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PHARMACEUTICAL COMMERCE

BUSINESS STRATEGIES FOR BIO/PHARMA SUCCESS

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IQPC Cold Chain International Forum p. 21

2014 Cold Chain Directory

Marketing approaches for specialty pharmaceuticals

Master Data Management (MDM) takes center stage

Seyed Mortazavi, IMS Health

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Contents

FEATURES

DEPARTMENTS

Converging the pharma business with its logistics and data functions

Sales was, is and always will be the driving force in the pharmaceutical business (as opposed to pharmaceutical science, which is shared among private companies, academia, the medical professions and governments). And while the pharma sales profession is under duress in terms of employment numbers and core functions (see p. 8, "Rep access: down, down, down"), we've consistently asserted that the often-heralded "death" of the profession is a figment—there will always be a need for a sales function, and people to perform that function in the industry.

With this issue, *Pharmaceutical Commerce* would appear to be at some distance from content relating to pharma sales. We've got our Cold Chain Directory (p. 19), a comprehensive source of vendor and service offerings for the industry, along with several articles on logistics and supply chain security. And there's a report on the vastly undervalued function of master data management (MDM; see p. 32). Here's how they relate to pharma sales:

With cold chain, the first thing to understand is that the field is gradually shifting from that specific function—keeping certain products in a refrigerated state—to one of ensuring the overall integrity of the supply chain. That, in turn, links to the directive the entire US industry is now under (catching up with many parts of the rest of the world) to tracking pharmaceutical shipments and ensuring that they are coming from, and going to, authorized entities. It's often been remarked that this tracking process, in turn, is a deep window into overall movement of products in the marketplace, and now you're close to a basic sales function of making sure that products are on hand when needed. (It's still true that the pharma supply chain, from API ingredients to finished, packaged products on pharmacy shelves, is one of the longest, time-wise, of any industry.)

With MDM, there appears to be a quiet revolution going on that's about to get quite a bit noisier. MDM got a boost (from a supplier or IT services provider perspective) by the Physician's Sunshine Act, which the entire industry has been busy complying with since about a year ago. (At presstime, CMS was sticking to its guns that the database of reported spending by industry on healthcare providers would go public around Sept. 30, but as the article points out, the medical professional societies, among others, are calling for a postponement).

MDM always has been intimately connected to sales—its historic function has been to help reps locate and qualify the physicians they hope to visit. Today, however, the picture is changing rapidly. MDM providers are fast at work clarifying the affiliation relationships among physicians—which hospitals, integrated delivery networks and other business relationships they have. Why? For the simple reason that as more and more prescribing gets influenced by formulary plans and payer policies, these relationships become more important to recognize in the sales process.

An even bigger transformation in MDM is the merging of physician identity and affiliation data with professional practices, including communication preferences, social media activity and prescribing trends. The pharma industry is in the early stages of being able to understand their key clients—physicians—in the same ways that consumer marketers are delving into the preferences of consumers.

The next stage of this transformation—understanding patient habits and preferences—is already started, and MDM techniques will accelerate that change.

Nick Basta

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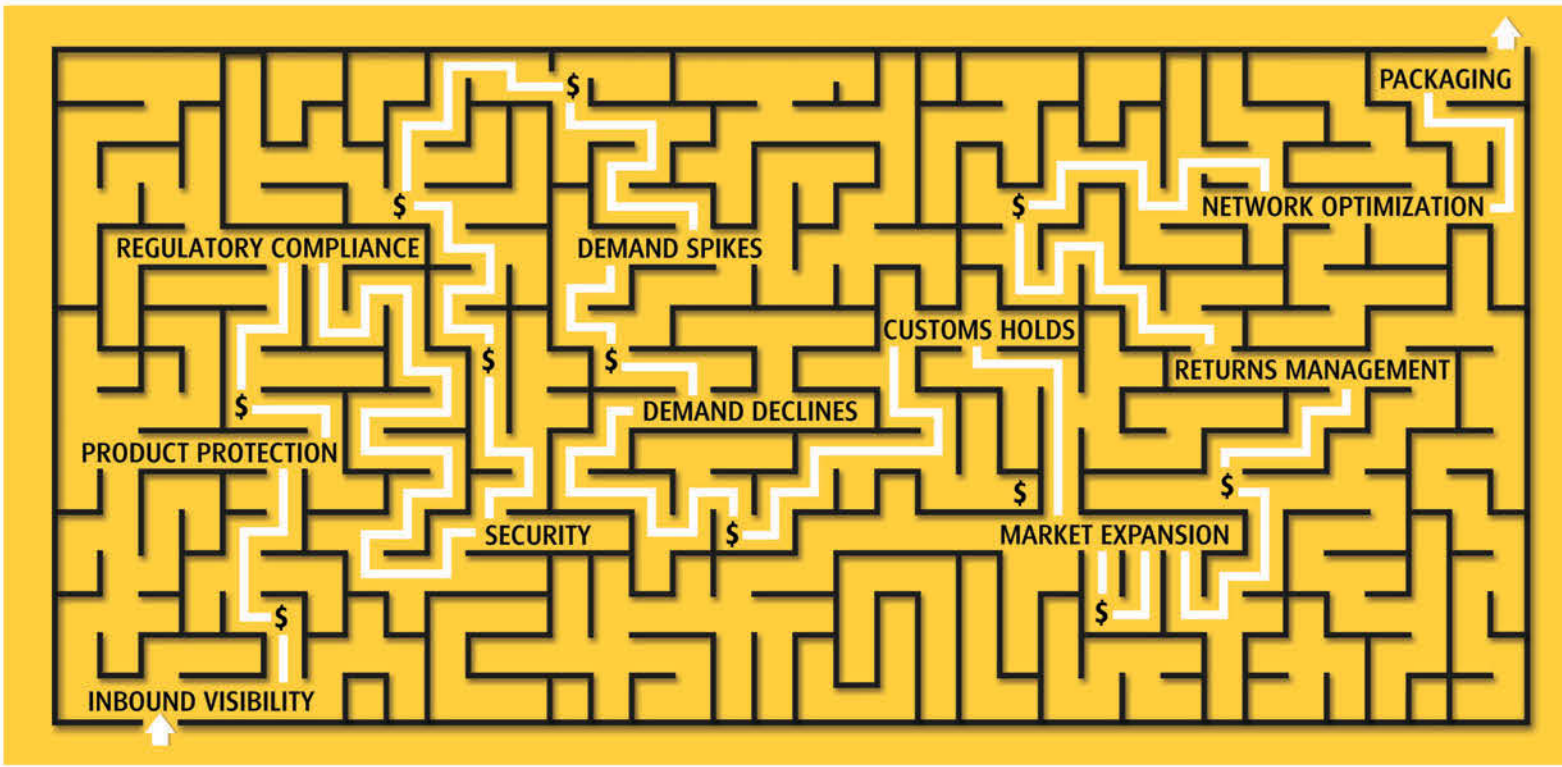

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Legal uncertainties in the DSCSA

The Drug Supply Chain Security Act creates uncertainty about which trading partners have responsibility for product verification

By Michael Druckman, Hogan Lovells LLC

The US Food and Drug Administration (FDA) faces a challenging schedule for implementing the Drug Supply Chain Security Act (DSCSA), enacted on Nov 27, 2013. The DSCSA revamps the requirements for securing prescription drugs throughout the supply chain, and mandates that an interoperable electronic system for tracing prescription drugs to the package level be put into effect in phases over 10 years. Among the DSCSA's requirements are new verification obligations imposed on manufacturers, distributors and pharmacies regarding "suspect" and "illegitimate products," designed to identify and eliminate counterfeit and diverted prescription drugs from the supply chain. By Jan 1, 2015, all parties in the supply chain must have systems in place to comply with these verification requirements. How FDA interprets the interlocking and sometimes ambiguous obligations that the DSCSA imposes may have a significant impact on the contractual obligations among trading partners and on the relationship among parties in the supply chain.

Draft guidance

On June 11, 2014, FDA announced the availability of a draft guidance entitled "Drug Supply Chain Security Act Implementation: Identification of Suspect Product and Notification." This guidance is the first of many FDA is required to issue under the statutory mandates included in the DSCSA.

The draft guidance provides practical suggestions for how trading partners may identify suspect products, such as to be skeptical of prices that are "too good to be true," and to closely examine the package and transport container for signs that the product has been compromised. The document also recommends that trading partners "discuss with each other any observations, questions, or concerns they have related to the status of a drug as a suspect product to aid them in determining whether the drug should be considered a suspect product," and that trading partners "contact regulatory authorities, law enforcement, or other available resources to aid in that determination . . . ." (see draft guidance p. 6) The draft guidance does not clarify which party has the final word, however, nor resolves certain other ambiguities about the interlocking responsibilities of the parties involved. These ambiguities include:

• **Suspect product** - The DSCSA obligates manufacturers, wholesale distributors, dispensers, and repackagers, upon determining that a product in their possession or control is a suspect product or upon receiving notice that the Secretary has made such a determination, to quarantine the product and investigate, "in coordination with trading partners, as applicable," to determine whether the product is an illegitimate product." The statute does not impose a corresponding duty on trading partners to coordinate regarding suspect product not within their possession or control. Nor does the statute dictate what happens when trading partners disagree. FDA's draft guidance does not address that ambiguity.

• **Product at high risk of illegitimacy** - The DSCSA also imposes an additional duty on manufacturers, not imposed on other parties, to notify FDA and certain trading partners if they determine—or are notified by FDA or a trading partner—that there is a "high risk" that one of the manufacturer's products is illegitimate. The statute does not provide a comprehensive definition of what products are at such "high risk," but makes clear that the manufacturer's duty applies to product not within the manufacturer's possession or control, and to product "purported" to be manufactured by the manufacturer. Therefore, a manufacturer necessarily must rely on trading partners to cooperate in determining if the product is at high risk of being illegitimate, as well as for the initial notice about the product.

Yet, the statute does not explicitly impose corresponding duties on the manufacturer's trading partners. Nor does it clarify what criteria the trading partners are to apply (except for listing scenarios that could increase the risk of a suspect product entering the supply chain),

continued on page 38

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Mike Druckman (mike.druckman@hoganlovells.com) is a partner at Hogan Lovells who counsels life sciences companies and organizations on FDA law and regulation. He formerly worked for seven years in FDA's Office of Chief Counsel, first as Associate Chief Counsel for Enforcement and then as Associate Chief Counsel for Biologics.

Is tech running you? Four ways to retake control

Modern training technologies make the prospect of days-long training courses an obsolete practice

By Bob Cannan, Eagle Productivity Solutions

"Man is the creator of change in this world. As such he should be above systems and structures, and not subordinate to them."

- Steve Jobs

In Stanley Kubrick's classic, *2001: A Space Odyssey,* the defining moment came when the artificial intelligence known as HAL refused the spacecraft commander's orders, saying, "I'm afraid I can't do that, Dave." It was then that Dave knew he'd been outgunned—at least temporarily—by his computer.

Ever feel like Dave? Throughout history, humans have been tool-using animals. From sharpened sticks to artificial intelligence, our tools have adapted to the demands of our work. Today, our work is more complex than ever, and our tools have progressed the same way. CRM, CLM, MLR, analytics, multi-channel marketing, compliance, logistics, business applications and other software systems are robust and interconnected. They have to be, for our people to do their jobs effectively.

Say you're a small startup pharma that's launching a CRM system. You manage to get it off the ground with marginal success, but then the new releases start rolling—a never-ending schedule of upgrades, bug fixes, new functionality. Your high performers figure it out but their less tech-savvy colleagues aren't as adaptable, and adoption starts to slip. Your two-person IT team is too busy answering help desk calls to provide any real relief, and senior management just wants a quick and manageable solution.

"I can't do that, Dave." The system has taken control… A bad end to a big investment.

Here's another story: A large company introduces its salesforce to a new CLM system. They go the traditional route, pulling teams from the field for multiple days for a huge deployment. The cost due to lost business? Hundreds of hours of field time and potentially hundreds of thousands of dollars. And when the software is upgraded, they'll do it all over again.

What's the common denominator? Failure to realize that change is constant. The only way to maintain control? Stay on top of the changes. But everyone is too busy for that.

Who serves who?

Tech tools are here to stay, and so is their complexity. But you don't have to be subordinate to them. Here are four tips to ensure your people push the technology, not the other way around.

- **Make them want their tools.** Only good initial training can do this. How? By helping people see how their tools will work for them. If they believe the tools are valuable to their daily work, they'll want to use them and they'll look forward to improvements down the line. Don't underestimate this first step.
- **Do tweaks, not overhauls.** By definition, your initial deployment will be big and disruptive; you're introducing a tool that changes the way people work. After that, training should not interfere with operations. A training vendor that offers Training as a Service (TaaS)—my company is one—will anticipate new system iterations and structure training in small bites to mirror those upgrades. (Bonus tip: Don't save them up and do another mammoth training. Unless you've got time and money to burn.)
- **Cut non-training costs.** Typically, one-third of the training budget is wasted on non-training expenses such as travel costs, repeated RFPs, and resource ramp-up. A TaaS training partner can eliminate those expenses so your training dollars are actually spent on training.
- **Don't retreat.** Taking your people out of the field for training leaves an opening your competition is only too happy to fill. A good training partner will offer virtual delivery options that reduce time away from the field. Through the miracle of inexpensive technology, it doesn't take a $20,000 media room to bring the classroom to where your people are. Stop sending more people to training and start sending more training to people.

Adding up the savings

More and more pharma companies are seeing the

continued on page 38

ABOUT THE AUTHOR

Bob Cannan is CEO of Eagle Productivity Solutions (www.eagleproductivity.com). Eagle designs and delivers custom training solutions to serve the critical needs of bio/pharma companies, including 18 of the top 20 companies, for whom it has trained every major hardware and software platform. Eagle has trained in more than 40 countries and 20 languages and has offices in the US, UK and Spain.

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Pharma brand teams need to reset their patient-journey analysis, says IMS Consulting

Real-world data sources can provide new dimensions to marketing plans

That there are better and broader data sources available to analyze how products will enter the marketplace, or how existing products can compete effectively, is not news to the pharma industry. But evidence cited by IMS Consulting (New York), the advisory arm of IMS Health, shows that all too many brand teams are still locked into traditional analyses based on physician-panel inputs. The impact of consumer-driven healthcare, and the influence of payer stances on drug availability, are still only hazily being addressed.

That's the subject of a newly published white paper from IMS Consulting, "A New Foundation for Designing Winning Brand Strategies." Lead author Maneesh Gupta, senior principal, brand and commercial strategy, says that overall, not only are pharma companies still grappling with the concept of a "patient journey" from initial symptoms through to treatment and maintenance, but that there is a need to combine that journey with the perspectives and impacts of the physician and the payer (aka market access issues). "For a long time, it's been said that the pharma industry is behind consumer packaged goods (CPG) manufacturers in their approach to the market, and that's still true today," he says. "Many brand managers are still basing their initial marketing efforts on the results of a survey of physicians. That no longer works." Only one out of 10 brand teams have what IMS Health considers the state of the art in analyzing the patient journey, resulting in "sub-optimal brand performance."

The patient journey (see figure) as a concept has been around for a long time: origination; awareness/presentation; diagnosis/referral; treatment; etc. There is ample information now available from the growing array of datasets pouring out of social media, claims data, longitudinal patient data and other sources to fill in the details of this journey. But, even for the few companies that undertake this analysis, says Gupta, the problem is that the analysis is done piecemeal by different groups: sales, health economics, market access; and others. "Companies are spending more than they should, repeating analyses already done, and not getting the full value of their investigations," he says.

Key questions

The better approach is to address key questions, and with a coordinated, integrated approach. Among these questions are the following:

- What is happening at each step of the patient journey?
- Why are decisions being made along these steps?
- Figuring out where the manufacturer can add value to the decisionmaking (for example, introducing a copay card)?
- Measuring progress against objectives along the journey.

JOURNEY PHASE	INFORMATION AVAILABLE	DATA SOURCES (US EXAMPLE)
Origination	• Incidence and prevalence • Patient demographics (age, income, education, geo) • Co-morbidities/underlying conditions	• Consumer database • Social media analytics • Lab values data • Longitudinal patient data from pharmacies • Claims data from health plans • EMR/physician office data • Hospital data • OTC data • Scripts written by physicians • Institutional purchases • Managed care benefit design • Formulary details • Rejection/reversal data
Awareness / Presentation	• Patient's perspective – symptoms, awareness, information search, presentation decision	
Diagnosis / Referral	• Diagnosis rates • Lab values • Newly diagnosed/previously diagnosed • Severity & staging • Referral and patterns	
Treatment	• Continuing • Dynamic - new/add on/switch • Share by line of therapy • Dose titration	
Fulfillment	• Substitution and abandonment • Method of payment/tiering • Co-pays and patient cost burden	
Adherence	• Time on therapy • Compliance and persistence	

It is advisable to start building the Patient Journey with secondary data and use primary research to plug in the gaps.

IMS Consulting, of course, is positioning itself to provide this guidance, and is banking on the inputs of the newly acquired assets of IMS Health in social media, online campaign development and the yet-to-be-consummated acquisition of Cegedim Relationship Management. But whether a brand team uses IMS Health Consulting as a single-source provider, or as one of several providers, Gupta says that the industry needs to raise the level of its game.

The paper is available at this address: http://www.imsconsultinggroup.com. PCm

Pharma rep access: down, down, down

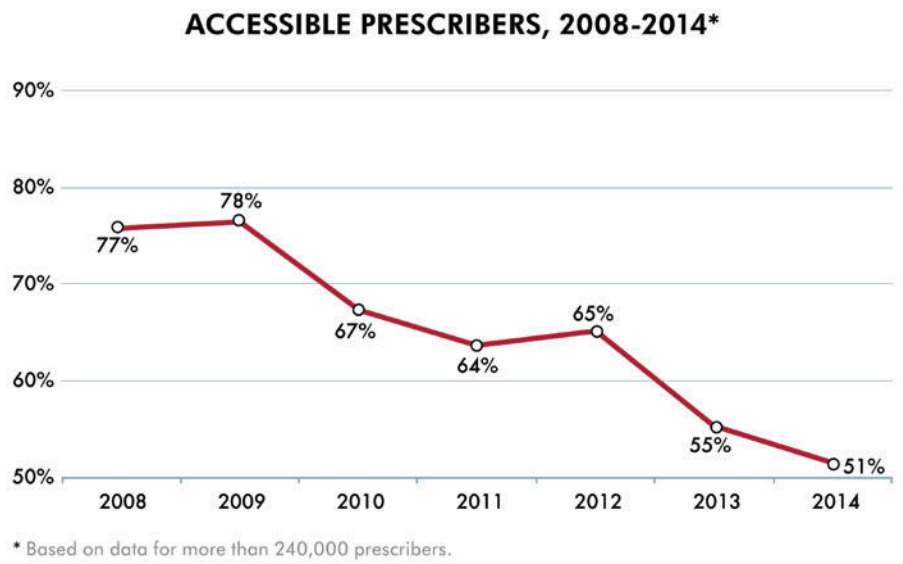
Latest ZS AccessMonitor asks, 'Who are physicians listening to?'

The annual update from ZS Associates (Chicago), a consulting firm on sales and related practices in life sciences, finds that 51% of physicians were considered "accessible" this year, as compared to 55% in 2013. "Though this year's drop was less precipitous than in previous years, it reflects the steady decline in access over the past decade," concludes the report. Data are based on call reports for over 200 pharma sales teams, meeting with approximately 325,000 prescribers. "Accessible" means those who were *not* either "access restricted" (who met with 31–70% of the reps who called on them) or "severely access restricted" (those who met with 30% or fewer). Access to so-called "rep friendly" specialties like dermatology or gastroenterology also declined, by double-digit numbers.

Pratap Khedkar, managing principal at ZS, writes that even though the likelihood is that rep ranks will be rising in the near future (due to the growth in new drug introductions), pharma companies need to pay more attention to alternative channels of communication. Reps need to become "orchestrators" who first and foremost find out what channels physicians prefer for communication. ZS itself is planning to introduce a new service, the ZS AffinityMonitor, to gauge physician preferences for Internet, email and other channels.

Rep count

ZS, which regularly monitors the sales activities and resources of pharma companies, calculates that the count of reps has declined from 101,800 in 2005—its peak—to 63,000 today. "There will always be room for reps," says Khedkar, "The pipe won't be eliminated, but the diameter will shrink. Companies need to use other channels—not only must pharma reps live with the other channels but work with them, coordinating all sources of information." PCm



CVS/pharmacy earns URAC accreditation for 'community pharmacy'

First to gain newly established program reviewing therapy management and chronic care

CVS/pharmacy, the Woonsocket, RI, chain with over 7,600 stores nationally, has been granted the first "community pharmacy" accreditation issued by URAC (Washington, DC). URAC, in turn, is a standards-setting body for healthcare providers, pharmacies and other parts of healthcare delivery (*Pharmaceutical Commerce,* May/June, p. 6). Its standards, which have legal status with federal programs and most states, validate quality systems, recordkeeping and other functions; it "is a symbol of excellence for organizations to validate their commitment to quality and accountability," according to URAC.

