GS1 and Healthcare

January 17 & 18, 2006
Advisory Council - Melbourne

The global language of business

www.gs1.org

AGENDA

- Integration Meeting HUG and HLS
- Global Healthcare Initiative
  - Governance
  - Roadmaps
  - Communication
- Next Steps

Meeting with HUG & HLS leadership teams December 6, 2006 - Pfizer NY

Participants

HLS
- Ron Bone - McKesson
- Mike Rose - J&J Corporate
- John Howells - HDMA
- Tom Pizzuto - Wyeth
- Ted Ng - McKesson
- Tim Marsh - Pfizer

Global Office Staff
- Chris Adcock
- Michel van der Heijden
- Gay Whitney
- Chuck Schramek
- Bob Celeste
- Ulrike Kreysa

HUG
- Rich Hollander - Pfizer
- Volker Zeinar - B.Braun
- Ed Dzwill - J&J Pharma
- Tom Werthwine - J&J Med Device
- Jackie Elkin - Medtronic
- Peter Tomicki - Baxter
- Steve Hess - Merck
- Mark Walchak - Pfizer

GS1 US Staff
- Mike Meranda
- Dennis Harrison

Consultant
- George Simeon

Reminder of the GS1 vision

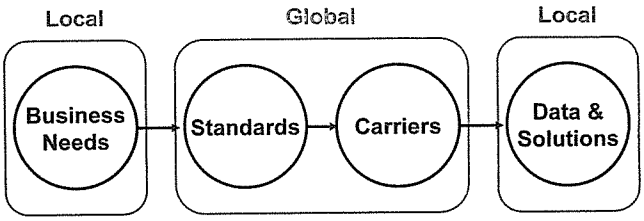
GS1 is now a single global organization with offices in over 100 countries.

At GS1, we see one vision, speak with one voice, act as one organisation.

Our strength is our single face to the outside world.

Needs

What we need



To meet these challenges and needs

Users, service providers & regulators are asking for...

- **One** global strategy for healthcare
- **One** point of contact
- **Coordination** across all GS1 activities
- **Unified** activities in standards development

HUG-HLS Integration

Our thoughts today...

- HUG and HLS have overlapping memberships
- User resources are stretched
- ONE approach and strategy is needed when talking to regulatory bodies
- The more users are behind the standards, the better and quicker will implementation take place
- With one group, interactions between groups and alignment work is not necessary
- Solutions which reflect and consider all possible GS1 standards will be better and stronger
- This reflects the structure of GS1

Alone we are strong – together we are stronger!

One global healthcare standard

One roadmap

One organisation

Global Healthcare Initiative

Key thoughts on integration

Successful collaboration is required

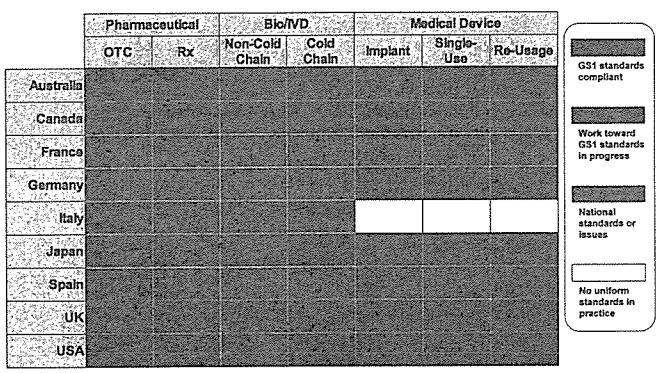
- Learn from the experiences of HUG & HLS
  - ✓ what did each do right?
  - ✓ what were the key skills?
  - ✓ where were there inefficiencies?
- What are potential enablers?
- What are potential barriers

Strategy

1. Develop and propose user-led global standards that proactively meet the demands of regulators.
2. Integrate the full range of healthcare stakeholders into our steering committee, advisory and working groups. Specifically develop communication tools to interest healthcare providers.
3. Consider the full healthcare sector when developing standards in order to maximize global interoperability.
4. Involve Solution Providers early on in the appropriate technical, implementation and technology search, working and advisory groups.
5. Ensure that healthcare standards are interoperable with other GS1 business group standards and requirements as far as possible.
6. Proactively propose solutions to meet evolving regulatory and legislative needs as well as actions which enhance patient safety and supply chain efficiency.

Global Healthcare Initiative

- Initial focus on Top 9 Countries:
  - ✓ USA, Japan, Germany, UK, France, Italy, Spain, Canada, Australia
  - ✓ They represent the major markets in terms of spending on healthcare world-wide
  - ✓ They are often leaders in the implementation of new healthcare initiatives
- Does not mean that we will not continue to include the needs and engage the industry in all GS1 Countries
- GS1 Member Organisations (MOs) will
  - ✓ utilize their contacts with all healthcare stakeholders
  - ✓ act as forums for building consensus
  - ✓ be drivers of consistent and interoperable standards implementation



Global Healthcare Initiative

Healthcare is a unique sector in terms of complexity of products, service providers, regulation, legislation, and variance across nations.

