I.360

ims | INTELLIGENCE. APPLIED.

The eZine of Global Pharmaceutical Perspectives

THE 2009 LANDSCAPE: BALANCING FIVE BUSINESS IMPERATIVES

> MYTH BUSTING: Is the Industry Still Recession-Proof?

> Specialty: A Defining Moment

> In Pursuit of Launch Excellence

And More...

SPRING VIEW 2009

We create the alignment within.

Discover enhanced Commercial Effectiveness with IMS.

If you think the IMS name just stands for data, think again. We've made quite a name for ourselves consulting on Commercial Effectiveness in the global healthcare market.

We've worked closely with clients to develop customer-centric organizations and innovative go-to-market approaches. Our end-to-end perspective of an integrated sales and marketing process ensures a coordinated allocation of both your field force investments and your marketing promotion mix.

Only IMS can lead your sales and marketing team to consistent segmentation, integrated resource optimization, and common performance metrics. Our patient-level lens helps you look beyond traditional physician detailing and promotion paradigms. Resulting in deeper customer relationships and enhanced equity.

So the next time you're thinking about commercial effectiveness, find out what we're thinking.

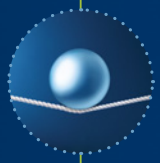
Contact our consulting team at **800-255-4110** or visit **imshealth.com/insights**.

ims

INTELLIGENCE.
APPLIED.

IN THIS ISSUE

FEATURES



SECTIONS

EDITORIAL PERSPECTIVE

COPING WITH UNCERTAINTY

CHANGE HAS ALWAYS BEEN a given in the pharmaceutical industry. And now, with 2009 in full swing, we must also accept the fact that uncertainty is a defining feature of the global pharmaceutical marketplace.

The pharmaceutical industry used to have the resilience of those bottom-weighted punching dummies — the ones that automatically right themselves after every punch. They may rock a bit, but they're never really fazed to the point of being laid low. Of late, the punches have come in the form of patent expirations, a tougher regulatory environment, fewer new product approvals and widespread cost-containment measures…with the latest blow being a weakened economy.

While it would have been cavalier to think that our industry was immune to the effects of a weak economy, it was common to think of pharmaceutical manufacturing as at least "recession resistant." After all, people will always need medications.

Since the last U.S. recession in 2001, which the industry weathered quite well with U.S. growth of nearly 17 percent, there has been a significant change. A substantial amount of the cost burden for pharmaceuticals has been transferred to patients in several countries, most notably the world's largest market, the United States. Healthcare premiums, deductibles and copayments have been rising steadily, and on average all have nearly doubled since 2001.[1] This has rendered the pharmaceutical sector more sensitive to shifts in consumer confidence and spending. And we are beginning to see the impact on healthcare consumption.

We see evidence in the U.S. that the cost burden on patients, combined with a tighter economy, has reached a tipping point. The results of primary research (such as work by the Center for Studying Health Systems Changes) and our own analyses of new-to-brand prescription volumes and trends in the number of office visits suggest that, increasingly, patients are delaying treatment in order to save money.

While our research into this phenomenon is further along in the U.S. than elsewhere around the globe, there is no reason to think that it is strictly a U.S. reaction. Any country in which the patient's out-of-pocket contribution is high — including

[1] *The Kaiser Family Foundation and Health Research & Educational Trust, Employer Health Benefits annual survey, 2008.*

Brazil, India and Russia — could fall victim to the same development if local market conditions put patients under enough economic pressure.

So, what does all of this mean? Broadly speaking, it means that the correlation between economic factors and pharmaceutical growth is stronger during the current economic slowdown than it has been in the past. Macroeconomic conditions, while naturally factored into our *2009 IMS Global Pharmaceutical Forecast* (discussed in *"A New World Order"* and *"The 2009 Landscape: Balancing Five Business Imperatives"* on the following pages), remain a wildcard.

In practical terms, this means that you must keep a close eye on leading indicators of patient dynamics to anticipate how demand for your products will be changing *within each patient segment*. With this understanding at the patient level, you can then be prepared with the right supporting programs — be they coupons, a new sampling strategy, special DTC messaging, online compliance initiatives or others — to counteract the impact of the economy.

And, the economic stress is one more nail in the coffin for the business and commercial models that, while enormously successful for many years, are struggling to deliver the returns that shareholders have come to expect. Regardless of the commercial model you pursue, you must develop a systematic approach to optimizing your resources and making the most of the assets you already have. *"In Pursuit of Launch Excellence"* reports on our findings into the macro trends within the launch environment and the responses that determine launch excellence. *"Meeting the Needs of Patients in Play"* reveals more efficient ways of spending promotional resources to achieve brand excellence.

No commentary on 2009 would be complete without a discussion of the changes we might expect in the U.S. market during the Obama presidency. President Obama's campaign platform contained a number of positions on healthcare that, if enacted through legislation, would be momentous for the market and manufacturers. (For more details, see *"Change on the U.S. Healthcare Agenda"* on the following pages.) The President has made it clear that he wants to see healthcare reform legislation signed into law by the year's end. In his address to Congress in late February, he said, "Healthcare reform cannot wait, it must not wait, and it will not wait another year." It remains to be seen if this is possible, but the first steps are underway as a healthcare summit convened at the White House the very next week. Congress had already moved swiftly to extend insurance coverage for children.

Our hope is that you will find the following pages full of valuable insights that will help you secure a successful future in 2009 and beyond — come what may.

Sincerely,

Murray Aitken
Senior Vice President
Healthcare Insight
IMS Health

Change on the U.S. Healthcare Agenda

U.S. President Barack Obama made healthcare reform a major plank in his campaign platform. Below is a snapshot of his proposals and our thoughts on the implications for the pharmaceutical industry, given his early days in office.

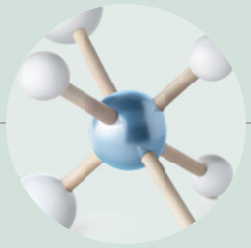
Area	Campaign Position	Implication
Healthcare Coverage	Require all children to have health insurance; expand Medicaid and SCHIP[1]; provide subsidies to help individuals buy insurance; create National Health Insurance Exchange.	Would expand demand for preventative care medications and increase government role in providing healthcare.
Medicare Prescription Drug Coverage	Repeal the ban preventing direct negotiation between the government and drug manufacturers; close the gap in coverage (the "doughnut hole").	Only possible with extensive re-writing of the Medicare legislation. Congress recognizes that the program's beneficiaries view it as highly successful as it is and may not be eager to tamper with it.
Drug Reimportation	Allow the reimportation of drugs, provided they are safe and cost less.	Must overcome a major hurdle in that the Department of Health and Human Services (the HHS) has to verify that the safety of the drug supply could be maintained. The FDA already has a full agenda.
Biosimilars	Provide a legislative pathway for the FDA to approve generic biologics and establish the shortest possible period of market exclusivity for original drugs.	Will be further stalled by the FDA's scientific concerns about immunogenicity related to biologics, even if an approval pathway is clarified. The appropriate length of exclusivity for the original brand will be a source of great debate and will have a clear and immediate impact on originators.
Comparative Effectiveness	Establish an independent institute to guide reviews and research on comparative effectiveness.	Has the potential to be a significant move toward Health Technology Assessment at a national level and would have a major impact on drug usage and the value of medicines—particularly if the research is to take into account cost comparisons as well as clinical comparisons.

[1] On his 16th day in office, President Obama signed legislation to expand the State Children's Health Insurance Program, providing coverage for an additional four million children.

Area	Campaign Position	Implication
Health Information Technology	Invest $50 billion in e-medical records and other health IT initiatives.	Would boost the slow advances in health IT, potentially increasing the flow of information. Expectations are high that this would result in significant system savings in the short term, though capturing these will be challenging.
Transparency	Require transparency in the quality and cost of services from hospitals, providers and health plans.	Represents a further push toward evidence-based medicine and improved compliance with clinical guidelines, including appropriate use of pharmacotherapies.
Scientific Innovation	Double federal budgets for basic research over 10 years and for cancer research over five years.	Could provide important support for basic research that would flow into the private sector, although the impact may not be seen for 10 to 20 years.
Generics	Prohibit generic drug manufacturers from accepting "reverse payments" from brand manufacturers in exchange for keeping generics off the market.	May result in some generics entering the market earlier.

