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REPORT: TOP
100 MEDICINES

With Lipitor no longer the world's best-selling medicine, Humira has overtaken the No. 1 spot in sales. Humira is expected to generate strong sales growth in 2013 and beyond.

18 SAMPLE OF
TRENDS

In China, the demand for drug samples remains low; the number of samples distributed in the United States continues to shrink; but the Brazilian market is surprisingly lively.



20 MORE SHOTS
OF POTENTIAL

Up and comers in the vaccines pipeline mostly are focused on treating cancer, but several target allergies, hepatitis B, influenza, and other infectious diseases.



Summer conference recap

By Dorothy Wetzel

People don't change when they see the light, they change when they feel the heat.

The heat is certainly on in the pharmaceutical industry if the conferences I recently attended are any indication. The changes bearing down on the industry touch the very core of the industry—its value proposition and even what constitutes “the product” being offered.

I lived through pharma painfully and begrudgingly adapting to the Managed Care Model in the '90s. So I haven't felt much hope for the type of radical reinvention of the commercial model that will be required to capitalize on the rapidly evolving healthcare landscape. Change is never easy, and the pharmaceutical industry is particularly resistant to change, preferring “rearguard” battle tactics rather than “offensive” innovation.

At the conferences I attended there were glimmers of progress on the commercial side. I couldn't help but imagine the major uphill battle that each innovation would face inside the walls of Big Pharma. However, the talks about the radical reinvention that has already occurred within the R&D function makes me hope that change is possible, even in Big Pharma marketing.

My travels took me to two conferences, generally off the beaten path of conference goes—the Marcus Evans Pharmamarketing Summit and Convergence East, the Life Sciences Leaders Forum. The Pharmamarketing Summit attracted inline marketers while Convergence attendees were a mix of R&D folk and early development marketers. However, while the audiences were different, the theme about the need to change was clear. Here's my take on what's in-store for the future.

The new value “beholder”

If value is in the eye of the beholder, then the value of a pharmaceutical product is experiencing a dramatic shift from the physician to the payer. According to Kurt Graves, CEO Intarcia, who spoke at the Pharmamarketing Summit, the decision to proceed with a product now comes down to one question, “Is there enough value in this product for payers to pay for it.” Bringing a drug to market today involves a radically different game plan including:

- Creating a payer value story in pre development
- Proactive engagement of external stakeholders in Phase I and II
- Patient reported outcomes (PRO) as part of clinical data
- Adaptive trial design to find the right patient type
- Adherence studies – pre and post approval

The tactics and mindset of pharmaceutical marketers will also have to change, according to Steven Pal, corporate VP, Global Strategic Marketing

at Allergan. In his Pharmamarketing talk, gone says Pal, are the days of the large mass-market field force. Instead, companies need to deploy, “smaller, more agile sales forces that are more attuned to customer needs.” And pharma marketers need to approach payers with a greater emphasis on “providing real solutions” instead of profiting at the expense of other parts of the healthcare delivery chain.”

Beyond the little white pill

Furthermore Pal says that the future of pharmaceuticals is going to involve not only products but also health services and diagnostic tests. One interesting example is ICTA 650, currently in development by Intarcia. The “product” converges medicine and technology, delivering diabetes medication through a subcutaneous delivery device that is implanted annually. As Kurt Graves, CEO of Intarcia told Pharmamarketing attendees, the product has the potential to offer “better efficacy and the unique aspect is that you can guarantee compliance. This is something payers get.”

But for those wanting to go beyond the little white pill, the path is far from clear. Consider the development of companion diagnostic tests that identify the appropriate patient for a particular drug. Many believe Pharma may give a test away for free to sell more medication. If the tests are ultimately free, it may become difficult for entrepreneurs to find funding. Even the regulatory path for diagnostic tests is somewhat murky depending on where the test is used and how it is distributed.

The buck stops with the patient

At the end of the day, the most significant change in healthcare requires the patient to adopt new behaviors. And this means focusing on patient problems rather than just pharmaceutical solutions. Citing Oliver Wyman data, Steven Pal spoke about how CareMore, a California Medical Group, keeps hospitalization rates low by using unconventional tactics such as providing air conditioners to prevent the normal spikes in emergency room visits by the elderly during heat waves.

In his whirlwind talk at the Pharmamarketing Summit, the Honorable William H. Frist, M.D., 18th Majority Leader, U.S. Senate, pointed out that any meaningful change in health outcomes and cost reduction will require consumer behavior change. According to Frist, 40 percent of longevity is traceable to personal behavior versus only 10 percent to the health services a person receives. While doling out air conditioners to patients isn't an option, there is an opportunity to think more expansively about the relatively anemic patient support programs offered by most companies.

Better outcomes also entail a more meaningful attempt at incorporating the voice of the patient into drug development according to Convergence

speaker, Ben Heywood, President of Patients Like Me. There is a need to inject a deep understanding about what a patient cares about in real time. To do this, Patients Like Me is creating a real-time health learning system for the development of patient-centered health outcome measures. Heywood's belief is that at the end of the day, what patients' value is going to drive market value.

Radical reorganization of R&D leads the way

Normally pessimistic about the Industry's ability to change, the radical reorganization of the R&D functions discussed at the conferences gives me hope. It was clear at the Convergence conference that Big Pharma was increasingly looking outside their walls to fix the drug pipeline problem. Virtually every company that was represented was piloting a new organizational structure charged with harnessing the entrepreneurial spirit from emerging biotech organizations.

For example, J&J has set up four innovation centers around the world designed to create relationships in integrated communities of academics, research institutions, early stage biotech, venture capital and entrepreneurs. The remit of these innovation centers spans J&J's three business units: pharmaceutical, consumer and devices. The goal is to make J&J the partner of choice when there is an interesting opportunity to be commercialized.

This new R&D approach is also exemplified by Sanofi's partnership with a prominent Harvard professor, Dr. Gregory Verdine, to create warpdribebio. Warpdribebio has a proprietary “genomic search engine” to identify “powerful drugs that are now hidden within microbes.” With an aligned vision and additional funding from venture capital, Sanofi co-created the company with Dr. Verdine.

The path forward

It is this radical reinvention of the R&D model that gives me hope. Key healthcare pundits have noted that healthcare innovation is likely to come from outside the industry—from the retail, technology and service sectors. At its essence, the new R&D model is about proactively reorienting their sights on the outside world. The same has to happen on the commercial side of the business. Change in the commercial model needs to occur everywhere—from reorienting the rabid focus on the physician at the expense of payer and patient marketing to creating new definitions of a pharmaceutical “product” offering. The commercial organizations that set their sights on the outside world will feel the heat and start to change.

Dorothy Wetzel is the founding partner of the healthcare marketing agency Extrovertic.

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Top 200 Medicines: See the expanded chart of top-selling drugs only on PharmaLive.com

Vaccines – Beyond awaiting approval: Cancer vaccines dominate the Phase III landscape, but there are several prominent candidates for treating infectious diseases.