

Five Megatrends Driving the Seismic Shift in Healthcare: How Should Pharma Respond to Succeed in a Transformed Market?

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Much of the focus on the future of the pharmaceutical industry in the United States has been on the very real challenges of research productivity, the development of compelling clinical evidence demonstrating product effectiveness, post-marketing safety, and threats to pricing and reimbursement. Industry leaders, however, have paid less attention to the trends in the overall healthcare system that will be equally important and may force companies, large and small, either to change their strategies or fail in a remade healthcare world.

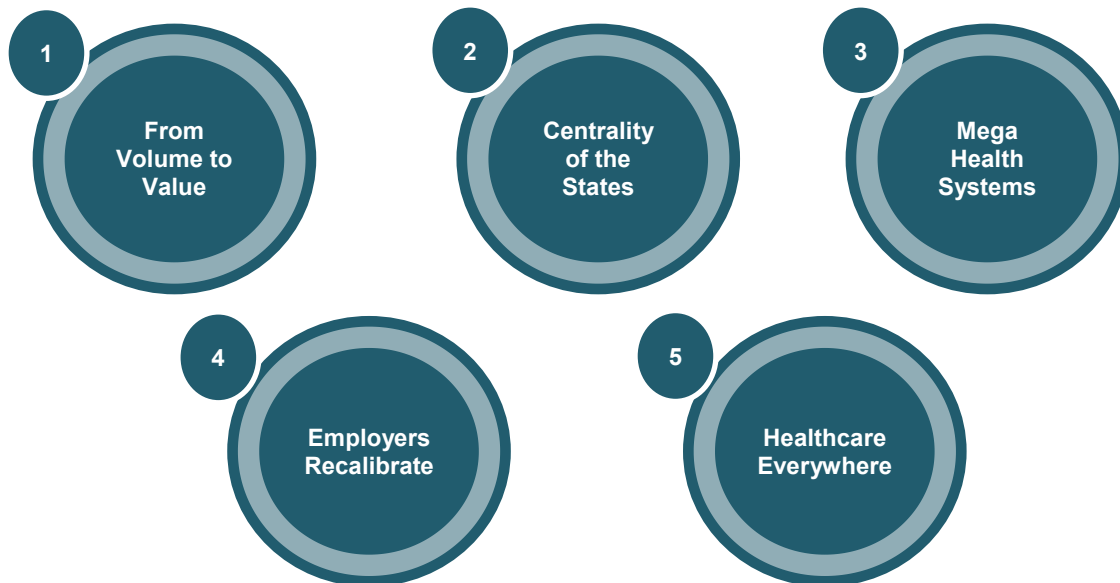
Although the impact of these trends on the pharmaceutical industry in 2014 and beyond is uncertain, it is clear that “business as usual” will not maximize the industry’s success in the changing healthcare environment. While the industry may benefit from tailwinds, such as expanded private and public coverage options, which signal the potential for greater patient access to healthcare and healthcare products, it will need to navigate strong headwinds, as well.

Manatt Health has identified a number of megatrends that will shape the healthcare landscape in the years to come.¹ This paper discusses five that we believe will have the most impact on the pharmaceutical industry. In order to strategically plan for the next several years of market activity, as well as effectively engage, experiment, and participate in the new environments that are emerging, the pharmaceutical industry needs to be aware of – and prepared to respond to – these five megatrends.

We propose these to generate discussion and debate. We welcome your feedback.

Five Megatrends

The five healthcare megatrends of most relevance to the pharmaceutical industry are:



¹ Enders T, Brown K, Smith M, Augenstein J, Detty A, & Osius E. “10 Megatrends Shaping Healthcare’s Next 10 Years.” *Manatt Health*. November 2013.

In this paper, Manatt Health provides an overview of each megatrend and how pharmaceutical manufacturers can actively participate in shaping the future of healthcare.

1. More with Less: From Volume to Value

Current healthcare cost trends and their impact on government, corporate and personal budgets are not sustainable. America's appetite for healthcare products and services is not diminishing. New technologies, including pharmaceuticals, while continuing to offer patients improved health, will likely do so at increased costs. The increasing shift of costs to patients in the form of higher premiums and cost-sharing has limits. Further, rationing in the form of service and product denials or longer wait times is not likely.

Something has to give.

