharmacy stores in 37 states and the District of Columbia. On January 23, 2006 CVS announced that it had entered into a definitive agreement under which it will acquire approximately 700 Sav-on and Osco drugstores, as well as a distribution center located in La Habra, California, from Albertsons, Inc. Upon the closing of this transaction, CVS will operate 6,100 stores in 42 states.

As the nation's largest provider of pharmaceutical care, CVS recognizes the paramount importance of a secure pharmaceutical supply chain to ensure the health and safety of our patients. To that end, CVS has taken a leadership position in retail pharmacy with respect to implementing practical measures that have an immediate impact upon the security and integrity of the supply chain.

In May of 2005, CVS was the first retail pharmacy to announce that it would require certification from its pharmaceutical wholesalers that they do not engage in trading on the secondary market. Historically, secondary market trading among wholesalers (also known as horizontal trading) has allowed a potential entry point for counterfeit product to enter the legitimate supply chain. CVS' certification requirement results in the wholesalers ensuring that the products they sell to CVS are acquired directly from the drug manufacturer (or the manufacturer's exclusive distributor in

those cases where the manufacturer awards exclusive distribution to a limited number of wholesalers).

On the regulatory front, CVS has worked extensively with legislators and regulators from a number of states over the past two years on laws and regulations that strengthen the requirements for the licensing of wholesale distributors. Most recently, CVS was the first retail pharmacy to have one of its distribution centers be awarded Verified Accreditation of Wholesale Distributors (VAWD) accreditation from the National Association of Boards of Pharmacy (NABP). CVS will be pursuing VAWD accreditation for our other distribution facilities in the near future. CVS has specifically selected to support and pursue these initiatives because they represent practical and effective measures that have an immediate impact upon fortifying integrity and security of the pharmaceutical supply chain.

In the FDA's May 2005 report entitled "*Combating Counterfeit Drugs: A Report of the Food and Drug Administration Annual Update*", it was disclosed that while there were more incidences of counterfeit drug cases initiated in 2004, as compared to 2003, most of the suspect counterfeits were found in smaller quantities. Additionally, the report states that "most of these drugs were destined for the black market or internet distribution, rather than for widespread distribution in the nation's drug supply chain." CVS believes this result to be directly attributable to the numerous changes that members of the legitimate supply chain have made in recent years to improve the integrity of the supply chain.

While not discounting the possibility that some of today's emerging technologies such as RFID and others may at some point provide future improvements to supply chain integrity, these technologies currently remain unproven. More time and research is required to fully develop and understand their capabilities and application. In the interim, practical measures, such as those already taken by CVS, have had an immediate impact towards improving the integrity of the U.S. drug supply chain. In the long term, we believe that practical approaches such as these will in all likelihood be more effective and provide timelier security to the supply chain, than will currently emerging technologies.

Supply Chain Integrity Initiatives

Provided below is a discussion of some of the recent initiatives that CVS believes has had a positive impact upon the supply chain's integrity. These initiatives have largely been driven by industry stakeholders, as well as through legislation.

Community Pharmacy Initiatives

Many community pharmacies, both chain and independent, have made changes in their purchasing practices to ensure the integrity of the products they are receiving and dispensing to their patients. As mentioned earlier, CVS was the first retail pharmacy to announce that it would require certification from its wholesalers that they do not trade in the secondary market. This certification all but eliminates the opportunity for counterfeit product to enter the supply chain, by ensuring that CVS' wholesalers purchase their products directly from the manufacturer. Other pharmacies are now taking similar approaches and the nation's largest wholesalers have

curtailed many of their historical actions in this regard as is evidenced by their recent public statements.

Wholesale Distributor Initiatives

One of the most significant changes involves the domestic wholesale distribution industry's move away from the horizontal trading among other wholesalers (i.e. the secondary drug market). We believe this practice was historically a potential entry point for counterfeit products in the supply chain, as product could be sold multiple times through networks of wholesalers. Each point of contact representing a potential opportunity for the integrity of the product to be corrupted. The eradication of horizontal trading creates a direct flow of product from the manufacturer to a wholesaler to a pharmacy, or in the case of a warehousing retail pharmacy chain a flow of product from the manufacturer to a wholesaler to a chain pharmacy warehouse to their intracompany pharmacy, thereby reducing the potential points of supply chain corruption. Notably, each of the country's three largest wholesalers, Cardinal Health, McKesson Corporation, and AmerisourceBergen have made public announcements during the past year that they will no longer trade in the "secondary" market.

