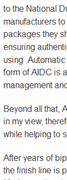
Track And Trace May Improve Patient Adherence: Monroe Explains

Posted Mon, 07/15/2013 - 9:47am by Ed Silverman | 0



As Congress moves closer to requiring drug and device makers to use technologies to track their products through the supply chain, a host of possibilities arise, not just added costs. Besides the basic notion of weeding out counterfeits, some maintain that improved systems can also be exploited to enhance patient adherence, for example. Napoleon Monroe, who is managing director of New Directions Technology Consulting which, in the interest of disclosure, holds five patents for protecting technology for mobile medication management, explains…

The barcode now required by the FDA on prescription pharmaceuticals is currently limited to the National Drug Control Number (NDC Number), but federal legislation that requires manufacturers to have added 'electronically readable' labeling on prescription drug packages they ship is working its way through Congress. That legislation is focused on ensuring authenticity of Rx drugs by labeling with added information, which can be read using Automatic Identification and Data Capture (AIDC) equipment.The most prevalent form of AIDC is a barcode, and some in industry acknowledge there will be inventory management and supply chain benefits from greater use of AIDC.

Beyond all that, AIDC has important implications for the expansion of telemedicine. AIDC, in my view, therefore also creates significant new opportunities for pharma-related profits, while helping to substantially reduce America's overall healthcare costs.

After years of bipartisan efforts to create a national standard for drug-distribution security, the finish line is possibly in sight, with the June 3 approval in the House of the "Safeguarding America's Pharmaceuticals Act," HR 1919 (see this), and the Senate having voted to combine its version of the legislation with another bill, the "Pharmaceutical Compounding Quality and Accountability Act," S 959.

Sponsors of the Senate legislation said in an that these new rules would replace the "patchwork of state product tracing laws with a strong, uniform standard that would ultimately result in electronic, interoperable unit level product tracing for the entire country." The draft bill was approved by the Senate committee on health policy in May and on June 9, the Senate sponsors Lamar Alexander, Republican, and Tom Harkin, a Democrat, urged Senate leaders to bring the legislation to the Senate floor in July.

Some interest groups, which initially opposed any national system of AIDC for pharmaceuticals, have largely acceded to the inevitability of a federal system. For example, as of 2011, the National Community Pharmacists Association essentially opposed any national AIDC on grounds that track-and-trace technologies were largely unproven and that such systems might prove to be prohibitively expensive for independent community pharmacies.

As *Pharmalot* reported in May 2013, the "National Community Pharmacists Association – which is a member of an influential industry coalition that has been floating its own proposals – is now willing to back either bill" (back story). Resistance to AIDC in healthcare is being overcome by logic, regulation and legislation. But there are still fights over the specifics, primarily if lot-level tracking suffices or if unit-level tracking, as required by California statutes, should prevail.

I believe Congress should pass legislation on AIDC for prescription drugs to start implementation at the lot level, so industry can have some regulatory clarity to begin to DO SOMETHING! The data carrier systems already have the capability to include serialization to the unit level. Software for unit-level tracking can be implemented on an as-needed basis.

On a parallel track, final FDA rulemaking for Unique Device Identification (UDI) for medical devices is targeted for later this year. While the Rx pharma and device sections of law are different, many stakeholder needs, objectives and underlying realities are the same. Many pharma companies are also device manufacturers; most healthcare distributors sell drugs and devices; and practitioners prescribe and patients use both drugs and devices. The same advantages, downsides and caveats discussed later for AIDC on prescription drugs apply to UDI, as well.

Track and Trace: Benefits to Pharma Beyond Product Security

And here is another key point: I believe implementation of track-and-trace rules presents the potential to positively affect the issue of medication non-adherence by patients, which leads to poor treatment outcomes and drives up to $300 billion of avoidable US healthcare costs. And related lost productivity is arguably even greater.

Because dosing for most pharmaceuticals takes place outside the healthcare setting, the "point of care" for medication is wherever the patient doses. Currently, there is little information on patient use once prescribed drugs leave the pharmacy or other healthcare setting.

Industry and government are already spending huge sums to digitize healthcare to allow for the use of technology to improve outcomes and reduce cost. AIDC is essential to communicating remotely and remote communication is critical to establishing the patient-centered medical home (PCMH).

