BY ROBIN ROBINSON

NICHEBUSTERS vs. BLOCKBUSTER$

Following the science instead of the money will warrant a radical shift in commercial model strategies.

"Drug companies are recognizing that the old model is changing and the change will be for the good."

BILL LITTLE
Delta Marketing Dynamics

"Marketing will be less about Product A vs. Product B and more about where does the product fit into the overall therapeutic course."

DR. RICHARD VANDERVEER
GfK

Transformation in the industry is everywhere, driven by healthcare reform, increased regulatory scrutiny, patent expiry cliffs, and thinning pipelines. The old ways of doing anything — drug development, drug research, sales, marketing, launch activities, market research — are no longer effective and need serious revamping.

Enter the nichebuster model — a business paradigm that involves following the science of a disease to determine where a drug can intervene along its pathway to create a positive treatment outcome for a smaller population of patients. The model isn't new; companies have been looking to smaller targeted indications, sometimes as added indications for their blockbuster drugs, for more than 10 years. What is new is the industry's increased focus on reinventing its commercial strategies, and the nichebuster model has moved front and center of this focus.

A recent IMS Health special report, Understanding New Commercial Models in the Pharmaceutical Industry, shows that the industry has been trying outmoded methods for building revenue over the past few years with no discernable positive outcome.

According to Sydney Clark, VP, practice leader for commercial effectiveness at IMS Health, maximizing the efficiency of commercial operations is standard fare for companies operating in a difficult economy with budget constraints. Yet, because the biopharma world is being upended, creating commercial efficiencies is no longer simply about managing costs; it's about devising a new commercial model that better leverages available or yet-to-be-discovered approaches to suit the new market reality.

The Industry's Failed Responses to a Changing Market

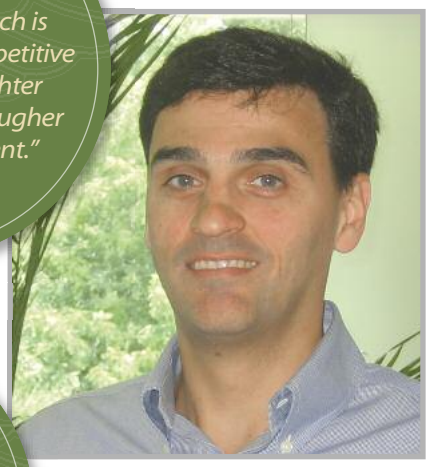
IMS LISTS FIVE REACTIVE STRATEGIES PHARMA COMPANIES HAVE EMPLOYED TO FIGHT THEIR DECLINING BOTTOM LINE, NONE OF WHICH, ACCORDING TO ANALYSTS, MEET WITH MUCH LONG-TERM SUCCESS, FURTHER PROOF THAT A PARADIGM CHANGE IS NEEDED.

- **ACQUISITIONS:** There is no evidence that mergers add value in the long term. Although in the short term companies benefit from removing overlap, fundamental issues remain post merger.
- **REDUCING THE SALESFORCE:** Although this was a reasonable method for improving investment returns in the short term, it's been insufficient to change the unhappy course of P&L trends.
- **INVESTING IN PHARMERGING MARKETS:** The world's pharmerging markets have decidedly strong growth prospects, yet the numbers will not be large enough in the next five years to fill the gap.
- **RESTRUCTURING THE ORGANIZATION:** This could be a good first move if the goal is to operate against fundamentally different metrics.
- **EMPLOYING A NEW MANAGEMENT TEAM:** In actuality, what is needed is new thinking, not necessarily new leadership.

Source: IMS Health report, Understanding New Commercial Models in the Pharmaceutical Industry. For more information, visit imshealth.com.

"The niche-buster commercial model will require both science and marketing to align."
GIL BASHE
Makovsky + Company

"Physicians are losing their power, and payers are gaining power, which is creating a more competitive landscape with tighter regulations and a tougher launch environment."
SYDNEY CLARK
IMS Health



"There will need to be a very considered approach to balancing the need for rigor vs. market research spend."
JULIANA MASTROSERIO
Johnson & Johnson

These attempts fail because they miss the fundamental issue, Mr. Clark says.

"The landscape has changed and the tried-and-true methods do not work," he says. "Pharma companies need to operate in a more integrated fashion with more internal coordination instead of looking at their commercial model in isolation or making changes piecemeal."

Developing a new commercial model is one component of what should be a very broad and coordinated response that includes R&D portfolio management, pharmerging market presence, and overreaching business models.

The shift will not be made quickly, however, says Sushiel Keswani, executive director, advisory services, life sciences customer domain, for Ernst & Young Advisory Services.

"Companies will have to maintain their current course for a while, because niche markets require new capabilities and new services and, most importantly, new ways to secure reimbursement," he says. "A major shift requires a long-term strategy and those companies that have the coffers will invest first, and once they realize the value, more will follow. But even then, the shift will not be from one model to another, but more of a hybrid of the two."

According to Trevor Mundel, global head of development at Novartis, the nichebuster model has emerged, in some ways, unintentionally, stemming from researchers following disease pathways of established indications and discovering smaller indications that fulfill unmet needs of a smaller, targeted population.

He cites, for example, Novartis' Gleevec, which started out as a niche drug and then with further testing, was found to treat other indications both in and out of the leukemia family of diseases. Gleevec was first approved in 2001 for adult and pediatric chronic myelogenous leukemia (CML) and for the treatment of a rare form of cancer called gastrointestinal stromal tumor (GIST).

