The Patent CLIFF

As companies look to fill the estimated $16 billion in annual revenue expected to be lost to generics over the next five years alone, they must become more adept at life-cycle management, pursuing viable reimbursement strategies, and developing evidence-based communications.

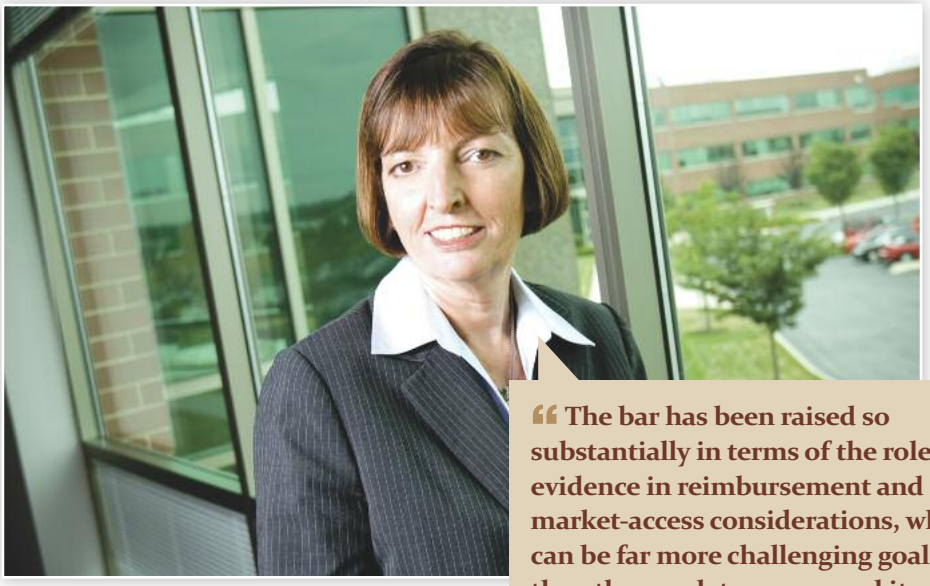
If it seems as though pundits have been talking about the billions of dollars that will be lost to generic competition for 10 years, that's because they have. The pharma industry is practically on tilt because of the number of blockbusters scheduled to lose patent protection in the next few years, yet, it seems that only recently has there been significant movement to counter the loss of revenue.

Historically, pharmaceutical branding has been limited to a patent-exclusivity constraint, but today brands are finding new life even in the world of generics because of new media channels and positioning, says David Cunningham, president and CEO of TrialCard, which provides solutions to support direct-to-consumer and professional marketing.

"Pharmaceutical marketers would work relentlessly to build brand equity, only to abandon loyal patients with the intrusion of generics," Mr. Cunningham says. "Today, we're seeing something new and exciting with manufacturers. It starts with a change in expectations about post-patent brand loyalty. It's fascinating to watch tactics develop in support of a belief that hard-earned pharmaceutical brand equity exists after patent loss. This is exemplified as one of the leading manufacturers employs tactics designed to support its mega brand amidst the approaching impact of patent expiry. We can all learn volumes about the fight for the brand from a simple $4.00 copay tactic."

The presence of generic medicines across almost all major disease states is a significant, high-impact game changer facing the life-sciences industry.

"The need for companies to adapt thier business models and practices to public and private payers' agendas is fundamental change in the industry," says Keith Ruark, VP of Avos Consulting, a division of INC Research and a strategic consulting and research products firm. "Recent statistics have cited that 77% of all approved molecules have direct generic equivalents. Further, emerging comparative effectiveness data have led to the adoption of low-cost generic products as therapeutic equivalents to branded pharmaceuticals in some conditions. Optimizing market access and reimbursement issues is now critical for new medicines facing a much more competitive market. This starts with early decision-making early in the R&D process."



> **"The bar has been raised so substantially in terms of the role of evidence in reimbursement and market-access considerations, which can be far more challenging goals than the regulatory approval itself."**
>
> **JULIA RALSTON** / MedErgy

According to Matt Wallach, chief strategy officer of Veeva Systems, a provider of SaaS-based CRM solutions, the end of patent life for so many blockbuster medicines has driven more change in the past 24 months than the industry experienced in the prior 10 years combined.