Products

- Pharmaceuticals: Rx, OTC
- Medical Device: Implant, Re-usable, Single-use
- Bio/IVD: Cold-Chain, Non Cold-Chain

Scope of Principal Stakeholders

- Manufacturers: Global
- Distribution/Wholesale: National/Regional
- Service Providers: National/Regional
- Regulators: Local (USA)/National/Regional(EU); some have global view

Global Healthcare Initiative

Implications

- Specific healthcare sectors may need individualized solutions (e.g. implants)
- Variable speed of adoption of carriers and solutions across medical sectors and countries
- Solutions may be locally adapted to local supply chain particularities and legislation (i.e. privacy)
- National drivers behind standards adoption are different:
  - ✓ USA: Counterfeit Pharmaceuticals -> e-Pedigree
  - ✓ Spain & Italy: Traceability
  - ✓ UK: Patient Safety
  - ✓ France & Australia: e-Commerce and Supply Chain Efficiency

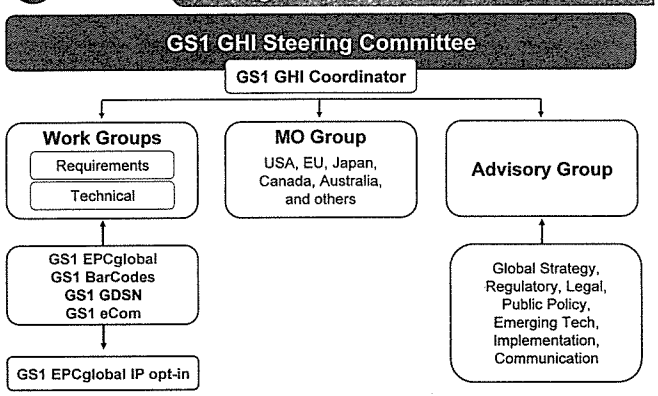
Stakeholder Approach

- Understand the needs and requirements of different groups
- Focused communication and invitations to participate
- Distinguish between global language issues and local implementation issues

Global Healthcare Initiative

Only Global Standards can ensure that the healthcare supply chain evolves in an interoperable manner.

- Users will only be asked for requirements once
- The number of working groups will be reduced
- Development will be done in a harmonized manner
- There will be one pace and one direction



The GS1 Global Health Initiative Steering Committee

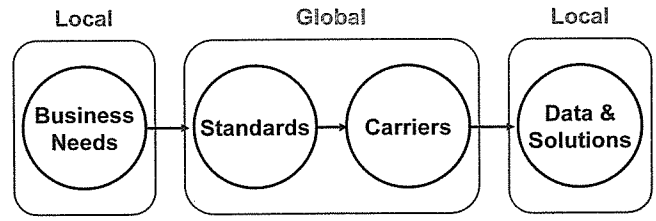
Will provide legitimacy, direction, speed and ability to commit for all actors in our major countries

- Strategic, not operational
- Makes decisions from a selection of options
- Validates and assigns resources to projects
- Sets priorities when resources are scarce

The GS1 Global Health Initiative Steering Committee

Should be composed of users whose corporate business strategy include standards designed to increase patient safety and increase the efficiency of the supply chain.

- Members (Voting and Non-Voting)
- Regulatory
- Hospital
- Sectors
- National insurance/healthcare (i.e. VA or national system)
- Distributors/wholesale
- Retail pharmacy
- GPO