"This was a niche population at the time," Mr. Mundel says. "When we started that program for CML there were only about 30,000 patients; this is a very targeted group. We discovered a number of indications for the treatment of other acute leukemias and other disorders — there have been four to five additional indications outside of the oncology area — and some of these turned out to be bigger than people expected. They are all considered niche indications but were sequentially built out of that one program."

The Impact of the New Paradigm on Commercial Activity

The industry is in the early stages of investigating new commercial models to meet the needs of the emerging nichebuster environment. With new market realities coming into play, changes will have to be made, and some of them may be drastic, our experts say.

According to IMS Health, in less than five years, companies in the mature markets will be forced to evolve their commercial practices in fundamental ways. Our experts discuss how companies can be prepared for transformations in marketing and sales, market research, and the need to develop relationships with payers.

PAYERS

The single biggest change facing the industry is the shift of power to payers from physicians. As payers become the gatekeepers for determining which drugs reach patients, companies will need to target sales and marketing efforts accordingly.

According to the Ernst & Young report, Progressions, Pharma 3.0, sales strategies will target payers rather than prescribing doctors and pharma companies will focus on comparative research to generate data specifically for that purpose. In the report, Ernst & Young refers to the emerging commercial model as the "healthy outcomes" model driven by healthcare reform, demographics, personalized medicine, health information technology, and the rise of the superconsumer. All these factors will radically change the playing field as the value proposition moves from developing drugs to delivering healthy outcomes.

"Payers, with respect to reimbursements, will be in the driver seat, not physicians," says Mr. Keswani. "Reimbursement will become the key driver for success in the niche market."

Companies that adopt a nichebuster model will have to prepare for a major paradigm shift that involves proving comparative effectiveness and healthy outcomes to payers and managed care organizations that their drugs should be the preferred therapies on formularies. Mr. Keswani says pharma companies will also need to build new capabilities and learn how to negotiate the reimbursement landscape.

Another challenge to this new model will be the need to prove the value of one drug over its competition.

"Proving comparative effectiveness requires having mechanisms and capabilities in place to measure outcomes, and that is a major challenge for pharma," Mr. Keswani says.

As a result of comparative effectiveness, the niche model is going to require a focused effort not only on what population to target but what population not to target.

"Companies will need more data to prove clinical and economic value of their drugs and the decision-making becomes more complicat-

"The old model that served the industry so well for 20 years isn't working today and new opportunities need to be evaluated."

HARRIS KAPLAN
Healogix

"The industry is struggling with the hurdles of the harmonious marriage of science and money."

TREVOR MUNDEL
Novartis

ed," Mr. Clark of IMS Health says. "Pharma companies need to make these decisions early on in the process and they need to make sure they have the data to convince stakeholders that the drug will be differentiated in the marketplace."

According to Bill Little, president of Delta Marketing Dynamics, federal and state legislators are going to shape what the industry is able to do in terms of sales and marketing, so as a result, companies will start moving toward a value-based comparative effectiveness model.

"Drug companies are recognizing that the old model is changing and will change for good," Mr. Little says. "Companies will be moving from a blockbuster model into a nichebuster model, because it's better to own a space with a smaller population of patients than to add one more product to a large mature market with many other brands."

MARKETING

Marketing efforts will become more targeted and the focus will shift from the product to the overall health of the patient, our experts say.

"There is a move toward personalized medicine, driven by payers' unwillingness to fund branded pharmaceuticals uniformly across all patients," says Harris Kaplan, president and CEO of Healogix. "As a result, product marketers need to be prepared to narrow their focus, which means the old marketing model that served the industry so well for 20 years won't work very well in the future, and new opportunities need to be evaluated in the context of a world where payers often hold the keys to the kingdom."

Juliana Mastroserio, senior manager of marketing research at Johnson & Johnson, has only worked on products intended for large patient markets and a broad physician base of support, but she expects the industry to start moving toward niche marketing, as fewer drugs are likely to achieve the billion-dollar plus status.

"Successful companies will learn how to become more nimble, make decisions faster, and adopt different marketing strategies and tactics," Ms. Mastroserio says. "Advertising agencies accustomed to producing ad/visual aid concepts, journal ads, sales messaging, and other traditional sales communication methods will likely need to evolve to be a more clinically oriented strategic partner."

Gil Bashe, executive VP at Makovsky + Company, says such a model will require science and marketing to align. In the blockbuster model, science is very separate from the marketing side of the business, however, nichebusters require a different set of skills and a different type of organization where science, advocacy, policy, and reimbursement are more important than the physical aspects of traditional marketing, he says.

"Consumers are very wired into patient and physician networks and have become very savvy, so patient-access programs become much more important from the moment the product is launched," Mr. Bashe says.

There will be a need for stronger marketing staff on the reimbursement end to deal with both private and government payers. Advertising for these products may become less important in the marketing mix over the long term, but digital communications, education, ongoing science, and scientific exchange will become much more important.

"Advocacy is also important and companies will have to make sure patients have a listening post," Mr. Bashe says.

Other changes in marketing strategy will include a shift to providing services, such as compliance programs, as part of a holistic treatment program as opposed to just selling a bottle of pills, says Richard Vanderveer, Ph.D., CEO of GfK Healthcare.

"Marketing will be less about Product A vs. Product B and become more about determining where a product fits in the overall therapeutic course and what else should be done in terms of patient compliance programs and to support the product," Dr. Vanderveer says. "There is a tremendous opportunity to expand beyond a bottle of pills into a complete treatment program and by using in-depth exploratory market research; the industry can create a very different business model."