The community pharmacy accreditation, which was established only in May, measures quality of service in patient counseling and education; medication therapy management; chronic disease management; adherence consultation, among other factors. A CVS/pharmacy spokesman tells *Pharmaceutical Commerce* that the company did not need to create new programs to meet the URAC standards, but rather to validate existing practices. CVS Caremark, CVS/pharmacy's parent, already has URAC accreditation for four other standards: Pharmacy Benefit Management; Drug Therapy Management;

Vaccination experts struggle to raise medication practices of physicians and treatment programs

Vaccine working group tries to build consensus on temperature control and dispensing practices

It is not a secret that the supply chain breaks down once vaccines (which are generally cold chain products that need to be refrigerated) are delivered to doctors' offices and clinics. Household refrigerators are used to store them (and hopefully not in the refrigerator freezer, which destroys most vaccines); inventory is not tracked; and which patients received which product lots are not recorded. A 2010 study by the HHS Office of Inspector General ("Vaccines for Children Program: Vulnerabilities in Vaccine Management") found that within a select group of high-volume dispensers, none met all VFC program oversight requirements; specifically, 76% of providers exposed vaccines to inappropriate temperatures for at least a cumulative five hours—possibly damaging the efficacy of the vaccines—and 13 providers had expired and unexpired vaccines intermingled. A physician survey* conducted by TempTime Corp., maker of cold chain sensors, in that same year found that 83% of pediatricians (who dispense most childhood vaccines) had experienced a "cold chain break" at first hand.

Since then, two groups have grappled with the problem, which is a combination of technology, training and medical standards and practices. One, the Immunization Action Coalition (St. Paul, MN; www.immunize.org), conducts healthcare provider training and performs public advocacy on behalf of medical professionals. The other, the SHAPE (Storage, Handling, Administration and Preparation Experts) Vaccine Delivery Working Group, is a self-selected team of immunization experts that has been meeting regularly to develop better provider practices. Dr. L.J. Tan, chief strategy officer of the Coalition and member of the SHAPE Group, tells *Pharmaceutical Commerce* that it is a struggle to raise the bar on vaccine delivery performance. "For many, this is a low-priority activity, constrained by limited public-health dollars, and a lack of training and standards," he says. (Tan also stresses that his involvement in the Working Group is not necessarily an endorsement by the Coalition.) Jurisdictional issues also affect the situation: FDA does not regulate pharmacies or doctors' offices, and multiple state and other regulatory bodies have a say in healthcare delivery practices.

There are vendors of refrigeration and related equipment for healthcare facilities, but the cost of the equipment is an impediment. Manufacturers are supportive of, for example, the educational activities of the Coalition through unrestricted grants, but there are regulatory entanglements to more-direct support of how facilities are managed and funded. In the meantime, the Working Group has published a paper proposing next steps ("From Refrigerator to Arm: Issues in Vaccine Delivery," Vaccine 32 [2014] 2389–2393) and will be holding an invitation-only meeting of healthcare providers in Raleigh, NC, next month as part of a national educational and fact-gathering program. PCm

*www.pharmaceuticalcommerce.com/latest_news?articleid=2191&keyword=cold%20chain-Temptime-pharma-logistics

Specialty Pharmacy; and Mail Service Pharmacy.

URAC is fast becoming the mark of distinction for specialty pharmacies (a separate URAC program); now the standard might spread across many retail chains. For manufacturers interested in collaborating on adherence, chronic care and other high-touch patient services, the accreditation might become a competitive advantage for pharmacy partners. PCm

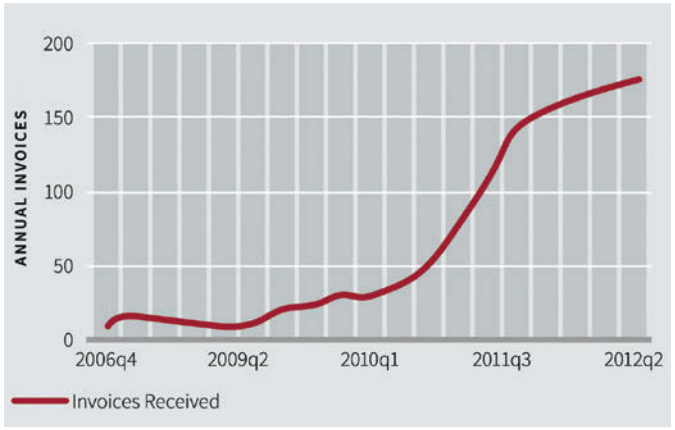
For pharma, it's getting harder and harder to follow the money

Outsourced contract-administration provider highlights growth in invoicing and financial stewardship burdens

It's no secret that managing the basic billing, payment collection and reconciliation of the pharma industry is more complicated today. Even before Obamacare (which is expanding both the number and complexity of billing entities), pharma finance departments were dealing with a bewildering array of federal and state programs, and more complicated fee-and-chargeback arrangements with wholesalers. Add to this the variety of patient-support programs, analysis of coupon programs and other financial arrangements, and the overall picture becomes ever more obscure. Nor should the trend toward more—and bigger—penalty settlements in government programs be overlooked.

Compliance advisor and outsourcing contract-administration provider Compliance Implementation Services (CIS; Morrisville, NC) has surveyed the landscape among the clients it serves. Through the end of 2012 (see Fig. 1), the number of invoices to be reconciled in just state Medicaid programs, and just for one labeler code (i.e., one type of product) has zoomed from a few tens in 2006 to nearly 175. Other data from CIS suggests that current Medicaid activity is running at 68 invoices per quarter for its clients, which include emerging biotech companies with essentially one product.

"Even though this invoice volume is growing, and even though many contracts have gray areas that leave contract terms open to interpretation, all too many companies still run this process off spreadsheets," notes Karen Brown, marketing VP at CIS. The other choice is to implement complex—and expensive—dedicated software systems, with the attendant IT and staffing requirements. CIS' offer is to manage the contract administration with its dedicated, proprietary IT system, and deliver results to clients via cloud-based applications. Among CIS clients in the $50-million to $1-billion annual revenue range (Fig. 2), the reduction in staffing and IT expense can be from nearly $5.5 million to under $3 million, or 40–50%. A white paper on the topic is available from the firm. PCm



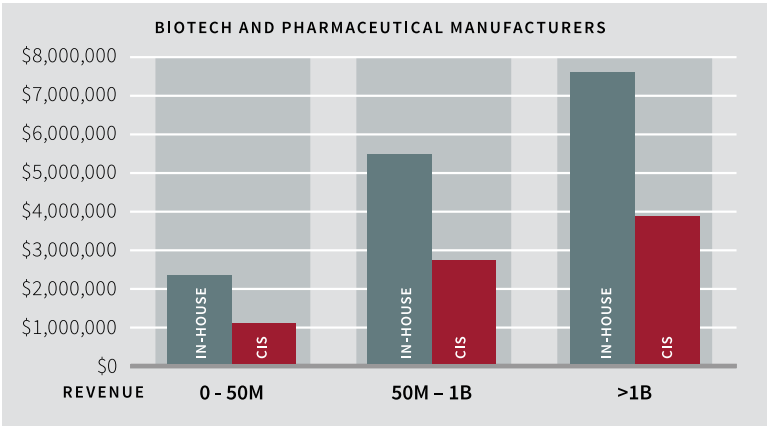


Fig. 1. State Medicaid invoices are growing... ...but outsourcing contract administration can reduce processing costs; Fig. 2.

Envirotainer wins FAA approval for its cold-chain containers on US air freighters

Meanwhile, competitor CSafe Global broadens its containers' usability

The active-powered unit-load device (ULD) for shipping temperature-controlled products was pioneered by Envirotainer (Upplands Väsby, Sweden) years ago, but its use by air carriers has been limited to flights originating outside the US because it lacked FAA approval. Now, the company has been granted FAA approval for its RKN unit, putting it in direct competition with CSafe Global (Dayton, OH), whose RKN unit has been approved by both FAA and the European Aviation Safety Agency. The wider use of the Envirotainer ULD won't be immediate; the company says that a technical-acceptance process will be carried out with airlines over the next 2-6 months. And the company says that it now has a "baseline" for quicker approval of its newer RAP unit, which is sized to accept up to four pallets of product.

But in a tit-for-tat action, CSafe recently announced that its RKN unit has been approved by FAA for use in both the upper and lower decks of air freighters. "In the last six years, we've seen an increase in conversions to narrow-body aircraft for freight service," said Brian Kohr, CSafe CEO, in a statement. "After consulting with our key global partners, we sought FAA approval for use of the CSafe RKN on the upper deck." That capability enables shippers to transport products originating from closer to the ship location and the receiving location, reducing road transport and speeding up deliveries.

RKN units are metal boxes sized to contain a pallet of product (which, if the entire trip is maintained under temperature-controlled conditions, obviates the need for cartons to have their own insulation and cooling). There are "passive" designs that employ dry ice, wet ice or a phase-change material as a coolant, and then the "active" units either have a fan to circulate cool air and coolant, or contain batteries, compressors and refrigerants—essentially, an insulated box with a refrigerator inside. Power cables enable the active units to be recharged in transit by connecting to a vehicle's electrical system, while passive units need to be recharged with dry ice on extended or delayed trips. An active unit can also provide heating to protect products harmed by sub-freezing conditions.

Envirotainer and CSafe aren't the only games in town: Lufthansa Air Cargo has a unit of its own, and UPS has made use of the PharmaPort unit from Cool Containers LLC (Marietta, OH). Even so, Envirotainer is generally considered the largest vendor (based on the number of ULDs in use), and will be adding 400–500 RKN units, and 100–150 RAP units, by the end of this year. The company also touts its "open" network of carriers and Envirotainer-certified maintenance centers globally ("open" in the sense that other carriers can join in). PCm

Envirotainer RKN unit

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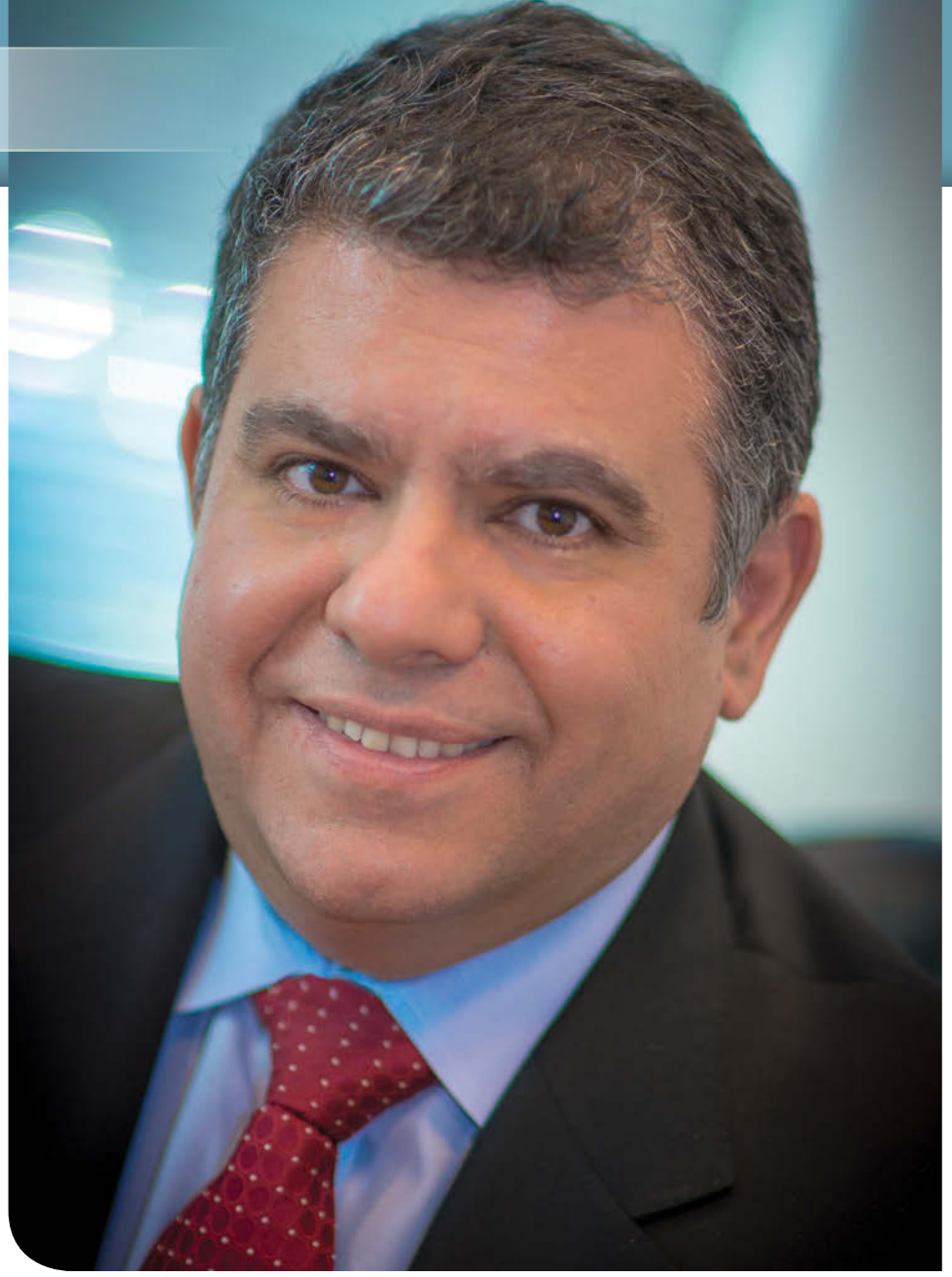

A conversation with Seyed Mortazavi, IMS Health

IMS Health (Danbury, CT) is a giant in the healthcare data field, best known for its comprehensive reporting on global pharmaceutical prescribing and sales, but now complemented with a growing array of software analytics and consulting services. It re-entered the public arena earlier this year with a successful IPO and is now listed on the New York Stock Exchange as IMS. Founded in 1954, the company boasts around 10,000 employees worldwide, and gathers data from 100,000 suppliers covering 45 billion healthcare transactions annually.

IMS Health is organized into nine regional business units, plus IMS Consulting, Clinical Trial Optimization Solutions, Government and Payer Provider Solutions, and Real-World Evidence Solutions. Seyed Mortazavi is President, US. *Pharmaceutical Commerce* sat down with Mr. Mortazavi recently; here's what he had to say.

1 **Many people know IMS Health for its data services on pharmaceutical sales but the company has been going through some changes and now describes itself as a healthcare technology company; what's been going on?**

Without a doubt, many people know us for our data and analytics and we're tremendously proud of this heritage. It's still core to what we do but the reality is the healthcare industry has become exponentially more complex: new stakeholders, an explosion of new data sources and, of course, the Affordable Care Act. On top of all of this, clients are still working hard to cut costs. The IMS Institute recently completed a study showing that the largest 17 multinational pharma companies will have to reduce annual operating cost by $36 billion from their 2012 levels in order for that margin level to be maintained in 2017—while also maintaining current levels of R&D activities. Our clients need help. So we've been busy investing in new capabilities to address the complexity and provide practical solutions to assist them as they transition to where healthcare is headed in the future—demonstrating the value of medicines.

The transformation of our US business, which mirrors the rest of IMS Health, is in three key areas: New data sources, an intelligent technology infrastructure and the expansion of our service capabilities across the broader healthcare industry. We believe this delivers tremendous value to our clients. In fact, at our recent client conference in June, we presented and demonstrated these new capabilities to hundreds of our customers and the feedback was very positive. Across the board, our clients see IMS Health as a strategic partner providing information, technology and services across the healthcare industry.

2 **Part of the transformation is the expansion of your services across the broader healthcare landscape like healthcare insurance companies and healthcare providers. Should life sciences clients expect to benefit from this broader focus? And is there a potential conflict of interest here?**

Historically IMS Health focused on pharma customers, primarily in the commercial space, offering data and analytical services. As the industry converges and seeks answers to common questions it made sense for us to expand our business into the payer and provider space. We made a couple of acquisitions along with significant organic efforts in RWE, and we now sit squarely at the intersection of these healthcare stakeholders. There are no conflicts of interest because all stakeholders are asking the same questions and redefining their relationship around value instead of volume. We see value manifesting itself in the form of improved outcomes, lower costs, better quality and risk reduction. For instance, payers, increasingly under cost constraints, want to understand the real-world performance of treatments and the true cost and quality of providers. Providers and hospital systems (IDNs) are forced to take on risk, and also need to understand cost and outcomes of treatments. Payers are holding providers accountable and we help them measure, benchmark and track physician performance. As payers transfer risk to providers, we help providers better segment and profile their patient populations and understand fully costed patient pathways.

Life sciences companies also want to control costs and provide greater value. To address these areas we've made significant investments in our Real World Evidence practice to understand the real-world performance of drugs and prove their value. For example, we can help clients make better R&D pipeline decisions; plan more efficient clinical trial recruitment; address payer demands for comparative effectiveness; develop outcomes-based reimbursement models; and improve patient drug adherence.

In essence, we are helping to show how each stakeholder connects with each other—providing insights to help address their fundamental questions.

In fact, during our June Client Conference we had a four-person panel of health systems and payer experts discussing how pharma and hospital systems can better collaborate, sharing real-world evidence to improve the value of their decisions and ultimately the performance of the healthcare system. It was one of the most popular presentations of our two-day meeting.

3 IMS Health has made several acquisitions over the past year including the recent announcement of Cegedim's Customer Relationship Management and Information Solutions Businesses. Is there a common element to all of it? What should IMS Health clients expect from this?

Over the past few years, we have continued to invest globally in technology and services to bring our information and analytics closer to decisionmakers and make it more actionable. This is a large part of our transformation plan. Last year, we introduced IMS One—our intelligent cloud-based technology platform. This was a direct response to our customers' need to improve their commercial infrastructure.

Around the world, many life sciences companies are adapting their commercial models to address today's demands, but often face fragmented and incomplete data that can't provide the business intelligence and insights needed to stay competitive. Many customers also struggle with legacy systems and processes that can't accommodate today's substantial data and analytic requirements. The reality is that their commercial functions often operate in silos, leading to colossal inefficiencies. IMS One brings together massive amounts of data in the cloud: IMS Health, third party data and client's data, into a consistent, orchestrated manner to create a "single version of the truth" for sharing, analyzing and reporting information across commercial functions. The result is better, faster insights and more cost-effective operations. Our customers welcome any solution that will help them reduce costs and improve efficiency.

Clients can also connect all of their disparate applications through IMS One, giving them shared access to common sets of data. So when information changes in one application, those changes are reflected throughout all of the applications connected to IMS One.

To enable clients to gain even more value from IMS One, IMS Health developed and acquired a number of Software-as-a-Service (SaaS) applications and formed an interoperable suite we call the Nexxus Commercial Application Suite. To address the unique needs of Life Sciences companies, such as compliance and transparency and the unique, complex data relationships, all of these applications have been built solely for our industry.

In the spring of 2013 we acquired Appature, a company offering clients an innovative and patented cloud-based relationship marketing application to enable the measurement and optimization of relationship marketing programs across channels. This novel application has become the basis for our Nexxus Marketing application. We made several other strategic acquisitions rounding out the Nexxus Application Suite. They include Nexxus Social Media, a robust set of cloud-based tools that automate the collection of healthcare-specific social media content, providing real-time monitoring for reputation and opportunity management and delivering extensive insights into consumer and physician behavior and sentiments. Nexxus Sales, a cloud-based multi-channel CRM and closed loop marketing application along with incentive compensation, data management and business intelligence applications for more effective, results-driven sales operations. We also have a set of performance management tools called Nexxus Performance, which we developed from the ground up by ourselves. The tools provide a consistent set of key performance indicators across geographies and departments. We just introduced what we call the Mobile Sales Edition as part of Nexxus Performance. This allows clients to take their national strategies and make them actionable at the local level. Reps, using their tablets, get nearly instant access to relevant market data so they can adjust their marketing mix to

continued on next page

drive better decisions with their clients on a daily basis. This application received a lot of praise from clients at our recent client conference.

In early July we announced our intent to acquire Cegedim's CRM offering including OneKey, a leading healthcare professional database. We believe this proposed transaction, once completed, will accelerate our ongoing transformation, bringing together complementary businesses to extend our information and technology services capabilities for our clients. This intended acquisition will create more choice and reduce operating costs for our customers. These solutions used by life sciences organizations in 80 countries, would become part of our Nexxus Commercial Application Suite and connect to IMS One, our intelligent cloud. As a result, IMS Health market information would be readily available within the CRM system, streamlining processes, simplifying implementation and driving savings for clients.

OneKey would join our complementary information assets available through IMS One and deliver insights on nearly 14 million healthcare providers across the globe.

Each component solves specific industry problems and together, as part of the Nexxus Commercial Application Suite, they give clients greater consistency, integral insights to improve decisions and lower operating costs.

4 **IMS Health also stands out for its global perspective and you mentioned that most of your technology acquisitions are global in nature. What's your take on the commonality of issues inside the US as compared to the rest of the world?**

While each global region has its own set of market challenges, there are more commonalities than differences across countries because at some level, every health system is tackling issues of affordability, access and quality.

Across the world we're seeing pharmaceutical companies looking for new ways to cut costs. They're turning to IMS Health for help to streamline operations to improve the bottom line without impacting R&D, market focus and the delivery of medicine.

Healthcare companies also want to create new approaches to their commercial strategies so they have better access and engagement with their own customers. This is where our investments in real-world data and technology acquisitions are helping to give clients the information they need, when they need it and how they need it.

Lastly, security of information and privacy remain paramount concerns across the global healthcare community. We are dedicated to protecting individual patient privacy and only utilize anonymous healthcare data to deliver real-world disease and treatment insights. It's these insights that help our customers identify unmet treatment needs and improve overall health outcomes around the globe.

