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Preparing for, Surviving and Thriving in a Consolidating Pharmaceutical Industry

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The pharmaceutical industry is experiencing heightened merger and acquisition activity, due in large part to rising competition, increasing regulatory challenges and expiring patents' periods of exclusivity. In 2018, the industry saw 248 mergers worth approximately $198 billion; one law firm predicts that the value of transactions will soar to $331 billion in 2019.

In the course of these transactions, many pharmaceutical companies have encountered information governance challenges that they did not anticipate—or budget for—prior to the merger. As they begin to assess the disparate data source landscapes in an effort to unify their systems, issues in their document retention, preservation and retrieval become readily apparent, requiring a substantial amount of time and monetary investment to resolve—resources that are typically scarce after a transaction closes. This generally means that the necessitated data mapping, remediation and integration endeavors are deprioritized, leaving these combined organizations even more exposed in the event of litigation or a regulatory or compliance investigation.

This white paper takes a closer look at the status of mergers and acquisitions in the pharmaceutical industry, the challenges that these transactions exacerbate for the combined companies and solutions for mitigating those risks.

The State of the Pharmaceutical Market

Over the last year, we've seen more blockbuster mergers in the pharmaceutical industry than ever before. At the end of 2018, Takeda Pharmaceutical bought Shire for $58 billion. In January, Bristol-Myers Squibb announced that it planned to buy its rival Celgene in a deal worth $74 billion. Eli Lilly completed its $8 billion purchase of Loxo Oncology in February. And in June, AbbVie agreed to buy Allergan for $63 billion.

Megamergers like these have become de rigueur in the industry—and for good reason. Advances in technology are lowering the barriers to competition and forcing pharmaceutical companies to find new ways to innovate. By coming together, companies can jointly shoulder the costs of the research and development required to bring new pharmaceuticals to market, which averages around $2.6 billion per product. Mitigating the risk of failure is another significant benefit of scale with ~90% of pharmaceutical companies' research and development spend going towards products that never make it to market.

Increased size and global scale is also a significant advantage that accelerates the time to market for new drugs, by enabling companies to expand clinical trials to nations with lower cost structures, seek regulatory approval in many countries at once, and extend their global marketing reach. Finding synergies becomes especially important as the brand-name drugs that contributed to the dominance of larger companies see the period of exclusivity for their patents expire, resulting in significantly lower profitability.

Furthermore, consolidation equals savings, as organizations on both sides of a transaction benefit from combining and streamlining their market presence, infrastructure and development capabilities. As an illustrative example, Takeda predicts that its merger will yield at least $1.4 billion per year in pre-tax cost synergies by the end of the third fiscal year after the deal closes.

The upshot is that it has become far more practical for pharmaceutical companies to compete through consolidation than through the more expensive research and development path. Unfortunately, many companies have missed a line item when calculating the costs of these transactions, however: the integration of two vastly disparate information infrastructures.

The Challenges and Costs of Data Consolidation for Life Sciences Companies

The pre-transaction due diligence process is exhaustive. Deal advisors scrutinize an organization's finances, assets, liabilities, contracts and policies, garnering a complete picture of the target and its business, to determine whether to proceed with the transaction. Given that information is one of a company's most important assets—especially for a pharmaceutical company whose value is in its research—why is it so frequently overlooked in the valuation process?

In part, the issue arises because pharmaceutical companies' data is dispersed across a range of systems and potentially geographies, spanning the entire enterprise: clinical trial and research information, scientists' lab books, email systems and archives, document management systems, matter management systems, ebilling systems, human resources and benefits systems—and the list continues. Most of this information is highly sensitive and confidential, including trade secrets, legal settlements and personal health information, and because it is frequently stored in the cloud or across borders, it is subject to a patchwork of governing data privacy laws.

Whatever the reasons, the failure to account for the need to manage these scattered sources of information leads to a host of challenges. After a merger or acquisition, the amount of information being stored doubles, as do the costs and risks associated with it. Supporting two distinct data environments increases the complexity and challenges associated with managing legal holds, supporting litigation and investigations, ensuring business continuity, securing information and preventing data loss. Some of these systems need to be consolidated; others need to be scuttled.

However, as we too frequently see, in the absence of a looming litigation or investigation, few legal departments have any funds in their budget to allocate to proactive initiatives like information integration.

Accordingly, the key to ensuring the expense associated with the management of disparate data sources is covered—especially in a rapidly consolidating industry - is to account for the costs associated with information integration in the budget for the transaction itself. While many acquiring organizations will not have the time *before* the transaction to adequately understand the target organization's information landscape, a cursory review of what data exists, where it exists, and how amenable systems will be to consolidation, should provide enough insight to properly assess the required budget.

Considering Data Consolidation in the Merger Process

Organizations that have allocated resources and formed a defined strategy for consolidating their information systems during a transaction have mitigated significant costs and risks overall. Additionally, as a business enters into a merger or acquisition, the more the buy-side knows and understands about their own information assets as well as the seller's, the better they can anticipate and manage risk and compliance.

That is not to say that the process is painless. However, gaining an understanding of where information resides in both organizations—before trying to centralize systems and data stores—can eliminate the hassle and expense of hosting and managing duplicative information or information that no longer needs to be retained.

The Hazards of Not Including Data Assets in Due Diligence Efforts

Earlier this year, the UK's data privacy enforcer, the Information Commissioner's Office, proposed fining Marriott $124 million under the General Data Protection Regulation due to a data breach in Starwood Hotels' guest reservation database that occurred before Marriott acquired Starwood. During its due diligence, Marriott failed to discover that hackers had already compromised 339 million guest records in Starwood's database, including passport information and payment details. Making matters worse, Marriott waited two months after discovering the breach to disclose it to the authorities.

Creating an updated and accurate data map is the first and least invasive phase of the information integration process. This identification and accounting of informational assets results in numerous immediate benefits:

- accelerating system and data consolidation,
- reducing the manpower required to find information,
- streamlining information extraction and retrieval for legal matters,

- satisfying government mandates and deadlines,
- complying with legal hold and other preservation responsibilities,
- mitigating the risk of data loss and security breaches, and
- reducing the cost of data storage.

Organizations can also leverage these data maps to improve cross-functional information flows and cross-system reporting, delivering new insights into:

- supply chain efficiencies,
- R&D activities and spend,
- sales and marketing spend,
- target areas for improving operational efficiencies, and
- improved knowledge management.

The primary goal of any merger or acquisition is to accomplish a business objective. However, it can also serve as the impetus for information governance activities. By budgeting for these activities, such as data mapping and system integration, before the transaction has closed, the acquiring company's legal department can amass the financial resources and tools required to identify and protect business-critical data, streamline information storage and retrieval systems and mitigate overall exposure and risk.

About the Author

Jamie Weissglass is a Senior Director at Consilio, a global leader in eDiscovery, document review and legal consulting services.

Jamie specializes in providing Fortune 500 Corporations and AmLaw 200 Law Firms with comprehensive electronic discovery and document review solutions for complex legal matters. She concentrates on discovery consulting and helping clients to comply with discovery requirements and production requests in government investigations as well as a wide range of large scale litigations. As a former litigator with extensive technical knowledge, Jamie strives to bridge the gap between lawyers and technologists while assisting in-house and outside legal counsel in understanding the most effective processes and technologies to manage complex workflows while generating maximum quality, accuracy, cost reduction and return on investment.

Jamie is a proficient discovery consultant and business development executive. Prior to joining Consilio, Jamie practiced law as an associate at a boutique litigation firm in New York City, focusing on complex litigations and large scale document reviews.