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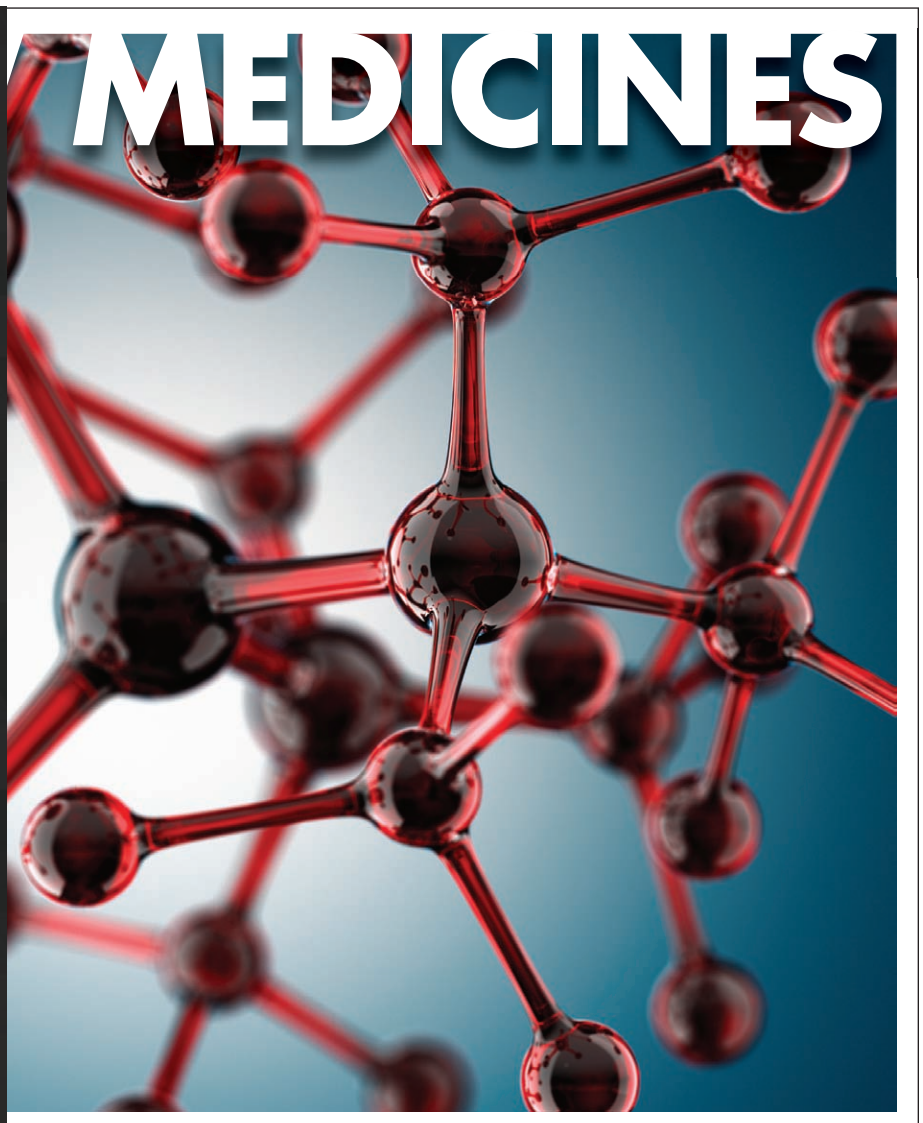

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The 39 NME/BLA approvals of 2012 include about a dozen oncology-related products. That grouping consists of **Perjeta**, a personalized medicine designed to specifically block the HER2 protein on the surface of some cancer cells. This **Roche/Genentech** biologic antibody is believed to work by attaching to HER2 receptors to stop signals that make tumor cells grow and divide, and additionally by signaling the body's immune system to destroy cancer cells. The drug is approved in combination with the Roche/Genentech mega-blockbuster **Herceptin** (trastuzumab) and docetaxel chemotherapy for treating individuals with HER2-positive metastatic breast cancer who have not received previous anti-HER2 therapy or chemotherapy for metastatic disease. Industry trackers have forecasted Perjeta global sales of nearly $2.5 billion for 2018.

Another anticipated annual billion-dollar sales generator from the Class of 2012 New Medicines is **Xeljanz**. Composed of the active ingredient tofacitinib, the new drug was FDA-approved for treating adults with moderately to severely active rheumatoid arthritis (RA) who have had an inadequate response or intolerance to methotrexate. The **Pfizer** product represents the first approved RA treatment in a new class of medicines called Janus kinase (JAK) inhibitors and the first new oral disease-modifying antirheumatic drug for the disease in more than a decade. Xeljanz is available as a second-line medicine