5 **IMS Health had a successful IPO in April 2014. Give us an overview of what the IPO means for your customers and how it may have impacted your focus as a company.**

Becoming a public company again is a great recognition of how far we have come over the last four years. It is an acknowledgment of our leadership position as a leading worldwide provider of information, technology and services dedicated to making healthcare perform better. Our customers were not affected by the IPO; going public changed our capital structure but not our day-to-day operations or the way we interact with our clients—it's business as usual. We remain focused on our customers, delivering value while expanding our technology and services footprint to help clients drive cost savings and operational efficiency.

6 **You've had a lengthy career at IMS Health, and before that, additional involvement in healthcare information. From your vantage point, where is healthcare headed in the US? What have the major turning points been over the past couple of decades?**

In terms of significant, transformational changes impacting our clients, you have to start with the Affordable Care Act of 2010. The ACA is fundamentally changing the US healthcare landscape, which affects a fragmented group of stakeholders—from physicians, patients, insurers and health exchanges to value-based care delivery entities like integrated delivery networks (IDNs) and accountable care organizations (ACOs). The growth in complexity isn't just a US phenomenon, it's global.

In the more than two decades I've been working in this industry, blockbuster drugs carried the day, but that's coming to an end. Today our customers need to understand the nuances of their markets and the interdependencies and interactions among customer segments. One size no longer fits all, so they need to be able to deliver the right messages to the right audiences at the right time and more efficiently run their businesses. For instance, targeted therapies and a focus on improving the efficiency of R&D are motivating life sciences organizations to invest in innovative new technologies. During the past 10 years, targeted therapies have dramatically increased their market share, especially in mature markets. The focus on more efficient clinical trial enrollment has led to the emergence of specialized organizations such as our own Clinical Trial Optimization Solutions (CTOS), which is designed to identify patients for enrollment based on a specific geographic area. This helps accelerate the results process, while eliminating time and expense from the entire trial.

As I noted earlier, the changing healthcare stakeholder landscape in the US is actually part of a global phenomenon that IMS Health has observed for some time, and we believe we're in a unique position to help. While the US market is bigger, more competitive and complex, the changes being ushered in by the Affordable Care Act in some ways are analogous to my experiences in the late 1990s in the UK, with the emergence of primary care organizations. PCOs that were highly sophisticated had the greatest level of success in terms of driving decisionmaking and realizing better patient outcomes. And by sophisticated, I mean they set up common IT systems, established centers of excellence and efficiently worked with multiple stakeholders to outline optimal treatment paths. We're seeing the same thing today in the US. The more sophisticated IDNs are the ones taking advantage of technology, EMR systems, and new sources of data like real-world evidence and treatment protocols.

Pharmaceutical companies have to adapt to this changing landscape. That's where IMS Health comes in to play: advising customers on the new stakeholder landscape and how to interact with it, guiding them to better information and insights, helping them operate efficiently, and allowing them to leverage sophisticated and centralized data and common IT systems. PCm

Investor group calls on biotech manufacturers' boards to be more forthright on biosimilars

Absence of agreed-on FDA guidance keeps biosimilars off the US market even as their use grows abroad

A new front is opening up in the ongoing debate over biosimilars and how they will enter the market in the US: activist investors. "Activist" might be too strong a word, because these investors are the institutional managers of trust funds, mostly for labor- or union-related organizations who manage benefit funds for retirees. The lead group is the UAW Retiree Medical Benefits Trust (Detroit); 18 other groups, representing $430 billion in assets, are members of the coalition.

This coalition wrote an "Investor Statement on Oversight of Biosimilar Issues" in August (available at www.uawtrust.org), requesting that the boards of 25 leading pharma companies "ensure that information provided to policymakers on patient safety is balanced, investor dollars used for political lobbying [are] aligned with shareholder interests, and disclosure on significant business partnerships is transparent." These principles sound like good governance for any board, but the detailed language makes clear that these investors want biosimilars on the market sooner rather than later, and want pharma manufacturers to be more forthright in their dealings with FDA and the public on the safety and efficacy of biosimilars.

"The information that is being disseminated in the state and federal policy debates related to the dispensing, naming and oversight of the biosimilar market is imbalanced," the statement reads. "Companies seeking to downplay the patient safety record of European biosimilars have also challenged the capacity of the FDA to promulgate rules and determine when biosimilars may be substituted for biologics."

The investor statement is pointed at the current campaign among several pharma companies to push state governments to mandate different nonproprietary names for biosimilars (when matched against the branded originator drug).

Already, Novartis and Amgen have agreed to be signatories to the statement. The coalition is now pushing the 23 other pharma companies to do the same. Not coincidentally, those two pharma companies have active biosimilar-development programs going on; Novartis' Sandoz subsidiary has filed the first FDA application under the so-called 351(k) rules for filgrastim, the biosimilar version of Amgen's Neupogen.

Roche/Genentech has told the coalition that it will not sign the statement, according to a report from WSJ Pharmalot.

There's a clear set of conflicting interests on the part of the institutional investors; on the one hand, they have funds invested in the very same biotech companies whose biologics pricing and patent-protection policies they are challenging. On the other hand, the disbursements from these funds go, in large part, to paying for the health benefits of their retiree members. That might be the reason that the statement says nothing about divestiture from pharma companies who don't sign the document.

For its part, FDA has generated several draft guidances on biosimilar evaluation and regulation, but none of them has been finalized. Even when such guidance does become available, it's easy to predict that its details will be argued over by the biotech manufacturers. PCm

PBM formulary exclusion lists continue to grow

Battlefield over drug pricing

It's almost becoming an annual summer rite of passage: the release of formulary exclusion lists by the major pharmacy benefit managers (PBMs). Both CVS Caremark and Express Scripts have added to their lists—CVS Caremark's is now 95, up from 72 the year before, and Express Scripts' is 66, up from 48 in 2013 (the new lists are for the coming year, 2015). Roughly half of prescriptions filled by Americans are contracted for by the two of them.

Formulary exclusion means that, for health plans managed by these PBMs, the drugs are not available, with some exceptions, for the prescribed conditions indicated, unless the patient covers the full cost: a key market-access issue for manufacturers. Some major brandnames are now on these lists: AstraZeneca's Symbicort, Amgen's Aranesp and Epogen. Lunesta (which went generic this year) is excluded from CVS Caremark but not Express Scripts. And, although the lists are presented with a general sense that clinical efficacy is the driver, some interesting contradictions crop up: Express Scripts drops Novo Nordisk's Victoza while recommending AstraZeneca's Byetta, while CVS Caremark does the exact opposite.

According to Adam Fein, president of Pembroke Consulting (Philadelphia) and a *Pharmaceutical Commerce* Editorial Board member, plan sponsors (payers) get better rebates and/or lower plan costs when they follow the formularies; Express Scripts will provide $1 billion in savings across its millions of members with the exclusions in place.

Many analysts look on the exclusion lists as PBMs' way of exerting market forces—including playing off one manufacturer's similar product to another's—on drug pricing. Amgen told Reuters that its erythropoietin-stimulating factors, Epogen and Arenesp, are mostly sold to hospitals and clinics and dialysis centers; the pricing through the PBMs is incidental.

Besides wheeling and dealing on discounts to the PBMs, manufacturers' other important tactic is to build a body of clinical knowledge for specific conditions, as opposed to general categories like diabetes or high blood pressure. The PBMs note that drugs are often offered for multiple conditions and different evaluations result.

Gilead Sciences' new hepatitis C therapy, Sovaldi, has generated enormous friction in healthcare circles for its cost—$84,000 for a 12-week regimen (*Pharmaceutical Commerce*, July/Aug, p. 12). CVS Caremark says that "Evaluation and identification of drugs requiring prior authorization for medical necessity will be made upon approval of the new hepatitis C agents;" while Express Scripts says inclusion "to be determined after FDA approval" (which has already occurred in the case of Sovaldi). PCm

Catalent goes public in a successful IPO

Blackstone Group-owned CDMO nets over $800 million

Catalent Inc. (Somerset, NJ), spun out of Cardinal Health back in 2007, has now taken the "next step in our growth journey" by going public, at CTLT on the New York Stock Exchange. Blackstone Group, the private investment firm which acquired most of the business, will retain majority ownership. The money raised will be used primarily to retire debt the company has undertaken in the past few years.

Catalent's financial filings indicate the company grossed about $1.8 billion in 2013, in three business segments: Oral Technologies (about 66% of revenue), Medication Delivery Solutions (about 12%) and Development and Clinical Services (about 22%). That makes it a leader in clinical development and manufacturing organizations (CDMOs) globally. The oral technologies group has 14 manufacturing and development plants, located globally. Recent investments include expansions in its Softgel and clinical supply business in China and Brazil, a new Biologics Center of Excellence in Madison, WI, and an expansion of its oral technologies manufacturing site in Winchester, KY. PCm

Specialty pharmaceuticals demand integrated patient and prescriber approaches

True 'market access' should involve coordinated approaches to patients and their healthcare providers

By Steve Stefano and Dan Piggott, Ashfield

All signs point to a lucrative future for specialty drugs and biologics. The decline of primary drug blockbusters and the lack of replacements in the pipeline have shifted industry focus to specialty portfolios. Although specialty medications reach smaller markets, their significantly higher pricing and quicker investment return from getting to market faster due to fewer clinical trial requirements, make them very attractive. As a result of this shift, Express Scripts, a leading pharmacy benefits manager (PBM), forecasts growth in their specialty drug and biologic sales to reach as high as 40% of their total sales this year, reaching 67% in 2015. It expects cancer drugs to grow 77.4% by 2016 and indicates other major growth categories include those treating diabetes, multiple sclerosis and inflammatory conditions such as rheumatoid arthritis. [1] This growth translates into significant dollars, with IMS projecting global revenues to reach $236 billion for the specialty medicine market in 2017. [2]

With such significant revenues at play, optimizing patient access to these new medicines is critical to success. Integrating market-access and patient-support programs certainly provides the concerted effort that will lead to such optimization, however, achieving such integration calls for a services provider who can deliver it. It is possible—and it happens all the time—that pharma companies themselves coordinate the delivery of these services, from themselves and their own sales forces, or with service providers that deliver one or more of these services. There are a few companies—our own, Ashfield Commercial & Medical Services, is one—that can deliver all, or most of them. Whether to use one integrated provider, or several that can be aggregated to deliver the full range of services, is a determination to be made by a pharma company's management.

To say that optimizing patient access is a difficult task at best is certainly an understatement in today's healthcare delivery marketplace. Once a life science company decides its specialty drug or biologic is ready to commercialize, the hard part—ensuring that the medicine actually reaches the intended patient population—begins. This journey from clinical trial to patient's home is an arduous one as illustrated in Fig. 1. It requires careful planning with diligent execution to ensure integration of outreach efforts by market access, sales and nurse educator teams, as well as call centers and digital outreach to a multitude of touch points including commercial and government payers on local and regional levels; the various groups of healthcare providers—including physician offices, Integrated Delivery Networks (IDNs), Accountable Care Organization (ACOs), hospitals, various other influencers on healthcare delivery; and hub services and specialty pharmacies.

Making sure that all these elements are integrated into the medicine's overall marketing plan is not only paramount to a successful launch and take-up, but also saves significant resources throughout the medicine's lifespan. With IMS reporting that large pharmaceutical manufacturers need to find cost reductions totaling $35 billion through 2017 in order to maintain current research levels and operating margins [3], the impetus to find savings through integration of patient access outreach efforts has never been greater.

Gaining market access

As shown in the patient access timeline, the first step to reaching the patient with a new medication is to obtain position on the targeted payers' formularies. The difficulty of this endeavor is rapidly escalating. The state of the overall economy and pressures to find affordable health care are primary drivers in the level of difficulty, along with such payer specific factors as:

- Payer plan and PBM consolidation resulting in "power" brokers dictating contract terms
- Copay assistance pushback
- The magnitude and frequency of price increases
- Open government payer networks moving specialty pharmacies into Medicare Part D prescription drug plans.

Today's life science company certainly faces a much different market access landscape than what was available before 2010 as shown in Fig. 1. New products very rarely land above Tier 3 on the reimbursement schedule, where copays are normally set at $70 and more, and are often accompanied by step edits or prior authorization. Reaching an attractive, affordable reimbursement schedule for the patient takes time and well-designed and executed strategies for influencing payer perceptions.

To be successful in influencing payer perceptions and subsequent actions, it is critical to understand those perceptions and likely actions prior to Phase II clinical trials. This means drawing upon previous experience in the medicine category or working with market access providers who offer such experience. Payers want to be assured that the medicine will help patients meet treatment goals at the lowest possible cost. They need to understand such items as how patients are able to adhere to the medicine's protocol, how patient outcomes are impacted, and how the medicine treats the disease severity while eliminating costly system resources like hospital stays, to name just a few of the measures on which a medicine is evaluated. Developing messaging to this payer audience addressing these key issues is critical.

To hit the ground running, the market access team must be armed with appropriate studies and understand where the medication should fit in reimbursement schedules. Reimbursement strategies vary greatly across regional and local plans. The types of public and private coverage in the region as well as patient demographics come in to play here. These factors are further impacted by employers now offering more options in health benefit plans while increasing the payment burden to the employee, often resulting in increased out-of-pocket costs. The market access team must wrestle with questions such as:

- What will it take to get the medication on formulary and then pull it through?
- Who are the other healthcare influencers in the region?
- What degree of influence do IDNs, ACOs, health information exchanges, specialty pharmacies, and sometimes patients themselves play in the mix?

Therefore, in order to be successful in obtaining the best formulary position, one must develop a payer strategy within the marketing plan that incorporates payer research by individual markets. The strategy should incorporate realistic resource allocations based on market optimization. For instance, if research indicates that the payer environment in Boston is more amenable to a certain therapeutic category than the environment in Philadelphia, initial outreach of market access teams would be slanted toward Boston, particularly in resource-strapped organizations. Determining the quickest route to a product launch at a negotiated best price, supported by the appropriate pull-through, is certainly key and should drive the market access plan.

Account managers implementing the plan should be experienced with good contract negotiation skills along with long-standing relationships with key decisionmakers in the commercial and state/federal markets. The goal is to balance the economics of broader patient access with preserving the financial margins of the manufacturer.

It is also important that the plan be realistic, with emphasis on establishing a revenue foundation based on Tier 3 reimbursement for broad access at launch through the life cycle of the product. For example, when a medicine is in a competitive class such as diabetes, payers could be looking for a discount or a rebate, substantially reducing the revenue stream. This is particularly true of pills rather than biologics. The market access team will need to have a plan for meeting these demands based on size and rate of anticipated market capture. Again, statistical analysis of key Metropolitan Statistical Areas (MSAs) will assist in developing such strategies.

Beyond the formulary

Once the medicine has achieved or is approaching formulary status, two parallel outreach efforts ensue. The first would be contact with the prescribers and influencers in the market; the second would be the distribution channel, namely specialty pharmacies and hub service organizations.

Here is where an integrated plan between internal or outsourced market access and field sales teams is truly advantageous. In such integration, as market access teams start to finalize position on formularies, they can alert the sales team, who can then use a call center or field sales rep to contact

Pre-2010	Today
New products land in Tier 2 until reviewed by PBM(s) and plans	New products ***rarely*** land in Tier 2 until reviewed by PBM(s) and plans
6-9 month free-ride	6-9 months of Tier 3, Tier 3 with Step Edits, or Tier 3 Prior Authorized
Change between Tier 2 and Tier 3 is approximately $10-15	Change between Tier 2 and Tier 3 approximately $25-40
PBM(s) and plans were apathetic about co-pay assistance programs	PBM(s) and plans are responding negatively to co-pay assistance programs vis-à-vis "Exclusion Lists".
PBM(s) and plans rarely excluded coverage of products (preferring Tier 3 positioning)	PBM oligopoly (ESI/Caremark equal 150 million prescription insured lives)
Prior authorization and step-edit formulary management tools were in their infancy	Prior authorization and step-edit formulary management tools are well established
No Affordable Care Act	Affordable Care Act is in place

Fig. 1. Market Access Landscape

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[1] Staton, Tracy. Specialty drugs to rocket upward by 67% by 2015. http://www.fiercepharma.com/story/specialty-drugs-rocket-upward-67-2015/2013-05-22

[2] IMS, Riding the information technology wave in life sciences: Priorities, pitfalls and promise, March 2014, pg. 4.

[3] IMS, Riding the information technology wave in life sciences: Priorities, pitfalls and promise, March 2014, pg. 1

physicians alerting them that a new medicine is on the horizon, and helping them identify appropriate patients for that medication within each practice. This preemptive contact primes the pump for a formal detail on the medication to initiate script writing when it does reach formulary.

Market access can also coordinate with brand marketing, who may start direct-to-consumer (DTC) advertising to generate brand awareness and patient inquiries. A well-integrated plan alerts sales representatives to these DTC activities within their territory, so they can educate the physician on how to respond to this marketing push, making sure the right patient population is given access to the medication. By working brand advertising and sales in conjunction with market access, these efforts can also be allocated on a rolling basis, covering individual markets as the medicine becomes unshackled in its respective territories. This goes a long way in keeping sales expenditures efficient and effective.

Sales representatives need to be armed with information on these formulary positions and reimbursement issues when dealing with the physician practices. However, in the instances when the medication is beyond the patient's ability to pay, most physicians are unable to assist the patient in finding proper reimbursement. Specialty pharmacies and hub service companies can step in at this point to help patients navigate their way to access. They assist the patient with finding grants, coupons or co-insurance plans to make the medication affordable.

To ensure the best possible outcome, the life sciences organization needs to include a call plan to back-end hub services and specialty pharmacies in its overall marketing and sales strategy. This will make sure all touch points know what needs to be done to make sure the medication reaches its intended user.

In a plan that integrates outreach throughout the commercialization process, the market access team can be tapped to cover much of the specialty pharmacy channel, since many payers, both large and small, now own specialty pharmacies. With IDNs, health systems and some physician practices also entering the specialty pharmacy business, integrating outreach with the field sales team covering these targets becomes an important tactic in executing the plan. Many companies are now instituting patient support plans that point the patient to those specialty pharmacies and/or hub service organizations that can best help the patient afford the medication.

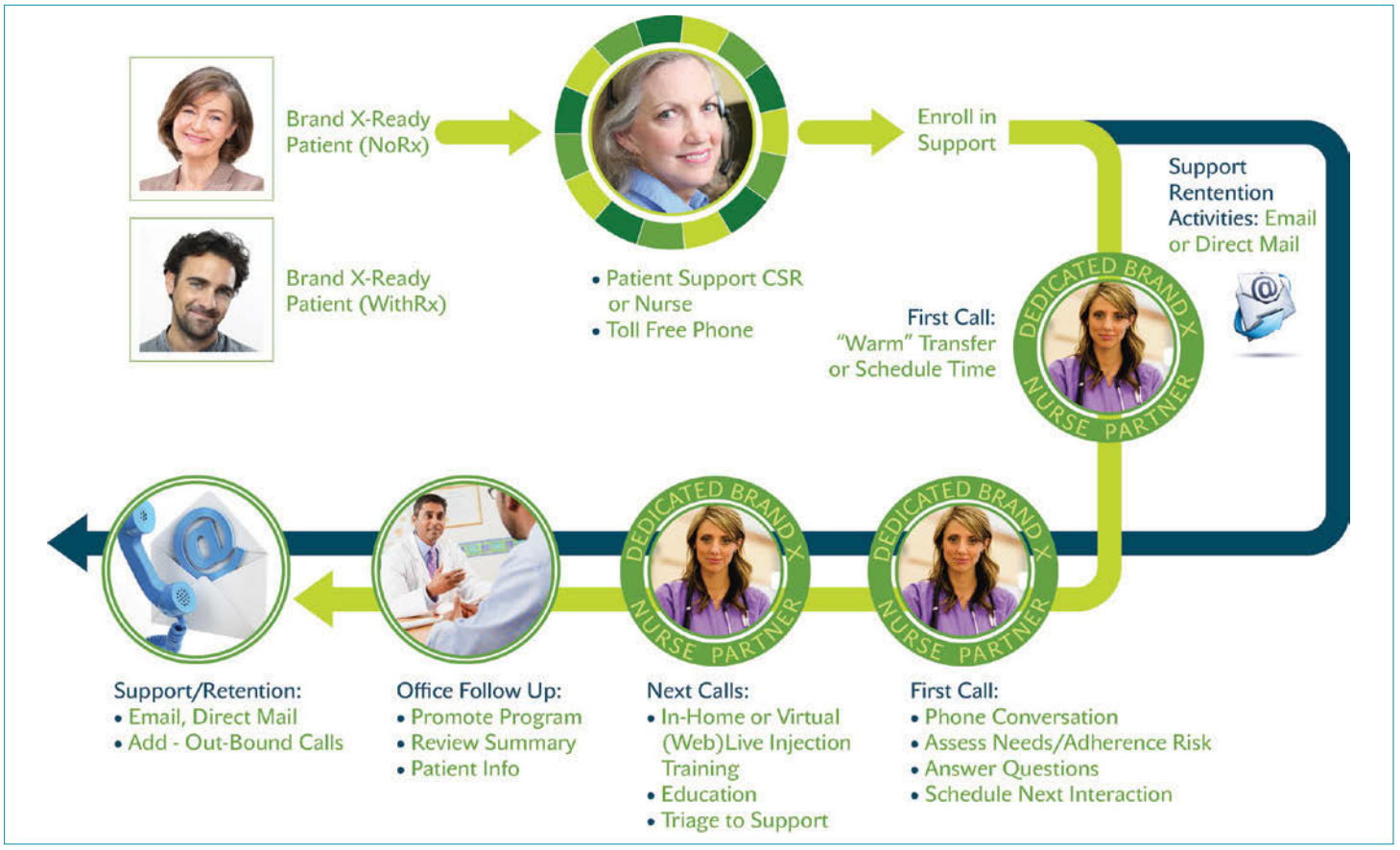

Fig. 2. Providing Patient Support for Access, Adherence and Retention.