Some, clearly, have the potential to increase demand for pharmaceuticals, while others could make life considerably more difficult for manufacturers. It is important to remember that pharmaceutical costs are growing more slowly than other sectors of healthcare and that pharmaceuticals are only a small portion of the total healthcare budget (10 percent as of 2006) to begin with. Thus, they may not be the highest priority on a legislative agenda, although historically, the industry has been an "easy target" for criticism.

MARKET DYNAMICS



MYTH BUSTING: Is the Industry Still Recession-Proof?

THE CONVENTIONAL WISDOM THAT THE PHARMACEUTICAL MARKET IS "RECESSION-PROOF" is a holdover from previous recessions when the global pharmaceutical market maintained growth in the high single-digits, and the U.S. market managed double-digits. But, is that notion still valid today when the market is achieving only 1–2 percent growth in the U.S. and 4–5 percent growth in other mature markets such as the top five in Europe?[1] The current global recession is hitting the industry when it is already under pressure from structural and environmental issues that include mounting patent expiries, declining numbers and contribution from new products, and payers increasingly questioning the value of medicines.

More to the point, to what extent will the present economic crisis impact pharmaceutical growth? IMS recently sought to answer that question for the eight mature and seven pharmerging markets around the world.[2]

[1] IMS Market Prognosis, Sep 2008, % Growth constant US$ forecast in 2008.

[2] Eight mature markets (U.S., Japan, Germany, France, Italy, Spain, U.K., Canada) and seven pharmerging markets (China, India, Brazil, Mexico, Russia, Turkey, South Korea).

Sensitivity Training

In our *2009 Forecast* (released in October of 2008 and based on assumptions from June 2008), we foresaw that the pharmaceutical market in these 15 countries would grow by 4–5 percent in 2009. This would be essentially the same rate of growth as in the *2008 Global Forecast*. In advance of our April update of this forecast, we've analyzed the sensitivity of each of these markets, indicating likely response to the changing economic outlook. These countries, which together represent 84 percent of the global market,[3] provide a clear indication of the economy's impact on the pharmaceutical market as a whole. To clarify, our sensitivity analysis is not a revision of our *2009 Forecast*, but rather focuses on the implications of the changing economic conditions.

Although the situation is extremely volatile, we had to base our assessment on a specific point in time, and so we selected December 2008. The scale of the economic crisis that has become apparent in the short period between June 2008 (when we made our *2009 Forecast* assumptions) and December 2008 is unprecedented, with nearly all of the markets experiencing significant revisions to GDP. *(See Figs. 1 and 2.)* Indeed, expectations of economic growth have been revised sharply downward in all 15 markets we assessed.

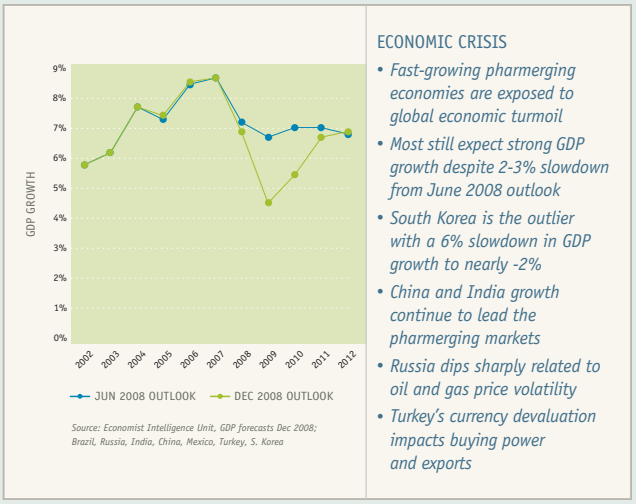
A key component of our forecasts has always been the historical correlation between macroeconomic factors — such as GDP, employment, consumer spending and government spending — and pharmaceutical market growth. These correlations

[3] *IMS Market Prognosis, Sep 2008, % Market share US$ forecast in 2009.*

Figure 1: *GDP Growth Forecasts in 8 Mature Markets*

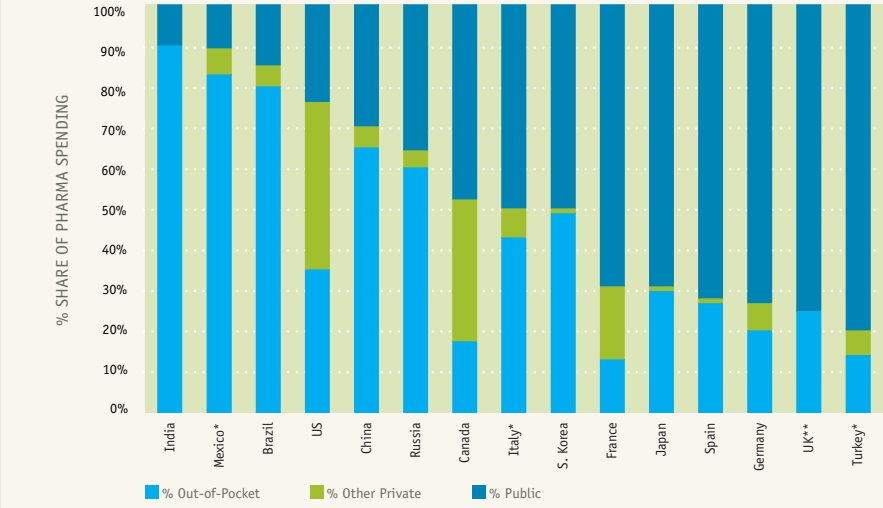
GDP growth forecasts reflect a deep downturn through 2009 and 2010 in major markets.

Figure 2: *GDP Growth Forecasts in 7 Pharmerging Markets*



Most pharmerging economies expect more robust growth, with key exceptions: South Korea and Russia.

Figure 3: *Total Pharmaceutical Spend by Payer*



*Source: OECD 2008; WHO 2008; Canada, CIHI 2007. *Estimated from available sources. **OOP vs. other private not available.*

The relative importance of funding sources within each market impacts patient and policy responses.

explain much, but not all, of the short-term impact; a more detailed look at the environmental factors in each pharmaceutical market reveals fault lines that will be of greater significance than can be determined through a purely historical analysis. By adding into the mix the changing expectations for macroeconomic growth over the next five years, we are able to determine a net sensitivity to the changes in the macroeconomic outlook.

Due to the ongoing degree of economic change, the results of our analysis may not represent the final outlook when all is said and done, but our work does address the immediate need to understand the scale of risk the industry faces and to develop necessary action plans in response.

Lowered Expectations

On the basis of our recent analysis, we estimate that the global pharmaceutical growth rate for 2009 will be 1 percent lower than previously forecasted. In percentage terms, the impact is much less severe than in other industries, some of which are near collapse. Yet, because of the scale and essential nature of most healthcare spending, the impact will not be trivial in absolute terms.

At a market level, however, we expect significant variations in the amount of impact, as each market will be influenced by a combination of patient and policy responses. The relative proportion of the cash-pay/out-of-pocket market will have a bearing in the near future. *(See Fig.3.)* Other key factors

include the relative price of pharmaceuticals across countries and in comparison to other necessary goods. Additionally, the significance of specific industries (such as automobiles, exports or consumer electronics) to a national economy may temper the urgency of policy responses. In the short term, we expect policy solutions to be applied primarily in those countries with pre-existing budget challenges, or where reforms were in progress and may have been brought forward in light of the crisis. In the longer term, changes in GDP and tax revenues will influence policymakers and may compromise their willingness to fund healthcare expansion, particularly if the global crisis deepens or becomes protracted.

The credit crisis and economic downturn will not have a uniform effect around the world. While all countries expect a slowdown in healthcare spending this year, the rate of that slowdown varies greatly. At one end of the spectrum are countries such as Japan, Germany and Spain, where market sensitivity to the economy is relatively low. That's the case either because these countries are seeing a more modest impact on their economies so far or because their pharmaceutical markets are somewhat insulated given the level of government funding. The highest sensitivity to the economic crisis is found in Turkey and Russia, two countries experiencing severe currency and commodity price fluctuations.

