At the Serialization Crossroads: Deciding Which Path to Take

Pharmaceutical manufacturers are confronted with a major decision regarding compliance with current and impending serialization requirements for products they sell in the United States. California state law has been the driver of serialization legislation, and most pharmaceutical companies have already begun to plan or implement their serialization efforts. A new federal law is pending in Congress, and the requirements differ significantly from those of the California law.

To better understand the requirements and implications of the current and proposed legislation, we prompted a discussion with two of Clarkston's Serialization experts, Don Eberts and David Treadaway.

Why are there state and federal laws?

Don: Each state is free to establish its own laws. While state laws apply in the absence of conflicting federal legislation, the United States Constitution (Article VI, Clause 2) establishes federal law as "the law of the land." If a federal law has requirements that differ from state law requirements, federal law preempts conflicting state laws. Obviously, most pharmaceutical companies would prefer to comply with a single federal law rather than a range of individual state laws. To date, the California ePedigree Law has been the de facto U.S. legislation, as it establishes the most stringent requirements for serialization, and products manufactured for sale in California are typically sold in other states, as well.

Specifically for pharmaceutical manufacturers, what are the notable differences between the California law and proposed federal legislation?

David: The California State Board of Pharmacy issued the California ePedigree Law, which mandated that at least 50 percent of products sold in California be identified "at the smallest or immediate container" level by a unique serial number that is traceable by means of "an interoperable electronic system" before January 1, 2015. The remaining 50 percent of products sold in California must be serialized with electronic pedigree before January 1, 2016. The California Board of Pharmacy has indicated that it may not insist on strict 50 percent compliance if a manufacturer exhibits a good faith effort to comply with the 2015 and 2016 deadlines.

Don: By contrast, the proposed federal Drug Quality and Security Act is considerably more lenient. Unlike California law, the federal law would require all pharmaceutical products to be serialized four years after enactment. If, for example, the federal law is enacted on November 1, 2013, serialization would not be required for all products until November 1, 2017 – which is nearly three years after the first California deadline.

Moreover, the proposed federal law does not require the implementation of an interoperable electronic pedigree system until ten years after enactment. It does require that pharmaceutical manufacturers define pedigree in a single document, but the document can be a hard copy, paper document or an electronic version. Again, assuming a November 1, 2013 enactment date, pharmaceutical manufacturers would not be required to provide ePedigree before November 1, 2023.

David: Both the California law and proposed U.S. federal legislation establish minimal requirements for manufacturers, which they must comply with by the respective deadlines. Of course, pharmaceutical manufacturers are free to implement serialization and/or ePedigree functionality before those deadlines.

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California Timeline vs. Federal Timeline

JAN 2014

JAN 2015

California: 1st 50% of Products sold in California serialized at unit level with ePedigree by Manufacturers

JAN 2016

California: 2nd 50% of Products sold in California serialized at unit level with ePedigree by Manufacturers

JUL 2016

California: ePedigree provided by Repackagers & Wholesalers

JUL 2017

California: ePedigree provided by Dispensers

JAN 2018 *(approx.)*

U.S. Federal: 100% Serialization & Verification by Manufacturers

JAN 2019 *(approx.)*

U.S. Federal: Serialization & Verification by Repackagers

JAN 2020 *(approx.)*

U.S. Federal: Serialization & Verification by Wholesalers

JAN 2021 *(approx.)*

U.S. Federal: Serialization & Verification by Dispensers

JAN 2022

JAN 2023

JAN 2024 *(approx.)*

U.S. Federal: ePedigree Required

JAN 2025

What is the background of the proposed federal legislation?

David: Initially, two different bills were introduced to Congress, H.R. 1919 in the House of Representatives, and S.957 in the United States Senate. The two bills differed in many respects, particularly in terms of deadlines and provisions. The House bill was approved in committee and passed in a voice vote on the floor. The Senate bill was reported favorably out of committee, but was not introduced to the Senate floor for a vote.

Don: Meanwhile, it had become evident that the differences between the bills made approval unlikely. In addition to the serialization provisions, the Senate bill included language governing safety regulations for compounding pharmacies. The House decided to write a new bill that would more closely resemble the Senate bill, including the compounding language. The new bill, H.R.3204, was approved by voice vote from the full House. At this time, H.R.3204 will need to receive majority approval from the full Senate, and then be signed into law by the President of the United States.

What is the current status of the federal legislation?

Don: Presidential approval appears likely, but passage by the Senate is still uncertain. The impasse in Washington, which has just been resolved, delayed consideration of all pending legislation. Additionally, with the House and Senate presenting similar positions on compounding, opponents of the compounding language appear to have stepped up their lobbying efforts. Finally, various California-based parties have indicated opposition to the proposed federal standard; among these, California's two Senators, Barbara Boxer and Dianne Feinstein, have expressed joint concern that the proposed federal law "would preempt strong state laws, including California's, with a weaker federal standard."

What happens if the federal law is not approved before the end of 2013?

David: The federal legislative process will start over. Serialization bills will have to be reintroduced in the new session of Congress in both houses, favorably reported to the floors of both houses by the respective House and Senate committees, approved by a majority in both the House and the Senate, and then signed by the president. If there is sufficient resistance in the Senate in the current session, continued resistance is likely in the new session, also. For now, without a preemptive federal law, the California state law will remain in effect.

What course of action do you recommend for pharmaceutical manufacturers?