Improving adherence and retention

The final step in an integrated marketing plan is to develop strategies for making sure the patient is compliant and continues to use the medication. To this end, many pharmaceutical companies have begun in-home patient education programs with nurse educators and call centers that not only help with compliance and adherence, but also provide the physician with data regarding patient usage and results. (Fig. 2)

A case in point is a recent program adopted by a specialty pharmaceutical company with an injectable medication. The company initiated a program with Ashfield Clinical to support new patient starts with injection training, and then to retain those patients by converting them to an auto-injectable device. The pharma company elected to work with a nurse-educator field team and a clinical-nurse call center. Deployment costs were optimized by deploying full-time nurses in high patient-volume territories, and per diem nurses for overflow and mid- to low-volume territories. The 24/7 clinical nurse call center was available to provide brand support and education as needed, and to provide virtual training to those who opted not to use in-person training.

An average of 1,500 new patients were visited each month resulting in a 42% conversion to the new auto-injectable device. This program also demonstrated significant uplift in impact (40%), when the prescribing physician was made aware of the patient training. The only mature brand in its class, it demonstrated monthly share increases and the program enjoyed an ROI of 344% in its first seven months of execution, clearly demonstrating the impact patient support integrated with prescribers can cost-effectively deliver.

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ABOUT THE AUTHORS

Steve Stefano (above, left) is managing director of Ashfield Market Access, offering payer, pricing and pull-through strategies and account management teams reaching both regional and national accounts covering 240 million lives.

Dan Piggott is CEO of Ashfield Commercial, Clinical, and Medical Information providing innovative, customized sales teams and call center services; nurse educator/advisor support teams; and consumer/patient information support, medical information request handling, legal compliance, adverse event expertise, escalated call handling, product recall services/crisis management, on- and off-label inquiries, and multichannel support.

Another specialty pharmaceutical case involved patient support of an injectable that tapped a call center, field clinical-nurse educators and the field sales team as part of an overall patient support/adherence/retention plan for its injectable. Patients with reimbursement concerns were coached to contact the appropriate department within the pharmaceutical company. Nurse educators were deployed to educate patients on the use of the injectable biologic with in-home or virtual online sessions. Sales representatives were tasked with disease state education, educating the physician on the training program underway and providing insights on patient feedback.

This particular assignment made use of Ashfield's proprietary cloud-based software platform, branded as TotalCare, which enables patient referral for support activities and scheduling of nurse visits. The program is typically integrated with a customer relationship management (CRM) system to provide a holistic view of program activity. Although the patient-sensitive data accumulated in TotalCare by the nurse educator team is not pushed out to the field team, certain key data points, such as number of patients seen by the educator, are available in the rep's sales force automation platform and can be shared with the physician during rep visits (Fig. 3).

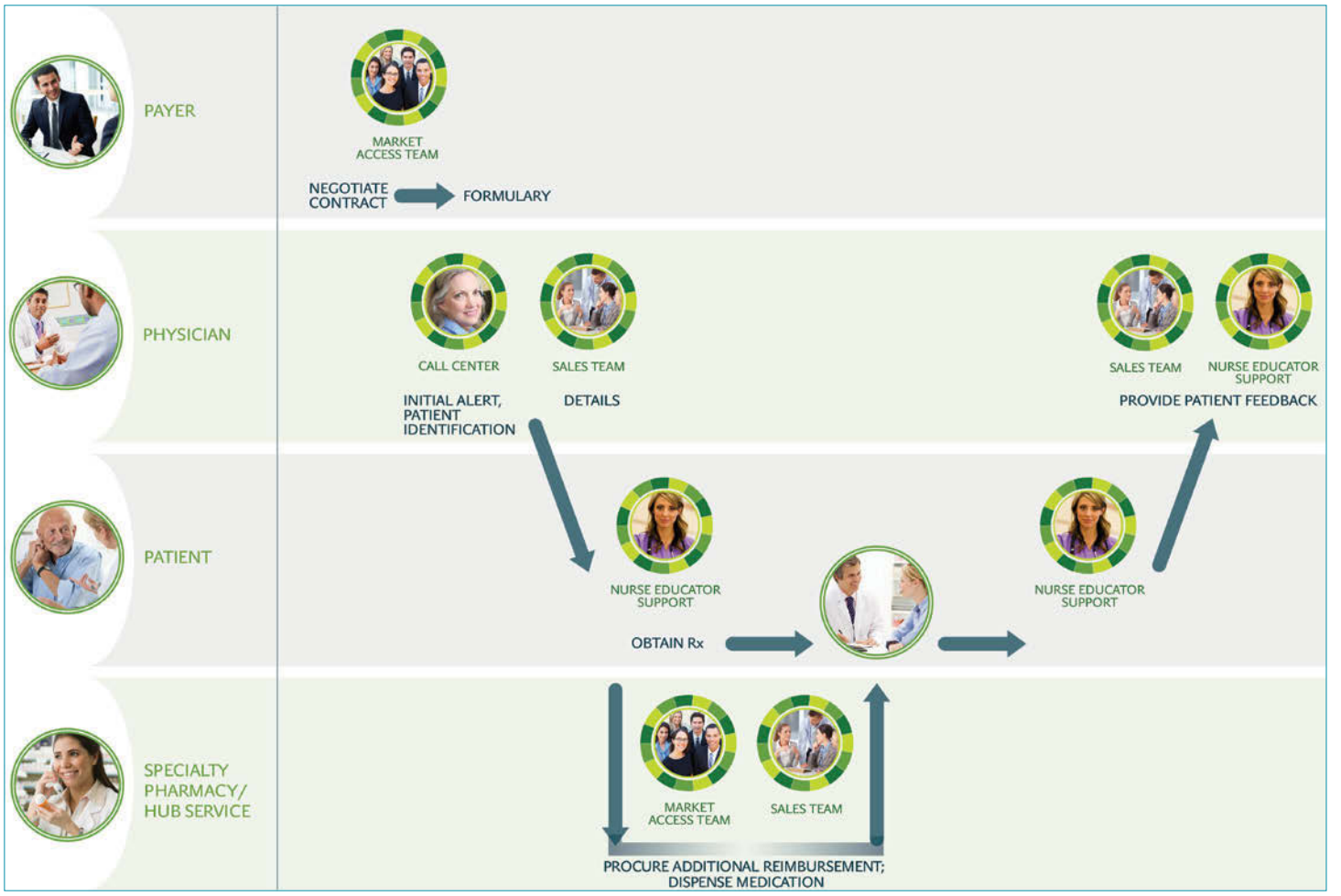

Fig. 3. A holistic TotalCare process for managing a patient's drug therapy.

Next steps for plan integration

Data is certainly a key element to any plan and much data is being collected along the touch point continuum. There are many technology platforms, both server and cloud-based, in use throughout the industry today churning data. Although the industry has much to gain by integrating patient access activities in terms of patient retention and overall cost effectiveness, and is finding ways to do so by coordinating internal and outsourced resources within their patient access planning, integrating the appropriate data pools into the planning process will take some time and vision. Meeting compliance requirements is one hurdle. The sheer complexity of the data being stored in individual siloes is yet another. Addressing how to merge free text data emanating from electronic medical records with cloud-sourced data and primary research will go a long way in improving market access research and outreach plans. Consolidating that with master customer data sets will put the industry light years ahead. More broadly, an infrastructure is developing that will improve the efficiencies of both pharma marketing efforts and healthcare delivery itself. PCm

EvaluatePharma forecast: 2020 global pharma sales of $1.107 trillion

After patent expiries, 'The industry has turned a corner'

The World Preview 2014 from EvaluatePharma (US HQ: Boston) totes up current worldwide pharma sales, assesses pipeline products, and projects industry growth to 2020. According to Paul Hills, head of operations, the "quality" (i.e., projected market value) of new drugs approved by FDA in 2013 increased by 43% over the previous year; this marks a "step change in innovation and output for the industry since 2009." Nine of the top 10 introduced that year (led by Gilead Science's Sovaldi) will be >$1-billion blockbusters, and the 2013 approvals are expected to add over $24.4 billion to total US drug sales by 2018.

More good news: as calculated by net present value (NPV), the industry's pipeline has grown by 46%, to $418.5 billion; "this is the largest figure we have published since the first edition of the World Preview in 2008," Hills writes. EvaluatePharma is very bullish on Bristol-Myers Squibb's nivolumab oncolytic, projecting 2020 sales of the product of $6 billion. (Nivolumab, a "programmed death-1" pathway product, is currently in Phase III development; the PD-1 pathway is also being explored by Merck, Genentech and GSK, among others.)

EvaluatePharma projects a 5.1% CAGR for the industry between 2013 and 2020. 2014 sales are projected to come in at $749 billion, up 4.4% over the prior year, and growth will accelerate through 2016, when 5.8% CAGR will be seen. Meanwhile, $24 billion is expected to be lost to patent expiries in 2014, continuing a downward trend from the peak "lost sales year" of 2012, when $38 billion was calculated to have been lost. Patent expiries will be in the $12–19-billion range annually through 2020. Over that span, biotech products (biologics and vaccines) will increase their market share globally from 22% in 2013 to 27% in 2020, says EvaluatePharma; however, the report is sketchy on the effects of biosimilars.

Worldwide R&D spending is on a 2.4% CAGR trend through 2020, going from $137 billion in 2013 to $162 billion (based on top 500 companies). The 2013 leaders, in order, were Novartis, Roche, Sanofi, Pfizer and J&J. PCm

Agency rides the rare-disease wave

Siren Interactive hires more executives, moves to downtown Chicago

Siren Interactive, a relatively small agency specializing in rare-disease therapies marketing, is taking some big steps forward as its business continues to grow. The company has hired Suzanne Tsuchiya, an industry veteran formerly with the agencies AbelsonTaylor and closerlook, as president; also Neil Rubenstein, a 15-year veteran of the agency business, as senior manager, media and analytics. Two other appointments were also announced. Wendy White, founder of Siren, remains as CEO; this year she is also the president-elect of the Healthcare Businesswomen's Assn., and member of the board of the Global Genes Project. At the same time, the company is moving from Oak Park, IL, to downtown Chicago.

Siren Interactive performs many conventional services for pharma manufacturers, including strategy, digital marketing and agency-of-record status. But the company has also spearheaded activities that dominate rare-disease therapy development: patient advocacy; community engagement; and even patient recruitment programs. Its latest service offerings include: patient advocacy landscape assessment, early stage patient engagement, influencer mapping, and clinical study recruitment acceleration.

One of the hallmarks of the rare disease category (which is traditionally defined as diseases that affect fewer than 200,000 patients in the US, but includes "ultra-orphan" diseases with a few hundred or few thousand patients) is that drug developers have learned the value of working closely with patient-advocacy groups both to develop suitable drugs and to manage what for many is an intense, chronic condition. Rare diseases are also an environment where some patient-advocacy groups play a leading role in funding development programs and even commercializing some drugs. At the same time, manufacturers have identified rare diseases as a market opportunity where competition is less intense, FDA approvals can be streamlined, and drug pricing can be robust. Rare-disease therapies accounted for a third of FDA drug approvals in 2012. PCm

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- PCI
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- Sonoco ThermoSafe
- UPS
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CONTENTS

The supply chain integrity imperative

Increasingly, temperature control is becoming part of overall supply-chain safety and performance

By Nicholas Basta

The fundamental driver of pharma industry growth in cold chain issues is the greater volume of products that require it. Most biologics need refrigerated transportation and storage, and as the dollar value of these products compose a greater portion of the overall pharma market (Fig. 1), there will be more refrigerated shipments, more temperature-controlled packaging, and more necessary documentation of supply chain practices.

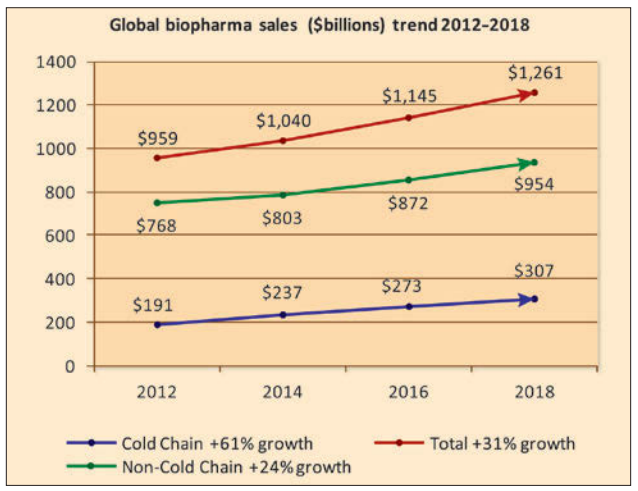


Fig 1. Overall trend for biopharma and biopharma cold-chain product sales. Source: 2014 *Pharmaceutical Commerce* Sourcebook

The *Pharmaceutical Commerce* directory (starting on p. 22) lists nearly 150 component vendors and service providers for healthcare temperature control, and while we're confident that we've captured nearly all of the industry leaders, there are undoubtedly dozens more vendors operating in local markets. The volume of vendors in this specialized area of pharmaceutical storage, transportation and distribution speaks to the growing importance of it for the global pharma industry.

At the same time, the pharma cold chain market is evolving. For one thing, it is becoming more and more out-of-date to speak of the "cold chain": new regulations are putting a greater focus on management of controlled room-temperature (CRT) products; basically everything else besides refrigerated products. The past year has seen greater use of blankets and other measures to keep products from extremes of heat and cold; and some logistics providers are using reefer trucks for ground transportation to protect CRT products in transit. Another possibility is to use the cargo bay temperature controls of the latest aircraft to keep product in a desired temperature range. All of these were only concepts just a few years ago in pharma industry circles.

Beyond temperature, there is a convergence occurring over the concerns the industry has for product security (anti-tampering, anti-theft) and the legislation passed in late 2013 under the Drug Supply Chain and Security Act (DSCSA; aka pharma "track and trace"). Altogether, these regulations and

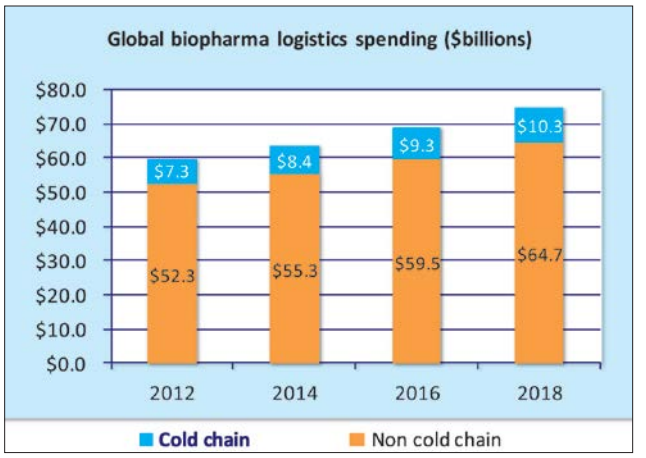


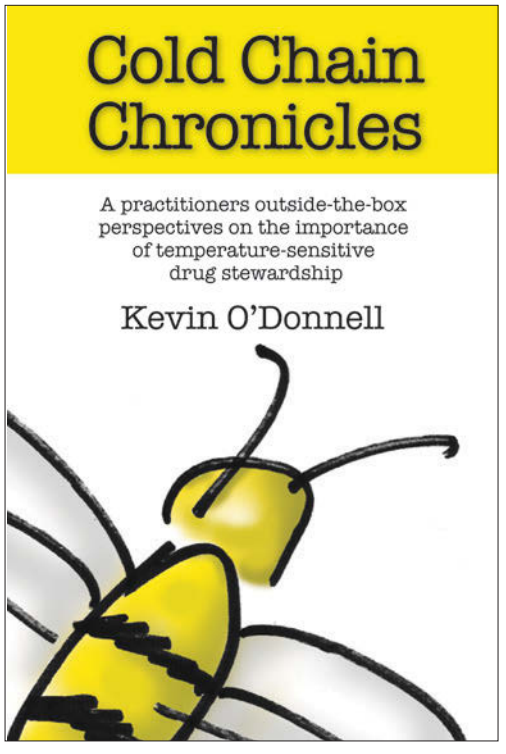
Fig 2. Cold chain logistics as part of total biopharma logistics 2014. Source: 2014 *Pharmaceutical Commerce* Sourcebook

concerns are calling for a tighter control of pharma products in transit. Documentation for a refrigerated product, for example, can now be part of the tracking system for deliveries under DSCSA. Other environmental factors, such as humidity or light, are also being brought into the tracking systems.

Security and product quality managers throughout the pharma industry have been focused on these issues for years, but the new regulations and technological capabilities are bringing these supply chain issues to the attention of pharma senior management. As it happens, these trends track nicely with the goals of pharma brand and marketing managers, who are developing tools to more closely track patient usage of pharma products, for such programs as patient adherence or product switching. There is a grand convergence of quality, security and commercial operations evolving. PCm

Telling cold chain stories

New book puts a light, but instructive focus on temperature control in pharmaceutical packaging and distribution



The multitalented Kevin O'Donnell, a recognized expert in cold chain and related practices in pharmaceutical distribution and storage, has gathered up a decade's worth of writing (on his blogs, in industry publications—including *Pharmaceutical Commerce*—and elsewhere) in a new book: *Cold Chain Chronicles: A practitioner's outside-the-box perspectives on the importance of temperature-sensitive stewardship*. For its publisher, the Parenteral Drug Assn., the book is a departure from its usual slate of technical reports and operational guidances—and maybe that's the point. As O'Donnell notes, "Let's face it: good temperature management practices for drug products isn't exactly a topic that excites the masses." Generating such excitement might be a lost cause among the general public (although there are patients who are excruciatingly aware—through administration of poorly stored drugs), but maybe some broader recognition of temperature control's importance among pharma business managers can be hoped for.

O'Donnell's approach is to tell stories: from 'A Year in the Life of a Vaccine,' to 'A Sled Dog, a Bacterium and a Drug Company' and others that highlight both the history and the current challenges of pharmaceutical distribution. "There Once Was a Woman from Pleasanttown," in particular, tells the story of how temperature control issues might have cut short the life of a patient. (O'Donnell's in-person presentation of this story can be seen at http://vimeo.com/58977765; it's well worth the 20 minutes for anyone involved in pharma distribution.)

Why the bees on the cover of Cold Chain Chronicles? O'Donnell uses them to give some helpful insights about heat, humidity and temperature control and, as it turns out, adds beekeeping to his other interests.

Cold Chain Chronicles can be ordered from PDA at: www.pda.org/bookstore. PCm

Specialty pharmacy links with UPS for faster delivery to patients, clinics

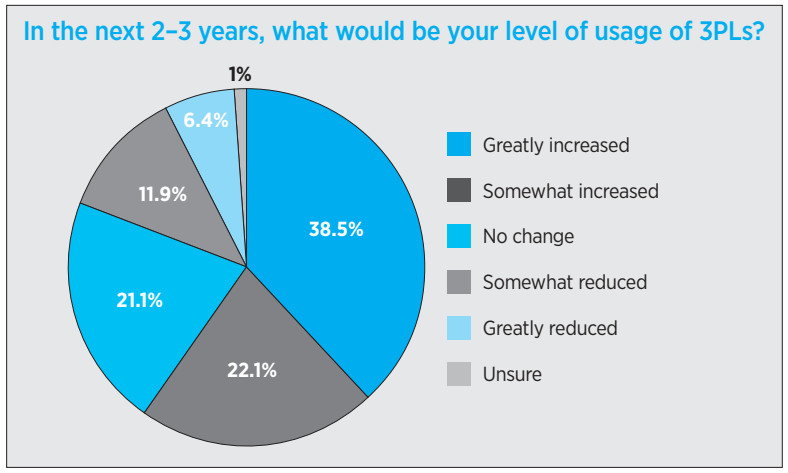
MedVantx pursues manufacturers looking for alternative distribution channels

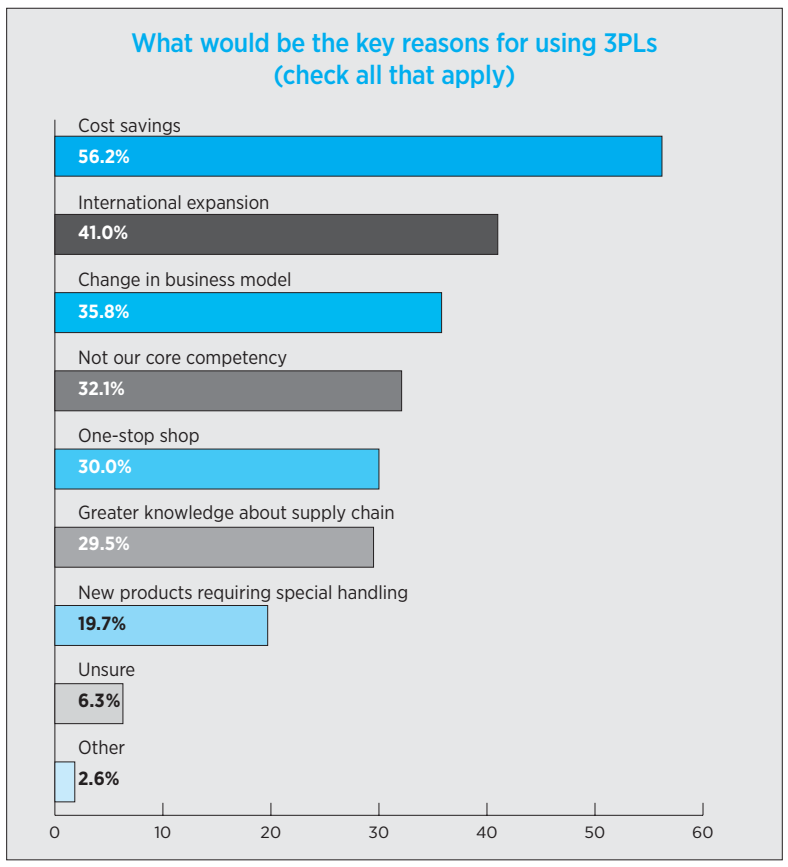
Here and there around the world, there are pharma distributors or logistics providers who locate a facility "at the end of the runway"—as close as possible to where cargo planes are loaded, with a view toward providing faster delivery with shorter turnaround time. In a way, MedVantx (San Diego), a distributor and specialty pharmacy company, is doing that idea one better by locating a pharmacy at the end of the runway. The runway in question happens to be at the WorldPort of UPS in Louisville, KY, one of the largest express-package delivery locations in the world, and home to several dedicated UPS Healthcare Logistics facilities.