Generally, markets where patients are responsible for a bigger share of out-of-pocket expenses are likely to see a more immediate drag on pharmaceutical market growth. The U.S. is a good example, where patients are responding to the downturn by being more cautious in their healthcare spending. And the expected increase in the number of uninsured will surely amplify this trend.

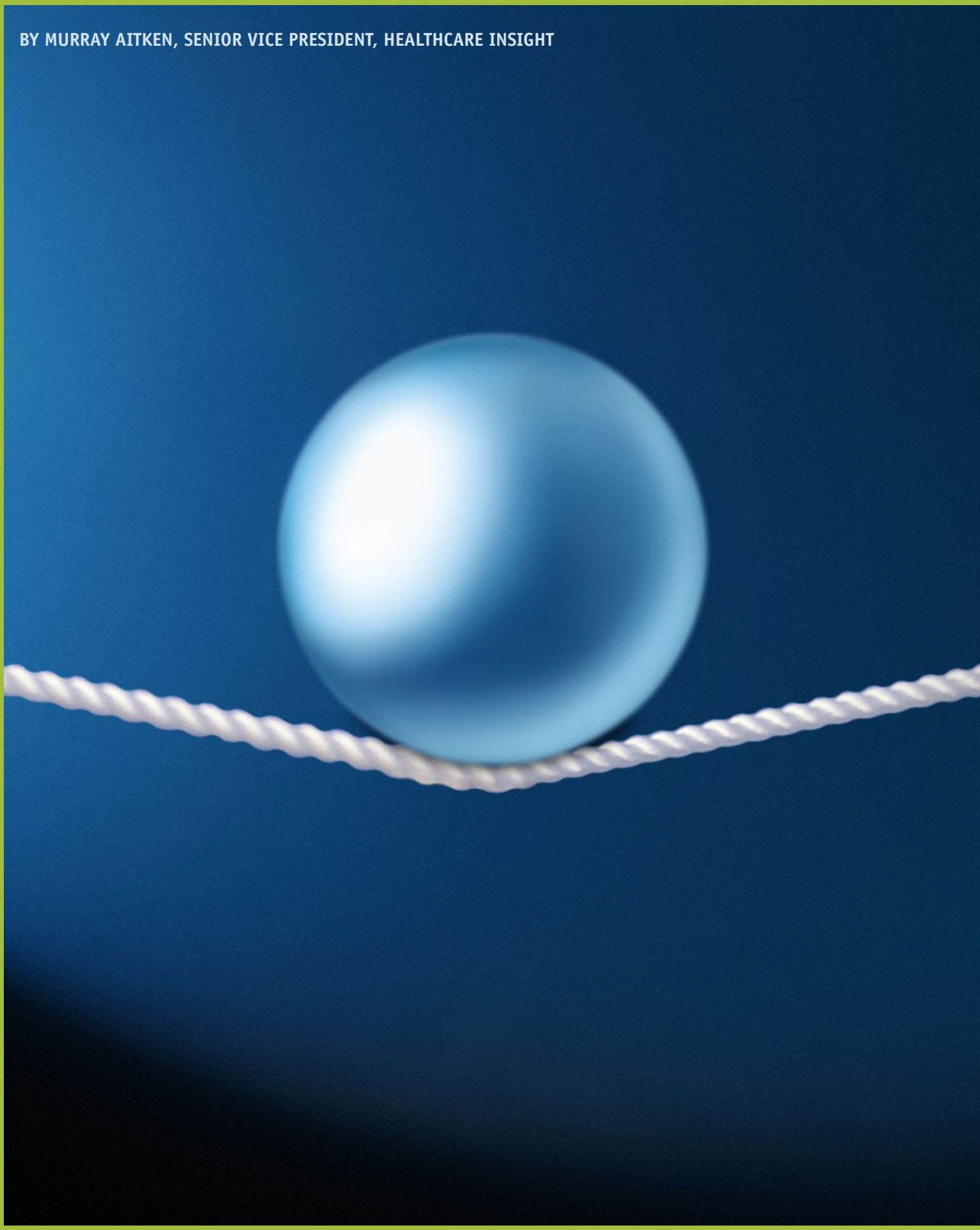
The Real Challenge

In a general sense, the old view that the pharmaceutical industry is recession-proof no longer applies; pharmaceuticals *do* have some exposure to the economic crisis. Yet, there is a silver lining: considering the scale of the crisis in the broader economy, the impact on the pharmaceutical market is relatively limited.

This news does little to address the existing challenging environment in the pharmaceutical market itself, and in order to succeed in these dynamic times, pharmaceutical companies will need to do more than simply understand the economy's impact. Success will depend on how well they adapt to the changing needs of patients, payers, governments and doctors as well as their commercial partners in R&D, production and distribution. There is also a clear need to reassess the assumptions that underlie many basic tactical and strategic decisions. The first step to addressing these issues will be to understand the problem.

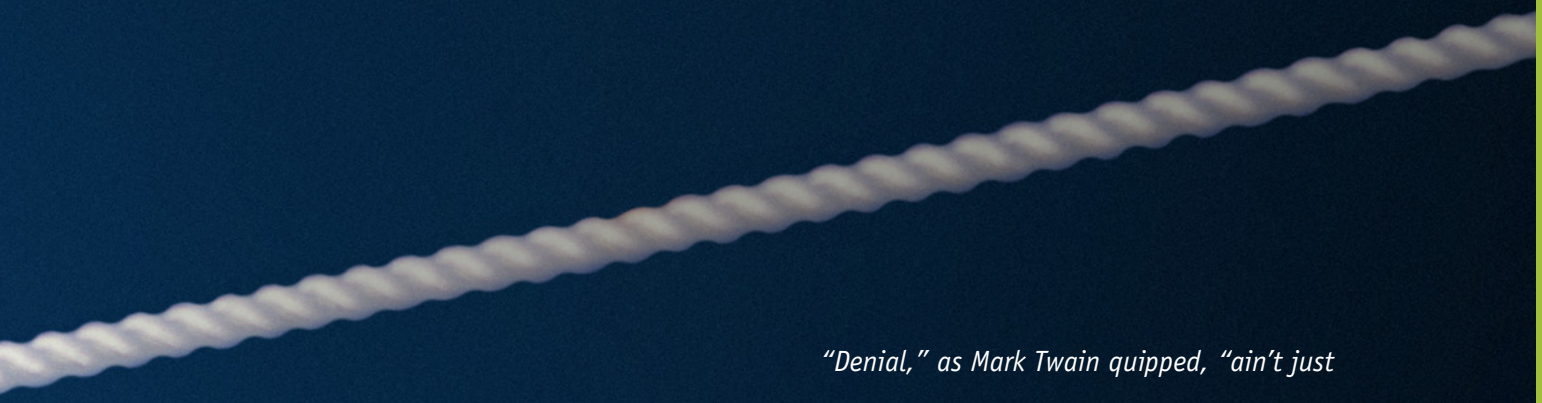
For more detailed information on the impact of the economy on the global pharmaceutical market, please contact your IMS account representative.

BY MURRAY AITKEN, SENIOR VICE PRESIDENT, HEALTHCARE INSIGHT



THE 2009 LANDSCAPE:

BALANCING FIVE BUSINESS IMPERATIVES



"Denial," as Mark Twain quipped, "ain't just a river in Egypt." According to the Mayo Clinic, it's an "unconscious coping mechanism that grants you time to adjust to a distressing situation." But—of course there's a "but"—it cannot go on too long, or it becomes an unhealthy response that prevents further action and progress. One could argue that there is no place (or time) for denial in business. Certainly, pharmaceutical manufacturers should not linger in the river of denial now.

2009 Market Conditions

The *2009 IMS Global Pharmaceutical Forecast* suggests that the market of the near future will be characterized by conditions that have been building for the past few years:

Slowing growth in mature markets, including extraordinarily low growth in the U.S. The top eight mature markets — including the U.S., Japan, Canada and the top five European markets — comprised 75 percent of world market growth in 2000, but will contribute slightly less than a third of all pharmaceutical growth in 2009.

