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THE MAGAZINE OF PHARMACEUTICAL BUSINESS AND MARKETING • MEDADNEWS.COM • MARCH 2012 • VOLUME 31 NUMBER 3 • $25

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Think small

***Med Ad News'* Best New Medicine of 2011, Incivek, is the very first approved product from Vertex Pharmaceuticals, an entrepreneurial company whose decision to go it alone has paid off in blockbuster fashion.**

By Joshua Slatko joshua.slatko@ubm.com

A small, entrepreneurial pharmaceutical company with no marketed products spends years developing a drug for an underserved disease. Not so very uncommon. As the drug wends through clinical trials and approaches regulatory approval, the small company decides to eschew domestic licensing or marketing deals and launch on its own, without the sales muscle or experience of a top 50 partner, even while a similar competing drug is being developed by one of the biggest pharmaceutical companies in the world. More uncommon. Right off the bat, in its first seven months on the market, the small company's new drug rolls up nearly a billion dollars in sales, blowing past its big pharma competitor product. Unprecedented.

This unusual tale is the true story of **Incivek**, **Vertex** Pharmaceuticals' new drug for hepatitis C. Approved the very same month as **Dendreon** and **Merck**'s **Victrelis**, another new hepatitis C drug, Incivek earned $420 million in revenue in the third quarter of 2011, its first full quarter on the market, plus another $457 million in the fourth quarter, ending up with a total of $951 million in revenue for the last seven or so months of the year, compared with $140 million for Victrelis. Incivek's spectacular launch has transformed Vertex's financial performance; the company's total revenue rose by almost ten times in 2011, from $143 million to $1.41 billion, and the bottom line went from a loss of more than $750 million in 2010 to a profit of $29.6 million in 2011.

May 24, FDA approved Incivek to treat certain adults with chronic hepatitis C infection. Incivek is indicated for patients who have either not received interferon-based drug therapy for their infection or who have not responded adequately to prior therapies. The drug is approved for use with interferon therapy made up of peginterferon alfa and ribavirin.

Prior to Incivek's approval, the current standard of care for patients with chronic hepatitis C infection was peginterferon alfa and ribavirin taken for 48 weeks. Less than 50 percent of patients respond to this therapy.

The safety and effectiveness of Incivek was evaluated in three Phase III clinical trials with about 2,250 adult patients who were previously untreated, or who had received prior therapy. In all studies patients also received the drug with standard of care. In previously untreated patients, 79 percent of those receiving Incivek experienced a sustained virologic response (i.e. the infection was no longer detected in the blood 24 weeks after stopping treatment) compared to standard treatment alone. The sustained virologic response for patients treated with Incivek across all studies, and across all patient groups, was between 20 and 45 percent higher than current standard of care.

According to FDA regulators, the studies indicated that treatment with Incivek can be shortened from 48 weeks to 24 weeks in most patients. Sixty percent of previously untreated patients achieved an early response and received only 24 weeks of treatment (compared to the standard of care of 48 weeks). The sustained virologic response for these patients was 90 percent.

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Vertex's Incivek, approved by FDA in May, earned $951 million in sales through the end of 2011.

This month on PharmaLive.com

- **FDA New Drug Approvals 1990-2011:** The U.S. Food and Drug Administration has approved for marketing more than 1,650 new medicines via an NDA or BLA since 1990.
- **A fuller view:** In eight transcripts and two video interviews, 10 women who lead healthcare agencies talk about what got them into the business, what keeps them interested, and how they balance home and work demands.

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OPTIMIZING SCIENTIFIC EXCHANGE

tothepoint

By Joshua Slatko joshua.slatko@ubm.com

We here today cannot even imagine what wonders will emerge from the labs of tiny biopharmas whose names we don't even know, or how they will transform the world of medicine.

Griping may be the pharma industry's favorite pastime these days. If someone from Mars were to read the industry's news sources, blogs, et cetera, he might get the impression that pipelines are drying up, sales forces are being laid off, companies are getting too big to manage, generics are taking over, research papers are being ghostwritten, patients are losing faith, FDA is sending mixed signals about marketing, the blockbuster drug is a dying breed, and pretty much everyone is pleading guilty to something or other and signing one of those "integrity agreements."

Our Martian might be right, too. But he wouldn't be seeing the whole story. As our frequent contributor Sander Flaum has said on at least one occasion, you can wallow in self-pity or you can do something about it, and at least a few folks in pharma are doing something about it.

Example number one is *Med Ad News*' New Medicine of the Year, Incivek. Like many if not most successful new drugs, Incivek was not born in the laboratories of big pharma; it was developed by Vertex Pharmaceuticals, a small biotech company that managed to survive for more than 20 years without bringing a single product to market, paying the bills with research partnerships and a public offering in 1991. But *un*like most successful new drugs, Incivek was actually *launched* by its developer, even though Vertex had essentially no commercial organization until relatively recently. Though the company did partner with Johnson & Johnson and Mitsubishi Tanabe for development and launches overseas, the American launch has been all its own.

And what a launch! Approved for the treatment of hepatitis C by FDA in May 2011, a few weeks after a potential competitor compound, Merck's Victrelis, had also earned approval, Vertex's Incivek accumulated $951 million in sales through the remaining months of the year. Yes, that's correct – from zero to $951 million in just over seven months, with a just-built commercial organization, and absolutely no history of marketing anything whatsoever. Victrelis? $140 million.

Think about the implications of that for a minute. A company with practically no commercial experience, that hadn't made a dime in profit in more than 20 years of existence, just had The Launch of 2011, in the process beating the pants off one of the world's largest pharma companies, a company that spends orders of magnitude more on marketing alone in a single year than our David has made in revenue in its entire history. On a financial and experiential scale, the difference between Vertex and Merck is practically beyond the scope of metaphor. And yet.

So what does this mean? The suits can argue that point forever, but I'll tell you what I think it means. I think it means that clichés like vision and entrepreneurship and pure research really matter in the marketplace. It means that science can win, no matter how much is spent on marketing. And most importantly, it means that the big boys had better step up their game, because their smaller competitors just don't need them any more.

Smart people in the industry, of course, are perfectly aware of this. A couple of months ago, in our Execs on the Rise feature, we noted the growing trend of top talent migrating from big pharma to the little guys, where they can stretch their minds without fear of the giant, groaning bureaucracies that tend to grow within the largest businesses. More than a few of Vertex's own executives are prime examples of this. And if the history of business has taught us anything at all, it's that, in the long term, big doesn't win – smart wins. The success of Vertex and Incivek, in the end, is just another example of that very ancient capitalistic truth: smart wins.

Whatever faults the pharma industry may display, you won't hear any griping from me. Because I think we are in for a lot of fun over these next 10, 30, 50 years. Companies like Vertex are going to remake the industry in their image; focused, courageous, willing to take chances to bring innovation to the marketplace and reap the benefits. We here today cannot even imagine what wonders will emerge from the labs of tiny biopharmas whose names we don't even know, or how they will transform the world of medicine, not to mention the names at the top of *Med Ad News*' Top 50 Companies chart.

So folks, stop griping. Don't waste time mourning the past, or even the quirks of the present. You are blessed to be, as Dean Acheson said, present at the creation. Enjoy every minute.

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Top Biotechnology Companies

REVENUE — TOP 100 BIOTECHNOLOGY COMPANIES

RANK IN 2009	COMPANY	REVENUE IN 2009
1	Roche	$23,340,147,000 (biotech estimate)
2	Amgen Inc.	14,642,000,000
3	Gilead Sciences Inc.	7,011,383,000
4	Genzyme Corp.	4,515,525,000
5	Biogen Idec Inc.	4,377,348,000
6	UCB SA	4,342,146,000
7	CSL Ltd.	4,044,118,500
8	Celgene Corp.	2,689,893,000
9	Cephalon Inc.	2,192,308,000
10	Actelion Ltd.	1,632,195,212
11	Talecris Biotherapeutics Holdings Corp.	1,533,209,000
12	Elan Corp.	1,113,000,000
13	Amylin Pharmaceuticals Inc.	758,419,000
14	Cubist Pharmaceuticals Inc.	562,144,000
15	Biocon Ltd.	529,142,437
16	Crucell NV	471,230,141

- Experts analyze the current state of the industry, challenges, and expected outcomes
- Top biotech companies are ranked by revenue, R&D expenditure, and other performance data

Top Medicines

TOP 200 PRESCRIPTION MEDICINES BY SALES

Rank 2009	Medicine	2009 sales ($ in millions)
1	Lipitor	12,535 Pfizer 11,434 Astellas Pharma 1,101
2	Plavix/Iscover	9,801 Bristol-Myers Squibb 6,146 Sanofi-Aventis 3,655
3	Advair/Seretide	7,794
4	Remicade	7,151 Johnson & Johnson 4,304 Schering-Plough 1,896 Mitsubishi Tanabe Pharma 520 Merck 431 Note: Merck and Schering-Plough merged effecti
5	Enbrel Note: Pfizer merged with Wyeth effective Oct. 15, 2009.	6,575 (estimate) Amgen 3,493 (actual) Wyeth 2,348 (estimate) Pfizer 378 (actual) Takeda Pharmaceutical 356 (actual) Notes: Wyeth reported 1H 2009 sales of 1,363 last two-and-a-half months of 2009 from Wyeth's one-and-a-half months of 2009 from Wyeth's inte
6	Diovan and Diovan HCT/Co-Diovan	6,013
7	Avastin	5,729 Note: Figure reported by Roche and includes sal and Chugai Pharmaceutical (373)
8	Rituxan/MabThera	5,605+ Roche 5,605 (includes Genentech N/A and Ch Zenyaku Kogyo N/A Note: Biogen Idec's share of Rituxan revenue tota of the company's share of U.S. co-promotion pro
9	Humira	5,561 Abbott 5,488 Eisai 73
10	Seroquel	5,126

- Medicine of the Year and other leading drugs are analyzed based on key performance metrics
- The top 200 prescription medicines are ranked by sales

Top Pharmaceutical Companies

TOP 50 COMPANIES RANKED BY HEALTHCARE REVENUE

Rank 2009	Company	Healthcare Revenue 2009
1	Johnson & Johnson	$61,897,000,000
2	Pfizer Inc.	50,009,000,000
3	Roche	45,166,666,667
4	GlaxoSmithKline Plc.	44,427,124,800
5	Novartis	44,267,000,000
6	Sanofi-Aventis Group	40,837,911,000
7	AstraZeneca Plc.	32,804,000,000
8	Abbott Laboratories	30,764,707,000
9	Merck & Co.	27,428,300,000
10	Bayer AG	22,279,278,000
11	Eli Lilly and Co.	21,836,000,000
12	Bristol-Myers Squibb Co.	18,808,000,000
13	Boehringer Ingelheim GmbH	17,726,713,500
14	Takeda Pharmaceutical Co.	15,173,502,829 (March 10)
15	Amgen Inc.	14,642,000,000
16	Teva Pharmaceutical Industries Ltd.	13,899,000,000
17	Baxter International Inc.	12,562,000,000
18	Otsuka Holdings Co.	11,165,603,460 (March 10)

- Top pharma companies are ranked by healthcare revenue, R&D expenditure, and other performance metrics
- Analyzes the strategic business actions and resulting performance of the top companies

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FDA New Drug Approvals 1990-2011
The U.S. Food and Drug Administration has approved for marketing more than 1,650 new medicines via an NDA or BLA since 1990

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Untangling Healthcare Reform: Accountable Care Organizations

Featuring **F. Randy Vogenberg**, Ph.D., R.Ph., Principal, Institute for Integrated Healthcare; **Jerry Clor**, M.B.A., principal, Managed Care, Managed Markets & Account Manager Training & Development; and **Ed Silverman**, editor, Pharmalot, and editor-at-large, *Med Ad News* and *R&D Directions*.

March 27th – 1:00PM ET

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ON THE COVER

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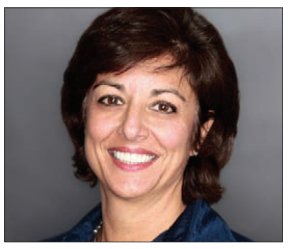

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inVentiv Health Communications/Europe has officially opened its new headquarters in London, which will serve as a hub for all European offices and support the rapid growth of the company's consolidated communications business.

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The overzealous regulation of token gifts represented by the "Sunshine" provision of President Obama's Healthcare Reform Act will only build roadblocks between drug developers and physicians, writes Sander Flaum of Flaum Navigators.

Med Ad News (ISSN 1067-733X) is published monthly by UBM Canon, 300 American Metro Blvd., Suite 125, Hamilton, NJ 08619, United States. Periodicals postage is paid at Hamilton, N.J., and additional mailing offices. POSTMASTER: Send address changes to *Med Ad News*, c/o UBM Canon, 300 American Metro Blvd., Suite 125, Hamilton, NJ 08619, 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. Canada Post: Publications Mail Agreement #40612608. Canada Returns to be sent to Bleuchip International, P.O. Box 25542, London, ON N6C 6B2

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WHAT'S ONLINE

DotPharma

THE "PARADIGM OF AWESOME!", INTROVERTS VS. EXTROVERTS, AND OTHER PHARMA THOUGHTS

Med Ad News Content Director Chris Truelove blogs about ZombieSymmetry's YouTube channel, where the industry's management cliches are turned inside out.

ABBOTT SCOOPS UP DOMAIN NAMES: GONZALEZSUCKS.US

Abbott Labs is preemptively protecting its incoming pharma CEO Richard Gonzalez by buying up domain names that might be used against him, writes Ed Silverman of Pharmalot.

ICONIC MOTH INVADES NYC OFFICE BUILDING TO HIGHLIGHT GAME FOR INSOMNIACS

The folks in charge of marketing Lunesta are using their famous brand icon in a free game to raise money for charity.

NON-STICK SITES

According to David Garson of imc2, the days of "sticky" are over; if marketers want their digital content to be passed around, it has to be greased up – valuable, navigable, digestible, shareable, and leave-able.

Go to pharmalive.com/dotpharma to read these stories

WHAT'S IN PRINT

Q&A with Pamela Stephenson

THINK SMALL • BEHIND THE MUSIC

Pamela Stephenson of Vertex Pharmaceuticals comments on the company's digital strategy for Incivek. Go to page 9

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ONCOLOGY FIRSTS IN 2011 • LAUNCHING WITH "E"

E-communications campaigns targeting physicians were an important part of the launch strategies for the new cancer drugs Provenge, Yervoy, and Zelboraf. Go to page 24

MULTICHANNEL SELLING – HOW TO MAKE EVERY SECOND COUNT

The average physician spends less than two minutes face-to-face with pharmaceutical sales reps. That's why it's critical to make every second count. Go to page 28

Event Date: May 15, 2012 | 10:00am - 4:00pm ET

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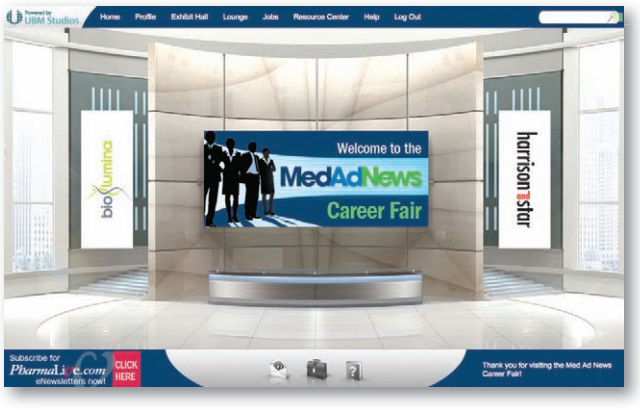

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continued from page 1

"With the approval of Incivek, there are now two important new treatment options for hepatitis C that offer a greater chance at a cure for some patients with this serious condition," says Edward Cox, M.D., director, Office of Antimicrobial Products in FDA's Center for Drug Evaluation and Research. "The availability of new therapies that significantly increase responses while potentially decreasing the overall duration of treatment is a major step forward in the battle against chronic hepatitis C infection."

In pursuing an innovative drug for hepatitis C, Vertex's leaders were aiming for the sweet spot of the old, reliable blockbuster drug market: a transformative medicine for a large, underserved disease population. According to the U.S. Centers for Disease Control and Prevention, about 3.2 million people in the United States have chronic hepatitis C infection, a viral disease that causes inflammation of the liver that can lead to diminished liver function or liver failure. Most people with hepatitis have no symptoms of the disease until liver damage occurs, which may take several years. Most liver transplants performed in the United States are due to progressive liver disease caused by hepatitis C virus infection. After the initial infection with hepatitis C, most people develop chronic hepatitis C. Some will develop cirrhosis of the liver over many years. Cirrhosis can lead to liver damage with complications such as bleeding, jaundice (yellowish eyes or skin), fluid accumulation in abdomen, infections, or liver cancer.

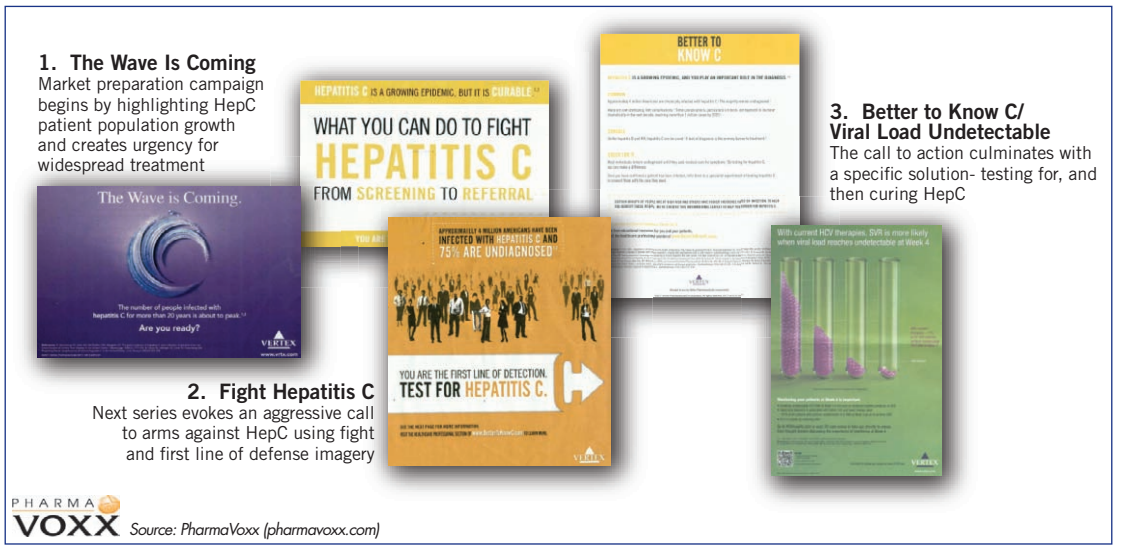
The month after Incivek's U.S. launch, the *New England Journal of Medicine* published data from two Phase III studies of Incivek which showed that the drug in combination therapy significantly improved rates of sustained viral response in a broad group of people with genotype 1 chronic hepatitis C who were new to treatment and those who were treated previously but not cured (relapsers, partial responders, and null responders).

In the ADVANCE study, Incivek combination therapy significantly improved viral cure rates in people who were new to treatment compared to those who received pegylated-interferon and ribavirin alone, two other medicines approved for hepatitis C. The majority of people who received Incivek combination therapy in this study were able to complete treatment in 24 weeks – half the time needed if they were to have taken pegylated-interferon and ribavirin alone. In the REALIZE study, which included people who were treated previously but not cured, viral cure rates were three-to-six-times higher with Incivek combination therapy compared to treatment with pegylated-interferon and ribavirin alone. Rash and anemia were the most common side effects reported with Incivek, which led to treatment discontinuation in about 1 percent of people in clinical studies.

"In the ADVANCE study, 79 percent of people with hepatitis C who had not been treated previously achieved a viral cure with Incivek combination therapy and the majority were able to cut treatment time in half," says Ira Jacobson, M.D., chief of the Division of Gastroenterology and Hepatology, Weill Cornell Medical College, and lead author and principal investigator for the ADVANCE study. "The results from this landmark study represent a paradigm shift in the treatment of hepatitis C and give us a new reason to encourage people to get tested and treated to potentially avoid the life-threatening consequences that can be associated with the disease."

In September, data from another Phase III trial of Incivek also published in the *New England Journal of Medicine* offered more good news for the drug's developers at Vertex. In the ILLUMINATE trial, Incivek was given for the first 12 weeks in combination with pegylated-interferon and ribavirin to people with genotype 1 chronic hepatitis C who were new to treatment.

Nearly two-thirds of patients responded early to Incivek combination treatment (measured by having undetectable hepatitis C virus at weeks 4 and 12 of treatment) and were randomly assigned to receive an additional 12 weeks or 36 weeks of treatment with pegylated-interferon and ribavirin alone. Similarly high rates of sustained viral response (SVR, or viral cure) were achieved by people in both treatment groups. Rash and anemia were the most common side effects reported with Incivek in this study and each led to treatment discontinuation of all medicines in about 1 percent of people during the Incivek treatment phase.

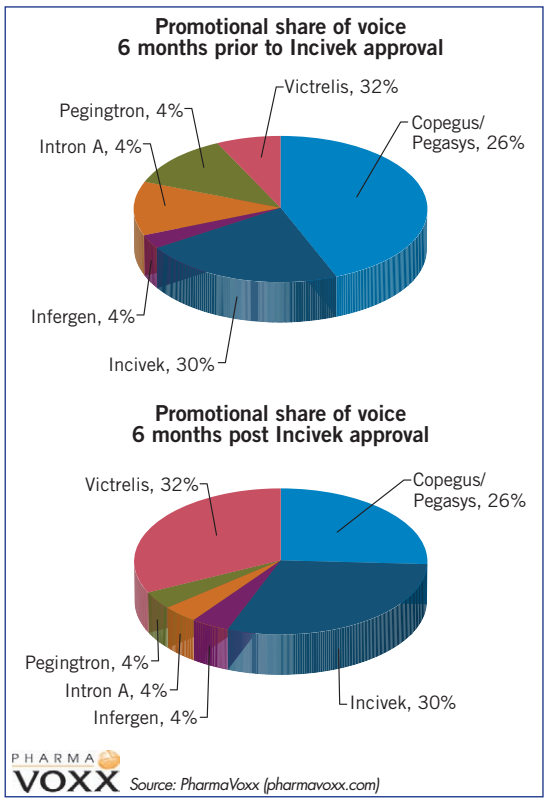


"These data are important because they showed that patients who respond early to Incivek combination treatment have a high likelihood of achieving a viral cure with 24 weeks of therapy," said Kenneth Sherman, M.D., Ph.D., professor of medicine at the University of Cincinnati College of Medicine and principal investigator for the study. "With Incivek, we know by week four how patients are initially responding and, for people who have not been treated before, we know by week 12 what their chances are of completing all therapy in 24 weeks. I believe these are important motivators for patients to start and stay on treatment."