Seeking a way out, payers increasingly will transition to more innovative payment mechanisms to drive down costs. Value is the buzzword as payers will seek to move from volume-based to value-based payment methodologies. This shift already has begun. In 2013,² more than 35% of the nearly 50 million Medicare beneficiaries received care from providers operating under some form of shared savings or risk type of pay-for-performance incentive program, such as the Medicare Shared Savings Program (MSSP),³ the Centers for Medicare and Medicaid Innovation's Bundled Payment for Care Improvement Initiative⁴ and private accountable care organizations.⁵ It is unclear, however, if or when value-based frameworks will completely supplant volume-based constructs, particularly since most health systems remain reliant on volume-based reimbursement to remain financially viable.

As a result, at least for the time being, the pharmaceutical industry will need to be successful in two business paradigms:

- The volume-based model, which is still in play, and
- The emerging value-based environment which consists of new payment methodologies that are either being formally tested in demonstration projects or are spreading through the market as they are adopted by payers, providers, and integrated delivery networks.⁶

Abandoning the volume-based system too quickly could mean reduced sales and profits. At the same time, failing to actively explore new ways of doing business puts industry participants at risk of being left behind by competitors and alienating key stakeholders.

A key element to success in the value-based system is defining value. In the post-Affordable Care Act era, definitions of value revolve around the Triple Aim – improving the patient's care experience, improving the health of populations, and reducing the per capita cost of healthcare. Accordingly, the foundation of effective strategic planning in the pharmaceutical industry is understanding the meaning of value to each market segment, since value means different things to different healthcare stakeholders.

² The Henry Kaiser Family Foundation. Medicare Advantage Fact Sheet. May 2014. Available from: <http://kff.org/medicare/fact-sheet/medicare-advantage-fact-sheet/>. Accessed May 5, 2014. CMS. Fact Sheets: Bundled Payments for Care Improvement Initiative Fact Sheet. January 30, 2014. Available from: <http://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-Sheets/2014-Fact-sheets-items/2014-01-30-2.html>. Accessed May 5, 2014.

³ CMS. "Fact Sheet: Medicare Shared Savings Program Accountable Care Organizations," January 2013, <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/Downloads/2013-ACO-Contacts-Directory.pdf>. Accessed September 27, 2013.

⁴ CMS. Fact Sheets: Bundled Payments for Care Improvement Initiative Fact Sheet. January 30, 2014. Available from: <http://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-Sheets/2014-Fact-sheets-items/2014-01-30-2.html>. Accessed May 5, 2014.

⁵ Muhlestein, D. "Accountable Care Growth in 2014: A Look Ahead." Health Affairs Blog. January 29, 2014.

⁶ Wouters A, Campbell P, "Medical Technology Reimbursement: Finding the Value Proposition," Healthcare Financial Management Association, Payment and Reimbursement Forum. May 2011.

For each product line, manufacturers will need to consider which aspects of the definition of value are most important to the key customer segments for that product line. Strategies to develop value-based partnerships will need to address several questions:

- (1) Who are the new customers?
- (2) Which patient conditions are suitable targets for pharmaceutical interventions?
- (3) What is the scope of services involved?
- (4) Which old payment policy requirements may impede change?
- (5) What is the appropriate balance of provider and patient incentives that leads to desired change?

For example, among accountable care organization (ACO) customers, approximately 51% of ACOs are physician-led, and 33% are jointly led by physicians and hospitals.⁷ Physician leaders can be expected to ask different questions about value than pharmacy directors or PBM executives. In bundled payment initiatives, several customers may emerge, as entities compete for control of the payment bundle.⁸

Products still subject to traditional coverage and payment methodologies based on site of service and route of administration will need to navigate payer requirements for medical benefits (e.g., infused chemotherapy) and/or prescription benefits (e.g., oral chemotherapy). They also will be subjected to existing payment methods and refinements, such as increased packaging of drug components under Medicare's hospital outpatient prospective payment system or fee-for-service payments based on average sales price, new definitions of average manufacturer price, or state laws regarding oral drug payment parity.

Finally, it will be important to identify and demonstrate how products help providers succeed under pay-for-performance systems overlaid on existing fee-for-service systems. For example, companies will need to show providers how their products can help reduce preventable readmissions, or prevent or treat hospital-acquired conditions, improving the opportunity to earn bonuses tied to performance-based metrics. Regardless of which medications are covered in the new payment models, standardization of medication therapies is often a part of care redesign.⁹

As the market shifts to more value-based paradigms, it will be important to identify which products may be good candidates for value-based pricing or risk-share strategies. For manufacturers, value-based pricing arrangements open the door to greater product adoption, even when there is uncertainty among the payer or provider community about the value of the technology, i.e., these arrangements provide a mechanism for suppliers and payers to negotiate the value of technologies. Value-based pricing provides protection from loss while offering positive health benefits to a population. Value-based pricing usually presents opportunities to link clinical evidence and outcomes to coverage and payment. Therefore, it is more than just a financing mechanism designed to amortize payment for a medical technology over the benefit lifespan of a particular technology, i.e., a "mortgage" instead of a lump sum payment.

