UBM Canon

PharmaLive.com

MedAdNews

THE MAGAZINE OF PHARMACEUTICAL BUSINESS AND MARKETING • MEDADNEWS.COM • MAY 2013 • VOLUME 32 NUMBER 5 • $25

IN THIS ISSUE:

MOVING THE NEEDLE

n use to reach patients in the (Too Much) Information Age,
od old TV set – to get their messages across.

the acronym
rketers imag-
y's toolbox
elled far
muni-
with
-

r.
der.
. That
this phe-
1.8 million
cent over last
work news in

g rotation to
nolly, TV re-
ay to quickly
meaningful,
ght brands."
a well-crafted
s many chan-
onsumers en-
years. Digital
of the brand
umers engage

ng to employ
to reserve TV
ra), Connolly
ns embracing

the medium. The logic behind this choice becomes clear when one remembers the price tag attached to many of these niche products. "Many of these brands have made admirable decisions to accept a good deal of media waste to drive scale for brands treating less prevalent conditions, knowing they'll make it up on the back end from their higher-priced treatments," Connolly says. "When your brand costs $100,000 per year to be on a therapy, it's not hard to realize how one might generate a nice ROI. It's often too easy for brands to just rely on the most efficient media spend and it's certainly easier to sell it to upper management. Regardless of this fact, the most iconic brands were not built by making the safest choice and not rocking the boat – success rewards those brands that take chances."

Beyond that, brand managers would be wise to consider the expanding capabilities of television and how it can be linked to other media.

"TV has always been an awareness tool, but by adding technologies like Shazam (the music finder app that can also read a commercial soundtrack and

continued on page 8

his month on PharmaLive.com

gic Advantage Through A 360 Customer View • Date: June 12, 2013 / Time: 12:00 pm ET

of the new marketing model is creating a cogent customer experience, as well as effective campaign
s all channels. A full 360 view of the customer is foundational to the process, yet companies generally
in making it happen. First, getting all the data in one place remains a struggle; e.g., the marketing data is
from field data, and some sources such as digital may be left out altogether. Second, once you've pulled
, what exactly do you do with it in practice? Learn how to gain competitive advantage by overcoming
ntinue to trip up so many organizations even today.

DATA PROVIDES THE **FOUNDATION**, EXPERIENCE PROVIDES THE **INSIGHT**.

Katalyst is a fast, simple, customized 4 step process that delivers the knowledge you need to solve your most important marketing challenges.

WHICH KATALYST IS RIGHT FOR YOU?

Spark™

Katalyst Spark is designed for *pre-launch*. When you need to know more about the competitive landscape, behavioral profiles, or media and device habits of HCPs, patients, and caregivers; engaging KOLs; and market shaping, consider Katalyst Spark.

Accelerate™

Katalyst Accelerate is designed for *early lifecycle*. When you need to know about accelerating growth, maximizing mobile use, benchmarking competition, reaching your widest audience, engaging patients, and developing robust analytics frameworks, consider Katalyst Accelerate.

Optimize™

Katalyst Optimize is designed for *later lifecycle*. When you need to reach more no-see physicians, increase the efficiency of your online and offline media spend, and make your CRM program work harder, consider Katalyst Optimize.

RESERVE YOUR FREE ROADMAP.

Meet your digital future at **klick.com/meet-katalyst**

Klick Health

UBM Canon

PharmaLive.com

MedAdNews

THE MAGAZINE OF PHARMACEUTICAL BUSINESS AND MARKETING • MEDADNEWS.COM • MAY 2013 • VOLUME 32 NUMBER 5 • $25

IN THIS ISSUE:

MOVING THE NEEDLE

Marketers have a whole array of tools they can use to reach patients in the (Too Much) Information Age, and they'll need to use them all – even the good old TV set – to get their messages across.

By Joshua Slatko joshua.slatko@ubm.com

Once shorthand for a short list, the scope of the acronym DTC has grown far beyond the scope of what marketers imagined when it was legalized by FDA in 1997. Today's toolbox of potential DTC campaign components has travelled far beyond the television spot and print ad to include online communications and interactive tools, social media, and much more, with accompanying mountains of audience data and a degree of granularity in targeting unimaginable even a few years ago. For all this, though, leaders of pharma ad agencies seem to agree that balance is the order of the day; a marketer should no more fall in love with the "It" medium of the moment than they should blindly stick with what's worked in the past. To be strong a brand must communicate with the patient wherever they may be – and that means everywhere.

TV, REIMAGINED

While digital and mobile communications have been rapidly infiltrating space that was once the domain of the television set, TV commercials remain a good way to reach some audiences, including the industry's most important piece of the demographic pie.

"The good old TV commercial has a place in the hearts of DTC marketers because the tool still delivers something special: broad reach to the most important demographic," says Jay Carter, senior VP, director of strategic services, AbelsonTaylor. "Pharma's sweet spot continues to be adults who are 55 and older. The network news delivers 16 million of those people every night. That drives awareness and predictable action. The center of gravity for this phenomenon is moving rapidly, however. Facebook now averages 11.8 million unique visitors of the same age demographic per day, up 48 percent over last year. At that pace, the social networking site will surpass the network news in reach next year."

It is clear, though, that television has moved from the starting rotation to situational relief. According to Evoke Health CEO Reid Connolly, TV remains what it has always been for the right brands: an efficient way to quickly reach a large audience with a brand message and hopefully make a meaningful, memorable connection. The key phrase, of course, is, "for the right brands."

"When scale is your primary concern, there is no doubt that a well-crafted TV strategy – be it DRTV or GA – is still able to deliver in ways many channels cannot," Connolly says. "There is also no doubt that how consumers engage with health information has drastically changed in recent years. Digital and mobile engagement cannot be seen merely as an extension of the brand experience but rather, it must serve as the backbone of how consumers engage with brands."

It is also interesting to note which brands have been choosing to employ DTC TV to drive their brand business. While the norm has been to reserve TV for mass demographic conditions (cholesterol, depression, et cetera), Connolly notes a recent move towards niche brands with smaller populations embracing the medium. The logic behind this choice becomes clear when one remembers the price tag attached to many of these niche products. "Many of these brands have made admirable decisions to accept a good deal of media waste to drive scale for brands treating less prevalent conditions, knowing they'll make it up on the back end from their higher-priced treatments," Connolly says. "When your brand costs $100,000 per year to be on a therapy, it's not hard to realize how one might generate a nice ROI. It's often too easy for brands to just rely on the most efficient media spend and it's certainly easier to sell it to upper management. Regardless of this fact, the most iconic brands were not built by making the safest choice and not rocking the boat – success rewards those brands that take chances."

Beyond that, brand managers would be wise to consider the expanding capabilities of television and how it can be linked to other media.

"TV has always been an awareness tool, but by adding technologies like Shazam (the music finder app that can also read a commercial soundtrack and

continued on page 8

ISTOCKPHOTO.COM: VLADIMYR, BELCHONOCK, MBBIRDY, F9PHOTOS, HOCUS-FOCUS, FRENDER

Agency of the year! Now that's Giant.

Thanks to all who've been part of our success.

Ready to grow with us?
Call Larry Wolheim
at 415 655 5220

Don't think big. Think **Giant**.
Giantsf.com

tothepoint

By Christiane Truelove chris.truelove@ubm.com

I write this still basking in the satisfaction of completing another successful Manny Awards and April issue. At the end of April, more than 500 advertising industry executives gathered at Pier Sixty in New York to celebrate each other's achievements. I got to wear a black sparkly dress, my compatriots Dan Becker, Joshua Slatko, and Andrew Humphreys joined me onstage looking dapper in their tuxedos, and a good time seemed to be had by all.

Some of the afterglow was obliterated the next day, however, when a piece of luggage was left on my homeward-bound NJ Transit train. No, not my luggage. Someone completely, or deliberately, left a bag on the train. With the Boston Marathon bombings and the manhunt for the surviving bombing suspect having taken place a mere week before then, NJ Transit officials were taking no chances, making everyone get off the train and board another train instead. I have no idea what happened to the luggage. It's probably in little tiny exploded pieces, courtesy of the Amtrak police.

Before we got off the train, one of the conductors made an announcement on the intercom, frustration crackling in his voice about, "how in this day and age, leaving a piece of unattended luggage in a public place is not a great idea."

No argument there from me, but the fact is, despite being affected by significant events, humans do forget and can push things so far to the back of their mind those memories will rarely, if ever, make it out.

That's the only explanation I can find for why Novartis had not just one, but two, lawsuits filed against it at the end of April by the Department of Justice for alleged bad marketing practices. In the first lawsuit filed, Novartis is accused of giving kickbacks, in the form of rebates and discounts, to at least 20 pharmacies in exchange for switching transplant patients from rival medicines to its Myfortic immunosuppressant treatment.

Manhattan U.S. Attorney Preet Bharara put it this way: "The widespread kickback fraud alleged in our two lawsuits against Novartis – which only a few years ago settled a False Claims Act case involving violations of the Anti-Kickback Statute based on illegal payments to doctors – makes us question whether Novartis is getting the message."

According to Ed Silverman of Pharmalot, the second lawsuit alleges that from January 2001 through at least November 2011, Novartis violated the Anti-Kickback Statute and its own internal policies concerning speaker programs, which require that the programs have an educational purpose and that slides about company drugs be presented. Instead, Novartis paid doctors to speak about certain products, including the hypertension drugs Lotrel and Valturna, and the diabetes drug Starlix, at events that were "often little or nothing more than social occasions for the doctors."

If readers can recall, in 2010, Novartis agreed to pay $422.5 million in penalties and pleaded guilty to a misdemeanor to resolve allegations that the company improperly marketed the epilepsy drug Trileptal. Novartis is under a five-year corporate integrity agreement with the government, in which the company agreed not to engage in such practices and to report any violations.

Silverman writes, "As the feds make clear, the alleged kickbacks took place before and after the CIA was signed. This could mean that Novartis may face exclusion – a term that means the drugmaker could be excluded from having contracts with federal healthcare programs. This would amount to a huge penalty and lessens its leverage in any settlement talks."

From the Justice Department's own press release on the matter: "Even after entering into the CIA, Novartis' compliance program was inadequate to prevent kickbacks from being paid in conjunction with Novartis' speaker programs. Novartis did not adequately review its speaker program to determine whether the programs were being used for an illegitimate purpose. Furthermore, although many instances of speaker program abuse were reported to Novartis, sanctions were generally mere slaps on the wrist. In some cases, sales representatives who violated Novartis' own speaker program policies were nevertheless promoted. Even after September 2010, Novartis continued to conduct bogus speaker programs that were simply vehicles for paying kickbacks to doctors in the form of honoraria and expensive meals."

Manhattan U.S. Attorney Preet Bharara put it this way: "The widespread kickback fraud alleged in our two lawsuits against Novartis – which only a few years ago settled a False Claims Act case involving violations of the Anti-Kickback Statute based on illegal payments to doctors – makes us question whether Novartis is getting the message."

Someone at the company may have been thinking, "It couldn't happen to me." Or maybe not even thinking at all, like that idiot who left a piece of green luggage on the Northeast Corridor train headed to Trenton, N.J. Either way, Novartis has a lot of explaining to do.

MedAdNews

CEO
Sally Shankland
sally.shankland@ubm.com

BRAND DIRECTOR
Daniel Becker
daniel.becker@ubm.com

DIRECTOR OF CONTENT
Christiane Truelove
chris.truelove@ubm.com

MANAGING EDITOR, SPECIAL REPORTS
Andrew Humphreys
andrew.humphreys@ubm.com

MANAGING EDITOR, *MED AD NEWS*
Joshua Slatko
joshua.slatko@ubm.com

EDITOR AT LARGE
Ed Silverman
ed.silverman@ubm.com

LEAD ART DIRECTOR
Marco Aguilera
marco.aguilera@ubm.com

ASSOCIATE ART DIRECTOR
Jennifer Field
jenny.field@ubm.com

PRODUCTION MANAGER
Venkatraman Jayaraman
venkatraman.jayaraman@mpe.hcl.com

PRODUCTION COORDINATOR
Saravanan Somasundaram
saravanan.somasundaram@mpe.hcl.com

SENIOR ACCOUNT MANAGER
Andrew McSherry
andrew.mcsherry@ubm.com

SENIOR ACCOUNT MANAGER
Dave Huisman
dave.huisman@ubm.com

MARKETING MANAGER
Joanna Siddiqui
joanna.siddiqui@ubm.com

ONLINE MANAGING EDITOR
Barbara Lempert
barbara.lempert@ubm.com

ASSOCIATE WEB EDITOR
Mia Burns
mia.burns@ubm.com

DATA SPECIALIST
Silvia Arriola
silvia.arriola@ubm.com

HOW TO CONTACT US

EDITORIAL
Send all press releases to editorial@pharmalive.com. Please note that we prefer all press releases and other documents to be sent to us in electronic format, via the e-mail system to editorial@pharmalive.com. All visuals, photographs, illustrations, and images should be submitted to editorial@pharmalive.com in .JPG, .TIF, or .PDF format at 300 dpi or higher. We do not accept press releases through the post or through facsimile. All press releases will be posted on our electronic-information resource at pharmalive.com. Appropriate press releases will be published in various departments in *Med Ad News*. Although we welcome article ideas, please note that we do not accept articles or manuscripts for publication. For general inquiries, call 609-759-7680, or e-mail Director of Content Chris Truelove at chris.truelove@ubm.com.

SUBSCRIPTIONS
For new subscriptions, renewals, payments, address changes, and back issues, call 877-361-2911, or e-mail PLsubs@sunbeltfs.com.

REPRINTS AND PERMISSIONS
To order reprints of articles, or for permission to copy or reuse material from *Med Ad News*, call Wright's Media at 877-652-5295, or e-mail sales@wrightsmedia.com.

BPA WORLDWIDE

FOR EDITORIAL TO BE POSTED ON PHARMALIVE.COM
Call Barbara Lempert, 609-759-7663, or e-mail barbara.lempert@ubm.com
Send press releases for posting on PharmaLive.com to editorial@pharmalive.com.

inside

ON THE COVER

FEATURES

DEPARTMENTS

Med Ad News (ISSN 1067-733X) is published monthly by UBM Canon, 2901 28th St., Ste. 100. Santa Monica, CA 90405, United States. Periodicals postage is paid at Santa Monica, CA, and additional mailing offices. POSTMASTER: Send address changes to Med Ad News, PO Box 5060, Brentwood, TN 37024, United States. The U.S. subscription rate is $285 for one year; the Canadian subscription rate is $325 for one year; and the subscription rate for the rest of the world is $425 for one year. Advertising and editorial offices are located at 300 American Metro Blvd., Suite 125, Hamilton, NJ 08619, United States; telephone: 609-759-7600. For advertising, call extension 7674; for editorial, call extension 7680; facsimile: 609-759-7676.

BOLD NEW LOOK.

SAME GREAT FLAVOR.

HEALTH4BRANDS HAS A NEW LOOK!

Other than that, we wouldn't change a thing.

The H4B agencies connect audiences to health and wellness brands—seamless, unified, and focused on you—all around the world. Haven't had the H4B experience yet? Give us a call—we've got some bold answers for you.

THE H4B HEALTH4BRANDS NETWORK

H4B CHELSEA

H4B CATAPULT

H4B BACK BAY

H4B TORONTO

H4B EUROPE

These are just a handful of our full-service and specialty agencies—all told, we cover 90% of the world's market.

For more on the Health4Brands network, contact Meredith Levy at 212-251-7909 or mlevy@havashealth.com

contents | interactive&digitalmarketing

WHAT'S ONLINE

WEBCAST:
GAINING STRATEGIC ADVANTAGE THROUGH A 360 CUSTOMER VIEW

Date: June 12, 2013
Time: 12:00 pm - 1:00 pm ET

A key component of the new marketing model is creating a cogent customer experience, as well as effective campaign optimization, across all channels. A full 360 view of the customer is foundational to the process, yet companies generally face two challenges in making it happen. First, getting all the data in one place remains a struggle; e.g., the marketing data is often disconnected from field data, and some sources such as digital may be left out altogether. Second, once you've pulled together a 360 view, what exactly do you do with it in practice? Experts in this webinar will outline the most progressive approaches to pulling this view together, and even more importantly using it on a day-to-day basis to design and optimize their campaigns. Learn how to gain competitive advantage by overcoming the hurdles that continue to trip up so many organizations even today.