A week after the ILLUMINATE data was published, the European Commission approved **Incivo** (the drug's European brand name) for the treatment of genotype-1 chronic hepatitis C virus, in combination with peginterferon alfa and ribavirin, in adults.

"We are delighted by the European Commission approval of telaprevir and that we can now offer patients a significantly improved treatment option for HCV compared to the previous standard treatment," said Ramon Polo, telaprevir compound development team leader for the Janssen Pharmaceutical Companies, Vertex's European development and marketing partner for the drug. "Telaprevir is a cornerstone of the Janssen Companies' expanding infectious disease portfolio, which includes therapies in HIV/AIDS, tuberculosis, serious infections, and now HCV that are helping to redefine and improve treatment outcomes. The Janssen Companies remain dedicated to improving the lives of patients and supporting healthcare professionals around the world."

In October, Vertex announced the initiation of a Phase IIIb study called CONCISE that will evaluate the potential for treatment with Incivek combination therapy to be shortened to 12 weeks in people with genotype 1 chronic hepatitis C who have the 'CC' variation near the IL28B gene. About one-third of people with hepatitis C have the 'CC' genotype, which has been associated with higher sustained viral response rates and faster response to interferon-based treatment. The study is expected to enroll 350 people in the United States and Europe who are new to treatment or who have relapsed after at least one prior course of treatment with pegylated-interferon and ribavirin alone. The primary endpoint of the study is the proportion of patients who achieve a sustained viral response 12 weeks after the last planned dose of study drug.



"Incivek combination therapy is a significant advance over the previous standard of care for the treatment of hepatitis C," says Robert Kauffman, M.D., Ph.D., senior VP and chief medical officer at Vertex. "As we enter a new era of treatment for hepatitis C, one of our goals is to offer patients a high chance for a cure in the shortest amount of time. This study is one of several ways Vertex is exploring the potential for people with hepatitis C to achieve high viral cure rates with just 12 weeks of total treatment."

CONCISE will evaluate the potential to reduce treatment time with Incivek combination therapy to 12 weeks and no more than 24 weeks for people with hepatitis C who have the 'CC' variation near the IL28B gene and who have undetectable hepatitis C virus at week 4 of treatment. This study design is supported by data from studies that have shown that people with hepatitis C who have the CC genotype have better and faster responses to treatment, including retrospective analyses for a group of people who were tested for IL28B genotype in the ADVANCE and REALIZE pivotal studies of Incivek. These analyses showed that people in these studies who received Incivek combination therapy had substantial improvements in viral cure rates across all IL28B genotypes compared to those treated with pegylated-interferon and ribavirin alone. The highest rates of RVR, extended rapid viral response (eRVR, measured at weeks 4 and 12) and viral cure were observed among people with the CC genotype.

Incivek's developers have no intention of settling for a hepatitis C indication alone. In November, Vertex announced positive interim results from an ongoing Phase II study designed to evaluate the safety and tolerability of Incivek in combination with pegylated-interferon and ribavirin in people who are co-infected with chronic genotype 1 hepatitis C and HIV. Data showed 74 percent of patients who were treated with Incivek combination therapy had undetectable hepatitis C virus at week 24 of treatment compared to 55 percent who were treated with pegylated-interferon and ribavirin alone. Changes in CD4 counts were similar between the treatment groups and no HIV viral load breakthroughs were observed in either treatment group during the study. Adverse events that occurred more frequently in the Incivek arms compared to placebo were abdominal pain, vomiting, nausea, fever, dizziness, depression, and itchiness. No severe rashes were reported through 24 weeks.

"Treating hepatitis C in people who also have HIV

Behind the music

Med Ad News spoke with Pamela Stephenson, VP of HCV marketing for Vertex, to get the story behind Incivek

Med Ad News: Very few folks would have guessed a year ago that the monster launch of 2011 would come from a company that isn't even in the top 50 worldwide in pharma sales, and has no U.S. marketing partner. How did a small company with such limited resources achieve this?

Pamela Stephenson: Incivek was our company's first launch, so there was a lot of dedication and commitment to getting it right. We spent years studying and understanding the needs of physicians, nurses, patients, and caregivers and kept our focus on helping the patients dealing with this very serious disease. We were tightly coordinated in quickly disseminating clear, easy-to-understand information upon approval, and the market was receptive to our messages.

Given the competitive environment and the thousands of patients who were waiting for Incivek, we also focused on how to move quickly to deliver the product. We got Incivek out to patients within three days after approval, and physician and patient materials were expedited so that we helped people not only learn about Incivek, but also learn how to use it appropriately and what to expect from treatment.

Med Ad News: What went into the choice of your agencies for Incivek?
Pamela Stephenson: We wanted to work with the best thinkers in each of our areas of outreach, so we put together a network of agencies rather than having a single agency of record. These agencies brought expertise in HCP, patient and digital marketing, patient services, program implementation, and educational programs.

Med Ad News: Give us a general overview of your marketing strategy for Incivek. What targets are the most critical? What channels are the most important?
Pamela Stephenson: Given how complicated hepatitis C and its treatment are, we wanted to make our messages and materials as simple as possible. We did our homework – studied all aspects of the market before we developed our plans and materials, and gathered years worth of research and insights from physicians and patients.

We knew going into launch that a patient's best chance for successful treatment depended on a clear understanding of the product's benefits and risks among the patients and providers. We know people have different styles of learning, so we used multiple channels and approaches to meet them where they were and in the way they want to receive information.

Our diverse channels include one-to-one education, group programs, print materials, a 24-hour nurse support hotline, and digital elements.

We also recognized the need to coordinate the messages across audiences, and we spent a lot of time making sure we were consistent in the information we were communicating to enable productive conversations between patients and their healthcare providers.

Med Ad News: How will the Incivek brand team use technology to enhance awareness of hep C and their product?
Pamela Stephenson: We utilize a full digital platform including interactive Websites – BetterToKnowC.com, Invicek.com, and HCVInsights.com. We have a text messaging program to remind patients to take their medicine on schedule and will soon be rolling out a mobile app for HCPs.

Med Ad News: How do you see the hep C marketplace, and Incivek as a part of it, developing over the next five to 10 years?
Pamela Stephenson: Incivek has shifted the paradigm of treatment for people with hepatitis C. It has shown unprecedented cure rates, but there is more to be done. We have several trials under way to demonstrate its effectiveness in additional patient populations, including those co-infected with HIV, diagnosed with cirrhosis of the liver, and post-transplant patients. Additionally, we're advancing several interferon-free combination regimens of our medicines in development with the goal of further improving treatment for people with hepatitis C.

Med Ad News: There are a limited number of hepatologists out there, so the primary care physician will help drive patient care of hep C. What strategies are Incivek's marketers using to educate this audience?
Pamela Stephenson: Hepatologists are limited in number because it is such a specialized field. However, there are approximately 10,000 gastroenterologists in the U.S. who also treat people with hepatitis C.

Primary care physicians are an important part of the initial diagnosis and referral to a specialist, especially considering that 75 percent of those infected are unaware they carry the virus. We piloted an educational program for PCPs last year that confirmed the significant need for education around HCV and testing and are continuing these efforts in 2012.

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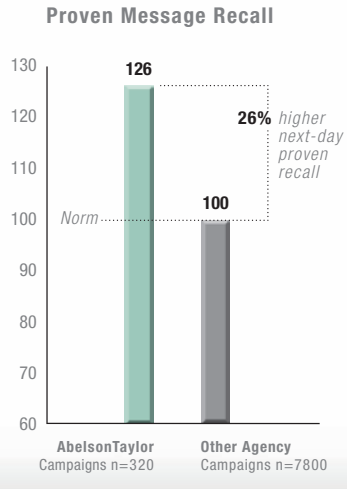

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is particularly challenging as only about 30 percent of people clear the virus after undergoing nearly a year of treatment with currently available medicines," Dr. Kauffman says. "As we prepare for our new Phase III study to evaluate Incivek combination therapy in a much larger group of people who are co-infected, data from this study give us hope that in the future we'll be able to help more co-infected patients clear the virus."

There are two parts to the ongoing HCV/HIV study: Part A is evaluating people who are not currently being treated with antiretroviral therapy for HIV infection, and Part B is evaluating those who are taking an **Atripla** or **Reyataz**-based regimen for HIV. This study enrolled patients who were new to hepatitis C treatment. Interim data also showed 63 percent of patients treated with Incivek combination therapy in this study had an extended rapid hepatitis C viral response (eRVR, measured as undetectable HCV RNA at weeks 4 and 12 of treatment) compared to about 5 percent who received pegylated-interferon and ribavirin alone.

"Complications associated with hepatitis C such as scarring of the liver typically develop much faster in people infected with both hepatitis C and HIV," says Kenneth Sherman, M.D., Ph.D., professor of medicine at the University of Cincinnati College of Medicine and principal investigator of the trial. "As HIV treatments have improved, liver disease associated with hepatitis C has become a leading cause of death among people who are co-infected, so offering patients a better chance at a cure for hepatitis C while maintaining their suppression of HIV would be a major advance in treatment."

The company is also exploring the usefulness of **VX-222**, its follow-on to Incivek, in combination with its new star product. Also in November, Vertex released interim results from ZENITH, an ongoing Phase II study designed to assess the safety, tolerability, and efficacy of multiple 12- and 24-week response-guided treatment regimens with VX-222 (100 milligrams or 400 milligrams), its lead polymerase inhibitor in development, in combination with Incivek, pegylated-interferon, and ribavirin in people with genotype 1 chronic hepatitis C who were new to treatment. On the basis of the results and previously announced data from other treatment arms of the ZENITH study, Vertex intends to start a Phase III study to evaluate a total treatment duration of 12 weeks with this four-drug regimen in treatment-naive and relapser patients with genotype 1 chronic hepatitis C.

"More than 85 percent of patients in the four-drug treatment arms of ZENITH had undetectable hepatitis C virus at week 4 and, regardless of treatment duration, 90 percent of them cleared the hepatitis C virus," Dr. Kauffman says. "Based on these interim results, Vertex began discussions with regulatory agencies about the regulatory path for this four-drug regimen, with the intent to initiate Phase III studies in a broad group of people with genotype 1 hepatitis C in the first quarter of 2012."

In late February, Vertex announced interim data from two treatment arms of ZENITH. This data showed that viral loads were below the lower limit of quantification for 80 percent (37/46) of patients with genotype 1 hepatitis C at week two and 83 percent (38/46) of patients with genotype 1 at week 12.

ZENITH was designed with strict response-guided criteria that determined whether a patient was eligible to stop all treatment at 12 weeks. Eleven patients met the criteria of having undetectable hepatitis C virus at weeks two and eight of treatment and were therefore eligible to stop all treatment at 12 weeks. Nine of these 11 patients achieved SVR4 (undetectable hepatitis C virus four weeks after the end of all treatment).

Based on these data, and pending discussions with regulatory agencies, Vertex intends to pursue a Phase IIb study evaluating multiple interferon-free combination regimens of Incivek, VX-222, and ribavirin with total treatment durations as short as 12 weeks in people with genotype 1 (1a and 1b) hepatitis C who are new to treatment. The study will not use response-guided treatment criteria. Data from this study will be used to design a Phase III program with the goal of submitting a new drug application to FDA for Vertex's first interferon-free regimen for genotype 1 (1a and 1b) patients by the end of 2014 or beginning of 2015, pending regulatory discussions.

"Since its approval Incivek has been used to treat tens of thousands people with hepatitis C and we're committed to further improving the care of those living with this disease by evaluating multiple interferon-free regimens," says Peter Mueller, Ph.D., executive VP, global research and development, and chief scientific officer for Vertex. "Our ultimate goal is to develop well-tolerated, interferon-free treatment regimens with high viral cure rates and short treatment durations for people with hepatitis C. We believe we're well-positioned to achieve this goal by exploring various combinations within our portfolio that includes Incivek, VX-222, and two structurally-distinct nucleotide polymerase inhibitors."

"Since its approval Incivek has been used to treat tens of thousands people with hepatitis C and we're committed to further improving the care of those living with this disease by evaluating multiple interferon-free regimens," says Peter Mueller, Ph.D., executive VP, global research and development, and chief scientific officer for Vertex.

80 NEW MEDICINES

The Food and Drug Administration's amount of new drug approvals for 2011 declined for the second consecutive year, but total new chemical entity approvals significantly increased.

By Andrew Humphreys andrew.humphreys@ubm.com **and Silvia Arriola** silvia.arriola@ubm.com

FDA during 2011 cleared for marketing 80 new medicines based on *Med Ad News* criteria, a decrease of eight products compared with 2010. There were 92 new products approved by the U.S. regulatory agency in 2009, 85 during 2008, and 73 for 2007.

On a positive note, the combined amount of approved new molecular entities submitted under new drug applications and therapeutic biologics filed via original biologic license applications increased to 31 for 2011 versus 21 during 2010. Previously, FDA's Center for Drug Evaluation and Research cleared for approval 26 NMEs/new BLAs during 2009, 24 in 2008, and 18 during 2007.

The Class of 2011 New Drug Approvals includes a variety of anticipated blockbuster medicines. One product nearly exceeded the $1 billion sales barrier during 2011: **Incivek**. Developed and marketed by **Vertex** Pharmaceuticals, Incivek (telaprevir) is FDA-approved for certain adults with hepatitis C. This oral medicine acts directly on the hepatitis C virus protease, an enzyme essential for viral replication.

Vertex holds exclusive rights to the medicine in the United States and Canada. Vertex collaborator **Janssen** is marketing telaprevir in Europe under the trade name **Incivo**. In Japan, **Mitsubishi Tanabe** Pharma is marketing the drug as **Telavic**.

Approved for marketing by FDA on May 23, 2011, Vertex's 2011 net revenue for Incivek totaled $950.9 million. Industry research indicates that no prescription drug has ever generated that level of sales during its first seven months on the market. Vertex management has projected that 2012 Incivek net revenue will fall in the range of $1.5 billion to $1.7 billion.

Incivek has been recognized by *Med Ad News* editors as the Best New Medicine of 2011. For more details regarding the product's very successful commercial launch, please see the cover story.

The combined amount of approved new molecular entities submitted under new drug applications and therapeutic biologics filed via original biologic license applications increased to 31 for 2011 versus 21 during 2010.

Another high-profile hepatitis C drug that was FDA-approved during 2011 was **Merck** & Co.'s **Victrelis** (boceprevir). Victrelis is a first-in-class HCV protease inhibitor. The Direct Acting Antiviral agent is designed to interfere with the ability of the hepatitis C virus to replicate by inhibiting a key viral enzyme (NS3/4A serine protease).

Approved by U.S. regulators on May 13, Merck reported Victrelis 2011 sales of $140 million. Industry analysts had projected a closer sales battle between the two hepatitis C products. However, they cite that since Victrelis is used for a longer period of time than Incivek, it is taking Merck longer to realize revenue from each patient than it does Vertex.

Other potential blockbuster brands from the Class of 2011 New Drug Approvals include **Xarelto** (rivaroxaban), **Brilinta** (ticagrelor), **Yervoy** (ipilimumab), **Xalkori** (crizotinib), and **Benlysta** (belimumab).

Xarelto is the first oral anticoagulant to offer patients both efficacy and the convenience of a one-drug solution, without the necessity for injections or monitoring. Xarelto gained FDA clearance for two different indications during 2011. July 1, the product was approved for the prophylaxis of deep vein thrombosis, which may lead to pulmonary embolism in people undergoing knee or hip replacement surgery.

Nov. 4, Xarelto was cleared to reduce the risk of stroke in people who have abnormal heart rhythm (non-valvular atrial fibrillation). More than 2.2 million Americans suffer from atrial fibrillation, which is one of the most common types of abnormal heart rhythm.

Titusville, N.J.- based Janssen Pharmaceuticals markets Xarelto in the United States. The anti-clotting drug is marketed in Europe by **Bayer** HealthCare.

The blood-thinning drug Brilinta got the approval nod from FDA on July 20 to reduce cardiovascular

death and heart attack in patients with acute coronary syndromes (ACS). ACS consists of a group of symptoms for any condition, including unstable angina or heart attack, that could result from reduced blood flow to the heart.

Brilinta acts by preventing the formation of new blood clots, thereby maintaining blood flow in the body to help reduce the risk of another cardiovascular event. Marketed by **AstraZeneca**, the oral antiplatelet medicine is branded as **Brilique** in Europe.

Yervoy represents the first FDA-approved therapy for unresectable or metastatic melanoma in more than a decade. The **Bristol-Myers Squibb** drug is available to treat patients with late-stage (metastatic) melanoma, the most dangerous form of skin cancer. Melanoma is the No. 1 cause of death from skin disease.

Administered intravenously, this monoclonal antibody blocks a molecule known as cytotoxic T-lymphocyte antigen or CTLA-4. CTLA-4 may have a role in slowing down or turning off the body's immune system, affecting its ability to fight off cancerous cells. Yervoy can potentially allow the body's immune system to recognize, target, and attack cells in melanoma tumors.

Pfizer's Xalkori treats certain patients with late-stage (locally advanced or metastatic), non-small cell lung cancers who express the abnormal anaplastic lymphoma kinase (ALK) gene. The kinase inhibitor was approved for use with the first-of-a-kind **Vysis ALK Break Apart FISH Probe Kit**. This companion diagnostic test can help determine if a patient has the abnormal ALK gene.

Xalkori represents the first therapy approved specifically for locally advanced or metastatic ALK-positive non-small cell lung cancer patients. Lung cancer is the No. 1 cause of cancer death in men and women worldwide. NSCLC constitutes about 85 percent of lung cancer cases and is difficult to treat, especially in the metastatic setting. About three-fourths of NSCLC patients are diagnosed late with metastatic or advanced disease, with the five-year survival rate at 6 percent.

Benlysta treats patients with active, autoantibody-positive lupus (systemic lupus erythematosus) who are receiving standard therapy, such as corticosteroids, antimalarials, immunosuppressives, and non-steroidal anti-inflammatory drugs. Delivered directly into a vein, Benlysta is the first inhibitor designed to target B-lymphocyte stimulator (BLyS) protein, which may reduce the amount of abnormal B cells believed to be a problem in lupus.

A serious and potentially fatal autoimmune disease, lupus attacks healthy tissues. The disease disproportionately affects women, and usually develops between the ages of 15 years and 44 years.

Benlysta is the first new drug approved for systemic lupus in more than five decades. **Human Genome Sciences** and **GlaxoSmithKline** developed belimumab under a definitive joint-development and joint-commercialization deal entered into during 2006. ■ MEDADNEWS

2011 NEW DRUG APPROVALS

Product	Chemical	Indication	2011 approval date	Marketer (or developer if no marketer is in place)
Abstral	Fentanyl	Abstral is indicated for the management of breakthrough cancer pain in patients with cancer, 18 years or older, who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain.	Jan. 7	ProStrakan
Adcetris	Brentuximab vedotin	Adcetris is indicated for the treatment of patients with Hodgkin lymphoma after failure of autologous stem cell transplant or after failure of at least two prior multi-agent chemotherapy regimens in patients who are not autologous stem cell transplant candidates; for the treatment of patients with systemic anaplastic large cell lymphoma after failure of at least one prior multi-agent chemotherapy regimen.	Aug. 19	Seattle Genetics
Anascorp	Centruroides (Scorpion) Immune F(ab')2 (Equine)	Anascorp is indicated for the treatment of clinical signs of scorpion envenomation.	Aug. 3	Rare Disease Therapeutics
AndroGel 1.62%	Testosterone	AndroGel 1.62% is indicated for replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone as primary hypogonadism and hypogonadotropic hypogonadism.	April 29	Abbott Laboratories
Anturol	Oxybutynin	Anturol is indicated for the treatment of overactive bladder with symptoms of urge urinary incontinence, urgency, and frequency.	Dec. 7	Watson Pharmaceuticals
Arcapta Neohaler	Indacaterol maleate	Arcapta Neohaler is indicated as maintenance bronchodilator treatment of airflow obstruction in patients with chronic obstructive pulmonary disease, including chronic bronchitis and/or emphysema.	July 1	Novartis Pharmaceuticals
Argatroban 0.9% in Sodium Chloride	Argatroban	Argatroban in 0.9% Sodium Chloride is indicated for the prevention or treatment of thrombosis in patients with heparin-induced thrombocytopenia; and as an anticoagulant in adults patients with or at risk for heparin-induced thrombocytopenia undergoing percutaneous coronary intervention.	May 9	Sandoz
NOTE: On June 29, 2011, Eagle Pharmaceuticals' New Drug Application for Argatroban in Sodium Chloride was approved for the prevention or treatment of thrombosis in adult patients with heparin-induced thrombocytopenia; and as an anticoagulant in adult patients with or at risk of heparin-induced thrombocytopenia undergoing percutaneous coronary intervention.				
Argatroban Injection in 5% Dextrose	Argatroban	Argatroban Injection in 5% Dextrose is indicated for the prevention or treatment of thrombosis in adult patients with heparin-induced thrombocytopenia; and as an anticoagulant in adult patients with or at risk for heparin-induced thrombocytopenia undergoing percutaneous coronary intervention.	May 9	Sandoz
Banzel Oral Suspension	Rufinamide	Banzel Oral Suspension is indicated as adjunctive treatment of seizures associated with Lennox-Gastaut syndrome in children 4 years old or older and adults.	March 3	Eisai
Benlysta	Belimumab	Benlysta is indicated for the treatment of adult patients with active, autoantibody-positive, systemic lupus erythematosus who are receiving standard therapy.	March 9	Human Genome Sciences and GlaxoSmithKline
Brilinta	Ticagrelor	Brilinta is indicated to reduce the rate of thrombotic cardiovascular events in patients with acute coronary syndrome (unstable angina, non-ST elevation myocardial infarction, or ST elevation myocardial infarction).	July 20	AstraZeneca Pharmaceuticals
Caprelsa	Vandetanib	Caprelsa is indicated for the treatment of symptomatic or progressive medullary thyroid cancer in patients with unresectable locally advanced or metastatic disease.	April 6	AstraZeneca Pharmaceuticals
Ceftazidime for Injection and Dextrose Injection in the Duplex Container	Ceftazidime	Ceftazidime for Injection and Dextrose Injection in the Duplex Container is indicated for the treatment of bacterial infections.	June 13	B. Braun Medical
Codeine Sulfate Oral Solution 30 mg/5 mL	Codeine sulfate	Codeine Sulfate Oral Solution 30 mg/5 mL is indicated for the management of mild to moderately severe pain when the use of an opioid analgesic is appropriate.	June 30	Roxane Laboratories
Combivent Respimat	Ipratropium bromide and albuterol sulfate	Combivent Respimat is indicated for the treatment of chronic obstructive pulmonary disease on a regular aerosol bronchodilator who continue to have evidence of bronchospasm and who require a second bronchodilator.	Oct. 7	Boehringer Ingelheim Pharmaceuticals
Complera	Emtricitabine, rilpivirine and tenofovir disoproxil fumarate	Complera is indicated as a complete regimen for the treatment of HIV-1 infection in antiretroviral treatment-naive adults.	Aug. 10	Gilead Sciences
Corifact	Factor XIII concentrate (human)	Corifact is indicated for routine prophylactic treatment of congenital factor XIII deficiency.	Feb. 15	CSL Behring
Daliresp	Roflumilast	Daliresp is indicated as a treatment to reduce the risk of chronic obstructive pulmonary disease exacerbations in patients with severe chronic obstructive pulmonary disease associated with chronic bronchitis and a history of exacerbations.	Feb. 28	Forest Laboratories
DaTscan	Ioflupane I-123	DaTscan is indicated for striatal dopamine transporter visualization using single photon emission computed tomography brain imaging to assist in the evaluation of adult patients with suspected Parkinsonian syndromes.	Jan. 14	GE Healthcare
Dificid	Fidaxomicin	Dificid is indicated for the treatment of Clostridium difficile-associated diarrhea in patients 18 years old or older.	May 27	Optimer Pharmaceuticals