In building a case to demonstrate value for a specialty drug, a risk-share arrangement may provide a mechanism to address resource constraints and engage one or more utilization management tools to target these drugs appropriately to the patients who need them. Recent experience suggests that products that are potentially good candidates for risk-share arrangements are those that are major determinants of the health outcome and have cost levels that justify the effort (e.g., treatments for chronic conditions).

Experience also suggests that manufacturers may need to pursue different strategies with emerging integrated delivery systems. Integrated delivery systems (IDS) and ACOs are still early in the learning

⁷ Colla, C. et al. "First National Survey of ACOs Finds That Physicians Are Playing Strong Leadership and Ownership Roles." *Health Affairs*. June 2014. 33(6).

⁸ Wilkerson, J. "Hospitals, Post-Acute Providers Push Competing Bundling Proposals." *InsideHealthPolicy* (Inside CMS). March 5, 2014.

⁹ Bailit, M. "Key Payer and Provider Operational Steps to Successfully Implement Bundled Payments." *HCI3 Issue Brief*. May 28, 2014.

curve for building value-based partnerships.¹⁰ For these players, manufacturers may want to support programs that help identify high-risk patients and improve their medication adherence. Ultimately, this leads to the best outcomes for patients, while secondarily resulting in patients refilling their medications more frequently.¹¹ While IDS and ACOs work to develop the infrastructure and systems to manage overall and product-specific financial risk over the next several years, they may, in the meantime, find significant value in medication-related program delivery support offerings.

Key Points for Pharmaceutical Manufacturers:

- Traditional fee-for-service is going away. It is not going away quickly, however. Therefore, manufacturers will need to maintain expertise in volume-based requirements while developing business and legal expertise in value-based paradigms.
- For certain products, especially those involving high expense and uncertain or debatable outcomes, risk-sharing agreements are likely to be key to product adoption.
- Developing appropriate metrics is critical for proactively offering ways to share the risks of participating in the market and decrease the probability of access issues.
- Particularly for organizations that are early in the learning curve when it comes to value-based partnerships, manufacturers may wish to consider providing medication-related program delivery support services.

2. New Sheriff in Town: Centrality of the States

The ACA has transformed the role of states in healthcare. The impact of the increasing state role in healthcare delivery, financing and regulation on pharmaceutical access is still unfolding. As the populations directly regulated by the states grow due to Medicaid expansion and health insurance marketplace regulation, states will increasingly influence the coverage, price and delivery of healthcare products and services. Medicaid is undergoing the most substantial transformation since its inception, moving out of the welfare space and squarely into the health insurance market. The interest in expanding Medicaid is being fueled by several factors, including:

- The potential expansion of Medicaid coverage to an additional 16 million people.¹²
- Concerns about the sustainability of the Medicaid program in the wake of growing federal and state budget deficits, Medicaid's countercyclical spending cycles, and the aging of the population with its associated long-term-care needs.

Despite enhanced federal funding rates for newly eligible beneficiaries, state Medicaid agencies have become increasingly active in driving payment and delivery innovation, with an eye to aggressive management of state budgets. Given expected increases in pharmaceutical spending and the centrality of pharmaceuticals in managing patient health, Medicaid formularies will be a critical component of reform efforts.

Traditionally, Medicaid programs have covered all drugs for which manufacturers enter into rebate agreements, with some exceptions. For example, under federal law, states may exclude drugs that do not have a significant, clinically meaningful therapeutic advantage in terms of safety, effectiveness or clinical outcome over other drugs in the formulary. However, with recent Medicaid expansion, growth in managed care, and an increasing focus on managing the care of dual eligible populations, manufacturers can no longer assume that entering into rebate agreements will ensure access for Medicaid beneficiaries.

¹⁰ National Pharmaceutical Council, American Medical Group Association, Premier. "Achieving Quality in ACOs: Are They Ready to Maximize the Value of Pharmaceuticals in Patient Care?" Webinar and Infographic. January 14, 2014.

¹¹ mobilehealthnews eBook. "How Pharma and Biotech Companies Are Leveraging Digital Health." May 2014.

