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LIFE SCIENCES INSIGHTS

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Life Sciences Part D Whitepaper: Get Ready for Part D Changes That Are Coming

For Medicare Part D, the initial dust has settled and a new activist administration is looking at all possible ways to reduce future program cost. The life sciences industry tends to be very reactive — often with a long delay — to changes in the legislative and political environment. This will have to change, because like it or not, the generous days of high pharmaceutical reimbursements are nearing their end, and life sciences companies will need to take real and dramatic steps to succeed in this new business environment.

Coming Legislative Changes to Part D

Since taking office in January 2009, President Obama has made it clear that his administration intends to bring change to Part D — as a way to lower costs, improve service, and bring more effective medicines to senior citizens. While many seniors have had a positive experience with Part D — compared to the absence of Rx coverage prior to its inception — there are still problems that participants find vexing (Figure 1), like plan complication and a sense that private plans drug companies are paid too much under the plan:

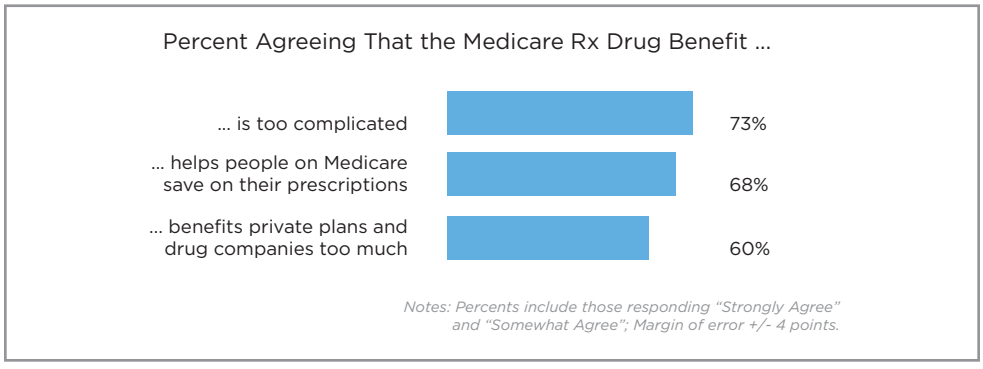

Figure 1: Seniors' View of the Medicare Rx Drug Benefit

(Source: Kaiser Family Foundation/Harvard School of Public Health
The Public's Health Care Agenda for the New Congress and Presidential Campaign
— conducted November 9 – 19, 2006)

Also, the Medicare Part D: Drug Pricing and Manufacturer Windfalls report (released in September, 2008 by the Democratic majority staff of the House Committee on Oversight and Government Reform) received extensive press — and hammered two points into the national consciousness: first, that Part D to date added $3.7 billion to pharma profits in just two years, and second, that Part D pays an average of 30% more for drugs than Medicaid does, largely because Part D — at present — precludes price negotiation by the Federal government.

The new administration seems to agree with the findings expressed in the "Windfalls" report. On March 30, 2009, the Centers for Medicare & Medicaid Services (CMS) issued the 2010 Combined Part C and D "call letter," which provides extensive background for private health insurers and other parties interested in offering Medicare Advantage Plans or Medicare Prescription Drug Plans. This is the first such "Call Letter" to be issued by the Obama administration, and provides a window into some of the President's policy goals around Part D.

Given President Obama's interest in healthcare reform and a Democratic majority in Congress, it is clear that a number of legislative changes are coming:

Direct Price Negotiation — The President's new budget specifically calls for price negotiation and generics (wherever possible) on all Part D formularies. Data from another bulk purchaser, the US Department of Veterans Affairs (VA), shows the VA price for the top 20 drugs prescribed to senior citizens is 25 – 91% lower than the lowest Medicaid prices. Based on these figures, the Boston Consulting Group estimates industry revenues could nosedive by $14.7 million to $30 million a year if the government rescinds the law preventing it from negotiating prices.