2011 NEW DRUG APPROVALS

Product	Chemical	Indication	2011 approval date	Marketer (or developer if no marketer is in place)
Docetaxel Injection	Docetaxel	Docetaxel Injection is indicated as a single agent for the treatment of locally advanced or metastatic breast cancer after chemotherapy failure; in combination with doxorubicin and cyclophosphamide as adjuvant treatment of operable node-positive breast cancer; as a single agent for the treatment of locally advanced or metastatic non-small cell lung cancer after platinum therapy failure; in combination with cisplatin for the treatment of unresectable, locally advanced or metastatic untreated non-small cell lung cancer; and for the treatment of androgen independent (hormone refractory) metastatic prostate cancer.	March 8	Hospira
NOTE: On May 3, 2011, Sun Pharmaceutical Industries' New Drug Application for Docetaxel Injection (branded as Docefrez) was approved for the treatment of locally advanced or metastatic breast cancer; for the treatment of locally advanced or metastatic non-small cell lung cancer; and for the treatment of hormone refractory metastatic prostate cancer. NOTE: On June 8, 2011, Accord Healthcare's New Drug Application for Docetaxel Injection was approved as a single agent for the treatment of locally advanced or metastatic breast cancer after chemotherapy failure; in combination with doxorubicin and cyclophosphamide as adjuvant treatment of operable node-positive breast cancer; as a single agent for the treatment of locally advanced or metastatic non-small cell lung cancer after platinum therapy failure; in combination with cisplatin for the treatment of unresectable, locally advanced or metastatic untreated non-small cell lung cancer; for the treatment of androgen independent (hormone refractory) metastatic prostate cancer; in combination with cisplatin and fluorouracil for the treatment of untreated, advanced gastric adenocarcinoma, including the gastroesophageal junction; and in combination with cisplatin and fluorouracil for the induction treatment of locally advanced squamous cell carcinoma of the head and neck cancer. NOTE: On June 29, 2011, Sandoz's New Drug Application for Docetaxel Injection was approved in combination with cisplatin and fluorouracil for the treatment of untreated, advanced gastric adenocarcinoma, including the gastroesophageal junction; in combination with cisplatin and fluorouracil for the induction treatment of locally advanced squamous cell carcinoma of the head and neck cancer; in combination with prednisone for the treatment of androgen independent (hormone refractory) metastatic prostate cancer; in combination with cisplatin for the treatment of unresectable, locally advanced or metastatic untreated non-small cell lung cancer; as a single agent for the treatment of locally advanced or metastatic non-small cell lung cancer after platinum therapy failure; as a single agent for the treatment of locally advanced or metastatic breast cancer after chemotherapy failure; as a single agent for the treatment of locally advanced or metastatic breast cancer after chemotherapy failure; and in combination with doxorubicin and cyclophosphamide as adjuvant treatment of operable node-positive breast cancer.			
Duexis	Ibuprofen and famotidine	Duexis is indicated for the relief of signs and symptoms of osteoarthritis and to decrease the risk of developing upper gastrointestinal ulcers; and for the relief of signs and symptoms of rheumatoid arthritis and to decrease the risk of developing upper gastrointestinal ulcers.	April 23	Horizon Pharma
Edarbi	Azilsartan medoxomil	Edarbi, either alone or in combination with other antihypertensive agents, is indicated for the treatment of hypertension.	Feb. 25	Takeda Pharmaceuticals North America
Edarbyclor	Azilsartan medoxomil and chlorthalidone	Edarbyclor is indicated for the treatment of hypertension to lower blood pressure.	Dec. 20	Takeda Pharmaceuticals North America
Edurant	Rilpivirine hydrochloride	Edurant, in combination with other antiretroviral agents, is indicated for the treatment of HIV-1 infection in treatment-naïve adult patients.	May 20	Janssen Therapeutics
Erwinaze	Asparaginase Erwinia chrysanthemi	Erwinaze is indicated as a component of a multi-agent chemotherapeutic regimen for the treatment of patients with acute lymphoblastic leukemia who have developed hypersensitivity to E. coli-derived asparaginase.	Nov. 18	EUSA Pharma
Exparel	Bupivacaine	Exparel is indicated for single-dose infiltration into the surgical site to produce postsurgical analgesia.	Oct. 28	Pacira Pharmaceuticals
Eylea	Aflibercept	Eylea is indicated for the treatment of patients with neovascular wet age-related macular degeneration.	Nov. 18	Regeneron Pharmaceuticals
Ferriprox	Deferiprone	Ferriprox is indicated for the treatment of patients with transfusional iron overload due to thalassemia syndromes when current chelation therapy is inadequate.	Oct. 14	ApoPharma USA
Firazyr	Icatibant acetate	Firazyr is indicated for the treatment of acute attacks of hereditary angioedema in adults 18 years old or older.	Aug. 25	Shire US
Fluoxetine 60 mg Scored Tablet	Fluoxetine hydrochloride	Fluoxetine 60 mg Scored Tablet is indicated for the treatment of major depressive disorder; for the treatment of obsessive compulsive disorder; for the treatment of moderate to severe bulimia nervosa; and for the treatment of panic disorder, with or without agoraphobia.	Oct. 6	Edgemont Pharmaceuticals
Fluzone Intradermal	Influenza virus vaccine	Fluzone Intradermal is indicated for the prevention of influenza caused by influenza virus subtypes A and type B contained in the vaccine in adults between 18 years and 64 years old.	May 9	Sanofi Pasteur
Forfivo XL	Bupropion hydrochloride	Forfivo XL is indicated for the prevention of seasonal major depressive illness.	Nov. 10	IntelGenx
Gadavist	Gadobutrol	Gadavist is indicated for diagnostic magnetic resonance imaging in adults and children 2 years old or older to detect and visualize areas with disrupted blood brain barrier and/or abnormal vascularity of the central nervous system.	March 14	Bayer HealthCare Pharmaceuticals
Gemcitabine Injection	Gemcitabine hydrochloride	Gemcitabine Injection, in combination with paclitaxel, is indicated as first-line treatment of patients with metastatic breast cancer after failure of prior anthracycline containingadjuvant chemotherapy, unless anthracyclines were clinically contraindicated; is indicated as first-line treatment of patients with inoperable, locally advanced (Stage IIIA or IIIB), or metastatic (Stage IV) non-small cell lung cancer; as first-line treatment for patients with locally advanced (nonresectable Stage II or Stage III) or metastatic (Stage IV) adenocarcinoma of the pancreas who were previously treated with 5-FU; in combination with carboplatin, is indicated for the treatment of patients with advanced ovarian cancer that has relapsed at least 6 months after completion of platinum-based therapy.	Aug. 4	Hospira
Gralise	Gabapentin	Gralise is indicated for the management of postherpetic neuralgia.	Jan. 28	Depomed
Heparin Sodium Injection	Heparin sodium	Heparin Sodium Injection is indicated for the prevention and treatment of venous thrombosis; for the prevention and treatment of pulmonary embolism; for the prevention and treatment of thromboembolic complications associated with atrial fibrillation; for the treatment of acute and chronic consumption coagulopathies (disseminated intravascular coagulation); for the prevention of clotting in arterial and cardiac surgery; for the prevention and treatment of peripheral arterial embolism; and as an anticoagulant to be used in blood transfusions, extracorporeal circulation, and dialysis procedures.	July 21	Pfizer
Horizant	Gabapentin enacarbil	Horizant is indicated for the treatment of moderate-to-severe primary restless legs syndrome in adults.	April 6	XenoPort and GlaxoSmithKline
Hydromorphone Hydrochloride Injection	Hydromorphone hydrochloride	Hydromorphone Hydrochloride Injection (in 1, 2, and 4 mg/mL ampules; 1, 2, and 4 mg/mL Carpuject Cartridges; 1 and 2 mg/mL iSecure Cartridges; and a 2 mg/mL vial) is intended for the management of pain in patients where an opioid analgesic is appropriate.	Dec. 1	Hospira
Incivek	Telaprevir	Incivek, in combination with peginterferon alfa and ribavirin, is indicated for the treatment of genotype 1 chronic hepatitis C in adult patients with compensated liver disease, including cirrhosis, who are treatment-naïve or who have previously been treated with interferon-based treatment, including prior null responders, partial responders, and relapsers.	May 23	Vertex Pharmaceuticals
Intermezzo	Zolpidem tartrate	Intermezzo is indicated for use as needed for the treatment of insomnia when a middle-of-the-night awakening is followed by difficulty returning to sleep.	Nov. 23	Purdue Pharma
Isentress 100 mg Scored and 25 mg Chewable Tablet	Raltegravir	Isentress 100 mg Scored and 25 mg Chewable Tablet, in combination with other antiretroviral agents, are indicated for the treatment of HIV-1 infection in pediatric patients 2 to less than 12 years old.	Dec. 21	Merck & Co.

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2011 NEW DRUG APPROVALS

Product	Chemical	Indication	2011 approval date	Marketer (or developer if no marketer is in place)
Jakafi	Ruxolitinib	Jakafi is indicated for the treatment of patients with intermediate or high-risk myelofibrosis, including primary myelofibrosis, post-polycythemia vera myelofibrosis and post-essential thrombocythemia myelofibrosis.	Nov. 16	Incyte
Juvisync	Sitagliptin phosphate and simvastatin	Juvisync is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus; as an adjunctive therapy to diet to reduce the risk of total mortality by reducing congenital heart disease deaths and reduce the risk of non-fatal myocardial infarction, stroke, and the need for revascularization procedures in patients at high risk of coronary events; as an adjunctive therapy to diet to reduce elevated total-cholesterol, low-density-lipoprotein cholesterol, Apolipoprotein B, triglyceride and increase high-density-lipoprotein cholesterol in patients with primary hyperlipidemia (heterozygous familial and nonfamilial) and mixed dyslipidemia; as an adjunctive therapy to diet to reduce elevated triglyceride in patients with hypertriglyceridemia and reduce triglyceride and very low-density-lipoprotein cholesterol in patients with primary dysbetalipoproteinemia; as an adjunctive therapy to diet to reduce total-cholesterol and low-density-lipoprotein cholesterol in adult patients with homozygous familial hypercholesterolemia.	Oct. 7	Merck & Co.
Kedbumin	Albumin (human)	Kedbumin is indicated for the treatment of hypovolemia; for the treatment of hypoalbuminemia (severe albumin deficiency) caused by illness or active bleeding; for the prevention of central volume depletion after paracentesis due to cirrhotic ascites; for the treatment of ovarian hyperstimulation syndrome; for the treatment of adult respiratory distress syndrome; for the treatment of burns, after 24 hours post burn in patients experiencing severe albumin depletion in order to favor edema re-absorption; for the treatment of hemodialysis patients undergoing long term dialysis or for those patients who are fluid-overloaded and cannot tolerate substantial volumes of salt solution for therapy of shock or hypotension; for the treatment of patients who cannot tolerate substantial volumes of salt solution; and in cardiopulmonary bypass procedures as part of the priming fluids.	June 3	Kedrion
LaViv	Azficel-T	LaViv is indicated for the improvement of the appearance of moderate to severe nasolabial folds or wrinkles in adults.	June 21	Fibrocell Science
Lazanda	Fentanyl citrate	Lazanda is indicated for the management of breakthrough cancer pain in patients 18 years old or older who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain.	June 30	Archimedes Pharma US
Levetiracetam in Sodium Chloride Injection	Levetiracetam	Levetiracetam in Sodium Chloride Injection is indicated as adjunctive therapy in the treatment of partial onset seizures in adults with epilepsy; as adjunctive therapy in the treatment of myoclonic seizures in patients with juvenile myoclonic epilepsy; and as adjunctive therapy in the treatment of primary generalized tonic-clonic seizures in adults with idiopathic generalized epilepsy.	Nov. 9	HQ Specialty Pharma
Levothyroxine Sodium for Injection (100 mcg, 200 mcg, and 500 mcg Vials)	Levothyroxine sodium	Levothyroxine Sodium for Injection (100 mcg, 200 mcg, and 500 mcg Vials) is indicated for the treatment of myxedema coma.	June 24	APP Pharmaceuticals
Lotemax Ophthalmic Ointment	Loteprednol etabonate	Lotemax Ophthalmic Ointment is indicated for the treatment of post-operative inflammation and pain following ocular surgery.	April 15	Bausch & Lomb Pharmaceuticals and Pfizer
Makena	Hydroxyprogesterone caproate	Makena is indicated to reduce the risk of preterm birth in women with singleton pregnancy who have a history of singleton spontaneous preterm birth.	Feb. 3	Ther-Rx
Morphine Sulfate Injection (2, 4, 8, 10, and 15 mg/mL in Carpuject and iSecure Syringes)	Morphine sulfate	Morphine Sulfate Injection (2, 4, 8, 10, and 15 mg/mL in Carpuject and iSecure Syringes) is indicated for the management of moderate to severe acute and chronic pain where an opioid analgesic is appropriate.	June 23	Lannett
NOTE: On Nov. 14, 2011, Hospira's New Drug Application for Morphine Sulfate Injection USP, 2, 4, 8, 10, and 15 mg/mL in Carpuject and iSecure Syringes was approved for the management of pain not responsive to non-narcotic analgesics.				
Natroba	Spinosad	Natroba is indicated for the topical treatment of head lice infestations in patients 4 years old or older.	Jan. 18	ParaPRO
Nithiodote	Sodium nitrate and sodium thiosulfate	Nithiodote is indicated for sequential use for the treatment of acute cyanide poisoning that is judged to be life-threatening.	Jan. 14	Hope Pharmaceuticals
Nucynta ER	Tapentadol hydrochloride	Nucynta ER is indicated for the management of moderate-to-severe chronic pain in adults when a continuous, around-the-clock opioid analgesic is needed for an extended period of time.	Aug. 25	Janssen Pharmaceuticals
Nulojix	Belatacept	Nulojix, in combination with basiliximab induction, mycophenolate mofetil and corticosteroids, is indicated for the prevention of organ rejection in adults patients receiving a kidney transplant.	June 15	Bristol-Myers Squibb
Omeprazole Delayed-Release Capsule 20 mg, Clarithromycin Tablet 500 mg, and Amoxicillin Capsule 500 mg	Omeprazole, clarithromycin and amoxicillin	Omeprazole Delayed-Release Capsule 20 mg, Clarithromycin Tablet 500 mg, and Amoxicillin Capsule 500 mg taken together are indicated for the eradication of Helicobacter pylori in patients with active duodenal ulcer or a history of duodenal ulcer disease.	Feb. 8	DAVA Pharmaceuticals
Onfi	Clobazam	Onfi is indicated for the adjunctive treatment of Lennox-Gastaut syndrome in patients aged 2 years old or older.	Oct. 21	H. Lundbeck
Opana ER (crush resistant)	Oxymorphone hydrochloride	Opana ER (crush resistant) is indicated for the relief of moderate to severe chronic pain in patients requiring continuous, around-the-clock opioid treatment for an extended period of time.	Dec. 9	Endo Pharmaceuticals
Oxecta	Oxycodone hydrochloride	Oxecta is indicated for the management of acute and chronic moderate to severe pain where the use of an opioid analgesic is appropriate.	June 17	Pfizer
Phoslyra	Calcium acetate	Phoslyra is indicated for the reduction of serum phosphorus in patients with end stage renal disease.	April 18	Fresenius Medical Care North America
Potiga	Ezogabine	Potiga is indicated as adjunctive treatment of partial-onset seizures in patients aged 18 years old and older.	June 10	GlaxoSmithKline and Valeant Pharmaceuticals International
Prezista Oral Suspension	Darunavir	Prezista Oral Suspension, in combination with other antiretroviral agents, is indicated for the treatment of HIV-1 infection in adults and pediatric patients 3 years old or older and weighing at least 10 Kg.	Dec. 16	Janssen Therapeutics
Rectiv	Nitroglycerin	Rectiv is indicated for the treatment of moderate to severe pain associated with chronic anal fissure.	June 21	ProStrakan
Rezira	Hydrocodone bitartrate and pseudoephedrine hydrochloride	Rezira is indicated for the relief of cough and nasal congestion associated with the common cold.	June 8	Hawthorn Pharmaceuticals

2011 NEW DRUG APPROVALS

Product	Chemical	Indication	2011 approval date	Marketer (or developer if no marketer is in place)
Sodium Fluoride F 18 Injection	Sodium Fluoride F 18	Sodium Fluoride F 18 Injection is indicated as diagnostic positron emission tomography (PET) imaging of bone to define areas of altered osteogenic activity.	Jan. 26	National Institutes of Health National Cancer Institute Division of Cancer Treatment and Diagnosis
Suprenza	Phentermine hydrochloride	Suprenza is indicated as a short-term adjunct (a few weeks) in a regimen of weight reduction based on exercise, behavioral modification and caloric restriction for the management of exogenous obesity for patients with an initial body mass index ≥30 kg/m2, or ≥27 kg/m2 in the presence of other risk factors (e.g., controlled hypertension, diabetes, hyperlipidemia).	June 13	Akrimax Pharmaceuticals
Topotecan Injection	Topotecan hydrochloride	Topotecan Injection is indicated for the treatment of adults with small cell lung cancer sensitive disease after failure of first-line chemotherapy.	Feb. 2	Hospira
NOTE: On Feb. 25, 2011, Sandoz's New Drug Application for Topotecan Injection was approved for the treatment of small cell lung cancer sensitive disease after failure of first-line chemotherapy; and in combination therapy with cisplatin for the treatment of stage IV-B, recurrent, or persistent carcinoma of the cervix which is not amenable to curative treatment with surgery and/or radiation therapy.				
Tradjenta	Linagliptin	Tradjenta is indicated as anadjunct to diet and exercise to improve glycemic control in adults with type 2diabetes mellitus.	May 2	Boehringer Ingelheim Pharmaceuticals and Eli Lilly
Victrelis	Boceprevir	Victrelis, in combination with peginterferon alfa and ribavirin, is indicated for the treatment of chronic hepatitis C genotype 1 infection in adult patients (18 years old or older) with compensated liver disease, including cirrhosis, who are previously untreated or who have failed previous interferon and ribavirin therapy.	May 13	Merck & Co.
Viibryd	Vilazodone hydrochloride	Viibryd is indicated for the treatment of major depressive disorder.	Jan. 21	Forest Laboratories
Viramune XR	Nevirapine	Viramune XR is indicated for use in combination with other antiretroviral agents for the treatment of HIV-1 infection in adults.	March 25	Boehringer Ingelheim Pharmaceuticals
Xalkori	Crizotinib	Xalkori is indicated for the treatment of patients with locally advanced or metastatic non-small cell lung cancer that is anaplastic lymphoma kinase-positive as detected by an FDA-approved test.	Aug. 26	Pfizer
Xarelto 10 mg Tablet	Rivaroxaban	Xarelto 10 mg Tablet is indicated for the prevention of deep vein thrombosis which may lead to pulmonary embolism in patients undergoing hip or knee replacement surgery.	July 1	Janssen Pharmaceuticals
Xarelto 15 mg Tablet and 20 mg Tablet	Rivaroxaban	Xarelto 15 mg Tablet and 20 mg Tablet (and Xarelto 10 mg Tablet) are indicated to reduce the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation.	Nov. 4	Janssen Pharmaceuticals
Yervoy	Ipilimumab	Yervoy is indicated for the treatment of unresectable or metastatic melanoma.	March 25	Bristol-Myers Squibb
Zelboraf	Vemurafenib	Zelboraf is indicated for the treatment of patients with unresectable or metastatic melanoma with BRAF V600E mutation as detected by an FDA-approved test.	Aug. 17	Daiichi Sankyo and Genentech
Zidovudine Tablet 100 mg	Zidovudine	Zidovudine Tablet 100 mg, in combination with other antiretroviral agents, is indicated for the treatment of HIV-1 infection.	Feb. 23	Matrix Laboratories
Zutripro	Hydrocodone bitartrate, chlorpheniramine maleate, and pseudoephedrine hydrochloride	Zutripro is indicated for relief of cough and nasal congestion associated with the common cold in adults 18 years old or older; and for relief of symptoms including nasal congestion associated with upper respiratory allergies.	June 8	Hawthorn Pharmaceuticals
Zytiga	Abiraterone acetate	Zytiga, in combination with prednisone, is indicated for the treatment of patients with metastatic castration-resistant prostate cancer who have received prior chemotherapy containing docetaxel.	April 28	Janssen Biotech

Source: eKnowledgebase.com

NOTES AND METHODOLOGY

This annual special report features the new prescription medicines approved in the United States during 2011. The information was gathered from pharmaceutical companies, the Food and Drug Administration, and the files of *Med Ad News*. The 80 new medicines detailed in this special report were approved by FDA regulators through a new drug application or biologics license application (with a couple of special exceptions).

The new medicines may include new molecular entities, biotechnology drugs, biologicals, imaging agents, branded generic drugs, and branded new formulations of existing products. Excluded from this list are medical devices, nonbranded generic drugs approved via an abbreviated new drug application, over-the-counter drugs, diagnostic tests, tentative approvals, and new indications for already-marketed drugs. All medicines were approved for U.S. marketing from Jan. 1, 2011, through Dec. 31, 2011.

FDA New Drug Approvals: 1990-2011

The U.S. Food and Drug Administration has approved for marketing more than 1,650 new medicines via an NDA or BLA since 1990.