¹² Currently, 27 states and the District of Columbia have moved forward with Medicaid expansion, 17 are not moving forward, and in 6 states the debate remains open. National snapshots: State Medicaid Expansion Decisions. Kids Well. The Atlantic Philanthropies. <http://www.kidswillcampaign.org/National-Health-Care-Reform-implementation-Snapshots>. Accessed: 5/21/14.

Manufacturers should anticipate that states may seek to exclude more drugs to increase their leverage for gaining supplemental rebates or other price concessions.¹³

Drug coverage will differ depending on what kind of Medicaid benefits a patient has. Adults that are enrolled in expanded Medicaid are entitled to coverage under alternative benefit plans (ABPs). Unlike standard Medicaid benefits, ABPs must cover the greater number of drugs, either one drug in every United States Pharmacopeia (USP) category and class or the number of drugs per category and class in the drug benefit of a designated essential health benefit base benchmark plan. Manufacturers will need to monitor states as they submit their ABPs to determine possible changes to pharmaceutical access.

In addition, patients enrolled in Medicaid managed care programs (MCOs) also will experience differential formulary coverage. As states expand these programs to include higher-risk populations and the ACA extends rebates to drugs dispensed by Medicaid MCOs, more states will be adding pharmacy benefits into managed care packages. Consequently, traditional MCO utilization mechanisms, such as prior authorization and generic dispensing requirements, will be leveraged to manage budgets more aggressively than traditional Medicaid fee-for-service programs.¹⁴

Finally, dually eligible beneficiaries represent a small, high-cost population. Constituting 15% of Medicaid beneficiaries, dual eligible beneficiaries account for almost 35% of Medicaid spending.¹⁵ The ACA includes initiatives to enable and encourage coordinated service delivery to mitigate differences in Medicare and Medicaid rules and misaligned payment incentives.

Medicare Part D and Medicaid prescription formulary requirements are quite different. Implementation of dual eligible demonstration projects is under way and interest in the program is strong. To date, these coordinated care efforts have placed drug coverage under Part D rules with provisions to include coverage of drugs that Medicaid covers but that Medicare does not. Going forward, we can expect efforts to blur the lines between Medicare and Medicaid with the goal of accessing Medicaid's drug price savings. Manufacturers will need to understand the factors that are driving the increased influence of the states and the possible impact of blended benefit structures.

Growing state influence is not limited to public insurance constructs. Through Medicaid expansion and the emergence of marketplaces, states are experiencing a growing alignment between public coverage and private insurance. Premium assistance strategies to expand Medicaid are a prime example of the convergence of the public and private insurance markets. Under premium assistance programs, sometimes called the "private option," Medicaid coverage is provided through enrollment into marketplace qualified health plans (QHPs), and commercial-level reimbursement rates are paid to providers. This signals the increasing influence of states in directing health benefits.

Rollout of the private option in Arkansas has been followed by similar proposals in Iowa, New Hampshire, and Pennsylvania. We anticipate the interest in the private option will continue to grow as states, under pressure to act before the 100% federal matching rate begins its decline at the end of 2016, look for alternative approaches to expand coverage.¹⁶ These trends indicate that not only has Medicaid transformed into a proactive purchaser of healthcare, but also there is a crossover to the marketplaces that makes states quite powerful.

Finally, states are increasingly looking at how to use their market power across purchasing funding streams – including health insurance purchasing for state employees – to influence care delivery and drive down costs. Some states are even considering some form of single payer to incorporate all current insurance, except perhaps employer-provided insurance covered by ERISA.

¹³ SSA Section 1927(d)(4).

¹⁴ Bachrach D, Boozang P, Dutton M, & Guyer J. "Manatt on Medicaid: 10 Trends to Watch in 2014." *Manatt Health*. January 2014.

¹⁵ Bachrach D, Boozang P, Dutton M, & Guyer J. "Manatt on Medicaid: 10 Trends to Watch in 2014." *Manatt Health*. January 2014.

¹⁶ Bachrach D, Boozang P, Dutton M, & Guyer J. "Manatt on Medicaid: 10 Trends to Watch in 2014." *Manatt Health*. January 2014.

Key Points for Pharmaceutical Manufacturers:

- State reimbursement of pharmaceutical costs under Medicaid is changing due to the implementation of ABPs for newly eligible adults, the extension of drug rebates in Medicaid Managed Care, and new efforts to manage high-need Medicaid patients and dually eligible populations.
- Several forces are coming together to drive the convergence of public and private markets, including alternative approaches to Medicaid expansion, efforts to align market influence across Medicaid, purchasing of health insurance for employees, and in some states, state-based marketplaces. This convergence will increase efforts to reduce pharmaceutical expenditures.