Marketers will have to identify where a product fits in an overall treatment program and what to offer physicians to show which patients are best suited for the product and how they will benefit.

"Make my product the No. 1 selection for hypertension is old speak," Dr. Vanderveer says. "We are headed into an era of outcomes data that will identify the patients best suited for the treatment and how the treatment will make the overall therapy efficient and effective."

SALES

As the paradigm shift moves through the different sectors, traditional sales models will also be impacted.

"In my opinion, salesforces will likely continue to be cut back," Ms. Mastroserio says. "Those sales reps who remain will need to become more specialized as their customers change. Whether a product is adopted is more likely to become the province of payers rather than physicians. Physicians may be required to seek product education through other means rather than through a traditional sales rep."

The cutbacks in salesforces over the past few years are examples of the industry trying to adjust to a new paradigm without making fundamental changes, Dr. Vanderveer says. The role of the sales rep needs a major rethinking, not a modification.

"Reducing salesforce numbers by 10% is tweaking the model, but that doesn't get to the root issue," Dr. Vanderveer says.

Changing the role of pharma sales reps would be what he calls disruptive change and most people are resistant to that much change.

"When we talk about changing to a completely new paradigm, there is a tremendous temptation to cling to the here and now because it is the known," Dr. Vanderveer says. "However, disruptive change is what it will take to revamp the sales role of the future. The industry has reduced the numbers, but the reps are still doing the same thing. We have not spent any time thinking about what it is that the rep of 2011 and beyond should be doing."

Mr. Kaplan from Healogix agrees. "The rea-

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Interact with your customer: Understand how to develop a social media program in corporate and brand communications and how to measure success

Bring Value: How to ensure your customer derives value from your online and virtual marketing efforts

"A very useful meeting, the speakers were excellent and the content was relevant."
Ruth Clements, *Director,* **Bayer**

Not just the usual suspects:


David Stern
Executive Vice President
EMD Serono


Walter Christensen
Senior Vice President
Neurometrix


Cynthia North
Consumer Marketing Director
Bayer


Christine Coyne
Senior Director, Adult Endocrinology
Endo Pharma


Shwen Gwee
Digital Strategy and Social Media Lead
Vertex Pharmaceuticals


Paul Butcher
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Not just another social media conference. I promise.

How many social media conferences have you been contacted about so far this year? Two hundred billion? Thought so. The market is abound with social media meetings – plus because it's social media it's deemed appropriate to contact you incessantly through every channel you actually used to like using. You're thinking this is just another face in the crowd, right? Wrong.

The rapidly changing face of web, search, social media, and with mobile now coming to the fore, it's getting harder to decide which channels to focus on. Then you need to successfully integrate it into your traditional marketing campaign. I know how overwhelmed with information you are, so I want to take a different perspective on the usual topics, look at the challenges and then show you how to put some solutions into action.

Here goes...

I have invited the most forward thinking leaders in the industry to discuss more than just what's out there and what they're doing in the space. They will also give you case studies, for example how to launch a branded app, or what SEO strategy to adopt for the best ROI. Beyond that, I have invited speakers from big pharma all the way to micro pharma, medical device and diagnostics companies, healthcare companies and and other regulated industries. This is designed to offer you a broad range of perspectives and an overarching look at what can be achieved with any budget in any part of the industry.

Linking online and offline techniques sounds simple – so why isn't everybody doing it? Integrating the two is a sure fire way to instantly make your overall marketing campaign cohesive and ensure you are capitalizing on and marketing every aspect of your brand or product. The first step on this journey is to hear from the people who are making it happen. Successfully. **eComunications 2010** is the highlight of the industry calendar for all professionals who are serious about the future of their campaigns. Don't forget, it's also a key opportunity to rub shoulders with the key thought leaders in the space, beware – sparks will fly!

This is a unique offering in a crowd of conferences that just focus on one channel or aspect of your overall marketing goal. It's simple, I want you to be able to take stock of your overall eMarketing efforts, consolidate and start 2011 with fresh impetus and the knowledge to really push the envelope.

Be a part of it.

Claire Poole
Vice President
eyeforpharma

Check the website for more information:
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David Stern
Executive Vice President
EMD Serono

Walter Christensen
Senior Vice President of Global Sales
Neurometrix

Paul Butcher
Director of Communications
Citi

Cynthia North
Consumer Marketing Director
Bayer

Paul Kang
Director
Pfizer

Preeti Pinto
Executive Director, Promotional Regulatory Affairs
AstraZeneca

Marc Monseau
Director of Media Relations
Johnson & Johnson

Ruth Clements
Director
Bayer

Christine Coyne
Senior Director, Adult Endocrinology
Endo Pharma

Shwen Gwee
Digital Strategy and Social Media Lead
Vertex Pharmaceuticals

Heather Bertha
Senior Product Director
Aton Pharma

Mark Lightowler
Global Brand Director Respiratory Franchise
Novartis

Simon Goldberg
Director, Electronic Communications, Corporate Public Affairs
Abbott

Harold Johns
Manager - Global Web Solutions - Worldwide Commercial Pharmaceutical IT
Johnson & Johnson

Dave Bierut
Associate Director Integrated Marketing Communications
Genzyme Biosurgery

John Vieira
Senior Director - Marketing Operations and Strategic Services
Daiichi Sankyo

Haya Taitel-Becker
Group Product Director
Ortho-McNeil Pharmaceuticals

Hank Parish
Vice President
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Key learnings

Know your Customer
- How the healthcare landscape is affecting customer
- What makes the consumer/patient tick?
- Examine physician behaviour
- Key Opinion Leader panel: How physicians think