Speakers:

Anindita Basu, Principal and COE (Resource Optimization), IMS Management Consulting

Mark Karch, executive VP, Appature

Go to http://bit.ly/13kUTwa to register for this Webcast

WHAT'S IN PRINT

MOVING THE NEEDLE
Ad agency leaders are encountering all sorts of interactive-related demands from their clients – of which media mix modeling, market granularity, "solving" social media, and taking advantage of "Big Data" are just a few.
Go to page 10

HERE, THERE, EVERYWHERE
Continuing medical education is avoiding the resort-based events of old in favor of PC-based courses, intense group workshops, and events that blend live faculty with mobile technology.
Go to page 20

PROLIFIQ VIRTUALLY CONNECTING PHYSICIANS, MSLS
The software company Prolifiq has developed a mobile solution called CONNECT that allows sales reps to put physicians in touch with medical science liaisons immediately, efficiently, and compliantly.
Go to page 24

DIGITAS EXAMINES EFFECTIVENESS OF DIGITAL MARKETING IN PHARMA
Digitas Health has announced the release of "Effective Review and Approval of Digital Promotional Tactics," written by Dale Cooke, the agency's VP/group director, regulatory review.
Go to page 26

We've moved.

But don't expect any changes. Same brand-building creative. New location.

centron

Contact Marcia McLaughlin. Now located at 1745 Broadway. mmclaughlin@centroncom.com. 646-722-8902.

A healthstar vivactis global company

continued from page 1

take you to a microsite for more interaction) you can turn the limited first impression of a great TV spot into a lasting one," says Bruce Rooke, worldwide director of creativity, GSW. "Shazam (and soon, other 'second screen' technologies like Zeebox, Get This, and Flingo's Samba) can also make unbranded TV commercials more effective at transitioning to branded relationships – with more creative freedom to create those motivating, shareable spots consumers demand. Also, connecting your TV spot to branded entertainment content (i.e. product placement and "plot placement" by folks like brandarc.biz) is a powerful way to modernize and magnify your sixty seconds."

Rooke is also an advocate of what might be an unexpected use of television for pharma brands: the infomercial. "I still believe the 'good old' long-form infomercial still holds a lot of promise for healthcare (It's not just reserved for Shake Weight and ShamWow)," he says. "Look, you have a full 30 minutes to deliver the safety information, tell powerful human stories, and deliver a call-to-action. (And the average infomercial viewer probably has a host of relevant comorbidity issues…)"

To properly take advantage of television, though, brand managers must account for the way that most consumers interact with the TV today. Viewership is increasingly time-shifted to skip commercials, and viewers may be accessing TV content across one or several non-TV devices.

"We are well beyond just experimenting with digital 'TV like' experience formats," says Tim Pantello, managing director, Philadelphia, Digitas Health. "Each media plan today typically includes Hulu, YouTube and others that offer hyper-targeting, as well deep context that delivers an even more effective and efficient experience."

However marketers choose to use TV, though, they ignore it at their peril, no matter how trendy other channels may appear. With viewership and viewing time numbers continuing to grow, the good old TV set is still the quickest pathway to the largest numbers, and seems likely to remain so for some time.

"Even though the internet and social media are the hot and exciting trends, television remains the best medium to reach a broad audience," says Mike Peto, managing director at H4B Chelsea. "Over 99 percent of people have at least one television in the home and average viewing time of over four hours per day continues to grow. The challenge marketers face is not about whether you do or don't do TV, it's how you break through all the clutter given all the programming and channels today."

WHAT'S NEW?

When asked what clients are asking for in the DTC field that they had not in the past, agency leaders are offering a cornucopia of responses. For Megan O'Connor of Intouch Solutions, the answer is "patient-centric."

"Obviously the trend is toward patient-centric programs," O'Connor says. "Our brands are really putting patients first and working to make every branded message relevant and valuable to patients. And this can't be done without thinking about how patients behave, what they do, where they are, and importantly how they interact with their physician. That moment of truth where your brand may or may not be prescribed or refilled. There is still a huge gap when it comes to that intersection between a physician and a patient. Closing that gap is the next frontier. And with physicians not only caring, but being required to care about outcomes, compliance programs and communication between doctors and patients is inevitable. The winning brands make that happen seamlessly – and with value."

The primary DTC shift encountered by

DTC drug expenditure in 2012 decreased for the sixth straight year

by Andrew Humphreys
andrew.humphreys@ubm.com

Total direct-to-consumer spend for prescription products in 2012 dropped by double digits versus the 2011 total. The 2012 expenditure amounted to $3.47 billion, down at least 12 percent (Internet spend was not included in the total for 2011) compared to the previous year based on data provided by **Nielsen**.

The three largest media groups for DTC experienced year-over-year decreases. Television expenditure for 2012 was down 11 percent to $2.17 billion. Magazine spend for prescription medicines came to $1.01 billion, falling 16 percent compared to the 2011 level. For 2012, the newspaper total was $192.3 million, dropping 21 percent versus the prior year. The No. 4 DTC spend group in 2012 was the Internet at $68.4 million (the 2011 amount was not applicable). As the No. 5 group, radio also fell by double digits (34 percent), coming in at $23.1 million. On the other hand, outdoor expenditure during last year rose 61 percent versus 2011 to almost $3 million.

The leading disease/medical use categories in terms of DTC expenditure during 2012 included arthritis, erectile dysfunction, chronic obstructive pulmonary disease, depression, and pain.

Top DTC companies and brands

For the sixth consecutive year, **Pfizer** was the highest spender for Rx brands with a direct-to-consumer expenditure of $622 million, per data provided by Nielsen. That amount represented a decrease of 30 percent compared to the 2011 level. The decline in DTC spend for the New York-based biopharma company can be attributed to the loss of marketing exclusivity for **Lipitor** in November 2011. During that year, Pfizer spent $220.8 million on promoting the cholesterol therapy to consumers (the 2012 total was not available). From 2000 through 2011, Lipitor was the most-promoted Rx medication to consumers at about $1.65 billion. More than $700 million of that total was spent during 2009-2011 as Pfizer ramped up DTC advertising for the top-selling prescription medicine of all-time before U.S. generic competition arrived.

Pfizer's top DTC brands during 2012 were the arthritis drug **Celebrex**, the erectile dysfunction medicine **Viagra**, the fibromyalgia treatment **Lyrica**, and the smoking cessation product **Chantix**. More than $65 million in DTC dollars was spent per brand. Celebrex lead the way with an expenditure of $129.8 million, up 14 percent versus the 2011 total. The 2012 expenditures for Viagra, Lyrica, and Chantix were all down by percentages in the teens.

Eli Lilly has ranked as the No. 2 industry spender for three consecutive calendar terms. The Indianapolis corporation spent $433.5 million on DTC promotion in 2012, a 3 percent decrease compared to 2011. Promotion for the pain medication and antidepressant **Cymbalta** benefitted from $243 million of that 2012 total – the highest spend on one brand last year – compared to $271.3 million in 2011, also tops for that year. Lilly's erectile dysfunction medicine **Cialis** was the No. 3 most-promoted product to consumers in 2012 at $162.9 million, an increase of 13 percent compared to 2011.

Abbott Laboratories finished 2012 as the third-highest DTC spender in 2012 at $301.1 million, rising 65 percent versus the company's 2011 amount. The significant increase can be attributed to the rise in **Humira** promotion to consumers. After spending $91.6 million on the brand's DTC promotion for arthritis and psoriasis in 2011, the 2012 tally came to $195.1 million. For 2012, Abbott spent $84 million on Humira's arthritis indication ($49.2 million in 2011), $57.2 million on promoting the drug's use for Crohn's disease to consumers (no spend in 2011), and $54 million for its psoriasis usage ($42.4 million during 2011).

Merck spent nearly $100 million more on DTC brand promotion in 2012 compared to the previous year. The company's 2012 total came in at $285.7 million, versus $186.6 million during 2011. Merck of Whitehouse Station, N.J., did not spend more than $54 million on any one medicine as none of the company's products cracked the top 20 brand spend listing.

Biotech force **Amgen** climbed the leading company ranks, from No. 9 for 2011 to fifth place during 2012. After more than doubling its

continued on page 10

TOP 20 BRANDS — DIRECT-TO-CONSUMER ADVERTISING EXPENDITURE

2012 Rank	Brand	Disease/Medical Use	Expenditure in 2012 ($)	Expenditure in 2011 ($)	% Change	Company
1	Cymbalta*	Pain	165,789,484	166,973,828	-1	Eli Lilly
2	Cialis	Erectile dysfunction	162,919,188	143,904,406	13	Eli Lilly
3	Celebrex	Arthritis	129,839,953	114,175,156	14	Pfizer
4	Enbrel	Arthritis	127,123,094	99,648,734	28	Amgen
5	Abilify	Depression	114,785,016	131,485,578	-13	Otsuka Pharmaceutical
6	Viagra	Erectile dysfunction	107,864,008	127,584,641	-15	Pfizer
7	Advair Diskus 250/50	Chronic obstructive pulmonary disease	99,813,852	82,061,930	22	GlaxoSmithKline
8	Lyrica	Fibromyalgia	91,730,828	103,045,359	-11	Pfizer
9	Spiriva	Chronic obstructive pulmonary disease	89,752,398	76,149,219	18	Boehringer Ingelheim Pharmaceuticals
10	Humira**	Arthritis	83,952,141	49,174,867	71	Abbott Laboratories (now marketed by AbbVie)
11	Pradaxa	Blood clots	80,412,422	108,626,008	-26	Boehringer Ingelheim Pharmaceuticals
12	AndroGel	Low testosterone	79,988,234	0	N/A	Abbott Laboratories (now marketed by AbbVie)
13	Cymbalta*	Depression	77,197,688	104,368,750	-26	Eli Lilly
14	Chantix	Smoking cessation	65,367,852	80,412,117	-19	Pfizer
15	Prolia	Osteoporosis	60,004,031	21,366,953	181	Amgen
16	Symbicort	Chronic obstructive pulmonary disease	57,292,363	58,489,098	-2	AstraZeneca
17	Nexium	Acid reflux	57,251,438	19,973,537	187	AstraZeneca
18	Humira**	Crohn's disease	57,224,371	0	N/A	Abbott Laboratories (now marketed by AbbVie)
19	Restasis	Dry eye	56,689,312	52,472,840	8	Allergan
20	Humira**	Psoriasis	53,953,703	42,401,887	27	Abbott Laboratories (now marketed by AbbVie)

*Note: *Cymbalta is listed twice, segmented by the product's DTC promotion for pain and depression; **Humira is listed thrice, segmented by the product's DTC promotion for arthritis, Crohn's disease, and psoriasis.*
Sources: Nielsen (nielsen.com) and Med Ad News (PharmaLive.com)

A FRESH MIX OF EXPERTISE

No two fingerprints are the same. Neither are any two Fingerpainters.

We bring a diverse blend of skills, expertise and fresh thinking to your brand—from strategic planning and analytics to brand development and digital marketing.

Together, we'll help your brand make a memorable mark in the minds of your customers.

Curious? Call Ed Mitzen **518.488.8304** | **fingerpaintmarketing.com**

fingerpaint
Create
Something
Original

the leaders at Digitas Health has been that brand managers are asking for more media mix modeling and channel planning. The agency used to just get the traditional "What's the ROI?" question, but now clients want and expect much more granularity and a validated approach to arrive at Digitas' models.

"DTC marketers and their professional counterparts know they need to spend against each channel and target, but they aren't sure how much, when, where, and why," Pantello says. "So they need help with mix allocation and attribution modeling. This year we are starting to see real momentum and energy being put to mobile beyond just what the sales force needs on the iPad. Clients want to know how mobile can have impact on their business and be relevant/useful for their consumer/customer."

At GSW, leaders have found that the new DTC trend is really just a variation on an old theme: how to "solve" social media.

"Clients are still begging for answers on how to maneuver effectively through the Great Social Media Promise," Rooke says. "'Fake Social'" may cut it with some clients, but not with their customers. New and better answers have to be explored. I expect to see brand managers widening their vision of the audience, and starting to ask how we reach friends and caregivers more, knowing that, in this day and age, breakthrough information gets shared more quickly and effectively through a trusted loved one – rather than a brand."

Rich Levy, executive VP, chief creative officer of Draftfcb Healthcare, has noticed that spreading the various parts of a brand's marketing across a long list of specialist agencies is going out of style with clients.

"Today, brand managers are more and more looking for a single solution for completely integrated campaigns," Levy says. "One agency doing Professional, Consumer, Digital, Social, Market Access, et cetera. I think that the pendulum has swung back away from multiple agencies only doing only one part of the total communications platform. That model proved too expensive to sustain. That's why you're seeing so many 'stand-alone' digital agencies and 'stand-alone' advertising agencies merge. Silo structures don't usually work for long."

AbelsonTaylor's team has found that Big Data is, well, big.

"Few people have tapped the power of the data that we receive in the process of implementing promotion and CRM," Carter says. "In the course of the coming year, those requests will grow, especially as pharma companies take advantage of the insights that big data can provide. Today we're scratching the surface … analysis of the data available to us, coupled with a growth of the Internet as a communications medium, should allow us to increase reach and frequency to important customers more cost effectively than we can today."

(UN)BRANDED

As much as anything else, though, the one tool that brand managers are demanding in the fastest-growing frequency is something that belies their own titles: unbranded patient education materials. A number of developments in the marketplace have conspired together to make this so – empowered patients seeking answers on their own, aggressive review of brand-related claims by FDA's regulators, and even the questionable credibility of branded materials in the eyes of many patients – but their end result has been an explosion of brands who market without speaking their names.

"In the age of instant information, patients are becoming more adept at seeking an explanation for their symptoms and conditions, and are feeling increasingly knowledgeable and empowered," says Paul O'Neill, president of Ogilvy CommonHealth Wellness Marketing. "It's important that we as pharma marketers provide the critical information that the empowered consumer requires. It has been an ongoing request from DDMAC/OPDP for years and it's incumbent upon all of us to ensure that patients have the benefit of disease education, both with and without a brand story."

Coincident with this too is the appearance of an increase in warning letters around the gray area of 'quality of life outcomes,' where reviewers are forbidding any reference to an outcome that may speak to the qualitative benefits of a treatment. "Unbranded patient education, therefore, becomes an even more important approach to creating a deeper understanding of the benefits of therapy," O'Neill says.

According to Pantello at Digitas, rather than simply pushing out product messages repeatedly and hoping they cut through the media clutter, marketers are looking more holistically at the needs of HCPs and patients to make informed decisions about their healthcare. "Much of the information they need is best provided in product promotions, but some of those information needs are better presented in disease awareness materials that are not promoting any specific product," he says. "This is especially true for the larger number of high science products where a good deal of education is needed to help patients understand their treatment options. When implemented correctly, such disease awareness efforts by definition are not product promotions so they don't carry the risk of enforcement action for inappropriate promotional activity."

In addition, disease awareness communications lend themselves to certain new media opportunities. Since by definition they are not product promotions, there's no requirement to provide product risk information. "In some of the space-limited formats that can be a huge advantage," Pantello says. "So, many companies that want to start incorporating new communications channels (such as Twitter) into their mix are taking their first steps via unbranded, disease awareness communications and patient education efforts that are not directly tied to a specific product."

Like any tool, though, unbranded may not fit into every scenario. According to Connolly of Evoke, the usefulness of unbranded can be considerable, but only in a clearly delineated band of time.

"I believe there is a role for unbranded patient education, often as a way to set-up a strategic problem that your brand can solve," Connolly says. "This is a medium however, that should be used early in the patient's decision journey or during pre-launch. There is a time and a place for everything. In today's highly competitive, high patient value, short life cycle market, the time to establish your brand's core differentiating benefit has shrunk quite a bit. You need to get in and establish your brand in the consumer mind at the earliest possible moment. Don't let unbranded get in the way."

The key goal of any good unbranded effort, it seems, is inspiring conversations between patients and their physicians – raising awareness of Condition X sufficiently in the mind of a potential patient that they will seek out advice from their doctor. But doing this assumes a high degree of confidence in one's brand and its place in the physician's mind; otherwise, a marketer is just writing checks to the competition. Along these lines, O'Connor at Intouch notes that unbranded is particularly powerful as a tool for first-to-market or market leading brands. GSW's Rooke puts it a slightly different way, but the end result is the same.