Another major change in the wholesaler industry has been the migration towards a Fee- For-Service / Inventory Management Agreement (FFS/IMA) relationships between wholesalers and manufacturers that eliminate speculative purchasing on the part of the wholesaler. Traditionally, wholesaler's business models were dependant upon the incremental revenue that could be garnered through the surreptitious purchasing of extra inventory in advance of a manufacturer's price increase. The wholesaler would then capitalize on the inflationary value of the standing inventory in their possession at the time of the manufacturer's price increase. Speculative purchasing practices also provided the economic incentive that fueled horizontal trading among wholesalers in the secondary market. CVS believes the evolution of these types of agreements has resulted in new relationships between wholesalers and pharmaceutical manufacturers in which speculative purchasing by in large has been eliminated. This results in less excess inventory in the supply chain at any given point in time, as well as helping to eliminate the secondary drug market – both of which have a positive impact upon the integrity of the supply chain.

Pharmaceutical Manufacturer Initiatives

The pharmaceutical industry has undertaken initiatives to secure the integrity of the supply chain. Most notably, it has become more restrictive with respect to its selling practices. In an effort to weed out unscrupulous wholesalers, many manufacturers have instituted a review process by which certain standards must be met before a wholesaler is allowed to purchase and distribute the manufacturer's products.

Through the implementation of FFS/IMA agreements with wholesalers (as discussed in greater detail in the previous section), the pharmaceutical industry has eliminated the economic model upon which the secondary market was established. Inventory management agreements also provide the manufacturers with tighter control over the quantity of product in the supply chain.

Lastly, some manufacturers have incorporated overt counterfeit measures such as color shifting inks into their product labels to make it difficult for the products to be counterfeited.

State-level Legislative Initiatives

During the past few years, numerous states have enacted laws and regulations to help ensure the integrity of the prescription drug supply. A hallmark and common element of these state-level legislative initiatives has been the strengthening of wholesale distributor licensing requirements. These new requirements include, surety bonds, criminal background checks, facility inspections and the designation of facility representative at each licensed facility to be held accountable for the operation of the site. Additionally, these laws have increased the penalties for "known" violations. We believe these stricter licensing requirements have made a tremendous impact in the removal of unscrupulous wholesalers from operating within these states. CVS fully supports these activities and has worked extensively with other stakeholders to promote similar initiatives in other states. That being said, due to the lack of consistency between individual state regulations and requirements, the potential exists for significant confusion in the marketplace.

Other state-level initiatives also included the requirement of pedigree documentation for prescription drugs that are distributed outside a defined "normal distribution channel." In most states, the normal distribution channel is defined as a chain of custody for a prescription drug that is moving in path closer to the ultimate patient with each transaction, and includes those transactions involving chain pharmacy distribution centers. It is our belief this concept has been endorsed not only by National Association of Chain Drug Stores (NACDS), but also by the National Association of Boards of Pharmacy (NABP), the Healthcare Distribution Management Association (HDMA), and the Pharmaceutical Research and Manufacturers of America (PhRMA).

Summary of Supply Chain Integrity Initiatives

The initiatives outlined above represent practical and immediate solutions to ensuring the integrity of the prescription drug supply chain. CVS believes the efforts on the part of the various constituencies identified above have resulted in an immediate and effective positive influence on supply chain integrity. While emergent technology may potentially play a role and hold some promise for the future, they are not currently readily deployable or utilizable. The role of emergent technologies is yet to be defined and proven.

Prescription Drug Marketing Act of 1987

The Prescription Drug Marketing Act of 1987 (PDMA) and the Final Rule published in 1999, require pedigree documentation for all wholesale distributions where the wholesale distributor is not an Authorized Distributor of Record (ADR). The ADR concept, while well intentioned, is fundamentally flawed and we would point out that it provides no additional assurance of the product's integrity. For instance, under the ADR concept a wholesaler that is designated as an ADR will have no pedigree responsibilities regardless of the source of the product, whether from the manufacturer or through another wholesaler. Essentially, the ADR concept does not provide any assurance to a pharmacy or a chain pharmacy warehouse that the product was purchased directly from the manufacturer.