"The threat of patent expirations has driven mergers and acquisitions, changed R&D investment strategies, triggered major declines in work force size, and pushed the necessity to implement multichannel customer relationship management strategies," Mr. Wallach says. "The loss of these billions of dollars of revenue will continue to drive major change, as the industry learns how to remain profitable while attacking smaller and more specialized diseases."

And for the first time, it's not just small-molecule drugs that are vulnerable to generic competition; the introduction of biosimilars is dramatically changing the playing field.

"Owning a biological was like having an exclusive cash cow, but now there's strong competition," says Ken Ribotsky, president and CEO of The Core Nation, a family of

> "In a more mature world, the fight for survival will drive convergence of market participants at all levels: payers, providers, and pharmaceutical companies."
>
> **ROBIN ARNOLD** / IMS Health

healthcare marketing and medical communications companies. "By 2015, biologics worth $60 billion in annual sales will lose patent protection; as a result there will be rapid growth of the biosimilar business."

Who Pays?

Nothing will dramatically shape the industry over the next 10 years more than who pays and what they pay for therapies, says Patrick Durbin, president of biopharma services at Thermo Fisher Scientific, a provider of scientific services to the industry.

"Governments, industry, and front-line consumers will reshape and transform the whole model of innovation, development, and provision of therapies by what they're willing to pay — it will be fascinating," he says.

In the 1990s, the prescriber was still king; prescription drugs lived and died by the physician's pen.

"Over the last 10 years, the pharmaceutical industry's largest audience has become the formulary committee," says Luis Gutierrez, senior VP of pharmaceutical and life-sciences operations at MedAssurant, a medical informatics solutions provider. "Whether government- or health plan-based, this economic intermediary now plays the central role in the financial success of any drug and has recast the tenor of product development decisions throughout the industry, with a much greater emphasis on understanding, and then positively affecting, the economics outcomes of care."

In the last 10 years, the healthcare delivery system has focused on therapies targeting the rapidly growing senior population, as well as those in the biologic space, says Chris Cresswell, general manager of patient innovations at DrFirst, a provider of stand-alone electronic prescribing solutions. "While this has resulted in many people living longer, enjoying a higher quality of life, or enabling people to live productive lives with a chronic condition, it has also driven healthcare costs higher.

> "It's fascinating to watch tactics develop in support of a belief that hard-earned pharmaceutical brand equity exists after patent loss."
>
> **DAVID CUNNINGHAM** / TrialCard

"As a result, there has been an increase in more restrictive health plans, as well as an increase of member share of that cost," Mr. Cresswell continues. "Lastly, with the economic challenges of the last few years, employers are feeling increased pressure to balance the company needs with those of their employees, often reducing benefits. All of these factors have led to a focus on wellness and the need for individuals to be responsible for preventive medicine, wellness, and maintaining adherence to prescribed therapies."

Some experts say perhaps the largest change is the approach that drug companies have used to be successful.

Benefits of Risk Evaluation Program Uncertain

Drug developers, healthcare providers, insurance companies, and others involved in the delivery of healthcare in the United States are uncertain about the benefits of a risk evaluation program introduced three years ago by the FDA, according to the Tufts Center for the Study of Drug Development.