"Believe it or not, triggering a conversation, which may or may not include your brand, is better than no conversation at all," Rooke says. "In the short time a patient has with an HCP, the ability to get to a realistic, intelligent dialogue around a sensitive subject will always benefit, more than hurt. It takes confidence in your brand and in your differentiating POV, it takes confidence in your professional communications – and it takes an enlightened view that it is in the patient's best interest to be on medication, ours or not." ■ MEDADNEWS

continued from page 8

DTC spend total from 2010 to 2011, the Thousand Oaks, Calif., company increased its 2012 amount 63 percent to $229.5 million. **Enbrel** once again was the product most heavily advertised to consumers for Amgen, rising 28 percent to $127.1 million for just its arthritis indication, placing the drug at No. 4 based on individual disease/medical use and No. 5 overall when combining all indications for each brand.

After ranking as the third-highest DTC spender of 2011, London-based **AstraZeneca** dropped to No. 6 for last year. The company's direct-to-consumer expenditure went down from $339.8 million for 2011 to $209.2 million in 2012. AstraZeneca's leading DTC brands were the chronic obstructive pulmonary disease product **Symbicort** and the acid reflux drug **Nexium**. Those brands had a 2012 spend of about $57.3 million apiece.

Allergan of Irvine, Calif., increased its expenditure from $160.7 million for 2011 to $185.7 million during 2012. The company's leading product in terms of direct-to-consumer spend was the eye drop medication **Restasis**. DTC promotion for this product grew 8 percent to $56.7 million for 2012.

Boehringer Ingelheim's DTC spend dropped from $190.5 million during 2011 to $174.7 million for last year. The chronic obstructive pulmonary disease drug **Spiriva** ranked amongst the top 10 DTC brands for 2012 at $89.8 million, accounting for an 18 percent increase compared to the prior calendar term. The blood clot drug **Pradaxa** had a DTC expenditure of $80.4 million versus $108.6 million during 2011.

The 2012 DTC spend for **GlaxoSmithKline** fell off its previous year's amount, dropping 16 percent to $171.8 million. Almost $100 million of that total was allocated to consumer promotion of the COPD medicine **Advair Diskus 250/50**, increasing 22 percent compared to 2011.

Rounding out the top 10 company spenders for 2012 was **Otsuka** Pharmaceutical for the second consecutive year. Otsuka's top DTC brand was **Abilify** at $114.8 million for promotion of its depression usage, down 13 percent compared to 2011.

TOP 20 COMPANIES — DIRECT-TO-CONSUMER ADVERTISING EXPENDITURE

2012 Rank	Company	Expenditure in 2012 ($)	Expenditure in 2011 ($)	% Change
1	Pfizer	621,989,812	884,991,312	-30
2	Eli Lilly	433,502,844	445,075,594	-3
3	Abbott Laboratories	301,141,094	182,574,375	65
4	Merck	285,660,094	186,614,266	53
5	Amgen	229,451,203	140,864,297	63
6	AstraZeneca	209,161,656	339,805,906	-38
7	Allergan	185,653,000	160,669,812	16
8	Boehringer Ingelheim Pharmaceuticals	174,708,656	190,450,094	-8
9	GlaxoSmithKline	171,839,500	204,558,984	-16
10	Otsuka Pharmaceutical	115,135,688	135,130,891	-15
11	Novo Nordisk	81,171,891	72,352,570	12
12	Novartis	72,655,633	99,041,961	-27
13	Bristol-Myers Squibb	60,827,570	83,913,266	-28
14	Johnson & Johnson	58,336,625	56,031,824	4
15	Teva Pharmaceutical Industries	49,768,660	30,321,363	64
16	Dainippon Sumitomo	47,840,082	74,371,789	-36
17	Roche	46,921,465	63,956,660	-27
18	Sanofi	38,335,590	44,054,168	-13
19	Astellas Pharma	30,816,090	42,830,520	-28
20	Shire	26,103,152	33,108,766	-21

Source: Nielsen (nielsen.com)

GROUPED MEDIA — DIRECT-TO-CONSUMER ADVERTISING EXPENDITURE

Media Type	Expenditure in 2012 ($)	Expenditure in 2011 ($)	% Change
Television	2,166,926,856	2,433,505,024	-11
Magazine	1,014,607,021	1,213,496,210	-16
Newspaper	192,281,015	244,229,517	-21
Internet*	68,435,617	N/A	N/A
Radio	23,146,864	35,125,884	-34
Outdoor	2,981,237	1,848,927	61
Total	3,468,378,610	3,928,205,562	-12

*Notes: Group Media Type Breakdown: TV = Network, Cable, Syndicated, Spot, Spanish Language Network, Spanish Language Cable; Magazine = National, Local, National Sunday Supplement, Local Sunday Supplement; Newspaper = National, Local; Radio = Network, Spot. *The following websites are excluded from internet spending: MySpace.com, Realtor.com, Yahoo! Mail, and YouTube. Source: Nielsen (nielsen.com)*

The **PULSE** has Risen!

The NEW

PharmaLive.com
Community

The *NEW* PharmaLive.com enhancements feature easier-to-access content and original reporting about the pharmaceutical & healthcare advertising industries you have come to love from the *Med Ad News*/PharmaLive/Pharmalot teams. This is *your* community where new ideas and new concepts are discussed, shared, and expanded upon, and where everyone can have a voice on the most pressing topics facing the pharmaceutical industry.

Check out the New PharmaLive.com now!

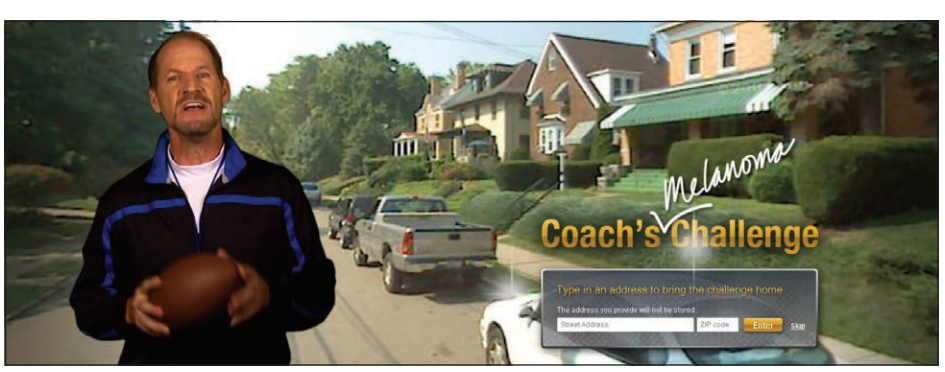
FAVORITES OF DTC

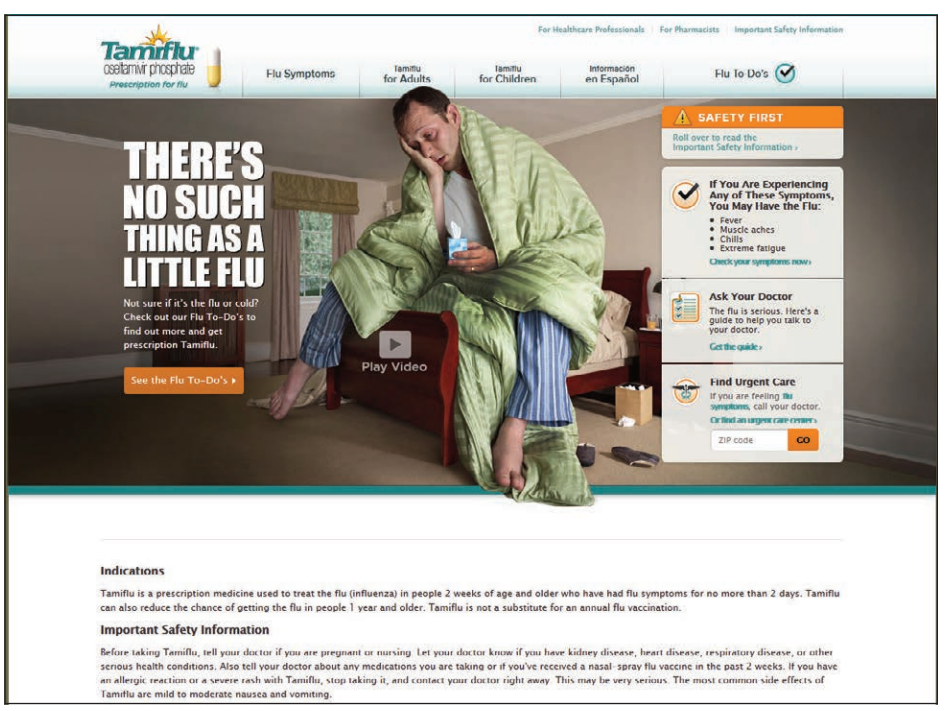
Med Ad News asked ad agency leaders to discuss their favorite DTC campaigns of the past year.

Tim Pantello, managing director, Philadelphia, Digitas Health: There is a lot of great activity being done in different channels. **Viagra** and **Lunesta** television commercials are definitely connecting with their audiences. **AstraZeneca**'s work on Twitter using @AZHelps to encourage people to report adverse events and get support with their medication costs is great. **Bristol-Myers Squibb** has a wonderful unbranded, disease awareness campaign for melanoma awareness making use of multiple channels, including social media.

Rich Levy, executive VP, chief creative officer, Draftfcb Healthcare: Two brands come to mind very quickly, not only because I love the creative work, but also because the work is helping propel the brand forward. The **Stryker GetAroundKnee** campaign is a great example of an advertising idea informing a product name and the name informing the way the product is sold. The second brand is **Tamiflu**. The "Don't Underestimate The Flu" campaign created a memorable campaign that made me stop and say, "Damn, I wish we had created that campaign." And because I'm male, and a big baby when it comes to getting sick, the message resonated with me, and made me think about what I would do if I got the flu. Kudos to both agency and brand teams.

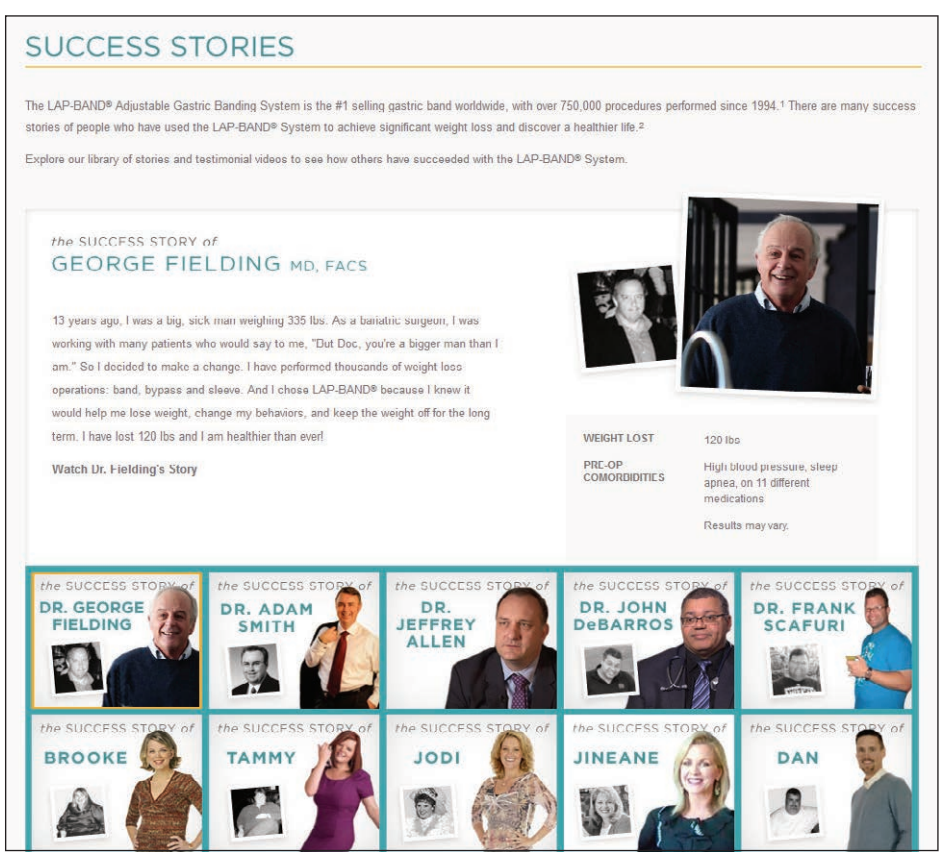
Michael Peto, managing director, H4B Chelsea: **Restasis** for chronic dry eye. **Allergan** has successfully utilized Dr. Allison Tendler in their "Doctor As Patient" television commercial for more than five years. Putting something in your eye is a scary and sometimes expensive proposition, especially when there are less expensive over-the-counter options available.





Knowing that a physician like Dr. Tendler uses Restasis gives patients the confidence that if she's doing it, it must be okay for me. They have incorporated Dr. Tendler into their physician, web, and loyalty programs.

Paul O'Neill, president, Ogilvy CommonHealth Wellness Marketing: **Lunesta** has done a great job of using its brand imagery (one could call it iconic) across a number of channels in a meaningful way and incorporating a clever TV media play utilizing the equity of this imagery. **Cymbalta** has stayed with a consistent message that provides realistic hope with a promise and execution that has remained consistent, yet also has been refreshed. **Lap-Band** combines the power of patient testimonials across venues and in a way that allows patients to take immediate action to find out more and get help. ■ MEDADNEWS



Last year, to celebrate our 15th anniversary we wrote Future15, giving a glimpse into our approach to digital health. Many of you wanted to know more. We decided the best way to help you get inspired by what's possible today was to conduct a full Katalyst digital planning process on Rellyant, our demo brand. Future15: Katalyst is a real-world example of a sophisticated digital health strategy. It's intended to educate and to inspire.

Don't be the last to reserve your FUTURE15: Katalyst Roadmap at klick.com/meet-katalyst

Klick Health


Rx

CLASS WARFARE

Pharmaceutical and biotechnology companies are fighting for diabetes market share via a variety of established and new-generation medicines.

By Andrew Humphreys andrew.humphreys@ubm.com

U.S. biopharma research companies are developing more than 200 innovative new medicines to help the nearly 26 million Americans affected by diabetes. These drugs – which are in clinical development or undergoing FDA regulatory review – include more than 30 for type 1 diabetes, about 130 for type 2, and 60-plus drugs for diabetes-related conditions, according to PhRMA.

One in 10 U.S. adults has diabetes and up to one-third could face the disease by 2050 if trends continue, per the Centers for Disease Control and Prevention. Prevalence is expected to grow sharply for different reasons, including an aging population more likely to develop type 2 diabetes, an increase in minority groups at high risk for the disease, and longer life spans among diabetes patients. If left untreated, diabetes can result in severe health problems and complications, including heart disease, stroke, vision loss and amputation. Diabetes was estimated to cost the United States $245 billion during 2012.

LEADERS OF THE PACK

Lantus has become one of the world's best-selling prescription medicines for any therapeutic indication. Marketed by **Sanofi**, Lantus generated 2012 sales of EUR4.96 billion ($6.38 billion), up 26.7 percent on a reported basis versus the 2011 amount. Approved by U.S. and EU regulators in 2000, this is the No. 1 selling insulin brand in terms of sales and units worldwide. Marketed in more than 120 countries, the three leading countries for sales of Lantus during 2012 were the United States, France, and Japan.

Composed of insulin glargine, Lantus is a long-acting analog of human insulin. The product offers improved pharmacokinetic and pharmacodynamic profile. The drug is indicated for once-daily subcutaneous administration in treating adult patients with type 2 diabetes mellitus who require basal insulin for the control of hyperglycemia; and for adult and pediatric patients 2 years and older with type 1 diabetes mellitus. A label extension for pediatric use was granted in the European Union during 2012.

Lantus is the most studied basal insulin with more than a decade of clinical evidence in diabetes treatment and a well-established safety profile. The medicine can be administered subcutaneously via syringes or specific pens including SoloSTAR, ClikSTAR, and AllSTAR.

The compound patent for Lantus is set to expire in the United States in August 2014, and in most of Western Europe as well as Japan during November 2014. A six-month pediatric exclusivity extension was granted in the United States (February 2015), and was pending clearance in the European Union (May 2015).

Lantus sales are forecasted to peak at EUR5.79 billion ($7.44 billion) during 2014, according to Sanford C. Bernstein analysts.

Another diabetes brand in 2012 that generated more than 23 percent year-over-year growth worldwide was **Januvia/Glactiv/Tesavel**. The dipeptidyl peptidase-4 (DPP-4) inhibitor is available for the treatment of type 2 diabetes. Containing sitagliptin phosphate, **Merck** markets the active chemical around the world under the brand name Januvia.