MedVantx has been pushing the envelope for several years now with an emphasis on getting prescriptions or drug samples into the hands of patients as quickly as possible. Last year, it announced the MedStart Connect program, which places a physical (not virtual) sample closet in physicians' offices that is stocked with commonly sampled products. The firm's first mail-order pharmacy is located in Sioux Falls, SD; the new one in Louisville will be its second. MedVantx also is building out a suite of hub services for specialty manufacturers, including reimbursement and adherence support services.

"More and more, the traditional marketing techniques like samples, copay cards or quick-fill programs are converging," says Robert Feeney, MedVantx founder and CEO. "The colocation with UPS, together with UPS' extensive cold chain capabilities there, enable us to be as close as possible to same-day delivery, nationally." Feeney notes that the company's running inventory of pharma products is $1.2 billion, from about a dozen pharma manufacturers.

For UPS, says Feeney, the advantage is to move the inventory sitting in their Louisville facilities more quickly. "Working closely with MedVantx," said John Menna, UPS Healthcare Logistics VP, "we developed an offering that answers their need by providing [their] second cGMP-compliant pharmacy location that supports a full range of temperature-sensitive products along with controlled substance storage, and best-in-class distribution services to their customers throughout the US." PCm





Sonoco ThermoSafe survey finds growing reliance on 3PLs for cold chain

A survey conducted by Sonoco ThermoSafe, one of the leading providers of passive packaging for life sciences products, shows that industry managers who place performance above cost as a container-selection qualification, are looking to increase their usage of third-party logistics (3PLs) providers, and are increasingly factoring in environmental concerns with recyclability and reuse of the containers.

Preliminary results are based on 165 respondents who were both personally interviewed and who filled out an online survey. *Pharmaceutical Commerce's* editor in chief, Nick Basta, was part of an industry/analyst panel that worked with Sonoco ThermoSafe (Arlington Heights, IL) to develop the questionnaire. Final results will be presented during a talk at the upcoming IQPC Cold Chain Forum, on Oct. 2.

With most of the non-manufacturing respondents (about 25% of the respondents) excluded, the data show that roughly 40% of pharma managers don't plan any changes in their use of 3PLs (Table 1) over the next couple years. But with "greatly" or "somewhat" increased usage added together, and the same for "somewhat" or "greatly" reduced, there is a clear trend toward more dependence on 3PLs: 24% want more, and 7.4% expect to use less.

When asked to identify key reasons for using 3PLs, respondents chose cost savings by a significant margin (Table 2; respondents could make multiple choices here). Both "international expansion" and "change in business model"—the second and third-most selected criteria, identify overall industry trends in the commercialization of temperature-controlled products, while the other key reasons mostly point to a higher degree of dependence on 3PL expertise.

All this fits well with the macro trends occurring in the global pharma industry, at least among branded products: more biologics (which are mostly temperature-controlled products); and more effort to reach out to emerging markets around the world. To an unusual degree, the pharma industry will depend on the extent, and level of quality, of 3PL services in order to reach those markets with the increasingly complex pharma products in development today.

Package perspectives

When asked what determines selection of packaging configurations, respondents chose "packaging efficiency" as the No. 1 criterion—which is looked on as being able to keep product within specified temperature for more extended periods. "Total cost of ownership (TCO)" and "low price" were secondary choices.

Respondents also voiced a preference for standardized containers (49%) vs. customized ones (30%)—which is a mixed message, because it could be that a custom design has a lower TCO than standard ones. On the other hand, the availability of the standard package, in many locations and depots around the world, could outweigh the potential cost savings.

A similar mixed message occurs when considering reuse and recycling of the packages: 51% said that they reuse packages now (which could be a regulatory infraction if improperly carried out), vs. 39% who do not. But, looking ahead, nearly 70% of respondents would engage in reuse/recycle, provided that it lowered TCO.

Sonoco ThermoSafe sees the results as fitting well with its longer-range planning. "Our company has made major investments in developing prequalified shipping containers, and it's gratifying to see that survey respondents are thinking the same way," says Russell Grissett, VP and GM of the group. PCm

Industry will gather in Boston for the 12th IQPC Cold Chain Forum

Meeting posits a shift to 'supply chain integrity'

Formally titled "GDP & Temperature Management Logistics Global Forum," this year's US cold chain event is said to have over 750 expected attendees. The shift from Chicago, where the last couple events were held, to Boston recognizes, in part, the growing concentration of biotechnology in that part of the country, and perhaps a more accessible stopping point for European attendees. Both of these factors, in turn, are recognition of the increasing importance of biotechnology in the global pharma industry generally, and the worldwide impact of Europe's Good Distribution Practices (GDP) standards, which were formally adopted in the past 12 months and are now setting the bar for regulators, manufacturers and service providers concerned with temperature-controlled products.

The Boston meeting, running Sept 29–Oct 3, starts with workshops and "master classes" on the 29th and 30th. Topics include:

- GDP and the regulatory environment
- Supply chain mapping and transport qualification
- Essentials of good temperature management and storage
- The role of quality management systems and agreements
- Implications of non-temperature hazards
- Making temperature data an approach for improving logistics performance

The formal program and exhibition will kick off with an appearance from Mayor Martin Walsh of Boston. Among the more than 100 technical sessions will be representatives of the World Health Organisation, FDA, US Pharmacopeia, International Air Transport Assn., Transported Assets Protection Assn. and National Research Council (Canada). An International Focus Day is held on Oct. 3 with speakers from Thailand, India, Russia and The Netherlands.

About 60 exhibitors were signed up (at press time) for the meeting. These exhibitors are listed in this Cold Chain Directory (see p. 22), highlighted. *Pharmaceutical Commerce*, a media sponsor of the event, will be in attendance as well—let's get together! PCm

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Transitioning to the Modern World of Data Monitoring and Analysis

In the world of pharmaceutical supply chains, where cost reduction is king and a growing number of products are temperature controlled—collecting, communicating and analyzing temperature and logistics data is critical to success. If data is the foundation of business intelligence, why are Pharma companies still using old practices for data analysis—reviewing data by hand, doing manual entries and using archaic reporting methods? All of these outdated practices and long processes create human error and surging hidden costs. Today, all of the important temperature data and automation tools are at the industry's fingertips, so why not use them?

By Courtney Becker-James

At some multinational pharmaceutical companies with tens or hundreds of receiving sites, it's difficult to know what happens with temperature controlled products at destination. Lack of visibility of shipment performance and how products were being handled can create many challenges, often involving lengthy and tiring processes to get data back from receiving sites to have a complete picture of product temperature conditions.

GDP Requirements

There are some 40 GDP regulatory documents around the world. They underline certain requirements for pharmaceutical manufacturers to provide evidence to customers and regulators that temperatures were within specification during transport and storage.

For example, China's 2013 revised "Good Supply Practice of Pharmaceutical Products" guidelines require pharmaceutical wholesalers and retailers to adopt an automatic temperature and humidity monitoring system for drug warehousing, and where a third party has been entrusted with drug transportation, the entrusting party shall examine the transportation capabilities and relevant quality assurance ability of the third party.

Specifically EU GDP Chapter 9.2 describes transportation mapping and qualification: "Risk assessment of delivery routes should be used to determine where temperature controls are required. Equipment used for temperature monitoring during transport within vehicles and/or containers, should be maintained and calibrated at regular intervals at least once a year." Also most relevant is Chapter 1.4 outlining what components of a Quality Management System companies need to have in place, including conducting CAPAs on systemic deviations to prevent future occurrences.

Therefore, static temperature monitoring is no longer a viable solution. Just throwing a data logger in a box will not create an audit trail and level of control regulators are looking for to meet cGDP. In pursuit of more robust processes for continuous temperature monitoring of medicinal products, pharmaceutical manufacturers are implementing new temperature monitoring devices and an aligned database for archiving and analyzing data.

Marilda Bezerra, a GDP industry professional, using ELPRO's liberoMANAGER database explains, "We wanted a system where the alarm limits and configuration profiles would be centrally managed by quality. Then the warehouses all over the world would configure the data loggers, based on the transport condition of the products they are shipping, using programs, which do not allow them to change the configuration profiles and alarm limits. We also wanted data loggers, which enable the recipients of the goods to identify quickly whether there was a temperature excursion during the shipment or not, in order to place only the pallets with alarm under quarantine. In addition to that we wanted a system that would support us not only with the temperature monitoring, but also with the review of our transportation routes, temperature control measures, and freight forwarder performance versus SOP."

Simplifying end-to-end Temperature Monitoring

The aforementioned new regulatory requirements coupled with businesses driving out costs and inefficiencies, result in most companies transitioning to this modern world of data monitoring. Sophisticated temperature monitoring devices have longer memory; higher temperature accuracies; and can be programmed with up to 18 indices of product or shipment specific data. This is useful if you have extensive stability data that you can use to program devices and set multi-level alarms. There are easy-to-use PDF Loggers that allow for a 'one-step' download of information at the destination, without software, that generates a PDF report including temperature graphs with embedded data, all in one file. This PDF can simply be emailed to any desktop worldwide, the users just need to establish strong SOPs.

One step further after using new temperature devices to simplify end-to-end data handling processes is to collect and use the data. Software as a Service (SaaS) platforms are allowing users to log in and access data from anywhere in the world. QA managers control access to their data in a secure cloud environment and are able to run customized searches on their temperature control products. These database platforms lend to creating more agile, visible cold chains, all in an easy to use virtual environment.

The value of a modern data monitoring system today is not just collecting temperature data but how it's used with other logistics, transport and quality information. Bezerra says, "by putting together the shipment tracking information from the freight forwarders with the temperature records, the graphic starts to have a meaning and tell the story of the transportation route, enabling us to identify the root cause for the excursions, and to determine the corrective and preventive actions, e.g.: changing transport mode, packaging solution, warehouse, freight forwarding agent or service."

In clinical studies, a quality issue could cost valuable time and knock on consequences. If a shipment came in with a temperature excursion or alarm on the data logger, the trial could be delayed. However using data loggers that generate a PDF report with embedded data automates the process by allowing the recipient to easily email the report to the QA or study manager for quick decision-making. If no alarm is displayed, a report is archived and there is no need to review, significantly cutting down the time for the clinical project leader.

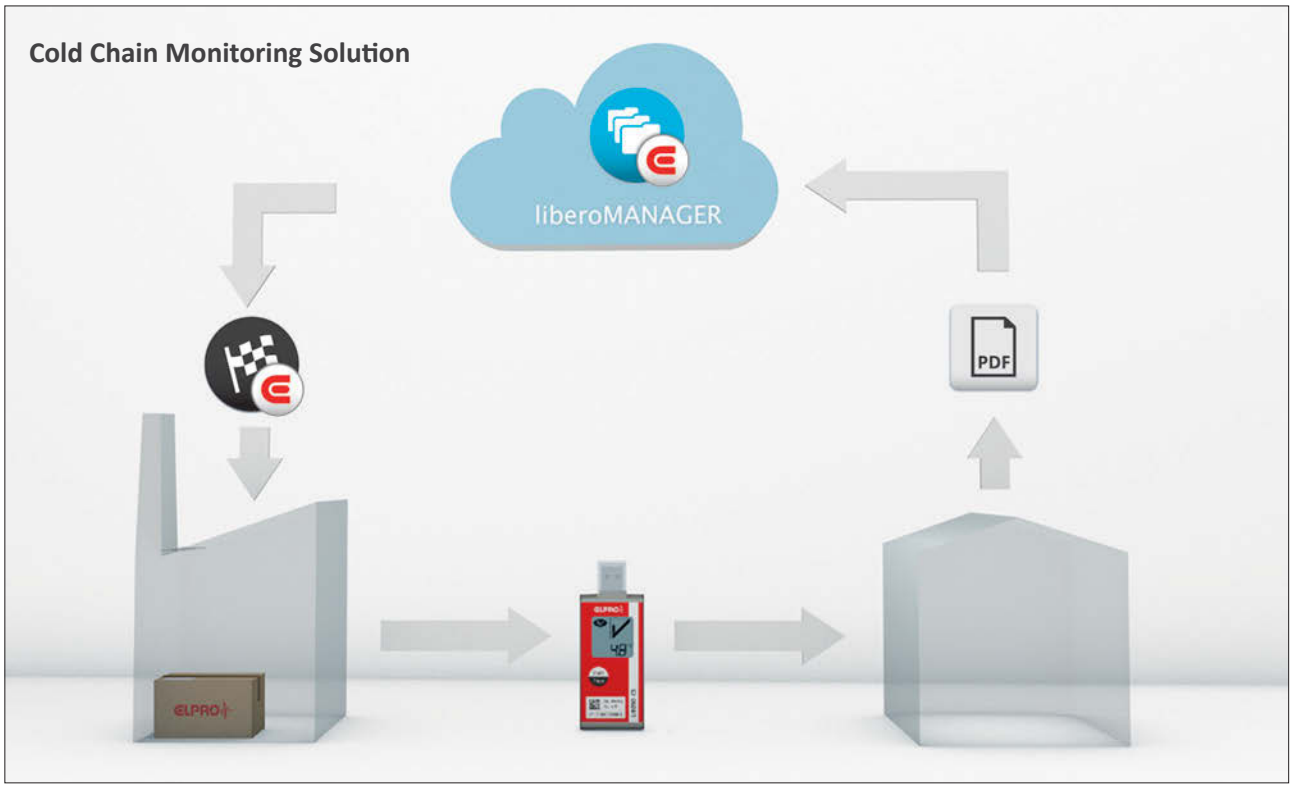
Lisbeth Nielsen, Senior Clinical Supply Technician, Lundbeck, uses ELPRO's LIBERO PDF Loggers. "My team defines the temperature profiles using available stability data, then site personnel download the profile at point of receipt from depots. What's nice about the LIBERO is that we can control what information is seen by whom. The clinical sites only see if there's an excursion, or not. This cuts down a number of unnecessary steps in confirming product quality and administering the trial patient."

Fear of Change

If the benefits of implementing a new data monitoring system are clear, why aren't more organizations making the shift? Such a massive undertaking can leave some organizations spinning their wheels.

The cost of change can also create major stumbling blocks, including 1) physical cost: new equipment and purchases required for initial set-up; and 2) organizational cost: man hours, new SOPs, training supply chain partners. In large multinational corporations there are many different stakeholders and senior management to convince, at times in different cities or countries.

But what about the cost of not changing? How long can clinical sites continue to discard products that are subjected to inadequate monitoring and storage? Companies not



only have to consider business implications such as loss of product, reproducing and reshipping medicines; but also ecological aspects of unnecessary waste of resources, additional transport pollution and extra pharmaceutical waste.

Can you put a price tag on errors? Some say yes, definitely. By taking the time to quantify how many products are wasted or unnecessarily discarded because the right data isn't collected or used, you will have a strong business case. Is there a magic number for cost savings to either switch or implement a new data system? Often, companies only look at the tangible numbers—device, service, software, and database costs. Instead, companies should calculate the costs not to change. Too often data disappears due to the data loggers not being read, lost or disconnected. Without data, action is delayed, incurring significant hidden costs.

Project Success Factors

Beyond convincing the powers that be internally, there are fundamental lessons companies have employed to get a new data monitoring project off the ground. Just like any major project, consideration and roll-out need to be carefully planned, including:

1. Have a first draft of the requirements ready before start
User Requirement Specifications (URS) should be your first step. Document exactly what you want from the devices and database, breaking down processes and roles step by step. Ideally do this first before your business plan to uncover any areas you need more information or evidence. See Figure 1.1

Ask yourself, and the data monitoring vendor, some tough questions for your «URS»: (Figure 1.1)

- What information do I want to collect, and how do I want to use it?
- Can I use the same provider for all shipment temperature ranges?
- Can all of the information from all temperature ranges be housed in a database?
- What is the overall process from start to finish
  - Ordering devices, how inventory is affected
  - Programming / packaging devices
  - Receiving devices, generating reports, and uploading information
  - Searching information in the database
  - Generating reports and releasing products
- How can I reduce data handling errors or overcome them?
- What is the cost?
- What do I need to validate?
- How easy it is to train users and rollout the solution globally?
- Do I need a solution that integrates with my company's ERP system?

What if I currently have a database solution? Is there a reason to change? Ask:

- What is the total cost of ownership including all fees?
- Can you improve the overall process? (error reduction, time, inventory requirements)
- How easy it is to use the data logger and the database?
- Is the end to end data handling process simple enough for everyone involved to ensure you, as the product owner, get the information you need?

2. Define roles and responsibilities
Beyond the project leader, who will manage the new system ongoing, long term? Who will be the future system owner?

3. Involve Logistics, QA and IT early in the process
"Looking back, I would have set up the Steering Group earlier: Managers from Sourcing, IT, Quality, Logistics and Depot Management. Their input is critical to ensure a cross-functional approach is taken. Although they rely on us as project managers to narrow down vendors and criteria, their agreement to secure resources and prioritizing the project early on is critical", says Lisbeth Nielsen from Lundbeck.

4. Having the long-term scope in mind, define realistic short-term goals
Don't sell an unattainable goal. Sell the ability to sustain long-term bottom line impact with the new solution, while scheduling short term achievable goals.

5. Choose a design which is modular, implement step-by-step
Implementing enterprise solutions is easier in phases. Roll-out plans for modular applications can have clear milestone markers with clearly defined goals for training and implementation.

6. Run an effective pilot
Choose only sites that are regularly used and available to fully participate in pilot; schedule training for key users; and send detailed protocol including data logger and database instructions to appropriate users.

Advancing Data Management Practices

Although there are challenges rolling out a new global data monitoring system, pharmaceutical companies are quickly realizing greater data access, transparency and simplified processes are enabling their cold chains like never before. Being able to access all shipment's temperature data centrally opens up opportunities for companies to gain tighter control of their temperature control supply chain.

For example, being able to compare total deviation time with product specific requirements can help avoid costly product loss. Some companies call this managing a stability budget, calculating total time out of refrigeration across multiple legs in a supply chain, or adding deviation time across shipping, handling and storage. Technical Report 53 of the Parenteral Drug Association (PDA) recommends this approach as best practice, "use scientific data and rationale necessary to determine an appropriate stability budget for a drug product over the entire lifecycle of a product." This becomes very important when a product is questionable to be released at destination. "Right now we manually calculate total time out of refrigeration against allowable excursion time. The challenge is adding up all deviations across the different supply chain 'levels'," explains Takanori Aasberg Miyashita, System Manager Temperature Control, at Novo Nordisk.

Beat Rudolf, CEO, ELPRO describes the recent advances in liberoMANAGER, a cloud SaaS platform, and elproVIEWER, data analysis software: "Customers want to easily manage product stability across the supply chain, without the manual work. Today it is now possible for QA to check the availability of remaining stability budget of former transport 'legs' and assign unspent stability budget to remaining transport 'legs' using elproVIEWER. From a QA perspective, avoiding using spreadsheets eliminates the possibility of data manipulation because the data is embedded in the PDF and cannot be changed."

Other advances in data management tools include some companies working toward an integrated platform of logistics data. Being able to integrate a cold chain database with ERP reduces duplication of information such as origin, destination, air bill number, etc. that is already in the ERP system. Although such an integration would drastically streamline processes, there are some challenges to manually integrating the two systems.

Bezerra described their dream data monitoring system as "a system integrated with ERP, which, through bar code reading, reduces the number of manual entries, by the warehouse when configuring the data loggers. This system would also be integrated to the freight forwarder shipment tracking system, and would automatically add the product location information to the temperature records report. This system would also automatically notify the customers about the delivery status, and follow up on open shipments, in order to ensure they send all temperature records to the database, which proves not only that the shipment included a data logger, but that the records were reviewed. Finally, the system would automatically notify the customer with regards to the product usage decision, if applicable, e.g.: in case of alarm."

For Novo Nordisk, advanced data management would be integrating clinical study data with shipping and temperature data. "We have discussed the possibility to integrate communication between IVRS and data loggers with the suppliers, because this is an interesting perspective. However no concrete projects are planned at the moment," says Miyashita.

As companies' approaches and goals for temperature data management may vary, one thing is for certain across the industry—modern data monitoring technology today can help reduce significant hidden costs, simplify end-to-end data handling and bring your cold chain into compliance. What's stopping you?