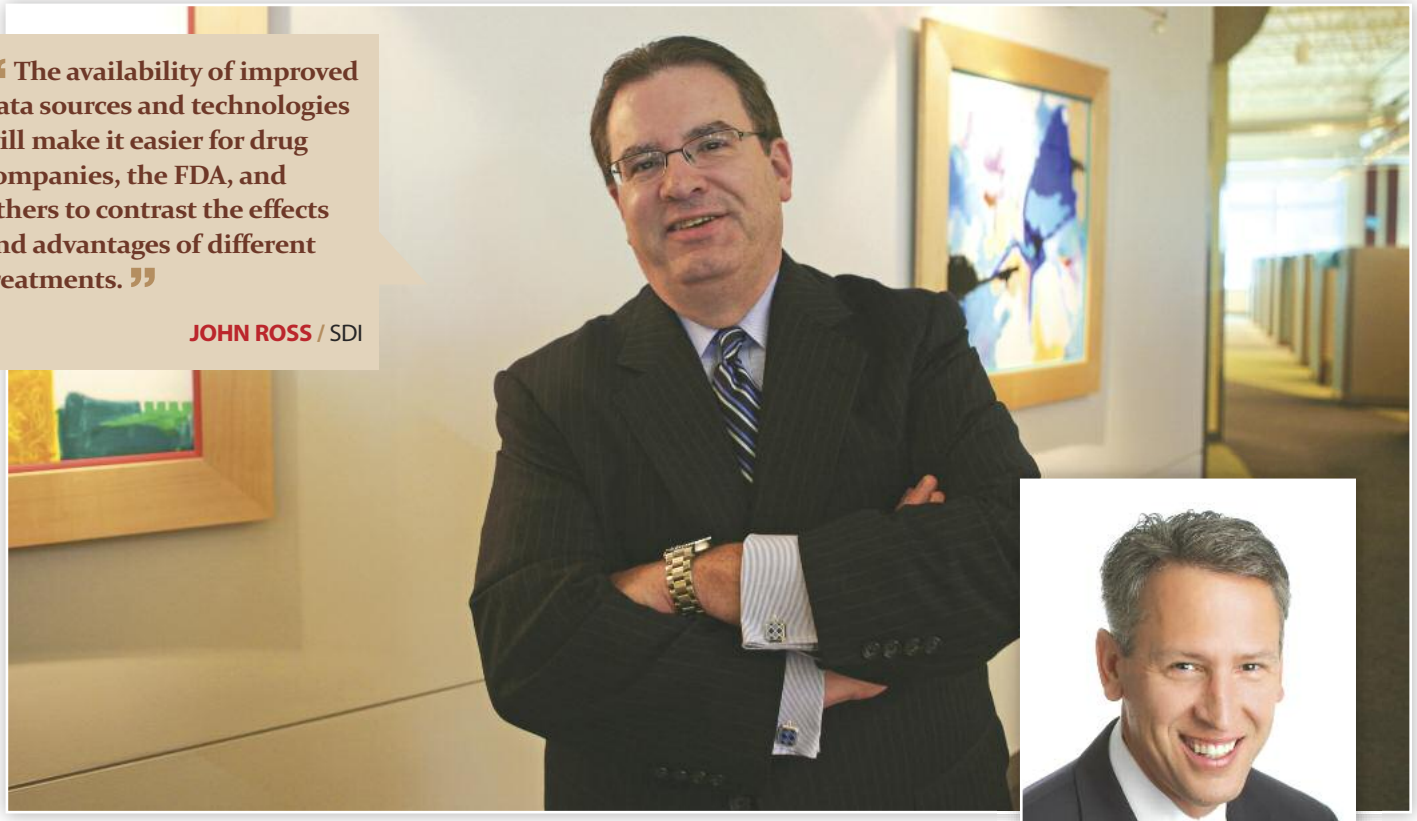
- **86%** felt that under current guidelines, **risk and benefit information was not well balanced** in REMS communications.
- **75% of respondents** thought that the **REMS program needed a major overhaul**.
- **68%** said that **REMS were a poor substitute for other improvements** needed systemwide in drug education, communication, monitoring of use, patient access and delivery of care.
- **22%** of respondents thought the **REMS program has been an improvement** over the existing risk management system.

Source: The Tufts Center for the Study of Drug Development. For more information, visit csdd.tufts.edu.

"Earlier in the decade it was still possible to develop and launch a new product into a large, primary-care-driven market, invest heavily to promote it, and gain market share," says John Ross, chief operating officer at SDI, a healthcare analytics organization. "Then, over the years as these markets became saturated, strong generic competition was introduced, and when R&D pipelines failed to produce superior follow-on compounds, manufacturers had to change their strategies. Pharmaceutical companies began investing in finding innovative treatments for conditions with smaller populations of affected patients. With this shift came new challenges as many of these drugs are prescribed by non-primary-care physicians, have much higher price tags, and are distributed outside of the retail pharmacy channel."