continued on page 8

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ow to leverage technology, automation, and data to deliver a high touch strategy
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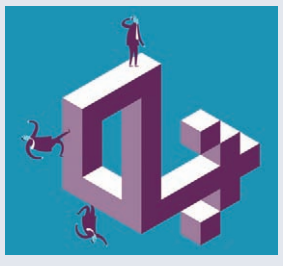
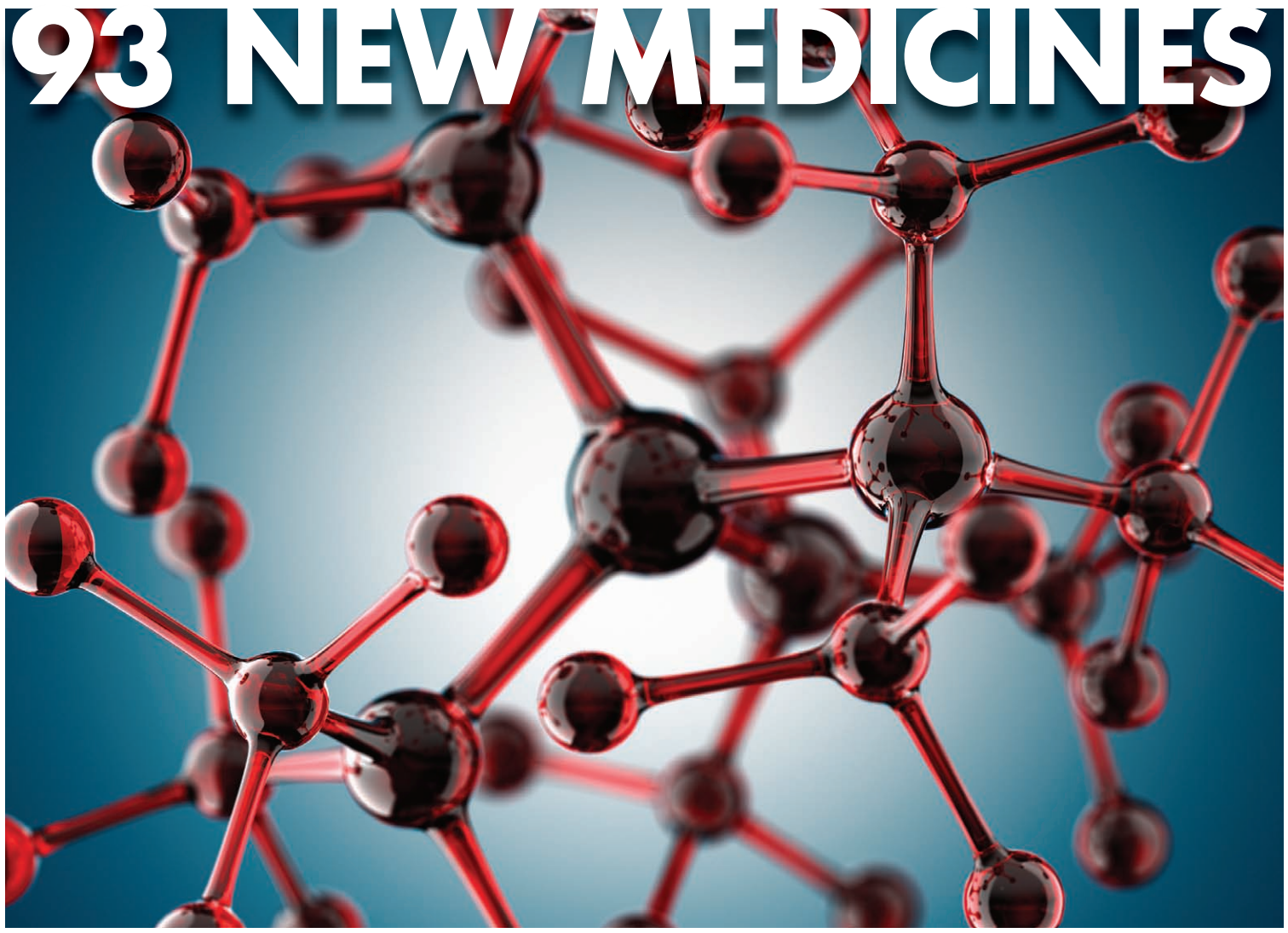
IN THIS ISSUE:



93 NEW MEDICINES



FDA during 2012 approved 39 new molecular entities, the highest amount in one year since 1997.

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

U.S. regulators last year approved for marketing 93 new medicines according to *Med Ad News* criteria. This figure represents an additional 13 products versus the 2011 amount of 80. Previous years' totals of new drug approvals by the Food and Drug Administration numbered 88 in 2010, 92 during 2009, 85 for 2008, and 73 in 2007.

The total of approved new molecular entities (NMEs) filed under new drug applications and therapeutic biologics submitted through original biologic license applications (BLAs) rose to 39 during 2012 compared to 30 in 2011. The Food and Drug Administration's Center for Drug Evaluation and Research gave the green light to 21 NMEs/BLAs in 2010, 26 for 2009, 24 during 2008, and 18 in 2007. The 2012 amount was the highest since 39 new molecular entities were approved in 1997, which followed a one-year record of 53 during 1996.

The recent two-year increase in NME approvals is significant during which time the industry has experienced the patent-expiration losses of some of the best-selling prescription medicines ever. Total U.S. brand-drug sales reportedly declined in 2012 as generic competition increased and the average internal rate of return from the leading pharma companies' R&D decreased.