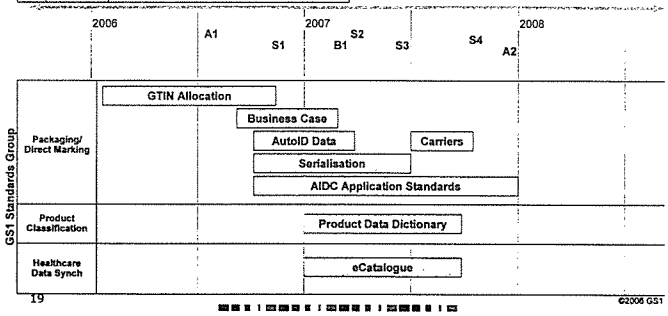


HUG Standards Development Strategy

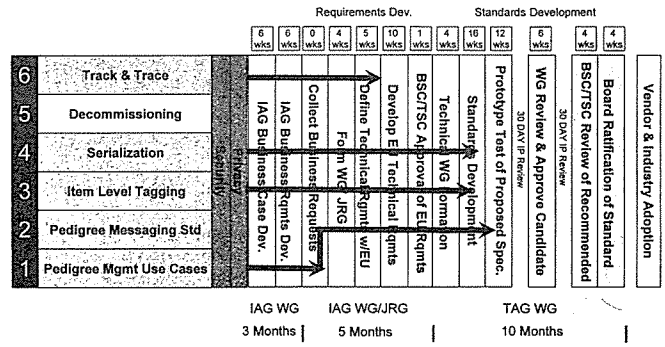
Version 1.1
13 Nov 06

Milestones

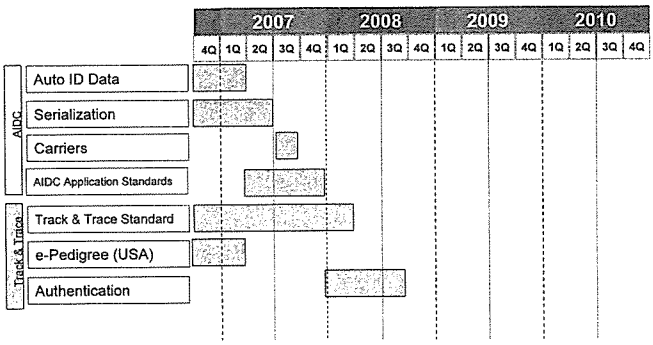
A1	28 Jul 06	Adopt existing GS1 Application Standards in Healthcare
A2	31 Dec 07	GSMP: Prioritised AIDC Application Standards
S1	31 Oct 06	GSMP: GTIN Allocation Rules for Healthcare
S2	31 Mar 07	GSMP: Healthcare Business Data AutoID Standard
S3	30 Jun 07	GSMP: Healthcare Product Serialisation Standard
S4	30 Sep 07	GSMP: Healthcare Data Carrier/Scanning Standard
B1	28 Feb 07	HUG Business Case for Packaging/Marking AIDC



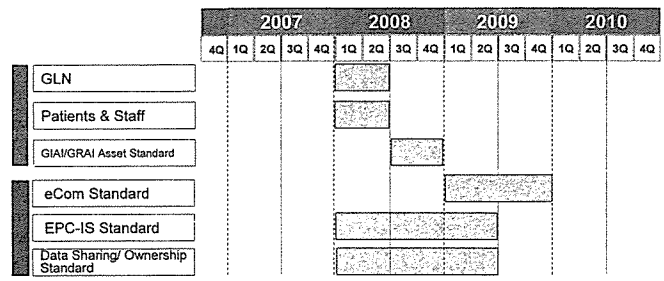
HLS Standards Roadmap
As of October 2006



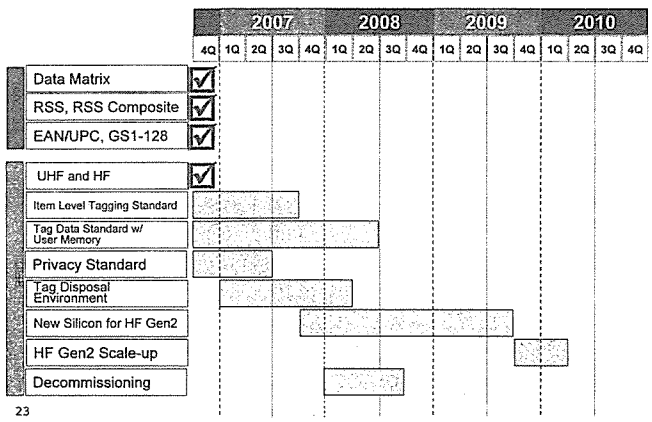
Roadmap: Standards



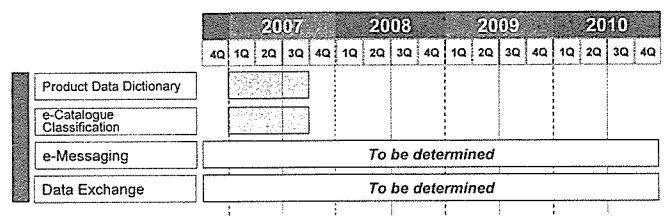
Roadmap: Standards



Roadmap: Carriers

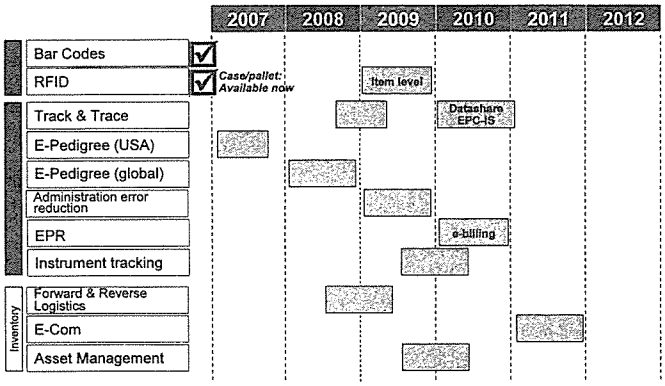


Roadmap: Data



Medical catalogue and a GDSN extension in healthcare is an urgent issue for the healthcare industry. To prevent diversion GS1 has to start the work on this topic and to develop a strategy for it.

Roadmap: Solutions



Serialisation as an example of collaboration and coordination

Serialisation

Initial discussion: How to address some current and potential U.S. regulations at the state and federal level about controlled substances and electronic pedigree.

Evolved to defining a way to **serialise pharmaceuticals** at **pallet, case and packaging and item level.**

Focus then moved to global work, covering all healthcare themes.