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WAY TO GO

Unlike their pharma and biotech clients, a look at many healthcare advertising agencies finds women in the c-suite—as CEOs, presidents, and managing partners. 10 women at the top share insights about their career paths, what's kept them engaged, and how they juggle careers and families.

by Chris Truelove chris.truelove@ubm.com

Take a look at top 50 pharmaceutical and biotech companies, and you'd be hard-pressed to find a woman at the top as CEO or president. But a glance at an equal number of healthcare advertising agencies reveals a startling number of women at the helm. Ranging from big networks such as Digitas Health, Draftfcb Healthcare, Havas Health, Medicus, Rosetta Healthcare, Sudler & Hennessey, and Torre Lazur McCann to smaller outfits such as Centron and Flashpoint Medica, a larger number of women are calling the shots. *Med Ad News* talked with 10 of these executives, including exclusive video interviews, to find out the career paths they took, the reasons why they believe women are thriving on the agency side, and their strategies to be successful at work and at home.

Today's healthcare advertising agencies, and the advertising business in general, are a far cry from the agency Sterling, Cooper, Draper, Price depicted in the popular television series "Mad Men." Although some of the executives interviewed did run into some vestiges of discrimination at the beginning of their careers, all agree that the industry now is an equal opportunity place – and its less-rigid structure, compared with the client side, provides more ways to advance.

"Since I started in the business more than 23 years ago, women have been hired in large numbers for their brain trust, management style, and ability to multi-task through it all," says Marci Piasecki, CEO of Torre Lazur McCann. "Perhaps the most notable difference for me is previously women were considered more of an internal force at the agency, rather than a strong external force with clients. In years past, I recall the highest level women still taking a second-in-command position to their superiors, and sometimes male counterparts, especially with high-level male clients. Men at the agency were often considered a 'better fit' – especially with male clients. Now, in contrast, women are present with even the highest level clients – many of whom are male, and we are not only considered competent, we are considered critical."

"In years past, I recall the highest level women still taking a second-in-command position to their superiors, and sometimes male counterparts, especially with high level male clients ... Now, in contrast, women are present with even the highest level clients – many of whom are male, and we are not only considered competent, we are considered critical," says **Marci Piasecki, CEO of Torre Lazur McCann.**

Louisa Holland, co-CEO, the Americas, Sudler & Hennessey, says she felt some of that assessment in the early part of her career.

"I do know that early on, I felt that women were being watched and kind of assessed to see if we could do this," she told *Med Ad News*. "It was much more of a testing environment, and that was what created a lot of the pressure. If you were going to do it, you had to do it better than anybody because they were watching you."

Dana Maiman, CEO of Drafrtfcb Healthcare, says she has not found overt gender discrimination in healthcare advertising. "This is definitely an industry where job excellence and hard work are rewarded," she told *Med Ad News*. "I've always found that talent is the primary determinant of how far one can go. There are many women who are in the account service function who move up through the industry eventually attaining the top positions."

Many of the executives interviewed started their careers and spent significant time on the client side, but found the structure of healthcare advertising agencies more congenial to their advancement.

"Although the pharmaceutical industry and the healthcare advertising industry are closely tied to each other, they could not be more different," says Marcia McLaughlin, president of Centron. "The pharmaceutical industry is a slice of corporate America, run how *Fortune* 500 companies are run. They have very traditional organizational structures, attitudes, and guidelines. On the other hand, healthcare advertising agencies are far less traditional and attract talent that thrives in an entrepreneurial environment. The organizational structures within healthcare advertising agencies are less rigid and truly reward talent based on performance."

Ms. McLaughlin remembers when she began her career at KPR, "there were very few women in positions of authority or power."

"Most of the women were in support functions, including administrative, traffic, media, studio, and junior to mid-level creative and account positions," she says.

Ironically, it was the clients who were instrumental in the advancement of women in healthcare advertising. "As our importance to the client grew, our importance in the running of individual pieces of business grew, and ultimately our role in running and managing the day-to-day operations of the agency," Ms. McLaughlin told *Med Ad News*. "First we were entrusted with the agency's clients, and then the agency itself."

The C-word, the D-word, and gender

Again and again, these executives brought up the words "collaborative" and "diversity" to describe what set the ground for them and other women to succeed in the healthcare ad game.

"Advertising agencies are much more collaborative in nature – people who work well in the team environment and can lead a team to superior performance are valued," Ms. McLaughlin says. "I believe these basic differences in structure and definition of an employee's value creates an environment that has been more open to women succeeding."

Lisa Ebert, managing director at Medicus, acknowledges that there are male-dominated industries, but healthcare advertising embraces diversity. "In healthcare advertising in particular, we see a very unique dynamic and mindset, and that is one that is an appreciation for diversity," Ms. Ebert says. "If you think about it, it's an environment where you have to foster an interdependency of highly diverse disciplines. So what comes together is high scientific acumen, strategy, creative genius, technology, all of these different disciplines have to come together and people have to excel based on their merits, and in my opinion it has very little to do with gender."

Shannon Hartley, managing partner of Rosetta Healthcare, says an ability to collaborate is key if one wants to rise to the top in healthcare advertising. "It's about collaboration, being able to work within matrix and networked environments, and it is absolutely critical in this age," Ms. Hartley says. "Whether that's within your own healthcare advertising agency, being able to partner with creative and partner with project management and partner with technology, and understand how to bring all those services together with the clients, working across their brand teams, with their medical/legal/regulatory review teams, it's all about that collaboration and working within a network to be able to get things done."

"What I love about this business is its relevance – the fact that we are constantly immersed in advances in healthcare that are relevant to our everyday lives, to people that we know and love. I just find it very exciting to be in this environment," says **Lisa Ebert, managing director, Medicus.**

Several of the executives interviewed say the ability to collaborate is a particular skill of women. In looking at how many women are thriving in healthcare advertising agencies, Charlene Prounis, managing partner and co-president of Flashpoint Medica, says, "it's possible because in a service business, the skills that women have, and this is all from style differences, are probably more rewarded with more business and growth."

According to Ms. Prounis, women tend to have skills that are "more collaborative, more partnering, more service-minded."

"They're listening to clients, they're hearing what their issues are, and they're collaborating with multiple people to be able to come back with great solutions," Ms. Prounis says. "They're not sitting alone in their office trying to come up with the idea on their own. They're listening, they go back now to the client and have a natural affinity for the client. Relationships bloom, work gets done, and there's always so much to do in an agency environment, multitasking is really very big because everyone has so much on their plate.

"Managing teams within an agency requires a higher level of emotional intelligence, and current wisdom says women are particularly strong in this area. And that's one of the reasons why women have advanced so well within agencies," says **Louisa Holland, co-CEO, the Americas, Sudler & Hennessey.**

"This is definitely an industry where job excellence and hard work are rewarded. I've always found that talent is the primary determinant of how far one can go. There are many women who are in the account service function who move up through the industry eventually attaining the top positions," says **Dana Maiman, CEO of Draftfcb Healthcare.**

"You can't have the expectation every single day, it's a perfect balance. There are pitches that come up, very late nights, there are client needs that may come up, but on average, it's finding those times where you can say, over the course of a week or a month, do I feel like I have the right balance," says **Shannon Hartley, managing partner of Rosetta Healthcare.**

"So if you can be collaborative, be a partner, you can listen, you can multitask – those are skill sets that women often have over men, which are very valuable in a service-based business."

Ms. Holland says she tried for years not to think that there were differences between mens' and womens' management styles, but came to believe differently.

"I do think for the most part, men and women manage people differently," she says. "Again, there are certainly people who go counter to the generalities. But I do think men are more black and white, and women are more comfortable with shades of gray, and I think that leads to the softer side. Women can be more consensus-focused, not as quick to make decisions, and I don't think it's fair to say that we're soft, we have a different style and it's unjust to say that we're soft, because it shortchanges women. And that's one of the things in the past that interfered with their growth. But when women are tough or single-minded or very focused, we're very quick to be called 'difficult.' And that's a different pattern to break, not just in our industry but in a lot of industries."

Ms. Hartley echoes some of these sentiments. "Women have a tendency to be collaborators and communicators, and that's a generalization, but you really see a lot of women who have that skill to multitask, to bring groups together, to be able to empathize with the clients that we're serving, the end customers," she says. "And that's a unique ability that has enabled so many women to be successful in the advertising area, being able to bring collaboration, empathy toward understanding the conditions, and also understanding that women are predominantly the caregivers of people within healthcare, so being able to have that connection serves women well as they accelerate their careers."

However, Ms. Hartley and others interviewed caution that viewing women as more collaborative and their male co-workers less so can be a stereotype. This also applies to the management styles between men and women.

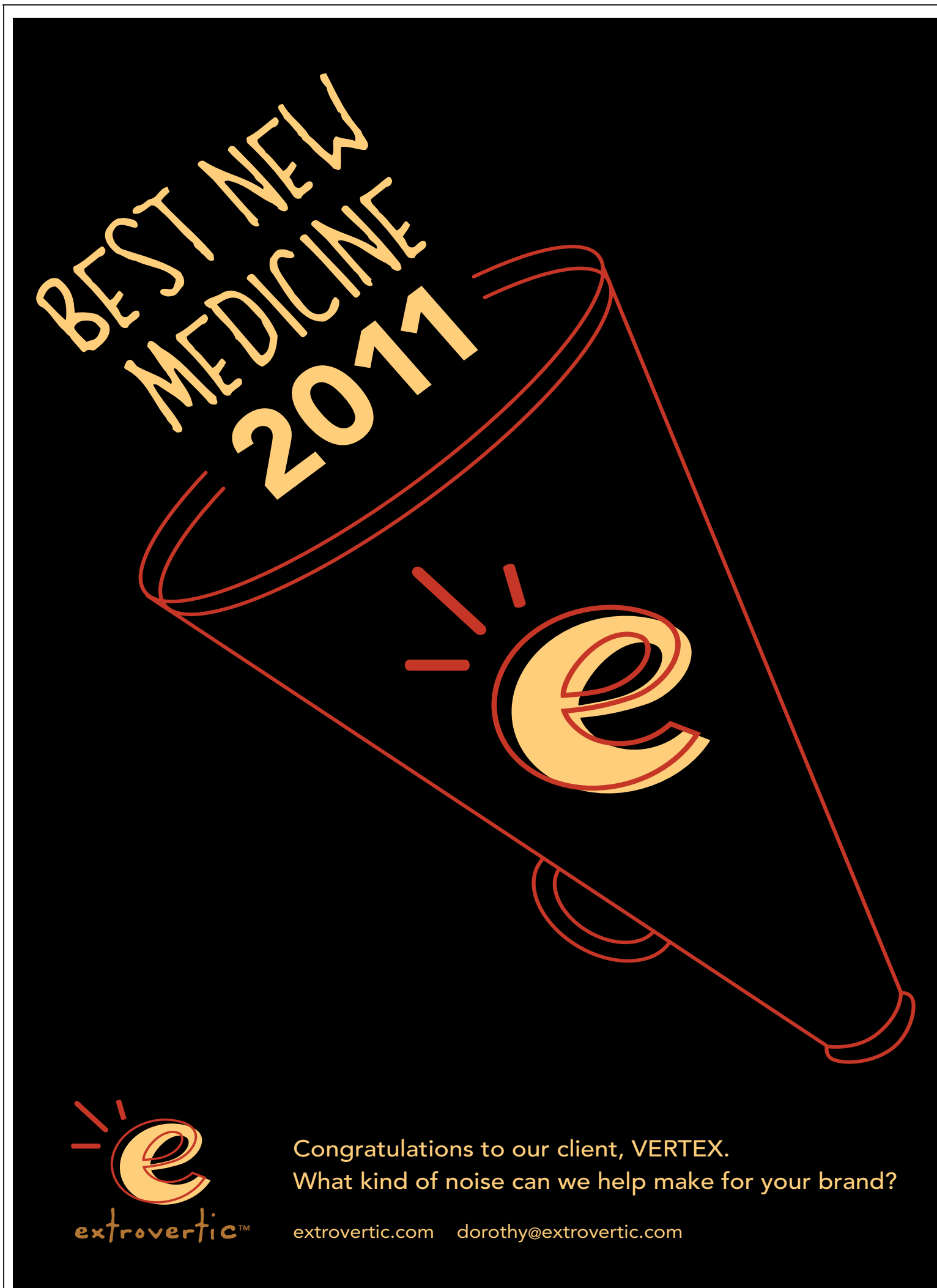
"I don't think there is necessarily a difference in management styles between men and women," Ms. McLaughlin says. "I do, however, think there is a big difference in management styles between people. There are some people who manage in a very heavy-handed and controlling way, where everyone who works for them must do things their way. There are other people who are very empowering managers and have mastered the art of delegation. Those individuals tend to focus on the end result and don't get lost in how people get there.

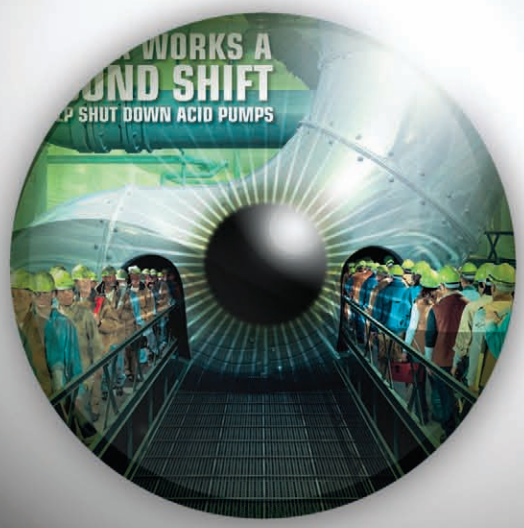
"There is also a big difference in the styles of support that managers offer," she adds. "Some managers make it clear to their employees that they are there to support them and will happily roll up their sleeves to help out. Other managers make it clear that they have no intention of doing the work in the trenches. I believe these different styles of management have more to do with the type of people we are rather than being male or female. It's more about the difference in humans, not men versus women."

Ms. Ebert also says leadership skills are not tied to gender. "In general, no one would question that men and women are wired differently," she says. "But when it comes to management style, my experience has been that variances that exist are not necessarily gender-based. When I think of really good leaders, [there are] men and women that exhibit some commonalities in what, my opinion, is really effective leadership."

According to Ms. Ebert, the commonalities are about people who are results-oriented. "They lead with a vision," she says. "They establish a vision for a group of people and engage them in that vision. And they understand the importance of listening to the people they're trying to lead so that they can relate to them, they can engage them, rather than just directing them. So when I think about those people and that kind of leadership, I can give examples of both men and women who have done that, so it's hard for me to say it's gender-based."

"After being a nurse, I wanted more autonomy and respect, I became a sales rep. I was a sales rep for three years, and then I wanted to write the sales aids, I wanted to be in charge of the marketing plans. Then I found a job in an advertising agency, called Gross Townsend Frank Hoffman, and I began my advertising career," says **Charlene Prounis, managing partner, co-president of Flashpoint Medica.**

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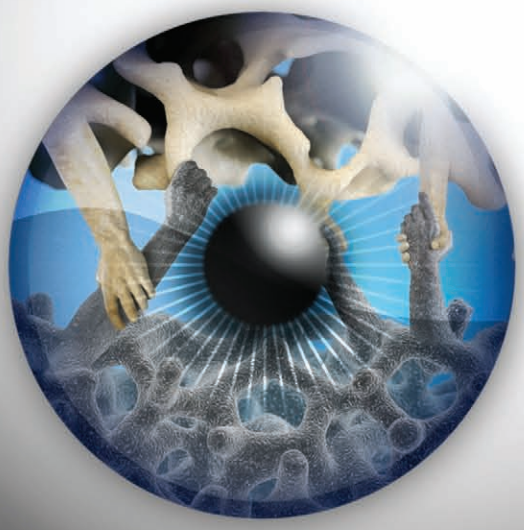

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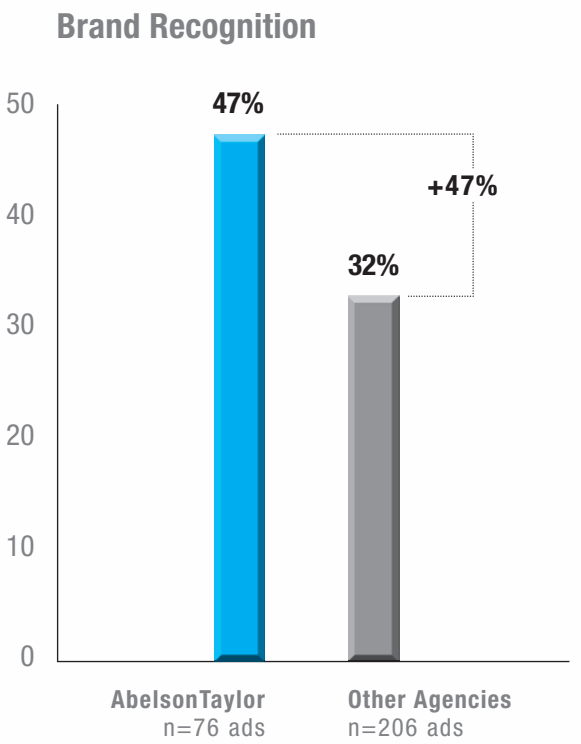

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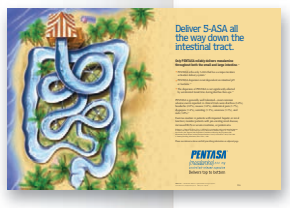

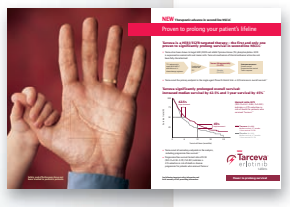

Ms. Piasecki says there are differences in management styles both between and among genders today.

"Years ago the differences between genders seemed much more apparent," she says. "Stereotypes had been set and many professionals fit them. Generally speaking, women were considered to have a more nurturing management style and men more direct and unemotional. Since then, the workforce has become more diverse and professionals are being viewed more as individuals. This has not only helped remove some of the stereotypes, but also gives people a chance to be measured based on their individual management style irrespective of gender."

According to Kelly Gratz, head of Blue Diesel, management style is a personal thing, not truly tied to gender.

"Everyone has their own management style," she told *Med Ad News*. "When you find what your style is, you need to embrace it. Too many people, men or women, try to anticipate or mimic what they believe is a good management style. When you do that, it never really works, because it's not natural. For me, I like being part of a team approach. Ultimately I have to make the decisions for the business, but I love getting everyone around the table to define the solution, because it ultimately takes an army to implement."

Donna Murphy, worldwide managing partner of Havas Health, agrees with this sentiment. "I do not think one can generalize regarding management styles in this or any industry," she says. "So, I would not say that there is a difference in management styles between men and women, per se, but that each leader certainly has his or her own style of leading

"I do not think one can generalize regarding management styles in this or any industry. So, I would not say that there is a difference in management styles between men and women, per se, but that each leader certainly has his or her own style of leading," says **Donna Murphy, worldwide managing partner of Havas Health.**

The juggling act

These executives did take the time to start families, and found ways to balance their home and work lives. But it was never easy, and balance is always a struggle.

Ms. Holland says her generation was raised under a myth that they could have it all – career and family, with minimal sacrifices. But she found that was not the case.

"I don't think anyone told me when I was starting how hard it would be, certainly no one told me how much juggling I would do, and probably how much of my personal and family life that I'd ultimately give up," she says. "Not that I haven't been there for them, but I certainly think that I did give a lot of things up. For my generation, we were raised under this myth of having it all, and I think it's a really big misnomer and something that the feminists before me shouldn't have been encouraging us all to reach for. I think we felt we had a lot to prove, that we could do the job that men were doing,

"I had the 'pleasure' of also weathering the dot-com bust. As a leader of an organization, weathering something like that was either going to be educational or a disaster. I chose to make it a learning experience for myself as to how to move an organization through a tough time, and come out the other side with a stronger offering," says **Kelly Gratz, CEO of Blue Diesel.**

and we were giving up a lot to make that point. And what I would hope is that the women today, who are in a position I might have been in 10 or 15 years ago, don't feel as much pressure to prove themselves and therefore find the juggling a little bit easier."

Some take a more long-term view about work-life balance.

"I find, it's rare to achieve balance in a day," Ms. Hartley says. "I think you need to take a little bit longer-term horizon when you think about work-life balance."

Being a single mother with a 10-and-a-half-year-old son, Ms. Hartley says she is fortunate to be in a financial position to afford help, but she checks in with with her son frequently to see if balance is being achieved.

"I am not going to be the pizza mom serving pizza every day at his school, but those important pieces, I want to make sure that I'm there," she says. "That's a commitment that I've made to him, and it's a commitment that I make to my company and my clients. For me to be effective in the job, I have to feel like I'm also being the type of mom I want to be. But I think you can't have the expectation every single day, it's a perfect balance. There are pitches that come up, very late nights, there are client needs that may come up, but on average, it's finding those times where you can say, over the course of a week or a month, do I feel like I have the right balance. If it's off, what do I need to adjust, and keep on checking in with yourself, and in my case, I check in with my son, to make sure that we feel like we have that balance on the whole."

Being present is also important, but quality can win out over quantity of time spent. "One of the things my son told me at a very early age is that he hated my BlackBerry," Ms. Hartley says. "And so, I said, 'What do you mean, I'm here?' And he said, 'I hate your BlackBerry, you're not paying attention.' And it really was an eye-opener for me, that I need to be present. Being present is more than just physically being there, if I am physically there and am checking my BlackBerry, I'm not really there."

Ms. Ebert also says achieving work/family life equilibrium is still a work in progress.

"On some level, I think I've given up on balance, but for me, it's more for me, it's not about balance, it's about impact," she told *Med Ad News*. "What I try to do is focus my energy to where it will have the most impact for work and family. Sometimes it's more of an emphasis on one versus the other, depending on what's happening at the time, but again, if I focus on impact, that works for me. There's one overriding principle that I've tried to follow, as it relates to family, it's very much about planning ahead so that you never miss the events that are really critical to your kids and your family. So while you can't be there for everything, it's about making the choices and planning ahead to be there when it matters most."

Ms. Gratz says with the support of her husband, she makes sure she doesn't forget the "can't miss" moments.

"The first day of kindergarten, the first recital, their first heart break, et cetera.," she says. "These are times where you can't recreate the moment. As I make scheduling decisions, I think about that every time I schedule to be out of town. If my boys have a game, or a meeting, we talk about it. We decide together and adjust accordingly. But I always remember to ask myself, is this a 'can't miss' event. That always helps me keep things in balance. If all else fails, my husband is always there to keep me in check as well!"

Ms. Murphy also attributes success on the home front to teamwork.

"My husband and I are a team, and we support each other's careers – and we have done so throughout our life together," she told *Med Ad News*. "We have been fortunate enough to raise two great kids, and I would attribute that in part to the hard work both my husband and I have put into finding that balance."