The "Doughnut Hole" Will Change — The "doughnut hole" (coverage cap where enrollee pays 100% of drug costs) has worked very well — perhaps too well, and is likely to be narrowed significantly at the very least. Originally designed as a way to keep Part D costs from growing at unmanageable rates, the doughnut hole has, in the minds of many policy makers now in power, served as a mechanism to preserve the profitability of drug manufacturers. While the most radical proposals include calls to completely remove the doughnut hole provision, it is at least likely that the doughnut hole will be significantly narrowed (Figure 2) from the 2009 low end (up to $2,700 in drug costs) and the high end (above $6,154 in drug costs).

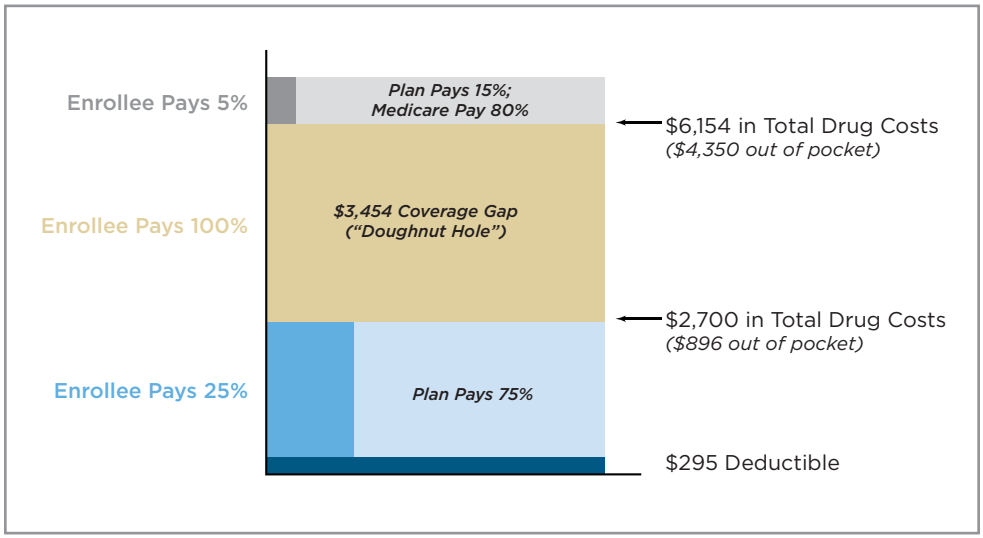

Figure 2: 2009 Standard Medicare Prescription Drug Benefit

(Source: Kaiser Family Foundation)

Formulary Changes — There has been a general increase in use of generics to fill Part D prescriptions (see below), and there will probably be a drive to ensure that generic drugs are always offered on formularies related to Part D Contracts (wherever generic options exist).