Chain pharmacy distribution centers (although they are licensed wholesalers) are not included as authorized distributors of record according to the definition of some manufacturers. While chain

pharmacy warehouses may have "on-going relationships" with manufacturers, these relationships may not include financial transactions between the two and subsequently manufacturers do not consider them to be "authorized" to distribute their products. In many cases, chain pharmacy distribution centers purchase and receive manufacturers products through a traditional wholesaler to leverage efficiencies in distribution and logistics networks. These purchasing arrangements are entered into with the full knowledge of, and in some cases at the direction of, the manufacturer. In this case, the manufacturer is aware the chain pharmacy distribution center, a licensed wholesaler, will be distributing their products.

In the past year, CVS has worked collaboratively with other industry stakeholders in addressing some of these concerns, with the "normal distribution channel" concept being the hallmark of these efforts. The "normal distribution channel" is defined as a chain of custody during distribution of a prescription medication that goes from either [1] the manufacturer to a wholesale distributor to a pharmacy to a patient or [2] the manufacturer to a wholesale distributor to a chain pharmacy distribution center to their intra-company pharmacy to a patient. Direct sales of prescription medications by a manufacturer to a pharmacy or chain pharmacy warehouse are also comprehended within the "normal distribution channel".

Wide consensus has been reached that so long as products are distributed within the defined normal distribution channel there is little to no opportunity to introduce counterfeit product, thus eliminating the pedigree requirement. Products that are distributed outside of the normal distribution channel provide a greater opportunity for counterfeit product to be introduced, and therefore pedigree documentation should be required.

While ADR and "normal distribution channel" both seek to achieve the same purpose, we believe that the "normal distribution channel" approach is the only one of the two that results in a safer and more secure pharmaceutical supply chain. **In the interest of furthering the public health and safety as it pertains to the matters previously discussed, CVS strongly urges the FDA to not only consider extending the effective date for the relevant portions of the PDMA of 1987, but also to revise the final rule to consider these initiatives discussed, specifically the adoption of the "normal distribution channel" concept.**

I thank you for your consideration of these comments. The CVS organization is willing to avail itself to the FDA for any additional assistance, input, or information that it may need regarding this issue. Please contact me directly at (401) 770-3402 if I may be of further assistance.

Sincerely,

Matthew J. Leonard
Senior Vice President, Pharmacy

APPENDIX

This Appendix contains CVS' responses to specific questions posed by the FDA.

Implementation of RFID

What incentives are needed for more rapid and widespread adoption of RFID in the U.S. drug supply chain? How can these incentives be achieved?

At this point in time it is extremely difficult to define which, if any, incentives would be needed for more rapid and widespread adoption of RFID. RFID is still an emerging technology with frequent changes, in addition to which the standards are not fully defined making any assessment regarding cost for implementation and expected benefits difficult to quantify. Without a clear understanding of the total cost of full-scale implementation and the benefits associated with this technology, it is nearly impossible to understand the total investment required and any incentives that may be useful.

That being said, since retail pharmacy has no pricing elasticity to cover the costs of any large-scale implementation, financial incentives should be made available not only for testing but also for long-term use.

What are current obstacles to widespread adoption of RFID in the U.S. drug supply chain? How can these obstacles be overcome?

There are a variety of obstacles to widespread adoption of RFID including, technical, operational and financial. From a technical perspective, standards have not yet been developed although the process is moving forward with EPCGlobal and other industry stakeholders. To date, there has not been any RFID solution that has been widely tested through the supply chain, to include the interoperability of any proposed solution within the supply chain.