Januvia entered the U.S. arena in October 2006. DPP-4 inhibitors represent a class of prescription medications that improve blood sugar control in patients with type 2 diabetes by enhancing a natural body system known as incretin, which helps to regulate glucose by affecting the beta cells and alpha cells in the pancreas.

Whitehouse Station, N.J.-based Merck reported Januvia 2012 sales of $4.09 billion, compared to $3.32 billion during 2011. Sitagliptin is also marketed in Japan by **Ono** Pharmaceutical under the trade name Glactiv, and in Spain by **Almirall** via the brand name Tesavel. Including sales reported by all three companies, branded sitagliptin sales totaled about $4.51 billion in 2012 and $3.67 billion for 2011.

Merck's blockbuster **Janumet** combines Januvia with metformin hydrochloride in one tablet for treating type 2 diabetes. Sitagliptin plus metformin is marketed in Spain by Almirall as **Efficib**. The oral antihyperglycemic agent targets all three key defects of type 2 diabetes. Janumet gained U.S. marketing clearance on March 30, 2007, less than six months after FDA approval was granted for Januvia. Januvia/Efficib produced worldwide sales of about $1.72 billion in 2012 and $1.41 billion during 2011, with the majority of those amounts accounted for by Janumet.

During February 2012, U.S. regulators approved the type 2 diabetes medication **Janumet XR**, which brings together sitagliptin and extended-release metformin. Janumet XR provides a convenient once-a-day treatment option for health-care providers and patients who need assistance to control their blood sugar.

The main compound patent for sitagliptin is scheduled to expire in the United States in 2022. The drug's salt patent is protected in the United States until 2026. In 2018, the sitagliptin franchise of products is expected to be the best-selling worldwide for any therapeutic indication at more than $9.7 billion.

NovoLog/NovoRapid exceeded $2 billion in yearly sales for the third consecutive calendar term during 2012. After producing DKr12.8 billion ($2.21 billion) in 2011 global sales, the 2012 total amounted to DKr15.69 billion ($2.71 billion). Composed of insulin aspart, NovoRapid was introduced in the European Union in 1999 and NovoLog entered the U.S. marketplace during September 2001.

According to the Danish company **Novo Nordisk**, NovoLog/NovoRapid is the world's most widely used rapid-acting insulin for use at mealtimes. For patients with type 2 diabetes who have uncontrolled blood glucose levels while on a basal insulin, intensification with the product helps attain and maintain treatment goals. NovoLog/NovoRapid is used by patients with type 1 and type 2 diabetes.

NovoLog's U.S. compound patent expires during 2014 and the formulation patent is protected until 2017. The compound patent has expired in Germany, France, the United Kingdom, China and Japan. Analysts for EvaluatePharma (EP) have projected NovoLog/NovoRapid to rank as the world's No. 3 diabetes medicine in 2018 with sales of $4.93 billion and an 8.5 percent share of the worldwide market.

TOP-SELLING DIABETES PRESCRIPTION MEDICINES

Medicine	2012 sales ($ in millions)	2011 sales ($ in millions)	2010 sales ($ in millions)	2009 sales ($ in millions)	2012 reporting company	First approval date and/or launch date
Lantus	$6,378	$5,036	$4,514	$3,961	Sanofi	U.S. approval: April 20, 2000 EU approval: June 9, 2000 EU launch: June 15, 2000 U.S. launch: May 2001
Januvia/ Glactiv/ Tesavel	4,511	3,665	2,535	1,952	Merck & Co. (Januvia), Ono Pharmaceutical (Glactiv), and Almirall (Tesavel)	Januvia U.S. approval: Oct. 16, 2006 Januvia U.S. launch: October 2006 Tesavel Spain launch: April 2009 Glactiv Japan approval: Oct. 16, 2009
NovoLog/ NovoRapid	2,709	2,211	2,054	1,683	Novo Nordisk	NovoRapid EU launch: 1999 NovoLog U.S. launch: September 2001
Humalog	2,396	2,368	2,054	1,959	Eli Lilly	EU approval: April 30, 1996 U.S. approval: June 14, 1996 U.S. launch: Aug. 12, 1996
Janumet/ Efficib	1,715	1,410	987	672	Merck & Co. (Januvia) and Almirall (Efficib)	Janumet U.S. approval: March 30, 2007 Efficib Spain launch: April 2009
Levemir	1,690	1,326	1,188	902	Novo Nordisk	EU approval: June 2004 U.S. approval: June 16, 2005 U.S. launch: March 28, 2006
Victoza	1,639	1,034	400	15	Novo Nordisk	EU launch: Summer 2009 U.S. launch: Feb. 16, 2010
NovoLog Mix/NovoMix	1,613	1,429	1,350	1,122	Novo Nordisk	NovoMix EU launch: March 26, 2002 NovoLog U.S. launch: Sept. 30, 2002
Humulin	1,239	1,249	1,089	1,022	Eli Lilly	U.S. approval: Oct. 28, 1982
Actos Note: Lilly markets Actos in certain non-U.S. countries.	1,203+ (estimate)	3,305	4,283	4,045+	Takeda Pharmaceutical and Eli Lilly	U.S. approval: July 15, 1999 U.S. launch: Aug. 2, 1999 Japan launch: December 1999 EU launch: October 2000
Onglyza and Kombiglyze XR	1,032	684	227	35	Bristol-Myers Squibb and AstraZeneca	Onglyza U.S. launch: August 2009 Kombiglyze XR U.S. launch: Jan. 7, 2011
Galvus and Eucreas	910	677	391	181	Novartis	Galvus EU approval: Sept. 28, 2007 Eucreas EU approval: Nov. 14, 2007 Galvus EU launch: Early 2008 Eucreas EU launch: Early 2008

Sources: eKnowledgeBase.com and industry reports
Notes: This chart presents the top-selling diabetes medicines in order by their sales for 2012. Certain products are represented by more than one company due to joint-marketing or joint-promotion accords. Joint-promotion profit or royalty revenue are not included in product sales totals.
** + = Sales are assumed to be higher than the represented total.*
**All foreign product sales are reported in U.S. dollars using Federal Reserve exchange rates. 2012 average rates of exchange were used to translate all yearly figures.*
**Takeda 2012 product sales are an estimate for the fiscal year ended March 31, 2013 (2011= year ended March 31, 2012; 2010 = year ended March 31, 2011; 2009 = year ended March 31, 2010).*

ARRIVAL OF THE SGLT2 INHIBITORS

The next wave of new diabetes drugs expected to follow the market success of the DPP-4 inhibitors are the sodium glucose co-transporter 2 inhibitors. The kidneys of individuals with type 2 diabetes reabsorb greater amounts of glucose back into the body compared to non-diabetic people, which may lead to elevated glucose levels. SGLT2s block the reabsorption of glucose by the kidney, increasing glucose excretion and lowering blood glucose levels.

In late March 2013, the Food and Drug Administration approved the first SGLT2 inhibitor to reach the U.S. market: **Invokana**. Containing the active chemical canagliflozin, Invokana is available to improve glycemic control in adults with type 2 diabetes. This is the only oral, once-daily medication available in the United States offering improved glycemic control, while also demonstrating reduced body weight and systolic blood pressure in clinical studies.

"Patients with type 2 diabetes struggle managing their blood sugar, and nearly half of adults with type 2 diabetes do not achieve recommended levels of glucose control, increasing their risks for potentially life-threatening complications," noted Richard Aguilar, M.D., medical director of Diabetes Nation and Diabetes Care Foundation, a non-profit organization dedicated to improving diabetes care. "Invokana is thought to work differently than other currently available medicines because it reduces blood glucose by acting on the kidneys as a 'glucuretic,' increasing

True CREATIVITY COMES FROM *innovation* IN THE FACE OF REGULATION

Our work doesn't stop at just building award-winning digital.
We create engagement with tools you won't find anywhere else.

pharmawall
Facebook moderation
thepharmawall.com

allora
iPad® platform
alloraheath.com

ssshare.it
URL shortener
ssshare.it

share»send»save®
Social sharing
sharesendsave.com

INTOUCH SOLUTIONS®
digital | social | mobile

REDEFINING PHARMA MARKETING

intouchsol.com

the loss of glucose in the urine. What has historically been viewed as a sign of diabetes – glucose in the urine – may also reflect the efficacy of a new and unique approach to treatment."

Janssen Pharmaceuticals and its affiliates have rights to Invokana via a license deal with **Mitsubishi Tanabe** Pharma. Janssen and other **Johnson & Johnson** companies hold marketing rights in North America, South America, Europe, the Middle East, Africa, Australia, New Zealand, and parts of Asia.

Pharma powers **AstraZeneca** and **Bristol-Myers Squibb** have thus far been unsuccessful in bringing to the U.S. market their own SGLT2 inhibitor: dapagliflozin. The regulatory filing for this drug was accepted for FDA review in March 2011. Three months later, a regulatory agency advisory committee voted against approval. In January 2012, FDA issued a complete response letter regarding the new drug application for the novel compound for treating type 2 diabetes in adults. The letter requested clinical-trial data from continuing studies, and potentially information from new trials. A refiling of the NDA is expected to occur in 2013.

AstraZeneca and BMS were able to gain EU regulatory clearance for the drug in November 2012, marking the first approval anywhere for a SGLT2 inhibitor. The EU approval of dapagliflozin – branded as **Forxiga** – was based on the results of a broad clinical study program that included 11 double-blind, randomized, placebo-controlled Phase III trials with 5,693 patients globally. The studies assessed the safety and efficacy of the drug as a once-daily oral therapy.

Dapagliflozin was discovered by New York-based Bristol-Myers Squibb. BMS and AstraZeneca of London entered into a collaboration during January 2007 to research, develop and commercialize select investigational medicines for type 2 diabetes. The Bristol-Myers Squibb/AstraZeneca diabetes collaboration is committed to worldwide patient care and improving patient outcomes in treating type 2 diabetes. The portfolio of type 2 diabetes products developed as a part of the BMS/AstraZeneca collaboration includes the first-in-class SGLT2 inhibitor Forxiga, as well as the DPP4 inhibitors **Onglyza** (saxagliptin) and **Kombiglyze XR/Komboglyze** (saxagliptin and metformin HCl extended-release fixed-dose combination).

Onglyza was introduced in the United States in August 2009 and Kombiglyze XR debuted on the U.S. market in January 2011. Komboglyze was approved for EU marketing on Nov. 29, 2011. The Onglyza and Kombiglyze XR product line breached the billion-dollar sales barrier for the first time during 2012. After generating combined sales of $684 million in 2011, the products brought in $1.03 billion for 2012.

During August 2012, Bristol-Myers Squibb completed the acquisition of **Amylin** Pharmaceuticals. Bristol-Myers Squibb and AstraZeneca proceeded to expand their existing alliance in diabetes to incorporate Amylin's portfolio of diabetes medications. The products included the glucagon-like peptide-1 receptor agonists and first-in-class meds **Byetta** (exenatide injection) and **Bydureon** (exenatide extended-release for injectable suspension).

Byetta was launched in the United States in June 2005. Byetta injection was the first in a new class of type 2 diabetes drugs known as incretin mimetics. The GLP-1 receptor agonist was co-promoted in the United States by **Eli Lilly** and Amylin until Nov. 30, 2011, when Amylin took over the drug's marketing in that territory. Bydureon was cleared for approval in Europe in June 2011 and the United States during January 2012 for treating type 2 diabetes. Bydureon is the first once-weekly treatment for T2D.

Another top 15 pharma company partnership for developing diabetes drugs exists between Eli Lilly and **Boehringer Ingelheim**. During first-quarter 2013, EU health authorities accepted for review the marketing authorization application for **empagliflozin** as a treatment for type 2 diabetes (T2D) in adults. The NDA filing is awaiting acceptance by FDA. A regulatory submission in Japan is anticipated for 2013.

Empagliflozin has been studied for the reduction of blood glucose levels in adults with T2D. As a SGLT2 inhibitor, the drug has been demonstrated to reduce blood glucose by removing excess glucose independently of beta cell function and insulin resistance. Analysts from Sanford C. Bernstein have predicted that Lilly's share of 2020 global sales for empagliflozin will total $676 million.

Boehringer Ingelheim and Eli Lilly during January 2011 first announced their alliance in the area of diabetes. The partnership is focused on several compounds representing a few of the largest treatment classes.

Tradjenta/Trajenta/Trazenta (linagliptin) is one of the drug compounds from the BI/Lilly partnership to reach the marketplace. The drug was approved for marketing by U.S., EU and Japan health regulators during 2011 for the treatment of adults with type 2 diabetes. Linagliptin was the first DPP-4 inhibitor approved at one dosage strength (5 mg, once daily) for adults with type 2 diabetes, without any need for dose adjustments. The drug is primarily excreted unmetabolized through bile and gut, thus no dose adjustment is necessary in adult patients with kidney or liver impairment.

Tradjenta can be used as monotherapy or in conjunction with other commonly prescribed meds for type 2 diabetes: metformin, sulfonylurea or pioglitazone (the latter is marketed as the blockbuster **Actos**). Sanford C. Bernstein analysts have projected Lilly's portion of Tradjenta global sales in 2020 will reach $455 million.

The most recent diabetes alliance for the development of a SGLT2 inhibitor brings together two industry forces, **Pfizer** and Merck. Announced during late April 2013, the parties

agreed on a global (excluding Japan) collaboration for the development and commercialization of Pfizer's **ertugliflozin**. The investigational oral sodium glucose cotransporter inhibitor is being developed for treating type 2 diabetes. Phase III studies for the new drug compound are anticipated to launch during 2013.

Merck, via a subsidiary, and Pfizer will collaborate on the clinical development and commercialization of ertugliflozin and ertugliflozin-containing fixed-dose combos with metformin and Januvia tablets. Merck will continue to hold the rights to its existing portfolio of sitagliptin-containing medicines. Merck and Pfizer will share potential revenues and certain costs on a 60/40 percent split.

"The diabetes alliance between two big pharma rivals, Pfizer and Merck & Co, is driven by a familiar desire to share the risk of developing drug classes facing increasing regulatory scrutiny that nevertheless target huge potential markets," noted analysis from EP Vantage. "The deal gives Merck access to Pfizer's SGLT2 inhibitor ertugliflozin, as well as putting in play its combination with Merck's $4bn DPP-IV inhibitor, Januvia, and it will be interesting to see how other diabetes players respond. The deal is of immediate relevance to Boehringer Ingelheim's alliance with Lilly, and to the U.S. biotech group **Lexicon** Pharmaceuticals."

Lexicon of The Woodlands, Texas, is proceeding with preparations for the initiation of a new stage of clinical trials for **LX4211**. This oral, dual inhibitor of sodium glucose transporters 1 and 2 will be entering Phase III trials in type 2 diabetes and a Phase II study in type 1 diabetes. While SGLT2 is the transporter responsible for most of the glucose reabsorption performed by the kidney, SGLT1 is the main transporter responsible for glucose and galactose absorption in the gastrointestinal tract. Lexicon says LX411 is unique as the first dual inhibitor of SGLT1 and SGLT2 in clinical development for diabetes.

"Merck had been one of the likelier potential licensees for LX4211, and the big pharma group's choice of a straight SGLT2 inhibitor does undermine Lexicon's contention that dual 1 and 2 subtype inhibition improves tolerability," according to EP Vantage analysis. "Nevertheless, Sanofi is a natural partner for LX4211."

"The (Merck-Pfizer) collaboration underscores the heated race in the diabetes market and, in particular, to develop a new type of treatment that can avoid the sort of side effects that have raised questions about drugs that mimic a hormone called GLP-1 to stimulate natural insulin production," commented Ed Silverman of Pharmalot. "Recently, different studies have generated concerns about not only pancreatitis, which is not a new potential side effect, but also the possibility that patients may develop pre-cancerous cellular changes. The findings have prompted watchdog groups to call for additional studies and, in one case, for the FDA to ban the drugs."

According to a Johns Hopkins research report, individuals who take GLP-1 (glucagon-like peptide-1) based therapies to control blood sugar are twice as likely as those on other types of sugar-control medication to be hospitalized with pancreatitis. In an article posted online in JAMA Internal Medicine, the scientists say GLP-1 drugs are associated with an increased risk of hospitalization for acute pancreatitis. Sitagliptin and exenatide evidently may contribute to the formation of lesions in the pancreas and the proliferation of ducts in the organ, leading to wellsprings of inflammation.