Ms. McLaughlin agrees that the question of work/life balance should not be addressed by the women alone. "I view this as a dual working parent problem," she says. "When I began having a family, both my husband and I worked full-time. Even with the support of a nanny, the challenges were tremendous."

After the birth of her second daughter, they decided to try something that at the time was unconventional. "My husband sold his business to stay home full-time and raise our girls," she says. "This gave me the freedom and flexibility to do whatever I needed to pursue my career. Twenty years later, my husband continues to be the full-time, stay-at-home parent and the task of balancing home/work life is less challenging for me than most parents because of my support system.

"No one ever asked this question decades ago when all our moms stayed home and all our dads pursued careers. It is truly a dilemma for the dual working parent families of today that impacts both men and women and the career opportunities they pursue. Regardless of sex, when raising a family both parents must take responsibility for supporting that family financially, emotionally, and physically. The way in which parents divide those responsibilities impacts both parents' career paths."

What keeps them going

All of the executives interviewed said they never intended to go into healthcare advertising, but what attracted them – and keeps them there – is the real prospect of helping patients.

"What intrigued me then – and to this day – is the mix of scientific, strategic, and creative talent masterfully combined to promote products that can make a difference in people's lives," Ms. Piasecki says.

Ms. Prounis points out that the healthcare advertising business encourages continuous learning. "Healthcare advertising brings in a lot of variety; I'm always learning about a new drug, working with a new company," she says. "And so I might work in breast cancer, lung cancer, I might do something with a magnesium replacement, I might do something with multiple sclerosis; one day, I'll be doing a pitch for HIV ... We run the variety of things, so it's just full of a lot of diversity and variety, and because you have to be creative in the terms of the ideas and how you approach them, I like that part of it as well."

Ms. Ebert also enjoys the continuous learning aspect. "What I love about this business is its relevance – the fact that we are constantly immersed in advances in healthcare that are relevant to our everyday lives, to people that we know and love," she says. "I just find it very exciting to be in this environment. The other thing is the opportunity that exists, there are always continuing emerging technologies that give us new opportunities to enhance how we work and engage with our customers, and again the fact that the interconnectivity between the stakeholders is very dynamic, it just never gets old. I feel like it's always fresh and there's always new things to help us be better at what we do."

Several of these executives have backgrounds in healthcare and science. Ms. Prounis and Lynn O'Connor Vos, CEO of Grey Healthcare Group, started as nurses, moved into the pharmaceutical industry as sales representatives, and then made the jump to healthcare advertising. Ms. Ebert and Ms. Holland were biology majors; Ms. Ebert has a Ph.D. and was a molecular biology research associate at Cold Spring Harbor before going back to school for a marketing degree.

Lynn O'Connor Vos, CEO of Grey Healthcare Group, started out her career as a nurse; she says the medical knowledge obtained during this phase has been valuable in her time in healthcare advertising.

All say healthcare advertising allows them to use that scientific/healthcare background. For Ms. Holland, she has used the theories of evolution she learned in school to expand S&H's business.

"One of the other things that I like to think about, because I've studied basic evolutionary biology classes with Stephen Jay Gould, who's one of the premier evolutionary biologists, he came out with a theory right before he died that's much debated, but rather interesting – something called punctuated equilibrium, which is that evolution didn't happen with these very very gradual stages, but that something big happened all at one time, and there were leaps," she says. When you think about that, it's an interesting approach to how businesses should or could evolve, that you don't always have to think about the gradual, but sometimes just making a fast change and pushing yourself to be adaptive more quickly." ■ MEDADNEWS

A fuller view

In eight transcripts and two video interviews, 10 women who lead healthcare agencies talk about what got them into the business, what keeps them interested, and how they balance home and work demands.

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Congratulations, Donna Murphy,
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A GUIDE TO mobile learning deployment strategy

The world of mobile learning technology is chaotic, requiring sales training decision makers to be strategic in how they choose to deploy training content on mobile devices.

By Nathan Pienkowski, Ph.D.,
instructional design director, Pharmaceutical Institute

With more pharmaceutical companies equipping their sales professionals with mobile computing devices, interest is growing in using them to deliver training. Mobile devices do have the potential to make high-impact training more convenient than ever. However, with the plethora of devices available, the legacy systems and content that must be accommodated, and the various interoperability issues, many companies are now finding that porting or developing training content for mobile technologies is not nearly as straightforward as it seemed.

Navigating this maze can be a challenge, with every path forward appearing to come with significant tradeoffs. For any company to yield the full benefit of its training content, it is imperative that decision makers define the optimal mobile learning strategy.

Mobile learning has the potential to provide significant productivity gains for field-based team members, but as the technology stands, no silver bullet solution exists to create or port high-quality content to all devices that will also integrate with a learning management system. Given the ever-evolving technology, the ideal strategy for companies exploring mobile learning is to assess the existing e-learning content and near-future needs and port/create only the highest-priority content for mobile devices. Save the rest for a time and place when the technology and tools have caught up with the technological requirements of the mobile devices. Most importantly, work with a vendor with the experience to help you make those assessments and the skills to get under the hood of the technology and make it all work.

Challenges

The challenges of developing e-learning content for mobile devices fall into three categories: porting existing content, creating new content, and integrating with a learning management system.

PORTING EXISTING CONTENT

Currently, converting existing content for use on mobile devices is time consuming and costly. Most content originally developed for larger devices such as desktops, laptops, and tablets will not work on smart phones very effectively. Content designed for a larger screen can contain more information than will fit visually on the smaller screen of a smart phone. As a result, content designed for a larger device needs to be completely re-engineered in order to work on a smart phone.

Meanwhile, existing content created for non-mobile devices may not port to tablets. Any content that was produced with Flash, for example, is not going to work on the iPad due to Apple's lack of support for the software. Adobe, the company that developed Flash, has admitted that even on mobile devices other than iPads, the Flash software works inconsistently, and the company has given up supporting Flash for mobile devices as a result.

The alternative to Flash is HTML5, a relatively new but stable standard for creating interactive content. Training content developed using HTML5 will theoretically work across any device, but developers have not been creating authoring tools that will produce HTML5 for very long. The tools that do exist are buggy and lacking in features.

Currently, no reliable tools exist to port Flash-based content to mobile devices. The tools that do claim to be able to perform this function are in their nascent stages and frequently do not work in the desired fashion.

Without authoring tools to create the training content in HTML5, it becomes necessary to code the content in HTML5 from scratch. This level of programming expertise requires a significantly deeper skill set than is possessed by the instructional designers currently on staff in most organizations. As a result, producing content for mobile devices today will likely require a significant investment in time and money.

CREATING NEW CONTENT

When developing brand new training content for mobile devices, one option is to hard code the software for the specific device. The drawback to this approach is that the resulting content will likely only be compatible with one type of device. The content creator will need to hard code different versions of the content for every type of device desired.

Theoretically, however, one can create a training program in HTML5 and have it be compatible with almost every device type. Although HTML5 does maximize the portability of content across devices, even in this scenario differences exist in the way individual browsers will interpret and render the HTML. In addition, it takes a lot of time, talent, and skill to hard code in HTML5. Even the most experienced HTML5 programmers today are likely still experimenting. Meanwhile, the HTML5 authoring tools that exist today may reduce the time and cost involved, but they possess minimal features.

Choosing an appropriate vendor for a company's HTML5 coding needs is also challenging. HTML5 vendors for non-learning content do not necessarily understand the unique needs of e-learning content. The most common context for HTML5 coding is the creation of Websites or games for marketing purposes. While a vendor may have great capabilities, good creative, and a reasonable price quote, the vendor may later claim to have underbid the project as a result of underestimating the sheer amount of content required by an e-learning program.

CONNECTING TO A LEARNING MANAGEMENT SYSTEM

An important component of an e-learning training program is the ability to link up to a learning management system (LMS), a database designed to track learning activities. Most LMSs become portals for all training activities, both online and off. It is an important tool for finding new training opportunities, registering, receiving reminders, and archiving one's training history. However, content developed for mobile devices often may not communicate well with an LMS.

HTML5 is just a base technology and neither allows nor prevents a developer from integrating a program into an LMS. Some authoring tools may have the LMS integration software built in as a template, but in most situations, that integration will need to be hard coded into the program. Alternatively, tools do exist that can track learning data outside of an LMS, but in this scenario, the company would be utilizing two separate tracking systems: one for standard content and one for mobile content.

Determining strategy

How should you navigate this maze? As mentioned numerous times in this article, because of the current state of the technology, moving all content to a mobile platform is impractical and costly. Determining the most effective strategy comes down to two things: a) determining the right audience and b) determining the right content.

DETERMINING THE RIGHT AUDIENCE

Companies interested in pursuing mobile learning initiatives should concentrate on creating/porting content only for learners who would benefit the most from training on mobile devices. So who would benefit most?

First, it is important to remember that the communication and interactive capabilities of laptops, desktops, and tablets are identical. The only difference is the interface, whether it be a keyboard, mouse, or touch screen. A PDF file, for example, will display in the same way whether one views it on a laptop or on an iPad, the only difference being the mechanism by which one scrolls through the document. Tablets provide no additional interactive capability.

The primary advantage of smart phones and tablets is their mobility. Therefore, mobile learning offers the most benefit for field-based workers without ready access to a desktop or laptop computer and who spend significant time in passive activities. Tablets, as opposed to smart phones, offer the most benefit for workers who engage in hands-free passive activity, such as sitting in a waiting room or commuting on a train. Audio-based training content available on smart phones offers the most benefit for workers who engage in hands-on passive activity, such as driving in a car. Thus, the first step is to narrow your mobile learning audience down to those individuals who spend significant passive time in the field. Naturally, sales reps, account managers, district managers, and medical science liaisons all fit this description.

HIGH-VALUE	Wait 12 months and re-evaluate	Hire e-learning mobile app developer to build courses from scratch—expect greater than normal cost and longer timelines
LOW-VALUE	Wait 12 months and re-evaluate	Create with an authoring tool—expect lower-quality output
	LOW-PRIORITY	**HIGH-PRIORITY**

When selecting content for mobile learning, classify first by value and priority.

DETERMINING THE OPTIMAL CONTENT

Once you have determined your audience for mobile learning, you need to determine which content to provide for them. We offer a simple framework and five-step process for accomplishing this. First, inventory your training content for each target audience. Second, classify each unit as either high-value or low-value, depending on the company's unique business needs. High-value content is any content that you feel would have a significant and immediate impact on the job performance of your target audience. Low-value content is any content that would be helpful but would not necessarily have a significant impact on job and business performance.

Third, the content should also be classified as high-priority or low-priority, with high-priority content being anything associated with an upcoming product launch or anything else that is critical to the company's business objectives over the next 12 to 18 months. Fourth, place each unit of content in the appropriate matrix cell depicted in the figure below. Finally, determine your mobile learning content development strategy using the following as your guide.

When developing new content, our recommendation is to work with an HTML5-capable e-learning vendor to create only the content that is considered high-value and high-priority. For this material, one should anticipate greater than normal costs and longer timelines. Companies can then choose to use authoring tools to produce content considered lower-value but still high-priority.

For companies looking to port legacy training content developed for standard devices to mobile devices, our recommendation is to concentrate only on existing content that is business-critical and must be delivered to mobile learners within the next 12 months. Once the content has been selected, companies should hire a vendor that has HTML5 expertise, doing so with the full expectation that the process is potentially going to be expensive.

For all other content not deemed critical, hold off until the authoring tools begin to mature, at which point it will be more feasible to use in-house staff or to work with a vendor without as high a level of HTML5 expertise. Either option is going to be faster and less expensive. What is critical content will depend on the business context. An upcoming product launch, for example, may require significant therapeutic area training for the field force, in which case porting training content to a mobile platform may be worth the investment.

Finally, LMS integration can be achieved in exchange for a significant compromise in the quality of the content by using an authoring tool, or it can be achieved at a very high cost by hand coding LMS integration for each course. Again, our recommendation is to work with an HTML5 vendor to create courses with hand-coded LMS integration only for high-priority, high-value content needed over the next 12 months. Then reassess the available tools to see what has evolved within that year for low-priority, high-value content. For high-priority, low-value content, one might consider using an authoring tool. ■ MEDADNEWS

Editor's note: Nathan Pienkowski, Ph.D., is an instructional design director with the Pharmaceutical Institute (pharmainstitute.com), a subsidiary of Campbell Alliance (campbellalliance.com) and a provider of specialized training programs for the pharmaceutical and biotech industry.

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Oncology FIRSTS in 2011

A trio of new cancer drugs launched in the last two years have followed similar strategies to draw the attention of physicians through late-stage development, regulatory approval, and market introduction.

By David Rittenhouse, manager of analytic services, DTW Marketing Research Group Inc.

According to "Cancer Facts and Figures 2012," published by the American Cancer Society, an estimated 1.6 million new cancer cases will be diagnosed in 2012, along with an estimated 577,190 deaths. With statistics like these, it becomes clear why anticipation for new treatment options for all forms of cancer is at a constant fever pitch and R&D in this therapeutic area is a long-term commitment with a hefty price tag. In 2011, three products took to the stage to make their mark as innovative options.

Although **Provenge** (prostate cancer), **Yervoy** (melanoma), and **Zelboraf** (melanoma) provide oncologists with three novel approaches, all of which were a "first" in some way, shape, or form, the majority of the press these products received focused on cost versus survival benefit. For Provenge, a full course of treatment costs $93,000 with an overall median survival benefit of 4.1 months. Similar survival benefits were also seen with Yervoy (overall median of 4 months); however, the cost of a complete course of treatment is $120,000. As for Zelboraf, median survival time had still not been reached for patients involved in clinical trials when the product was approved, but the cost for treatment is $112,000 annually.

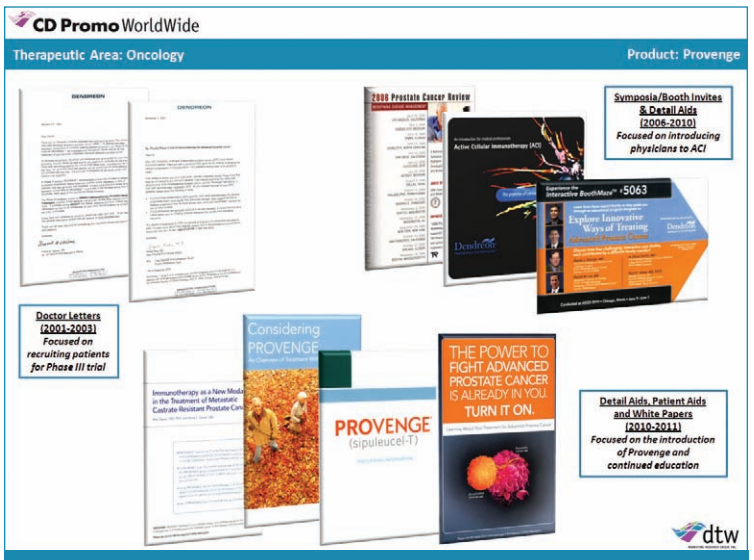
While all three brands have similar hurdles to clear now that they are available, they are taking comparable approaches with regard to their marketing campaigns.

PROVENGE

Dendreon's Provenge (sipuleucel-T) initially received FDA approval in April 2010, but the brand received the majority of its attention throughout 2011 due to its cost versus survival benefit information. Typically referred to as a "vaccine," Provenge was approved by FDA to treat asymptomatic or minimally symptomatic prostate cancer that has spread to other parts of the body and is resistant to standard hormone treatment. In addition, Provenge utilizes the patient's own immune cells from the blood and needs to be manufactured for each individual patient, making it the first in a class of treatments known as immunotherapy.

Provenge has had a long journey to reach the market. The drug has been mentioned by name for at least a decade; an available "Dear Doctor letter" from January 2001 was sent to physicians requesting patients for a Phase III clinical trial for the brand, with a similar letter sent in November 2003. As clinical trials were being conducted, various symposia were announced between 2006 and 2009 that highlighted the progress being made along with materials published by Dendreon that focused on introducing physicians to active cellular immunotherapy, or ACI. In addition, booth invites were sent to physicians in early 2010, prior to the approval of Provenge.

Upon the April 2010 approval from FDA, a flood of Provenge-related materials were distributed, including detail aids, professional ads, patient aids, and additional direct communications with physicians, some of which touched on expanding manufacturing facilities (the first facility was established prior to FDA approval in Morris Plains, N.J. and was expanded in March 2011, followed by approval for new facilities in Los Angeles, Calif., in June 2011 and Atlanta, Ga., in August 2011). Since then, direct communications with physicians and white papers, along with various forms of education (audio and further symposia) have been the primary promotions captured for Provenge.



Provenge's long road to FDA approval provided an extended period of time for Dendreon to educate physicians on Active Cellular Immunotherapy. In addition, a variety of core sales materials were quickly made available to physicians upon the brand's April 2010 FDA approval (29 percent of the materials in the database for 2011 were classified as core sales materials).

In 2011, core sales materials and medical education/clinical data were the top two object types captured in DTW's database for oncology. As part of this trend, 66 percent of the pieces received in 2011 for Yervoy fell into these two object type classifications.

With Zelboraf being the newest brand among these three (August 2011 approval) plus the recent release of important clinical trial data that was not available at launch, the brand has relied heavily on e-media to convey information to physicians (attributed to 37 percent of the materials in the database) versus core sales materials and medical education/clinical data (included early physician directed e-mails regarding clinical trial results, an introduction to BRAF inhibition, and FDA approval).

YERVOY

Bristol-Myers Squibb's Yervoy (ipilimumab) was approved by FDA in March 2011 to treat patients with unresectable (inoperable) or metastatic melanoma. Yervoy is also a form of immunotherapy designed to use the patient's own immune system to fight tumors. Although Provenge was the first in this class, the brand became the first melanoma drug approved by FDA in 13 years. Similar to Dendreon's tactics with Provenge, Bristol-Myers Squibb reached out to physicians via a letter in an attempt to recruit patients for a clinical trial (the earliest letter seen in our database was dated May 2007) and educated physicians regarding CTLA-4 blockade immunotherapy via symposia and webinars up to and through the brand's FDA approval.

After Yervoy was officially launched, Bristol-Myers Squibb began an e-communications campaign that included follow-up e-mails to physicians and invitations to various Internet webinars to help further familiarize them with the product and reveal crucial Phase III clinical trial results. Professional ads, along with hard copy materials doled out by sales reps in the form of physicians' aids, round out the current approach being taken by Bristol-Myers Squibb to market Yervoy.

ZELBORAF

Approved five months after Yervoy (August 2011) and two months ahead of the FDA's original schedule, Zelboraf (vemurafenib) became the second melanoma product to hit the market in 2011 and the first drug to treat melanoma by targeting a specific gene mutation known as BRAF V600E. In order to identify if a patient is "BRAF positive," FDA simultaneously approved a companion diagnostic test called the cobas 4800 BRAF V600 Mutation Test, developed under an agreement between **Roche** and **Plexxikon** Inc. A November 2010 press release from **Genentech** (a member of the Roche Group) was sent to physicians electronically touting positive Phase II clinical study results for Zelboraf, then known as RG7204. As was the case with Provenge and Yervoy, various e-communications and direct mail promotions were used to get the word out about "oncogenic BRAF inhibition" and provide physicians with the opportunity to "explore and get answers." Similar methods were employed as a new drug application was filed with FDA, additional clinical trial results were made public, and Zelboraf was approved by FDA. Since the product and test became available, Genentech and joint marketer **Daiichi Sankyo** have used a variety of materials when detailing physicians, including detail aid brochures, promotional package inserts, physician aids, patient aids, and clinical study results. Most of these pieces have a consistent visual theme, which has also been incorporated into new e-communications that have been sent to physicians. ■ MEDADNEWS

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WHAT IMAGE PROBLEM, Y'ALL?

Novo Nordisk makes a risky bet on Paula Deen.

By Ed Silverman ed.silverman@ubm.com

Nearly one year ago, the *National Enquirer* reported that Paula Deen had diabetes. Yet the Queen of Southern Cuisine and Food Network chef never publicly acknowledged the illness. There was irony in this, of course, because the sort of meals that made her rich and famous were also about to make her a poster child for diabetes. Just the same, she continued to cook unhealthy foods on her program. And despite the contradiction, **Novo Nordisk** eagerly pursued her as a celebrity spokesperson.

The relationship, as many now know, led to a controversy nearly as jaw dropping as a famous Deen dish – a breakfast sandwich piled high with burger meat, eggs, and crispy bacon on a sliced donut. And in the aftermath of the debacle – both Ms. Deen and Novo Nordisk were criticized for being hypocritical and insensitive to diabetics – the drug maker is still being second guessed about the wisdom of its decision and the extent to which its move may have harmed its corporate message and brand.

The issue resonates beyond any one drug maker, though, because the dust up occurs at a time when the pharmaceutical industry, as a whole, continues to grapple with issues of trust that can be traced back to safety scandals and pricing flaps over the past decade. By hiring Ms. Deen, however, Novo Nordisk may have also created another public relations problem – the lengths to which a drug maker is willing to go to generate revenue when hiring celebrity spokespeople, who are generally seen as role models, and whether this will come at the expense of respecting patients.

"It's almost like the fire department hiring an arsonist," says Richard Meyer, publisher of *World of DTC Marketing* and owner of Online Strategic Solutions, a healthcare marketing consulting company. "To me, the biggest mistake was in hiring somebody who knew she had diabetes and continued to promote unhealthy meals. By hiring Paula Deen, they're sending a message that says, 'Go ahead and eat what you want and you can always use a drug to compensate.' And that's the wrong message to send, especially when we're spending so much on healthcare and this is largely a preventable disease."

Whether a backlash will ensue remains to be seen. Although the Internet has empowered consumers to take steps many would have thought unimaginable just a few years ago, such as organizing online protests, memories are also notoriously short. And Ms. Deen continues to have a large base of fans, many of whom may be untouched by diabetes or not particularly bothered by any perceived incongruities between her cooking and her relationship with Novo Nordisk.

As a result, this may allow Novo Nordisk enough time to pursue its hoped-for strategy of recasting Ms. Deen as a change agent. Remember that the slogan for the campaign is, "Diabetes in a New Light," and Ms. Deen's two sons, Jamie and Bobby, are part of a package deal – they will demonstrate healthier meals during myriad public appearances as a sort of counterweight to whatever their mom continues to serve. The first demonstration occurs in May at an American Diabetes Association expo in Chicago.

"She's trying to help people by trying to change her recipes," says Ambre Morley, associate director of product communications at Novo Nordisk (novonordisk.com), who says the drug maker was unaware that Ms. Deen had diabetes until negotiations began last year. However, the disclosure, she adds, gave Novo Nordisk time to prepare its message that Ms. Deen would become an example of how someone with diabetes could learn to alter their behavior. Still, she concedes the company was unprepared for the reaction.