The 39 NME/BLA approvals of 2012 include about a dozen oncology-related products. That grouping consists of **Perjeta**, a personalized medicine designed to specifically block the HER2 protein on the surface of some cancer cells. This **Roche/Genentech** biologic antibody is believed to work by attaching to HER2 receptors to stop signals that make tumor cells grow and divide, and additionally by signaling the body's immune system to destroy cancer cells. The drug is approved in combination with the Roche/Genentech mega-blockbuster **Herceptin** (trastuzumab) and docetaxel chemotherapy for treating individuals with HER2-positive metastatic breast cancer who have not received previous anti-HER2 therapy or chemotherapy for metastatic disease. Industry trackers have forecasted Perjeta global sales of nearly $2.5 billion for 2018.

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continued on page 8

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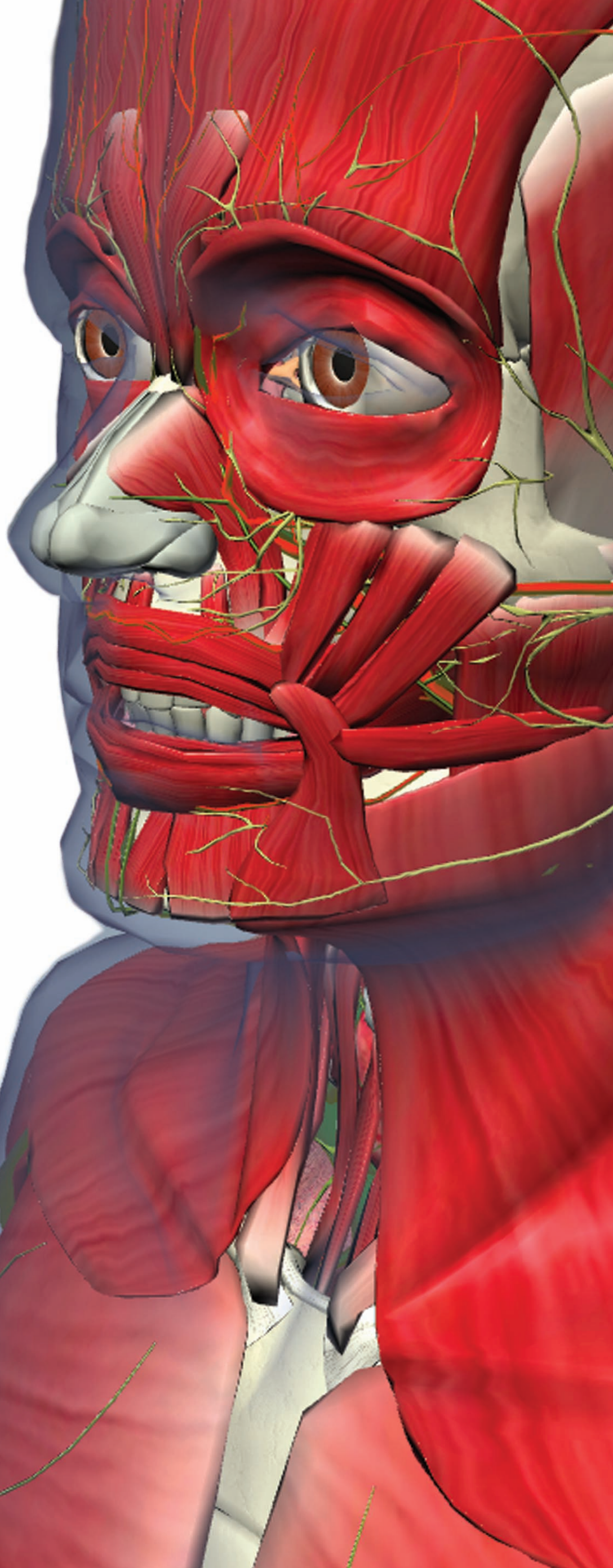

tothepoint

By Christiane Truelove chris.truelove@ubm.com

RXWiki's use of the meme also got me thinking about whether a pharmaceutical company could do something like that, or should. And my reaction to that thought, to quote another meme, is "NOPE NOPE NOPE NOPE."

If you are like me, and you spend a significant amount of time online, you are aware of Internet memes. Recently, I got tagged on Twitter by a company that wanted me to view their version of the Harlem Shake meme. RxWiki, a Texas-based company that has a network that provides drug information to pharmacists, calls it "PharmaShake."

If you're unfamiliar with the meme, it's a very short video in which Baauer's song "Harlem Shake" plays and people dance. According to the AP, there are 4,000 or so Harlem Shake videos being uploaded to YouTube each day. In the first part of every Harlem Shake video, one person dressed in a crazy costume dances around while the rest of the people stand or sit quietly, ignoring the dancer. Then the bass drops, there's a jump cut, and everyone is dancing, wearing costumes and holding kooky props (in RxWiki's case, it was giant Google+, Twitter, Pinterest, and Facebook symbols). RxWiki did the video in conjunction with their new "Social Media-as-a-Service" offering that allows pharmacists to share information about drugs with patients across social media networks.