At the FDA Public Workshop, there were a number of RFID pilot results presented. Unfortunately, these pilots were extremely limited in scope and the results presented may not provide and accurate assessment of the technology. For example, the Purdue Pharma/H.D. Smith pilot was limited to a single product from Purdue and subsequent transactions only with one wholesaler, H.D. Smith. Additionally, IBM and GlaxoSmithKlein presented the results of a pilot that involved one product, on one production line, at one manufacturing facility. These pilots did not include interactions with other wholesalers and most especially retail pharmacy. It was mentioned during the workshop and the subsequent testimony that the "pilot" phase of RFID testing was largely complete. Since there has not been any end-to-end testing performed with all participants of the supply chain, especially retail pharmacy, CVS would suggest the "pilot" phase of testing has not been completed and additional testing still needs to be performed.

CVS was one of the participants in Accenture's "Jumpstart" pilot programs that were discussed during the Public Workshop. From CVS' perspective the results of the pilots were interesting however, there are many open questions that remain unanswered and must be addressed before

widespread adoption. Some of those questions include, global standards, component and software costs and technology reliability. In addition, the results determined that any RFID implementation would require significant modifications to existing business processes and systems that have yet to be fully identified. Considering this is still emerging technology that is constantly changing there are legitimate concerns with changing existing systems to fit technology available today that may be drastically different tomorrow.

From an operational perspective, there are a variety of business/trading partner issues with which to contend such as: serialization of the EPC, inclusion of the NDC, data ownerships, sharing of data, and access to data. In addition, there is a large concern regarding the ability to adopt such a universal change in processes given the sheer number of parties within the supply chain, from manufacturers to wholesalers to chain pharmacy warehouses to the pharmacies themselves. Additionally, due to the constraints associated with the number of available resources, CVS has elected to dedicate more resources to promote and support current state level and internal initiatives that will yield an immediate impact as opposed to this more speculative approach.

Finally, the financial implications of widespread adoption of RFID are largely unknown. Considering this is still emerging technology, many of the costs have yet to be fully defined. Much of the financial burden will rest with wholesalers and community pharmacies, both of which have little if any opportunity to offset these large investments in their current economic models.

What is FDA's role in further facilitating adoption of RFID across the drug supply chain?

The FDA has an important role in further facilitating adoption of RFID, or other technology that seeks to attain the same goals. First, the FDA should continue to monitor the progress of EPCGlobal and help to reach consensus among the participants on some of the more contentious issues facing this group, such as including the NDC in the EPC, and privacy concerns. The FDA should be integral in educating the American public regarding RFID, or other technology, and its value as there is sure to be privacy concerns that left un-addressed will only delay implementation. Most importantly, the FDA should allow the industry more time to make sure the standards and the technology being developed will produce the desired result and ultimately evaluate the usefulness of this technology as a safeguard.

Finally, to the extent that this is determined to be a necessary direction, CVS suggests limiting the scope of RFID implementation considering sixty percent (60%) of all prescriptions dispensed in the U.S. are for generic pharmaceuticals that historically have had a minimal propensity to be counterfeited.

What is the timetable for widespread adoption of RFID across the drug supply chain, with and without additional incentives?

The timetable for widespread adoption of RFID is unknown. Any timetable is based on a number of factors that at this point cannot have any definitive dates assigned. The EPC standards first need to be finalized. In addition, the vendor community will need to develop products and software to meet the needs of wholesalers, chain pharmacy warehouses, and

pharmacies; each with potentially different business requirements. Bearing in mind, there are over 55,000 retail pharmacies across the U.S., and hundreds of wholesale distributors supporting those pharmacies, each requiring hardware and software installation.

During the Public Workshop a number of participants suggested the FDA consider a "phased-in" approach starting with those items more susceptible to counterfeiting. While this approach may make practical sense for a manufacturer since it will limit their "up-front" investment, it does not help the wholesale or pharmacy industries. Regardless whether it is ten items, a hundred items, or all items that electronic trace and trace is mandated, all wholesalers and pharmacies must have the required technology in order to accept the product.

RFID Standard Setting

Who should set the standard for RFID? Currently we are aware of the efforts of only one organization, EPCGlobal, to develop standards for the use of RFID in the drug supply chain. Are there other entities within the United States of abroad that are also developing standards for the use of RFID for the drug supply chain?

EPCGlobal is the appropriate organization to set the standards for RFID. Unfortunately, due to the costs associated to join EPCGlobal, there is a concern that smaller organizations whether that be manufacturers, wholesalers, or pharmacies are not being represented and may be unaware of the implications the standards process will have on their businesses. Unfortunately, it is this same barrier to participation that leads to under representation and unbalanced standards, specifically as it relates to key issues for community pharmacy such as inclusion of the NDC in the EPC and privacy concerns.