High growth in "pharmerging" markets. China, Brazil, India, South Korea, Mexico, Turkey and Russia will remain dynamic markets where we will see mostly double-digit growth. Collectively, these markets contribute about a third of the total global market growth.

A smaller contribution from new products. Several new products that launched in 2006 continue to yield very strong growth; however, the products introduced since then are contributing very modest growth. This relates not to the absolute number of launches, which has leveled out, but to the fact that many are niche products, contributing to both lower initial sales and slower uptake which is impacting growth rates.

Lost value from patent expirations. We have seen about $18 billion in products lose their market exclusivity in 2008, and we'll see another $24 billion this year. What is more, biosimilars are starting to gain traction in some European markets. And in both the U.S. and the E.U., intense competition among generic manufacturers is resulting in a decline in market growth in dollar terms, even though volume growth is substantial.

Intensified involvement of payers and health technology assessors. Markets are increasingly defined by the extent to which payers are dictating protocols and imposing cost-containment measures. This is a global phenomenon and not entirely new, but it becomes more intense with each year.

Better science applied to risk/benefit decisions by regulatory bodies. Regulators are applying better science and a better understanding of the way drugs are being used in the real world to assessing product risks and benefits.

A tenuous macroeconomic environment. Consumer demand for healthcare, including pharmaceuticals, is broadly correlated with GDP growth. As economic forecasts become bleaker, it is clear that the need to articulate the value that medicines bring to patients, payers, health systems and society in general has never been greater.

The Implications for Manufacturers

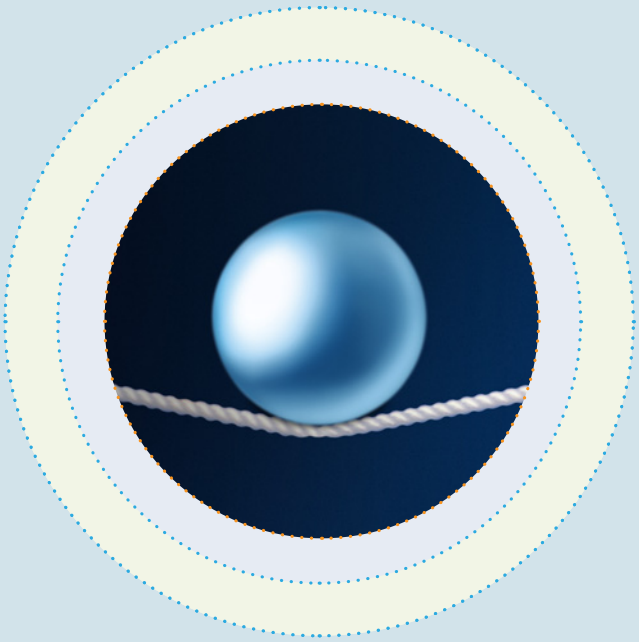
What will this mean for pharmaceutical companies? While companies can create opportunities through their response to the changing environment, these conditions, by and large, portend tougher times for manufacturers. In broad terms, the implications are:

- Less growth and lower profitability from U.S. operations. For companies having the majority of their business interests in this country, this will be a jolting change.

"Market conditions, by and large, portend tougher times for manufacturers."

- For those companies with a global footprint, more growth — and potentially more profit — from other markets, including the "pharmerging" markets.
- More growth from specialty therapy areas, with the general decline of the primary-care sector.
- Higher stakes for product launches and brand performance. Since there are fewer launches and fewer brands driving growth, more hangs in the balance with each one.
- Greater risk in the R&D pipeline. Companies face greater uncertainty about what it will take to get approval from regulators, the endorsement of health technology assessment agencies and acceptance from physicians and patients.

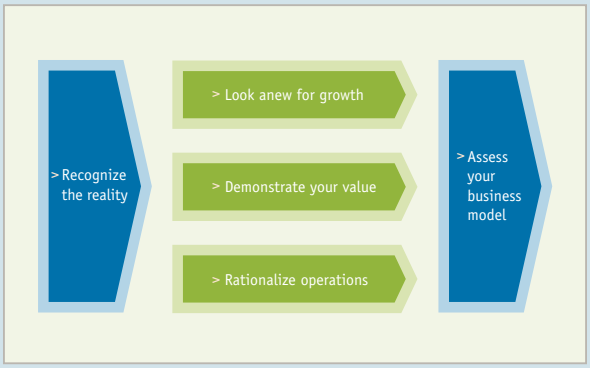
Each of these conditions contributes to more uncertainty and volatility in the market. Change can be upon us almost overnight with sudden pricing policy shifts in countries such as Germany, the U.K. and Italy; the unexpected discovery of safety issues; or economic shifts.



Hope Is Not a Strategy

If the next few years were to come with a survival guide, we would expect there to be a chapter on each of the following business imperatives. These represent broad directions that should figure into every company's "to do" list, but are certainly not all-inclusive.

Figure 1: *A Five-Point Agenda*



These five undertakings are essential for any company wishing to seize the opportunities that exist, despite an altered market reality.

The first imperative is to face reality squarely in the eye. To remain competitive, you need a sharper understanding of what is happening and a keener sense of how the future is likely to unfold. This may mean refreshing your forecasts to build-in more event-based variables than in the past. It may mean creating a new forecast for a given product, starting with a bottom-up assessment of patient demand. Or, it may mean planning for scenarios in which the bars for regulatory and reimbursement approval are set at previously unimagined heights.

The key point is that you mustn't assume that things will continue as they are, or that the current hurdles you face will be lowered or removed. Recognize the reality, and take a disciplined approach to thinking through what it means for you and your company.

Second, look for double-digit growth…just not necessarily in the places you've found it before. It may be in an emerging market, or it may be in a segment of the U.S. market that can only be recognized by understanding patient flows and the dynamic (rather than the static) part of the market. It may be found in a positioning that is tailored to a patient segment's perception of side effects — a viewpoint that may differ from that of a regulator or physician.

The good news is that we still see plenty of double-digit growth when we measure sub-segments of therapy areas, patients, physicians and country markets. However, finding it and claiming it will require some new approaches and creative thinking. Don't assume that you will find it by doing the same things the same old way.

Third, demonstrate the value of your products… and communicate it effectively to payers, physicians, patients and to all other stakeholders. To pay this more than lip service (which many companies are still doing), you must know what health outcomes and economic benefits each of your products brings to your patients, employers and payers. And it means being able to articulate the benefits and the risks or costs associated with a drug in ways that are credible with the audience and based on real-world data.

"You mustn't assume that things will continue as they are, or that current hurdles will be lowered."

Fourth, rationalize operations. There is a growing urgency to cutting excess costs from multiple areas of the business — in manufacturing, distribution, sales and marketing. Although every company has made efforts to improve productivity and its return on investment, there is still much to be done. Many improvements can be made by better using information and analytics to make decisions, and by seeing that those decisions actually are implemented.

Part of the rationalization of operations involves freeing up spending in one area of the business so that it can be allocated to another area. There are indeed significant shifts in spending that need to be tackled in order to react to the trends and market dynamics covered above.

Lastly, assess your business model. Is it really sustainable in the longer term? Does your company need a fundamental change or further incremental change? Consider the very business that you are in, not merely how you go about performing that business. To evaluate your business model, you should assess the landscape of the future, pressure-test today's model against that, build the case for change when it is warranted, list and explore the possible options and design the road map that will take you where you want to go.

These five undertakings are essential for any company wishing to seize the opportunities that do exist. And remember, there are ample reasons for manufacturers to be encouraged. The global pharmaceutical market continues to grow; in absolute terms, $30–40 billion of value is added each year. Medicines are becoming more important, not less, and the unmet medical needs around the world remain very substantial; patient needs are not going to be exhausted anytime soon.

Visit the Viewpoints section of our website at http://imshealth.com/viewpoints to access additional information about our 2009 global pharmaceutical market forecast.