3. Big Is Bigger: Mega Health Systems

Mergers and acquisitions among insurance companies, hospitals and health systems, physician practices, pharmaceutical supply chain members and other healthcare entities will result in mega healthcare systems managed by giant organizational entities. The number of independent practitioners and stand-alone community hospitals will decline significantly.

Between 2007-2009 and 2010-2012, hospital mergers increased by 25 percent.¹⁷ Large systems offer the potential for greater efficiency through shared resources, consistency in delivering services to patients, and transparency regarding health outcomes. Conversely, large systems may make it difficult to provide personalized services to patients. The demise of community-based physician practices, hospitals and neighborhood pharmacies may erase important touch points within local communities and diminish patient access. Unchecked, future healthcare systems might consist of a few players with immense market influence, which may have consequences for market access and product pricing.

Large health systems will seek to manage pharmaceutical use more aggressively, as the pharmaceutical supply chain is a visible area of interest to manage costs. Currently, manufacturers interact primarily with wholesale distributors, retail pharmacies and pharmacy benefit managers to distribute products to different care settings. Manufacturers enter into contracts with each type of entity, offering discounts and rebates based on the ability of purchasers to influence the choice of products.¹⁸ Pressure from large health systems will likely impact the structure of these contracts and disrupt already thin distributor margins. For those few manufacturers that sell directly to hospitals or health systems, it will become increasingly difficult to engage in discussions to preserve pricing without a significant demonstration of product value or risk-sharing based on clinical outcomes.

In large IDS, the clinical systems will likely share even more information with payers to proactively manage the provision of healthcare services and costs. As a result, IDS will be interested in manufacturers that offer program delivery support services that address disease states for a patient population. To build trust, these programs should be unbranded educational or medication monitoring offerings directed toward improving appropriate medication use and medication adherence.

A significant upside to creating large healthcare systems includes the ability for system participants to align their electronic health records to manage medications more actively. As a result, they can decrease adverse drug interactions while monitoring for adherence issues. More efficient systems, however, also may mean increased use of utilization management mechanisms, therefore channeling patients to preferred drugs. Further, consolidating pricing data may present challenges to manufacturers in preserving product pricing due to greater transparency of prices across all products, including the competition.

¹⁷ "Seeking Lower Prices Where Providers Are Consolidated: An Examination of Market and Policy Strategies." *The Commonwealth Fund*. <http://www.commonwealthfund.org/publications/in-the-literature/2014/may/seeking-lower-prices>. Accessed: June 3, 2014.

¹⁸ "Follow the Pill: Understanding the U.S. Commercial Pharmaceutical Supply Chain." *Kaiser Family Foundation*. March 2005. <http://kaiserfamilyfoundation.files.wordpress.com/2013/01/follow-the-pill-understanding-the-u-s-commercial-pharmaceutical-supply-chain-report.pdf>. Accessed: May 23, 2014.

Clinical integration has the potential to increase the market power of large healthcare providers. Evidence suggests hospital mergers in concentrated markets generally lead to significant price increases of almost 20%.¹⁹ There are multiple ways, however, for payers to counteract the higher prices of mega health systems.

For example, through increasingly integrated information systems, payers can better estimate patient out-of-pocket costs. Therefore, they can identify opportunities to lower patient liabilities by creating limited networks that do not include high-cost providers.²⁰ In addition, some studies predict that hospitals will specialize in particular service areas and look to differentiate themselves as high-quality, competitive providers in these areas. Payers may direct patients to these specialized centers using reference pricing and point-of-service cost-sharing incentives. If patients perceive that higher cost means better quality, they will be responsible for the cost above the reference price or the out-of-network cost-sharing amounts.²¹

Although mega health systems may garner some market power to improve negotiations with payers, payers have numerous tools to incentivize these mega health systems to contain costs and improve quality. Payers also will need to reconfigure coverage and benefit designs, which were created to support silo-based payment models, to be in synch with new value-based paradigms.²² Mega health systems will look to pharmaceutical manufacturers to establish the various types of value-based partnerships already discussed above.

For many of these mega health systems, the future of the 340B drug discount program is critical. Mega health systems, along with pharmaceutical companies, will be closely reviewing the highly anticipated 340B proposed “mega-rule.” The 340B drug pricing program was created in 1992 and requires pharmaceutical manufacturers to provide outpatient drugs at discounted prices to eligible healthcare providers. Participation in the program has grown significantly in recent years. The number of participating facilities doubled between 2001 and 2011, and one-third of all hospitals currently participate.²³ In addition, the ACA expanded 340B eligibility to five new categories of hospitals: critical access hospitals, sole community hospitals, rural referral centers, freestanding children’s hospitals and freestanding cancer hospitals.