During the FDA's Public Workshop, testimony was provided by EPCGlobal that stated the Healthcare Life Sciences group within EPCGlobal has achieved more relative to standards setting in a shorter period of time than any other group. Additionally, there was wide consensus from many of the workshop's participants, NACDS, HDMA, Johnson & Johnson and Pfizer, that EPCGlobal should drive the standards setting process.

Is there a role for Federal leadership by FDA to advance the standard setting efforts? What is that role? Is there a role for other Federal entities, such as the DEA or the DOD?

The FDA has been an active participant at a number of meetings regarding standard setting. While it may not be necessary for Federal leadership in the standards settings process, clearly there is an opportunity for the FDA and others to fully understand the process and the challenges associated with the standards. In addition, this participation would lead to a better understanding of the technology and its capabilities to better prepare the FDA to lead discussions with interested parties.

Should standards remain voluntary? Why?

Standards should remain voluntary; especially considering RFID is an emerging technology with changing capabilities and benefits. Allowing the standards to remain voluntary enables the industry to continue to improve the standards to meet these changing capabilities.

Specific Drug Supply Chain RFID and E-pedigree Issues

What numbering conventions are being used or considered for mass serialization?

Currently there are no standards developed surrounding numbering conventions.

Should there be a single numbering convention or are different conventions compatible?

There should only be one numbering convention. Considering the number of participants in the U.S. drug supply chain, it would be nearly impossible to ensure the compatibility of different numbering conventions by manufacturers.

Should the NDC be part of the unique identifier or should the identifier be a randomly generated number? What is the extent of privacy concerns with using the NDC and how should they be addressed?

The NDC must be a part of the unique identifier. Currently, wholesalers and pharmacies use the NDC in a wide variety of their operations; more so for pharmacies. In order for pharmacies to realize any operational benefit to RFID, the NDC must be included in the identifier. The NDC is the single most widely used numbering convention in pharmacy operations, from inventory management, to electronic reimbursement transactions, to the safety and quality checks designed to ensure patient safety. NACDS provided valuable testimony during the Public Workshop of some of the many areas retail pharmacy utilizes the NDC.

In terms of privacy, there are a few options being considered that would eliminate the argument that the inclusion of the NDC, in the identifier, represents a privacy concern. Security measures could be built into the tags and the readers. In addition, many of the prescriptions filled at retail pharmacies are placed in another container rather than the manufacturers original shipping container, eliminating any patient privacy concern.

What is the timetable for widespread mass serialization for prescription drug products, with and without additional incentives?

Similar to the timetable for RFID adoption, the timetable for widespread adoption of mass serialization is unknown. The timetable is based on a number of factors that at this point in time cannot have any definitive dates assigned. Manufacturers, wholesalers, and pharmacies would need to work together to understand the implications and serialization methodology before any timetable could be developed. Bearing in mind, there are over 55,000 retail pharmacies across the U.S. and hundreds of wholesale distributors supporting those pharmacies, each requiring hardware and software installation.

Universal Pedigree Fields

Are there logistical concerns or barriers to passing a pedigree for a drug that moves from one State to another with different pedigree requirements?

There are numerous logistical concerns and barriers to passing a pedigree from one State to another with different pedigree requirements. Most wholesale distributors, including chain pharmacy warehouses, operate a single facility servicing pharmacies in multiple states making it impossible to know at the time of product receipt which States that product will be shipped. Therefore, it is nearly impossible to ensure another state's pedigree requirements will be met. Consistency among standards and pedigree requirements were a common theme from many of the participants at the FDA's Public Workshop including, NACDS, HDMA, McKesson and the Indiana and California Boards of Pharmacy representatives.

For these reasons CVS advocates for a consistent pedigree requirement across the country that includes an exemption for products purchased and distributed within the normal distribution channel.

Would a universal pedigree alleviate these concerns or barriers? How?