Celebrity chef and newly-minted Novo Nordisk spokeswoman Paula Deen stands accused of hypocrisy for hawking high-risk recipes while concealing her own diabetes diagnosis.

"We planned for this," Ms. Morley says. "Although [the reaction] is something that people were surprised about. But we really don't dwell on everything that happened. We're looking at all the things she's doing now … and what her sons are doing at ADA expos and what she'll be doing with the ADA. Organizations have called her and asked her to talk to them … We're so far beyond that and looking at what she'll be able to do to help people with diabetes … We really have stayed true to the point of what our message is – she has diabetes and she's changing. And our goal is to continue with that message."

Nonetheless, Novo Nordisk may have a difficult task. Although Ms. Deen may well pepper her recipes with healthier ingredients or avoid cooking certain dishes altogether, any substantive move away from her traditional approach to preparing meals may pose a different kind of risk – that she will lose part of her core audience. While the deal with the drug maker may be rewarding, Ms. Deen is now in the difficult position of attempting to balance competing goals.

Much of this could have been avoided if Ms. Deen had more readily announced earlier that she has diabetes, according to Keith Vance, an adjunct assistant professor of marketing at the New York University Stern School of Business. Instead, Novo Nordisk is in the uncomfortable position of having to defend her as its spokesperson, rather than being able to get down to business and discuss diabetes treatments.

"It could have been an extremely positive public relations move if she had announced she has diabetes around the same time that she was announced as their spokesperson," he says. "But it sounds like extremely poor business judgment to announce she's a spokesperson without announcing all the other details … One reason you hire spokespeople is to hold them up as a role model and as someone who has learned to live with a problem. I don't see how she's done that. There's an aspect to this that makes them look incompetent, although I don't think this will hurt them in the long run."

Indeed, a long-standing principle may be at work here – any publicity is better than no publicity. Of course, that is not always true. Sometimes, remaining in the shadows is better than becoming a target. But Novo Nordisk has never been a household name among large pharmaceutical manufacturers, at least not in the United States. Although familiar in the medical community, where its diabetes franchise is well-entrenched, the drug maker has been looking for a way to raise its profile.

Controversy or not, Ms. Deen may be the company's ticket. "They did get a lot of criticism and it was sustained for a while, but this clearly advanced the company name and its diabetes franchise," says John Kamp, executive director of the Coalition for Healthcare Communication. "Yes, they might have done some things differently – you know, why didn't she fess up sooner about diabetes? – but in our society, the confessed are notorious and famous. And who is better than the sinner to address the congregation?"

This does, however, raise another thorny public relations issue for drug makers. Unlike paid actors who presumably will do what they are told in front of a camera, a celebrity spokesperson can be a loose cannon. Yes, Ms. Deen is an authentic diabetes sufferer, but she does have a fan base that expects certain food and, to date, she has not shown the sort of discipline that suggests she will easily become the sort of role model that translates well to adhering to proper eating or medication.

For instance, in an interview that ran in late February on A Sweet Life, a diabetes site, Ms. Deen was asked about managing her diabetes. She responded that she initially would visit her doctor for readings, but eventually obtained a "little blood sugar monitor" herself. Then she was asked if she uses the monitor. What was her response? "When I can find it," she said. "If you knew how many people were in my house every day moving my crap around..." Imagine, though, if other diabetics followed her lead.

I'm not "quite sure if she thinks she's being cute when she says 'little blood sugar monitor' or if she's angling for another endorsement from a blood glucose monitoring company," Diabetic Investor analyst David Kliff wrote in a note to his clients. "You can bet the ranch if she had such a deal she would call it a glucose monitor and that the three month average is called A1c. And what message does it send to patients when she states that she monitors her sugars when she can find her little thing?"

As Mr. Vance notes, it can be difficult to ascertain in advance everything that a company gets when a celebrity is signed as a spokesperson. There can always be a surprise in the package. And in this case, Novo Nordisk admitted to knowing what it was getting into when the decision was made to pursue Ms. Deen, which makes the relationship all the more daunting to transform into a successful campaign.

"I think it was a risk and they could have made a better choice," says John Mack, publisher and editor of *Pharma Marketing News*, and author of the Pharma Marketing Blog. "There are other people out there who they could have worked with. I think they have hurt themselves [with the diabetes community], but if they continue to develop good products it won't hurt them in the long run. And I've noticed more ads on TV, so they're trying to counterbalance. They might have lost some credibility, but I'm sure it's a big community of people and they can make it up in the future.

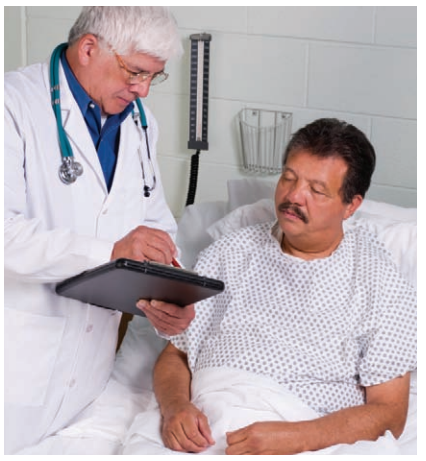
"We'll have to see if there's a return on the investment and whether it helps sales. It's not a branded type of sponsorship. So no matter how bad the press, they still get access to her audience, but we'll have to see how much that's worth and how she handles it as a trustworthy spokesperson. And they could still get a lot of good exposure, even if it's not mainstream media coverage. And by now, the worst is probably behind them."

Meanwhile, though, Novo Nordisk will have to work hard to manage the situation and hope that Ms. Deen gets the right sort of media training that brings her closer to becoming a role model who is capable of educating an audience in a convincing fashion. If the drug maker can pull that off, then the public relations disaster that characterized the relationship so far may just fade away. If not, then Novo Nordisk will have a bigger image problem than being an unknown.

"I think it may have been a brilliant move," Mr. Kamp says. "But I don't know how we can know yet. So I could be wrong. It could still blow up in their face. Every company that uses a celebrity endorser has a dangerous road in front of them, because some of them wind up being bums and she could yet be a bum. But my guess is that she'll wind up being the reformed prostitute or the reformed alcoholic – the Betty Ford of the diabetic world." ■ MEDADNEWS

By Joshua Slatko joshua.slatko@ubm.com

El poder del paciente hispano



As pharma marketers grow more aware of the cultural nuances that may differentiate patients from various backgrounds, Univision Communications Inc. has offered help with at least one group with its recent Hispanic Patient Journey study. The company's researchers, surveying respondents who reported symptoms or diagnosis of a chronic condition, found that gaps exist along the patient journey due to factors including cultural traditions, language barriers, and lack of targeted messaging.

"The good news is that gaps represent opportunities for healthcare marketers," says Eric Talbot, VP of Brand Solutions/Healthcare at Univision. "We know that if the Hispanic share of prescription sales equaled their share of the total U.S. population, the pharma industry could capitalize on a $12 billion growth opportunity. Our study will help marketers understand Hispanic patients and develop campaigns to truly engage them."

Although Hispanic disease prevalence is on par or higher than the general population for many conditions, Univision's researchers found that Hispanic perception does not reflect that situation. Forty-seven percent of Hispanics rate their health as very good or excellent as compared to 38 percent of non-Hispanics. Hispanics also rely more heavily on word of mouth for health-related information than non-Hispanics; 57 percent said friends and family are a primary source of information, versus 41 percent of non-Hispanics. Similar to the general population, mothers are the primary caregivers of the family, with one focus group participant telling the researchers, "My wife is always telling me to go get a check up!"

Symptomatic and diagnosed patients reported TV (33 percent) and online (20 percent) as their top two media sources. The study also showed that proactively obtaining information about health is a newer concept for many recent immigrants, but the desire and need for information is strong. "In my country, there was not a lot of information," one focus group participant said. "It was only when I got here and had the Internet that I found treatments."

"It is really a two step process," Mr. Talbot says. "First, patients and caregivers need to become aware of health issues and symptoms. With the Hispanic community, this is best done through traditional media sources such as TV. The second step is to provide more information to increase health literacy. Virtually every brand has a Website, but the Spanish-language content does not provide the same level of information as is available in English. This is a miss. It is important to health outcomes and a brand's success that marketers ensure that word of mouth doesn't lead to misinformation."

According to Univision's researchers, longitudinal data demonstrates that Hispanics are 21 percent less likely than non-Hispanics to get diagnosed; however, once diagnosed, treatment rates are at near parity with non-Hispanics according to United Healthcare's OptumInsights. In addition, Univision's data showed 45 percent of Hispanics reported visiting a doctor/specialist three or more times a year for their primary condition, compared to 32 percent of non-Hispanics.

Another interesting conclusion from the Univision research: Hispanics tend to desire a deeper relationship with their doctor than non-Hispanics, but feel they are not realizing that relationship. Across the board, the company's study indicates that Hispanics described their relationship with their doctor in less favorable terms than non-Hispanics. Thirty-six percent of Hispanics, as opposed to 49 percent of non-Hispanics, said that their doctor "respects their opinion," while just 40 percent believe that their doctor "understands my needs and makes me feel at ease" – 15 percent less than non-Hispanics. Hispanics were also significantly less likely to report that doctors discussed benefits and side effects with them, by 29 percent to 53 percent.

"Healthcare marketers should consider portraying doctors in campaigns as personable and willing to spend time to cultivate a relationship," Mr. Talbot says. "This could help build trust."

According to Univision's research, an equal percentage of Hispanics and non-Hispanics reported being prescribed treatment. Focus group participants expressed an internal tug of war when it comes to adhering to treatment – they understood that medication can help cure or manage their problems, but also had negative associations related to potential complications. Despite this, patient level data reports that 54 percent of Hispanics filled their first prescription, versus 57 percent of non-Hispanics, according to United Healthcare's OptumInsights.

"We found that targeted communications have a strong influence during the adherence phase," Mr. Talbot says. "If marketers connect with Hispanics in their language and culture, they tend to feel more comfortable about taking the medication."

Overall, Spanish-language online health queries grew an average of 588 percent per sub-category from 2006 to 2011. Google compared Spanish-language and English-language search terms including "salud" (plus 272 percent) versus "health" (plus 29 percent) and saw a higher growth rate in Spanish-language terms over the same time period.

"Our research proves that Hispanics crave more health content in Spanish as they empower themselves to learn more," says Google's Hispanic Industry Manager Manny Miravete.

Obama budget and pharma: highlights or lowlights?

By Ed Silverman

The latest annual budget from the White House was, not surprisingly, met with disappointment by the pharmaceutical industry. The Obama administration proposes a significant boost in rebates for Medicare Part D, limiting so-called pay-to-delay patent settlements, and reducing data exclusivity from 12 years to seven years for drugmakers that develop biosimilars.

The response was swift. In a statement, PhRMA CEO John Castellani lambasted most everything and warned that the "proposed mandatory rebates in Medicare Part D are a short-sighted proposition that could destabilize the program and threaten hundreds of thousands of American jobs … This is not an investment in America's future and these proposals should not be considered."

Drugmakers are being asked to provide $156 billion in discounts over the next decade as part of a proposal to save $362 billion. Pharma, you may recall, agreed to provide $80 billion in discounts and rebates under the 2010 healthcare law. And brand-name drugmakers currently provide rebates of up to 15 percent for Medicaid, but the White House wants to cover the so-called dual eligibles, or about 9 million seniors who qualify for both programs. "Under current law, drug manufacturers are required to pay specified rebates for drugs dispensed to Medicaid beneficiaries," the budget proposal explains. "In contrast, Medicare Part D plan sponsors negotiate with manufacturers to obtain plan-specific rebates at unspecified levels. The Department of Health and Human Services Office of Inspector General has found substantial differences in rebate amounts and net prices paid for brand name drugs under the two programs, with Medicare receiving significantly lower rebates and paying higher prices than Medicaid.

"Moreover, Medicare per capita spending in Part D is growing significantly faster than that in Parts A or B under current law. This proposal would allow Medicare to benefit from the same rebates that Medicaid receives for brand name and generic drugs provided to beneficiaries who receive the Part D Low-Income Subsidy beginning in 2013. Manufacturers previously paid Medicaid rebates for drugs provided to the dual eligible population prior to the establishment of Medicare Part D. The Fiscal Commission recommended a similar proposal to apply Medicaid rebates to dual eligibles for outpatient drugs covered under Part D."

Despite the prospect of additional rebates, AARP, for instance, was not thrilled. In a statement, AARP CEO A. Barry Rand says the group remains "concerned about proposals that would not address high health costs, but would simply shift those costs to other payers, particularly Medicare beneficiaries. We remain opposed to such cost-shifting, whether through higher copayments and deductibles, or through higher premiums, including further income relating the premiums of better-off seniors who already pay more for Medicare."

Meanwhile, the White House noted that the FDA budget would total $4.49 billion for the year beginning October 1, which would amount to a 17 percent boost, reflecting increased user fees, in particular. These include a new user fee totaling $299 million to support generics, and another $20 million for biosimilars.

Over the past five years, about a third of FDA funding was generated by industry fees, but this would increase to 45 percent in the proposed budget. About $10 million of the FDA budget would be used to hire 19 inspectors to focus on China, with 16 working there on food and drug safety and standards

Ed Silverman is the editor of Pharmalot.com and editor-at-large for Med Ad News *and* R&D Directions.

FACTS & FIGURES

According to a study by **Cegedim Strategic Data**, pharmaceutical companies' investment in print advertising decreased by **10 percent** in the 12 months to September 2010. Use of advertising in medical journals continued to decrease for the following 12-month period ending September 2011, dropping by another **4 percent**.

Overall for the top five European markets, print advertising decreased by **11 percent**. Only two of the five countries showed an increase in print advertising spend: Italy by **8 percent** and Spain by **5 percent**. France showed a marked **19 percent** drop, which may be due to many factors including a general decrease in promotional budgets and the decline in the number of product launches and therefore advertising campaigns in 2011.

Meanwhile, print advertising in the United States showed signs of a turnaround, with an increase of **10 percent** for moving annual total Q3 2011 compared to a decrease of **13 percent** for MAT Q3 2010.

In contrast to the United States, Japan continued to decline, falling **2 percent** for MAT Q3 2011, though this was less than the **8 percent** drop for the previous 12 month period.

Of the main emerging markets, China and Russia showed increases of **20 percent** and **12 percent** respectively. Brazil, however, showed a decrease of **4 percent**.

According to a study by the **Altarum Institute's Center for Sustainable Health Spending**, U.S. national health expenditure in 2011 grew at an annual rate of **4.4 percent** to **$2.71 trillion**, compared to the **3.9 percent** increase for 2010 reported last month by the Centers for Medicare & Medicaid Services.

In December 2011, national health expenditure grew by **3.8 percent** relative to December 2010, an increase from **3.6 percent** in November, but still reflecting an overall downward trend since early in the year.

The health spending share of gross domestic product was **18.1 percent** in December 2011, up from **18 percent** in November and **16.4 percent** at the start of the recession (December 2007), but down slightly from the all-time high of **18.2 percent** in June. The increase since the start of the recession is largely attributable to slow GDP growth rather than high health spending growth, as the December share of potential GDP was **16.8 percent**.

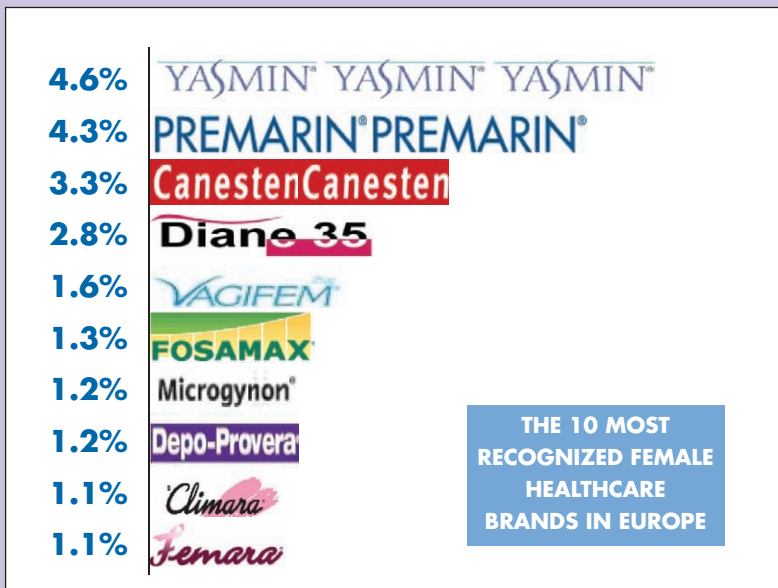
Spending in December increased in all major categories over the past year, with prescription drugs showing the highest year-over-year growth (**7.9 percent**) and nursing home care the lowest (**0.2 percent**).

In 2011, hospital spending increased to **$863 billion** and represented **31 percent** of total health spending. Physician and clinical services spending was **$535 billion**, remaining at **19 percent** of total health spending. Prescription drug spending was **$285 billion**, **10 percent** of total health spending. Nursing home and home health spending combined were **$220 billion**, **8 percent** of total health spending. Spending on personal healthcare goods and services accounted for **84 percent** of total health spending. Other major components of health spending include public health, research, construction, and net cost of private insurance.

THE DESKTOP STUDIO/ISTOCKPHOTO.COM

MOST-RECOGNIZED BRANDS

FEMALE HEALTHCARE



The most recognized female healthcare brand in North America is **Premarin**. The brand was most-recognized by 13.5 percent of physicians in a survey conducted by **Brand Institute** Inc. during the third quarter of 2011. Premarin, comprising conjugated estrogens, is marketed by **Pfizer** Inc. (pfizer.com). The drug was first approved by FDA in 1942 for the treatment of vasomotor symptoms associated with menopause, for the prevention of osteoporosis, and several other indications.

Monistat is the second most-recognized female healthcare brand in North America. About 5.6 percent of physicians recognize this brand the most. Monistat, comprising miconazole, is marketed by McNeil Consumer Healthcare, a division of **Johnson & Johnson** (jnj.com). The product is indicated for the treatment of vaginal yeast infections.

The third most-recognized female healthcare brand in North America is **Estrace**. About 4.6 percent of physicians recognize this brand the most. Estrace, comprising estradiol, is marketed by **Warner Chilcott** (warnerchilcott.com). The product was first approved by FDA in January 1982 for the treatment of breast cancer (for palliation only) in appropriately selected women and men with metastatic disease. An additional approval was received in September 1992 to prevent osteoporosis.

The most-recognized female healthcare brand in Europe is **Yasmin**. About 4.6 percent of physicians recognize this brand the most. Yasmin, comprising ethinyl estradiol and drospirenone, is marketed by **Bayer Schering** Pharma AG (bayerschering.de), and was approved in the European Union in August 2000 for the prevention of pregnancy.

Premarin is the second most-recognized female healthcare brand in Europe. This product was recognized the most by 4.3 percent of physicians.

The third most-recognized female healthcare brand in Europe is **Canesten**. About 3.3 percent of physicians recognize this brand the most. Canesten, comprising clotrimazole, is marketed by Bayer Healthcare for the treatment of vaginal yeast infections and other fungal infections.

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 female healthcare. Brandpoll is a marketing tool designed to help clients monitor the competitive marketplace and identify the potential strengths and weaknesses of their brands.

Lipitor losing ground despite Pfizer's best cost-cutting efforts

A recent report by the InThought research group suggests that managed care and prescription plans are working to switch patients to generic atorvastatin despite **Pfizer** Inc.'s (pfizer.com) efforts to reduce patient costs for branded **Lipitor**. According to the most recent Source Dynamic Claims data, although branded Lipitor currently has 41 percent market share of all dispensed prescriptions of atorvastatin, the branded product holds only 35 percent of the payer approval volume.

Payers are moving quickly to switch patients to generic Lipitor in spite of Pfizer's efforts to reduce patient costs for the branded version.

"At 41 percent market share, Lipitor is ahead of the game, at least compared to Aricept and Cozaar, both blockbuster drugs that lost patent protection in the last two years," says Rusty Jones, an inThought analyst and author of the report. "Our latest data, however, show that it may be losing more ground than the traditional prescription data suggest, especially on the important battle ground of managed care coverage."

According to InThought's researchers, Pfizer has employed several managed care strategies to maintain its brand share with Lipitor, including aggressive rebating with payers and the use of co-pay cards to reduce patient out-of-pocket costs. Even with the lowered patient costs, however, Pfizer has retained less than half the total atorvastatin pill count ten weeks after the generic became available. Further, recent data show that only 35 percent of approved atorvastatin claims are for brand name Lipitor.

"Since the 35 percent approval volume is lower than Lipitor's current market share, the claims data suggest that Lipitor volumes will continue to decline," Mr. Jones says. "Despite the discounts, managed care plans are still financially motivated to put their patients on generic atorvastatin."

inThought's Dynamic Claims data offer a detailed look into the Lipitor market share by compiling pharmacy claims, the financial transactions that transpire between the pharmacy and the managed care plan when a prescription is filled. This, researchers say, allows a view into the tactics that managed care organizations use to control access to branded and generic products. According to the Dynamic Claims data, rejected claims for Lipitor increased immediately after the availability of generic atorvastatin to nearly 8 percent in December. In addition, patient reversals also increased to nearly 10 percent. Reversals are when a patient abandons a prescription at the pharmacy, often because the co-payment is deemed too high.

As a result, the report concludes, "a sharp increase in both plan rejection rate and patient reversal rate for top Lipitor payers shows that plans are moving aggressively to migrate patients to generic atorvastatin."

"Even if Pfizer is successful at forestalling the generic erosion of Lipitor, the question is, 'is it worth it?,'" says Ben Weintraub, director of research, inThought. "Pfizer is well on the way to becoming the lead payer for branded Lipitor, meaning that even if it sells more pills, its profit-per-pill is declining significantly. Matching the number of dispensed prescriptions to the quarterly Lipitor revenue reported by Pfizer will quantify this issue, but these early data suggest that Pfizer's best efforts, sure to be expensive, may not lead to better performance than those of other branded blockbusters that have recently lost patent protection."

The inThought research group is a part of Wolters Kluwer Pharma Solutions.

Merck parceiros no Brasil

With an eye to opportunities in the pharmerging markets, **Merck** has formed a new joint venture with **Supera** Farma Laboratorios SA, a Brazilian pharmaceutical company jointly owned by Cristália and Eurofarma. The new venture will market, distribute, and sell a portfolio of innovative pharmaceutical and branded generic products from Merck, Cristália, and Eurofarma solely in the Brazilian retail sector.