Reach your Customer
- The impact of no FDA regulations
- Integrate online and offline marketing
- Key trends in mobile marketing
- How to launch a mobile App
- Customer engagement with mobile

Networking cocktail reception sponsored by: Physicians Interactive

Day Two – November 9

Key learnings

Reach your Customer (continued)
- Foster communication with your website
- SEO to ensure you customer can find you
- DTC 2.0: how to ensure the time is right to engage
- Content and services to meet Physician demand
- e-Sampling

Interact with your Customer
- Leverage data to understand and interact
- How and why to use social media?
- Integrate social media in a definite way
- Wireless Health in patient support programs

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You want to hear about new products and solutions, but you don't want to be sold to. You want to understand how products work and see them in action, but you still want some down time during breaks. We know. That's why we only invite leading solution providers to collaborate with us and pride ourselves on maintaining the integrity of their involvement. With that in mind space is strictly limited. If you are interested in reading more about which solution providers are joining us this year, please go to: **www.eyeforpharma.com/ecomm/event-sponsors.shtml**

I learned a tremendous amount and thought speakers and panelists were a very high quality. A really informative session.

Leslie Heyison, *Director*
Pfizer

"It was great to network with pharma colleagues who have similar issues and challenges."

Jennifer Merrick, *Interactive Marketing Manager*
Roche

For more information on networking opportunities visit:
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Day One - November 8, 2010

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Session 1: Know Your Customer

Get clarity in the chaos: An overall perspective

- Hear how the current dynamics of the evolving Healthcare Environment affects Biopharmaceutical marketing and the physician/patient
- How to deliver brand messages while increasing the value proposition to your audience (including how to leverage the Blogosphere)
- Hear enhanced campaign management ideas, beyond individual products to integrate franchises and brands

David Stern, *Executive Vice President,* **EMD Serono**

What makes your customer tick? Storytelling as a key weapon in your arsenal

- Delve deeper into the narrative aspect of your eCommunications plans to connect with the humanity of your customer
- Leverage storytelling to understand and connect with your customer more effectively
- Why storytelling is of paramount importance for a patient to get behind their disease and your product

Mark Lightowler, *Global Brand Director Respiratory Franchise,* **Novartis**
Storytelling blogger:
www.newbrandstories.wordpress.com

Embrace open communication and engagement with customers in a regulated industry: a banking perspective

- Hear experiences from the regulated world of financial services to develop a scalable global framework to leverage social media
- Understand how to manage global social channels and how to develop and share best practices
- A look at technology platforms to manage social media framework and governance surrounding internal and external social media use

Paul Butcher, *Director of Communications,* **Citi**

The evolution of physician behavior: Implications for new digital physician access models

- Examine physician behavior to access quality engagements with high value physicians
- Examine effective new approaches to address your online coverage challenges
- Understand the implications for building integrated digital and sales force strategies for more effective physician access, engagement and relationships

Mark Gleason, *Senior Vice President, Corporate Development,* **Aptilon**

Key Opinion Leader Panel Know your audience: How physician's think

PANEL

- Understand what truly brings value to the physician: Q&A session
- Hear how physicians consume and access on-line and virtual information to ensure you are working optimally to understand and connect with them
- A closer look at how physicians view e-technology to understand how this information can be used tactically

Moderator - Hank Parish, *Vice President,* **Doctor Directory**
Joined by 4 physicians to discuss their experiences with digital communications

No crystal ball? Trends that will affect your customer in 2011

- Hear what new social, mobile and search trends are on the horizon and how they will influence your planning
- How are growing patient communities are influencing decision making?
- Understand exactly how companies are shifting to strong patient engagement

Brian O'Donnell, *Executive Vice President Interactive Services,* **Klick**

Session 2: Reach Your Customer

Still no FDA guidance: Let's move forward

- A year on from the 2009 FDA public hearing – really how close are we to a regulated environment?
- Is it feasible to modify offline regulations for online purposes to self-regulate your social media efforts to connect with your customer?
- Understand if you can achieve higher ROI by allocating resources to regulated and accessible areas, rather than waiting for FDA guidelines

Preeti Pinto, *Executive Director, Promotional Regulatory Affairs,* **AstraZeneca**

Cover all your bases: Integrate online and offline tactics

- Integrate your online and offline marketing to work harder for your product and ensure that your coverage reaches the customer from every angle
- Develop combined online and offline tactics that make sense for your brand and your customer, not just those that are standard procedure
- Linking offline and online marketing sounds simple, why isn't everyone doing it?

Heather Bertha, *Senior Product Director,* **Aton Pharma**

Dialing into the future: Mobile trends and implications for Pharma

- What key trends in mobile mean for your brand and customer and what we can expect in the next 3-5 years
- Hear innovative uses of mobile technology and why this channel will become so important to connect with your customer
- Understand the possibilities that mobile applications present and how they will boost your customer engagement

Paul Kang, *Director,* **Pfizer**

Please turn ON your cell phones: Launching a Mobile App in Pharma

- Hear about the first branded pharma app in the MS community and the first unbranded app in the hemophilia A community: how were these promoted within the community and to the sales force?
- Understand the strategies behind the decision to build a branded vs. unbranded asset and what the challenges and benefits are
- Review and debate the lessons learned from a legal, medical and regulatory perspective

Cynthia North, *Consumer Marketing Director,* **Bayer**
Ruth Clements, *Director,* **Bayer**

Mobile: a wonderland for your brand

- How mobile is changing the face of brand communications and innovative ways to leverage mobile marketing to reach your target audience
- Drill down to the value you can provide your customer when you capture them with mobile marketing
- Hear case studies about the inherent value mobile can bring to your overall multi-channel marketing campaign

Ryad Ali, *Associate Director, eStrategy,* **Novartis Oncology**

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Day Two - November 9, 2010

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What has your website done for you lately?