BY PAM SAUERWALD, GENERAL MANAGER, SPECIALTY OFFERINGS

In 2005, we covered the emergence of home healthcare providers in Europe in a Harbinger of Change. In the intervening years, various distribution channels for specialty products have entered the scene in Europe and, at the same time, have become quite sophisticated with discrete business models in the U.S. The attributes of specialty products that have inspired these new channels and business models — and indeed the new channels themselves — make specialty products very difficult to measure through standard, traditional means. For this reason, IMS is developing new solutions to do so. We must, however, begin with a common understanding of just what specialty pharmaceuticals are, and are not.

A DEFINING MOMENT:

CHARACTERIZING SPECIALTY PHARMACEUTICALS

Definitions can be tricky. Just ask the International Astronomical Union, which in 2006 voted on the criteria required for a celestial object to qualify as a planet. After much debate, the group agreed upon three criteria, with the immediate result being that Pluto lost the planetary status it had held for 75 years — a change that still rankles many.

In a more earthbound example, the challenge of defining a specialty pharmaceutical has also spurred debate. What makes a product a specialty product has been a matter of opinion until now, a situation that was bound to pose problems with the category growing in importance and the creation of new market measures.

Ideally, the industry, like the Astronomical Union, will embrace a definitive new description, authored by IMS, to help drive a globally consistent understanding of this critical sector of the market.

A Stake in the Ground

So, just what is a specialty pharmaceutical product? We developed a working global definition that has, in fact, been affirmed by both the Pharmaceutical Business Intelligence Research Group (PBIRG) and the European Pharmaceutical Market Research Association (EphMRA). We've also reviewed it with clients in individual meetings and through a workshop at our annual client conference and have been gaining consensus. Our working definition is rapidly becoming validated.

Based on our research, we are defining specialty products as those having at least five of the following eight attributes:

- Targets and treats specific, characteristically chronic, often rare conditions.
- Initiated only by a specialist.
- Generally not taken orally (but rather are administered through injection).
- Requires special handling (e.g., maintaining a cold chain).
- Unique distribution management, administration and/or paperwork.
- Very expensive, ranging from $6,000 to $750,000 a year.
- May warrant intensive patient supervision and counseling to ensure compliance.
- Patients may require assistance in securing reimbursement.

The last two attributes are more U.S.-centric than the first six. Individual therapies may have exceptions to up to three of these qualifications and still be classified as specialty products. *Figure 1* is a snapshot of how various therapeutic categories fit the definition.

The Broad View

Specialty products are typically, but not exclusively, produced through biotechnology. They treat such conditions as:

- Cancer
- Crohn's disease
- Cystic fibrosis
- Gaucher's
- Growth hormone deficiency
- Hemophilia
- Hepatitis C
- Immune deficiency
- Infertility
- Multiple sclerosis
- Pulmonary hypertension
- Rheumatoid arthritis

Products in these areas are driving market growth and dominating pipelines. We've seen a surge in their growth since 2003, and at this point, sales for specialty products are growing at twice the rate of the rest of the market. The global market, with sales of $59 billion in 2007, is expected to near $98 billion by 2011. Currently, there are over 600 specialty medications under development.

Figure 1: *Sample Therapeutic Categories Across Specialty Criteria*

ATTRIBUTE / CATEGORY	Biotech	Parenteral Admin	Patient Monitoring & Education	Chronic Condition	Specialist-Initiated	Special Handling (e.g., Cold Chain)	Expensive ($6K–$750K Annually)	Unique Distribution
Oncology Drugs	And small molecule	Oral and IV	■	■	■	Only for bio	■	■
Auto-Immune Agents (Biologics)	■	■	■	■	■	■	■	■
Immunomodulators (Hep C, MS)	■	■	■	■	■	■	■	■
Anti-Virals (HIV Drugs)	■		■	■	■	May not be for oral	■	■
Erythropoietins	■	■	■	■	■	■		
Infertility	■	■	■	■	■	■	■	■
Growth Hormones	■	■	■	■	■	■	■	
Hemophilia	■	■	■	■	■	■	■	■
Gaucher's		■	■	■	■	■	■	■
Pulmonary Arterial Hypertension	■	■	■	■	■	■	■	■

■ = *Priorities*

Products must meet at least five of these objective criteria to be classified as specialty products.

Like Nailing Gelatin to the Wall

Specialty products are notoriously difficult to measure — even in the simplest terms of tracking product volume — for multiple reasons:

- They are sold in low volumes so they are hard to find in the distribution system.
- They require special handling, such as the maintenance of a cold chain, so are distributed narrowly.
- They have limited therapeutic windows and high-risk profiles so specialists must initiate treatment and often also maintain these patients.
- Because many are administered parenterally (sub-cutaneous, intramuscular or infused), they are often administered in select settings such as hospitals, doctors' offices or clinics rather than dispensed at the corner drugstore.
- Product distribution differs by channel and by geography, so it is challenging to collect the same data types for each product and from every country.
- In the U.S., there has been some jockeying as to what benefit covers these products. There's been, and will continue to be, some back and forth between covering specialty products under medical benefits and pharmacy benefits. It is important to understand what is included in both benefit types to have a complete picture.

In the U.S., a new business model has evolved since the late 1990s to accommodate the unique attributes of these products. Many Specialty Pharmacy Providers have developed within the major Pharmacy Benefit

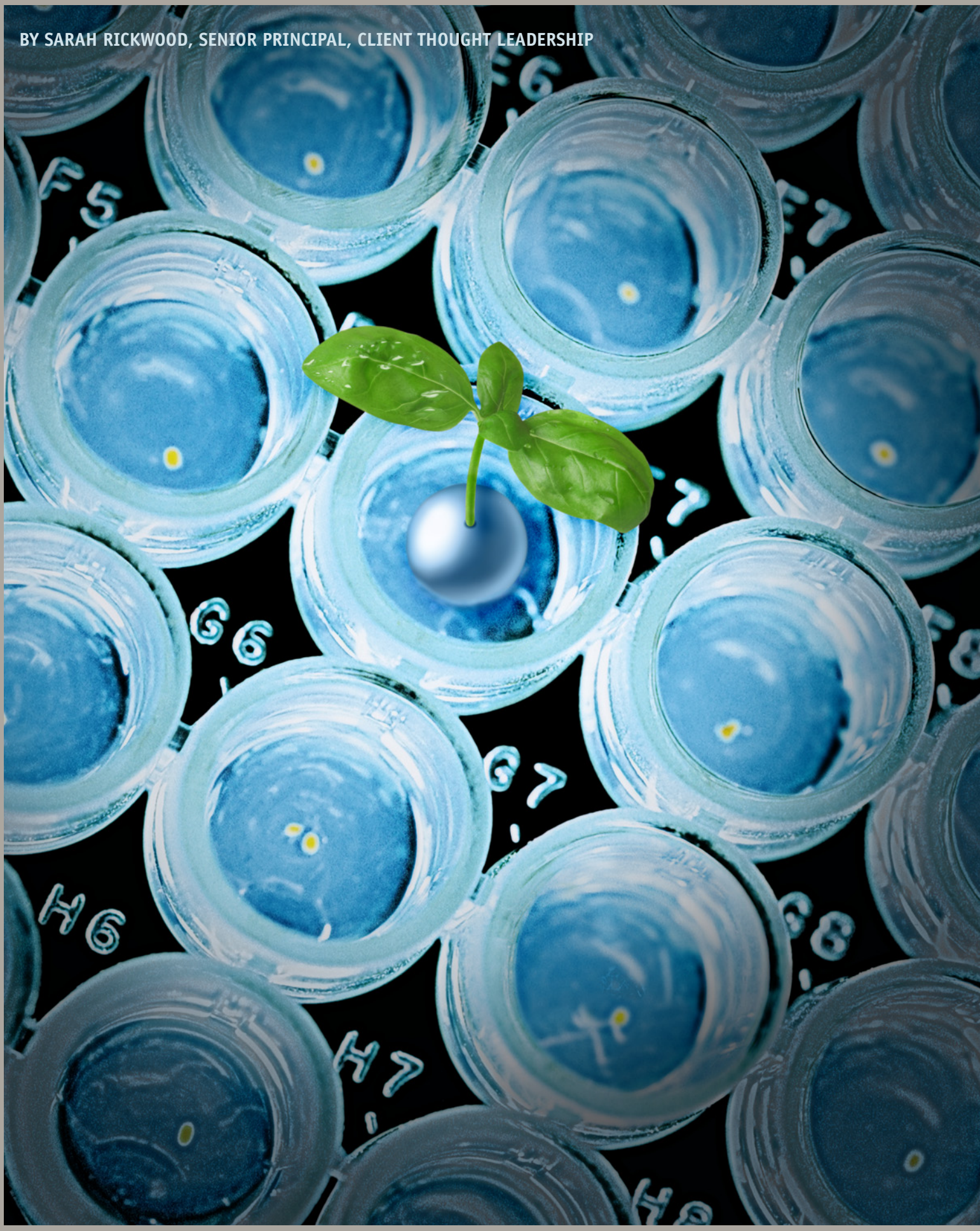
Managers (PBMs) as an extension of their mail service facilities. Still others have sprung up and then quickly aligned themselves with PBMs or major retailers. They deliver products to infusion centers, doctors' offices, ambulatory facilities and even homes, where home healthcare professionals administer the product.