HUG-HLS Integration

HLS + HUG

Our joint work on serialisation is just one example of how joining forces makes us stronger…

Communication objectives & goals

- Inform GS1 stakeholders of the amalgamation of the three existing healthcare task forces into the 'Global Healthcare Initiative'
- Position the GHI as a positive step to making GS1 the *de facto* global standard in healthcare
- Inform the internal audience (GS1 members and subscribers) why GHI has been created and what it means
- Inform the external audience (the wider healthcare industry) that GHI is relevant to them, and is a 'step forward'
- Capitalize on this news to further increase awareness of the GS1 brand and sub-brands and understanding of their potential contributions to the Healthcare sector
- Attract new participants from the Healthcare sector to the GS1 standards development process

Next Steps

Action Items and Conclusions

- **Actions**
  - Agreement to develop one common Roadmap for Healthcare
  - Agreement to review the Governance
  - Agreement that broad Communication is a Key Success Factor
- **Conclusions**
  - Goals and Objectives of HUG and HLS are different. We reached a better understanding where they converge, but also where convergence is not meaningful.
  - GS1 will need to get better grip on a joint face to the user. We made good progress, but there is ample room for improvement.
  - By working together, in joint teams, we will learn how to act as one organization

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

MEMORANDUM

DATE: June 8, 2006

TO: Randall Lutter, Ph.D.
Associate Commissioner for Policy and Planning

Margaret Glavin
Associate Commissioner for Regulatory Affairs

FROM: Andrew vonEschenbach, MD
Acting Commissioner of Food and Drugs

Thank you for submitting to me the Counterfeit Drug Task Force Report – 2006 Update. I strongly concur that increasing the safety and security of the nation's drug supply and protecting it from the increasing sophisticated threat of counterfeit drugs is critically important. I commend you and the rest of the Counterfeit Drug Task Force on your efforts in developing this report and its recommendations to further this goal. I appreciate the fact-finding efforts that the Task Force undertook, such as holding the February 2006 public workshop and soliciting public comment, to understand the issues and provide me with informed recommendations.

I endorse the report and its recommendations. This includes the recommendation not to further extend the stay and to issue a compliance policy guide (CPG) that discusses FDA's enforcement focus regarding pedigree requirements. Please move forward with these recommendations, pursuant to FDA's good guidance practice (GGP) process (21 CFR § 10.115), as appropriate.

Andrew C. von Eschenbach, M.D.

FDA COUNTERFEIT DRUG TASK FORCE REPORT: 2006 UPDATE

I. INTRODUCTION

This report is based on the work of the Food and Drug Administration's (FDA or Agency) Counterfeit Drug Task Force.[1] It is the third report issued by the Agency since 2004 to address FDA's and the private sector's response to the emerging threat of counterfeit drugs entering the U.S. drug supply. This report contains recommendations to FDA's Acting Commissioner regarding actions that the public and private sector can take to further speed the adoption of electronic track and trace technology and for the use of pedigrees in general, to increase the safety and security of the U.S. drug supply.

After discussing the background and public comment on the issues addressed in this report, we discuss our recommendations or conclusions regarding:

- The expiration of the stay of 21 CFR §§ 203.3(u) and 203.50;
- The extent to which electronic track and trace technology is being used across the supply chain for electronic pedigrees and the use of radio-frequency identification (RFID) for drug products in the drug supply chain; and
- Technical issues related to the implementation of electronic track and trace technology, such as mass serialization, universal and uniform pedigrees, data management, and privacy issues.

II. BACKGROUND

A. The Counterfeit Problem

Counterfeit prescription drugs are illegal, generally unsafe, and pose a serious threat to the public health. Many are visually indistinguishable from authentic drugs. As we stated in our first Counterfeit Drug Task Force report in 2004 (2004 Report),[2] we believe that counterfeiting is quite rare within the U.S. drug distribution system because of the extensive scheme of federal and state regulatory oversight and the steps taken by drug manufacturers, distributors, and pharmacies, to prevent counterfeit drugs from entering the system. However, we are concerned that the U.S. drug supply is increasingly vulnerable to a variety of increasingly sophisticated threats. We have witnessed an increase in counterfeiting activities and a more sophisticated ability to introduce finished dosage form counterfeits into legitimate drug distribution channels over the years.

B. The 2004 Counterfeit Drug Task Force Report & 2005 Update

In 2004, the Task Force issued a report outlining a framework for public and private sector actions that could further protect Americans from counterfeit drugs, including implementation of new track and trace technologies to meet and surpass goals of the Prescription Drug Marketing Act (PDMA).[3] This framework called for a multi-layer approach to address the problem and included the following measures:

- Secure the ***product and packaging***
- Secure the ***movement of drugs*** through the supply chain
- Secure ***business transactions***
- Ensure appropriate ***regulatory oversight and enforcement***
- Increase ***penalties***
- Heighten ***vigilance and awareness***
- International ***cooperation***

In order to implement these measures, the Task Force Report stated, among other things, that:

- Widespread use of electronic track and trace technology would help secure the integrity of the drug supply chain by providing an accurate drug "pedigree," which is a record of the chain of custody of the product as it moves through the supply chain from manufacturer to pharmacy;
- RFID is a promising technology as a means to achieve electronic pedigree (e-pedigree);
- Widespread adoption and use of electronic track and trace technology would be feasible by 2007; and
- The effective date of certain regulations related to the implementation of the PDMA should be delayed until December 1, 2006 in order to give stakeholders in the drug supply chain time to focus on implementing widespread use of e-pedigree.