But my first thought after watching the video was, "Why?"

I have no idea who this video was aimed at – was it meant for pharmacists, pharma industry people, or patients? And what was the message, exactly? "We are online and are aware of the Internet cool stuff"? Except it's not so cool – the meme is pretty much over, the sign that the end is near because "The Simpsons" recently spoofed it in the beginning credits (with "Homer Shake."). But even if the trend wasn't being close to played out, the message being offered by the video was still not very apparent. So, as a message about the company itself, it was a fail.

RxWiki's use of the meme also got me thinking about whether a pharmaceutical company could do something like that, or should. And my reaction to that thought, to quote another meme, is "NOPE NOPE NOPE NOPE."

Although pharma needs to build a better relationship with patients, and social media outreach can be a great tool for doing so, hopping on a meme train would not be the way to do it. If I am a patient looking for information about my disease, finding a series of LOLCATS pictures of "I can haz drugz nao?" or videos of sales reps doing the Harlem Shake would be disconcerting, to say the least. Fortunately, although pharma has been fairly cautious about its online interactions, the material that companies are providing through social media is valuable. Infographics about breast cancer survival on Pinterest, videos on how to spot counterfeit drugs, YouTube channels devoted to specific diseases, all of these and more can be found by people wanting to understand more about their conditions and the medicines that they take. Some of the top pharmaceutical companies are on Facebook, sharing news and information geared towards patients with diabetes, cystic fibrosis, hemophilia, epilepsy, influenza, and multiple sclerosis. Many companies can be found on Twitter, officially sharing news and information – though this medium is less geared towards patients than journalists.

Though the content provided by pharma may not be "viral video" material, it serves a purpose beyond mere entertainment.

Pharma companies also have to be careful about appearing as if they are talking about the use or effectiveness of their products off label. Even though the U.S. 2nd Circuit Court ruled that "truthful" communication about off-label use is covered under the First Amendment, no one is rushing to revamp their marketing materials, as shown in the story on page 24.

What some industry observers believe, however, is that the decision will give companies more latitude to engage in online conversations about off-label use, providing data and information. The prevailing attitude is, "Why is it all right for others to talk about using our drugs off label, but we can't step into a conversation with information?"

This all sounds reasonable – considering that in many cases, off-label use is the standard of care for a product, and if a company can offer information and data that can help patients, they should be allowed to speak up. They won't be able to initiate conversations about off-label use, but they should be able to respond to questions from physicians or, if they notice a Twitter conversation in which clinicians are discussing off-label usage, they should be able to join the conversation and contribute their knowledge – so long as the communications are truthful and not misleading.

I'm pretty sure what these conversations won't turn into is a Harlem Shake free-for-all where the messages are as confusing as the popularity of the meme itself.

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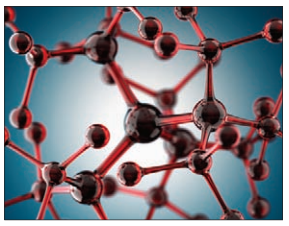
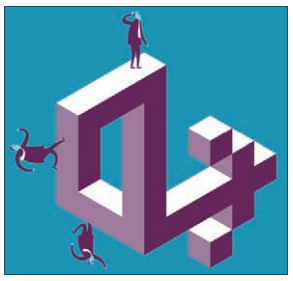
inside



ON THE COVER

SPECIAL REPORT: NEW MEDICINES • 93 NEW MEDICINES
FDA during 2012 approved 39 new molecular entities, the highest amount in one year since 1997.

FEATURES



DEPARTMENTS

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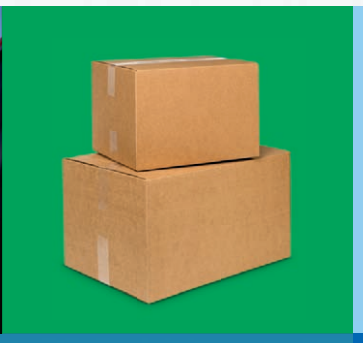

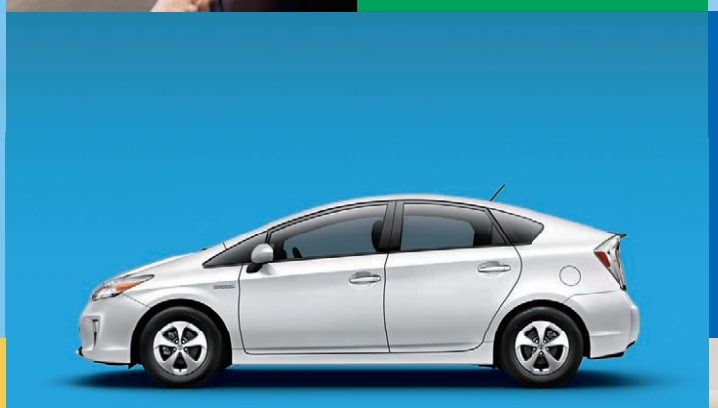

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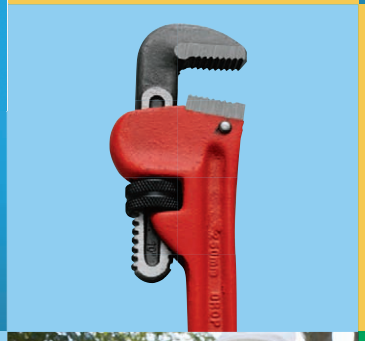