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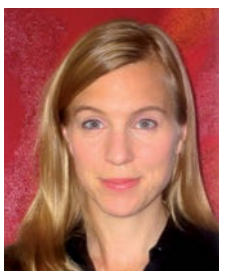

Courtney Becker-James is Strategic Marketing Manager at ELPRO. Courtney has been working in the temperature control pharmaceutical industry for ten years creating industry-leading events and working with advisory boards that have helped shaped the cold chain industry. ELPRO will be teaching a workshop at the IQPC Boston GDP event on using and trending data.

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Saving lives with cold chain products in austere locations

Logistics contractors worked with Sonoco ThermoSafe to rationalize a complex and failure-prone supply chain

There is an impending need for experience and expertise when it comes to importing and re-distributing the essential medicines, diagnostic panels, reagents with exceedingly short expiration, vaccines, and other biological products to austere locations. The logistics to supply to these regions are complicated and highly challenging so in many cases, it is necessary to identify and outsource these services to a qualified and highly experienced logistics and fulfillment organization.

RISKS ADDRESSED

The risks of supplying critical, temperature-sensitive products to these underdeveloped and remote locations are numerous and can include:

- Transportation infrastructure and support vehicles throughout many regions can be damaged, unreliable, under construction, or subject to unexpected road closures. Thus, reliable lines of transportation and refrigerated storage can be extremely limited and in many areas, non-existent.
- Drug product manufacturers are sometimes unable or lack the means to export their products directly and ensure clearance through complex, often corrupt and overwhelmed customs, without experiencing extensive delays and rendering the products unusable.
- Some bulky, single-use, dry ice shippers or refrigerated truck transport for shipments to remote locations are not only expensive but they also lead to many failures.
- Single-use containers can be prohibitively large for regional aircraft and make distribution to remote areas very challenging. At the same time, smaller packages reduce effectiveness of the payload, which increases cost and risk, with more packages needed per shipment just to cover demand.
- Large quantities of dry ice are necessary to protect the product and HAZMAT certified personnel are required to ensure the proper packing and documentation. The hazardous nature of the payload and the size of the containers often result in shipment delays or cancellations due to air transportation related constraints.
- 2° to 8°C products packed using wet ice or gel packs in parcel size boxes require replacement along the way. Leaks or damaged packaging are a frequent occurrence.
- The product's journey could be preceded by several physical hub stops along the supply chain before it becomes available for use.
- Availability of shippers, certified local personnel, and refrigerants cannot be relied upon when aircraft is arriving and/or departing.

Collectively, the above pitfalls contribute to travel times often exceeding 21 days and cold chain shipment failures of 20–25%, posing a serious risk to health, quality of life, and the safety of our citizens abroad.

SOLUTIONS IDENTIFIED

CHSi enlisted the expertise of Coldchain Technology Services (CTS) (San Antonio, TX), an exclusive partner of Sonoco ThermoSafe that operates cGMP storage, reclamation and fulfillment facilities specializing in the use of high performance, reclaimable, and reusable temperature-controlled shipping solutions. Their discrete customer directed fulfillment services presented an opportunity to mitigate many of the risks inherent to the logistical environment facing CHSi.

CHSi needed an overall shipping process adaptable to the dynamic conditions of its diverse business areas. Transit times to some remote areas of the world can be very unpredictable, due to local laws and regulations, and cultural and political factors. CTS demonstrated and recommended the component driven nature of the ThermoSafe Greenbox® shipping system. The dimensions of the shippers, ease of assembly, range of maintainable environments, duration, and the nonhazardous nature of their PureTemp® phase change materials were all seen as advantageous attributes for CHSi. Sonoco ThermoSafe's reusable product solutions and CTS's reclamation experience, with hundreds of thousands of shippers recovered, along with a qualified system of sanitization and fitness performance testing prior to reuse, worked together to develop a closed loop system for using and recovering the most advanced and secure thermal management system available for moving critical temperature-sensitive products around the globe.

CTS's comprehensive SHIP2Q® process (Safe Hygienic Irradiation Performance Process & Qualification), would ensure fitness, thermal reliability, and cleanliness of the system components within the manufacturer specifications equal to new "off-the-shelf" shipper systems. The systematic SHIP2Q® process meets all cGMP and cGDP compliance standards and generates shipper-specific track & trace documentation key to any deployment and reuse (learn more at www.thermosafe.com/reclamation). SHIP2Q® applied a system of control over the recovery and reuse phase of the logistics loop. CHSi is able to recover and reuse the Greenbox® shipper, amortizing its total cost across numerous shipments making it cost-neutral in the first few cycles. Some specific Greenbox® shippers have made a 16,000-mile loop more than 20 times (or 320,000 miles).

The switch from active refrigeration units, dry ice containers and inferior passive package components to the Greenbox® shipping system also allows CTS/CHSi to use commercial freight carriers and multiple aircraft equipment instead of expensive specialty carriers and dedicated service providers previously required.

ADVANTAGES GAINED

Together, Sonoco ThermoSafe, CTS and CHSi have designed and implemented a closed-loop fulfillment and reclamation solution that extends more than 16,000 miles and confidently boasts a 99% return rate for the shippers.

- The implementation of Sonoco ThermoSafe's Greenbox® shipping system, application of CTS's SHIP2Q® process and fulfillment services, CTS's comprehensive SHIP2Q® process ensures each shipper's thermal performance during reuse every time. This seamless coordinated effort has reduced the cold chain failure rate by more than 98%.
- The PureTemp® phase change materials and reusable containers can be used as redistribution packages. These smaller sized Greenbox® shippers are easier to load into small aircraft cargo bays and since the PureTemp® phase change materials are vegetable oil based, the need and expense of hazardous materials classification and declaration is not required. CTS simply takes advantage of the Zero Bench Time™ attributes of the PureTemp® panels while following a simple packing configuration that ensures temperature continuity during re-shipment.
- Using commercial freight carriers and legacy carriers has given CHSi much greater flexibility and a larger customer service and communications pool to draw from and require no additional logistical support along the way.
- The reusable Greenbox® shipping systems are also an environmental advantage to CHSi. The return of the reusable VIP containers to the CTS reclamation center eliminates the concern and expense for shipping waste out of the country or leaving residual EPS or PUR in these austere locations. Greenbox® can be shipped at regular freight costs, eliminating the need for expensive and unreliable refrigerated trucks.

Through a dedicated and coordinated effort, CHSi has been able to reduce the risk to life-saving medicines in austere locations, solve a wide variety of unique shipping and transportation challenges, provide greater control of the supply chain, improve visibility of the product, and reduce landfill waste and save money, but more importantly lives.

To view a more detailed presentation on this case study and to meet the authors in person, visit the 12th Annual Global Cold Chain Forum from Sep 29–Oct 3, 2014 in Boston, MA. To receive discounted passes, please register at https://register.iqpc.com/ using code "12CCGF_SONOCO".

Comprehensive Health Services, Inc. (www.chsimedical.com) has extensive experience in all of the medical service areas. CHSi capabilities have been built through solid performance in providing this array of medical services to both commercial and government customers. Since 2007, CHSi has been a dynamic presence in support of medical services operations in the Middle East and other international locations. CHSi services focus on Level I medical support to maintain the health and medical readiness of the workforce.

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Creating the first, pharma-only 3PL network

The drive for lower costs, safer products

By Sanjeeth Pai, Cardinal Health Specialty Solutions

For years, manufacturers have been challenged to lower the cost of moving pharmaceuticals from Point A to Point B, while keeping them safe every mile of the way. These challenges are more pronounced today than ever before, as manufacturers address three ongoing issues. First, there is the mounting cost pressures resulting from the 'patent cliff' that began in 2010, with one of the biggest waves of drug patent expirations in history. [1] As the patent expires for one top-selling drug after another, lower-priced generics are taking market share and profits away from manufacturers every day.

The second challenge is the waste that's inherent in pharmaceutical transportation, particularly of cold chain products. If carried by unrefrigerated trucks, these products need to be transported in coolers, which creates excess packaging and increases costs. Imagine a tiny vial requiring a large cooler filled with gel packs, and you begin to see the problem.

Finally, there is the challenge of product security. While the cargo theft of pharmaceuticals in the US continues to fall according to the Pharmaceutical Cargo Security Coalition (PCSC), it remains a constant concern of transportation managers and requires ongoing vigilance as part of an overall cost and risk management strategy. [2]

Shared-resources logistics is a creative solution for addressing all three of these challenges. In fact, other industries—such as consumer packaged goods—have already used this approach to significantly cut costs. For example, in 2010, Kimberly-Clark teamed up with Colgate to co-load freight and share truck capacity. The goal was to help offset rising transportation costs as they both delivered to the same locations: a limited number of CVS Caremark retail stores. According to Kimberly-Clark, the collaboration cut total truck miles by 10% and line-haul and fuel-haul costs by 18%. [3]

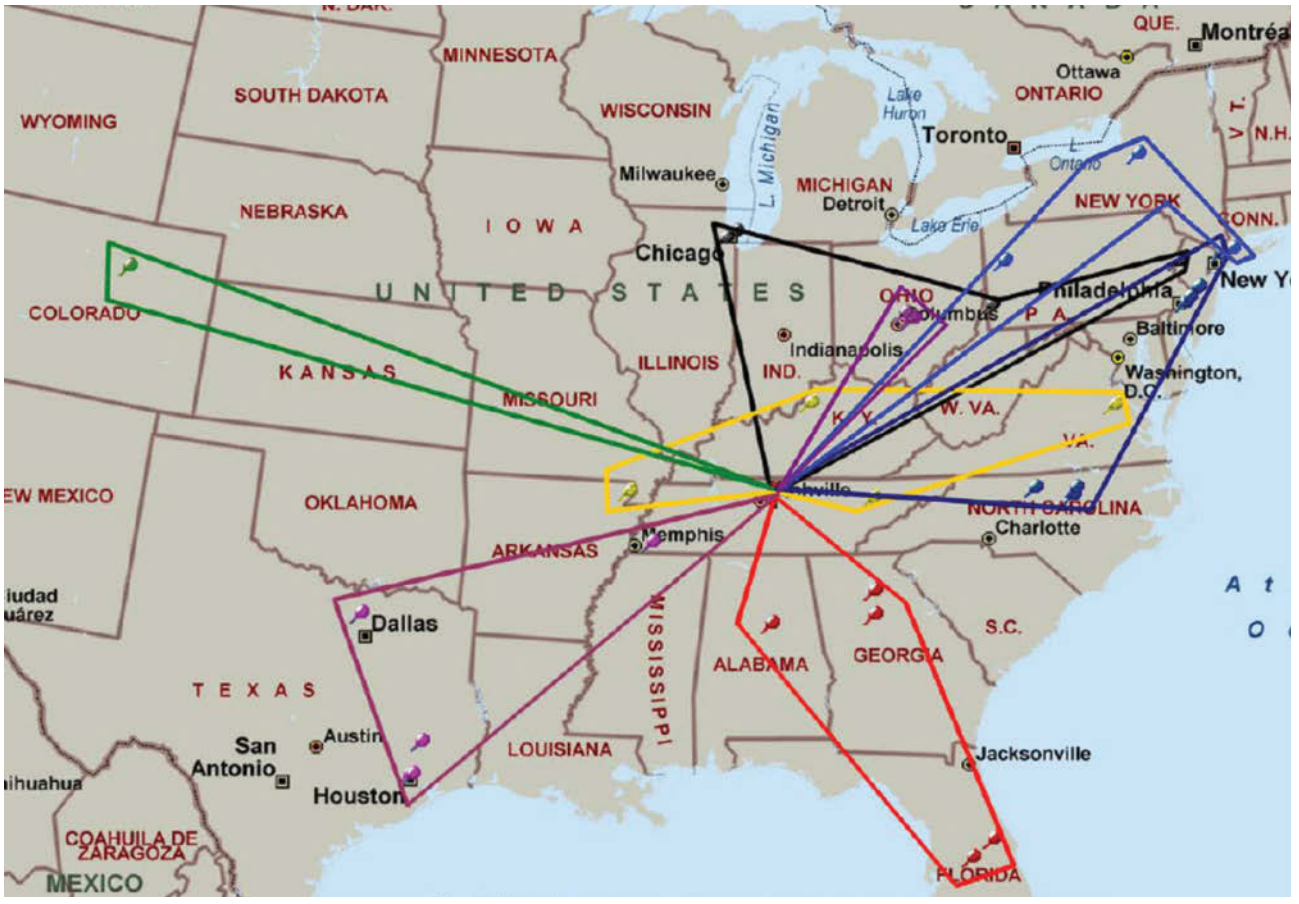
By sharing resources—from warehousing to truck capacity to shipping lanes—manufacturers can optimize their transportation operations, eliminating the high cost of less-than-truckload shipments and empty back hauls.

Sharing resources in pharmaceutical distribution

In 2007, we began to develop our own approach to shared-resources logistics at Cardinal Health Specialty Solutions. At the time, we were transporting products for approximately 80 pharmaceutical manufacturers. Through an in-depth analysis of ordering and shipping data we identified key locations where the vast majority of products were being delivered.

With the understanding that comingling these products would save manufacturers money, we worked with our carriers to develop a new shared-logistics solution. The result was the Exclusive Pharmaceutical Transportation Network (EPTN), which combines the best practices of shared-resources logistics: consolidating warehouse space, comingling freight from different manufacturers and creating more efficient shipping lanes to common destinations.

What sets EPTN apart from other shared-logistics models is that it's the first and only 3PL network in America that is dedicated exclusively to the pharmaceutical industry, covering 70% of all trade volume shipped. Other logistics providers offer some pharma-only services—such as warehousing. But EPTN is the only comprehensive solution, providing both warehousing and transportation services for all types of pharmaceuticals, including brand names, generics, over-the-counter and specialty.



Cardinal Health Specialty Solutions transportation network. Credit: Cardinal Health

These drugs arrive at their destinations in 48 hours or less via eight routes that deliver to the East, South, Midwest and Colorado. All deliveries are point-to-point 'milk runs': once a product is loaded onto a truck it stays there, without being sorted or removed until unloaded at its destination. Currently, there are nearly 40 of these destinations: a mix of wholesale, specialty distribution and retail relocations.

The network is not exclusive to Cardinal Health distribution centers and products and is open to the entire US pharmaceutical industry, from manufacturer to wholesaler to point-of-sale. EPTN can accommodate any size of load, from a single package to a pallet. Manufacturers pay only for the space needed on the truck.

By consolidating shipments from multiple manufacturers, EPTN lowers transportation costs for manufacturers an average of 10–15%. The savings are in addition to regular discounts from Cardinal Health contracted freight rates. Also, because EPTN has regular routes, there's less need for expediting shipping and the related, higher costs.

Lowering costs further

After narrowing the shipping lanes to eight, we began to look at the trucks themselves to create more efficiency and cost savings. Turning to data analysis once again, we identified the common destinations that different types of products have, from controlled to ambient to cold chain. Instead of using a separate truck for each product type bound for the same destination, we wanted to combine all three onto a single truck.

The solution was to build an entire fleet of trucks refrigerated to 40°F (regardless of the temperature outside), accommodating cold chain products without the need for special packaging and handling. Each truck is calibrated and quality monitored to ensure temperature control. Ambient products can safely travel at 40°F for the 48-hour or less length of the network's routes.

Keeping products safe

The final cost management measure was to ensure the safety of products from warehouse to destination. Because of EPTN's shared-resource, point-to-point delivery, there are zero third-party touches. Unlike traditional LTL shipping, products are handled less. And that minimizes the potential for damages and claims, as well as product shortages and losses. So the root cause for product write-offs is eliminated.

The EPTN network embraces other safety best practices as well. For example, contracted team drivers are required to have background checks. The trailers and seals are unmarked, and the trucks are always attended. Each truck is also GPS-tracked along the entire route, from origin to destination. An additional safeguard—a geofence—tracks the movements of each truck. If it deviates from the intended route, the carrier is automatically notified and the truck contacted. If necessary, law enforcement is also notified.

Looking to the future

Shared-resources logistics is a creative, proven way for manufacturers to lower costs and keep products safe in transit. To date, EPTN has focused on outbound shipping. The next step is to add backhauling, filling the trucks with products inbound to any destination, not just Cardinal Health. To us, shared-resources logistics means just that: a solution for us all to work more collaboratively, be more efficient and focus more on what matters most: the patients we all serve. PCm

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Master data management (MDM) takes center stage

MDM practices are moving far beyond compliance concerns

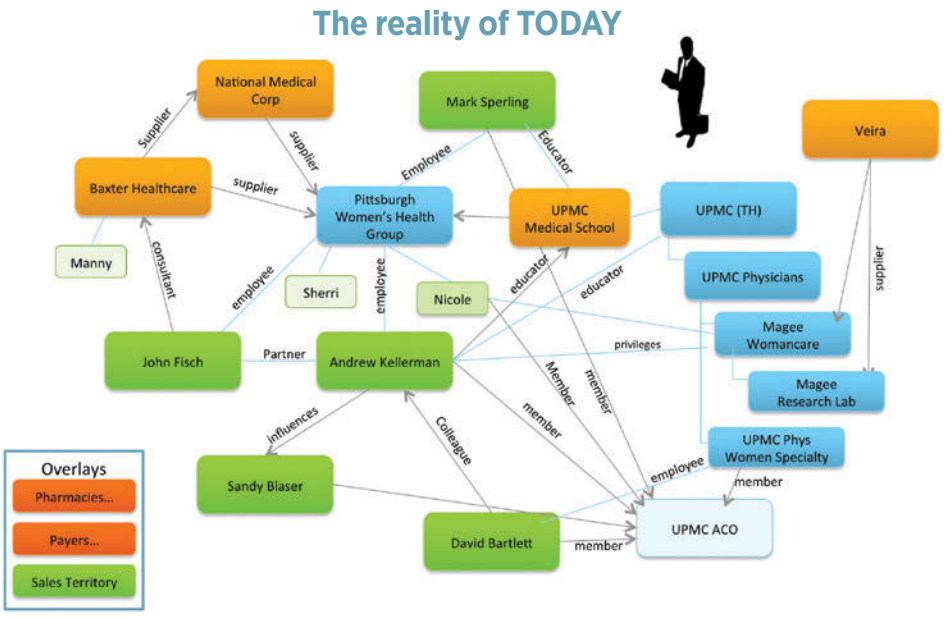
by Nicholas Basta

There's no question that the Physicians Sunshine Act—that part of Obamacare that mandates the reporting of payments and contributions of "transfers of value" to healthcare providers (HCPs) by the life sciences industry—has had a major impact on the business of providing HCP identifications, locations and affiliations. These "master data files" have been a steady business for years for the American Medical Assn. (which sells its data to a group of database licensees) and a host of private companies. The Sunshine Act mandates public disclosure of industry payments, aggregated by HCP over the course of a year; at presstime, the first national, industry-wide disclosure was to occur around Sept. 30—but if AMA and others have their way, could be delayed to March 2015 (see box).

Being able to report accurate "agg spend" data depends on reliable identifications of individual HCPs, and that has set in motion an aggressive drive by pharma companies to get their internal lists cleansed and verified. But along the way—hastened by a rapid evolution in master data management (MDM) software—pharma IT departments are looking at master data as the foundation to organize many aspects of HCP interactions—sales calls, website subscriptions, prescribing patterns, and even non-health-related data like credit reports, personal travel and the like to create a comprehensive view of the prescriber, his or her professional affiliations and preferences for (and reactions to) multichannel media outreach. MDM is fast becoming a core functionality of customer relationship management (CRM) as well as overall marketing strategies.

A good example of this is the actions by Veeva (Pleasanton, CA), a leading CRM vendor, to add the Veeva Network, incorporating an MDM vendor acquisition, AdvantageMS, to its slate of offerings last year. More recently, IMS Health made a $520-million bid (to be voted by the Cegedim board in November) to acquire Cegedim Relationship Management (Bedminster, NJ), which includes the OneKey master database, an MDM platform, Nucleus360, and a CRM platform, Mobile Intelligence. "OneKey would join our complementary information assets available through IMS One and deliver insights on nearly 14 million healthcare providers across the globe," says Seyed Mortazavi, president, IMS Health US (see p. 12).

Historically, MDM software was a type of business intelligence application, meant to connect customer interactions across multiple business areas as a way to provide insights to customer behavior. Vendors like Informatica and Information Builders joined offerings from IBM, SAP, Oracle and others to provide the platform into which pharma companies could load customer data. One of the newest contenders in this field, Reltio (Palo Alto, CA)—chosen this year by Gartner Group as one of its acclaimed "cool companies"—has built a cloud-based MDM system as part of a "data as a service" offering. In the past year, Reltio has partnered with several traditional HCP data providers: MedPro Systems (Mt. Arlington, NJ), Health Market Science (King of Prussia, PA) and Enclarity, a LexisNexis Company (Minneapolis, MN) to deliver HCP data to life sciences companies and vendors in the healthcare arena.



Reltio is seeking to create richer MDM records by organizing a 'fabric' of connectivity among healthcare providers and organizations. Credit: Reltio

Cegedim Relationship Management had already developed its own MDM platform, called Nucleus360, to provide comparable, cloud-based MDM data. "We've been very successful with Nucleus360 in the past year," comments Drew Bustos, a company spokesman. "In addition to multiple

AMA and 110 other medical associations seek Sunshine Act delay

Postponement of public data for six months is justified by slow rollout of CMS rules, they say

The pharma industry, among other life sciences firms, has been busy for most of this year preparing its reports to CMS on payments made to prescribers and some of their hospital affiliations. But over on the physicians' side, near-panic seems to be setting in as the Sept. 30 date for public release of the spending data approaches. A letter* has been sent to Marilyn Tavenner, CMS Administrator, seeking a six-month publication delay as required by the Open Payments System established under the Physician Payments Sunshine Act (which was passed as part of the Affordable Care Act). At presstime, there had been no CMS response.