As mentioned earlier, a universal or consistent pedigree requirement would alleviate these concerns. The adoption of the "normal distribution channel" concept would also go a long way in reducing the unnecessary tracking of product in the legitimate supply chain for those who have committed to buying from limited sources. To date, other industry stakeholders, NABP, HDMA, PhRMA, as well as numerous states have endorsed this concept. In addition, it provides for equal treatment for both wholesale distributors and chain pharmacy warehouses (that are licensed as wholesale distributors).

What common fields/information are the most important in a pedigree? Why?

More importantly than the fields/information to be included in a pedigree is maintaining consistency for when a pedigree is necessary. As mentioned earlier, numerous states have adopted the "normal distribution channel" concept and only require pedigree documentation for products distributed outside of normal distribution. This approach has been met with wide acceptance from a number of industry stakeholders.

How can a universal pedigree be achieved?

Given the size and diversity of the pharmaceutical supply chain and the volume of prescription drugs distributed each year, it is unknown how a universal pedigree can be achieved without federal leadership advocating for consistent requirements.

Data Management and Security

Central Database v. Distributed Approach. Can/should the pedigree information be passed and authenticated using either model? If some stakeholders subscribe to a central database and others use a distributed approach, can the pedigree information still be passed and authenticated?

If pedigree information is to be passed, a distributed approach would be the easiest and most reliable method. Peer to peer transactions already exist, related to ordering and invoicing, and those relationships between parties can be leveraged to meet pedigree requirements. EPCGlobal is actively working on developing approaches for peer-to-peer pedigree transactions.

If there is to be a central database, who should host it? Why?

A central database does not need to be developed and may in fact delay any implementation of electronic pedigrees. There would be significant costs related to the development and testing of any central database. There would also be a significant time requirement to build and test the central database and the redundant systems that must also exist. In addition, a central database approach would pose additional concerns regarding access to confidential and proprietary information.

What measures can be taken to secure the databases themselves in either the central database or distributed approach?

Database security is an issue that each member of the supply chain must consider. Clearly that is one of the obstacles to the central database given the flow of information from so many participants back and forth to the central database. Most companies that are already electronically exchanging ordering and invoicing information take all necessary steps to ensure the security of those transactions as well as overall data security.

Consumer Education

What type of consumer education is needed as the use of RFID in the drug supply chain becomes more prevalent? What messages should be conveyed? Who should develop consumer education program(s)? Should there be a notice on the product package that an RFID tag is affixed to the product package? If so, what should the notice say?

Consumer education is integral to the success of any new technology. This has become evident given the wide concern surrounding a few pharmaceutical manufacturers who have started tagging product without any ability for the retail pharmacy to kill or destroy the tag since it has been placed under the label. There has been a great deal of negative information regarding RFID and the ability for anyone to read the information on the tags. Patient privacy must be a guiding principle to any RFID implementation. Consumer level education should be a combined effort from all participants and possibly the public sector, such as the FDA.

Public Health Emergency Use

How can RFID be utilized in types of public health emergencies, such as pandemic influenza? Should RFID be used on other types of medical countermeasures besides drugs in the Strategic National Stockpile?

RFID is an emerging technology and its full uses and capabilities have not been completely identified. While there may be opportunities for it to be utilized in public health emergencies such as pandemic influenza it may be premature at this point in time to plan for its uses beyond the initial case studies.

What is the role of the Federal Government in encouraging or requiring RFID or other electronic track and trace technologies for drugs most likely used in these situations?

At this point in time it may be premature to look beyond the initial uses for RFID technology until the technology has been implemented and proven reliable.

Delay of the Effective Date of the PDMA Requirements

If the delay of the effective date is not extended, how will implementation of the rule affect primary and secondary wholesalers? Would it impact the distribution of drugs to smaller retail outlets or rural communities? Will secondary wholesalers have access to the information they need to meet the pedigree requirements?

If the delay of the effective is not extended, implementation of the rule will have a severe affect on the distribution of prescription drugs in the U.S., not only for smaller retail outlets but chain pharmacy locations as well. Currently, the PDMA pedigree requirements only apply to wholesalers that are not authorized distributors of record for the manufacturer. The ADR concept, while well intentioned, is fundamentally flawed and CVS would argue that it provides no additional assurance of the product's integrity. A wholesaler that is designated as an ADR will have no pedigree responsibilities regardless of the source of the product, whether from the manufacturer or through another wholesaler. Unfortunately, chain pharmacy warehouses (while licensed wholesalers) are not included as authorized distributors of record according to some manufacturers.