In 2005, the Task Force issued an annual update report (2005 Report)[4]. The 2005 Report assessed FDA's and industry's progress toward implementing the 2004 recommendations. In the 2005 Report, the Task Force found, among other things, that:

- Stakeholders had made significant progress in developing and implementing RFID during the previous year;
- FDA was encouraged by the progress stakeholders, standard-setting bodies, and software and hardware companies had made toward implementing an e-pedigree for drug products and that we were optimistic that progress would continue in an expeditious manner toward meeting FDA's 2007 goal of widespread use of e-pedigree across the drug supply chain;

- If it appeared that the 2007 goal would not be met, we planned to consider options for implementing the provisions of the PDMA rulemaking that are the subject of the stay; and
- FDA would identify what we could do to address obstacles to the widespread adoption of RFID.

C. 2006 Fact-finding Efforts: Public Workshop, Vendor Display, and Docket

As the Task Force continued to monitor the adoption and implementation of e-pedigree and electronic track and trace technology, we recognized that adoption across the U.S. drug supply chain was slower than originally anticipated. To determine whether widespread use of e-pedigree by 2007 was still feasible, and to solicit comment on the implementation of certain PDMA-related regulations, we held a public meeting on February 8 and 9, 2006.[5] Our objectives for the meeting were to:

- Identify incentives for, as well as any obstacles to, the widespread adoption of RFID across the U.S. drug supply chain and possible solutions to those obstacles;
- Solicit comment on the implementation of the pedigree requirements of the PDMA and the use of an e-pedigree; and
- Learn the state of development of electronic track and trace and e-pedigree technology solutions.

Over 400 people attended the public meeting. Forty-six presentations were made and 27 vendors participated in the vendor display.

Members of the drug supply chain, the technology sector, special interest groups, academia, health professionals, and consumers also filed sixty comments to the public docket that we opened as part of the public workshop.

In addition, we have been attending conferences, meeting with stakeholders, tracking the status of pilot programs, monitoring changes in and use of technologies, participating in standards development, and closely following other influences to remain up-to-date on the relevant issues.

This report is based primarily on information gathered from these fact-finding efforts. It contains our views on outstanding issues related to e-pedigree and RFID implementation, as well as recommendations for additional public and private measures to support our continuing efforts to further secure our nation's drug supply.

III. WHAT IS NEXT FOR PDMA IMPLEMENTATION?

What should FDA do regarding the stay of 21 CFR §§ 203.3(u) and 203.50?

Issue/Background

The PDMA as modified by the Prescription Drug Amendments of 1992 (PDA) amended the Food, Drug, and Cosmetic Act (the Act) to, among other things, establish requirements related to the wholesale distribution of prescription drugs. Section 503(e)(1)(A) of the Act requires that

> "...each person who is engaged in the wholesale distribution of a drug***who is not the manufacturer or authorized distributor of record of such drug *** provide to the person who receives the drug a statement (in such form and containing such information as the Secretary may require) identifying each prior sale, purchase, or trade of such drug (including the date of the transaction and the names and addresses of all parties to the transaction.)"

PDMA defines an authorized distributor of record as a wholesaler that has an "ongoing relationship" with the manufacturer to distribute the drug. However it does not define "ongoing relationship."

In December 1999, the Agency published final regulations (1999 final rule) (21 CFR part 203) related to the PDMA[6] that were to take effect on December 4, 2000. After publication of the final rule, the Agency received communications from industry, industry trade associations, and members of Congress objecting to the requirements in 21 CFR §§ 203.3(u) and 203.50. These provisions define the phrase "ongoing relationship" as used in the definition of "authorized distributor of record" (ADR), set forth requirements regarding an identifying statement (commonly referred to as a "pedigree"), and define the fields of information that must be included in the pedigree. Those objecting to the regulations explained that some secondary wholesalers may not receive pedigree information from their suppliers who meet the PDMA's definition of "authorized distributor" because the PDMA does not require authorized distributors to provide pedigree information. Without this information, they explained, secondary wholesalers would not be able to sell the drugs because they would be unable to pass a pedigree that met all the requirements of 203.50. Many secondary wholesalers are small businesses and expressed concern that their inability to meet the regulations' requirements would frustrate sales and drive them out of business.

Based on the concerns raised, the Agency delayed the effective date for those provisions until October 1, 2001[7] in order to reopen the comment period for the regulations and receive additional comments. In addition, the House Committee on Appropriations (the Committee) requested that the Agency review the potential impact on the secondary wholesale pharmaceutical industry and prepare a report to the Committee summarizing the comments and issues raised and the Agency's plans to address these concerns. The Agency's report, which

was submitted to Congress in June 2001 (2001 PDMA Report to Congress), concluded that we could address some of the concerns raised by the secondary wholesale industry through regulatory changes, but that some of the changes requested by the secondary wholesale industry would require statutory change.[8] Since submitting the report to Congress, FDA has continued to delay the effective date of these provisions.

In February 2004,[9] FDA again delayed the effective date of the particular provisions until December 1, 2006, because we were informed by stakeholders in the U.S. drug supply chain that industry would adopt electronic track and trace technology by 2007. When widely adopted, this technology could create a de facto e-pedigree that would document the movement of the drug from the place of manufacture through the U.S. drug supply chain to the final dispenser. If properly implemented, e-pedigree could meet the statutory requirements in section 503(e) of the Act.

In our 2006 fact-finding effort, we sought comment on whether to continue the delayed effective date, let the regulations go into effect, amend the 1999 final rule, or take other steps.