Don: Most pharmaceutical companies and a number of CMOs (contract manufacturing organizations) are in the process of implementing serialization programs. The best course of action is to continue their efforts without pause.

David: This question takes serious consideration. The legislative pathway is uncertain, so companies should first evaluate their current serialization program. In general, if companies have started serialization, they should contemplate continuing this effort for the near term. For track & trace, a cautious, or "wait and see" approach may be more appropriate over the next few months. Each company's circumstances will vary; therefore, it is important to consider product mix, patent expiration(s), manufacturing sites, and international distribution when defining their strategy and approach.

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If companies don't have a serialization and track & trace roadmap, they should create one. If they have one, then they should update it with an option for California law and an option with only federal legislation. This way, once the decision is apparent, they are prepared and vetted to move forward.

Why do you give that recommendation?

David: Serialization is inevitable for the pharmaceutical industry. Right now, the passage of a federal law is uncertain, but California's deadline for the first 50 percent of product (January 1, 2015) is only 14 months away. Slowing, or halting, current serialization efforts in order to correspond to the prospective federal requirements will put companies at serious risk of non-compliance with California's requirements. Further, serialization mandates are being enforced globally, with legislation already in place in Turkey and Argentina.

A second consideration is the disruption that would result if current plans were slowed or stopped. Project team members would invariably be transferred to other business efforts with consequent loss of institutional memory. Putting current efforts on hold would save some money in the short term, but those savings would be more than offset by efficiency losses, particularly if resuming efforts at the last minute to meet the tight California deadline.

Another factor that comes into play is the scarce availability of qualified vendor resources. Vendors of serialization equipment and systems are notably overcommitted, and struggling to hire and train new personnel. Pharmaceutical companies with current vendor engagements are experiencing problems in getting qualified, timely support, and this problem will be compounded as demand increases. We not only predict an ongoing shortage of vendor resources, but also the potential for premium pricing for emergency implementations.

Don: In addition to the concerns surrounding federal and state laws in the United States, most European nations have established a January 1, 2017 serialization requirement under the Falsified Medicines Directive (FMD). South Korea requires serialization for products sold in the country by January 1, 2015. Turkey and Argentina already have serialization requirements in effect, and other countries are in the process of drafting their serialization laws. Experience gained from current serialization plans and implementations in the United States can be applied towards meeting international serialization requirements, which most pharmaceutical companies will be required to comply with in varying degrees.

Wouldn't waiting on the U.S. federal legislation allow pharmaceutical companies to take advantage of new technological developments?

David: The key point is that serialization technology is well-established; revolutionary changes are unlikely. Investing in serialization to ensure compliance with the California's January 1, 2015 deadline is a sound technological and financial investment, irrespective of whether the U.S. federal legislation passes.

While serialization technology will remain stable over the next few years, there could be changes in the U.S. track & trace requirements. Therefore, companies should be cautious of committing to further investment until year end.

What other factors should pharmaceutical companies consider?

Don: Independent of regulatory concerns, many pharmaceutical companies and consumer groups have presented the moral argument that serialization will inevitably provide traceability throughout the supply chain, which will hinder counterfeit drugs from reaching consumers. This is obviously a concern that is being addressed globally because it will ultimately affect patient safety.

Beyond regulatory compliance, brand safety, limiting diversion or theft risks, a positive impact on chargeback tracking, and return logistics are also potential business benefits of implementing serialization.

If a manufacturer serializes its products early, would supply chain traceability be possible?

David: The California law requires wholesalers and repackagers to have full serialization and ePedigree processing capabilities by July 1, 2016, and pharmacies/dispensers by July 1, 2017. The proposed U.S. federal law would establish serialization – without ePedigree – four years after enactment for manufacturers, five years after for repackagers, six years after for wholesalers, and seven years after for pharmacies/dispensers. However, once serial numbers begin appearing on products,

the public will likely put pressure on companies to implement supply chain traceability on or before the legal deadline.

What's next for pharmaceutical manufacturers?

Don: Companies that have initiated or maintained their serialization programs may enjoy a competitive advantage over companies that slow or delay their efforts pending resolution of the federal law. Regardless, pharmaceutical manufacturers should stay informed of federal and state legislation, and consider the implications of each on their current distribution and business models. This decision requires companies to weigh a range of factors – and to do so quickly and strategically.

About the Experts

Don Eberts is a Senior Manager with Clarkston Consulting. He has over 45 years of experience including the fields of international program management, project management, process analysis, and engineering design and management. He has managed multinational programs and individual projects in Australia, Belgium, Germany, Ireland, Japan, and the United States. Mr. Eberts is currently serving as program manager for a client implementing a global serialization program consisting of simultaneous multi-phase projects in Ireland, the Netherlands, Japan, and the United States.

David Treadaway is a Senior Manager with Clarkston Consulting. He has over 25 years of information systems experience in the consumer products, pharmaceutical, medical device, and high tech industries. For the last three years, Mr. Treadaway has managed a Serialization and Track & Trace project involving pharmaceutical anti-counterfeiting efforts and regulatory compliance for the U.S. and EU. Mr. Treadaway is also working with several clients to design and develop their serialization strategies and prepare them for meeting worldwide serialization regulatory needs. He and his team also developed a serialization training course for Clarkston's clients.

For more information on the state and federal legislation, or implementing serialization at your company, contact ***Don Eberts / deberts@clarkstonconsulting.com*** *or* ***David Treadaway / dtreadaway@clarkstonconsulting.com.***

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