- Understand the huge value in reaching consumers online and how to make your website the destination for information and dialog
- Ensure your positioning on the web and in the market is optimal and implement a comprehensive SEO strategy to ensure your customer can find you
- How to use your website as a tool to foster communication and develop a relationship with your customer

Harold Johns, *Manager - Global Web Solutions,* **Johnson & Johnson**

Direct To Consumer 2.0: How to zig when everyone else is sagging

- Ensure the time and opportunity is right to engage patients and consumers with the review of your brand's lifecycle stages
- Understand how to co-ordinate communication to patients and consumers with the efforts of the sales force in both messaging and tactical execution
- Big budgets vs. small budgets – get to grips with economies of scale for investment

Christine Coyne, *Senior Director, Adult Endocrinology,* **Endo Pharma**

What Physicians Need: How to orient physician-focused content and services

PANEL

- How physician, media and professional resource preferences will evolve and how marketers can meet these on-demand service needs in the face of decreased access
- Utilize available opportunities to provide physician-focused content and services through mobile, videoconferencing and other digital media channels
- Hear how pharma companies approach centralized and distributed HCP customer service initiatives

Dave Bierut, *Associate Director Integrated Marketing Communications,* **Genzyme Biosurgery**

Other industry panelists TBC – please check the website for details

Moderator: Meredith Ressi, *Vice President, Research,* **Manhattan Research**

eSampling: Bright future or false dawn?

- The pros and cons of eSampling - is it right for your product? Can it assist your brand awareness and physician engagement?
- How can you successfully integrate eSampling into your marketing plan to understand the revenue potential of lower-decile physicians
- How industry change may affect how you view eSampling within your sales team and multi channel marketing mix

Senior level industry speaker TBC

Session 3: Interact with Your Customer

The 411 on 1:1 – the case (study) continues....

- How to build a 1:1 relationship with your customers and get the answer to the important question: "Now what"?
- Gain specific solutions to solve real world brand challenges: such as leveraging attitudinal data to develop "micro-segments"
- Combine disparate data sets from multiple venues to maximize customer understanding and avoid "intellectual hydroplaning"

Rob Likoff, C*EO and Co-founder,* **Group DCA**

Haya Taitel-Becker, G*roup Product Director, Pricara Div of* **Ortho-McNeil Pharmaceuticals**

Jim McDonough, *Managing Director, E-Analytics,* **Group DCA**

Social Media in Corporate Communications vs. Brand Communications

PANEL

- Examine commonalities and synergies as well as areas unique to each that need to be considered when developing a social program to interact with your customer
- Understand the process for developing social media initiatives: who are the key stakeholders and what role do they play?
- Get to grips with policies and guidelines for each and how they differ

Marc Monseau, *Director of Media Relations,* **Johnson & Johnson**

Simon Goldberg, *Director, Electronic Communications, Corporate Public Affairs,* **Abbott**

Moderator: Zoe Dunn, *CEO,* **Zoe Dunn Consulting**

Engage today's patients and physicians

Full presentation details not available. Please check the website for updates

Dorothy Gemmell, *Senior Vice President, Pharmaceutical and Medical Device Markets,* **WebMD**

Social Media? More like non-social media...

PANEL

- Understand how to leverage social media without it becoming an entirely defunct channel because of screening or fully censored interaction
- Is your company able to properly take advantage of social media and put the time and resources to moderate and monitor conversations?
- How to successfully integrate social media into your overall eCommunications plan. With governance issues, what can you really do right now?

Shwen Gwee, *Lead, Digital Strategy and Social Media,* **Vertex Pharmaceuticals**

Silja Chouquet, *CEO,* **whydotpharma**

Other industry panelists TBC – please check the website for details

Integrate wireless health into next generation patient support programs

- Explore the evolution of patient support programs and how to make your program more successful.
- Understand what patients want from patient support programs and what makes certain programs more successful than others
- How can patient-centric programs drive persistency?
- When does Smartphone integration boost program performance and what might the next generation of patient support program look like?

Alec Melkonian, *Senior Vice President Sales & Client Services,* **Klick**

Lori Grant, *Senior Vice President Brand Development & Digital Strategy,* **Klick**

Marrying your eCommunications campaign with your sales force

- Understand the impact that the changing face of the sales force will have on your eCommunications campaign and your interaction with your customer
- How to ensure your marketing team is working optimally with the sales force to effectively interact and convert your marketing into an increased bottom line
- Hear new possibilities to leverage non-personal digital media as complement to personal sales force

Walter Christensen, *Senior Vice President Global Sales,* **Neurometrix**

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- Understand how to incorporate social media tools into a private online community to help your brand
- Encourage scientific exchange with therapeutic specialists and enhance relationships with key opinion leaders
- Reach health professionals where they work, around the clock - to generate measurable results