Doctors and health authorities have been aware that pancreatitis could be a side effect of GLP-1 therapies, a risk that emerged in animal studies and reports to FDA. According to the Johns Hopkins investigators, their study is the first to accurately measure the strength of this risk in analyses that accounted for other pancreatitis risk factors, including gallstones, obesity and heavy alcohol usage.

OTHER PROMISING PIPELINE PROSPECTS

Lilly's diabetes product pipeline includes the GLP-1 analog **dulaglutide** as a once-weekly treatment. The company announced in April 2013 positive Phase III study results for the new drug candidate. Primary efficacy endpoints of non-inferiority to insulin glargine, as measured by the reduction of hemoglobin A1c (HbA1c) levels at the 1.5 mg dose, were met in the AWARD-2 and AWARD-4 trials. The five AWARD studies will support registration filings of dulaglutide, anticipated for 2013. Sanford C. Bernstein analysts have forecasted dulaglutide worldwide sales of $1.32 billion for 2020.

Sanofi is developing a GLP-1 receptor agonist as a next-generation version of its mega-brand Lantus. Lixisenatide represents the first once-daily prandial GLP-1 receptor agonist for treating adults with type 2 diabetes mellitus. During February 2013, the drug was accepted for marketing review by FDA and was granted clearance by the European Commission under the trade name **Lyxumia**. In-licensed from **Zealand** Pharma, lixisenatide has been approved for marketing in Mexico for type 2 diabetes.

Sanofi is developing a new version of Lantus for type 1 and type 2 diabetes. During the third quarter of 2012, the Paris-based company launched four new Phase III trials evaluating the new formulation of insulin glargine. The first Phase III headline results in diabetes are expected during second-quarter 2013.

Sanford C. Bernstein analysts have projected worldwide 2020 sales of EUR889 million ($1.14 billion) for the new Lantus version and EUR442 million ($568 million) for lixisenatide. ■ MEDADNEWS

HERE, THERE, EVERYWHERE

Continuing medical education is avoiding the resort-based events of old in favor of PC-based courses, intense group workshops, and events that blend live faculty with mobile technology.

by Christiane Truelove
(chris.truelove@ubm.com)

CME dodged a regulatory bullet in February, when the Centers for Medicare & Medicaid Services created a special exclusion under the National Physician Payment Transparency Program for payments to speakers at accredited continuing education programs. With that battle behind them, providers of accredited CME programs are focusing on creating programs that are a far cry from the junkets that plopped a couple of hundred doctors at a luxury resort for a few slide decks and a lot of golf. CME companies are focusing their efforts not only on physicians, but on all healthcare workers who need credits to retain certifications, such as pharmacists, nurses, nurse practitioners, and physicians. CME companies are using the advantages of mobile technology to boost learning, and key opinion leaders on the faculty of CME programs these days include not only eminent doctors, but patients as well. And providers of CME insist that with the changes coming from the Affordable Care Act, CME must come forward to play a vital role in improving the U.S. healthcare system.

FACING FUNDING CHALLENGES

In 2012, the Accreditation Council for CME released 2011 data that showed total commercial support for CME that year had slipped 11.4 percent from 2010 to $746.4 million. Part of the reduction was attributed to the fact that through 2010, ACCME-accredited and state-accredited providers reported the monetary value of in-kind commercial support they received, and included that amount in their total commercial support numbers. Beginning in 2011, due to a modification in ACCME commercial support reporting requirements, accredited providers no longer included the monetary value of in-kind support and reported only the dollar values for funds actually received. Examples of in-kind commercial support include equipment, supplies, facilities, and other nonmonetary resources provided by a commercial interest in support of the CME activity.

2011 was the fourth year in a row that industry funding for CME had declined, with grants from industry comprising about 33 percent of CME income, down from 50 percent during 2006.

With commercial support of CME slipping came a decline in the number of CME providers, going from a high of 736 in 2007 to 687 in 2011. According to the ACCME, most of the decline stems from nonprofit physician membership organizations, for-profit publishing/education companies, and hospital/health care delivery systems. For-profit CME providers are under particular pressure to prove the value of their product and demonstrate that their courses improve a doctor's knowledge and the practice of medicine. To that end, companies are finding digital is playing an important role in CME, but live events are still very important.

FROM ONLINE TO LIVE TO BACK AGAIN

For **Medscape**, which is known for its online publishing and educational activities, the company is starting to do more live events with a digital component. According to Jaime DeMaria, VP, education and marketing, the company is a believer in what he calls "blended learning."

"We're actually taking people from an online arena to a live event, then back online again," DeMaria told *Med Ad News*. "We've recognized that folks learn in different ways, and it's not just exclusive to live, or just exclusive to online. We can get someone online and get that prework in, where they get the knowledge transfer early on, and then we get them into the live event where they're at a conference."

After the live event, the main points raised then get pushed out to Medscape's membership online, he says. Medscape recently did its first blended learning event, "it was a smaller setting, we did a smaller, roundtable discussion, with faculty in a more moderated, back-and-forth, intimate discussion about some clinical points around the topic of rheumatology," DeMaria says. "And from there we'd take the information, and go back online and push it back out to our membership. So there was an engaging conversation that took place live, and then the pearls from that program and the follow-up expert commentary from the key opinion leaders in this field. With a three-step phase you can engage in all three steps, you can engage in step one, or step two, or step three."

These types of events can be done in any specialty, with Medscape's membership surveyed to determine what topics they would like covered. "We've seen this concept of blended learning is really something that physicians find interesting," DeMaria says. "We see in the educational literature that learning is a concept that you reinforce through online and then live activities. We've gotten some good receptions, we've gotten good turnout, and we're looking to do a few more of these later on this year."

Scott Weber, CEO of **Med-IQ**, also believes in the power of live events with a digital component before, during, and afterwards. But the type of live events has changed due to financial pressures.

"The data are fairly consistent that the live platforms still have a place from an educational point of view in that they increase knowledge and awareness in certain disease states and emerging treatments, emerging therapies," he told *Med Ad News*. "The challenge you have with that is first and foremost, from a budget standpoint. Those meetings tend to be expensive and you know that CME has undergone a reduction in funding during the last two years. And there's always the question of what are you getting when you fund an activity like that, what is the outcome you can measure. Again, it tends to be more short-term knowledge and awareness than anything else."

Instead of large live events, Med-IQ has focused on workshops.

"This is not a dinner meeting format, these are real hands-on, roll-up-your-sleeves kind of environments where healthcare providers are getting into cases and working with facilitators and faculty moderators, where it's a more hands-on type of experience and more engagement and interaction in those small group settings to really help driving the learnings and their application to practice," Weber says. "We're seeing those models are very effective, because they enable the interaction, enable physicians to ask questions, share stories. Again, it's not the one person sitting up in front of 600 people in a room just running through their deck presentation of slides. We're doing these events in multiple disease states and multiple audiences, with a fairly high success rate, not only in participation and in attendance, but in the outcomes we're able to generate as a result."

Weber says Med-IQ's workshops are going beyond just reviewing case studies, by bringing patients into the event as speakers. "What they're able to do is help to put a personal face on the information that's being provided," he says. "Patients share their experiences and provide feedback. It's a really effective tool for learning, because cases can only go so far, and by bringing a patient into the mix, we're seeing very high success rates as far as our outcomes data show."

According to Thomas Sullivan, president of the medical education company **Rockpointe** Communications, one trend in CME will be towards more integrated programs that include patient outreach and patient education.

Weber says incorporating patient outreach into CME is important, because "There is a disconnect between what physicians think their patients are hearing and what the patients are really hearing.

"There's also a disconnect between the patients' expectations for that experience with their physicians, and what the physician actually delivers And when you can close those types of gaps, learning gaps and performance gaps, you could only improve healthcare, you could only improve that physician-patient experience. We don't address them enough. We address the clinical side, the treatment side, all the different pieces and elements of the physician-patient interaction, but the gaps in communication, this is a big part of why we're doing this."

Like Weber, Sullivan also does not expect live CME meetings to disappear. "The end of the live meeting has been greatly exaggerated," he told *Med Ad News*. "I was recently at a conference with Microsoft, and they talked about how they had gone to all-digital meetings, and now they're going back to a live meeting model, because the interaction with people is just important. I think that when firms like Microsoft – and this was for their healthcare customers – if they say that they see the value of live meetings, I don't think the live meetings are going away. I think we have to look at digital just like you look at any other additional technology, it's just one more way of reaching people, it's just a different modality."

Digital does allow doctors in remote locations or time-pressed doctors to more easily fill CME requirements, Sullivan says. "I'm not a doctor, but given the fact that I could put things off to the last minute, perhaps some doctors do as well, and digital is a great way of allowing them to fill their requirements when they see themselves coming up short," he says.

THE ROLE OF MOBILE

Weber and Sullivan say mobile technology has become an important part of each company's live events, with iPads being used as part of the presentations.

"We used them during a program at the surgical oncology meeting," Sullivan told *Med Ad News*. "The slides were pushing through the iPad, so you could watch the slides, and take notes, and e-mail the notes to yourself when the program was over; you could ask questions on the iPad while the program was happening. And we were also doing questions for the audience through the iPad."

Additionally, physicians in that program were able to take their maintenance of certification tests immediately afterward, using the iPads.

Weber says the iPads' "cool factor" help keep audiences engaged. "[The iPad] keeps them active and engaged in the event, and from a learning standpoint, that's half the battle right there," he says.

DeMaria says physicians are looking to online as the place where they can get on-demand CME, when they want it, and mobile is playing a role in that. "We're seeing with physicians smart phones and larger smart phones are coming into the world, our mobile apps and all of our programs are mobile optimized," he told *Med Ad News*. "We're excited about what we're doing and where we're heading here."

Though most of Medscape's online CME is consumed at desktops, physicians are consuming CME on mobile devices as well, DeMaria says. "About 2/3 of all physicians on Medscape are active through their mobile devices as well," he says. "I think that's just a testament to the fact that if they're able to sit down and get a break in their days, physicians will access Medscape through their mobile device. I don't think we're seeing a dramatic shift from the desktop, what we're seeing is people are using the Web more frequently. With the advent of smarter phones and easier to use devices, we're seeing more point-of-care use during the day."

Weber says Med-IQ is not seeing a high demand for mobile-optimized CME from physicians.

"When we survey our physicians, we're not seeing that necessarily to be the case," he says. "What they want to do is be able to access education online, from a trusted source, that they're able to get to efficiently and effectively, and consume education in smaller bites, if you will. So not necessarily endure a 60-minute or 90-minute Webcast, but a series of Webcasts, maybe 15-minute or 30-minute modules – and in some cases, looking at even shorter interventions more frequently over a period of time. And we're still seeing that they want that on their PC, on their laptop, through an iPad perhaps. Not so much on the phones."

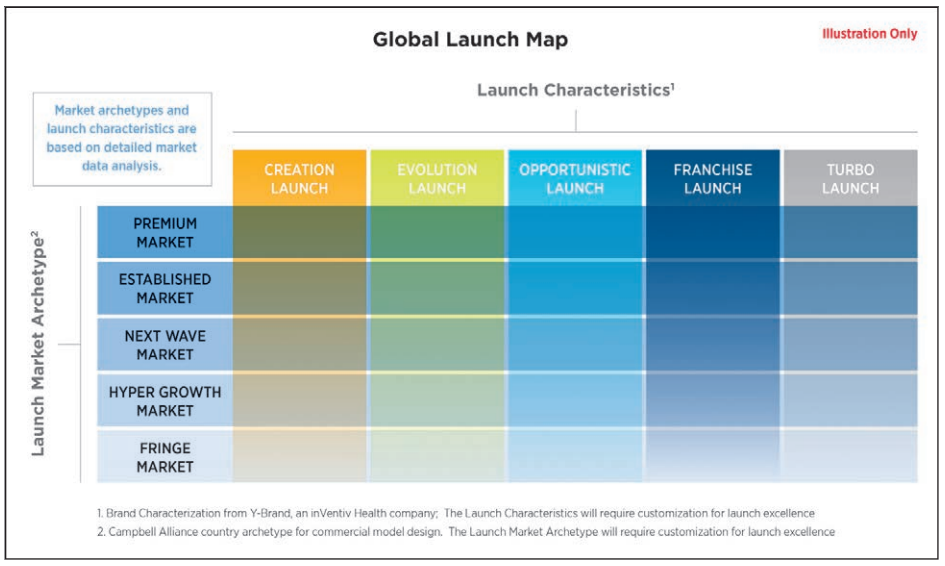
Though physicians are not going to view a 60-minute video on an iPhone, they are demanding educational tools that they can use at the point of care on smartphones and tablets, Weber says. "But the broader, didactic educational slides are more for the PC or laptop," he says. ■ MEDADNEWS

By Joshua Slatko joshua.slatko@ubm.com

The art of launch excellence: Guiding the future with a global launch map

By Rohit Sood and Philip Vorhies

True launch excellence comes from using the lessons of experience and market insights to drive proactive decision-making and planning. Harnessing data and experiences to characterize a launch facilitates the development of a Global Launch Map, which can be used to inform future launch investments, strategies, plans, and tactics to better ensure a successful roll-out for a brand.



Too many organizations fail to track, assess, and learn from past experiences or proactively plan to account for local differences. When brand directors get into a position to spearhead a launch, they will often try to put their own imprint on the launch and, in the process, try to reinvent the wheel. They will fail to take advantage of the key lessons that might have been learned during previous launches. Other times, organizations will hire someone from outside the organization to lead the launch because the individual was successful elsewhere. However, no two companies are the same. Launch team leaders need to understand what worked well and what has not worked well in the past given their specific organizational culture and customer group.

Organizations can also have a tendency to develop a standard approach to product launches that they will apply again and again. While this may be useful from a planning and logistics perspective, it does not allow them to take advantage of the uniqueness of their asset and maximize its uptake and value. Another common mistake companies make is to get too involved in their own science and fail to pay attention to what the market actually cares about.

When considering launch decisions, organizations should balance market needs, the product's value, and business needs and look at the investments, tactics, and strategies that have worked in the past to inform launch strategies and tactics going forward. They should look not just internally, but also externally, to gain insight from the experience of competitors. While an external view can be valuable, it needs to be balanced with the understanding that what worked well for one organization may not work for every organization. The experience of competitors must be weighed against the organization's own capabilities.

Build the Global Launch Map

Building the Global Launch Map begins by characterizing the launch. Organizations must first analyze market data to determine appropriate launch characteristics and launch country archetypes. Potential launch characteristics to consider include asset type, entry sequence, organization experience, competitive intensity and mix, pricing dynamics, and therapeutic area dynamics. Potential country archetype levers include size of market, growth rate, regulatory environment, patent status, competition, pricing dynamics, customer sophistication, and intellectual property protection.

Next, to assess how the organization can take advantage of its institutional launch experience and knowledge, internal stakeholder interviews should be conducted to identify launch success stories and lessons learned specific to the organization.

Questions that should be asked include (but are not limited to) the following: How should the company leverage its institutional launch experience and knowledge? How has commercialization been approached in each country archetype? How did it vary by asset type? What were the best practices and success stories (e.g., situation, strategies, investment, performance)? What went wrong, and why? When things have gone wrong, how can the organization effectively plan to avoid these issues in future launches?

Global brand teams should consider launch characteristics, launch country archetypes, and best practices as they categorize brand types and country types to inform how to optimize the launch at the country level. This will give country launch leaders a simple and logical way to categorize their launch and to inform their launch strategy, tactics, timelines, and investments.

Categorizing the launch can provide guidance on the appropriate resources that need to be allocated to the launch in terms of dollars and people. It can also suggest the level of advance market shaping and market preparation that may be necessary in the form of key opinion leader planning, medical education, non-promotional disease state awareness, and advocacy group partnerships.

For a successful launch, organizations need to ensure adequate cross-functional/regional alignment is put in place and actively manage the complexity in alignment. Typically, global will set the strategy, and the individual country affiliates will have to get in line; however, each country has unique needs. Alignment is needed among the global and country levels, especially in the key markets. Global strategies should be refined to meet country level needs in terms of support, communication, resources, and more.

Finally, organizations need to train trainers to institutionalize launch excellence. Organizations will need to determine the pull-through elements that are necessary to institutionalize launch excellence and develop a roll-out plan. It will also be necessary to determine which department will serve as the launch center of excellence or whether a new department needs to be created.