"Merck is pleased to partner with two of Brazil's leading pharmaceutical companies – organizations that share our commitment to enhancing healthcare for the people of Brazil," says Kenneth C. Frazier, chairman and CEO, Merck (merck.com). "This venture is an important step forward in our strategy to grow our business in key markets and improve global access to our medicines and vaccines."

By establishing the joint venture with Supera, Merck executives hope to gain additional local expertise, an expanded portfolio of products, and a strong distribution network to facilitate wider access to medicines for the people of Brazil. The initial portfolio of the venture will include about 30 products across a range of therapeutic areas. The venture will have its own dedicated sales force separate from Merck, Cristália, and Europharma, but will take advantage of the parent companies' infrastructures for activities such as sales force training. The parent companies will continue to maintain separate businesses in Brazil.

"We are sharing learnings and combining the very best of each company, making this joint venture more competitive in the Brazilian market," says Maurizio Billi, president of Eurofarma. "Partnering with Merck is a strategic move to advance access to innovative pharmaceutical products."

Merck, through a subsidiary, will own 51 percent of the joint venture, and Cristália and Eurofarma will collectively own 49 percent. The venture will be managed by a joint board and leadership team consisting of members of senior management from the three companies. Establishment of the joint venture is subject to satisfying certain agreed upon closing conditions but is scheduled to be completed later in 2012.

By *Med Ad News* staff

Multichannel selling—how to make every second count

By Paul Shawah, Veeva Systems

The average physician spends less than two minutes face-to-face with pharmaceutical sales reps – not because physicians don't like them, but simply because they don't have the time. With the clock always ticking, it's a real challenge for even the most skilled and experienced sales reps to foster supportive relationships with their physician customers. That's why it's critical to make every second count.

According to one Pa.-based family physician, Dr. Laurie Gallagher, "Each day is like playing 'beat the clock' as I try to give the best care to my patients, complete all of the necessary documentation, and make sure I am out in time to pick up my children from school programs. Often, I am working at home well past 10 PM, completing paperwork, reviewing labs, and returning correspondence from specialists. If I don't put in this time, then I end up playing catch-up the next day. With this kind of schedule, I can only meet with drug reps for a minute or two at a time and maybe only three or four a day – max."

So, how do you make an impact before the buzzer goes off? Go multi-channel. Forward-thinking life sciences companies have started taking advantage of Web-based and other digital technologies to establish additional sales and marketing channels that are available at all times of the day and night and from wherever a physician happens to be, whether that is at home, in an airport, or in their office. A few examples include video details, mobile apps, social media, and online details.

With so many different communication channels, though, how does a company use the collective strength of each to improve selling effectiveness? And how do you keep track of all of these interactions to become a more informed sales rep that supports physicians' needs to literally make every precious second spent with them count?

The answer is channel integration. New cloud-based technology funnels feedback collected from all channels – both new and existing – into a single system so that reps and marketers can see every physician's every interaction with the company. And, when integrated into a company's CRM system, all users benefit from working in a single system for a consolidated, 360-degree view of the customer. Reps and marketers gain valuable insight into what messages were most helpful to physicians, what times of day they were most available and receptive, channel preferences, and more. It's complete visibility. Empowered by meaningful, real-time data, reps can then follow up with more relevant information – for example, a rep could provide efficacy data for a new drug's use in children to a pediatrician who recently watched an e-detail featuring that drug.

Physicians appreciate the convenience and personalized responsiveness of reps – it's the foundation of a good customer relationship. "If I could review an online detail for a new drug at night or during lunch, then get relevant details on that drug from my rep, it would save me time while also ensuring that I get just the information I want for my patients," says Dr. Gallagher, who sees about 300 patients a month.

Brand teams, also, benefit from a multichannel solution by being able to see physician responses to their materials and then quickly refine marketing messages to better target marketing communications. Ultimately, the goal is to incorporate all of the interaction data about physician customers from every touch point in a single repository so marketing can segment physicians based on a wide variety of specific criteria. Highly targeted campaigns, therefore, can be executed with results of those campaigns dumped back into a repository … again, to further refine messaging and more accurately measure success.

Measuring the effectiveness of every channel now available – from traditional to nontraditional, online and off, from sales channels to marketing – is a huge challenge. Yet with declining marketing budgets, increased competition, and the fluctuating pharmaceutical business environment, measuring performance of the many layers is more crucial than ever. Having direct feedback from channels funneled in to one place for analysis can enable more precise metrics in the areas of engagement, brand awareness, message recall, and behavior change – all elusive metrics to quantify accurately,

where ROI is the presiding yardstick of a successful campaign.

"ROI is likely to remain the golden rule for the near future because managers, shareholders, and board members want to be able to identify spend," says Tom Jones, group VP of the health practice at Makovsky + Co. "[However] the measurement should be 'engagement,' particularly at the beginning of some efforts, not ROI."

Nowhere is this more obvious than in nontraditional sales and marketing approaches such as social media with things like number of Facebook "likes" and time spent watching online details – both factor into the engagement metric but are hard to detangle in today's multi-strand web of different channels. But, an integrated, centralized portal where all customer interactions across the company are collected offers life sciences companies a brand new opportunity to accurately measure individual messages, tactics, media, and selling strategies as well as the combined effect of various components on the target customer.

And, maybe best of all, sales and marketing can finally work together to increase effectiveness – with rep-triggered direct mailings and marketing-driven rep calls, for instance. This is the future and it's fueled by the flexibility enabled by maturing cloud technologies available today.

"The recent maturation of cloud-based platforms is the impetus to set in motion enterprise-wide, cross-channel integration," says Jo Ann Saitta, general manager for Group DCA and senior VP of IT at PDI, a contract sales organization that recently rolled out an integrated multichannel system for 600 users. "Multi-tenant cloud technology, with its inherent flexibility, ease of use, scalability, and open platform has led to more multichannel selling capabilities through the seamless integration of the many new and existing channel components. By adopting cloud technology, pharmaceutical companies of all sizes will be empowered with the ability to do rich, insight-driven, multichannel selling."

Specifically, Ms. Saitta's company integrated multiple Web portals where physicians can make self-directed information inquiries, request samples, and initiate outreach requests for live or 'tele-Reps,' view e-detailing programs, and participate in tele-sales activities. All of these channels have been integrated successfully through its CRM system so reps can see all of the physicians' requests and interactions from one screen. Additionally, sales reps are able to trigger marketing activities to drive and support targeted physician engagement efforts. The positive results are a testament to the incredible value of integrated multichannel strategy.

According to Ms. Saitta, an integrated system must be flexible enough to include all types of information, whether digital communications such as e-detailing, peer programs, trigger letters, or even a company's own team details on co-branded products – all right at the fingertips of users. "It offers a 360-degree view of the physician target which helps reps open up a richer dialogue with their customers and really drive home sales," she says.

Okay, you've got two minutes left on the clock – look at your current systems, run your best play, and use every communication channel available. How often did your message get through and how was it recorded? Does your system give you the ability to put all your best tools out on the table, gather the data necessary to capture the metrics, and measure results? If the answer isn't yes, then it's time to bring it all together in the cloud and go for the win.

Paul Shawah is VP multichannel strategy at Veeva Systems

Three surprising trends for consumer marketers

By Maureen Malloy, senior healthcare analyst, Manhattan Research

At Manhattan Research, we just released our latest ePharma Consumer study of how consumers use digital channels to learn about prescription drugs and interact with pharma. And now that the results are in, here are a few trends that some may find a bit surprising:

Few patients seek Rx-related UGC

About one half of online consumers go online to research a variety of prescription drug topics, from side effects to coupons to generics and more. Contrary to some marketers' beliefs, relatively few consumers actively seek out others' opinions on these topics online. Only about 1 in 10 online consumers research commentary and experiences about prescription drugs from other patients online. That being said, social media is increasingly blended into editorial content, search engine results, and the online experience as a whole. Consumers are still coming across treatment-related user-generated content whether they are purposefully seeking it or not, prompting some brands to at least gain an awareness of what's being said about them online. Additionally, many consumers expect manufacturers to play a role in the conversation, with 42 percent of online consumers agreeing that pharma companies should be involved in online health communities.

M. MALLOY

Consumers open to learning from pharma

Conventional wisdom may lead to the assumption that Americans are suspicious of patient education from pharma companies. In reality, very few consumers are against the idea of learning from pharma online. For example, only about one-quarter of online consumers say they mistrust prescription drug or condition information from pharma-sponsored disease Websites, and this finding holds true for branded prescription drug Websites as well. Additionally, trust in pharma online content increases among certain condition and caregivers groups, such as parents of pediatric ADHD patients. For brands, this means that it's likely their audience is open to learning from pharma online, and it's up to them to make it worth consumers' while.

Mobile isn't always apps

Apps tend to steal the spotlight in discussions of mobile health. However, online consumers are more than twice as likely to be using pharma-sponsored content from mobile Websites as from apps. And for brands aiming to reach audiences with limited smartphone penetration, text messaging provides greater access than apps. Although apps do hold tremendous potential for advancing mobile health, they require ongoing effort and engagement on the part of the consumer, which may be difficult to motivate if the app doesn't provide a concrete benefit to the user. In line with these trends, we are starting to see some marketers show a renewed interest in mobile initiatives beyond the app.

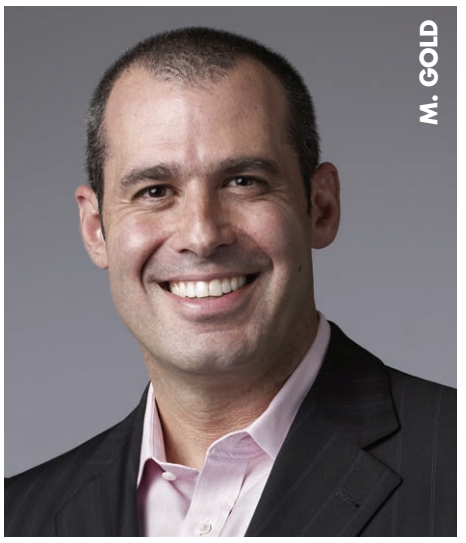
We're still digging through the results of the study, so stay tuned for more findings on other topics such as consumer use of pharma-related social media, DTC advertising, online health video, and pharma's role at the point of care. For more information about the study, please visit manhattanresearch.com/epc.

BARIS SIMSEK/ISTOCKPHOTO.COM

PeopleontheMove

By Joshua Slatko joshua.slatko@ubm.com

Dendreon names new CEO



The board of directors of Dendreon Corp. has elected **John H. Johnson** to the position of president and CEO, to succeed **Mitchell H. Gold**, M.D., who has served as president and CEO for nearly a decade. Dr. Gold has been elected executive chairman and will serve in that role until June 30, 2012, at which point he will continue to serve as a director and Mr. Johnson will become chairman.

Mr. Johnson has been a member of Dendreon's board since August 2011 and brings to Dendreon nearly 30 years of experience in the life sciences industry, including serving as president, CEO, and director at Savient Pharmaceuticals, president of Eli Lilly's Oncology Business Unit, CEO of ImClone Systems, and company group chairman of Johnson & Johnson's Worldwide Biopharmaceuticals.

"I am honored to take on this important role to help lead Dendreon into the next chapter of growth, and I have great respect for all that Mitch has accomplished over the past decade in ushering in a new era in medicine for patients with cancer," Mr. Johnson says. "With the important progress that has been made with the commercial launch of Provenge, I am invigorated by the challenge of taking Dendreon to the next level. I look forward to working with Dendreon's executive team and the board as we look to build a global, fully integrated oncology business."

After more than 15 years of research and development, FDA approved Dendreon's Provenge, the world's first autologous cellular immunotherapy, in April 2010. The Cleveland Clinic recognized Provenge as one of the top 10 medical innovations of 2010.

"John has spent most of the last decade successfully building oncology companies, and we believe his substantial oncology and global commercial, research and development experience makes him the ideal candidate to succeed Mitch," says Richard B. Brewer, director and former chairman of Dendreon's board. "During his tenure as a director, he has proven to be a meaningful contributor as Dendreon further evolves as a global commercial enterprise, and we welcome John to his new role. On behalf of Dendreon's board of directors, we thank Mitch for his exceptional leadership over the past decade and his unwavering commitment to patients with cancer. We believe that Mitch's role as executive chairman will ensure a stable and strong transition takes place as he hands over the reins to John."

Mr. Johnson was appointed CEO of Savient Pharmaceuticals in January 2011. Before this appointment, he served as a senior VP of Lilly and president of Lilly Oncology Business Unit, where he was responsible for multi-billion dollar franchises including a development portfolio of more than 30 oncology products. From August 2007 to November 2009, Mr. Johnson was CEO of ImClone Systems, and served on ImClone's board of directors until the company was acquired by Lilly in November 2008. While at ImClone, Mr. Johnson managed the market expansion of colorectal cancer treatment Erbitux, overseeing the global growth of the billion dollar brand and eventual sale of the company to Eli Lilly for $6.5 billion.

Before joining ImClone, Mr. Johnson had served as company group chairman of Johnson & Johnson's Worldwide Biopharmaceuticals unit since 2005. Mr. Johnson began his healthcare career with Pfizer in 1983, where he held positions of increasing responsibility in sales and sales management. He joined Johnson & Johnson in 1988 and advanced through positions of increasing responsibility with Ortho-McNeil. In 2000, he served as president and CEO for Parkstone Medical Information Systems. Mr. Johnson returned to Johnson & Johnson in 2001 as worldwide VP CNS/psychiatry, for Johnson & Johnson Pharmaceuticals Group Strategic Marketing. He was appointed president of Ortho Biotech Products L.P. in 2003 and assumed additional responsibility for Ortho Biotech Canada in 2004. He is currently a member of the boards of directors for Dendreon, Cempra Pharmaceuticals Inc., and Tranzyme Pharma, Inc.

Dr. Gold has served as president and CEO of Dendreon since 2003. He had previously served as the company's VP of business development and as chief business officer. Prior to joining Dendreon, Dr. Gold served as VP of business development and VP of sales and marketing for Data Critical Corporation, a company engaged in wireless transmission of critical healthcare data, now a division of GE Medical. Dr. Gold was the president, CEO, and a co-founder of Elixis Corp., a medical information systems company.

For contributions to science through his leadership at Dendreon, Dr. Gold received the Oliver R. Grace Award from the Cancer Research Institute and was a runner-up for "Smartest CEO" in *Fortune*'s "Smartest People in Tech" issue. He was voted "Entrepreneur of the Year" in the Pacific Northwest by Ernst & Young. Locally, *Seattle Magazine* named Dr. Gold the top influencer in medicine in 2010, and Dendreon was recognized as the most innovative company at the 2010 Washington State Governor's Life Sciences Summit. Dr. Gold serves on the board of the University of Washington/Fred Hutchinson Cancer Research Center Prostate Cancer Institute.

PHARMA

■ **Kenneth DiPietro** has been named executive VP, human resources, Biogen Idec. Mr. DiPietro has more than 30 years of experience in both human resources and organizational development, including broad cultural transformation and corporate re-engineering across Global 500 companies. He joins Biogen Idec from Lenovo Group, where he served as senior VP, human resources. Biogen Idec (biogenidec.com) discovers, develops, and delivers to patients worldwide innovative therapies for the treatment of neurodegenerative diseases, hemophilia, and autoimmune disorders.

BIOTECH/BIOPHARMA

■ Dr. **Frank Booth** is named chief medical officer, Sangart Inc. Prior to joining Sangart, Dr. Booth worked in clinical development roles at Novo Nordisk and at Eli Lilly & Co. **Mary Rose Keller** is named VP of clinical operations. Ms. Keller brings to the company more than 25 years of experience in clinical research and clinical trial execution and has been involved with numerous, successful regulatory submissions for companies such as Agouron, Pfizer, and Shire Pharmaceuticals. **Carmen Betancourt-Riche** is named VP of regulatory affairs and quality assurance. Ms. Betancourt-Riche joins Sangart from BioMarin Pharmaceutical, where she served as senior advisor in Regulatory Research. Sangart (sangart.com) is a global biopharmaceutical company dedicated to developing life-saving medicines specifically designed to enhance the perfusion and oxygenation of ischemic (oxygen deprived) tissues through targeted oxygen delivery.

■ **Jane Wasman** has been named chief, Strategic Development, Acorda Therapeutics. Ms. Wasman will also continue with her current responsibilities as general counsel, including management of the company's Legal, Compliance, and Quality departments. Ms. Wasman joined Acorda in 2004 as executive VP, general counsel, and corporate secretary. Previously, she held various leadership positions at Schering-Plough Corp., including staff VP and associate general counsel. Acorda Therapeutics (acorda.com) is a biotechnology company focused on developing therapies that restore function and improve the lives of people with MS, spinal cord injury, and other neurological conditions.

■ **C. Evan Ballantyne** has been named chief financial officer, Adeona Pharmaceuticals Inc. From 2006 until its acquisition in April 2011, Mr. Ballantyne served as executive VP and chief financial officer of Clinical Data Inc., a publicly traded biopharmaceutical company that was acquired by Forest Laboratories Inc. Adeona (adeonapharma.com) is a biotechnology company focused on the development of synthetic DNA-based therapeutics and innovative disease-modifying medicines for serious illnesses.

■ **Cynthia Smith** has been promoted to VP, market access and commercial development, Affymax Inc. Ms. Smith joined Affymax in October 2008 as executive director, public policy, payer strategy, and operations. Prior to joining Affymax, she held various positions at Merck & Co., including executive director, Medicare and healthcare systems strategy. Affymax (affymax.com) is a biopharmaceutical company committed to developing novel drugs to improve the treatment of serious and often life-threatening conditions.

■ **Sean Cunliffe** has been named chief business officer, Sirona Biochem Corp. and will also be joining the company's board of directors. Mr. Cunliffe has more than 25 years of pharmaceutical marketing and sales experience in a wide variety of therapeutic areas. Most recently, he served as senior VP of sales and marketing at Angiotech Pharmaceuticals. Sirona Biochem (sironabiochem.com) is a biotechnology company developing diabetes therapeutics, cancer vaccine antigens, depigmenting and anti-aging agents for cosmetic use, and biological ingredients.

SPECIALTY PHARMA

■ **David Y. Norton** has been appointed to the role of interim CEO, Savient Pharmaceuticals Inc. Mr. Norton is a member of the Savient board and former company group chairman, Global Pharmaceuticals for Johnson & Johnson. Mr. Norton succeeds **John H. Johnson**, who has resigned as CEO, president, and a director of Savient to become president, CEO, and chairman-elect of Dendreon Corp. The board will conduct

New leader for Pfizer Canada

John Helou has been named president of Pfizer Canada Inc., Canada's largest pharmaceutical company, effective Jan. 31, 2012.

Mr. Helou, a veteran of more than 25 years in the pharmaceutical industry and head of the Pfizer Specialty Care Business Unit for Canada and Puerto Rico, succeeds **Paul Lévesque**, who has been named chief marketing officer for Pfizer Primary Care in the United States. Mr. Lévesque will be moving to Pfizer headquarters in New York City to take up that position.

While taking this expanded leadership position in Canada, Mr. Helou will maintain his role as head of the SCBU. He is based at the company's Canadian headquarters office in Kirkland, Quebec.

Mr. Helou began his career as a chemical engineer with DuPont Canada in 1980, moving five years later to the company's pharmaceutical business where he took positions of increasing responsibility in sales, marketing, strategic planning, and business development in Canada, the United States, and at the global level.

In 1997, Mr. Helou set up and became general manager of Agouron Canada, the Canadian operations of a start-up biotech company specializing in HIV/AIDS and oncology treatments. Agouron was subsequently acquired by Pfizer and the business operations transferred in 2003, at which time he was appointed Pfizer Canada's director of sales for its Specialty Business. In 2006 he was named VP public affairs and stakeholder relations, before being named head of the SCBU when it was formed in 2009.

a search process for a permanent CEO. Also, **Louis Ferrari** has been promoted to the position of executive VP, president North American commercial operations. Savient (savient.com) is a specialty biopharmaceutical company focused on developing and commercializing Krystexxaa for the treatment of chronic gout in adult patients refractory to conventional therapy.

■ **J. Chris Houchins** has been appointed senior VP, Clinical and Medical Affairs, Delcath Systems Inc. Mr. Houchins has more than 21 years of experience in leading the global development and implementation of clinical, medical, and scientific operations in oncology. He most recently served as chief operating officer and senior VP - Clinical Operations for Arno Therapeutics Inc. Delcath Systems Inc. (delcath.com) is a development stage specialty pharmaceutical and medical device company focused on oncology.

■ PaxVax Corp. has announced the expansion of its executive management team with the appointments of **Nima Farzan** as executive VP and chief operating officer; **Thomas P. Monath**, M.D., as chief technology officer; and **Jonathan F. Smith**, Ph.D., as executive VP and chief scientific officer. Mr. Farzan joins PaxVax from Novartis AG, where he spent more than seven years in positions of increasing responsibility in pharmaceutical marketing, sales, and development in both U.S. and global positions. Most recently, he was VP of marketing for Novartis Vaccines USA, where he was responsible for marketing, market access, pricing and key account sales, and also helped launch multiple new vaccines. From 1992 to 2006, Dr. Monath was chief scientific officer and executive director at Acambis, a biopharmaceutical company, where he pioneered the development of ChimeriVax vaccines against dengue, West Nile, and Japanese encephalitis, as well as vaccines against yellow fever, *Clostridium difficile*, *Helicobacter pylori*, and smallpox. Dr. Smith joins PaxVax from Liquidia, where he was the company's chief scientific officer, responsible for overseeing research and development programs applying the company's novel nanoparticle technology to vaccines and other applications. PaxVax is a privately held company established in 2007 to develop and commercialize innovative and socially responsible vaccines against infectious diseases.

Congratulations to Carolyn Buck Luce

2012 Healthcare Businesswomen's Association Woman of the Year

Ms. Buck Luce's accomplished career includes over 20 years at Ernst & Young, where she is the Global Pharmaceutical Leader for life science clients. The HBA community recognizes Ms. Buck Luce for her decades-long leadership in healthcare and life sciences as well as her tireless efforts for the advancement of women in the industry.

Please join us in celebrating her special achievement at the annual HBA Woman of the Year luncheon.

The Hilton New York | Thursday, May 3, 2012

- Reception: 10:00 AM
- Luncheon: 11:45 AM

HBA will also honor:

Mike Kaufmann, 2012 HBA Honorable Mentor
CEO, Pharmaceutical Segment, Cardinal Health

Nancy Larsen, 2012 HBA STAR
CEO, PROmedica Communications, Inc.