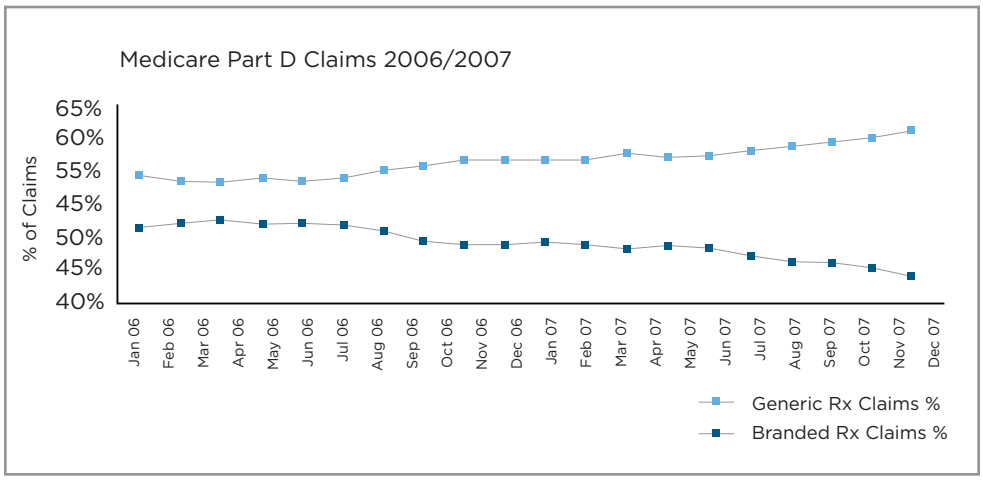

Figure 3: Part D Generic Expansion

(Source: Wolters Kluwer Health. Medicare Part D — Market Dynamics. Page 9)

Import Ban Removal — The President has stated that he wants to eliminate the ban on importing drugs from countries that have good safety records, such as Europe and Canada, where prices are considerably less than in the US. The key concept will be safety, and before any importation could occur — increased funding for inspection of foreign manufacturing facilities will have to make its way to the FDA.

Generics — President Obama's budget earmarks review fee funds for expanded review of generic medicines (contingent on congressional approval) with the goal of getting generic drugs to market faster. In the past, generic application review has tended to take a back seat as branded drug review is funded by fees.

Enforcement Expansion — Part D-related enforcement and compliance activity is expanding on a number of fronts. In their FY2009 workplan, the Office of Inspector General (OIG) devoted eight pages to describing specific Part D enforcement activities. In particular, "We will review Medicare Part D claims to identify aberrant claims, which are those that deviate from the usual patterns of claims, and determine how these claims relate to pharmacies, physicians, and/or beneficiaries."[1] This implies that there will be expanded use of computer analysis of claims, to identify potential enforcement targets. In another example, in December of 2008, CMS gave fair warning to Part C and D sponsors that they were expanding their "Secret Shopper" surveillance activity to monitor call handling quality and other expanded metrics.[2] The 2010 Call Letter specifies that Part D plans will be required to audit performance data submitted to CMS and will face expanded scrutiny of benefit plan designs that are potentially discriminatory. Further, the 2010 Call Letter spells out requirements that Part D plans must accept on-line enrollments, meet or exceed specific performance standards for complaint resolution, provide assurance that offered Part D drugs have FDA approval, and comply with new reporting and marketing requirements.

Getting Started

Life Sciences companies truly need to take a proactive approach to prepare for a completely new era of pricing and reimbursement. Their business model may change dramatically over the next few years, and companies need to carefully quantify implications of changes, and dynamically alter their way of doing business to survive and prosper. Below are five suggestions:

Get Lean — During the dramatic growth of the pharma industry since the 1950s, many Life Science companies have become bloated, bureaucratic behemoths. Companies operating with smaller footprints and leaner margins tend to be nimble in response to changes in market demands and other external factors. In recent years, sales and marketing become both a high cost and high risk area for pharmaceutical manufacturers. A credible alternate strategy might be to use "pull" marketing strategies using web-based services to draw high quality physician and health professional leads, with a dedicated set of knowledgeable product specialists in a call center to provide scientific and medical value to care providers.

Create Truly Compelling Business Cases for Each Product — Make true outcomes-based business cases for every product in development. Some guiding principles:

- Projects should have a clear, compelling, and exhaustive business case made at the very beginning of the development process. In this new era of tight cost control and potential pricing rules, accurate and compelling business cases are a must and should dictate where development resources are spent.
- Development of targeted diagnostics in tandem with products. This is a development strategy that provides an additional income stream and allows the company to gain additional ROI from their R&D spend on a specific product. Development of these "theranostics," can determine who will favorably respond to a given treatment (e.g., HER-2 diagnostics, which identify positive responders to Herceptin therapy).

"Theranostics"/Product-Tandem Diagnostic products can create a compelling business case for their related therapeutic product — by avoiding cost for patients the drug won't help, and specifically quantifying the outcome benefits for patients who will respond to the therapy.