A successful launch of a pharmaceutical or biotechnology product requires more than standardized methodology, processes, tools, and templates. While these are important, true launch excellence must capitalize on industry best practices, internal history, and market-specific competitive, customer, and brand insights to characterize the launch and thus allow an organization to build a Global Launch Map. The Global Launch Map will guide the brand team as it makes strategic decisions about launch strategy, planning, investments, and resources.

Rohit Sood and Philip Vorhies are VPs in Campbell Alliance's Commercial Center of Excellence.

FACTS & FIGURES

Family doctors receive little or no information about harmful effects of medicines in the majority of drug promotions during visits by drug company representatives, according to an international study involving Canadian, U.S., and French physicians.

Yet the same doctors indicated that they were likely to start prescribing these drugs, consistent with previous research that shows prescribing behavior is influenced by pharmaceutical promotion.

The study, which had doctors fill out questionnaires about each promoted medicine following sales visits, was published in the *Journal of General Internal Medicine*. It shows that sales representatives failed to provide any information about common or serious side effects and the type of patients who should not use the medicine in **59 percent** of the promotions. In Vancouver and Montreal, no potential harms were mentioned for **66 percent** of promoted medicines.

"Laws in all three countries require sales representatives to provide information on harm as well as benefits," says lead author Barbara Mintzes of the University of British Columbia. "But no one is monitoring these visits and there are next to no sanctions for misleading or inaccurate promotion."

Serious risks were mentioned in only **six percent** of the promotions, even though **57 percent** of the medications involved in these visits came with FDA "black box" or Health Canada boxed warnings – the strongest drug warning that can be issued by both countries.

"We are very concerned that doctors and patients are left in the dark and patient safety may be compromised," says Mintzes, an expert on drug advertising in UBC's School of Population and Public Health.

Doctors in Toulouse were more likely to be told of a harmful effect in a promotional visit, compared to doctors in Canada and the United States, according to the study. Researchers suggested that this may reflect stricter regulatory standards for promotion of medicines in France.

Specialty drugs to be half of all drug costs by 2018: study

Specialty drug costs are projected to rise to 50 percent of commercially insured total drug costs by 2018, according to a new study by pharmacy benefit manager Prime Therapeutics.

Prime's study found that in 2009, specialty drugs – those that require special handling, are typically injected, and are more expensive than traditional drugs – represented 20 percent of all drug (medical and pharmacy benefit) costs. By September 2012, though, specialty drugs increased to 28.7 percent of the total costs. Based on average increases in recent years, the company's researchers predict specialty costs will increase 15 percent per year, while non-specialty costs will remain flat. As a result, specialty costs are expected to make up 50 percent of the overall drug costs by 2018, for commercially insured individuals.

"The increasing rate of specialty drugs expenses is due to increased non-specialty generic drug use; expected continued pharmaceutical manufacturer, annual, double-digit price increases; increasing specialty drug use, and future pipeline of new specialty drugs," says Patrick Gleason, director of health outcomes at Prime. "Specialty drugs offer life-saving treatments for patients, but they also come with a high price tag. In the years ahead, health insurers and plan sponsors will need to increase their focus on managing specialty drugs to ensure the most cost-effective outcomes for their members."

Although specialty drugs have historically been associated with rare medical conditions, they are being used more frequently for the treatment of more common chronic conditions such as rheumatoid arthritis and multiple sclerosis. The rise in use combined with the high cost of these drugs, Prime researchers believe, will become an increasing strain on healthcare budgets over the next five years.

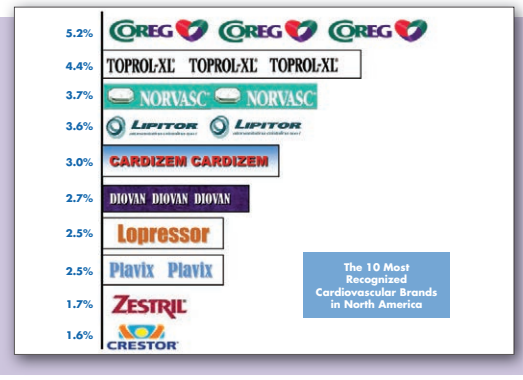
To identify monthly drug specialty and non-specialty costs and forecast when specialty drugs will become 50 percent of all drug expenditures, researchers from Prime reviewed integrated pharmacy and medical data from 6.8 million commercial members between January 2009 and September 2012.

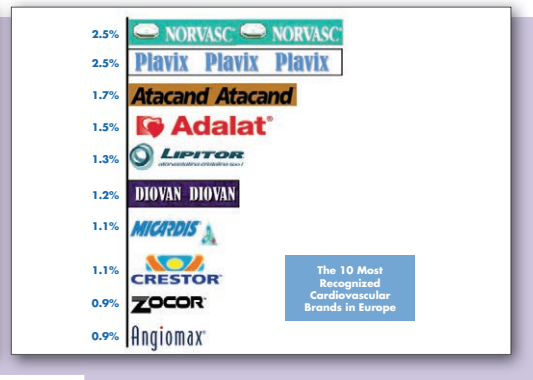
"In just five years, we expect specialty drugs to account for half of all drug spending," Gleason says. "This could become an alarming number for health plans and plan sponsors who haven't actively prepared to manage this significant area. Health insurers will need to increase their attention on specialty drugs and focus on four management opportunities: drug distribution channel, utilization management, contracting activities, and coordination of care."

MOST-RECOGNIZED BRANDS

CARDIOVASCULAR

The most-recognized cardiovascular brand in North America is **Coreg**. About 5.2 percent of physicians recognize this brand the most, according to a survey conducted by **Brand Institute** Inc. in fourth-quarter 2012. Coreg, comprising carvedilol, is marketed by **GlaxoSmithKline** (gsk.com). The drug was first approved by FDA in September 1995 for the treatment of mild-to-severe heart failure of ischemic or cardiomyopathic origin, usually in addition to diuretics, angiotensin converting enzyme inhibitors, and digitalis. Since then, Coreg's two formulations have added seven additional indications.





Toprol-XL is the second most-recognized cardiovascular brand in North America. About 4.4 percent of physicians recognize this brand the most. Toprol-XL, comprising metoprolol, is marketed by **AstraZeneca** (astrazeneca.com). The drug was first approved by FDA in January 1992, and has earned three indications: for the treatment of hypertension, angina pectoris, and heart failure.

The third most-recognized cardiovascular brand in North America is **Norvasc**. About 3.7 percent of physicians recognize this brand the most. Norvasc, comprising amlodipine, is marketed by **Pfizer** Inc. (pfizer.com). The drug was approved by FDA in July 1992 for the treatment of hypertension, chronic stable angina, and confirmed or suspected vasospastic angina.

The most-recognized cardiovascular brands in Europe are Norvasc and **Plavix**. These brands were recognized most by 2.5 percent of physicians. Plavix, comprising clopidogrel, is marketed by **Bristol-Myers Squibb** Co. (bms.com) and **Sanofi** (sanofi.com). The drug was first approved in Europe in July 1998 for the prevention of atherosclerotic events, including myocardial infarction, stroke, and death due to vascular causes in patients with a history of symptomatic atherosclerotic disease defined by ischemic stroke, myocardial infarction, or established peripheral arterial disease. The drug earned additional approvals in September 2006 for the treatment of patients with ST-segment elevation acute myocardial infarction who are eligible for thrombolytic therapy, and in July 2008 for the treatment of non-ST-segment elevation acute coronary syndrome (unstable angina or non-Q-wave myocardial infarction), including patients undergoing a stent placement following percutaneous coronary intervention, in combination with acetylsalicylic acid.

Atacand is the third most-recognized cardiovascular brand in Europe. About 1.7 percent of physicians recognize this brand the most. Atacand, comprising candesartan, is marketed by AstraZeneca and **Takeda** Pharmaceutical (takeda.com). The drug was first approved in the EU in October 1997, and is used to treat essential hypertension (high blood pressure) in adults, and to treat heart failure in adult patients with impaired left ventricular systolic function who are receiving treatment with angiotensin converting enzyme inhibitors or who cannot be given ACE inhibitors.

Brand Institute (brandinstitute.com) surveyed more than 2,000 physicians and hospital and retail pharmacists in North America and Europe to determine the most-recognizable brands in the category of cardiovascular. Brandpoll is a marketing tool designed to help clients monitor the competitive marketplace and identify the potential strengths and weaknesses of their brands.

Acting on feedback from consumers equals better bottom line: PwC survey

More Americans are spending their own money on healthcare, and consumers are searching for reviews and ratings to guide decision making. But they are not finding what they need, according to a new report from PricewaterhouseCoopers' Health Research Institute. The report, "Scoring Healthcare: Navigating customer experience ratings," finds companies that translate consumer feedback into improved quality and better experience have a better chance at reaping rewards.

HRI recently conducted a survey in which 48 percent of respondents said they have read healthcare reviews, although only 24 percent said they have written one. Reviews prove to be influential once consumers read them. Among those who have read healthcare reviews, 68 percent said they have used the information to select a doctor, hospital and to a lesser extent, a health plan, pharmacy, and drug or medical device.

"When I talk about a doctor or a hospital, it's more personal in nature," says Paul D'Alessandro, the leader of customer impact in PwC's Health Industries advisory practice. "The information that is out there is such that I seek out to inform something that is going to be near and dear to my heart. When I talk about something like a plan, or a pharmacy, the degree of personalization, or the need for me to inform myself more right now isn't quite out there yet, but as we go forward, and plans become more complex, when more and more options open up on the pharmacy front, which they are, then we foresee a time in which there will be reliance on the ratings those other two areas that are highly personal."

According to the report, clear generational differences exist among consumers. Those aged 65 and older prefer government sources while consumers aged 18 to 24 prefer reviews on blogs or social media sites such as Facebook or online patient discussion forums. Unlike the entertainment and retail sectors in which customers actively rate products and services and use reviews to make decisions, the health industry has not seen the same level of engagement.

"Get the docs, get the practitioners, get the nurses out to the eyes of the consumer," D'Alessandro told *Med Ad News*. "Have them walk in an observational state through the patient healthcare experience. Take them on the journey of a patient. Increasingly, we're seeing all of those models take place to better inform and change the patient experience."

Patient satisfaction is now embedded into Medicare payment policies. Insurers that serve Medicare beneficiaries stand to gain at least $5 billion in bonus payments linked directly to patient feedback. In 2013 alone, Medicare will shift $850 million in provider pay based in part on patient satisfaction scores. During the long term, proponents say greater consumer engagement translates into smarter care choices, healthier behavior and reduced costs.

"Healthcare organizations are increasingly operating in a world in which the voice of the consumer impacts the bottom line, and where customer experience is now a matter of dollars and cents," said Kelly Barnes, PwC's U.S. health industries leader. "As consumerism in healthcare gains steam, customer feedback has become a determining factor in the success of health organizations. Ratings connect consumers' experience to quality, and quality connects to financial performance, market share and reputation."

Patients need to adopt a proactive, rather than a reactive approach, says D'Alessandro. "They need to begin think about needs before they come through the door at a clinic or hospital and not survey it upon them leaving," he told *Med Ad News*. Patient advocacy groups would additionally be of assistance, according to D'Alessandro. "We have them in travel, in the airlines where actual leisure and business travelers who sit in with the board and talk about the things that drive them crazy or make them really happy. We foresee a day in the not too distant future and we know that it's happening today in some leading healthcare networks where there is a patient advocacy representative, oftentimes, a real patient who has been through recently there that is speaking on behalf of a patient base."

By Christiane Truelove chris.truelove@ubm.com

Prolifiq virtually connecting physicians, MSLs

When a physician has an off-label question about a product, the sales rep is placed into a bind. The rep can schedule a medical science liaison to come in and answer the doctor's question – with a lag of often three weeks until the visit can occur – or refer the doctor to a call center. Ultimately, however, the rep's sales visit has effectively ended. But the software company Prolifiq has come up with CONNECT, a mobile solution that allows a rep to put physicians in touch with MSLs immediately, efficiently, and compliantly. CONNECT establishes real-time, secure, compliant digital communications that sales reps use to direct their customers' medical questions while reinforcing their face-to-face relationships.

"CONNECT harnesses the immediacy of mobile," says Hemingway Huynh, chief technology information officer of Prolifiq. "In pharma, the medical information request form [MIRF] process can take three days to three weeks. With CONNECT, sales reps compliantly fulfill their customers' medical requests with the appropriate specialist in three minutes."

According to Huynh, CONNECT establishes real-time, secure, compliant digital communications that sales reps use to direct their customers' medical questions while reinforcing their face-to-face relationships. What used to take days or weeks now takes minutes.

"One of the key issues today in life sciences is a shrinking sales force, the sales force has to carry more than one drug in the bag, and there's a lot of specialist info, whether it's reimbursement or payor, that they can't answer because A, they don't have the knowledge, or B, legally, they cannot answer, based on compliance," Huynh says. "The medical teams will see the immediate impact with this platform, the ability to be able to connect in real time with a specialist."

When a rep wants to initiate a meeting between the MSL and physician, the rep first tests the wireless connection on his tablet to determine if features such as video and desktop sharing can be used. Then the rep sends out a ping to alert all available MSLs that there is a question to be answered, and what that question is about. The rep cannot choose which specialist will answer the question. MSLs have two minutes to respond to the request for a conversation, Huynh says.

Once the connection is established between the physician and the MSL, the sales rep can either leave the room, or stay but not be involved in the conversation. Whether the rep leaves or stays depends on what the company's legal department has decreed.

Prolifiq is in the process of rolling out CONNECT for a second client. Huynh says the impact of CONNECT will be felt beyond just the MSL teams, to allow office managers to get immediate answers on reimbursement questions and nurses to get information on adherence or how to counsel a patient.

"Typically, you do not have a lot of off-label requests in a day, every other week you might have an off-label engagement," according to Huynh. "But if you expand this outside of medical to all the different fields, it can make a big impact in terms of time, resolution, and follow up."

All of the data captured by CONNECT is routed back to the client's warehouse, allowing the company to measure the effectiveness of the program. "We capture length of time of engagement, we capture information, we capture the bandwidth also, and if they did video, voice and desktop sharing," Huynh says. "All those things capture that. And follow-up time in terms of did he answer the question or not is pretty critical."

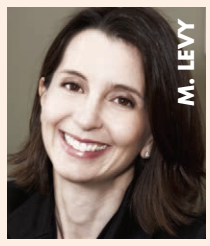
What pharma needs to know about patient self-tracking in 2013

By Monique Levy, Manhattan Research

Understanding health self-tracking is critical for pharmaceutical companies in 2013, given the momentum of this market and industry's push to provide value-added services "beyond the pill" to their customers.

Self-tracking, also being referred to as self-quantification, describes consumers monitoring and recording physiological, behavioral, and psychological data and using the data as feedback to change various inputs, ranging from medication dosage to food intake, exercise, and mood, in order to change outcomes.

This is nothing new to pharma brands, you might argue. Indeed, paper journals have been around as long as DTC marketing has, available via starter kits handed to patients in the office or sent to their home via snail mail. Since the early 2000s, brands have also invested in online tools to help patients track their conditions via product or condition websites or dedicated online patient support programs, a trend that has shifted more recently to mobile app initiatives. However, powerful shifts in the market, derived principally from policy changes and advanced technology, are making the promise of comparatively more successful use of health self-tracking more of a reality in 2013.



On the policy side, the Affordable Care Act and HITECH Act are driving payment reform toward performance models, coordination of care, and the meaningful use of electronic health records and patient portals and, in turn, driving patient self-tracking. Concurrently, the booming sensor and device market, as well as more-pervasive connectivity and big data capabilities, is enabling more-effective data capture and sharing. The ecosystem around self-tracking has taken on a life of its own, and numerous organizations and institutions are devoting significant resources to advancing self-tracking, most notably, the Quantified Self movement, the Robert Wood Johnson Foundation, and the Center for Connected Health.

A series of recent studies that Manhattan Research conducted with patients, physicians, pharmacists, and nurses provides a road map for brands, innovation, and other teams in pharma looking to leverage emerging opportunities around self-tracking. Here are the key findings from a recent report on this topic:

In the short-term, brands should continue to invest in basic self-tracking tools. Self-tracking among patient consumers is relatively pervasive. Just over one-fifth of patient consumers say that they track their health or medical measurements using electronic devices. Desktop or laptop computers, not smartphones or dedicated devices, are the most commonly used devices. At the same time, 70 percent of physicians report that at least one of their patients shared health measurements with them in 2012, although the methods patients used were primarily low tech, involving simple handwritten notes or printouts, not email or patient portals. In fact, less than one quarter of patients who self-track their data report that they share it electronically. Longer term, self-tracking initiatives will need to tie into telemedicine and electronic health records.