What We Heard

Most of the comments[10] to our February 2006 notice advised FDA to implement the regulations and let the stay expire. Some said the regulations should be implemented as currently written, without amendment. Others suggested amending the final rule to either 1) exempt the passing of pedigree along primary supply chain routes or the "normal chain of distribution," or 2) phase-in implementation, starting with requiring pedigrees for those drugs that are susceptible to counterfeiting and diversion, or 3) require a pedigree for "one forward-one back" in the distribution chain (as opposed to a pedigree that documents all prior sales transactions back to the manufacturer). A couple of comments suggested that we extend the stay in order to give industry more time to continue moving toward adoption of electronic track and trace technology and e-pedigree. A few wanted the stay to be extended in order to give time to amend the regulations. The amount of time requested for extending the stay varied from 5 years to indefinitely. We also received one citizen petition from a secondary wholesalers' trade association requesting that the stay be extended.

Some comments suggested that FDA work with Congress to eliminate the provision exempting the authorized distributor of record from having to pass a pedigree. They claimed that it was too confusing to recognize when a pedigree should or should not be passed.

Several comments asserted that implementation of the PDMA regulations would speed the development of new, less expensive ways to provide pedigree.

Discussion

We carefully considered several options and recommend that FDA no longer delay the effective date of §§203.3(u) and 203.50 past December 1, 2006. Regulations defining "ongoing relationship" and "authorized distributor of record" are scheduled to go into effect thereafter. In our 2006 fact-finding efforts, we gave stakeholders and the public ample opportunity to provide their input, but we did not hear the same arguments that we heard on previous occasions regarding why we should further extend the stay. Rather, this time, an overwhelming majority of the comments favored allowing the stay to expire.

The PDMA was signed into law in 1988. We believe that FDA can no longer justify delaying implementation of these regulations. In its 2001 PDMA Report to Congress, FDA shared the concerns that were raised regarding implementation of the regulations. By recommending implementation of the stayed provisions, we are supporting the law that Congress passed and has since retained. Furthermore, our extensive experience with counterfeit and diversion drug cases reveals that the secondary wholesale market is where much of the illegal activity occurs. Allowing the stay to expire will provide clarity in the drug supply chain regarding who is and is not an ADR, requiring those secondary wholesalers who may be involved in illegal activity to provide pedigrees. Continuing the stay would perpetuate the current confusion and further allow opportunities for counterfeit and diversionary practices to flourish.

We do not intend to put secondary wholesalers out of business. We continue to be sensitive to the concerns that they raised several years ago, even though we did not hear these concerns during our current fact-finding effort. Therefore, as explained below, we recommend that FDA take an enforcement approach that focuses on products most susceptible to counterfeiting and diversion, which should relieve some of the burden that secondary wholesalers might confront when these regulations go into effect.

Most of the comments we received in this fact-finding effort recommended that the regulations be implemented as is, while others advocated a phased-in approach, whereby the regulations would apply to a limited number of drugs at first. We agree that the regulations should be implemented as is. Many of the recommended changes to the pedigree requirements would require a change in the law. We believe that the regulations as currently written appropriately interpret and implement the PDMA, as Congress intended.

Although the regulations do not provide for a phased-in approach, we propose that FDA publish a Compliance Policy Guidance (CPG) before the stay expires that will contain a list of factors for FDA field personnel to consider in focusing their efforts when carrying out their duties in enforcing the law. We propose that these factors reflect a risk-based approach in which FDA uses its limited resources to focus on drug products that are most vulnerable to counterfeiting

and diversion. We do not propose the creation of a list of drugs that meet the criteria, but instead suggest that the CPG provide examples. However, we recommend that FDA not limit its enforcement to just those drugs that meet the factors. Rather, the factors would merely provide guidance for where our field personnel should target their enforcement efforts. The factors to consider for the enforcement focus may include drugs with a high value in the U.S. market, drugs with prior indicators (such as drugs that were involved in diversion cases or counterfeiting), and drugs that are easily counterfeited.

We believe that this CPG would be considered a Level 1 guidance under FDA's good guidance practice (GGP) regulations. (21 CFR §10.115.) Therefore, we recommend that FDA publish a draft version for public comment, evaluate the comments, and then publish a final guidance by December 2006.

We recognize that complying with the stayed regulations may require changes in business practices. Compliance may also require implementation of additional information technology systems to generate a pedigree. Each of these processes may take time to achieve. However, we note that, although the regulations at issue have been stayed since 1999, the fundamental statutory requirement to pass a pedigree has been in effect since PDMA was enacted. The regulations primarily serve to clarify who is an authorized distributor of record and what information a pedigree must contain. In addition, we believe that this report and the CPG we advocate herein will focus public attention on this issue such that any wholesalers who thought that they were not subject to the pedigree requirement will have adequate time to take appropriate steps to comply with the regulations.

Furthermore, many States have moved forward with their own pedigree requirements, which often contain requirements in addition to those in the PDMA. We are aware that stakeholders are preparing to meet these State requirements, both electronic (to meet California law) or otherwise. Consequently, they should be that much closer to meeting the federal PDMA requirements as well.

