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2011 Industry Predictions

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As we emerge into the New Year, it is as good a time as any to take stock of where we are as an industry and what we might expect in the months to come. There can be no doubt that 2010 was a watershed year. The mergers of Pfizer and Wyeth and GSK and Schering-Plough have brought unprecedented contraction in the U.S. marketplace and dramatically changed the competitive landscape. Around the world the market is poised to see if China can make the leap to parity with its western competitors by complying with its new, more rigorous cGMP regulatory guidance. In the U.S. we have seen consumer confidence in the FDA and the industry shaken. High profile quality issues with consumer, brand and generic drugs have created doubt as to whether the FDA can truly protect the public and whether industry can address the fundamental quality issues that lead to such a fall from grace.

Industries that experience such tremendous turmoil must evolve fast or learn to live with a new level of heightened scrutiny. I believe 2011 will be a pivotal year for several reasons. First, the organizations that made headlines have taken their medicine. They have made it clear that the practices of the past will not meet the market's needs for the future and are spending the resources and capital to try and directly address the issues.

So what can we expect to see in 2011? I believe we will see several trends continue or emerge:

1. **Payer cost containment pressure** will continue to challenge the industry. As long as the global economy is stalled, the cost of healthcare and medicine will remain in the news. Meeting the key enrollment and transition dates for the Federal Affordable Health Care Act that must take place in 2011 will serve to feed the chaos of the transformation. It is uncertain what the federal healthcare program will mean, but it is not a stretch to predict it will be windfall for the generic market sector as it tightens the screws on innovators and the brand market. The curious portion of this transformation will be its impact on innovation. Many industry analysts expect the drug delivery market sector to grow significantly in 2011. What will payer cost pressure and the complexity of a new federal health care program mean to insurance reimbursement? This uncertainty will continue to fuel the cost cutting focus the industry is immersed in today. However, on the positive side, it will also spur a renewed focus on business performance. Cost cutting and reductions in force are only effective if they can be done without hurting the overall business performance. This, in many cases, requires some level of organizational reengineering that will open up the opportunity for analyzing current and forecasted business processes. Holistically, this will strengthen companies as they brace for the ambiguity of the next five years. Regardless, it is likely that we will see the same sort of M&A strategy deployed across the country as firms license or buy product portfolios that will strengthen their existing market position.

2. QbD will get traction

The pressure on the FDA and industry to approve and manufacture safe and efficacious products will be at an all time high. Many would argue that this has been in the works since the agency issued their landmark guidance in 2004 but the adoption has been slow. The high profile quality issues of the last two years will begin to exert pressure on both FDA and industry to move away from their "business as usual" attitude. I believe 2011 will see a greater emphasis in this direction because of the FDA's new TRACK program. Any government agency that agrees to be monitored for performance is ripe for action. Accountability has never been a strong point within federal programs. The TRACK program will either catalyze the agency to enforce change or will become window dressing designed to create the illusion of change. Regardless, the risk exposure from not embracing a structured design approach during the development lifecycle will gradually escalate as a business performance issue. Whether the industry jumps in with both feet now or phases the transformation, the direction is clear where we need to go to be competitive.

3. **Operational Excellence in R&D**

Operational excellence has achieved traction on the shop floor over the last decade. Six Sigma â was able to orient organizations to the concepts of measurement and accountability as they pertain to process variation. Lean manufacturing provided the impetus for quick and near term efficiency gain. R&D represents nearly 19 percent of the overall cost of drug development within the pharmaceutical industry, with an annual CAGR of about 11 percent. *Do we need to do better?* It is likely that R&D will become the new focus for catalyzing business performance. Most multinational companies have been focusing on consolidating development activities. Site closures were commonplace in 2010 and the trend is likely to continue. However, this alone will not improve the cost basis for R&D. Productivity must become the mantra for the development organization. Because of this, lean will become more of a focus for R&D with business performance metrics creeping into the development lexicon. The challenge will be to establish metrics that are meaningful in the development world. Many large Pharma companies that have begun this journey have made the mistake of trying to apply conventional lean manufacturing principles to the development environment. Philosophies such as the Toyota Product Development program, are more appropriate. These focus on organizational empowerment, and most importantly, knowledge management as key pillars in the House of Lean as it applies to product development. Embracing these paradigm shifts will be essential if the development process is to be effectively managed and measured in terms of business performance.

4. **Drug delivery will supplant NME innovation**

The search for blockbuster drugs will take a turn in 2011. Over the last four or five years, we have seen large biotech expand to small molecule product development as a hedge against the protracted development timelines and risks inherent to biotherapies. And, during the same period, we have seen large pharma pursue M&A strategies to expand into the biotech markets with the intent of becoming biotherapeutic powerhouses. These initiatives will continue, but the next great thrust will be in the field of drug delivery. Drug delivery has the potential to circumvent many of the risks and hurdles of the aforementioned strategies. Drug delivery includes platform solutions, adjunct therapies

and new delivery principles such as nanotechnology that can offer both improved safety profiles and performance for existing therapies, opening the door for 505 (b)(2) strategies to the promise of maximum bioavailability for new molecular entities (NME). Maximum bioavailability translates into more toxicology head room and greater clinical dosing flexibility, both of which reduce the risk of failure in NME development.

More importantly, many large pharma companies are being challenged with the expiry of some blockbuster products. Conventional patent extension strategies revolve around developing controlled release or modified release delivery versions of the current therapy. These alone have been marginally successful in protecting revenues. Solubility enhancement or drug delivery alternatives will allow large pharma to leverage currently available toxicology, and rapidly bring patentable new therapies to the marketplace, which represents greater potential for more effective line extension strategy.

5. **FDA enforcement will escalate**

I believe the FDA is in a difficult position. Consumer confidence is at an all time low, and the disconnect between major pharma and the agency has not been this large for some time. The FDA must move to reinforce the new principles it has put forth in its guidances starting with the key components of the Critical Path Initiative of 2004. The timing could not be worse for many manufacturers, particularly in the generics industry, which has traditionally lagged behind the brand industry in terms of quality system development and product development rigor. I believe there will be more regulatory actions as the bar is raised in terms of CAPA investigation and resolution, and continuous improvement and QMS management of Deviation and Exception reporting. The ability to demonstrate process stability and correlate that data with product performance and safety will become critical to surviving a surveillance audit.

Conclusion

While there is no crystal ball that can be used to prepare for the coming year, there are unmistakable trends within industry and the marketplace that we can prepare for. Ignoring them will either put us further behind as an industry in terms of responding to competitive pressures, or encumber organizational ability to realize its strategic initiatives. It will be interesting to see how quickly the two mega-mergers Pfizer-Wyeth and Schering-Plough-GSK play out in moving these two mega corporations toward greater effectiveness and competitiveness. One thing is for sure, the approaches to product development and manufacturing we have used for the last decade will begin to wane under the pressures of the new marketplace and we will begin to see a shift toward embracing the principles necessary to be competitive in the global marketplace in the years to come.