"Manufacturers need to be able to quantify sales by indication and to access treatment pathways, best practices and prescribing dynamics."

Many of these products are like Swiss Army knives: they are indicated for multiple disease states. It is clear that manufacturers need to be able to quantify sales by indication as well as to assess treatment pathways, best practices and prescribing dynamics. The solution will require combining multiple sources of data and insight from across a continuum of capabilities.

Editor's Note: IMS is developing new services both in the U.S. and in the top five European markets as part of its "New Models, New Metrics" program. The services will combine a variety of data sources to provide sales measures by indication and even, where possible, insights gained from case management practices. Watch for more details soon.

BY SARAH RICKWOOD, SENIOR PRINCIPAL, CLIENT THOUGHT LEADERSHIP



In our IMS Launch Excellence™ study of 2007, we identified the four key drivers of launch excellence and which of the 4,000 launches we studied were truly outstanding. As a next step, we undertook fresh research in 2008 to understand the macro trends that are shaping the environment for all launches. Our latest IMS Launch Excellence™ study further explores an updated set of high-performing launches in their market context.

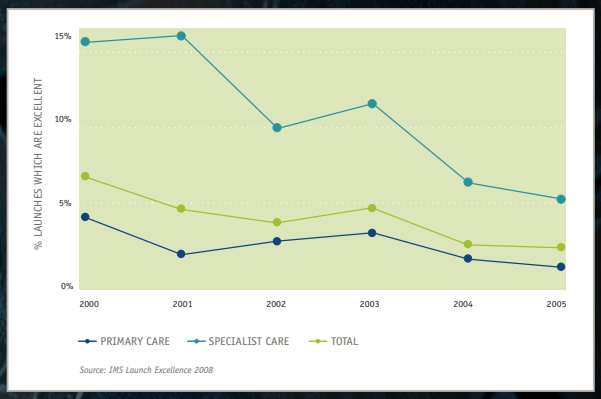
IN PURSUIT OF LAUNCH EXCELLENCE:

STUDY REVEALS THE BEST RESPONSE TO NEW PRESSURES, NEW INFLUENCERS

Excellence Is Elusive

In all, we identified only 21 products out of 3,081 that met our criteria (see our Study Methodology) for excellence — down from 35 in our earlier study. *(See Fig. 1.)* And, the number of excellent launches has dropped in percentage terms as well. Of all products first launched in 2000, 6.4 percent achieved excellence, while only 2.1 percent of those first launched in 2005 (and evaluated through 2007) did. Even among specialist-led products, the percentage achieving excellence has dropped to a third of its 2000 level. Among primary care launches, the 2005 level is less than a quarter of the 2000 level.

Figure 1: *Launch Excellence Trends*



Specialist care launches outperform primary care launches.

In comparing the excellent launches examined in the two studies, we found that in both cases:

- A minority of excellent launches had any claim to be first to market. In other words, excellent launches succeed even when the markets they enter are highly competitive.
- The majority of excellent launches are specialist-led, and the balance has shifted even more in that direction. In 2008, 62 percent of excellent launches were directed to specialists, compared to 51 percent in 2007.

Interestingly, only two of the excellent launches in our latest study gained the highest ratings by the French Transparency Commission, the body that evaluates therapies before they are priced for the French market, compared to one-third in the earlier study, which covered launches from the late 1990s to the early 2000s. It would seem that at least one advisory body to payers sees little significant pharmacotherapeutic advance deriving from our excellent launches (perhaps because most of the innovation has happened in the oncology sector).

The Launch Environment Is Fundamentally Different

Companies planning for launch must take as their starting point the fact that they are in a different environment, with different customers, different approaches to the market and a different timescale for securing their success. Our research revealed four characteristics of this altered state:

Payers rule. Payers are now the most important audience for a launch — their decision-making power outweighs that of prescribers in five out of the eight study countries, including, for the first time, the U.S.

Generics have relegated primary care products to second-line therapy. Once reasonably effective generic therapies are available, they dominate first-line treatment. Increasingly, although newly launched products in the primary care space are indicated for first-line use, they become second-line therapies in practice. Specialist-driven categories are not immune to this as soon as one product in a given class is genericized.

Consequently, market forces are naturally restricting market potential. One primary objective of future launches will be to adopt strategies that combine segment definition with market expansion to counter the constrained environment.

The launch window slams shut after six short months. This short window of opportunity still very much exists, and maximizing this now requires that companies address the right stakeholders in the right sequence. Early new-to-brand prescription (NBRx) share (the share of prescriptions for therapy-naive patients, those who are switched to the brand, plus those who are adding the brand to their existing therapy) correlates so strongly with later total prescription share that product performance can be predicted highly accurately after just three months on the market.

Thus, we foresee that the companies with excellent launches in the next decade will be those that:

- Develop a state-of-the-art approach to payers that demonstrates an understanding of their needs

and clarifies the value they will receive...while not losing sight of the role of the prescriber.

- Accept riskier research targets, invest more in R&D and prove the cost effectiveness and longer-term benefits of their new products over existing therapies.
- Segment, penetrate and expand markets. A first-line, every-patient-going approach is often no longer realistic and at times must give way to targeting more finite patient segments for whom payers will acknowledge a benefit. Most excellent launches then rely on at least one of five proven strategies for expanding their markets.
- Apply a systematic process to launch readiness and "put their best foot forward" investing more, earlier, in the preparation of the product, both at international and country levels, than has ever been the case before. This should be as early as 30 months pre-launch at the local level.

We are convinced that there will still be excellent launches in the future, but are equally certain that the rules they will play by will be very different. A confluence of forces — from crowding in mature markets to generic penetration and payer policies — means that companies need to take a hard look at their launch plans and challenge the status quo. The blueprint they used to introduce new products successfully even a few years ago will no longer work.

To receive a copy of the full IMS Launch Excellence™ study, "Launch in a Fundamentally Altered Environment," email us at launchexcellence@us.imshealth.com.

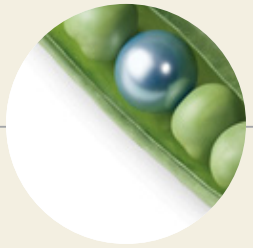
Our Study Methodology

The new IMS Launch Excellence™ analysis drew upon IMS MIDAS® sales and promotional data from the U.S., Japan, France, Germany, Italy, the U.K., Spain and Canada, which together represent 74 percent of global pharmaceutical sales.

We studied 3,081 products from 64 therapy areas that entered the office-based market between 2000 and 2005 and followed the market performance of each for two years, so that we tracked performance on the latest launches to the end of 2007. Of the total, 77 percent were primary-care-driven and 23 percent were specialist-driven.

We followed the same methodology as in 2007, so we were able to compare the results against our earlier analysis of over 4,000 products launched in the same countries between 1997 and 2004.

To make the cut and be considered "excellent," launches had to meet three criteria in at least two of the eight countries we covered: a steep, initial penetration curve; market-share leadership within two years; and an above-average market-share return for their promotional investment.