Moderated by: Lance Hill, *CEO,* Within3

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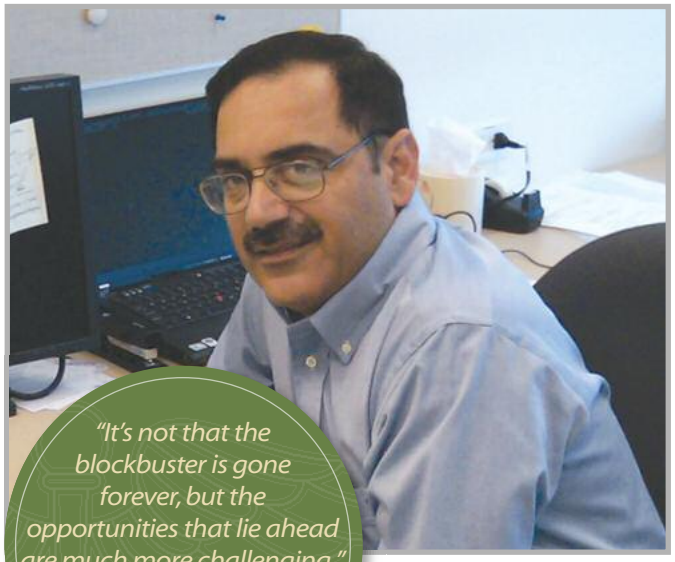

"It's not that the blockbuster is gone forever, but the opportunities that lie ahead are much more challenging."
SUSHIEL KESWANI
Ernst & Young
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son we are still seeing layoffs is because pharma companies, knowing the marketing model is broken, still have not found the right answers yet. So, by laying off noncritical personnel, they're freeing up cash to fund whatever strategies they believe will drive their growth. The question in the back of my mind is, when are the leaders going to shift their mindsets so they truly become the ones driving vs. reacting to change?"

To date, while companies talk about the new model, their actions, in terms of how they market products and even which products they choose to market, indicate they have taken few steps to address the new market environment, and Mr. Kaplan identifies this as a management challenge.

"Managers who came into significant leadership roles under the old business model — spending lots of money to market a product — will need to rethink their strategies as that old model is being neutralized by strong payers that are going to make it increasingly difficult to operate under that model," he says.

Mr. Kaplan predicts the new role of the sales rep under the nichebuster model will be a benefit for the industry.

"Sales reps who have a more differentiated product with a more compelling story to tell physicians may be able to significantly reduce call frequency," he says. "But the length of time of the detail will increase because the rep will bring more value, and the physician is generally interested in understanding the benefits of that product."

PRODUCT LAUNCHES

Niche product launches are going to take more preparation and planning than blockbusters, and the industry needs to prepare for this new model, according to Mr. Clark.

"Launching drugs is becoming harder; there's more competition, fewer unmet needs, and the window of opportunity to launch effectively is really short," he says. "In this new market environment, marketers need to get the launch right in the first six months, and the preparations must begin three or four years in advance."

Mr. Clark points out that organizational alignment is critical for launches in the new niche landscape, particularly between clinical and commercial, and global and affiliate.

"There can be a lot of disconnect between these functions," he says. "It's going to become critical for marketers to build what we call a five-step process to brand success, which includes building brand advocacy, obtaining brand regulatory approval, securing market access from the payer level, driving brand adoption, and ensuring correct adherence and compliance. Successfully working through these five steps is going to be increasingly critical."

MARKET RESEARCH

The role of market researchers and the type of market research conducted are likely to change too, Ms. Mastroserio predicts.

"There needs to be a considered approach to balancing the need for rigor vs. market research spending," she says. "Companies that conduct early-stage forecasting and pricing studies for niche brands may wish to employ greater rigor to inform go/no-go decisions and determine profitability. However, these studies have traditionally been expensive, large-scale, and extremely time-consuming. Market mix modeling is likely to be a greater determinant of resource allocation. And traditional prelaunch communications testing will need to evolve as companies move toward different types of communication vehicles."

According to Dr. Vanderveer, market research has taken a step back to more qualitative research and smaller scale projects.

"The practice of market research is getting more practical," he says. "Researchers are finding that they may need to talk to fewer doctors and they don't need huge findings that will never get used."

Market research will become more observational and will gravitate toward a different kind of forward thinking and creativity, Dr. Vanderveer says.

"Ethnography will be able to determine needs better than data sets that can be measured to the 50th decimal point or the responses from a focus group of consumers who can only think in the present tense," he says. "Companies will rely on market researchers who can think things through and come up with creative ideas to solve a problem." ✦

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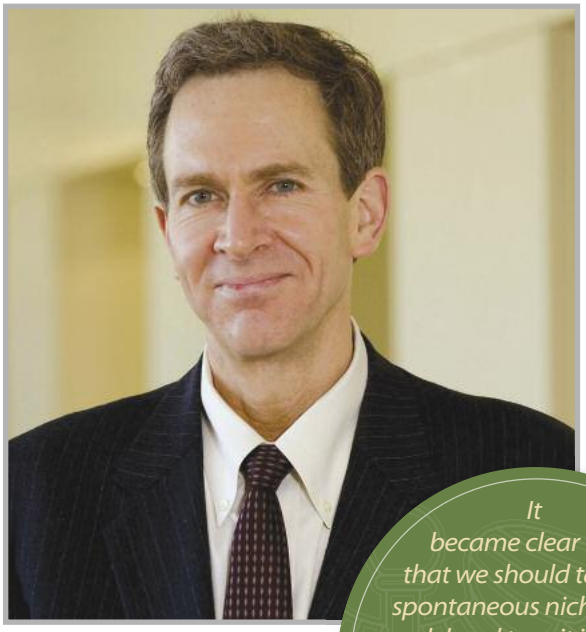
RICHARD VANDERVEER, PH.D. CEO, GfK Healthcare, a provider of integrated healthcare marketing research. For more information, visit gfkhc.com or e-mail richard.vanderveer@gfk.com.