Mr. Ribotsky says another game changer in terms of a development focus and potential payer access is the shift from symptomatic therapies to disease-modifying therapies.

"Concentration on therapeutic areas such as multiple sclerosis, rheumatoid arthritis, psoriasis, and cystic fibrosis have companies moving from mechanism of action to mechanism



> "The availability of improved data sources and technologies will make it easier for drug companies, the FDA, and others to contrast the effects and advantages of different treatments."
>
> **JOHN ROSS** / SDI

of disease, so they are actually changing the natural course of a disease," he says.

Bassil Dahiyat, CEO of Xencor, a biotechnology company, says the continuing pressure to reduce the cost of healthcare will directly impact drug pricing. In fact, he says, the biggest market shaper of the next decade will be the development of next-generation drugs that can reduce the total cost of therapy with superior performance and ease/cost of use.

For Nicholas Landekic, president, CEO, and director of PolyMedix, which is developing novel, first-in-class therapies for serious, life-threatening, and acute disorders, pharmacoeconomics has had the biggest impact on the life-sciences industry within the last decade.

"Old-school pharmaceutical thinking often sought to create me-too drugs and make money simply by aggressive marketing or developing 'new' drugs and by counting on physician demand to generate sales are no longer viable strategies," Mr. Landekic says. "Whether in the strictly price-controlled international markets or the de facto similar system in the United States where formulary and pharmacy benefits managers make the decisions as to what gets listed on formularies and the price that is reimbursed, every pharmaceutical product now needs to show a financial reason as well as a clinical efficacy and safety profile to cost-justify its use. Without a solid pharmacoeconomic rationale, products may be approved but may not be commercially viable."

The Evidence is in the Outcomes

The move from buying pills to paying for outcomes has been a recent game changer impacting the whole industry, says Patrick Flochel, Ernst & Young's life-sciences leader for EMEIA.

"Because of this evolution, the industry needs to now radically realign its incentives internally and externally to those of payers and patients," he advises. "The industry will also need to combine its own key assets and capabilities with those of companies from other sectors to provide solutions that enable the healthcare system to be sustainable in the long term."

Economic intermediaries, specifically formulary committees of governments and managed care organizations, are now leveraging patient-level decision making though higher co-payments and cost-sharing differentials and thus shaping revenue cycles in the pharmaceutical marketplace, Mr. Gutierrez says.

"Developing world markets have historically featured more cash payments for medical treatments," he says. "This will continue, and the Western world will begin to move closer to this model. This will require that pharmaceutical companies be extremely well-armed with informatics solutions that enable micro-level pricing intelligence, much as airlines, hotels, and other businesses with high-fixed costs already employ."

> "The biggest factor to shape the market over the next 10 years will be reimbursement rates — and possibly regulatory approvals — tied to product performance."
>
> **JIM DATIN** / Safeguard Scientifics

Robin Arnold, VP, product and portfolio strategy, at IMS Health, a market intelligence company, agrees that the biggest change will be the shift of pharma's thinking toward conventional business orthodoxy.

"More efficient markets will develop among buyers, and pharma's unique characteristics will continue to erode, requiring demonstrated value to savvy buyers doing their own research and sharing the results," he says. "As the quality of available therapies increases and value in use becomes the prerequisite for reimbursement, pharma companies will be challenged to find products that provide valuable outcomes in the real world for

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identifiable populations, and they must choose where and how to play in the value chain to meet the new customer standards. In a more mature world, the fight for survival will drive convergence of market participants at all levels: payers, providers, and pharmaceutical companies."

Mr. Ross anticipates that today's emerging emphasis on comparative effectiveness research will continue to increase as all stakeholders in the healthcare dynamic look for evidence of product efficacy and value in an increasingly cost-constrained healthcare system.

"Although health outcomes research and the use of findings in discussions with physicians and payers is nothing new, the availability of improved data sources and technologies will make it easier for drug companies, the FDA, and others to contrast the effects and advantages of different treatments," Mr. Ross says.