MEETING THE NEEDS OF "PATIENTS IN PLAY"

By Rob Harold, Senior Principal, Client Thought Leadership

PIONEERING MERCHANT JOHN WANAMAKER famously acknowledged that half the money he spent on advertising was wasted, but the trouble was that he didn't know *which* half. Any company, including pharmaceutical manufacturers, can have the same blind spot. IMS undertook an analysis of Brand Excellence across 10 chronic therapy areas in the U.S. and discovered that Wanamaker's predicament was mirrored in the pharmaceutical industry, but that in this case, it *is* possible to know which promotional resources are being wasted.

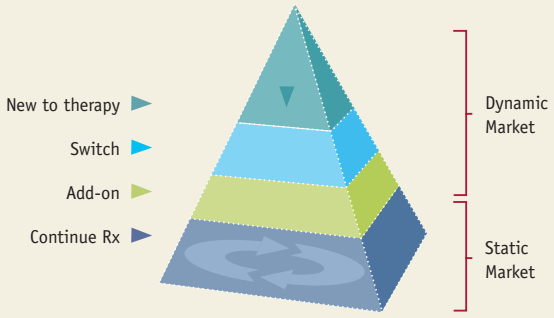
Brand Excellence Study Details

We started our study of Brand Excellence with the hypothesis that there are inefficiencies in the pharmaceutical industry's method of identifying opportunities to meet the needs of patients and prescribers. Traditionally, companies used counts of total (TRx) and new (NRx) prescriptions in selecting physicians for promotion. However, now companies have the ability to identify the number and type of patients making up the dynamic market. The dynamic market represents the portion of prescriptions coming from patients new to a given therapy, switched to that medication or receiving that medication in addition to another treatment for the same condition — all of which we call New-to-Brand prescriptions (NBRx). Logically, this is the portion of the market that is actually in play as physicians make prescribing decisions; the remainder of the market is static, consisting of prescriptions that continue existing therapy. *(See Fig.1.)*

We analyzed over 50 brands from 10 chronic therapy areas,[1] taking care to include a mix of symptomatic and asymptomatic conditions as well as therapies driven by specialists and primary-care physicians. Our goal was to reflect a variety of patient flows and reasons that would cause a patient to present for treatment. Our data sources reported national prescription volumes and physician-level prescribing volumes, both infused with anonymized patient-level data (APLD), as well as physician-level promotional efforts in contacts and samples. Our study captured results for one year, from the third quarter, 2007 through the second quarter, 2008.

[1] *Anti-depressants, Anti-psychotics, Alzheimer's, Benign Prostatic Hypertrophy, Cholesterol Reducers, Diabetes, Hypertension, Overactive Bladder, Osteoporosis, Proton Pump Inhibitors.*

Figure 1: *The Dynamic Market*



Focusing on a different framework provides for a more comprehensive view of market dynamics.

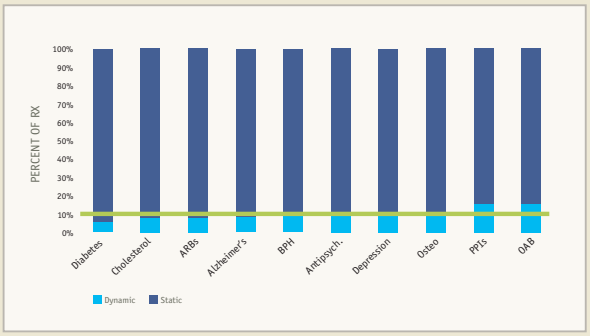
A Patient-Centric Look at the Market

Through our analysis, we established three fundamental facts about the makeup of these 10 markets:

- Over a one-year period, approximately one-third of all treated patients make up the dynamic market while two-thirds of treated patients remain in the static market.
- On average, the dynamic market is made up of approximately 10 percent of all prescriptions while refill prescriptions account for 90 percent of all prescriptions. As shown in *Figures 2 and 3*, these findings were generally consistent across the classes.
- Within the dynamic market, 60 percent of prescriptions were written for patients who were new to therapy, 30 percent for patients who switched treatments and 10 percent for patients who were prescribed add-on therapies. *(See Fig. 4.)*

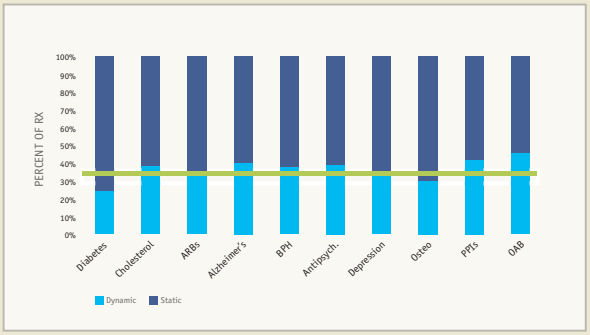
Primary research should be undertaken to further understand the reasons as to why patients enter the dynamic market.

Figure 2: *Percent of Prescriptions, Dynamic vs. Static Markets*



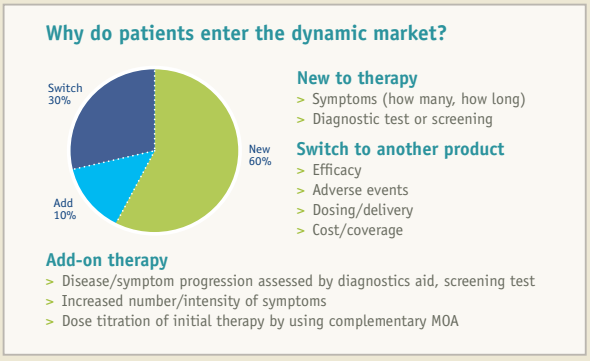
The dynamic market contributes only 10 percent of total prescription volume.

Figure 3: *Percent of Patients, Dynamic vs. Static Markets*



One-third of all patients are in the dynamic market.

Figure 4: *Dynamic Market Breakdown*



There are many potential reasons as to why patients enter the dynamic market.

Patients New to Therapy

For instance, patients could be new to therapy because they've been experiencing symptoms, or they could be asymptomatic but newly diagnosed through a diagnostic or screening test. With insight into how patients are being diagnosed and why treatment is being initiated, companies can hone their message and approach to both physicians and patients.

Patients Switching Therapy

We surmise that only rarely would a physician spontaneously change a patient's treatment without reason. Therefore, it is important to understand what triggers a switch in a patient's therapy. How often is it because patients have complained to their physician that their current product isn't working or that their symptoms have progressed? How often is it related to dosing or delivery or to other adverse events. Lastly, how often is a switch made simply due to cost (price or copay amounts)?

Patients Prescribed Add-On Therapy

And, too, companies should delve into the situations where a patient is prescribed a therapy addition. Has the patient's condition worsened or has a specific goal been missed? What other products are the patients taking?

Patients in the Static Market

When it comes to the static market, companies should not assume that all patients are satisfied with their existing treatment. There may be a great many people whose condition is not as well controlled due to non-adherence or disease progression. A subset of these patients may be mobilized with greater knowledge of the disease and its progression and if a more convenient or less expensive type of therapy were available.

The point is that not all patients are the same in terms of what propels them into the dynamic market. And the more you are able to understand the separate segments of the market, the better job you can do of adding value by meeting their needs and offering appropriate patient and physician education.

The Crossroads of Physician and Patient Dynamics

The real eye-opener in our Brand Excellence analysis came, however, when we looked at the physician sources of new-to-brand prescriptions (NBRx). We found, astonishingly, that across these 10 chronic therapy areas, only *5 percent of prescribers generated 50 percent of all new-to-brand prescription activity in the dynamic market*. The old "80/20 rule" has given way to a new "50/5 rule."