Innovate — To justify premium prices, companies simply have to deliver products with superlative outcomes and minimal side effects. A few guiding principles for innovation:

- "Me-too" doesn't cut it. Line extensions, Multiple ED products and other "pseudo" innovations will be quickly excluded from formularies. Development of "me-too" products and line extensions has had a cost, like the decline of innovative development of targeted new chemical entities (NCEs). The Pharmaceutical industry will always be looking for potential blockbusters, but as knowledge about what works for each subpopulation and disease state builds, specific markets will be smaller with a narrower focus. Delivering drugs that target certain genetic profiles (i.e., a subset of asthma patients) will be similar to orphan drugs of the past; smaller markets requiring different marketing, and distribution with new attention to the many variables in a "micro market" supply chain. Patient-centric R&D will require a far leaner organization and lower overhead as compared to the classic R&D model. As stated above, a compelling business case needs to be developed from the very beginning of a product's development.
- Explore opportunities for research in stem cells, genomics, biomarker-driven discovery, and other leading edge areas. The new administration will likely offer incentives to industry around new science initiatives. Also the President has signaled that Health Information Technology (HIT) will be an area of government investment in the future. Companies that can find ways to align their development programs with HIT initiatives will win.

The line between discovery and outcomes improvement must be as short as possible. This will require a new R&D model that is flexible, that integrates genomics and other advanced bioinformatics data, is receptive to rapid feedback from patients and providers, and is able to bring innovative products to patients faster.

Get Your Compliance House in Order — Federal policy makers continue to be wary of the relationships between the pharmaceutical, biotechnology, medical device industries, and physicians. Also, the enforcement focus of the Office of Inspector General (OIG) has been expanded and is clearly delineated in their annual work plans. As the OIG is self-funded, they have every incentive to aggressively pursue misconduct in the Life Sciences industry. To be prepared for increased regulatory and compliance scrutiny:

- Get ready for audits by OIG, FDA, CMS and other compliance organizations. First, understand the new rules, and be sure that your organization has a team in place to understand and prepare action steps to comply with evolving rules. As an alternative, there are a number of commercial organizations that provide compliance awareness services and can identify new laws or other rules that may impact your organization directly.
- Stage mock compliance audits in various areas of business related to enforcement. There are also companies that do this type of work as a service to industry, and their fee usually involves debriefs that point to compliance weaknesses and areas for improvement.
- Be able to produce accurate, compliant, and complete data to support submissions to CMS, FDA, and other agencies. This data will have to stand up to very rigorous scrutiny by regulatory authorities.

Get Connected — The President's plan also mentions getting generic drugs to market faster and conducting more comparative studies to see if patients are getting value from the money spent on their drugs.

- Plug in to the vast array of networked R&D databases — In this new age of shared information, scientists are able to connect, collaborate and share knowledge and data with academic institutions, healthcare providers, regulatory agencies and even payors. Unprecedented access to large stores of data relevant to every phase of the R&D process will give researchers access to "networks of knowledge" and offer new tools to enhance the value of their organization's development portfolio.
- Get comfortable with full transparency of clinical trial results. Fully-searchable trial registries have been introduced by some companies, and policy initiatives will make full trial transparency an industry norm — if not a requirement — in the next few years.
- Find Partners — Private/Public/Consortium — Become involved in industry consortiums that are working to develop standard solutions to industry challenges. Also, get connected with the latest thought from industry workgroups dealing with the ethical and privacy issues around broad-based collaboration. Establish relationships with potential partners: providers, payors, government health agencies, healthcare IT companies, academia and public sector research, to identify candidate projects that may be mutually beneficial.

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1 Centers for Medicare and Medicaid Services. FY2009 OIG Workplan. Page 39, Paragraph 2.

2 Centers for Medicare and Medicaid Services. 2009 Call Center Monitoring Memo. December 19, 2008. Page 1.

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