



Convergence in life sciences

Five things you need to know to get ahead of trends, lead in the industry, navigate risks and opportunities, and disrupt through innovation

Over the last two years, the life sciences industry has seen record-breaking levels of mergers and acquisition (M&A) activity. But convergence in the life sciences ecosystem isn't just about stereotypical acquisitions to fill product holes or adjacent services. The future of life science organizations has become intertwined with health insurers, providers, and information technology companies in unprecedented ways. Greater pricing pressures, driven by measuring the value and effectiveness of care, continues to challenge the leaders in the sector to innovate and consider opportunities outside traditional methods of care.

Moreover, the increasing use of third-party contracting and partnerships—giving life sciences companies the chance to focus on what they do best—presents reputational and technological challenges. Here are five things you need to know about the trends, risks, and opportunities in the life sciences industry from Jennifer Malatesta and Chris Caruso. Malatesta is a Deloitte Risk and Financial Advisory principal in Deloitte & Touche LLP's Life Sciences Governance Regulatory and Risk practice. Caruso is a Deloitte Risk and Financial Advisory partner in Deloitte & Touche LLP's Life Sciences and Health Care M&A Transaction Services practice.

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1. We're living in a post-sector world.

"Sectors and companies that were pure-play pharma, medical device, or even consumer are now becoming very integrated with adjacent sectors," says Malatesta. "We have pharma and consumer, pharma and technology, and—on the health plan and provider side—we've seen significant academic and medical institutions acquiring small health plans. I sometimes draw the analogy of a bunch of kids playing with baseball cards: I'll trade you my medical device company for your diabetes business. Before I may have had two components that weren't complementing each other, but now I have the pieces that will work. This cross-sector pollination allows these organizations to drive the effectiveness of care in many phases throughout the care cycle and be less dependent on others that may negatively impact the perceived value or effectiveness of the care."

2. An indemnification clause in a third-party contract isn't enough.

"Over the past year, we've seen companies in the news that were in co-marketing agreements—maybe they had a specialty pharmacy agreement—and really were inextricably tied to the business practices and the risk appetite of the counterparties they were working with," says Malatesta. "So my emphasis to boards and senior executive teams is: It's not really something you can just leave to an indemnification clause. Regardless of what you put in your contract, you're somewhat adopting the risk profile of the company you're taking on.

This is turning into real reputational risk with respect to safety, pricing, and cybersecurity. You can have a robust cybersecurity infrastructure, policy, and approach. But if you're doing R&D collaboration with a third party and it's infiltrated either electronically or through social engineering, you have clinical trial data or other intellectual property that's placed at some significant risk."

"Our recommendation is to extend your M&A skills to your policies and procedures on vendors," says Caruso. "For example, do due diligence on your partners—not just reputational due diligence but a deeper dive—to see if their controls are up to snuff. When you think of these risks, you can no longer just take brand recognition at face value. You really have a responsibility to do your due diligence and know who you're doing business with and whether your data, the quality of your products, or a component of your treatment cycle is on par with your quality standards and reputation."

3. Wireless technology enables care—but adds risk.

"On the tech side, an area to consider is wireless-enabled devices. There are the simpler systems like wearable fitness trackers, but we're also talking about atrial devices regulating the heartbeat or pumps delivering and regulating medication. How secure is that device?" asks Caruso. "Devices in the US are now wirelessly enabled or hardwired into a network—how safe is that device? If a patient is receiving morphine for

pain during cancer treatment, as a caregiver I want assurances that the administration of medicine is correct. This is where it gets back to accountable care. Not only do you affect the patient, but everyone from the device manufacturer to the provider is accountable if one of these devices is compromised. The FDA is taking this very seriously, and in the next few years we'll most likely see additional guidelines that require companies to be compliant on both the hardware and software sides. This represents significant risk and disruption in the industry, and it's something all players need to think about."

4. You can't entirely control the patient, but you can be hands-on when it comes to effective care and reducing costs.

"Patient compliance is probably one of the biggest factors in the cost of providing care," says Caruso. "For example, you may have a medical device company that makes a spinal implant and finds it important to control the overall cost of care. By providing effective care, they're ensuring that their bottom line isn't impacted. But more importantly, they're increasing the success rates with the patients.

"So what can they do to create effective care? One way is to ensure the surgical procedure occurs correctly. Most surgeons take pride in their work and do a great job. So some device makers may say you need to follow specific guidelines for their



device to be effective for the next 30 years. Otherwise, we may have two issues: We're going to have a patient who is in and out of the hospital, and the surgeon is going to have a potential lawsuit on his or her hands. Both these things are going to cost a ton of money," says Caruso. "Another strategic alternative for a device maker is to go out and do a joint venture with a rehab center. They can't influence what device is implanted. But if their device is implanted, they can influence the outcome by focusing on post-surgery compliance. Patient compliance can't be completely controlled. But trying to influence it during this aspect of the care cycle is important throughout the health care industry."

5. Regulations don't change as often as you might think, but enforcement does.

"If you really step back in life sciences, regulation has been relatively stable for the last couple of years," says Malatesta. "With the new presidential administration, it's quite possible that you will see a difference in enforcement. Several years ago, when we were seeing the billion-dollar fines for off-label and other areas, the rules didn't change. The enforcement posture changed. And now we see a migration from what was a heavy focus on sales and marketing to probably a much greater scrutiny of manufacturing quality and safety."

Opportunities for innovation and growth

As the life sciences industry continues to evolve, the people and companies working within this dynamic sector will see many opportunities for innovation and growth—if they manage the risks associated with industry disruption proactively. Embracing change and making it work for them can allow life sciences organizations to maintain and enhance their brand reputations, create value, and gain a competitive advantage for a bright future.

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