sodexo
QUALITY OF LIFE SERVICES

BEST PRACTICES FOR SUCCESSFUL MERGER INTEGRATION IN THE PHARMACEUTICAL AND BIOMEDICAL SPACE

DAVID CLARKE, ROSE LI AND ASSOCIATES, INC.

ABSTRACT

The U.S. pharmaceutical and biomedical sectors are experiencing a period of tumultuous mergers and acquisitions (M&A) as companies face pressures from financial investors, to increase growth and a changing healthcare system is shaping new business models. Pharmaceutical companies have experienced a decline in their research and development (R&D) productivity and are merging with biotech companies, that are using the scientific powers unleashed by the Human Genome Project to transform the drug discovery process. Biomedical companies are faced with new regulatory requirements, market dynamics and the proliferation of accountable care organizations. Like other players in the healthcare industry, they are seeking economies of scale and other benefits from M&A. But many mergers often fail, largely because of sharp cultural differences in the merged companies. An M&A must be well planned if its full value is to be achieved. Extensive research and experience have shown that effective integration requires top leadership to drive the transformation. A common vision and good plan are essential. Employees must be involved. Restructuring must be done early and fast. Communication with all stakeholders, from board members to all employees, is a must. And cultural differences must be understood and managed. The era of personalized medicine is fast upon us. With the extensive M&A activity breaking apart and recreating pharmaceutical and biomedical companies, we are seeing the future pharmaceutical company emerge.

INTRODUCTION

The United States' pharmaceutical and medical device markets are the largest and most advanced in the world. In 2014, the U.S. pharmaceutical market was estimated to be $395.2 billion, supporting more than 3.4 million jobs, and it is projected to hit $548.4 billion by 2020.[1] The U.S. medical devices market size is approximately $110 billion, with more than 6,500 companies, most of them small and medium-sized enterprises employing fewer than 50 people.[2] Although the two markets have been mostly separate, with their own products, cultures, and regulatory regimes, increasingly they are merging.

Today's pharmaceutical industry is best known for its blockbuster products that produce $1 billion in annual sales, such as cholesterol-lowering Lipitor and antidepressant Zoloft. Until recently, companies have relied on expensive, random pre-clinical screening of compounds to discover these drugs and used costly hit-or-miss clinical trials to bring products to a mass market.

But an explosion of new scientific knowledge and technologies spawned by the Human Genome Project, which was completed in 2003, has transformed the way drug discovery is made and redefined the pharmaceutical industry's business structure. Using the new molecular and genetic sciences to guide pre-clinical screening, companies are developing products tailored to specific patient segments. In addition, many new players are entering the field with a specialized focus on clinical trials, genomic databases, and other narrowly focused parts of the pharmaceutical business.[3] Likewise, the medical devices sector is undergoing dramatic changes, some forced by regulators, others by market dynamics, and still others by the advent of accountable care organizations, all factors that impact patient outcomes and costs.

Even as pharmaceutical companies face intense pressure from financial investors to show strong earnings growth, over the past decade the industry's research and development (R&D) productivity has suffered a "drug innovation crisis." R&D costs have more than doubled. In the past decade, costs rose from $78 billion during 2002 through 2004 to $128 billion during 2009 through 2011. But the industry's output of new chemical entities approved by the Food and Drug Administration declined over the same period from approximately 30

An explosion of new scientific knowledge and technologies has transformed the way drug discovery is made and redefined the pharmaceutical industry's business structure.

to approximately 25 a year.[4] As companies adopted aggressive pricing to counter flat sales in the United States from 2007 to 2012, cost-containment has become a major public policy issue as the Affordable Care Act has added millions of people to public and private insurance rolls.[5]

And there is the "patent cliff." Healthcare information provider IMS Health predicts that by 2016 branded drugs will lose $106 billion in sales from previous years as companies face an unprecedented level of patent expirations, with 2012 and 2013 being especially difficult years.[6]

M&A FRENZY

In this difficult environment, pharmaceutical companies have turned to what has been called a mergers and acquisitions (M&A) frenzy as a source of new products and growth. According to consulting firm KPMG, completed pharmaceutical deals in the first half of 2015 amounted to $221 billion, triple the number of deals in the first half of 2014.[7] Similarly, medical device companies are seeing record levels of M&A activity, including a quickening pace of mergers with pharmaceutical companies that create added difficulties because of the differences in products, operational models, and regulatory requirements.[8]

The larger hybrid company that results from a merger can achieve economies of scale, acquire new technology, reach new markets, and realize other gains. But the process also brings a variety of challenges as two sets of employees, each from different company cultures, become one. Emotions run high as people inevitably lose their jobs and survivors jockey for position. As management consultant Julie Gable observed, "At best, mergers and acquisitions are the melding of two cultures to produce a single, stronger entity. At worst, they

are politically fueled wars about which processes and systems will dominate once the dust settles."[9]