Recommendation:

- **We recommend that FDA not continue to delay the effective date of §§203.3(u) and 203.50 beyond December 1, 2006.**
- **We recommend that FDA issue a draft Compliance Policy Guide for public comment that would focus FDA's pedigree-related enforcement efforts on those drugs most vulnerable to counterfeiting and diversion.**

IV. WHAT IS THE STATUS OF ELECTRONIC TRACK AND TRACE ACROSS THE DRUG SUPPLY CHAIN?

A. What is the progress of the use of e-pedigree in the drug supply chain?

Issue/Background

In the 2004 Task Force Report, we said that adoption and widespread use of reliable track and trace technology is feasible by 2007. We stated that this would help secure the integrity of the supply chain by providing an accurate drug "e-pedigree," an electronic record documenting that the drug was manufactured and distributed under secure conditions. We particularly advocated for the implementation of electronic track and trace mechanisms and noted that RFID is the most promising technology to meet this need.

In our 2006 fact-finding effort, we sought comment on the progress of e-pedigree implementation in the drug supply chain to determine if the goals outlined in the 2004 Task Force Report would be met.

What We Heard

Several comments described completed and ongoing pilot programs for e-pedigree and their successful deployment of e-pedigree in a real-time production environment. Most pilot programs involved distribution with one manufacturer, one wholesaler, and, in some cases, one pharmacy. Many comments stated that e-pedigree can be achieved using either RFID or barcodes. A number of comments stated that standards for e-pedigree are complete and that interoperable software is available. A few comments from manufacturers of already-serialized products said that they have developed track and trace systems capable of providing an e-pedigree through existing internet technologies.

Most comments agreed that it was necessary to adopt mass serialization with unique identifiers on each package as an important step to facilitate e-pedigree, while some comments stated that it is not needed. A majority of the comments stated that although widespread use of e-pedigree is not far off, it is hard to predict when that might happen or set a new timetable or a new target date. However, many comments suggested that FDA set a specific date by which all products must have an e-pedigree, arguing that without a specific date progress toward adoption will continue to be slow. Some comments recommended that FDA establish realistic phased-in compliance dates for adoption of e-pedigree.

Discussion

In 2004, we were optimistic that widespread implementation of e-pedigree was feasible by 2007 because we were told by many stakeholders in the drug supply chain that this was a realistic goal. Although significant progress has been made to set the stage for widespread use of e-pedigree, unfortunately, this goal most likely will not be met. We will not issue a new forecast or target date for adoption

of e-pedigree because we do not have enough information to do so at this time. Most comments said that it is difficult to predict or designate a target date. We do believe that a timetable with achievable, realistic milestones is crucial to keep e-pedigree implementation on track. Therefore, we recommend that FDA continue to work with members of the drug supply chain to develop such a timetable.

We believe that members of the drug supply chain should be able to implement e-pedigrees in the very near future. We applaud those members who already are taking steps to implement an e-pedigree and States that have championed this cause, such as California. However, it is clear from our recent fact-finding efforts that the voluntary approach that we advocated in the 2004 Task Force Report did not provide industry with enough incentives to meet FDA's deadline. The mere "risk" of the PDMA regulations being implemented was not enough of an incentive. When PDMA was enacted, the state of technology was not as advanced as it is today, and, as a practical matter the industry could pass only paper pedigrees.

We understand the complexity in moving toward an e-pedigree and recognize that a hybrid approach using both paper and electronic pedigrees will be needed during a transition period. We continue to believe that RFID is the most promising technology for electronic track and trace across the drug supply chain. However, we recognize that the goals can also be achieved by using other technologies, such as 2D-barcodes. Based on what we have recently heard, we are optimistic that this hybrid environment of electronic/paper and the use of RFID/bar code is achievable in the very near future. We believe that efforts to ensure that hybrid pedigrees are secure and verifiable should be a priority consideration.

If legislation is considered in Congress related to e-pedigrees, we stand ready to provide technical assistance.

Recommendation:

- **We recommend that stakeholders work cooperatively to continue to expeditiously implement widespread use of electronic pedigrees across the drug supply chain.**
- **We recommend that FDA provide technical assistance if legislation related to electronic pedigrees is considered in Congress.**

B. What is the progress of the use of RFID on drug product packages?

Issue/Background

We sought comment on the implementation status of RFID, including a description of the obstacles to widespread adoption, an estimate of the timetable, the suggested role of FDA, and the incentives needed to promote adoption.

What We Heard

A majority of the comments agreed that RFID is the most promising technology for track and trace in the drug supply chain. We received many comments describing current obstacles to wider adoption of RFID, including:

- A lack of standards (for e-pedigree fields and format, data systems, international transmission standards, and hardware specifications);
- Privacy concerns;
- Concerns about the ownership of confidential business transaction data;
- Challenges in serializing all products;
- Concerns over the accuracy and speed of electronic devices and systems; and
- A lack of definitive data to determine how RFID will affect sensitive products (e.g., liquids, biologics).