Consider increasing investments in self-tracking. Physicians are optimistic about self-tracking; nearly three-quarters of physicians agree that self-tracking leads to better patient outcomes. More secure and reliable technology, established reimbursement and incentive structures, and improved services are among the benefits that physicians believe will accelerate adoption.

Electronic self-tracking tools are relevant for brands targeting conditions that skew toward an older demographic. The patients most active with self-tracking include those with diabetes, atrial fibrillation, heart disease, and osteoporosis. Consumers aged 55 years or older, who have a higher incidence of chronic conditions, are more than four times as likely to have adopted electronic health self-tracking as those aged 18-34, thus negating the assumption that older consumers are less tech-enabled when it comes to health.

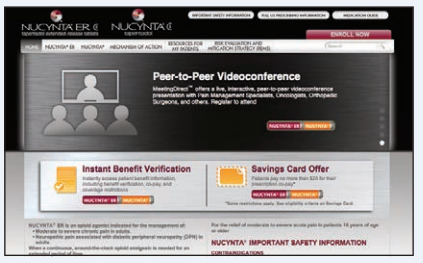
Source: Taking the Pulse U.S. 2013 (fielded online in Q1 2013 among 2,950 U.S. practicing physicians), Cybercitizen Health U.S. 2012 (fielded in Q3 2012 among 8,745 U.S. adults (age 18 and over).

Awards set the mark for pharma sites

The benchmarking company TGaS Advisors has named 11 pharmaceutical brands "Best in Benchmark" for 2012 consumer and healthcare professional digital marketing performance. According to Donna Wray, VP and leader of the Digital & Relationship Marketing Practice, the designation is the only industry award to use verified quantitative performance as the measure.

AstraZeneca and Cadient Group's professional website for Crestor was cited by TGaS as setting a benchmark in engagement for HCPs.

The winning brands all have one or more "outstanding" performance metrics, scoring significantly higher than all peers in the benchmark for 2012. These blinded, confidential studies compare against peers selected from more than 60 brands. The benchmark covers 60 different metrics, of which 25 qualify as key performance metrics. This year only 11 brands in these 25 categories qualified as "outstanding."



Janssen Pharmaceuticals, Razorfish, and ICC Lowe earned marks for the professional website for Nucynta in the area of visit volume for HCPs.

Winners in consumer categories are: Amgen Inc. and Evoke Health for Enbrel in Website Visit Volume; AstraZeneca and Digitas Health for Nexium in Digital Display Cost per Click (cohort B); Daiichi Sankyo Co. and Underscore for Benicar in Paid Search Click Volume; Daiichi Sankyo Co. and HealthEd, Encore, and Epsilon for Benicar in House Email Delivered Volume; Daiichi Sankyo Co. and Evoke Health and Epsilon for Welchol in House Email Open Rate; Gilead Sciences Inc. and TargetCast for Speak From the Heart in Completed Assessment Volume; and MedImmune for Flumist in Digital Display Cost per Click (cohort D).

Healthcare professional marketing winners are: AstraZeneca and Cadient Group for Crestor in HCP Website Engagement; Janssen Pharmaceuticals, Razorfish, and ICC Lowe for Nucynta in HCP Website Visit Volume; and Purdue Pharma and AbelsonTaylor for Intermezzo in House Email Delivered Volume.

The winners for Consumer Digital Display Impressions & Click Volume, HCP Digital Display Impressions Volume, and HCP Digital Display Cost per Click requested that their names not be used.

All of the winners used different tactics and budgets to achieve their successes, according to Wray. "Some winners are contrarians, while others use tried and true tactics," she says. "Some have larger budgets; others are working hard with a small budget. What unites these winners sounds simple but is not a standard in pharma. Brand teams that choose to focus on a goal and then work to optimize results come out on top every time."

Wray noted that brands work with TGaS to help them achieve that goal, so that "winners are succeeding in a select pool of brands that pay close attention to this critical channel." TGaS will present awards to the winning brand teams and their agencies.

TGaS also offers benchmarks in less quantifiable areas, such as offline and other marketing investments and the use of iPads for digital details with HCPs.

AdAgencyUpdate

By *Med Ad News* Staff

GSW report reflects value of non-physician prescribers

Non-physician prescribers are overlooked by healthcare marketers, yet represent a growing population of important decision makers with increasing access to patients and caregivers. Healthcare advertising agency **GSW Fueled by Blue Diesel** has detailed the driving forces behind the prescribing habits of NPPs in a new report, "The Non-Physician Prescriber Will See You Now." The report also outlines ways that pharmaceutical and medical device companies can collaborate with this audience to more effectively communicate with patients and caregivers to improve adherence rates.

Because physicians are increasingly not able to meet patient demand on their own, NPPs are frequently the first providers patients see when entering the healthcare system. These include nurse practitioners and physician assistants. There are several reasons that marketers overlook NPPs, says Brenda Rizzo, who also authored the report and is associate medical director with GSW.

"One is that decisions about which healthcare providers (HCP) are called upon by a pharmaceutical marketer is based by the HCP prescribing behavior," Rizzo told *Med Ad News*. "But the companies that track this information have not developed an adequate way to track prescriptions by NPP] so they are not visible to pharma industry and therefore do not appear on the target call list. Therefore NPPs are 'invisible' in the current system of how HCPs are identified and placed on the target list for pharmaceutical sales representatives to call on."

Another factor is that oftentimes pharma sales reps are unaware that other professionals can not only prescribe, but may do so independently. "One of the goals of this report is to improve that understanding, as you will see," Rizzo says. "There are many other reasons, including not realizing the level of influence that NPPs have in a practice, and not realizing that NPPs making independent prescribing decisions, not based on a protocol or direction of a physician."

The importance of NPP-led care and the changing role of NPPs was also recognized in the Affordable Care Act. A provision of the act authorized up to $50 million in funding for nurse-managed health clinics, $15 million of which has been allocated to support 10 nurse-led clinics, serving 94,000 patients around the country.

According to the report, historically, state laws have placed limitations on the role of NPPs; however, as their roles evolved, NPPs' ability to care for patients has also expanded. Because of the recent nature of these changes, their prescribing behaviors, role in patient interactions, and decision making processes are not always apparent and understood. The researchers set out to understand this important group of prescribers.

"Each state has different rules about how physicians and NPPs work together," Rizzo told *Med Ad News*. "Some have 'practice agreements' between the nurse practitioner and the physician where together they decide how they are going to set up the practice and manage the patients, others practice independently. In those states where a practice agreement is required then they will decide the number of random charts that need to be reviewed and checked by the physician as a quality control issue. In some states, nurse practitioners specifically are allowed to open up a practice without a physician on site. Physician assistants are typically more restricted with independent practices and the rules governing autonomy are different."

GSW conducted qualitative research, as well as a national survey in partnership with the online community Clinician 1. The agency surveyed a representative sample of approximately 400 NPPs from 46 states, encompassing staff at hospital-owned outpatient clinics, private practices, nonprofit clinics, private outpatient clinics, urgent care facilities, and retail healthcare establishments. Although the majority of these NPPs work in primary care, participants reported 13 subspecialties in total.

In addition to attitudes and beliefs that drive prescribing behaviors, the study examined the ways in which NPPs connect with each other and how they stay informed of the most up-to-date medical information. The study also looked at the media channels NPPs use, barriers to care, and how NPPs tackle adherence and other market dynamics affecting their practices.

Additional findings of the survey revealed that NPPs connect with their peers at national conferences or professional meetings (70 percent), online (51 percent) and via phone (48 percent); consider medical journals as a primary resource for medical information (98.8 percent); use online peer communities (94 percent); and use electronic medical records (74 percent).

"There have been many studies done comparing the care delivered by a NPP and a physician, and to my knowledge confusion regarding prescriptions has not been identified as a problem," Rizzo says. "In our study we found that greater than 90 percent of prescriptions are decided upon independently by NPPs and those prescription decisions are based on what is available in the market and approved by the FDA, what is on the state's formulary (in states where there is a separate formulary for NPPs), or what, in their clinical judgment, is the best course of therapy for the patient. In our study, NPPs reported that the efficacy of a drug, and what experiences they have had with a drug when prescribing it to other patients, are the top reasons why they prescribe a particular therapy."

In the report, NPPs reported that they are writing as many as 1,500 prescriptions per month. Ninety-two percent of prescriptions were written independently, meaning, without consulting a physician. The factors influencing NPP prescribing decision making were surprising. Based on the patient-centered nature of NPP patient care, researchers expected cost and formulary coverage to rank as strong factors, but they were not the most influential factors. Drug efficacy was the strongest consideration, and the NPPs' experience with the drug also was reported as more important than cost. Patient request and company reputation were the least important considerations.

Former Stonefly CEO dies

John Racik, founder and former president/CEO of Stonefly Communications Group, has died at 52, after a long battle with cancer.

"John was one of the sharpest strategic minds in our business," says Joe Daley, president of GSW. "He had remarkable drive and uncompromising expectations for everything he touched which led to countless relationships in the business and success for the agency. The only thing bigger than John's personality was the passion he had for our clients' success."

According to his peers, Racik inspired Stonefly, a former sister healthcare advertising agency in the inVentiv Health family of companies, to push for thinking that helped shape markets. He knew the difficult issues facing both established and emerging companies and loved working with them to secure the health of their brands.

In 2002, Racik was recruited to take over Blue Diesel, a communications agency that provides digital solutions to the healthcare marketplace, and who earlier this year merged with GSW. While leading Blue Diesel, Racik's teams generated a new wave of growth that powered the creation of a new agency, Stonefly Communications Group.

In the 20 years prior to founding Stonefly, Racik led pioneering successes in publishing, medical education, and brand management. Before moving to the Midwest, John's career had him building teams and driving results for WPP, Becton Dickinson, Euro RSCG, and Medical Economics.


J. RACIK

"John fought his cancer with the same intensity, bravery, and relentlessness that he brought to everything else he took on in his life," Daley says. "We are deeply saddened but are immensely honored and proud to call him a leader, partner, and friend of the inVentiv Health family of companies."

Throughout his career, Racik's contributions to the community were numerous. Among many volunteer roles, he served on the board of directors for the Susan G. Komen for the Cure Columbus Affiliate, the Crohn's & Colitis Foundation of America, and the advocacy group Men Against Breast Cancer.

Racik is survived by his wife, Donna, and two children, Morgan and JR.

AGENCY PEOPLE ON THE MOVE

■ AbelsonTaylor

Beverly Wright is named VP, account director, AbelsonTaylor (abelsontaylor.com). Ms. Wright was senior VP/account director at Leo Burnett Co., leading the agency's North American McDonald's business.

■ Dudnyk

Scott Harper is promoted to VP, account director, Dudnyk (dudnyk.com). Mr. Harper has been at the agency for five years; previously, he led accounts at Cline Davis & Mann and GSW Worldwide. **Dan Zaksas**, Ph.D., is promoted to VP, scientific director. Dr. Zaksas' experience includes a decade of research in biomedical science. **Heather Wagoner** is promoted to account supervisor. Ms. Wagoner has been at Dudnyk for four years; previously she was an account executive at Dorland Global Corp. **Kim Cosenza** is promoted to account executive. Ms. Cosenza joined the agency in 2011; previously, she worked at Poretta and Orr as a project manager.

■ fingerpaint

Cathie Wright joins Fingerpaint's (fingerpaintmarketing.com) account service team. Ms. Wright previously directed marketing initiatives for a fleet of automotive brands and dealerships at Potratz Partners. **Will Crain** joins the agency's creative team. Mr. Crain was with Media Logic. **Jessica Vedder** joins Fingerpaint's project management team. Ms. Vedder has been a supervisor, manager, and producer at ABC, Van Hill Entertainment, and Cutter.

■ Harrison and Star

Harrison and Star (harrisonandstar.com) has created a new Strategic Planning Group by consolidating several in-house departments under the leadership of **Brian Robinson**. As executive VP and chief strategy officer at the agency, Mr. Robinson has responsibility for developing the department and integrating medical, CRM, digital, and analytic services. Prior to joining Harrison and Star, he headed the Strategic Planning Department at Sudler & Hennessey.

■ Havas Worldwide

Sean Lyons is named global chief digital officer, Havas Worldwide (havasww.com). Mr. Lyons was senior VP, operations and business planning, R/GA.

■ HCB Health

Meg Nohe is promoted to director, strategic development, HCB Health (hcbhealth.com). She joined HCB in 2010 after serving as an imaging sales representative for Stryker.

■ Saatchi & Saatchi Wellness

Hensley Evans is appointed executive VP, director of analytics and digital strategy, Saatchi & Saatchi Wellness (saatchiwellness.com). Ms. Evans was previously chief strategy officer at imc2.

Digitas examines effectiveness of digital marketing in pharma

Digitas Health has announced the release of "Effective Review and Approval of Digital Promotional Tactics," written by Dale Cooke, the agency's VP/group director, regulatory review. In addition to an optimistic view of FDA's most recent guidance on social media use, the primer provides guiding principles for how pharmaceutical marketers can embrace digital, while ensuring compliance.

"People need to understand how to effectively review promotional tactics," Cooke told *Med Ad News*. "I have heard people at top companies proudly announce that they are responsible for developing company guidelines for using social media despite the fact that they don't have a Facebook account. Imagine someone trying to review a TV commercial without having ever seen a television. They wouldn't know the importance of asking about things such as how fast the voiceover is delivered or whether the music will overwhelm the audio. But those are extremely important factors that determine whether the resulting promotional material is compliant. Exactly the same is true of all media. Reviewers need to understand, and preferably use those media to appreciate all of the factors that contribute to whether a message is compliant."

The steps toward a successful concept review for digital tactics are to conduct the review with the same team that will be reviewing the developed project; devote adequate time to educating the committee about the relevant technology, its capabilities, and imitations; bring prototypes and/or examples of similar projects produced by other brands or companies; develop a tactic description detailed enough to elicit meaningful feedback – but don't spend too much of your budget before you start developing content; and be prepared to discuss source references and the types of claims that might be made.

"We aren't trying to slip things by a committee or hope they don't notice something," Cooke says. "Our goal is to educate our clients' review committees and provide them whatever info they need, so that they are comfortable with the promotional materials we are developing."

The role of PDFs in reviews is also covered in the primer, specifically as to why they shouldn't be elaborate. "Originators include both advertising agencies and others who create content," Cooke says. "They will create whatever reviewers require because the originator's primary goal is getting their material through the review process as quickly and smoothly as possible. Sometimes reviewers conflate the PDF they are reviewing with the promotional tactic itself, and that's when they start requesting that the PDF become more and more elaborate to more closely mimic the promotional material."

Cooke uses the script for a TV spot as an analogy. "No consumer will ever see that script," he says. "The script itself is not the promotional material. It's just something that is provided to the reviewers so they can provide input on whether the resulting TV spot will be compliant. You want to get feedback at that stage of development, but you are not, for example, worried about whether the font size on the script is too small. That doesn't matter. That same thing is true of the PDFs that we submit for review. The PDFs play certain very important roles. They provide a means for conveying comments back from a committee to the originator. They provide a snapshot of what an evolving, developing tactic looked like at a moment. They are not usually the same as the tactic itself."

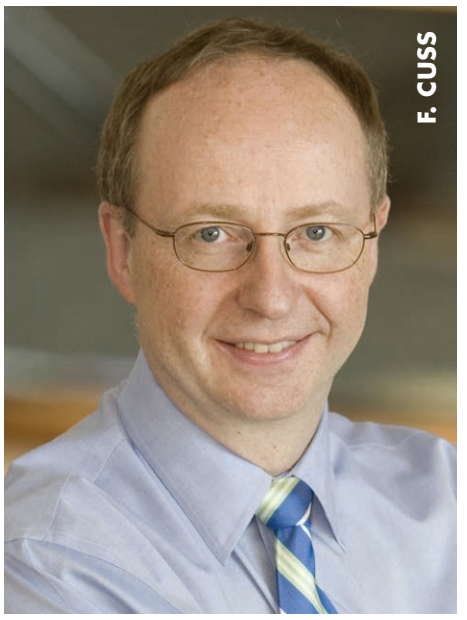
The primer states that in issuing its first letters related to search engine marketing, FDA took steps toward defining its understanding of this important venue. Certain principles can clearly be drawn from these letters such as the established name must always be present with the brand name. Other areas are still ambiguous, for example, whether SEM is an exemption from the ban on reminder advertising for black box drugs. But nothing in FDA's letters has placed SEM outside the arena of possibility for pharma companies that wish to use search as a marketing channel. The boundaries of what may be done have been drawn with greater clarity, and SEM remains within those boundaries.