prius *v*
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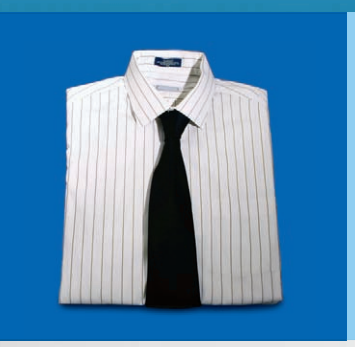
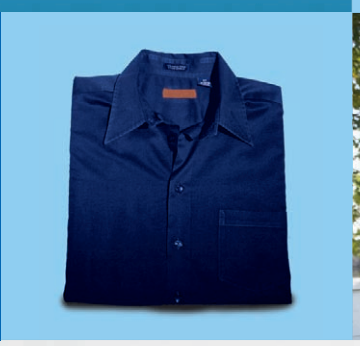
More than most small SUVs.[3]





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Options shown. [1]2012 EPA combined estimated 95 miles per gallon gasoline equivalent rating. MPGe includes consumption of electricity and gasoline energy during EV Mode. Actual results will vary. See fueleconomy.gov. [2]Cargo and load capacity limited by weight and distribution. [3]Based on manufacturers' data for cargo volume behind second-row seats; MY 2012 Small SUV segment.

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WHAT'S ONLINE

WEBCAST:
HOW TO LEVERAGE TECHNOLOGY, AUTOMATION, AND DATA TO DELIVER A HIGH TOUCH STRATEGY

March 20th • 12 PM ET

This webinar brings together three experts from different domains - commercial operations, RM strategy, and marketing technology - to outline the key steps needed to build scalable marketing programs in a new era of data-driven marketing. A personalized, high touch approach is now essential to address customer needs, yet few life sciences marketing organizations are fully equipped to execute this model in a way that is sustainable and delivers measurable returns to the business. The webinar will outline the key ingredients for marketing leadership in the future, with particular focus on how to apply automation to manage the customer experience, use data to plan and optimize campaigns, and identify gaps in the organization's current marketing technology capabilities to mitigate competitive threats and ensure effective performance in 2013 and beyond.

Go to http://bit.ly/W97Qoz to register for this Webcast

WHAT'S IN PRINT

IN THE TWILIGHT ZONE

The Caronia decision was excitedly hailed as a breakthrough for pharmaceutical marketing, but industry observers say as FDA continues business as usual, pharma companies are not changing their tactics—though the ruling could open the way for the industry to engage in online conversations.

Go to page 24

CIOS SEE MOBILITY AS PRIMARY CHANNEL FOR CUSTOMER ENGAGEMENT

Demonstrating the growing importance of incorporating mobility into enterprises, CIO respondents to an Accenture survey believe mobility will generate significant sources of new revenue for their businesses, and most will invest between 31 and 40 percent of their discretionary budgets to achieve that goal, compared with just 19 percent of CIOs surveyed last year.

Go to page 28

HAVAS TAPS WEBMD VETERAN TO LEAD NEW YORK AGENCY

The agency network Havas Health has named Dorothy Gemmell, a long-time WebMD executive, to lead the network's Havas Life New York office.

Go to page 29

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continued from page 1

for rheumatoid arthritis, thus treatment with a biologic is not necessary before taking it. Various analyst firms have projected more than $1-plus billion in global Xeljanz sales by 2016.

Approved by FDA in August 2012, the HIV medicine **Stribild** has been predicted to approach $3 billion in 2018 global sales. Marketed by **Gilead** Sciences, the complete once-daily single tablet regimen is intended for HIV-1 infection for treatment-naïve adults. Stribild unites four drug compounds in one daily tablet: the integrase inhibitor elvitegravir, the pharmacoenhancing agent cobicistat, and the nucleoside analog reverse transcriptase inhibitors emtricitabine and tenofovir disoproxil fumarate.

Perhaps the medicine with the highest annual sales potential to be cleared for marketing during 2012 is **Eliquis**. Approved by the U.S. regulatory agency in late December 2012, Eliquis is intended to reduce the risk of stroke and systemic embolism in patients with nonvalvular atrial fibrillation. Containing the active chemical apixaban, the oral Factor Xa inhibitor anticoagulant is jointly marketed by Pfizer and **Bristol-Myers Squibb**. By inhibiting the key blood clotting protein Factor Xa, Eliquis decreases thrombin generation as well as blood-clot formation. Some industry insiders have projected more than $4.7 billion in 2018 global sales for the drug. For more details about Eliquis, please see the *Med Ad News* Best New Medicine story on page 14.