340B pricing provides an approximate 51% discount off of average wholesale prices. In addition, reimbursement levels for drug administration costs in hospital outpatient facilities are on average an incremental 189% of the physician office reimbursed costs for commercially insured patients under the age of 65.²⁴ Accordingly, some healthcare systems, to take advantage of 340B prices and higher drug administration reimbursement in the hospital outpatient setting, have moved drug administration services from physician clinics to hospital outpatient settings.²⁵ The core controversy with the 340B program is whether eligible patients are receiving the discounted pharmaceutical products. It is possible that the definition of an “eligible patient” will be tightened in the forthcoming proposed rule. Depending on the

¹⁹ Gaynor, M. et al. “The impact of hospital consolidation—Update.” Synthesis Project. Robert Wood Johnson Foundation. June 2012.

²⁰ “Seeking Lower Prices Where Providers Are Consolidated: An Examination of Market and Policy Strategies.” *The Commonwealth Fund*. <http://www.commonwealthfund.org/publications/in-the-literature/2014/may/seeking-lower-prices>. Accessed: June 3, 2014.

²¹ “Seeking Lower Prices Where Providers Are Consolidated: An Examination of Market and Policy Strategies.” *The Commonwealth Fund*. <http://www.commonwealthfund.org/publications/in-the-literature/2014/may/seeking-lower-prices>. Accessed: June 3, 2014.

²² Wouters, A and McGee, N. “Synchronization of Coverage, Benefits and Payment to Drive Innovation.” *American Journal of Managed Care*. Forthcoming web exclusive. August 2014.

²³ Wynne B, “The Coming Storm Over the 340B Rx Drug Discount Program.” *Health Affairs Blog*. May 6, 2014. <http://healthaffairs.org/blog/2014/05/06/the-coming-storm-over-the-340b-rx-drug-discount-program/>. Accessed: May 23, 2014.

²⁴ IMS Institute. “Innovation in Cancer Care and Implications for Health Systems: Global Oncology Trend Report.” P. 47. May 2014.

²⁵ IMS Institute. “Innovation in Cancer Care and Implications for Health Systems: Global Oncology Trend Report.” PP. 45-46.

ruling, among other things, mega health systems may need to rethink where drug administration services are rendered.

Expansion of 340B prices can be expected to increase pressure to have high launch prices that take mandated discounts into account. To the extent that other payers can't access these discounts, they will seek to negotiate comparable discounts to save money. To the extent new regulations limit that expansion, which is far from certain, these mega systems will have to explore other tools to realize their current levels of savings.

Key Points for Pharmaceutical Manufacturers:

- Downward pressure on drug pricing will emerge as a result of the growing negotiating power of mega health systems and pressures on these systems from payers to improve quality while saving costs. Mega health systems will want to ensure their inclusion in preferred provider networks, remain competitive under reference pricing, and earn shared savings under ACO arrangements.
- Mega health systems are likely to have an interest in delivery support programs to improve appropriate medication use and medication adherence within patient populations served by the system. Nonbranded medication delivery support programs can be an important component of a value-based partnership that builds trust and recognizes that a rising tide lifts all boats.
- The future of the 340B drug discount program, if requirements are tightened, may create additional pressure to the bottom line of mega health systems. Value-based partnerships with manufacturers will become even more important, as these systems look for more efficiencies and reassess appropriate sites of service for drug infusions.

4. Change in the HR Office: Employers Recalibrate

Consumer choice marketplaces – public and private – are the future of health insurance for most employers and employees. The human resources (HR) office will help employees make intelligent selections based on fixed (or in some cases no) contributions from the employer. Fewer employers will choose health insurance for their employees. The only question is how fast this change will occur, not whether it will happen.

Employers will find it more appealing to step away from their traditional role as health insurance purchasers, as the marketplaces mature and grow, providing individuals with greater access, transparency, and opportunity to understand health insurance. For a few, competitive situations will allow them to abandon a role in healthcare completely, just like many current small employers. For others, in industries where providing health insurance is a competitive necessity, they will seek to control their costs and improve their employees' choices by creating defined contribution plans and outsourcing health insurance procurement to marketplaces.