Into this volatile mix has emerged the game-changing biotechnology sector, which is leading to a new industry paradigm in which medicine will focus on tailored health care for individuals with known genetic predispositions. The future survival of pharmaceutical companies depends on their ability to acquire and understand this sector's knowledge as they compete with generic drug manufacturers and other players.[10] But pharmaceutical and biotechnology mergers, while essential to cut R&D and other costs and create more productive R&D pipelines, pose unique difficulties. Why? For starters, the scientific basis of traditional companies is the clinical application of organic chemistry, but for biotechnology companies it is immunology and molecular biology. In addition, pharmaceutical companies are formally structured, with extensive hierarchy and slow decision-making processes. In contrast, biotech companies are organized flexibly and informally, with interdisciplinary teams openly communicating in a creative, risk-taking entrepreneurial culture. Biotech companies have the critical know-how. But pharmaceutical companies have the cash that's needed to advance the clinical development of biotechnology companies' promising drug discoveries, as well as the regulatory and worldwide marketing savvy to commercialize discoveries.[11]

People and cultural differences are the overwhelming reason that 83% of all M&As "failed to produce any benefit for the shareholders and over half actually destroyed value."

People and cultural differences are the overwhelming reason that 83% of all M&As "failed to produce any benefit for the shareholders and over half actually destroyed value," according to a KPMG study based on interviews with 100 senior executives involved in 700 deals over a two-year period.[12] Corporate culture—the norms and preferences that influence individual and group behavior in an organization—includes a company's management approach, the type and level of participation in decision-making, the degree of formality, policies toward budgetary control, and a host of other factors.[13] Clashes can occur in any areas of culture, from dress codes to quality expectations.

Fortunately, companies involved in M&A activity can draw on a wealth of thoughtful studies and insights from experience both inside and outside the pharmaceutical industry to help them navigate the merger shoals. Here are six insights that appear frequently on lists of keys to effective integration:

- ***Top leadership must drive the transformation.*** That was the first recommendation of a forum involving the likes of Lockheed Martin Corporation, Hewlett-Packard Company, and J.P. Morgan Chase that the Government Accountability Office (GAO) convened in 2002 as the government sought to merge 22 agencies to create the new Department of Homeland Security.[14] Strong leadership is indispensable for a successful integration.
- ***A common vision and good plan are essential.*** When companies merge, mismatches can occur as managers bring differing views on strategy and therefore different operational plans and priorities. Following his company's 2009 acquisition of U.S. drug manufacturer Schering-Plough Corp, Merck & Company's then-CEO Richard Clark had teams from both sides create a "merger intent" document. It defined participants' one- and two-year expectations for the merger in four categories: financial, strategic, operational, and organizational. And it was successfully used as a basis for planning and for tracking the merger's benefits.[15]

- ***Involving employees is a critical, often neglected, need.*** While legal, financial, and operational elements of an M&A receive attention, effectively managing the human side of change is indispensable. But too often it is seen as too soft and therefore unmanageable. Staff must be involved so they are prepared for change, making sure that new relationships are clearly defined and understood.[16] Involving employees can strengthen the integration process because they can share their experiences and take ownership of change, but experts caution that employees must give first priority to day-to-day operations and not become engulfed by transformation initiatives.
- ***Restructuring should be done early and fast.*** Within days, if possible, critical decisions should be made, announced, and implemented, such as management structure, reporting relationships, layoffs, and other key integration factors that will affect employee careers. Otherwise, lingering uncertainty and anxiety can drain value from a merger.[17]
- ***Communicating with all stakeholders is a must.*** The top management team, the board, employees at all levels, as well as external stakeholders such as the merged companies' shareholders and customers are all audiences for various types of communication. Speeches by the CEO and one-on-one meetings with affected staff should be consistent to avoid confusion and fear as people discuss what they think might be going on.[18]
- ***Pay attention to cultural differences.*** Cultural clashes are a primary reason for M&A failure. Successful culture management can also add to a company's bottom line. A Harvard Business School study found that companies with "actively managed" corporate cultures realized a 682 percent increase in revenue compared with only a 166 percent increase in companies lacking such culture management. For that reason, consultants underscore the need to identify and resolve significant cultural differences.[19] According to a McKinsey survey of M&A professionals, 92 percent said that greater cultural understanding prior to a merger would have substantially benefitted the deal.[20]

ORGANIZATIONAL AND FACILITIES INTEGRATION AFTER M&A

The M&A activity roiling the pharmaceutical, biotechnology, and medical device sectors creates opportunities, but realizing the potential of a combined company depends on a well-managed process. At the organizational level, a merger can lead to completely new structures. For example, after Merck KGaA merged with Lexigen Pharmaceuticals Corp., a maker of genetically engineered products, Lexigen's role within the new company was fundamentally changed. Merck created a separate company to focus on growing business in the United States, and Lexigen became a center of excellence to provide biological expertise. Lexigen was given a high degree of autonomy as a separate research center, but no responsibility for reporting, human resources, and controlling systems.[21]

