

beyond putting paper pedigrees in simple electronic format, and in many respects it was shelved as a coordinated national and global program.

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## THE SILVER LINING: SERIALIZATION

Throughout the ePedigree process, what was evident was that the technology was beginning to be in place to make track and trace a reality. Today, electronic track and trace can be done with existing technology and meet the upcoming product identification and product tracing regulations. The challenge comes with transferring the transaction data between entities in the supply chain. Each entity is likely to have its own technical standards and data definitions, and, in order to safeguard its information technology infrastructure, may not be willing to collaborate with other entities to deploy an efficient solution. By 2015, this change needs to be made manually, and by November 27, 2017, this change must be made electronically. The product identifier on all drug products must be imprinted or affixed on the label at the product and the case level.

The companies that have been working toward the California ePedigree standards may have a jump-start on the new track and trace mandate. One company example that falls into this category is Pfizer. “At Pfizer, we’ve been preparing for the California mandate for several years, so we are able to leverage that work to prepare for the federal mandate,” says Peggy Staver, Director, Product Integrity. “The Pfizer team is continuing to deploy serialization throughout Pfizer packaging lines and is building out a cloud-based IT solution that integrates with the company’s contract manufacturers to ensure Pfizer meets the November 2017 compliance deadline for lot-level serialization.”<sup>17</sup>

In addition, serialization laws have been in place in other countries. Michael Lewis, president and founder at Frequentz, a track and trace technology specialist, says, “The U.S. serialization law lags behind those of other countries. This law has marginal to no impact on the overall global traceability requirements and planning efforts. Serialization laws and regulations have already been piloted, if not fully executed abroad.”<sup>18</sup> The companies that are struggling with the new track and trace regulations are the ones that have deferred action in the past regarding serialization.

There exist a number of challenges in achieving true serialization in the pharma supply chain. Serialization is more than a simple print and apply