Private marketplaces are already being created to serve this need. Aon Hewitt reports growth in private exchanges from 150,000 members in 2013, to 600,000 in 2014. Of these enrollees, 75% felt that they chose the plan that offered the best value for them and their families. In addition, 87% liked the ability to choose between multiple carriers.²⁶ For employers, this sea change is not unlike the move employers made when they encouraged employees to manage their own retirement benefits, and pension plans dissolved.²⁷

²⁶ "Aon Hewitt: Year-Two Enrollment Results Show Private Health Exchanges Can Mitigate Costs and Create Greater Individual Accountability." *Aon Hewitt*. March 6, 2014. <http://aon.mediaroom.com/2014-03-06-Aon-Hewitt-Year-Two-Enrollment-Results-Show-Private-Health-Exchanges-Can-Mitigate-Costs-and-Create-Greater-Individual-Accountability>. Accessed: June 3, 2014.

²⁷ Irwin, N, "Envisioning the End of Employer-Provided Health Plans." *The New York Times*. May 1, 2014. http://www.nytimes.com/2014/05/01/upshot/employer-sponsored-health-insurance-may-be-on-the-way-out.html?_r=0. Accessed: May 23, 2014.

Plans that marketplaces create, sponsor or select may have drug benefits that differ greatly from those traditionally offered and paid for by employers. Recent formulary analysis of the exchanges indicates that individuals are twice as likely to experience utilization management controls on prescription drugs compared to people enrolled in employer-sponsored plans.²⁸ In addition, studies suggest that silver plans, the most often selected in the public marketplaces, are nearly four times as likely to have a combined deductible for pharmacy and medical benefits. In addition, enrollee cost-sharing is 38% higher than employer plans.²⁹ These combined deductibles disproportionately impose a much higher member cost-sharing burden for pharmacy benefits relative to other types of benefits.³⁰

State legislatures are responding to low marketplace premiums that are masking high patient out-of-pocket expenses by considering legislation to limit out-of-pocket spending on drugs. California's currently proposed bill would limit cost-sharing for covered prescription drugs at 1/24 of the annual essential health benefit out-of-pocket limit for a 30-day supply.^{31,32} Louisiana's bill would limit the co-pay or coinsurance for specialty drugs to \$150 per month for a 30-day supply while requiring an exceptions process for coverage of non-formulary drugs under certain conditions.^{33,34} Similarly, Delaware and Maryland also have legislation to cap out-of-pocket costs for specialty drugs. These legislative efforts, however, are not likely to have an impact on the largest employers, whose plans are protected from state legislative oversight by the federal ERISA law. It also is unlikely for the time being that government will attempt to regulate private marketplaces.

Key Points for Pharmaceutical Manufacturers:

- Employers may delegate the insurance role to marketplaces (e.g., federally sponsored, state, private). Therefore, formularies in marketplaces will take on new and growing importance.
- Employers providing generous drug benefits with low cost-sharing will decline in number.
- Some states are moving to rein in cost-sharing, but these efforts may have limited impact. Active monitoring of developing state laws is critical to understanding how individual states are working to serve the needs of the marketplace population.
- Marketplaces are a new "customer" for drug makers.

5. The Doctor's Not in the Office Now: Healthcare Everywhere

Driven by the rise of new technologies, experts anticipate that, over the next decade, as much as 50% of healthcare will move from hospitals and clinics to homes and communities. From smartphones to social media to sensors, new tools are empowering consumers with more information and control over their healthcare decisions – and physicians and other healthcare providers with more options for where and how they interact with patients.

Ubiquitous dissemination of powerful and affordable technology will put the power of connectivity, health information and healthcare applications into everyone's hands, enabling patient and consumer engagement (also known as m-health). Handheld technologies, such as smartphones, and the Internet of

²⁸ "Avalere Analysis: Consumers Face More Hurdles to Accessing Drugs in Exchange Plans Compared to Employer Coverage." *Avalere*. March 24, 2014. <http://avalerehealth.net/expertise/managed-care/insights/more-controls-on-drug-access-in-exchanges>. Accessed: May 23, 2014.

²⁹ Pradhan RD, "States Seek to Cap Drug Cost-Sharing as PhRMA Pushes Back on Exchange Plan Design." *Inside Health Policy*. Daily News: May 20, 2014.

³⁰ Gaal, M. et al. "Impact of Health Insurance Marketplace on Participant Cost-Sharing for Pharmacy Benefits." Milliman, Inc. May 13, 2014. p. 4.

³¹ California AB 1917, introduced February 19, 2014. http://www.leginfo.ca.gov/pub/13-14/bill/asm/ab_1901-1950/ab_1917_bill_20140219_introduced.pdf. Accessed: May 23, 2014.