Registration Deadline
April 17, 2012

Grand Ballroom

- Member: $220
- Nonmember: $250
- Table: $2,350 (seats 10)

WOTY

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HBA HEALTHCARE BUSINESSWOMEN'S ASSOCIATION

■ **Gregory T. Mayes** is promoted to chief business officer and **Jane Pepper**, Ph.D., becomes senior director, business development, Unigene Laboratories Inc. Mr. Mayes has served as VP, corporate development and general counsel since October 2010. He will remain Unigene's general counsel. Dr. Pepper joins Unigene after eight years in the development organization with Novartis Pharmaceuticals. where she was most recently a member of the business development and licensing team that evaluated strategic new business opportunities. Unigene (unigene.com) is a leader in the design, delivery, manufacture, and development of peptide-based therapeutics.

■ **Anthony J. Yost** is named senior VP and chief commercial officer, Prometheus Laboratories Inc. Mr. Yost joins Prometheus from EKR Therapeutics, where he served as chief commercial officer. Prometheus (prometheuslabs.com) is a specialty pharmaceutical and diagnostic company committed to improving lives through the development and commercialization of novel pharmaceutical and diagnostic products that enable physicians to provide greater individualized patient care.

■ **Joseph Truitt** is promoted to senior VP of business development, Achillion Pharmaceuticals Inc. Mr. Truitt will maintain his position as chief commercial officer and previously served as VP of business development. Achillion (achillion.com) is an innovative pharmaceutical company dedicated to bringing important new treatments to patients with infectious disease.

■ **Wills Hughes-Wilson** has been appointed VP, government affairs & policy, Sobi, with responsibility for the company's contacts with all stakeholders in the health policy area. Ms. Hughes-Wilson comes from Genzyme Corp., now part of the French Sanofi Group, where she was VP health/market access policy, Europe. Sobi (sobi.com) is an integrated biopharmaceutical company dedicated to bringing innovative therapies and services to improve the health of rare disease patients and their families.

SERVICE SUPPLIERS

■ **Richard Lifsitz** has joined Scientia Advisors as a principal. Mr. Lifsitz comes to Scientia Advisors with more than 25 years of operating and consulting experience in start-up, midmarket, and Fortune 500 health care and technology companies. Most recently, he was chief operating officer of HyperMed, a venture-backed hyperspectral imaging company focused on improving diagnosis and therapy for patients with critical limb ischemia and diabetic foot ulcers. Scientia Advisors (scientiaadv.com) is a growth strategy firm for the healthcare market.

■ **Mark Vince** is named European director, MedErgy, based in the agency's London office. Mr. Vince now has responsibility for MedErgy's European operations and will lead teams for existing and new clients in Europe, whether at a global, pan-European, or national level. He brings more than 25 years of pharmaceutical industry expertise and international experience in Europe and across other regions including Africa, the Middle East, Asia-Pacific, and Latin America. Mr. Vince has held a number of increasingly senior clinical development roles with Ciba-Geigy and SmithKline Beecham, and oversaw the establishment of regional clinical development centers, before moving to the consumer healthcare division of GlaxoSmithKline in 2002. MedErgy (medergygroup.com) is a scientifically-focused medical and marketing agency providing evidence-based communication solutions through the synergistic blend of strategy, science, and creativity.

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Options shown. [1]2011 IntelliChoice, www.IntelliChoice.com; based on hybrid and 4-cyl. models. [2]Based on Vincentric's 2011 Best Fleet Value in America analysis, mid-size sedan segment. [3]MotorIntelligence.com, CY 1997-2010 sales. [4]Do not rely exclusively on the Blind Spot Monitor to determine if a lane change is safe. Always look over your shoulder and use your turn signal before changing lanes. There are several limitations to the function, detection, range and clarity of the monitor. For a complete list of limitations and directions regarding use of the monitor, please see the *Owner's Manual*. [5]Available on XLE and Hybrid XLE models only. ©2011 Toyota Motor Sales, U.S.A., Inc.

AdAgencyUpdate

By Christiane Truelove christiane.truelove@ubm.com **and Joshua Slatko** joshua.slatko@ubm.com

New digs for InVentiv Health Communications/Europe

InVentiv Health Communications/Europe has officially opened its new headquarters in London, which will serve as a hub for all European offices and support the rapid growth of the company's consolidated communications business. Additionally, the agency has named new executives to lead its digital, social media, advertising, and creative services.

iHCE will provide governance and operational support to enhance customer service across all communications offices and foster closer collaboration with inVentiv Health's other commercial services, including sales and patient outcomes.

inVentiv Health, a global provider of clinical, commercial, and consulting services to the healthcare industry, announced the launch of iHCE last August. Although based in Switzerland, the operational headquarters has been located in London. Since its launch, iHCE has focused on building a "Super Agency" governed by a single management philosophy that facilitates true collaboration between inVentiv's best-in-class advertising, public relations, public policy, market access, medical education, marketing, branding, and digital services.

According to agency leaders, iHCE's new operational hub enables this "Done as One" management philosophy that removes barriers between communications disciplines to create teams that view problems from multiple perspectives and then draw upon the needed expertise to deliver programs that quickly achieve their goals.

"From deep collaboration emerge solutions that are unique in the healthcare industry," says Bob Chandler, senior VP of marketing and communications of inVentiv Health and head of iHCE. "Our company structure allows us to draw upon a wealth of talent and deep insight across many disciplines, while our new European headquarters helps us better serve our clients and facilitate growth throughout Europe. This is a very exciting time."

iHCE's leadership has appointed Nick Bartlett, Damon Caiazza, and Peter Comber to senior management roles. Mr. Bartlett will lead iHCE's digital and social media business, Mr. Caiazza will head advertising, and Mr. Comber will oversee the company's creative services.

Mr. Bartlett joins iHCE from Publicis Life Brands Resolute, where he held the position of digital strategy director. iHCE promoted Mr. Caiazza and Mr. Comber, who fulfilled similar roles at GSW Europe, an inVentiv Health company. All three will work closely within specific markets and with inVentiv business units to support ambitious goals for local and regional growth through the delivery of best-in-class services.

"Our company structure allows us to draw upon a wealth of talent and deep insight across many disciplines, while our new European headquarters helps us better serve our clients and facilitate growth throughout Europe," says Bob Chandler, head of iHCE.

"We are committed to providing clients with a multi-disciplinary approach that taps the expertise of all healthcare marketing disciplines, and [these] appointments reinforce this commitment," says Fiona Hall, senior managing director of iHCE. "As part of our senior management team, Nick, Damon and Peter will support our go-to-market strategy rooted in client demand for effective, actionable multi-disciplinary services that reach target audiences with greater speed and relevance."

Surely, Mr. President, you cannot be serious

By Sander A. Flaum, principal, Flaum Navigators
Chairman, Fordham Leadership Forum, Fordham University Graduate School of Business

I'm not calling you Shirley – but I am calling you – or at least the "Sunshine" provision in your Healthcare Reform Act Bill – terribly misguided. In case the details eluded you during the healthcare reform debates, this legislation, whose full name is the Physician Payments Sunshine Act, requires companies to disclose on a public Website any gift to a physician whose value exceeds $10.00. That's not $10,000. That's $10.

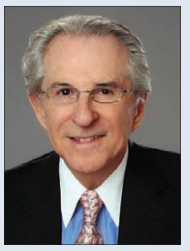
Dr. Thomas Stossel, a professor of medicine at Harvard Medical School, writing recently in the *Wall Street Journal*, points out that this lofty sum amounts to a box of bagels or donuts brought in by a sales representative for a lunch and learn. Regardless of who (if anyone) actually eats the bagels, the price must be posted on a public Website to reflect the representative's "gift."

Mr. President, do you really think that any doctor's prescribing decision will be influenced by a bagel? "Sorry, Jim, I'm taking a pass on prescribing your new heart drug. Your competition has an incredible pepperoni pizza." Give me a break! Can't you fathom how insulting such a petty regulation is to this esteemed profession?

What's next, making a federal rule prohibiting ballpoint pens with product logos on them? Banning tchotchkes? Oh, that's right, the Pharmaceutical Research and Manufacturers of America (PhRMA) voluntarily abandoned name-branded giveaways several years ago. They felt it cheapened the interaction between sales professionals and physicians.

Why didn't PhRMA ban bagels, too? Maybe because they realize there's absolutely no harm or undue influence created by bringing a token gift of food on a sales call. Far from cheapening a professional interaction, it humanizes it. In contrast, your "Sunshine" legislation does nothing to remove "conflicts of interest," but actually creates roadblocks between drug manufacturers and physicians. And this is a major problem because manufacturers are legally responsible for communicating the safe and effective use of their products!

Today, more and more doctors refuse to see industry representatives at all – not because they don't value their information, but because they don't want to be pilloried later by anti-pharma zealots. And how do these "no-see" doctors get their information about new drugs? Unfortunately, they often don't. Clinical trials are usually not published for many months after a new drug appears, and most doctors don't have the time to comb the literature for new discoveries. So they – and their patients – lose out.



As Dr. Stossel notes, "Such is the complexity of medical innovation that physicians' ability to keep up with it are dauntingly difficult. Keeping physicians up to date is extremely expensive. Yet if the [Sunshine Act] is implemented, hundreds of millions of dollars better applied to innovation and education will shift to "Sunshine" management."

The consequences of over-regulating healthcare are well known. For example, because some doctors carelessly or illegally prescribe narcotics, a labyrinth of federal regulations has been created, with the result that many physicians are wary about prescribing any scheduled drug because of the paperwork and potential scrutiny from regulators. Perhaps that's why, according to the Pain Foundation, chronic pain is notoriously undertreated in the United States, especially among the elderly and minorities.

I trust that your intention in creating the Sunshine act was not to impede manufacturer-physician interactions and thus create a stimulus program for accountants, malpractice and compliance lawyers, and bureaucrats. Yet, like so many decisions and policies of your administration, this act seems to be designed precisely to stifle the flow of information and further bloat the cadre of regulators.

No one is saying that conflicts of interest aren't a potential problem in any industry, but I am asserting that in seeking to uproot even the slightest hint of improper influence, you've gone totally overboard. You recently said it yourself, Mr. President, in the *Wall Street Journal*: "Where necessary, we won't shy away from addressing obvious gaps: new safety rules for infant formula; procedures to stop preventable infections in hospitals; efforts to target chronic violators of workplace safety laws. But we are also making it our mission to root out regulations that conflict, that are not worth the cost, or that are just plain dumb." (Emphasis added.)

Mr. President – the overzealous regulation of token gifts will not protect children, it will not prevent staph infections, it will make no workplace safer, and it will certainly not save money, but rather waste it.

Sometimes a bagel is just a bagel. But there's no doubt that your Sunshine Act is a lemon.

The CementBloc gathering soles

Healthcare advertising agency **The CementBloc** has teamed up with the nonprofit Coore Foundation in a campaign to send gently used shoes of all kinds to girls and boys in developing countries.

The Coore Foundation is a nonprofit organization whose primary goals are to provide education and resources designed to empower girls and build their self-esteem and to reduce HIV transmission among girls in developing countries. The CementBloc team is creating the branding and marketing communications for the organization.

The foundation's "The Healthy Sole Project" provides shoes for children throughout the world. Shoes are collected through mail in donations and also via designated drop-off locations throughout the United States. These shoes are then sent to countries where individuals cannot afford basic footwear. The foundation is particularly focused on providing children with appropriate shoes in order to prevent diseases and infections such as tetanus and polio. The children who receive these shoes live in poverty-stricken communities abroad, and are orphans or displaced and oftentimes have been devastated by war, diseases such as HIV/AIDS, and natural disasters.

CementBloc's Grow Soles campaign has appeared in posters and social media.

The foundation says that more than 3,000 shoes have been donated to children so far, and most have been donated by corporations, churches, and concerned citizens. The foundation had a key goal of providing shoes for 10,000 children between December 2009 and December 2010.

"The CementBloc is helping us making a meaningful impact on the lives of the children we serve," says Marie-Anne Coore, executive director of the Coore Foundation. "Their creative vision and commitment to the cause is bringing our cause to the forefront and I couldn't be happier with the work,"

For the Grow Sole project campaign, the agency merged the idea of shoes with soulfulness in true "360" fashion. The campaign is appearing on posters, print ads, postcards, and giant shoe donation bins around the world.

Elizabeth Elfenbein, partner, creative at The CementBloc, led the effort to launch the campaign. "Partnering with the Coore Foundation on Grow Sole has been extremely inspiring," she says. "I couldn't be more proud of the work and have been moved to go abroad with the foundation to volunteer on their next outreach program."

AGENCY PEOPLE ON THE MOVE

■ AbelsonTaylor

Adding to its digital capabilities, AbelsonTaylor (abelsontaylor.com) has promoted **Casey Lewis** to senior producer and hired **Kathleen Kirk** as interactive producer. As senior producer, Mr. Lewis, 27, will be responsible for overseeing digital and production projects, and coordinating the creative, account, and development teams. In his previous position as producer, he created interactive visual aids for the launch of treatments for acid reflux disease and type 2 diabetes.

In her new post as interactive producer, Ms. Kirk, 25, will be responsible for the creation of interactive visual aids for the treatment of lupus, hepatitis C, and infant nutrition. She has worked as a producer and consultant for several organizations, including Slingshot LLC, where she developed mobile applications using social media and created Websites for Jack Daniel's, Acai Liquor, and other accounts.

AbelsonTaylor has also hired **Lisa Rosselli** as senior interactive developer and **Chandana Reddy** as interactive developer—front end. Ms. Rosselli joins AbelsonTaylor from the Chicago offices of Digitas (now part of Publicis Healthcare Group), where she was senior software engineer, working on the development team for Maytag and Whirlpool global sites. Ms. Reddy comes to AbelsonTaylor from MarketSense, a B2B marketing agency, where she was a front-end web developer.

Travis Chandler is named interactive producer and **Matt Brown** becomes associate interactive producer. Mr. Chandler comes to AbelsonTaylor from his position as ingest supervisor and after effects artist at Found Films, a TV production company in Chicago that produces the A&E original series "The First 48: Missing Persons." Mr. Brown joins Abelson Taylor from his position as production coordinator at DreamWorks Animation SKG, an animation studio in Glendale, Calif., where he worked in the Lighting (CGI) and Layout (CGI) departments on the productions of "Kung Fu Panda 2" and "Rise of the Guardians."

■ Heartbeat Ideas

Alejandro Villageliu, a pharmaceutical marketing executive with more than 12 years of experience in consulting, HCP marketing, and sales strategy for pharmaceutical companies, has joined Heartbeat Ideas (heartbeatideas.com) as group account director. Prior to joining Heartbeat, Mr. Villageliu worked as VP/senior strategist at McCann Healthcare and as a manager at ZS Associates.

■ Ogilvy CommonHealth Worldwide

Neil Contess is named president, Ogilvy CommonHealth Consumer Care. Mr. Contess joins OCHCC with more than 25 years of agency experience, most recently as CEO and president of Euro RSCG Shake. He and his partners sold the entrepreneurial marketing shop they had founded (Shake) to Euro RSCG in 2007.

Also, Ogilvy CommonHealth Worldwide (ogilvychww.com) has announced the addition of **Iyiola Obayomi** as senior director, consulting at Ogilvy Healthworld's New York City office. In his new position, Mr. Obayomi will lead the consulting and analytics practices for Ogilvy Healthworld, including the exploration of new segmentations, channels, and platforms for healthcare media. He will also expand the analytics footprint of the group's current client base and develop new offerings designed to impact how pharmaceutical marketers use data and intelligence to drive marketing effectiveness. Some of Mr. Obayomi's most impressive vocational highlights include growing the Diageo analytics account tenfold while he served as VP, director of analytics at MRM Worldwide. While there, he was also responsible for the year-on-year account growth on the Lunesta account, using digital and CRM analytics to optimize and quantify campaign contributions.

■ Publicis Healthcare Communications Group

Publicis Touchpoint Solutions Inc., a provider of multichannel message delivery solutions for the life sciences industry, has announced that **Michelle Keefe** has joined the organization as chief operating officer. Publicis Touchpoint Solutions is a division of Publicis Healthcare Communications Group (publicishealthcare.com).

D&R acquires Lathian to create multichannel marketing agency

To meet a critical market need for a multichannel marketing agency that delivers a full suite of services, specialty direct marketing agency D&R Communications has acquired ePromotion provider Lathian Systems Inc., creating a new entity, **D&R Lathian**.

"With sales force reductions and patent cliffs, pharmaceutical companies are facing marketing challenges at almost every stage of the product lifecycle – from product launch to mid-stage to established brands working without reps," says Reide Rosen, D&R Communications co-founder and D&R Lathian partner. "These companies need a partner that can provide customized, strategic campaigns across numerous promotional channels to effectively reach physicians and positively influence prescribing behavior. D&R Lathian brings more than 20 years of pharmaceutical marketing experience and execution under one roof, enabling us to map our programs and recommendations to each client's goals for every product – with or without a sales force."

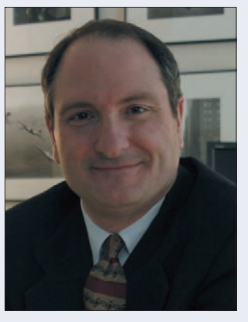
D&R Communications, founded in 1999 by David Schoonmaker and Reide Rosen, is an award-winning custom direct marketing agency with a history of developing innovative, strategic, and effective campaigns. Also founded in 1999 as MyDrugRep.com, Lathian Systems was the industry's first interactive e-detail provider to send physician response data to sales force automation/customer relationship management systems, and the first to produce Adobe Flash-based and KOL-video e-detailing programs.

"From initial joint projects with D&R, we saw firsthand that by combining forces, we will be filling an increasing market need for multichannel marketing that is customized to meet the needs of each client and result in positive ROI," says Quang Pham, Lathian founder and D&R Lathian partner.

The combined company, D&R Lathian, will enable pharmaceutical clients to target and reach professional, consumer, and sales force segments via a full range of printed and interactive digital tactics for Web and mobile, including custom strategic mail; e-detailing/interactive learning programs; e-newsletters, dynamic e-mail, and quick response microsites; and Physician Marketing Index, which offers customized reports drawn from a a proprietary database of millions of actual physician behavioral datasets and responses by therapeutic area, specialty, and channel.

"In order to reach physicians and impact brand performance, pharmaceutical marketers are challenged to look across all tactics in order to develop an ongoing strategy that meets both their sales goals and budget," says Quang Pham, Lathian founder and D&R Lathian partner. "From initial joint projects with D&R, we saw firsthand that by combining forces, we will be filling an increasing market need for multichannel marketing that is customized to meet the needs of each client and result in positive ROI."

Chinese acquisition for Publicis



"China is one of the fastest growing economies in the world, and UBS is a critical part of PHCG's footprint in this increasingly important market," says Nick Colucci, CEO and president of PHCG.

Publicis Groupe has acquired U-Link Business Solutions Co., one of the leading Chinese agencies specializing in healthcare communications. This acquisition is part of Publicis Groupe's commitment to expand its operations in Greater China.

Founded in 1997, U-Link Business Solutions employs about 170 people at its Shanghai headquarters and Beijing office. The agency offers PR, events management, medical association relationships and brand management, and marketing to its healthcare clients. UBS' multidisciplinary team and in-depth market intelligence ensure its global expertise and world-class best practice and innovation. Agency clients include companies such as Abbott, GenSci Pharmaceuticals, Johnson & Johnson, Novartis, Novo Nordisk, Pfizer, Roche, and Xian-Janssen. U-Link Business Solutions will become part of Publicis Healthcare Communications Group and will be renamed UBS Saatchi & Saatchi Health.

"China is one of the fastest growing economies in the world, and UBS is a critical part of PHCG's footprint in this increasingly important market" says Nick Colucci, CEO and president of PHCG. "Adding UBS to our portfolio brings the Saatchi & Saatchi Health flagship brand to China, and will make PHCG one of the largest healthcare communications groups in the region."

The UBS acquisition is a key move in strengthening PHCG's presence in Asia. In May 2011, PHCG acquired the Chinese agencies Beijing Dreams Advertising and Beijing Dreams Zhiyang Communication; in March 2011, the group acquired the India-based agency Watermelon. PHCG counts now 220 employees in greater China and is present through its agencies Publicis Life Brands Dreams, Publicis Life Brands China, and now UBS Saatchi & Saatchi Health.

U-Link Business Solutions co-founder and CEO Frank Xu will remain at the helm, taking the title of managing director and reporting directly to Ash Kuchel, president of PHCG Asia Pacific region.

"We are excited to be joining the world's leading healthcare network at such a pivotal time," Mr. Xu says. "Combining our best practices with the resources provided by the PHCG global network will help our agency stay one step ahead of the evolving Chinese market."

"We are delighted to welcome UBS into PHCG Asia Pacific – a critical step in reaching our rapid growth objective in China," Mr. Kuchel says. "In UBS, we have a world-class agency to take us to the next level in our China offering. Today's companies are taking a closer look at China's third- and fourth-tier cities and beyond. Adding on-the-ground expertise helps PHCG meet those demands.

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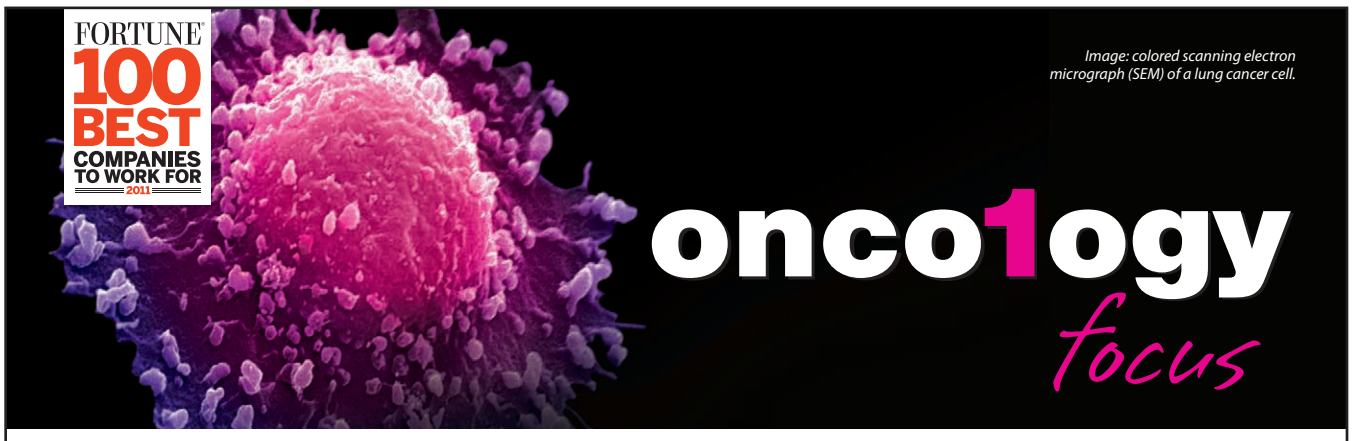

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Lead Brand Manager feedback

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