"There was a time in this industry when people saw receiving an enforcement action letter from FDA as a badge of honor, and some thought being able to slip things past review committees was a good thing," Cooke says. "We disagree. Our perspective is patients, caregivers, and healthcare professionals are faced with incredibly important decisions, and our clients have info that can help people make better healthcare decisions. We believe providing materials compliant with all applicable FDA regulations help that process."

PeopleontheMove

By Joshua Slatko joshua.slatko@ubm.com

BMS names new R&D chief

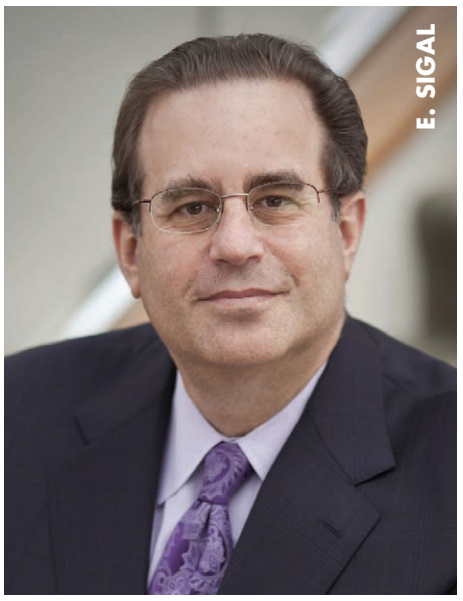


Bristol-Myers Squibb Co. has announced the appointment of **Francis Cuss** as executive VP and chief scientific officer, effective July 1 after **Elliott Sigal**, M.D., Ph.D., retires. Dr. Sigal has served as the company's chief scientific officer since 2004 and on the company's board of directors since 2011. He will retire from both positions effective June 30, 2013. Drs. Sigal and Cuss will continue to work together until that time.

"Francis is a strong and collaborative leader with broad experience in both discovery and development," says Lamberto Andreotti, chief executive officer, Bristol-Myers Squibb (bms.com). "He has been a key member of our productive R&D team who, under Elliott's leadership, has delivered our strong portfolio and pipeline. As our company embarks on the next phase of pipeline execution, this is a natural time for Francis to lead our R&D team. Having worked closely with Francis since 2010 when I invited him to join my Senior Management Team immediately after becoming CEO, I know that he can ensure the continuation of both the leadership and strategy that have been the hallmarks of our success."

Dr. Cuss has a strong medical background, and broad experience in both research and development. Prior to joining Bristol-Myers Squibb, he led teams in the successful development and approval of several blockbuster medicines. At Bristol-Myers Squibb, Dr. Cuss has a proven track record of leading the company's research organization to become among the most efficient in the industry. According to BMS leaders, he has built a high-performing team, and has delivered a differentiated and innovative early and mid-stage pipeline including making significant contributions in the advancement of the company's hepatitis C and immuno-oncology portfolios, particularly PD-1.

Dr. Cuss joined Bristol-Myers Squibb in 2003 as senior VP, drug discovery, adding responsibility for discovery medicine and clinical pharmacology in May 2006. Under Dr. Cuss' leadership, Bristol-Myers Squibb has consistently been rated a leading research organization based on cycle time, success rates and costs, having increased discovery output while maintaining a flat operating budget. Dr. Cuss and his team successfully integrated Adnexus, Medarex and ZymoGenetics into the research organization, and have driven innovation in the research operating model, processes, and governance. Dr. Cuss became a member of the company's Senior Management Team in 2010. Prior to joining Bristol-Myers Squibb, Dr. Cuss spent 14 years at Schering-Plough and three years at Glaxo, holding positions of increasing responsibility in discovery, clinical research and medical affairs in both the United States and Europe.



Before joining the pharmaceutical industry, Dr. Cuss was a practicing physician and held several academic appointments, including as adjunct associate professor at Jefferson Medical College at Thomas Jefferson University in Philadelphia. Dr. Cuss received his medical training in the U.K. and holds medical degrees from Cambridge University. He is also a Fellow of the Royal College of Physicians and of the Faculty of Pharmaceutical Medicine.

"I am honored to have the opportunity to lead this talented R&D team to fulfill our mission and find new ways to discover, develop and deliver innovative medicines for patients with unmet medical needs," Dr. Cuss says.

Dr. Sigal joined Bristol-Myers Squibb in 1997 as VP of the newly created department of Applied Genomics. He served as senior VP, early discovery and applied technology, head of drug discovery and exploratory development, and senior VP, global clinical and pharmaceutical development, before being appointed chief scientific officer and president of R&D in 2004. Dr. Sigal has been a member of the company's senior management team since 2001, was appointed executive VP in 2006, and was elected to the board of directors in 2011.

Under Dr. Sigal's leadership, 14 new products have been brought to market including medicines to treat diseases such as cancer, serious mental illness, HIV/AIDS, hepatitis B, rheumatoid arthritis, solid organ transplant rejection, as well as cardiovascular and metabolic diseases.

"Elliott has been a key leader in the development and execution of our company's strategy to become a BioPharma leader," Andreotti says. "He and his team have become one of the most productive and innovative R&D organizations in the industry. Elliott has had a significant impact on the transformation of our company and, most importantly, on the patients we serve. I am grateful for the many things that Elliott and I have been able to accomplish together."

PHARMA

■ **Ichiro Kikushige** becomes CEO, Teva Seiyaku Ltd., the Japanese unit of Teva Pharmaceutical Industries Ltd. Mr. Kikushige was head of sales for Eli Lilly Japan K.K. **Yoo Suk Hong** is appointed CEO of Teva-Handok, the Korean joint venture established in February 2013 between Teva and Handok Pharmaceuticals Ltd. Mr. Hong was marketing strategy director of emerging markets, Eli Lilly and Co. Teva (tevapharm.com) is a global pharmaceutical company, committed to increasing access to high-quality healthcare by developing, producing and marketing affordable generic drugs as well as innovative and specialty pharmaceuticals and active pharmaceutical ingredients.

■ **Songlin Xue**, M.D., Ph.D., is named head of global pharmacovigilance, Astellas Pharma Inc. Dr. Xue was senior VP, head global pharmacovigilance, Takeda Pharmaceuticals Inc. Astellas (astellas.com) is a pharmaceutical company dedicated to improving the health of people around the world through the provision of innovative and reliable pharmaceuticals.

■ **Lynn Kramer**, M.D., is appointed to the newly created position of chief clinical officer of Eisai Product Creation Systems. Dr. Kramer has been president of Eisai's Neuroscience and General Medicine Product Creation Unit since July 2009. Eisai (eisai.com) is a fully integrated pharmaceutical business with a commercial focus on neurology and oncology.

BIOPHARMA/BIOTECH

■ **Karthik Radhakrishnan** is appointed chief financial officer, Opexa Therapeutics Inc. Mr. Radhakrishnan was VP at ING Investment Management. **Kenny Frazier** becomes VP of clinical development and regulatory affairs. Mr. Frazier was senior director of clinical operations at Lexicon Pharmaceuticals. **Maryann Murray** is named clinical development manager. Ms. Murray was a research coordinator at the University of Texas Health Science Center. Opexa (opexatherapeutics.com) is dedicated to the development of patient-specific cellular therapies for the treatment of autoimmune diseases such as multiple sclerosis.

■ **Gregory I. Berk**, M.D., is named chief medical officer, BIND Therapeutics. Dr. Berk was chief medical officer, Intellikine. BIND (bindbio.com) is a clinical-stage biopharmaceutical company developing a new class of highly selective targeted and programmable therapeutics called Accurins.

■ **Thi-Sau Migone**, Ph.D., is appointed chief scientific officer, Igenica Inc. Dr. Migone was VP of research at Human Genome Sciences. Igenica (igenica.com) is a biopharmaceutical company pioneering breakthrough antibody-based cancer medicines.

SPECIALTY

■ **David A. Dodd** is appointed president and CEO, AEterna Zentaris Inc. From December 2007 to June 2009, Mr. Dodd was president, CEO, and chairman of BioReliance Corp. AEterna Zentaris (aezsinc.com) is an oncology and endocrinology drug development company currently investigating treatments for various unmet medical needs.

■ **Dave Lemus** is promoted to CEO, Sigma-Tau Pharmaceuticals Inc. Mr. Lemus had served as chief operating officer of the company since March 2012. Sigma-Tau (sigma-tau.com) is dedicated to the global development and commercialization of medicines for patients with rare diseases.

■ **Ajay Bansal** is named chief financial officer, Onconova Therapeutics Inc. Mr. Bansal was chief financial officer, Complete Genomics. Onconova (onconova.com) is a development-stage pharmaceutical company focused on discovering and developing novel small molecule drug products to treat cancer.

■ **Bruce A. Goldsmith**, Ph.D., becomes chief business officer, Lycera Corp. Dr. Goldsmith was senior VP corporate development at Allos Therapeutics. Lycera (lycera.com) is focused on the discovery and development of selective, oral, small-molecule immune-modulators for the treatment of patients with autoimmune diseases such as rheumatoid arthritis, psoriasis and inflammatory bowel disease.

■ **Mark A. Rothera** is appointed chief commercial officer, PTC Therapeutics Inc. Mr. Rothera was global president of Aegerion Pharmaceuticals Inc. PTC (ptcbio.com) is a biopharmaceutical company focused on the discovery, development, and commercialization of orally administered small-molecule drugs that target post-transcriptional control processes.

■ **James Kyle Bryan**, M.D., is named chief medical officer, VentiRx Pharmaceuticals. Dr. Bryan most recently was VP of global product development at PPD Inc. and VP of medical affairs at Seattle Genetics. VentiRx (ventirx.com) is a clinical stage biopharmaceutical company committed to the development and commercialization of novel Toll-like receptor 8 (TLR8) immunotherapies for the treatment of cancer, respiratory and inflammatory diseases.

■ **Theresa M. LaVallee**, Ph.D., becomes VP, translational medicine, Kolltan Pharmaceuticals. Dr. LaVallee was senior director, translational medicine, MedImmune, the global biologics arm of AstraZeneca. Kolltan (kolltan.com) is focused on creating novel biologic agents that can modulate the function of receptor tyrosine kinases.

SERVICE SUPPLIERS

■ **Andrew Adams** is named senior VP, HR and recruiting, Publicis Touchpoint Solutions. Mr. Adams was VP, human resources at Pfizer Inc. Publicis Touchpoint Solutions (touchpointsolutions.com) designs and implements customized, cross-channel, healthcare sales, service, and clinical teams.

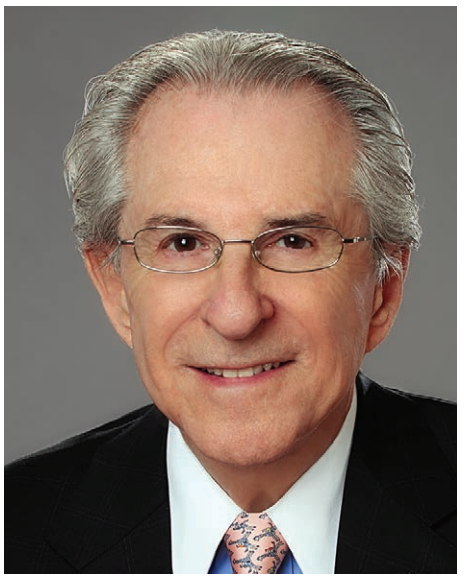
Let's cut women some slack – finally!

By Sander A. Flaum

A RECENT *Wall Street Journal* article ("Tyranny of the Queen Bee" by Peggy Drexler) took me back to the '70s. The feminist movement was gaining traction, and women were beginning to make their way into corporate boardrooms. Then, out of the blue, glossy magazines like *Redbook* and *Psychology Today* were telling us about a new stereotype – the Queen Bees. These were women who had risen to positions of power and, instead of giving their sisters a helping hand, were brazen enough to actually protect their turf – and from other women yet! Although no one would have been amazed at stories of men fending off competitors, this was seen at the time as a horrible irony.

Over the next four decades or so, women have continued to advance – in some cases smash through – the glass ceiling in formerly male-dominated companies. In my experience, primarily pharma, numerous women have become industry leaders, not only because of their intelligence, hard work, and drive, but also due to their ability to network, listen, learn, and empathize.

So you might think that over the years the stereotype would have died. But it hasn't. According to Drexler, Queen Bees are as common as ever, and she cites research to back her case.



In one recent study, Drexler says 45 percent of office workers reported that they had been bullied and that 40 percent of those bullies were women. And although both men and women may bully, men tend to be equal-opportunity tormentors, while female bullies almost always pick on other women.

Drexler asserts that many, if not most, men are oblivious to the digs, slights, slanders, and similar "mean girl" tricks that are going on around them. At this point, I have to raise my hand and confess, "guilty as charged." I am a romantic and I would like to believe that having more women in leadership roles could help civilize the workplace. So when and if "Queen Bee" struggles have taken place in companies that I have headed, I expect many have escaped my notice.

What I do notice, however, is when a woman who attains a top level position without warning abandons the efficient and cooperative work style that helped her get to the high point and abruptly switches to the testosterone-charged tactics associated with male bosses. Recently, the CEO of Yahoo ended a long-standing company practice of allowing staff to work at home, which was obviously a benefit of tremendous value to women with children. Her explanation was that working in isolation was stifling innovation at Yahoo, but I'm not sure I buy that. Surely a company founded on the concept of Internet connectivity could find a way to foster long distance connected innovation, no matter how geographically scattered its employees. My guess is that she was showing that she could crack the whip as hard as any man.

Here's why I'm having second thoughts about the validity of the whole "Queen Bee" debate. I, and many other men, admire women when they size up a problem, promote teamwork, and help humanize the office, but we can be squeamish, as can some female colleagues, when we get a glimpse of the brass knuckles in their business survival toolkits. Perhaps it's yet another double standard. Most men will certainly try to defend their position from someone who wants their job and they will certainly do their best to compete for the next rung up. Why shouldn't women have this right? When the gloves come off, the gloves are off.

So while I will continue to caution women who reach the top not to forget the skills of networking, relationship building and empathy that helped them succeed, I can't in good faith criticize them for doing what they think they need to do.

Since women often have to fight harder for their opportunities than most men, who am I – or anyone else – to be sanctimonious when the fight gets dirty? ■ MEDADNEWS

Sander A. Flaum is principal of Flaum Navigators and chairman of the Fordham Leadership Forum at Fordham University Graduate School of Business.

advertisers index May 2013

Pharmalot

Award-Winning Blog—Ranked by Forbes among the Top 10 Social Media Influencers: Wall Street

UBM
Canon

For more information, visit www.Pharmalot.com

- Industry news • Latest developments and issues in pharma • FDA approvals •
- Product news • Legislation • Litigation • Regulations • Patents • Rulings
- Marketing matters • *and much more...*

25375_PL13

OUR HIGH-DEFINITION WEBCASTS ARE SO REALISTIC,

YOU'LL FORGET YOU'RE WATCHING THEM ON A SCREEN.

ESSRX delivers premium network-quality webcasts you can almost reach out and touch.

Put your trust in ESSRX – the leaders in high-definition webcasts for the pharmaceutical and medical markets.

At ESSRX, we understand that your presentation must reflect the investment you've made in your product and people. Our full-service capabilities include:

- Flawless delivery thanks to our industry-leading technology
- Complete pre- and post-production services
- Experienced television directors and producers
- Professional on-air talent – hosts, narrators and presenters
- Studios and sets that rival what you see on TV networks.
- Interactive features for real-time polling and Q&A opportunities from mobile devices
- Anytime/anywhere viewing on multiple platforms – laptops, iPads and other iOs devices, desktops, tablets and smartphones
- Engaging on-screen graphics that offer flexible formats, branding opportunities, presentation slides, split-screen display and more

Visit ESSRX.com for more details about our high-definition webcast and satellite broadcast production services, or contact Howard Drazner at 973-575-4242 or hdrazner@essrx.com to discuss your needs. (Tell him you found Dexter in this ad.)

ESSRX
Virtually, the best.