A critical organizational integration issue is records and information management (RIM). Because the acquiring firm's information governance program may not be superior, it is critical to objectively assess the strengths and weaknesses of both companies' RIM systems and to choose the best from each.[22] Cool and objective attention are required to select the best accounting, human resources, and financial records systems. When pharmaceutical and medical device companies merge, sometimes important issues are overlooked, such as opportunities to combine the contract management and government pricing systems.[23]

The impact of M&A on pharmaceutical R&D has been a major topic of discussion in the industry. John LaMattina, the former President of Pfizer Global Research and Development, lamented the fact that in today's major mergers "not only are R&D cuts made, but entire research sites are eliminated."[24] As with RIM integration, careful attention must be paid to deciding which among different R&D IT platforms, data handling, or adverse event monitoring used by the two companies should be adopted or how best to create a hybrid.

With respect to facilities integration, Loralyn Mears, PhD, discusses the important role of facilities management providers in a 2015 article on BioProcess Online.[25] She emphasizes that "companies need solutions that enable a flexible structure with variable cost. Product transfer, ownership changes and policy updates are driving demand for flexibility yet fixed cost structures still dominate the market. FM providers will play a more strategic role, upstream of operations, assisting with capacity planning, workplace modeling, different asset-ownership structures, and scenario planning to prepare for up – and down – swings in production, and offer proactive solutions on how to maximize available space."

PERSONNEL INTEGRATION AFTER M&A

After a merger, layoffs are inevitable. Witness Pfizer's elimination of more than 56,000 jobs worldwide between 2005 and 2014. But equally inevitable will be the desire of the new company to retain key research and other personnel. Acquiring companies offer such incentives as salary increases, pension plans, or profit sharing/ bonus programs and awards for staying longer than two years. But as noted by biotech company Executive Vice President Peter Hirth, money is not the only factor that makes people stay. The company's micro-environment is more important, and how an employee's position impacts his or her future personal development.[26] In addition, younger employees of biotech companies often prefer stock options to pension packages and frequently leave when the new company does not offer such options. Research has also shown that relocation of employees can be an issue. As a case study of five companies discovered, employees who lived on the U.S. West Coast are often reluctant to move East, and vice versa.[27]

As noted above, cultural integration is one of the greatest challenges during M&A. But important cultural differences can be identified and resolved. With a clear plan, such as a "merger intent" document, transition team leaders can work with newcomers to show them the ropes. At that time, consistent communication, early and often, is vital. If employees have to wait for months to learn their fate in the new company, morale can suffer.

Money is not the only factor that makes people stay – the company's micro-environment is more important.

THE EMERGING FUTURE PHARMACEUTICAL COMPANY

With the tremendous M&A activity occurring among pharmaceutical, biotech and medical device companies, it is clear that new company models are emerging. In A.T. Kearney's view, many future pharmaceutical companies will no longer be vertically integrated, from research through sales. Instead, the future will see a greater number of specialized companies focused on R&D to discover new molecules, with commercially oriented companies that license R&D company's molecules focused on marketing and delivering therapies to patients.[28] The worldwide market for pharmaceutical contract manufacturing was projected to hit $40.7 billion this year, and possibly double early in the next decade.[29]

CONCLUSION

Decades of experience with M&A in all sectors, and recent developments in the healthcare field, have demonstrated that pharmaceutical, biotech and medical device companies that are combining can successfully manage the process if they plan well for the near certain challenges their new organizations will face. The era of personalized medicine is upon us, and with it are emerging new R&D needs, new collaboration among industry sectors, and many new hybrid companies that, if they play their cards right, can realize the full value that comes when the best of the best are blended to create new synergies.

NAVIGATING A PATH TO SUCCESS WITH SODEXO

Pharma M&A creates many challenges that must be overcome in order to produce benefits for shareholders and improve company value. As a Quality of Life company, Sodexo understands these challenges and provides solution-based services that can help companies navigate a path to success. Our facilities management professionals work with you on the operational aspects of the merger intent, partnering to provide the highest standards of service, safety, and comfort in a well-managed process for the transformation initiatives. Sodexo also knows that your people are your greatest asset, and we understand the challenges that may arise from differences in corporate cultures. Most importantly, we understand how critical a fully operational facility is to the employee experience. Our facilities management team takes the time to know your people and facility, so that together, we can achieve the best possible outcomes for your organization.

WHY SODEXO?