In addition to Xeljanz and Eliquis, the world's largest research-based pharma company Pfizer is the marketer behind several other new molecular entities approved during 2012. **Bosulif** (bosutinib) was approved for treating adult patients with chronic, accelerated, or blast phase Philadelphia chromosome-positive chronic myelogenous leukemia (CML) with resistance, or intolerance to prior therapy. This kinase inhibitor limits its cancer cell growth by inhibiting the Abl and Src signaling pathways. The once-daily medicine represents the only therapy FDA-approved with pivotal clinical-study data that included CML patients treated with imatinib followed by a second-generation tyrosine kinase inhibitor.

Another Pfizer orphan drug cleared for approval by U.S. regulators during 2012 was **Elelyso** (taliglucerase alfa). The product is available for long-term enzyme replacement therapy to treat a form of Gaucher disease, a rare genetic disorder. Elelyso injection replaces the missing enzyme in patients with a confirmed diagnosis of Type 1 (non-neuropathic) Gaucher disease. This represents the first FDA-approved plant cell-based enzyme replacement therapy for Gaucher disease. Elelyso additionally is the first approved plant cell-expressed drug derived from **ProCellEx**, a proprietary manufacturing system from **Protalix** BioTherapeutics that uses genetically engineered carrot cells.

> FDA during 2012 cleared the most NME approvals (39) in one year since 1997.

The kinase inhibitor **Inlyta** was approved by FDA during January 2012 for patients with a type of advanced kidney cancer. The medicine is available for treating advanced renal cell carcinoma (RCC) after failure of one prior systemic therapy. The Pfizer oral therapy is designed to inhibit tyrosine kinases, including vascular endothelial growth factor (VEGF) receptors 1, 2 and 3. Those three receptors can influence tumor growth, vascular angiogenesis, as well as progression of cancer (the spread of tumors).

Pfizer launched **Quillivant XR** in the United States during January 2013 for treating attention deficit hyperactivity disorder. This is the first once-daily, extended-release liquid methylphenidate for ADHD. Quillivant XR gained U.S. regulatory clearance in September 2012 for ADHD patients aged 6 years and older. The product was developed in alliance with **NextWave** Pharmaceuticals' manufacturing partner **Tris** Pharma using the latter's patent-protected drug-delivery platform. NextWave was acquired by Pfizer on Nov. 27, 2012.

An oral suspension formulation of **Revatio** was FDA-approved on Aug. 30, 2012. The new formulation is indicated for treating pulmonary arterial hypertension (WHO Group 1) in adults to improve exercise ability and delay clinical worsening. Revatio was first approved by U.S. regulators in tablet form during June 2005, and an injectable version was given marketing clearance in November 2009. This Pfizer product line generated 2012 global sales of $534 million.

Stendra's U.S. clearance during April 2012 represents the first new prescription medicine approved by FDA in nearly a decade for erectile dysfunction. Containing the main ingredient avanafil, the phosphodiesterase type 5 inhibitor is available as a tablet for the roughly 30 million American men suffering from ED. Licensed from **Mitsubishi Tanabe** Pharma, **Vivus** holds global (except certain Asian Pacific Rim countries) development and commercial rights to Stendra for treating sexual dysfunction. The product is marketed in South Korea by **JW** Pharma under the trade name **Zepeed**.

Myrbetriq is the first approved oral overactive bladder treatment with a distinct mechanism of action since the market introduction of anticholinergic agents roughly 30 years earlier. Composed of mirabegron, the extended-release tablet drug was cleared in April 2012 for treating overactive bladder with symptoms of urge urinary incontinence, urgency and urinary frequency. The once-per-day beta-3 adrenergic agonist was discovered and developed by **Astellas** Pharma. Myrbetriq was studied extensively in more than 10,000 individuals over a decade. The product offers a new treatment option for OAB patients as antimuscarinics serve as the current treatment standard. Antimuscarinics function by binding to muscarinic receptors in the bladder and inhibiting involuntary bladder contractions. Myrbetriq relaxes the detrusor smooth muscle during the storage phase of the urinary bladder fill-void cycle by activation of beta-3 adrenergic receptors that improves bladder capacity.

Another April 2012 approval by the Food and Drug Administration was **Amyvid**, the first radioactive diagnostic agent cleared for PET imaging of beta-amyloid neuritic plaques in the living brain. Amyvid is indicated for brain imaging of beta-amyloid plaques in patients with cognitive impairment who are being evaluated for Alzheimer's disease and other cognitive decline causes. Amyvid binds to amyloid plaques, a hallmark characteristic of AD, and is detected via PET scan images of the brain. **Eli Lilly** and its wholly owned subsidiary **Avid** Radiopharmaceuticals announced the product's U.S. launch on June 1, 2012. ■ MEDADNEWS

NOTES AND METHODOLOGY

This annual special report features the new prescription medicines approved in the United States during 2012. The information was gathered from pharmaceutical/biotechnology companies, the Food and Drug Administration, and the files of *Med Ad News*. The 93 new medicines detailed in this special report were approved by FDA regulators through a new drug application or biologics license application.