Jim Datin, executive VP and managing director of the Life Sciences Group of Safeguard Scientifics, a provider of growth capital for entrepreneurial and innovative life-sciences and technology companies, says the biggest factor to shape the market over the next 10 years will be reimbursement rates — and possibly regulatory approvals — tied to product performance.

"Additionally, the role of companion diagnostics will become a required precedent for assessing pharmaceuticals or medical procedures to determine the potential success before treatment begins," he adds.

Over the last 10 years the biggest game changer has been collective payer reluctance to continue accepting incremental pharma value propositions and the resulting flight to specialty areas, Mr. Arnold contends.

"The paradoxical winner has been oncology; companies focused in this area have developed a breadth of therapies that are having a huge impact on survival benefiting patients, and spawning a new business approach that may end up forming the basis for restructuring the industry away from functionally driven monoliths to more responsive businesses," he says.

No discussion of the changing payer environment would be complete without a nod to nationalized healthcare and its influence on the clinical practice of medicine.

"This will be biggest game changer over the next 10 years," says Charles Rockefeller, partner at Curry Rockefeller Group, a full-service healthcare communications agency.

"With a shortage of primary-care doctors, there will be more reliance on PAs and nurse practitioners, and they will likely have a more restrictive formulary at their disposal," Mr. Rockefeller says. "Given the enormous cost of medical school, combined with staggering malpractice premiums, it will become less appealing to bright young people to enter medicine unless the healthcare delivery system evolves. This is a complex set of needs, costs, and stakeholders."

Evidence-Based Medicine

The growth of evidence-based medicine has dramatically changed both market access and clinical practice.

"Cochrane reviews, other meta-analyses, and evidence-based literature reviews are now the norm in terms of driving physicians' treatment decisions or supporting treatment guidelines," says Julia Ralston, president and CEO of MedErgy HealthGroup, a medical communications agency. "Likewise the bar has been raised so substantially in terms of the role of evidence in reimbursement and market-access considerations, which can be far-more challenging goals than the regulatory approval itself."

The last 10 years heralded in a new era focused on more real-world and post-approval data, primarily with regard to safety issues.

Very public product recalls, such as the Vioxx withdrawal, drew increasing criticism of the regulatory approval process. And regulators began searching for data beyond controlled clinical trials, which may not adequately represent the target population of the product, to meet safety needs.

Richard Gliklich, M.D., president and CEO of Outcome, a provider of patient registries, studies, and technologies for evaluating real-world outcomes, stresses the importance of using real-world data for monitoring safety and managing risk. He suggests the FDA may require that more of these studies are included as requirements for approval.

"This increased focus on real-world safety data has changed the way the industry approaches product development, approval, and marketing," he says. "And the focus on real-world data will continue into the next decade. Efforts to monitor safety will be driven by a more active surveillance approach, as recent initiatives, such as the Sentinel Initiative, demonstrate. There will also be a move toward a higher focus on the risk-benefit ratio for product approval and reimbursement. While safety will continue to be an important focus, there will be an increased interest in demonstrating product effectiveness. All healthcare stakeholders, patients, payers, physicians, and regulators will be interested in using these data for determining which products should be on the market, how they should be used, and for whom."

> "The increased focus on real-world safety data has changed the way the industry approaches product development, approval, and marketing."
>
> **DR. RICHARD GLIKLICH** / Outcome

Michael Curry, partner at Curry Rockefeller Group, concurs that clinical research trials will increasingly be called upon to investigate real differentiable benefits from existing and developmental compounds."

"This requires that pharma companies, actually everyone engaged in physician and patient education, have an acute and timely understanding of real-world issues affecting patient care," he says. "Communication companies will have to become much more attuned to disseminating these benefits in a timely and responsible manner."

If the last 10 years is any indicator to the future, there will be lots of game changers, Ms. Ralston says.

She too believes that the role of evidence-based medicine will continue to be critical for the industry.

"Evidence will also continue to get more technical and present a greater communication challenge as we continue to go beyond blockbusters into more personalized medicine and other cutting-edge areas, such as regenerative medicine." PV

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