While chain pharmacy warehouses may have "on-going relationships" with manufacturers, these relationships may not include financial transactions between the two and subsequently manufacturers do not consider them to be "authorized" to distribute their products. In many cases, chain pharmacy warehouses purchase and receive manufacturers products through a traditional wholesaler to leverage efficiencies in distribution networks. These purchasing arrangements are entered into with the full knowledge of, and in some cases at the direction of, the manufacturer. At all times, the manufacturer is aware the chain pharmacy warehouse will be distributing their products.

As mentioned earlier, industry changes combined with practical state-level legislative efforts have immeasurably strengthened the legitimate supply chain without adding significant costs or unproven technology. The requirements for designated representatives, surety bonds, criminal background checks and on-site inspections are all examples of practical solutions.

What is the regulatory significance of the fact that current federal pedigree requirements apply only to wholesalers who are not authorized distributors of record? Please explain.

As mentioned above, the "authorized distributor of record" designation is not applied equally to all participants in the supply chain, notably chain pharmacy warehouses. In addition, even though a wholesaler may be an authorized distributor of record, that does prevent the wholesaler from purchasing product on the "secondary" market and not providing a pedigree, subsequently questioning that products integrity. Mr. Jim Dahl, formerly of the FDA, raised this same point during his testimony at the FDA's Public Workshop.

In the past year, the industry, as a whole, has worked collaboratively in addressing some of these concerns with the "normal distribution channel" concept being the hallmark of these efforts. The "normal distribution channel" has been defined as a chain of custody during distribution of a prescription medication that goes from a manufacturer to a wholesale distributor to a pharmacy to a patient or a chain of custody for a medication that goes from a manufacturer to a wholesale distributor to a chain pharmacy warehouse to their intracompany pharmacy to a patient. Direct sales of prescription medications by a manufacturer to a pharmacy or chain pharmacy warehouse are within the normal distribution channel.

Wide consensus has been reached that so long as products are distributed within the defined normal distribution channel, there is little to no opportunity to introduce counterfeit product thus eliminating the need for a pedigree requirement. Products that are distributed outside of the normal distribution channel provide a greater opportunity for counterfeit product to be introduced. Therefore, pedigree documentation is required.

Should the delay of the effective date be further extended? If so, how long should it be extended? Why?

The effective date should be further extended for a number of reasons. First and foremost are the positive steps that have been taken by the industry that have strengthened the integrity of the supply chain through practical cost-efficient means. An extension will allow the industry to continue to make these types of operational changes, while also dedicating resources towards technological opportunities whether RFID or other.

In addition, consideration must be given to the number of state-level initiatives that have been enacted or introduced with the past few years. Bearing in mind, many of the state-level requirements may conflict with the requirements of PDMA; notably "normal distribution channel" v. "authorized distributor of record" approaches. As mentioned earlier, while these approaches are different, both serve the same purpose and arguably the "normal distribution channel" approach achieves a more safe and secure supply chain.

If the delay of the effective date is not extended, would the 1999 rule ensure there is effective track and trace capability to combat drug counterfeiting? If not, why?

The 1999 rule would not ensure there is effective track and trace capability largely due to the fact there is currently no technology readily available to track and trace prescription drugs throughout the supply chain. While RFID may hold promise for the future, it is still an emerging and unproven technology. That being said, there are practical approaches such as the adoption of the "normal distribution channel" concept, in addition to improving licensing standards that can be accomplished immediately with a significant positive affect to the integrity of the supply chain.

It may be determined that these practical initiatives, which require no significant technological support, satisfy the objective of maintaining supply chain integrity and eliminate the need for further technological endeavors.

Minimum Standards for Wholesaler Licensing

The PDMA required FDA to issue minimum standard for wholesaler licensing. These standards were adopted by the states and incorporated into state law. How effective are these standards?

