Use of Mass Serialization and Radio-frequency Identification (RFID) in the Pharmaceutical Supply Chain

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I congratulate FDA for holding a workshop on mass serialization and RFID in the pharmaceutical supply chain. As a former member of the FDA's Counterfeit Drug Task Force I also wish to applaud FDA for its continuing leadership in promoting innovative approaches to securing the US drug supply.

At the workshop FDA heard a wide range of opinions on what it could do to promote the adoption of authentication and track and trace technologies. Based on workshop testimony it seemed to me that several areas were identified where FDA could make policy to facilitate the adoption of technologies that allow for product authentication, tracking, and tracing at the item level.

However, there were also some issues, such as the role of two dimensional bar coding as a means to attain mass serialization of pharmaceutical products at the pallet, case, and item level and the importance of global standards for the structure and registration of serial numbers at the item level, were not emphasized.

The purpose of my comments is to make recommendations as to where it is most appropriate for FDA to make policy. Below are specific recommendations, with accompanying rationale, for FDA policy initiatives:

1. FDA could issue guidance recommending that a single number structure for serializing pharmaceuticals at the pallet, case, and item level be used throughout the pharmaceutical supply chain.
    a. The global nature of the pharmaceutical industry makes it critical that a single number structure be adopted globally. This will permit authentication, tracking, and tracing of pharmaceuticals no matter where they are manufactured, shipped, or dispensed
2. FDA could issue guidance recommending that stakeholders evaluate the risks and benefits of using a completely random number at the pallet, case, and item level
    a. This is critical for addressing privacy concerns
    b. Concerns that a random number will increase pharmacist workload and delay dispensing need to be addressed. The use of internal logic in the number as well as association of the random serial number to the NCD code, lot number, and expiration date, of a product in an external database needs to be evaluated.
    c. Industry has been unable to come to consensus on this issue and has acknowledged that implementation of either random numbers or numbers containing the NDC code or other product information is feasible (at

similar cost). Moreover, at the workshop, stakeholders signaled that direction from the FDA on this issue would be welcome.
    d. FDA needs to consider whether a random number would be more likely to meet with global acceptance than a number containing the NDC code because of differing regulatory requirements in other countries
    e. At some point FDA will need to harmonize its recommendation with regulatory counterparts in Europe and the rest of the world
3. FDA could issue guidance recommending what fields of information should be transmitted when passing a pedigree
    a. Industry is close to consensus on this issue and FDA could facilitate the last steps of this process by issuing guidance
4. FDA could work with stakeholders to determine the role of third party logistic (3 PL's) suppliers in authenticating product and passing a pedigree
    a. 3 PL's are increasingly common and come in a variety of forms; their ultimate role in the supply chain has yet to be determined and working with industry to evaluate their role in the supply chain provides an opportunity for FDA to work pro-actively with industry to identify and address issues early on
5. FDA should initiate a dialogue as to where and how serial numbers are to be issued and registered and what FDA's role in the process should be (e.g., setting standards for such activities)
    a. Issuing and registering serial numbers is a global issue and one that industry has not been able to come to consensus on
    b. There are several potential vendors for this activity
6. FDA should determine, through use of an appropriate experimental protocol, as rapidly as possible, whether radiofrequency energy has any effect on the purity, potency, and quality of biologic products
    a. Biologics are very susceptible to counterfeiting and manufacturers should be allowed to place RFID tags on these products at the earliest opportunity
    b. The ability to authenticate, track, and trace vaccines , especially in a public health emergency is critical and vaccines are biologics
    c. Due to the lack of a standardized protocol that examines both thermal and non-thermal effects of RFID on biologics, industry has not been able to perform this testing on its own
7. FDA should announce, in the form of guidance, a revised adoption timeline for authentication and track and trace technologies. An important concept for FDA to consider is that the use of two dimensional bar codes to achieve mass serialization at the item level might not hinder the adoption of RFID if RFID is being used at the case and pallet level by entities throughout the supply chain. Application of two dimensional bar codes (as a transitional step and as a back-up to RFID tags) is inexpensive and would allow all stakeholders to develop an infrastructure for authenticating product and passing an electronic pedigree.
    a. It is important for FDA to set a timeline that fosters innovation and minimizes burden but that also requires a commitment from industry to continue adopting RFID

   b. Mass serialization of all pallets and cases of pharmaceuticals is feasible by the end of 2007
      i. The use of RFID to achieve this is also feasible technologically but faces a tough business case for manufacturers if wholesalers and retailers do not have the hardware and information infrastructure to read the tags and transmit information
   c. Authentication and E-Pedigree for all pallets and cases of pharmaceuticals is feasible by the end of 2007
      i. If necessary this could be accomplished, at low cost, by two dimensional bar codes or a combination of two dimensional bar codes and RFID
   d. Mass serialization, at the item level, of products susceptible to counterfeiting and products required in a public health emergency is feasible by the end of 2007
      i. Most likely using two dimensional bar codes on at least some products
   e. Authentication of products, at the item level, that are susceptible to counterfeiting and required in a public health emergency is feasible by the end of 2007
   f. RFID tagging of products (at the item level) susceptible to counterfeiting and products required in a public health emergency is feasible by 2009
   g. E-Pedigree of products, at the item level, that are susceptible to counterfeiting and products required in a public health emergency is feasible by 2009
   h. Authentication and E-Pedigree for all products, at the item level, is feasible by the end of 2010
8. If it chooses to do so, FDA could, under current authority, signal the importance of using use of track and trace technology for pharmaceutical products by:
   a. Requiring the manufacturer to submit, as part of a new drug application of biologics license application, information as to whether (and why) it did or did not implement the use of track and trace technology for the product
   b. Requiring manufacturers to submit, in annual reports, information as to whether (and why) they did or did not implement the use of track and trace technologies for the product
9. FDA should not require the use of track and trace technology at this time. Requiring mass serialization and RFID tagging would require a cost-benefit analysis across all pharmaceutical products which, in the current environment, would be highly speculative. Furthermore, a mandate to use RFID at this time would be more likely to stifle innovation than foster it.
10. FDA should consider revisiting its bar code rule to explicitly recommend that manufacturers place 2-dimensional bar codes or RFID tags on products at the item level in addition to requiring the use of linear bar codes (eventually as a back up) until 2-D bar codes and RFID were in widespread use.
11. FDA should consider proposing legislation that assures uniformity in the areas cited above. State laws regulating pedigree clearly affect interstate commerce and as such should be pre-empted by any federal legislation in this area.

    a. Workshop testimony indicated consensus that a uniform statutory and regulatory oversight system is critical to the adoption of authentication and track and trace technology.

12. FDA should consider working with other HHS agencies, DHS, and DOD to develop a combined regulatory oversight and federal government procurement environment that facilitates the adoption of electronic track and trace technology
    a. DOD could require the use of electronic track and trace technology on pharmaceuticals it purchases and HHS could require the use of electronic track and trace technologies on products required to combat a public health emergency (for both products in government stockpiles and private stores)
    b. FDA could work with those agencies to ensure that its regulatory requirements and recommendations were consistent with those procurement requirements
    c. FDA could also ensure that its regulatory oversight fostered innovation and minimized any compliance burden