"Fundamentally, we have no issue with efforts to increase transparency in the interactions between physicians and industry," says the American Medical Assn. "However, we have a number of serious concerns regarding how the Open Payments System has been implemented." AMA cites the delay in CMS issuing registration instructions for physicians into the system (so that they can review the data about them); a cumbersome registration process; procedural rulings for how educational activities and medical publications are covered; and industry's ability (as determined by CMS) to have final say on data disputes.

AMA was joined by 61 other physician professional groups, and the medical associations of 48 states and the District of

Dyax Corp's journey to MDM-driven multichannel success in the cloud

Life sciences companies of all sizes today are faced with a unique set of commercial challenges. In an environment where the customer could be anyone from a physician to an integrated delivery network (IDN), potentially based anywhere in the world, and accessible via a complex mix of communication channels, accurately identifying and targeting key customer segments is more important than ever. For Dyax Corp. (Burlington, MA), a rapidly growing Massachusetts-based biopharmaceutical, the answer was in the cloud.

At Dyax, keeping up with the constant changes in the medical community had fallen to the sales force. Field representatives managed HCP data in their CRM system, resulting in duplicate accounts, outdated information and extra labor. An in-depth analysis of their data revealed 2,000 duplicate or incomplete healthcare organization (HCO) records, several hundred duplicate HCP records, thousands of missing phone numbers and addresses, and limited use of unique identifiers like NPI numbers. "Many of the profiles lacked even basic enough information to make the profiles valuable," says Andrew Sheely, director of IT. "Essentially, we lost control of our data."

The key to making users more productive, according to Sheely, was centralizing data management with a solution that provided the information reps needed at their fingertips. To create the master data foundation required for a successful multichannel strategy, Dyax became an early adopter of Veeva Network, a cloud-based customer master solution. Part of Veeva Commercial Cloud for life sciences, Network combines industry data, services, and a globally accessible customer master application.

Seamless integration and interoperability between Veeva's commercial solutions in the cloud means Network's data is available directly in Veeva CRM, where Dyax's reps need it. Bringing life sciences companies together to contribute updates to customer information that are verified by data stewards and added to the master data repository, the solution generates a "network effect" that allows data to improve over time. As more and more companies join Network, the data grows in both quantity and quality, becoming more valuable to all.

"The network effect is one of the true differentiators between this product and other MDM solutions," says Sheely. "We liked that, as we make updates to our data, it gets fed into a master system and then gets pushed back out to all customers because we benefit from the same efforts they're making. Everyone in the long run benefits from that collaboration."

With access to over 10 million customer profiles that are kept current on an ongoing basis, Dyax is seeing higher user productivity, enhanced customer engagement, and better territory alignment. Network gave the company instant access to over 14,000 HCP/HCO records, 57,000 street addresses, and

multinational companies who have acquired the technology in the US, we've signed up 14 other business units in the past year in Europe and Asia-Pacific."

Obtaining reliable HCP data is now a global activity, for regulatory as well as commercial reasons—more about that later.

Latency goes away

LexisNexis, which acquired Enclarity last year, has a substantial business in providing HCP data for medical claims for insurers, and this business is under the gun these days as CMS tries to get a better handle on improper claims payments to HCPs under Medicare, Medicaid and related programs, says Warren Gouk, SVP for healthcare at the company. Notices of, for example, license restrictions on HCPs can take upwards of six months to pass from a state authority, into MDM databases, and out to pharma companies; in that time frame, a host of billing issues could have been generated. LexisNexis uses claims, legal and financial data (from other business lines in its Risk Solutions business unit) to propagate these data in a matter of days, he claims. "Zero latency is the goal."

Accurate status data of HCPs not only affects Medicare claims, but also compliance issues such as the distribution of samples under the Pharmaceutical Drug Marketing Act (PDMA) and DEA rules about controlled substances. Both of these, in turn, involve data that feeds into agg spend reporting requirements.

Gouk says that his company differentiates itself with the comprehensiveness of its reporting, providing information on up to 125 fields for each HCP, and its ability to draw on consumer-oriented data such as financial services used by HCPs to provide a richer profile. Another feature of its service is that profiles are rated with a "confidence score," meaning that there is information about how reliable the data are.

MedPro Systems, which has been in the HCP data business for 25 years, touts a 300-field profile of providers, and has been busy lately extending its data services into new areas, notably the license information that is coming into place under the Drug Quality and Security Act (DQSA), which will require—for the first time—an authorization of wholesalers and logistics providers to be distributing the drug products that they handle. Besides its alliance with Reltio, MedPro has also partnered with Concur

continued on page 38

Columbia (for whatever reason, Alaska and Wisconsin didn't sign on).

Information about the Open Payments System is front and center on AMA's website homepage, and the association has developed a "Sunshine Act toolkit" to assist its members. Several media organizations—including ProPublica, an investigative journalism enterprise that started a "Dollars for Docs" information service several years ago, are eagerly waiting to see what the data will reveal.

**(registration required): http://www.ama-assn.org/ama/pub/advocacy/topics/sunshine-act-and-physician-financial-transparency-reports/sunshine-act-toolkit.page*

6,000 email addresses that they didn't already have in their database. In the span of just several months, Dyax reps have already submitted 421 data change requests through Veeva Network, resulting in 177 edited accounts and 244 new accounts. Now, rather than spending time manually updating HCP profiles, field representatives are reducing call prep time and improving customer engagement with more up-to-date data. Incomplete or duplicate records have been eliminated, enabling Dyax to leverage full customer profiles that include specialties, primary parent, and degrees.

"With multiple Commercial Cloud applications working together in concert," Sheely concludes, "now we have that true multichannel capability to reach our physicians."

Adopting the TAPA cargo security standards in the pharmaceutical industry

Securing your supply chain

By Rafik H. Bishara, Technical Advisor and Susan Griggs, Eli Lilly and Company, Inc.

The Transported Asset Protection Association (TAPA) is a nonprofit, volunteer organization that unites global manufacturers, logistics providers, freight carriers, law enforcement agencies, and other stakeholders with the common aim of reducing losses from international supply chains. [1, 2, 3] TAPA began in 1997, initially focusing on high-value electronics thefts.

In 2013, TAPA exceeded 700 members, encompassing representatives from a variety of industries including pharmaceuticals.

The TAPA standards provide a set of security requirements that are specific enough to be effective, yet appropriate for global use in a variety of risk environments. Having a common set of requirements allows logistics services providers (LSPs) to focus on good security measures that protect a wide variety of high value cargo. A certifiable global standard increases efficiency, transparency, and provides a recognized level of security, both for the LSP and for the customers they serve.

LSPs achieving TAPA certification have demonstrated their commitment to security by complying with the TAPA standards, participating in independent certification audits, and conducting periodic self-audits. Certifications are granted for each individual warehouse or trucking fleet. One well known global LSP has achieved certification at more than 100 facilities. [4] In the future, TAPA expects additional focus on truck fleet certifications as cargo theft frequently involves theft of, or theft from a truck.

TAPA Standards:

1. **Warehousing/Distribution Centers: F**acility **S**ecurity **R**equirements **(FSR)**
2. **Trucking Fleets: T**rucking **S**ecurity **R**equirements **(TSR)**
3. **Airport Facilities: T**ransportation **A**ir **C**argo **S**ecurity **S**tandards **(TACSS)***

*not certifiable at this time

Fig. 1

Adopting TAPA standards

To maximize flexibility and customize security to risk, the TAPA standards are designed with three performance levels. For example, a warehouse complying with TAPA level A (or a trucking provider performing at Level 1) is the most protective. TAPA B or C level is more appropriate for lower risk locations or products.

The support of an organization's senior leadership is the number one leading indicator of success when implementing the TAPA standards. It should be noted that implementing TAPA standards in a large global pharmaceutical company is complex. It requires committed leaders and a corporate culture that recognizes the value of secure supply chains. While the organization's security department may lead the implementation and sustainment of TAPA, the most successful models also include key stakeholders from logistics, procurement, and quality.

Before launching an initiative to implement TAPA standards, there are three key areas for decisionmaking and research: scope, risk, and return on investment.

Scope: Will the TAPA standard be applied to all pharmaceutical products, such as active pharmaceutical ingredients (APIs), physician samples, clinical trial materials, animal health products, and return goods, or will it only apply to commercial human finished products? Will it apply to bulk product or only product in final packaging? Will it apply to company owned facilities or only to third party sites or transporters?

A good standards governance structure will include the following:

- ✓ standard format
- ✓ change control board
- ✓ technical writing support
- ✓ leadership approval
- ✓ documented exception process
- ✓ periodic reviews
- ✓ document management

Choosing the right standards structure, with the right amount of rigor will be key to success.

Fig. 2

Relative Risk: Will every country or facility be required to perform at TAPA Level 1/Level A or is it acceptable for some lower risk areas to adopt TAPA Level B or C?

To help differentiate risk, one company used a model that recognizes three risk factors commonly referred to as the three Vs: Value, Volume, and Vulnerability. Product Value and Volume, in a particular warehouse or country region, can be confirmed through internal company data. The Vulnerability score can be obtained through external sources that rank particular countries or regions for cargo theft risk, such as the Incident Information Service (IIS) Report published by FreightWatch and/or TAPA. [5] Once the three Vs are quantified for a company's product portfolio, a review of the data allows a risk ranking, or categorization, to be made.

Whatever risk ranking method is chosen, it should be easily understood, repeatable, and based on data. The organization should update their risk rankings annually or as company operations and risks change over time.

Return on investment: The most important reason for securing pharmaceutical products is to protect patients. However, it is very difficult to estimate the cost impact of such an unfortunate event such as theft, tampering or diversion. Fortunately, in most cases, TAPA standards produce an attractive ROI, even without including the cost of patient impact.

There are four steps to this:

- Make some educated assumptions: If TAPA, or an equivalent standard, is not implemented, how many major warehouse burglaries will occur over a 10-year period? How many truckloads will be stolen each year? How many pallet- or case-level losses can be expected on an ongoing basis?
- Estimate the cost of failure: What does a typical warehouse burglary of finished pharmaceutical products cost? What is the cost of manufactured product, impact to brand, impact to operations, lost productivity, incident response, down time? What is the cost impact of a recall or delays to market? What is the projected cost to insurance rates and the potential regulatory impacts caused by uncontrolled losses? Is the likely loss over a 10-year period $50 million or $200 million?
- Estimate the cost of security: Projected costs can be extrapolated in two ways. One method is to model security at 2–3 warehouses or trucking operations and then simply multiply by the total global count. Another method is to estimate a percentage of the company's global logistics expenses. For example, if the company spends $100 million per year on logistics, depending on locations and risks, it may be able to estimate a percentage for security expenses (ex: 4% or $4 million).
- Calculate the net impact: The net ROI can be calculated over a five to 10-year period as major losses may not occur every year.

Getting started

When determining ownership, ask "Which functions are most invested in cargo security?" Is it logistics, security, quality, or procurement? In the most successful models, security partners with another key function (e.g., logistics). Cross-functional ownership supports a balanced approach and can provide a broader range of skill sets versus a single function trying to manage it alone.

When identifying key stakeholders, consider which ones are active participants and which are passive supporters (i.e., need to be informed but not active participants). The core group should include at a minimum representatives from security, logistics, warehousing, and quality.

Before launching the initiative, document a project charter and have it approved by whichever functions own the standard (ex: logistics and security). Putting it in writing helps identify any overlooked steps or risks in the project. The project charter should contain a goal statement, scope (in/out), business rationale, business impact, project timeline, project sponsors, project leader, steering team members and functions, working team members and functions, and approvals.

To provide the best governance and oversight of the standards, a critical decision is deciding where the TAPA responsibilities will be hosted internally. Options may include the company's engineering standards, security standards, or quality standards.

Form a working team

The standards working team should be a relatively small group which includes a knowledgeable representative from each of the key functions (i.e., security, logistics, and quality). Global companies should consider including a representative from each geo-region (i.e., Americas, EMEA, and APAC).

It is during this phase that the TAPA requirements are closely evaluated to be sure they are sufficient for the specific product risk. For example, if highly sensitive or theft-attractive products are being moved by truck, the company may require truck escorts in certain countries, in addition to the TAPA requirements. While the TAPA standards are sufficient for most pharmaceutical products, the working team will provide valuable insight and foster healthy discussions about what level of security is necessary.

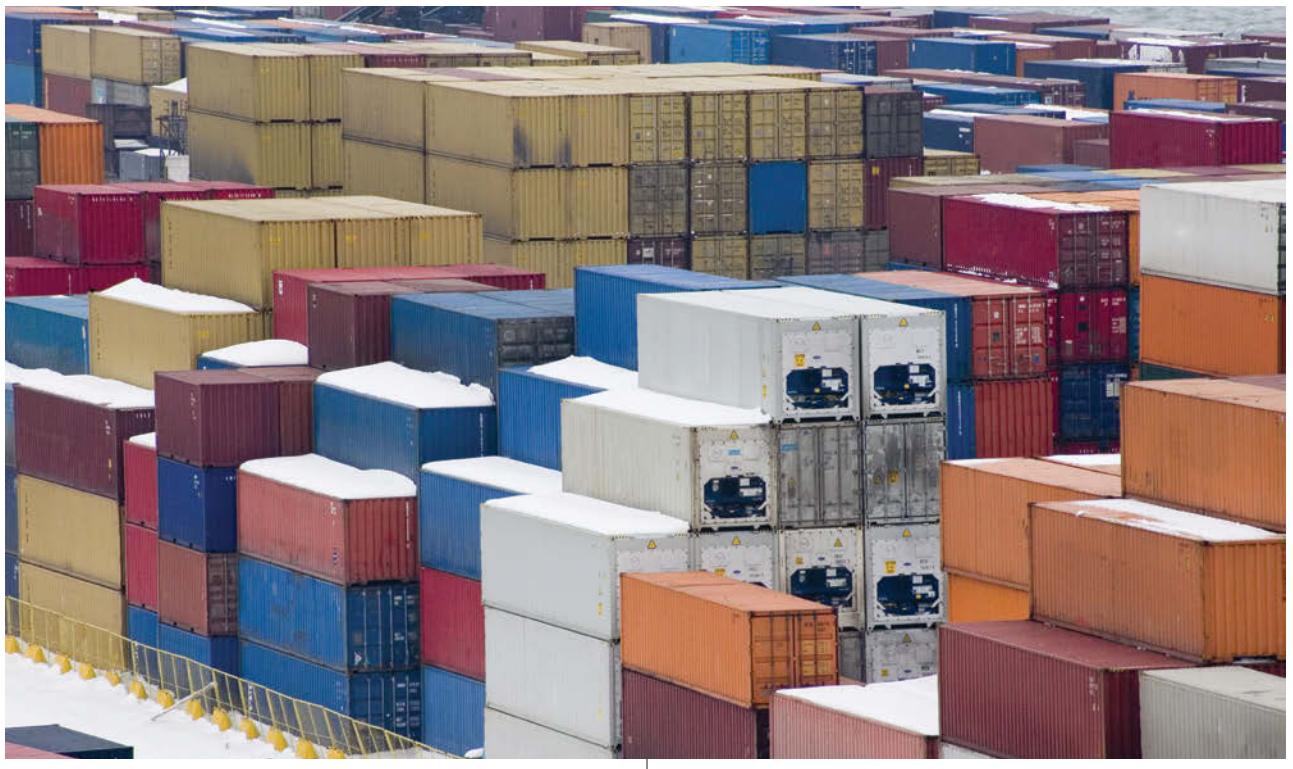
Once the standard is drafted, it should be sent out to all appropriate stakeholders across the company for a global review and comment period. If appropriate, consider asking key suppliers to provide comment also. The request for review/comment should include the following supporting information:

- Data or cargo theft trends that support pro-active measures to protect pharmaceutical products from theft
- Senior leadership: quotes or communi-cations about the importance of supply chain security
- Benefits of the TAPA standards
  - specific enough to be effective
  - general enough to be globally applicable
  - global: LSPs can focus on complying with TAPA standards instead of multiple individual customer standards
- Recognition of team members and contacts for follow up.

Consider setting a deadline for comments (e.g., 30 days), to include a simple comment form, and a collaboration site or central repository for comments to be uploaded and permanently archived.

Communication

Mass communications, web meetings and in-person training should begin as soon as the standard is officially approved and published. The launch message should contain another message from senior leadership to reinforce support and accountability for supply chain security:



- What is this?
- Why are we doing this?
- Who does this impact?
- When is this effective?
- How to proceed?

TAPA standards should be referenced in all communications. Global companies should purchase TAPA memberships in each of the TAPA regions (Americas, EMEA, and APAC).

Web Conferences

- ✓ Repeat leadership message
- ✓ Review standard
- ✓ Deadlines for gap assessments, action plans
- ✓ Deadline/Plan for full compliance
- ✓ Clarify scope
- ✓ Address costs
- ✓ Share exception process (if any)
- ✓ Establishment/Introduction of Global Resource Team

Fig. 3

Training

Internal training: Most pharmaceutical companies require mini-training for new standards. This is typically done through the company training system.

External training: It is highly recommended that key stakeholders and practitioners attend a TAPA meeting and receive TAPA standards training (free to members). The additional benefits of attending are benchmarking, networking, and learning about emerging crime trends and countermeasures.

Within two to three weeks after launch message and training roll out, regional web conferences should be held and include the following:

Sustaining the effort

Once the basic initiative is underway, it is helpful to bring in other management perspectives, such as the legal and procurement departments. This phase includes additional communication with, and support from, legal and procurement. From a legal perspective, make the standard (based on TAPA) a legal appendix or addendum to all logistics service contracts. Work with procurement to make logistics security one of the company's recognized risk events. This will help ensure that procurement professionals appropriately incorporate the standard.

To sustain performance, a compliance monitoring program must be authorized and resourced. Questions to consider include:

- Will compliance be monitored at in-house company locations in addition to third party LSPs?
- Assessment frequency and type:
  - Self-assessments, onsite audits, or combination?
  - Every two years for high risk countries?
  - Less frequent for TAPA certified (i.e. money saver)?
- Decide when compliance monitoring will begin (e.g., six months after implementation phase ends)

Finally, continuous development of best practices and guidelines can drive consistency and save money. Examples may include:

- SOP to prevent fictitious pickups
- How to choose a good trucking company
- Theft response checklist
- Secure pallet design
- Technical requirements/system architecture
- Intrusion detection systems
- Power supplies.

The pharmaceutical industry and its supply chain partners must ensure patient safety.

Adopting the TAPA standards will help protect pharmaceutical cargo from theft, diversion or tampering, thus ensuring the quality, safety and efficacy of the pharmaceutical between the manufacturer and the end user, the patient. PCm

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Lifecycle solutions: aiming for better patient outcomes through high-quality prefillable solutions

By Tibor Hlobik and Kevin Cancelliere, West Pharmaceutical Services, Inc.

The increasing concern for patient safety in addition to increased quality and regulatory requirements have contributed to the evolution of improved drug delivery. Choices for primary containment and delivery systems can impact time to market, and more importantly, patient outcomes. A poor choice for primary containment can increase risks for long-term drug stability, and may contribute to ineffective dose delivery, recalls and increased patient risk. Incompatibility between the drug product and its containment or delivery system can result in particulate and leachables formation, poor device performance and can negatively impact patient compliance to prescribed therapeutic regimens.

To achieve the best possible patient outcomes, pharmaceutical companies developing complex and sensitive biologic or biosimilar injectable therapies must consider how the drug product will interact not only with the primary container, but also with the delivery system and the patient to help ensure compliance to prescribed regimens.

By partnering with a component manufacturer early in the drug development process, pharmaceutical manufacturers can identify and mitigate many of the risks associated with poor containment selection. Flexible containment solutions use the same materials for drug contact, but in a variety of configuration options that aid in stability and delivery from discovery through commercialization and through drug lifecycle management, may help achieve better patient outcomes.

Primary containment issues

In a recent draft guidance, "Immunogenicity Assessment for Therapeutic Protein Products," the United States Food and Drug Administration (FDA) called attention to issues commonly associated with container closure systems, including:

- denaturation and aggregation of proteins at glass-air interfaces
- glass delamination and particulate formation in certain drug formulations
- protein aggregation associated with silicone-lubricated containers
- leachables from container components

These issues may affect the therapeutic activity of the drug product, and the recommendations come at a time when such issues have led to an increase in the number of recalls. For instance, in 2011, 10 drug product recalls were caused by glass particulates in the drug product solution. The pace continued in 2012 with recalls of 19 lots of four different injectable oncology products caused by the discovery of glass particles.

To help solve fundamental incompatibilities that may exist between a drug formulation and its primary container, manufacturers are exploring and adopting alternative materials of construction, such as cyclic olefin polymers, that may help assure stability during a drug product's shelf life.