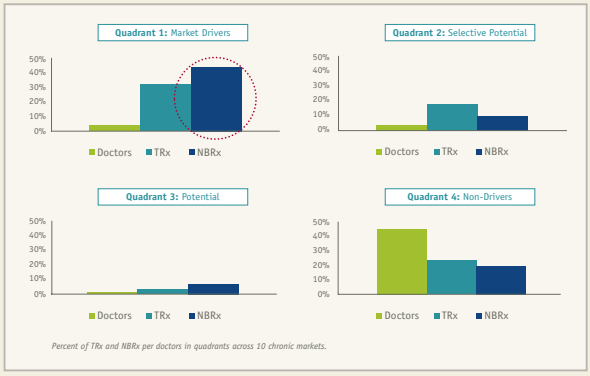
This finding prompted us to investigate where these "dynamic prescribers" were. To determine this, we first overlaid details of physicians' total prescription volume decile (which most companies use to allocate their promotional resources across prescribers) with their NBRx decile. In the cholesterol market, for example, we found that while 4,336 physicians were in the top decile by total prescription volume, only 1,172 of those were also in the top NBRx decile. These are the real dynamos, the physicians who have large practices and are actively making therapy decisions.

When we broadened the view a bit and looked at the overlap between the top five deciles of each measure, we found that 24,282 physicians could be considered "market drivers." At the opposite end of the spectrum, over 400,000 physicians were "non-drivers" in that they write few new prescriptions and few total prescriptions. The other two groups of physicians (21,000 in all) were either in the

top decile by total prescriptions or NBRx, but not both. Those who were in the top NBRx decile offer limited potential; those in the top total prescription decile offer selective potential.

Figure 5 illustrates what we found across all 10 therapeutic categories when we compared total prescription volumes to NBRx volumes by individual physician. *Just 4 percent of all physicians generate 44 percent of all new prescriptions.*

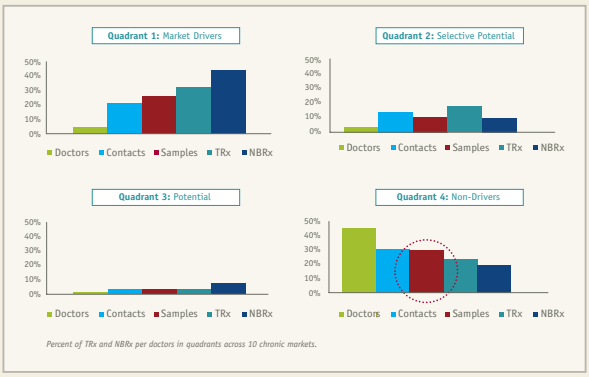
Figure 5: *Percent of Total Prescriptions vs. NBRx by Doctor*



Across 10 chronic markets, we found that 5 percent of all physicians generate 44 percent of all New-to-Brand prescriptions (NBRx).

Next, we examined how companies are currently allocating their physician contacts and promotional spending in relation to the NBRx-volume segments. The results would probably not surprise John Wanamaker: over 60 percent of pharmaceutical company contacts and 60 percent of samples are directed to the least productive group of NBRx prescribers. *(See Fig. 6.)* That is not to suggest that there aren't still a lot of new prescriptions coming from the "non-drivers" in Quadrant 4 of the graph; this Quadrant does produce 40 percent of all new prescriptions, but it takes over 400,000 physicians to do so. On average, they write .3 new prescriptions a year and so are the least productive physicians when it comes to the dynamic segment of the market.

Figure 6: *Resource Allocation by Physician Segment*



Samples and contacts are being allocated disproportionately to least productive quadrant of prescribers.

Looking at the market in this way makes it very clear where precious field force contacts and promotional dollars are being spent unproductively and where they should be reallocated for optimal efficiency. One company that applied a similar analysis to its market was able to reduce its sampling by 20 percent, a move that yielded nearly $2 million in incremental revenue for a profitability gain of nearly $5 million.

Given the findings of this study, one of the quickest routes to achieving brand excellence would seem to be for the entire commercial organization of sales, managed markets and marketing management alike to be asking, "What am I doing to understand patient and prescriber dynamics and what are we doing to win in the dynamic and static markets?"

Click here to access more information about our IMS Marketing Excellence Series.

IMS NEWS ROUNDUP

FROM AROUND THE GLOBE

A NEW MODEL FOR SUCCESS: How are pharmaceutical companies' sales and marketing strategies adapting to the new market reality? Which commercial model will make the most efficient use of resources given rising consumer and payer influence, increased competition, genericization and a growing specialty product focus? Answers to these questions and more will be presented at a May 12 *Pharmaceutical Executive* webcast, sponsored by IMS. Drawing on extensive research conducted on commercial practices for over 80 therapeutic markets across the world's top eight markets, IMS thought leaders will provide fresh perspectives for designing and implementing the best commercial model. For more information, click here.

U.S. PRESCRIPTION SALES GROWTH: IMS recently reported annual U.S. prescription sales growth of 1.3 percent for 2008, to $291 billion. Dispensed prescription volume in the U.S. grew at a 0.9 percent pace. Factors influencing the slower growth included higher demand for less-expensive generic drugs, lower new product sales and reduced consumer demand due to the economic downturn. For more information about the U.S. pharmaceutical market and the top therapeutic classes, products and sales distribution channels, click here.

AGING REPORT: In conjunction with its involvement in the European Union health event last fall in Paris, IMS published a special report, "Aging Well: A Healthy Deal for Older Citizens of the European Union." Tapping IMS's unique insights on pharmacotherapy consumption in older citizens, the report outlines an extensive study across 25 of the 27 European Union member countries. To download a copy of the "Aging Well" report, click here.

GLOBAL GENERICS MARKET OUTLOOK: In conjunction with the International Generic Pharmaceutical Alliance's annual conference in Geneva, Switzerland, late last year, IMS issued its "Global Generics Market Outlook" press release, detailing current and long-term marketplace trends. According to IMS, generic firms must adjust to slowing growth similar to R&D-based pharma due to competition and price pressures that are forcing consolidation. The release generated 230 articles globally in media outlets such as The Financial Times, Bloomberg, Reuters and the Associated Press.

Coming Next

Our annual edition of *IMS Intelligence.360* is scheduled for release in late spring 2009. This year's global report will offer our unique, evidence-based perspectives on global healthcare trends and imperatives at a critical turning point in the industry's history. In association with *I.360*, we will also be sharing our annual review of the most critical "harbingers of change," events that tell us where healthcare is going, how stakeholders are likely to respond and the implications for global healthcare. To ensure your name is on our distribution list for these materials, please click here and complete the registration form.

Today's universe is patient-centered.

Discover its power with IMS.

Your business models have changed. So have the metrics that keep the healthcare industry moving forward. Today, a patient perspective is a must.

Through the global IMS LifeLink™ program, we provide a powerful patient lens to drive focus and alignment across your business, deepening your understanding of critical patient, physician and payer dynamics. Our tools allow you to identify the right patient segments early on, in order to gain competitive advantage in today's complex environment.

We make a patient-centered perspective simple — by integrating patient-level intelligence into our industry-leading offerings and giving you expert consultants who apply it to your key issues.

IMS LifeLink has everything you need to succeed in a patient-centered universe. Let us power your patient perspective.

Call our team at **800-255-4110** or visit **imshealth.com/insights**.

ims

INTELLIGENCE.
APPLIED.

ABOUT IMS

OPERATING IN MORE THAN 100 COUNTRIES, IMS provides clients with evidence-based, customized intelligence about the pharmaceutical and healthcare markets — delivering critical information, analytics and consulting that drive superior client business strategies, decisions and results.

IMS HEALTH®
CORPORATE HEADQUARTERS
901 Main Avenue
Suite 612
Norwalk, CT 06851
USA
Tel: +1 203 845 5200

EUROPE, AFRICA & THE MIDDLE EAST
7 Harewood Avenue
London NW1 6JB
United Kingdom
Tel: +44 0 20 3075 5888

THE AMERICAS
660 West Germantown Pike
Plymouth Meeting, PA 19462
USA
Tel: +1 610 834 5000

ASIA-PACIFIC
10 Hoe Chiang Road
Keppel Towers # 23-01/02
Singapore 089315
Tel: +65 6227 3006

JAPAN
Toranomon Towers Office 4-1-28
Toranomon, Minato-ku
Tokyo 105-001
Japan
Tel: +81 3 5425 9000

ims | INTELLIGENCE. APPLIED.

imshealth.com