BY ROBIN ROBINSON

NOVARTIS Adopts a NICHEBUSTER MODEL



> *It became clear to us that we should take the spontaneous nichebuster model and turn it into a real paradigm shift that involves tracking the emergence of where the science is going.*
>
> **TREVOR MUNDEL**
> Novartis

Novartis began turning its attention toward genetics and molecular pathways for finding new drugs and now with several successes under its belt, it has developed a new commercial model, says Trevor Mundel, global head of development at Novartis.

"It became clear to us that we should take the spontaneous nichebuster model and turn it into a real paradigm shift that involves tracking the emergence of where the science is going."

Novartis focuses on specifically targeting important pathway nodes along a disease area and once it can demonstrate a therapeutic advantage for one disease in the pathway family, it moves on to test if the treatment can be used for other diseases involving a similar underlying process.

"The science allows us the ability, with a single therapeutic agent, to target other diseases in that pathway family and it happens very naturally," Mr. Mundel says. "Companies need to think about and try to follow the underlying biology toward disease where there are inadequate therapies. In some ways, our model is not purely a nichebuster model because we are not specifically looking to design drugs for only niche indications. We are looking to design drugs that address unmet medical needs for patients."

Following a scientific need can lead to addressing a niche disease but it can also lead to much larger indications, which is a real upside to the strategy, Mr. Mundel says.

For example, Ilaris, first approved for the treatment of children and adults with cryopyrin-associated periodic syndrome (CAPS), was later found effective for a very rare disease within the CAPS family called Muckle-Wells Syndrome. Further investigation discovered that patients with gout also have an analogous problem and Novartis is studying Ilaris in gout patients, which has a population of almost 800,000 in the United States alone.

"We discovered Ilaris and that became the magic bullet for patients affected by Muckle-Wells Syndrome, which affects about 10,000 people worldwide," he says. "We then discovered the treatment worked well on gout, a similar but much more prevalent condition."

Mr. Mundel says by following the science of the molecular pathway, new therapeutics should naturally emerge from the scientific understanding and that is exactly what Novartis has experienced.

However, Mr. Mundel notes that the old blockbuster mindset is still prevalent.

In many companies, discovery may be artificially constrained by marketing consideration. Companies are still choosing to invest only in the indications that will affect a blockbuster-sized population, Mr. Mundel says.

"This is fundamentally the old model, which is still prevalent and does not lead to a successful business model," he says.

The industry can no longer deny the science and make decisions on pursuing indications based on market reach. Sound clinical scientific judgment is the only reason to not pursue a certain pathway, he says, although Mr. Mundel concedes that it is a difficult decision to make in an industry that survives only by providing good returns to its investors.

Targeting a drug just for blockbuster indications and a heterogeneous population, such as myocardial infraction or cardiopulmonary disease, is a risky proposition these days, Mr. Mundel says.

"Yes, a company may get lucky and hit the jackpot, but when working with a targeted indication where there is a real understanding of how the drug works, the odds for success are greater," he says. "This is especially true from a productivity perspective in the industry, and that's important." ✦

Sound Bites From The Field

PHARMAVOICE ASKED EXPERTS IN THE FIELD TO IDENTIFY SOME OF THE CHALLENGES OF MOVING TO A NICHEBUSTER MODEL.

Steve Davis is VP and General Manager, Life Sciences, at Humedica, a next-generation clinical informatics company. For more information, visit humedica.com.

"One of the most significant challenges to the nichebuster strategy is the current lack of transparency into the clinical presentation, identification, treatment, and associated outcomes of niche patient segments. This lack of detailed clinical understanding will hinder commercial efforts across a product's lifecycle. In order for the nichebuster strategy to be successful, brand teams must be able to leverage real-world, longitudinal data to profile patient populations with detailed clinical specificity (e.g., patients with specific co-morbidities, severity of disease, and underlying complications based on lab results, patient history, physician assessment, etc). This increased understanding will inform and ensure the success of market sizing, product positioning, targeting, messaging, and reimbursement efforts."

Robert Dickinson is Client Service Officer, Life-Sciences Practice, of Grail Research, a global strategic research and decision-support firm and subsidiary of Integreon Inc. For more information, visit grailresearch.com.

"The greatest challenge pharmaceutical companies will face with the rise of a niche-oriented approach will be encountered in sales and marketing. The blockbuster model and the high margins associated with multi-billion-dollar-a-year drugs made it feasible to deploy thousands of reps to detail physicians and to support broad direct-to-consumer marketing campaigns. The economies of this approach don't apply for niche drugs. By their nature niche drugs are indicated for fewer patients and are prescribed less frequently by physicians. Pharmaceutical companies will need to be more targeted in their marketing and sales efforts, even as the increased focus on comparative effectiveness promises to demand even greater precision. More sophisticated patient and physician segmentation and specialized salesforces will be big drivers of success."

Jim Mercante is Partner of TGaS Advisors, which provides benchmarking and advisory services to pharmaceutical commercial operations. For more information, visit tgas.com or e-mail vjmercante@tgas.com.

"The most significant challenge is changing the mass-market commercial mindset. Defining the roadmap down to a granular level, while remaining flexible and adaptable to rapid recalibration, is crucial. Cross-functional internal and external changes will require simultaneous, not linear, execution. Companies will want to focus on recalibrating operations to support smaller salesforces, variable resourcing, strategic regionalization, and rigorous performance-based analytics around marketing campaigns and channels. Companies are revisiting roles and responsibilities across all functions and redefining the customer. Critical to success will be fluid, flexible information-sharing channels and processes, advanced planning, analysis and project management skills, a collaborative ego-less culture, and performance-based, objective measurement of all functions, most notably promotional campaigns, tactics, and channels."