Another consideration in this process is the need to integrate primary containers into drug-device combination products. As patients take a more active role in their individual healthcare, and the administration of injectable drug products moves from physicians to caregivers and patients, there is a greater need to provide an easy-to-use delivery system or combination product that assures safe and reliable administration. This may include the use of prefillable syringes, which help to assure dose accuracy and minimize errors when compared to a vial and disposable syringe format. There is also an increase in the use of disposable auto-injector systems (Fig. 1), which aid in dosing convenience, reduce patient fear because the needle is hidden and include safety features that hide the needle before and after injection. Finally, there is a trend toward new systems that allow for even greater patient convenience. These cartridge-based systems include the use of pen injectors for frequently administered products, as well as large-volume electronic wearable injector delivery systems that can offer either less frequent administration or conversions of products from intravenous to subcutaneous administration.

	Primary Drug Container Typical Components	Device Typical Parts
Auto-injector (single dose)	-Syringe with attached needle -Rigid needle shield -Plunger stopper	-Main Body -Needle cover -Spring -Activation button
Pen Injector (multi-dose)	-Cartridge -Lined Seal -Plunger stopper	-Main Body -Disposable needle -Dose dial mechanism -Activation button

Fig. 1. Single- and multiple-dose injector designs.

Identifying material risks

In order to ensure drug product integrity, containment materials must be compatible with both the drug product itself and the delivery system. The selection of the proper containment system will aid the drug by reducing potential extractables and formation of leachables, or other interactions with the product, including glass delamination and protein aggregation. In turn, that containment system should be suitable for use and function properly within the final delivery system.

As noted in Fig. 2, companies with drug product lifecycle strategies seek to move the product to market quickly, which often means that the product will arrive on the market in a vial and syringe format. As use increases, the delivery system may transition to a prefilled syringe system, and finally a delivery device such as an auto-injector or a wearable patch injection system. However, if the drug is in a highly competitive therapeutic drug class, companies will launch with a prefilled syringe or delivery device format. Selecting a primary containment material, such as a cyclic olefin polymer, as well as components that enable efficient delivery and functionality with the device or system, may aid in patient compliance and efficacy of the drug product through accurate dosing and ease of self-administration.

Prefillable syringe systems may increase compliance through ease of use and decrease errors through precise dosing, provide caregiver safety through use of safety devices, and a lifestyle preference when combined with an auto-injector because of self-injection convenience.

Proper material and design selection for components, including the barrel in a prefillable syringe must consider requirements such as long-term drug compatibility, dimensional tolerance and fit for container closure integrity, the force required to remove the tip cap or needle shield cover—which may be an issue with those suffering from limited dexterity—breakloose and extrusion for optimized injection forces and needle size. Components must be

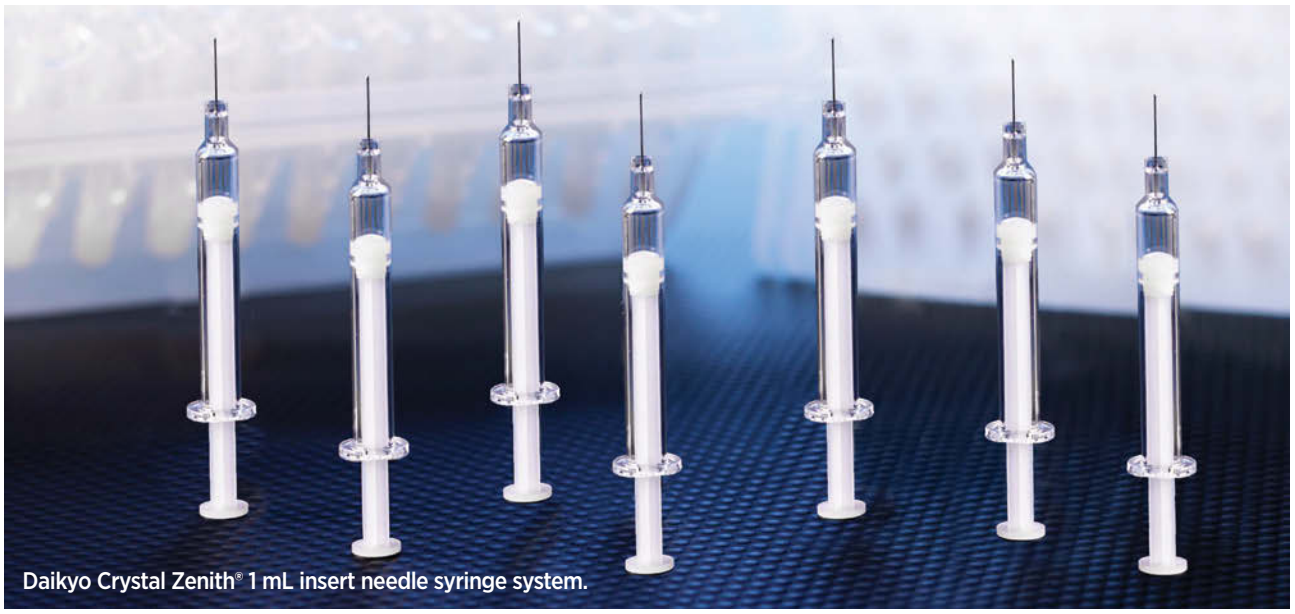
West dedicates a manufacturing plant in India

In July, West Pharmaceutical Services, Inc. dedicated its manufacturing plant in the Sri City Special Economic Zone (SEZ), where the company will expand its growing primary packaging for injectable medicines business. Construction of the 15,300 sq. m. (approximately 164,700 sq. ft.) facility began in 2012. It will produce seals used in primary packaging of injectable medicines manufactured by West's pharmaceutical and biopharmaceutical customers in India and the wider Asia Pacific region. There are future plans to expand production at the site to include West's elastomer component business.

"This investment is important to our strategy of partnering with customers in India and the Asia Pacific region to help them provide medicines to patients more efficiently, reliably and safely," said Warwick Bedwell, president, pharmaceutical packaging systems, Asia Pacific Region. "With the facility complete, we anticipate a reduction in lead times for supply to our customers in India."

West's presence in the Asia Pacific market includes a plant in Singapore, two plants in Qingpu, China and sales offices in Australia, China, India and Singapore. The company also owns 25% of Daikyo Seiko, Ltd., (Tokyo, Japan), a developer of pharmaceutical packaging and medical device components.

West's SmartDose® electronic wearable injector.


Daikyo Crystal Zenith® 1 mL insert needle syringe system.

matched to meet the requirements over the intended shelf life of the drug product and under all conditions of storage and use.

When selecting proper materials for a specific drug product, the following questions should be considered:

- How does the container closure system interact with the drug product? Is the material chemically stable and inert?
- Is the primary container system suitable for use in an auto-injector or patch injection system?
- Will the drug product require sterilization or low-temperature storage?
- Will the presence of metal ions—which are often a potential extractable from materials or even residuals left behind after processing—cause issues such as protein degradation or particle formation?
- For a prefillable syringe, is the combination product fit for manual injection and automatic injection?
- Is the drug compatible with silicone oil, which can induce particulate in many drug products?

Many biotech and sensitive drug products have unique requirements, and polymer systems provide key solutions for patient safety and compliance. There are a variety of products on the market that can help mitigate these risks, including barrier films for elastomer components that help to reduce potential extractables and leachables formation. For materials that are sensitive to glass, cyclic olefin polymers can be molded into a variety of shapes and sizes to accommodate not only the drug product, but also large-volume doses. In addition, cyclic olefins can be molded to suit innovative delivery devices, offering differentiation in the market. An insert needle prefillable syringe, such as the Daikyo Crystal Zenith® 1mL Insert needle syringe, may be required for a drug product with metal and silicone oil sensitivities.

System selection

While the primary focus of most pharmaceutical companies is on the drug product itself, early collaboration with a packaging and/or device partner during the lengthy development stages can result in a delivery system that meets the needs of both the drug and the patient. Research and development for a biologic drug product can typically last as long as 15 years and cost as much as $1.2 billion. [1] So when the drug product reaches the market, the originator may have only a few years remaining on the patent. Often, the delivery system is only thought of during the final stages of development and not fully considered during primary container selection. If the drug product cannot be stored effectively or reacts chemically to the containment materials, or if the system does not function well with a high-viscosity drug or is not a good fit for the intended patient population, it can be a costly issue for the manufacturer. Considerations relating to dosing volume, delivery technique and frequency, and if the drug product will be delivered in a system such as an auto-injector, should all be taken into account at an early stage to ensure optimum speed to market and opportunity for success.

As noted previously, there is a strong trend for biologic delivery to move from its original containment system, such as intravenous delivery, to formats like subcutaneous injection via a prefillable syringe system or auto-injection device. Pharmaceutical manufacturers have several options for drug delivery solutions, but for some, compromises may be required.

Select an off-the-shelf system – while this selection may work for many drug products, it may require re-working for specific drug products and adaptation costs may be considerable. Functionality challenges may remain throughout use.

Increase existing device complexity – often highly expensive and complicated, this option may extend time to market.

Simplify an existing device – excluding features of a system that is prone to breakage, such as a spring-driven delivery device, has always posed a risk of incomplete injection.

Market in a prefillable syringe system only – this will require significant adoption, compliance and adherence on behalf of the patient, and many barriers, such as needle phobia, may exist.

Create a new device – By working with a packaging partner that has experience in contract manufacturing, a device can be created using the same materials throughout the drug product's lifecycle while providing differentiation in the market, and ensuring ease of use for the patient.

Even with these challenges, there are opportunities to improve the patient experience via formulation and delivery device technologies. By partnering with packaging and delivery systems companies, drug companies can optimize treatment regimens through initiatives such as:

- Formulating drugs to higher concentrations, to reduce dosing frequency
- Using higher-volume delivery systems to deliver a larger volume and reduce dosing frequency
- Using higher-volume systems to allow for more diverse formulation options that may not be possible if the dose is limited to a small volume

Collaborating with a single partner with diverse expertise in primary packaging, delivery systems, custom design and analytical testing early in the drug process can help at a variety of stages. For example, packaging manufacturers who also provide analytical laboratory services can offer product recommendations to the latest alternative technologies and provide prescreen stability work early in the process to ensure that the containment materials do not react with the drug product. Many biologics, by their very nature, do not respond well to glass containment, which can result in higher levels of extractables and leachables, protein aggregation or the risk of glass delamination. Cyclic olefin polymers (COPs) offer an alternative to traditional glass and, since COPs can be molded to a variety of shapes, they can provide containment throughout the drug product's lifecycle. Such choices early in development may also aid decisions later in the manufacturing cycle. COPs also offer improved dimensional tolerance and design flexibility, so innovative container/device combinations can be considered to help optimize overall system design based on the needs of the patient. Companies challenged with multiple containment needs during drug development and lifecycle strategies can work closely with the partner to match technology, collaborate during development and ensure the primary container is compatible with the drug and device for best patient outcomes. PCm

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	LIFE CYCLE STRATEGIES		
	First in Class	**Emerging Class**	**Highly Competitive**
Phase I and II	Vial and Syringe	Vial and Syringe	Vial and Syringe
Phase III and Initial Launch	Vial and Syringe	Basic Device	Basic Device Advanced Device
Life Cycle Management	Vial and Syringe Basic Device Advanced Device	Basic Device Advanced Device	Incremental Improvements

Fig. 2 Life cycle strategies from development to commercialization.

Reference:
[1] PhRMA slide pack, "Biopharmaceuticals in Perspective."

Is tech running you? Four ways to retake control

continued from page 6

benefits of this approach firsthand. For one company that needed to train a salesforce of 400, it allowed them to reclaim hundreds of hours of sales time for their field force. By restoring one sales day per month per rep (4,800 days), they realized the equivalent of 23 additional sales reps. That's a return on investment they couldn't afford to do without!

Unlike space travel, it's not rocket science. But it does require rethinking… about the inevitability of change and the role of training in managing it cost-effectively. PCm

Legal uncertainties in the DSCSA

continued from page 6

or whether manufacturers are bound by a trading partner's determination or may make its own determination. FDA's draft guidance does not resolve these ambiguities.

• **Illegitimate product** - Unlike for the prior two categories, the DSCSA does impose an explicit duty on manufacturers, wholesale distributors, dispensers, and repackagers to "take reasonable and appropriate steps to assist a trading partner to disposition an illegitimate product" not in its own possession or control. The statute also requires each trading partner, upon determining that a product in its own possession or control is an illegitimate product, to "notify the Secretary and all immediate trading partners" that the party has reason to believe they may have received "such illegitimate product" of such determination not later than 24 hours after making such determination.

The statute is ambiguous about whether "such illegitimate product" means only the particular package or unit of the product, or more broadly includes other units within the same shipment, the same lot, or even the same product category as the illegitimate product. FDA's recent draft guidance does not resolve or even address such ambiguity.

Will FDA resolve the ambiguities in time?

The agency requests comments by Aug 11, 2014. Whether the final guidance will address these ambiguities and will be issued before the Jan 1, 2015 implementation date—let alone in time for affected companies to put systems in place necessary to comply with these and other DSCSA obligations—remains to be seen.

As of July 30, FDA had received only two comments on the draft guidance and had not posted either. Absent timely FDA interpretation, parties subject to the DSCSA's verification requirements will need to resolve these issues and other ambiguities regarding their mutual obligations themselves. Prudence suggests that the parties review their internal policies and the contractual obligations governing their relationships, and engage in explicit conversations among themselves to try to resolve these ambiguities to the extent possible. Otherwise, the gaps left open may create situations in which counterfeited or diverted products are not adequately investigated and disposed of because parties may assume another party is taking responsibility for investigating and handling the product. PCm

Master data management (MDM) takes center stage

continued from page 33

Technologies, a travel-and-expense reporting system popular among pharma companies, and Databasics (Reston, VA), another T&E vendor. In both cases, these alliances make agg spend reporting by sales reps smoother. In addition, it works with Porzio Pharmaceutical Services, a regulatory compliance company, for an agg-spend offering specifically.

Ray Ungemach, VP at MedPro, says that the Sunshine Act has forced pharma companies to take a step back and reconsider the entire MDM process, looking at it not just for compiling the spending data but as an asset in marketing. "One of the most important factors currently is affiliation data—which organizations an HCP belongs to, is employed by, or affiliated with," he notes. Affiliations intersect with the formulary plans of insurers and healthcare networks, which in turn affects the prescribing practices of the HCPs.

MedPro's longevity in the business has given it a better level of access to certain data—espeically from state-level regulatory bodies. The company counts over 800 such sources; and Ungemach says that MedPro not only obtains the licensing and validation data as it becomes available, but also tracks what it has done in the past month or year with the quality of that data, so that it can anticipate what followup is needed (for example, through the use of a call center) when data records are updated. "Some of these processes can be automated, but our belief is that everything can't be done by an algorithm," he says.

Technology advances

But algorithms are exactly what's on the minds of experts at Health Market Science, which provides both comprehensive data on HCP and HCO identities and demographics, as well as technology to perform analytics on that data. The company just announced the awarding of a US Patent (8,731,971) for "data models and algorithms leveraging columnar and graph databases" and to do so while preserving historical versions of the entities in the system. All this feeds into the MDM and analytics system that HMS markets, called Current. The company notes that the technology decreases latency when data are being processed across a range of computers.

Theresa Greco, GM of Life Sciences at HMS, reinforces the reality that MDM is being called on to support more and more functions in pharma such as Compliance departments, focused on global agg spend, disclosure initiatives and commercial operations supporting account-based selling initiatives. Like MedPro, the company has also licensed its data services to Concur Technologies for agg-spend reporting; HMS has also been involved in providing the data necessary to demonstrate that clients are in compliance with corporate integrity agreements regarding how they market their products. And while there has been talk of tapping more directly into the electronic health records (EHRs) that are being more widely used in healthcare settings, HMS is finding a desirable market among EHR vendors themselves, who need help in identifying potential new clients, their affiliations, and the types of EHR systems they might be using. The company is expanding its platform to incorporate data from social media feeds—a trend that many MDM providers are trying to get in front of, in order to present richer data on HCP communication and influence patterns. And it is handling "bidirectional" data gathering—cases where clients, in effect, can update records that come back to HMS for verification.

Such bidirectionality opens up the prospect of pharma companies performing their own updating of HCP records, then sending them to the MDM provider for verification (the example would be that a pharma rep might be the first to know that an HCP has opened a new office). That, in turn, raises the possibility of pharma companies themselves pooling their resources to generate needed HCP data, presumably at a lower cost than what individual vendors are charging. LexisNexis' Gouk says that his company does exactly this for leading insurers, and the idea has been proposed in the past to pharma manufacturers but not broadly accepted.

That could change, to some degree, through the efforts of Veeva, the CRM vendor. The company announced Veeva Network a year ago, then acquired a US-based MDM company (AdvantageMS) as well as one in China for that market. Veeva proactively maintains this data by continuously aggregating and verifying data from hundreds of authoritative data sources. For participants in Veeva Network—at their option—Veeva accepts updated information from them, verifies it and then shares it with Network participants. "This is absolutely happening," says Paul Shawah, VP of product marketing at the firm. He adds that it's not necessarily a cost-saving approach, but one that can improve the value and accuracy of the databases. "Conventional data sources can take days or weeks for updated information to flow back into the database; in this case, the update can happen in 24 hours and be more accurate," he says.

Shawah also makes a point that pharma companies are benefiting by outsourcing the "data stewardship" to companies like his—something that many of the leading MDM providers are beginning to do. Clients can share some data, but retain some of it within their own Veeva-operated database that is managed by the company. Like other Veeva products, the databases are cloud-based, and interfaces between Veeva CRM and Veeva Vault (a service for approving and distributing digital content across all channels) are fast and clean. At this year's Veeva customer event, the company rolled up all these services (including a multichannel resource allocation service called Align) as the "Commercial Cloud for the Life Sciences."

With its integration of MDM services into CRM, Veeva is following the pattern set by its arch-rival Cegedim Relationship Management, with which it has competed aggressively in the CRM space. For its part, Cegedim Relationship Management hasn't stood still. Besides developing the MDM platform, Nucleus360, the company has arguably the most comprehensive global master database, OneKey, which brought together its US business (primarily developed through an acquisition, SK&A Information, several years ago) and master data compilations provided by Cegedim SA, its French-based parent.

Jack Schember, senior director, US marketing at Cegedim Relationship Management, notes that for years, Cegedim had touted its extensive call center operations, which provided direct, semiannual updating of HCP records. This has been complemented by purchased or licensed supplemental data; Schember says that 2,000 updates come into the databases daily. OneKey also entails data-stewardship services, and Schember says that the SK&A resources can be tailored to provide specific market research goals for clients.

Additionally, other parts of the Cegedim organization run activities such as copay coupon programs for clients, and those data can provide important insights to prescriber practices. Finally, the Cegedim organization has been rolling out its own online community for physicians, DocNet, which has been up and running in Europe for several years, but was introduced only in the past year in the US. (Where DocNet winds up following the merger with IMS Health remains to be seen.)

"Multinational biopharma companies are confronting regulatory transparency requirements similar to the US' Sunshine Act around the world, and many companies are now consolidating their various databases to achieve a single view of a customer," he says. Part of this is to ensure a meaningful level of standardized compliance practices wherever that is an issue, he says, but equally important is the cost of implementation. "There is a big IT department advantage when we can provide global data organized under one data model, and accessed in a standardized manner," he says. "There are incentives for companies that purchase provider data for multiple countries, but the single- data model is a big implementation advantage." PCm

2014 PDA/FDA Joint Regulatory Conference
Sept 8–10, Washington, DC
Parenteral Drug Assn., 301 656 5900, www.pda.org

PharmaForce
Sept 3–5, Baltimore, MD
WBResearch, 888 482 6012, www.pharmaforceus.com

Clinical Trial Supply USA
Sept 16–18, Boston, MA
IQPC, 800 882 8684, www.coldchainiq.com

PDMA Sharing Conference
Sept. 14–17, Leesburg, VA
PDMA Alliance, www.PDMAalliance.org

12th Annual Cold Chain GDP & Temperature Management Logistics Global Forum
Sept 29–Oct 3, Boston, MA
IQPC, 800 882 8684, www.coldchainiq.com

e-Rx and EHR Master Class
Oct 1, Philadelphia, PA
Center for Business Intelligence, 800 767 9499, www.cbinet.com

HPCLC Fall Meeting
Oct 6–8, Longboat Key, FL
Health and Personal Care Logistics Conference, Inc., www.hpclcnet.org

2014 Universe of Prefilled Syringes and Injection Devices
Oct. 6–7, Huntington Beach, CA
Parenteral Drug Assn., 301 656 5900, www.pda.org

Adverse Event Reporting and Safety Strategies Summit
Oct 15–16, Philadelphia, PA
ExLPharma, 212 400 6240, www.exlpharma.com

Procurement & Outsourcing for Life Sciences Congress
October 16–17, Philadelphia, PA
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NORD's Rare Diseases and Orphan Products Breakthrough Summit
Oct 21–22, Alexandria, VA
Center for Business Intelligence, 800 767 9499, www.cbinet.com

Digital Pharma East
October 21–24, Philadelphia, PA
ExLPharma, 212 400 6240, www.exlpharma.com

HDMA 2014 International Pharmaceutical Distribution Conference (IPDC)
Oct 22–23, Beijing, China
Healthcare Distribution Mgmt. Assn., 703 885 0278, www.hdmanet.org

Real-Time Benefit Verification & ePrior Authorization
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Center for Business Intelligence, 800 767 9499, www.cbinet.com

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Pharma EXPO, Co-Located with PACK EXPO International 2014
Nov 2–5, Chicago, IL
PMMI and ISPE, 866 833 3569, www.packexpointernational.com

AAPS Annual Meeting and Exposition
Nov. 2–6, San Diego, CA
American Assn. of Pharmaceutical Scientists, 703 248 4793, www.aaps.org

Real-World Data/Late Phase Summit
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