The new medicines may include new molecular entities, biotechnology drugs, biologicals, imaging agents, branded generic drugs, and branded new formulations of existing products. Exclusions from this list include medical devices, nonbranded generic drugs approved via an abbreviated new drug application, over-the-counter drugs, tentative approvals, and new indications for already-marketed drugs. All medicines were approved for U.S. marketing from Jan. 1, 2012, through Dec. 31, 2012.

2012'S NEW MEDICINE APPROVALS BY THE U.S. FOOD AND DRUG ADMINISTRATION

Product Name	Active Chemical	Approved Indication(s)	2012 FDA Approval Date	U.S. Developer/Marketer
Absorica	Isotretinoin	Absorica is indicated for the treatment of severe recalcitrant nodular acne in patients 12 years old or older.	May 25	Developer: Cipher Pharmaceuticals Marketer: Ranbaxy Pharmaceuticals
Adasuve	Loxapine	Adasuve is indicated for the acute treatment of agitation associated with schizophrenia or bipolar disorder.	Dec. 21	Alexza Pharmaceuticals
Adrenalin	Epinephrine	Adrenalin is indicated for the emergency treatment of allergic reactions (Type I) – including anaphylaxis – which may result from allergic reactions to insect stings, biting insects, foods, drugs, sera, diagnostic testing substances and other allergens, as well as idiopathic anaphylaxis or exercise-induced anaphylaxis (the signs and symptoms associated with anaphylaxis include hypotension, airway swelling, laryngospasm, bronchospasm, urticaria, pruritus, angioedema, swelling of the eyelids, lips, and tongue, vomiting, diarrhea and abdominal cramps); and for the induction and maintenance of mydriasis during intraocular surgery.	Dec. 7	JHP Pharmaceuticals
Afinitor Disperz	Everolimus	Afinitor Disperz is indicated in pediatric and adult patients with tuberous sclerosis complex for the treatment of subependymal giant cell astrocytoma that requires therapeutic intervention but cannot be curatively resected.	Aug. 29	Novartis Pharmaceuticals
Amyvid	Florbetapir F 18	Amyvid is indicated for positron emission tomography imaging of the brain to estimate amyloid neuritic plaque density in adult patients with cognitive impairment who are being evaluated for Alzheimer's disease and other causes of cognitive decline.	April 6	Developer: Avid Radiopharmaceuticals Marketer: Eli Lilly
Argatroban Injection 100mg/mL	Argatroban	Argatroban Injection 100mg/mL is indicated for the prevention and 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..	Jan. 5	Developer: Exela Pharma Sciences Marketer: Hikma Pharmaceuticals
Aubagio	Teriflunomide	Aubagio is indicated for the treatment of patients with relapsing forms of multiple sclerosis.	Sept. 12	Developers: Sanofi US and Genzyme Marketer: Genzyme
Auvi-Q	Epinephrine	Auvi-Q is indicated for the emergency treatment of allergic reactions (Type I) including anaphylaxis.	Aug. 10	Developer: Intelliject Marketer: Sanofi US
Belviq	Lorcaserin hydrochloride	Belviq is indicated as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adults with an initial body mass index of 30 kg/m2 or greater (obese) or 27 kg/m2 or greater (overweight) in the presence of at least one weight-related comorbid condition, (e.g., hypertension, dyslipidemia, type 2 diabetes).	June 27	Developer: Arena Pharmaceuticals Marketer: Eisai
Bethkis	Tobramycin	Bethkis is indicated for the management of cystic fibrosis patients with *Pseudomonas aeruginosa*.	Oct. 12	Developer: Chiesi Pharmaceuticals Marketer: Cornerstone Therapeutics
Binosto	Alendronate sodium	Binosto is indicated for the treatment of osteoporosis in postmenopausal women; and as a treatment to increase bone mass in men with osteoporosis.	March 12	Developer: EffRx Pharmaceuticals Marketer: Mission Pharmacal

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2012'S NEW MEDICINE APPROVALS BY THE U.S. FOOD AND DRUG ADMINISTRATION