HEALTHCARE REFORM and Pricing in the NICHEBUSTER MODEL

BY ROBIN ROBINSON

As the industry moves toward a more niche-based business model under new healthcare reform, pricing will become an increasing concern. Pricing will have an impact on the development pipelines, as well as on marketing strategy.

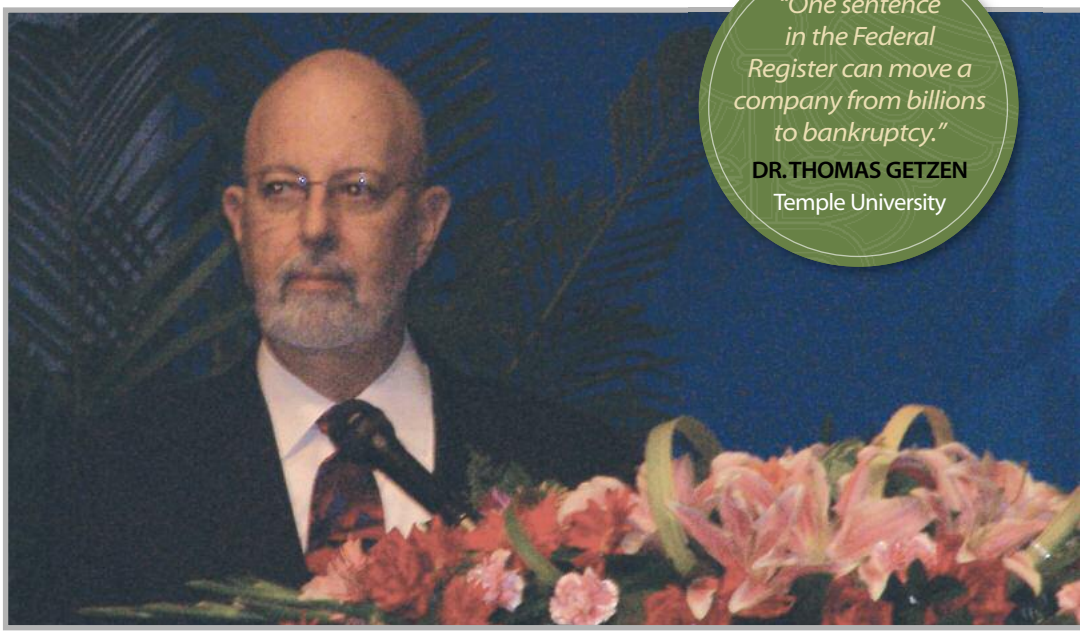
According to Thomas E. Getzen, Ph.D., executive director, International Health Economics Association, Temple University, pricing is a central issue in this policy environment of healthcare reform where people are concerned with controlling costs.

"Healthcare reform is going to have a giant influence on the pharmaceutical model," Dr. Getzen says. "We've made a deal with the devil. In the past, the private payer market would determine the price bases of drugs, and the government payers would follow their lead. However, with Medicare and Medicaid projected to pay the majority of healthcare costs, it will have more input on pricing and potentially become the price setter. When that happens, it will be a whole new ball game. We will have to wait and see to what extent other payers take the lead from Medicare."

There are two widely divergent schools of thought on drug pricing. One camp believes that drugs should be priced at what the market will bear, while the other group believes drugs should be compensated at a reference price basis, which would put most drugs at a much lower reimbursement level.

"This is the fundamental philosophical divide that is exacerbated by the shift in postmarketing in certain orphan drugs," Dr. Getzen says. "In other words, something originally approved for orphan use, such as infliximab (Remicade), was later put into fairly widespread use, but the pricing and innovation incentives that were granted for the niche or orphan-type drug stays the same."

Or the opposite case could happen, as in the case of thalidomide, a 50-year-old drug with a new indication for use in chemotherapy.



"One sentence in the Federal Register can move a company from billions to bankruptcy."
DR. THOMAS GETZEN
Temple University

"Thalidomide had been very inexpensive, but 50 years later it is being sold as if it were a niche drug with a fairly high price," Dr. Getzen says.

Under healthcare reform, this type of pricing will have to be justified and that may be problematic for older drugs with new indications, such as thalidomide, that do not require any research and development to justify the high-end pricing.

Pricing will also affect commercial strategy and innovation, Dr. Getzen says.

Pricing is very much a factor in determining whether a company will bring a drug to market. If the price of a drug is only going to be $2,000 a year instead of $200,000, a company is not going to push it or even put it in a trial, according to Dr. Getzen.

"Pricing is also related to innovation," he says. "If there is money to be made, companies will create products. But if there's no money to be made in malaria, then chances are companies are not going to investigate malaria drugs."

As companies anticipate more government intervention in terms of pricing, they are struggling to make sure in the short run that they can maintain profit margins.

"Companies are aware of the pricing structure overseas where there is heavier government regulation and they know they are not getting anything near the prices they are getting here in the United States for these drugs," he says. "This should serve as a warning to the industry as to where pricing may be headed under healthcare reform."

The pricing issue will not be settled for years to come, and although healthcare reform will start to affect change in the next year or two, Dr. Getzen expects the issue to still be playing out over the next 10 years.

"Nobody in the White House knows what's going to happen, so how are we supposed to know what will happen 10 years from now?" he asks. "In the meantime, the pharma industry should be on alert, because one sentence in the Federal Register can move a company from billions to bankruptcy." ✦

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