Many comments stated that it is not possible to predict or estimate a timetable for widespread adoption of RFID, or stated that widespread RFID adoption is at least many years away. Some comments estimated that it will take up to 10 years. Many comments suggested that technical issues (e.g., adoption of standards, product/software development) would need to be settled before a more accurate timetable could be estimated. A number of comments suggested a phased-in approach for RFID adoption to provide industry sufficient time to explore all options. One comment from a stakeholder closely involved in the development of RFID technology stated that the FDA timeline for RFID adoption is technically feasible, that is, widespread adoption of RFID is feasible by 2007.

Comments noted that progress toward the full adoption of RFID technology is occurring, but that adoption is moving more slowly than previously anticipated. Several pilot projects have been conducted or are underway to test the feasibility of RFID deployment along the prescription drug supply chain, but data is limited.

Most comments said that FDA should not mandate or require the use of RFID in the drug supply chain. Instead, some comments said that FDA should continue to encourage the use of RFID. Many comments said that FDA should actively participate in, support, and facilitate RFID activities, especially those activities of groups working to establish RFID standards and implementation. In addition, many comments said that FDA should take a lead role in developing a public education program about the use of RFID technology on drug products.

Most comments said that incentives would help in the adoption of RFID across the supply chain. Only one comment said that no incentives are needed. Comments suggested the following incentives:

- Financial/tax incentives;

- Mandating mass serialization on drug products, but allowing industry to determine the most appropriate technology to ensure compliance;
- Statutory changes.

Discussion

We continue to believe that RFID is the most promising technology for implementing electronic track and trace in the drug supply chain and that stakeholders should move quickly to implement this technology. We appreciate the candid views and concerns that were shared with us during this fact-finding effort in identifying obstacles to implementation. Within this report, we have tried to address the issues related to those obstacles that are within FDA's purview.

Although we are encouraged by the efforts of GlaxoSmithKline, Pfizer, and PurduePharma in tagging their products, and the efforts of many other companies and wholesalers in exploring and piloting RFID, we are disappointed with the lack of overall progress across the drug supply chain. In the 2004 Task Force Report, we laid out milestones and goals for RFID implementation based on credible information that stakeholders gave us. Many of these milestones have not been met. The technology vendors uniformly told us that their RFID and e-pedigree solutions and technologies are ready to go, but manufacturers, wholesalers, and retailers are slow to implement them.

We recognize that progress may have been delayed because standards have not yet been established. However, we are encouraged by the progress that industry has made to develop and adopt universal standards. Based on what we heard, those standards are close to completion. Once completed, we would expect to see a rapid growth in the implementation of RFID in the drug supply chain. We look forward to continuing to participate and support this standards development process.

In November 2004, FDA issued a CPG for conducting pilot studies for RFID tagging. In that CPG, FDA excluded biological products as eligible for these pilot studies because we had insufficient information about the impact of radio-frequency (RF) on biologics. To date, we have not received sufficient information to change this policy. Therefore, the CPG continues to remain in effect as written until December 31, 2007. In order to further our understanding of the impact of RF, we have begun our own study to evaluate the potential impact of RFID on drug and biological products. We expect to share the results of this study later this year.

We recognize that implementing an RFID-enabled drug supply chain is challenging. We appreciate the comments advocating a phased-in approach and urge manufacturers to take a risk-based approach to implementation by first tagging the products that are most vulnerable to counterfeiting and diversion, based on factors such as the sales price, volume sold, demand, ease of

counterfeiting, and prior history of counterfeiting or diversion, among other things. If a company's products are not "at risk", then we would suggest the company choose its highest volume/highest sale drug(s) and start piloting. Although RFID deployment does have significant start up costs, based on our discussions and what we heard, most stakeholders agree that there are also significant benefits. Not only does the track and trace capability of RFID provide anti-counterfeiting and supply chain security benefits, but it also offers significant savings in the form of better inventory management, reduction in theft and product loss, improved recall efficiency, and reduced paperwork burdens.

RFID also has tremendous potential benefits for drug products used in public health emergencies, such as a pandemic influenza or a bioterrorist attack. RFID tracking could help in expeditious deployment and redeployment of medical countermeasures in times of crisis. FDA should, therefore, encourage manufacturers of these types of products to explore the use of RFID.

We agree with the comments that FDA should not mandate RFID. Although in 2004, we sought voluntary adoption and more widespread use by 2007, we believe that the private sector momentum is moving and that our input on some of the perceived obstacles may jumpstart further adoption interest and momentum. In the 2004 Task Force Report, we laid out a timetable for mass serialization and RFID implementation, as well as steps for businesses and standard-setting issues. Although the timetable goals were not met, we continue to stand by this approach and are prepared to work with stakeholders who wish to take the lead in developing a new, feasible, yet ambitious, timetable.

Recommendation:

- **We recommend that stakeholders continue moving forward in implementing RFID across the drug supply chain.**
- **We recommend that stakeholders consider a phased-in approach, placing RFID tags on products most vulnerable to counterfeiting and diversion as a first step.**
- **We recommend that FDA remain committed to facilitating RFID implementation and working with stakeholders, standards organizations, and others.**
- **We recommend that FDA work quickly to complete its RFID Impact Study examining drugs and biologics, and publicly share the results.**
- **We recommend that stakeholders explore the use of RFID for tracking medical countermeasures.**

V. WHAT TECHNICAL ISSUES RELATED TO ELECTRONIC TRACK AND TRACE NEED RESOLUTION?

1. Mass Serialization