The minimum standards for wholesale licensing, issued by the FDA, have recently been strengthened through state-level legislative initiatives that have had a positive affect on eliminating the unscrupulous wholesalers operating within the legitimate supply chain. These requirements include, designated representatives, surety bonds, inspections and criminal background checks. While the full affect of these new standards cannot yet be quantified, the reduction in the number of licensed wholesalers operating in these states that have enacted such legislation must be considered a positive step.

How would recent actions by various states that have implemented stricter wholesale licensing and oversight laws impact compliance with the 1999 final rule?

The recent actions by various states implementing stricter wholesaler licensing standards have had an enormous impact on eliminating the unscrupulous wholesalers from operating within the legitimate supply chain. These licensing standards are another example of a practical and immediate approach that can be taken to further secure the U.S. drug supply chain.

The other element to many of these laws that have been enacted by various states is a pedigree requirement. As mentioned earlier, many states have adopted the concept of "normal distribution channel" and require pedigree documentation only for those products that are distributed outside of the defined normal distribution channel. This approach is drastically different than that required within the PDMA and the subsequent final rule that requires pedigree documentation for all wholesalers that are not designated "authorized distributors." While different in approaches, the goals remain the same and arguably, the "normal distribution" approach achieves a more safe and secure supply chain.

Adoption of E-pedigree Across the Drug Supply Chain

What is the status of developing standards that allow for the interoperability of e-pedigree solutions across the drug supply chain?

EPCGlobal is developing standards for the interoperability of e-pedigree solutions. However, significant issues remain with the technology available and the ability for any solution to operate with existing legacy systems. Any technological pedigree solution must be focused on the individual serialization of products rather than just electronic data transfers.

To what extent are stakeholders using e-pedigree?

There are currently few, if any, stakeholders using e-pedigree in a large-scale environment.

If you are not using an e-pedigree program now, do you anticipate having this capability in the future? If so, when do you plan to use e-pedigree?

Any technological "solution," whether e-pedigree, RFID, or other, will be evaluated and the benefits and required investment of each weighed against other technological "solutions" to determine the best approach. Each of these emerging technologies will need to be further evaluated for their ability to interact with other existing systems.

Our current focus remains implementing immediate and practical measures and devoting resources to work on state-level initiatives to implement these measures. While the technology aspect remains intriguing, our limited resources remain committed to the supply chain integrity issue through the promotion and implementation of measures that can, and should, be done today. Emerging technology does not address this issue in the context of what is most important, the immediate distribution of product within the legitimate supply chain.

Paper to E-pedigree Transition

Discuss the feasibility of a paper and e-pedigree system co-existing across the drug supply chain?

There is little feasibility of both paper and e-pedigree systems co-existing across the drug supply chain. Truly one of the greatest challenges the industry faces are inconsistent requirements from state to state. Adding another layer of complexity related to the format of the pedigrees would make any system impossible to manage to acceptable levels.

Can the authenticity and validity of the pedigree be maintained in such a system? How can this be done?

The authenticity and validity of pedigrees would in all likelihood be unable to be maintained in this hybrid approach. When one member of the supply chain passes an e-pedigree to another member that cannot accept or pass it on and must therefore create a paper pedigree, the pedigrees authenticity would invariably be in question.

Please provide cost estimates for the minimal equipment and infrastructure needed for members of the supply chain to accept and pass a paper pedigree. Cost estimates for use of e-pedigree. Is there a difference in cost if the drug product has a unique identifier versus one that does not?

At this point in time, it is nearly impossible to fully and accurately evaluate the costs for the supply chain to pass paper pedigree or e-pedigree. It is clear that while manufacturers have some degree of price elasticity, that is not the case with virtually all other providers whose revenues are largely controlled by fixed contract pricing.

What is the timetable for widespread adoption of e-pedigree across the drug supply chain, with and without additional incentives?

Similar to the timetable for RFID adoption, the timetable for widespread adoption of e-pedigree is unknown. The timetable is based on a number of factors that at this point cannot have any definitive dates assigned. Manufacturers, wholesalers, and pharmacies would need to work together to understand the implications and methodology before any timetable could be developed. Bearing in mind, there are over 55,000 retail pharmacies across the U.S. and hundreds of wholesale distributors supporting those pharmacies, each requiring hardware and software installation.