- Sodexo is a proven facilities management partner to Fortune 500 companies, universities, and healthcare and government institutions around the world that expect the highest standards of service, safety and comfort.
- Globally, Sodexo's footprint in the pharmaceutical industry includes:
  - Number of Countries: >50
  - Number of Sites: >150
  - Environments: R&D, Manufacturing, Corporate Headquarters, Sales & Marketing
  - Services: Scientific Services (including regulated spaces), Hard FM and Soft Services
- Unlike many companies that have a financial stake in specific equipment or supplier recommendations, we don't. Sodexo cares first and foremost about providing the right customized solution for your facilities.

REFERENCES

1. Global Data. (2015). US Pharmaceutical Market Value Will Approach $550 Billion by 2020, says GlobalData. Retrieved from http://healthcare.globaldata.com/media-center/press-releases/pharmaceuticals/us-pharmaceutical-market-value-will-approach-550-billion-by-2020-says-globaldata
2. United States Department of Commerce. (n.d.). The Medical Device Industry in the United States. Retrieved from http://selectusa.commerce.gov/industry-snapshots/medical-device-industry-united-states
3. Universitaet Bamberg. (2002). Case studies of organizational integration of biotechnology companies after the M&A deal. Retrieved from http://www.ub.uni-bamberg.de/elib/volltexte/2002/3/Chapter_3.pdf
4. A.T. Kearney. (2013). Unleashing Pharma from the R&D Value Chain. Retrieved from https://www.atkearney.com/innovation/ideas-insights/featured-article/-/asset_publisher/BqWAk3NLsZIU/content/unleashing-pharma-from-the-r-d-value-chain/10192
5. Stella, P., & Gold-von Simson, G. (2014). Pharmaceutical pricing, cost containment and new treatments for rare diseases in children. Orphanet Journal of Rare Diseases. Retrieved from http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4221662/
6. Jimenez, J. (2012). The CEO of Novartis on Growing After a Patent Cliff. Harvard Business Review. https://hbr.org/2012/12/the-ceo-of-novartis-on-growing-after-a-patent-cliff
7. Wieczner, J. (2015). The real reasons for the pharma merger boom. Fortune. Retrieved from http://fortune.com/2015/07/28/why-pharma-mergers-are-booming/
8. Huron Life Sciences. (2014). Drugs and Devices Do Mix: Challenges and Opportunities for the Integrated Life Sciences Manufacturer. Retrieved from http://www.huronconsultinggroup.com/Insights/Perspective/Life_Sciences/Drugs_and_Devices_Do_Mix
9. Gable, J. (2014). Leveraging the Principles in Mergers, Acquisitions, and Divestitures. Information Management Journal, 48(3), 32-37.
10. Universitaet Bamberg, op. cit.
11. Ibid.
12. Gitelson, G., Bing, J.W., & Laroche, L. (2001). The Impact of Culture on Mergers & Acquisitions. Retrieved from http://www.itapintl.com/index.php/about-us/articles/culture-impact-mergers-acquisitions
13. Miller, R. (2000). How Culture Affects Mergers and Acquisitions. Industrial Management, 42(5), 22-26.
14. Government Accountability Office. (2002). Highlights of a Forum, Mergers and Transformation: Lessons Learned for a Department of Homeland Security and Other Federal Agencies. GAO-03-293SP.
15. Ashkenas, R., Francis, S., & Heinick, R. (2011). The Merger Dividend. Harvard Business Review, 89(7/8), 126-133.
16. Schuler, R., & Jackson, S. (2001). HR Issues and Activities in Mergers and Acquisitions. European Management Journal, 19(3), 239–253.
17. Ibid.
18. Knilans, G. (2009). Mergers and Acquisitions: Best Practices for Successful Integration. Employment Relations Today, 35(4), 39-46.
19. Miller, op. cit.
20. McKinsey & Company. (2010). Perspectives on merger integration. New York. McKinsey & Company.
21. Universitaet Bamberg, op cit.
22. Gable, op. cit.
23. Huron Life Sciences, op. cit.
24. LaMattina, J. (2011). The impact of mergers on pharmaceutical R&D. Nature Reviews Drug Discovery, 10, 559-560.
25. Mears, L. (2015). Facilities Management in BioPharma: Why Is It Important? Retrieved from http://www.bioprocessonline.com/doc/facilities-management-in-biopharma-why-is-it-important-0001
26. Universitaet Bamberg, op cit.
27. Ibid.
28. A.T. Kearney, op. cit.
29. PharmaLive.com Special Report. (2011). Global Contract Manufacturing Companies: Pharmaceutical and Biotechnology. Retrieved from http://www.pharmalive.com/global-contract-manufacturing-companies-pharmaceutical-and-biotechnology/

Sodexo
9801 Washingtonian Blvd.
Gaithersburg, MD 20878
888 SODEXO 7
www.sodexo.com

QUALITY OF LIFE SERVICES