The PCMH allows healthcare practitioners and patients to store and receive information from a central location through office-based information capture, mobile health (mHealth) applications and other telemedicine-related programs. Accountable care organizations (ACOs), electronic medical records (EMRs), and patient medical records (PMRs) and telemedicine initiatives can't reach their potential without AIDC for pharmaceuticals and other medical products.

Hospitals are already penalized for readmissions, many of which can be attributed to patient noncompliance. The Centers for Medicare & Medicaid Services, meanwhile, has already indicated that it will gather data on effectiveness of medicines and medical devices through the use of EMRs.

ACOs, unlike individual doctors or even individual hospitals, have the scale, interest and resources to justify expanding the use of AIDC and medication management systems. Hardware costs are declining and software for medication management inside healthcare facilities has already been developed.

Perhaps drugmakers can tailor their labeling to supply hospitals with expanded at-source AIDC labeling to reduce the current burdens of locally barcoding medications.

Nonetheless, AIDC can be a pivotal enabler for communicating with smart devices to help encourage medication adherence at the true point of care. It can also be used to build concordance among stakeholders, facilitate timely intervention, populate medical records, and assess outcomes.

Imagine a patient with an expensive serially numbered drug compounded specifically for his or her variables and conditions. The patient can use a barcode on such a drug to communicate using a smartphone to record the time the patient takes the prescribed medication, as well as other important information. This other data could include the patient's vital signs before and after taking the drug and the condition of the drug.

Apps already exist for taking vital signs remotely. Ruggedized, miniaturized sensors that can monitor drug condition are readily available and are already embedded in many devices. Drugmakers can use their collective imagination to find more valuable information that could be captured and used.

While Pharma has been concerned about the implications of the Affordable Care Act and other major business issues, it hasn't generally recognized or fully explored the opportunities that AIDC presents for them. When the barcode technology is in place, Pharma will have new opportunities to develop superior medication management systems for their products and then will be in a position to benefit.

For example:

- new revenue streams from services related to sales of its pharmaceuticals and sales of similar products made by other companies (e.g., sales of companion products when patients use their smart phones to scan products already in their hands);
- new possibilities for cross-selling other products, services and devices (e.g., providing information on air-quality monitoring systems to asthma patients who have just received their new inhaler;
- greater product loyalty, even for generics (e.g., your generic has a bidirectional smartphone-based support system; others don't);
- facilitation of reorders, especially for products that are outdated or used only as needed (e.g., notifying patients when each of their epinephrine injectors reach expiration;
- provision of better patient information and ability to intervene in the event of inappropriate activity (e.g., knowing that the patient is noncompliant with the dosage regimen or having an immediate side-effect reporting mechanism);
- enabling the monitoring of a specific container of fragile or high-value product to determine product condition (e.g., knowing if the container has been broken or that a home-use biotech product that, until use, must be kept refrigerated has been subjected to extreme heat);
- supply chain and inventory management efficiencies (e.g. not having to visually verify lot numbers in the event of a recall);
- added capabilities for meeting Risk Evaluation and Mitigation Strategies (REMS) requirements;
- helping to lessen product liability risks;
- enhanced abilities to demonstrate superior effectiveness; and
- clinical trials that are more accurate, less expensive and speedier, leading to faster market entry.

There are downsides and caveats worth acknowledging. There will be costs to implementing AIDC and related improvements to our healthcare systems. There are possibilities for data security breaches. There are possibilities for various institutions to misuse the data or abridge patient's rights. These are largely being addressed with advances in scanning and sensing technologies, capabilities for handling big data, security technology and data-use regulations.

The legislation and regulations are moving forward to require added AIDC for healthcare products. The pharmaceutical industry, whether it wants to or not, will be using more AIDC. But how will this technology be deployed to do more than just fulfill its currently envisioned purposes? Will pharma develop the uses for AIDC to help transform healthcare, specifically medication management? Will pharma get lost in "the forest" or will it cultivate the trees of opportunity that this legislation and regulation presents?

About Ed Silverman

Ed Silverman is a prize-winning journalist who has covered the pharmaceutical industry for the past 18 years. In addition to editing Pharmalot, he is currently an editor-at-large for Med Ad News.

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