³² Pradhan RD, "States Seek to Cap Drug Cost-Sharing as PhRMA Pushes Back on Exchange Plan Design." *Inside Health Policy*. Daily News: May 20, 2014.

³³ Louisiana R.S. 22:1060.5, specialty drug tiers; prohibitions; limits on co-payments.

<http://www.legis.la.gov/legis/ViewDocument.aspx?d=898644&n=SB165%20Reengrossed>. Accessed: May 23, 2014.

³⁴ Pradhan RD, "States Seek to Cap Drug Cost-Sharing as PhRMA Pushes Back on Exchange Plan Design." *Inside Health Policy*. Daily News: May 20, 2014.

Things (IoT), a network of everyday objects embedded with sensors and the ability to communicate, hold the potential to transform any place into a doctor's office.

Devices, from smartphones to refrigerators to toilets to running shoes, will be used for monitoring glucose, blood pressure, heart rate and just about every other vital sign. Implanted devices will serve as remote sensing computing devices. Remote monitoring of conditions and compliance with treatment plans will become routine, with alerts to a provider just a subscription away, similar to home alarm services.

This technology also will capture and allow the de-identified aggregation of enormous amounts of data on healthcare treatments and their real-world effectiveness. Everyone, everywhere has the potential to form a patient registry with sophisticated data mining and analysis, yielding real-time, regularly updateable data on clinical effectiveness.

This technological transformation also holds the promise of a transformation in the distribution of care delivery. Care sites will move out of acute settings and into ambulatory settings and retail clinics, where treatment will be delivered by lower-cost care providers, including pharmacists, nurse practitioners and physician assistants. There also will be a related development of systems of care, which will aim to optimize the allocation of care delivery across the care continuum.

For pharmaceutical companies, these changes have huge implications. Clinical and real-world trial costs could, potentially, drop dramatically as the opportunities to study patient medicine use expand to new locations and far cheaper data collection modes. The already underway shift of information dominance from manufacturers to customers will continue as payers know, perhaps up to the minute, information on utilization and effectiveness.

In this new, healthcare everywhere world, there will be more and more people whom companies will need to inform about the benefits and risks of their medicines. Of course, the consumer will become an even more important player in selecting his or her drugs. Reaching all the new places that healthcare delivery will occur is, potentially, a daunting and expensive undertaking. It is also one hampered by the limits imposed by the U.S. Food and Drug Administration on using the Internet and social media.

Key Points for Pharmaceutical Manufacturers:

- The doctor's office and hospital will lose their primacy as the locus of healthcare delivery.
- The ability to understand the changing places and modes of delivery will be a core competency of all healthcare organizations.
- Partnering with m-health and other connected healthcare technology providers will provide pharmaceutical manufacturers with a leg up in understanding these changes and getting ahead of them.
- Expanding pharmaceutical manufacturers' ability to use social media will be critical to ensuring they can continue to reach patients and providers.

Conclusion

In the face of the five megatrends discussed here, the pharmaceutical industry will not likely succeed under "business as usual" strategies. For the next five to ten years, manufacturers will need to maintain and build expertise in both volume-based and value-based paradigms. As healthcare systems assume more risk under value-based payment reforms, it is inevitable that manufacturers will need to find ways of participating in risk-sharing and to build partnerships with providers and payers around product solutions rather than just products.

Each of the trends discussed here embeds pricing pressures of one sort or another, such as the possibility of value-based pricing, reference pricing, changes to the 340B program, mega system negotiating power, and heightened awareness of costs from data aggregation efforts looking at the real-world effectiveness of healthcare services. Although physicians certainly will continue to play a lead role in decision making involving medications, the industry also will face many new customers and

stakeholders, including ACOs/IDS, states, managed care entities, private marketplace benefit managers, and patients supported by healthcare everywhere.

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Five Megatrends Driving the Seismic Shift in Healthcare. Authors: Nancy McGee, Helen Pfister, Ian Spatz, and Annemarie Wouters. July 2014.

This paper draws on two papers previously produced by Manatt Health:

10 Megatrends Shaping Healthcare's Next 10 Years. Authors: Thomas Enders, Kathleen Brown, Molly Smith, Jared Augenstein, Andrew Detty, and Elizabeth Osius. November 2013.

Manatt on Medicaid: 10 Trends to Watch in 2014. Authors: Deborah Bachrach, Patti Boozang, Melinda Dutton, and Jocelyn Guyer. January 2014.

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