Product Name	Active Chemical	Approved Indication(s)	2012 FDA Approval Date	U.S. Developer/Marketer
Bio-T-Gel	Testosterone	Bio-T-Gel is indicated for replacement therapy in males for conditions associated with a deficiency or absence of endogenous testosterone.	Feb. 14	Developers: Teva Pharmaceuticals USA and BioSante Pharmaceuticals Marketer: Teva Pharmaceuticals USA
Bivigam	Immune globulin (human)	Bivigam is indicated for treatment of primary humoral immunodeficiency.	Dec. 19	Biotest Pharmaceuticals
Bosulif	Bosutinib	Bosulif is indicated for the treatment of adult patients with chronic, accelerated, or blast phase Philadelphia chromosome-positive chronic myelogenous leukemia with resistance or intolerance to prior therapy.	Sept. 4	Pfizer
Bydureon	Exenatide synthetic	Bydureon is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus in multiple clinical settings.	Jan. 27	Developers: Amylin Pharmaceuticals and Alkermes Marketer: Amylin Pharmaceuticals
Choline C 11 Injection	Choline C 11	Choline C 11 Injection is indicated for positron emission tomography imaging of patients with suspected prostate cancer recurrence and non-informative bone scintigraphy, computerized tomography, or magnetic resonance imaging.	Sept. 12	Mayo Clinic PET Radiochemistry Facility (MCPRF)
Cometriq	Cabozantinib	Cometriq is indicated for the treatment of patients with progressive, metastatic medullary thyroid cancer.	Nov. 29	Exelixis
Cosopt PF	Dorzolamide hydrochloride and timolol maleate	Cosopt PF is indicated for the reduction of elevated intraocular pressure in patients with open-angle glaucoma or ocular hypertension who are insufficiently responsive to beta-blockers.	Feb. 1	Merck & Co.
Cystaran	Cysteamine hydrochloride	Cystaran is indicated for the treatment of corneal cystine crystal accumulation in patients with cystinosis.	Oct. 2	Sigma-Tau Pharmaceuticals
Docetaxel Injection 40 mg/mL	Docetaxel	Docetaxel Injection 40 mg/mL is indicated for the treatment of patients with locally advanced or metastatic breast cancer after failure of prior chemotherapy; in combination with doxorubicin and cyclophosphamide as adjuvant treatment of patients with operable node-positive breast cancer; as a single agent for the treatment of patients with locally advanced or metastatic non-small cell lung cancer after failure of prior platinum-based chemotherapy; in combination with cisplatin for the treatment of patients with unresectable, locally advanced or metastatic non-small cell lung cancer who have not previously received chemotherapy for this condition; in combination with prednisone for the treatment of patients with androgen independent (hormone refractory) metastatic prostate cancer; in combination with cisplatin and fluorouracil for the treatment of patients with advanced gastric adenocarcinoma, including adenocarcinoma of the gastroesophageal junction, who have not received prior chemotherapy for advanced disease; and in combination with cisplatin and fluorouracil for the induction treatment of patients with locally advanced squamous cell carcinoma of the head and neck.	Jan. 11	Apotex
Dymista	Azelastine hydrochloride and fluticasone propionate	Dymista is indicated for the relief of symptoms of seasonal allergic rhinitis in patients 12 years old or older who require treatment with both azelastine hydrochloride and fluticasone propionate for symptomatic relief.	May 1	Meda Pharmaceuticals
Elelyso	Taliglucerase alfa	Elelyso is indicated for long-term enzyme replacement therapy for adults with a confirmed diagnosis of Type 1 Gaucher disease.	May 1	Developers: Protalix BioTherapeutics and Pfizer Marketer: Pfizer
Eliquis	Apixaban	Eliquis is indicated to reduce the risk of stroke and systemic embolism in patients with nonvalvular atrial fibrillation.	Dec. 28	Bristol-Myers Squibb and Pfizer
Erivedge	Vismodegib	Erivedge is indicated for the treatment of adults with metastatic basal cell carcinoma, or with locally advanced basal cell carcinoma that has recurred following surgery or who are not candidates for surgery, and who are not candidates for radiation.	Jan. 30	Genentech
Evarrest	Fibrin sealant	Evarrest is indicated for use with manual compression as an adjunct to hemostasis for soft tissue bleeding during open retroperitoneal, intra-abdominal, pelvic, and non-cardiac thoracic surgery when control of bleeding by standard surgical methods of hemostasis (e.g., suture, ligature, cautery) is ineffective or impractical.	Dec. 5	Developer: Omrix Biopharmaceuticals Marketer: Ethicon
Fabior	Tazarotene	Fabior indicated for the topical treatment of acne vulgaris in patients 12 years old or older.	May 11	Stiefel
Flucelvax	Influenza virus vaccine	Flucelvax, an inactivated vaccine, is indicated for active immunization for the prevention of influenza disease caused by influenza virus subtypes A and type B contained in the vaccine in persons 18 years old or older.	Nov. 20	Novartis Vaccines
Fulyzaq	Crofelemer	Fulyzaq is indicated for the symptomatic relief of non-infectious diarrhea in adult patients with HIV/AIDS on anti-retroviral therapy.	Dec. 31	Salix Pharmaceuticals
Fycompa	Perampanel	Fycompa is indicated as adjunctive therapy for the treatment of partial-onset seizures with or without secondary generalized seizures in patients with epilepsy 12 years old or older.	Oct. 22	Eisai
Gattex	Teduglutide	Gattex is indicated for the treatment of patients with short bowel syndrome who are dependent on parenteral nutrition.	Dec. 21	NPS Pharmaceuticals
Giazo	Balsalazide disodium	Giazo is indicated for the treatment of mildly to moderately active ulcerative colitis in male patients 18 years or older.	Feb. 3	Salix Pharmaceuticals
Iclusig	Ponatinib	Iclusig is indicated for the treatment of adult patients with Philadelphia chromosome-positive acute lymphoblastic leukemia that is resistant or intolerant to prior tyrosine kinase inhibitor therapy; and for the treatment of adult patients with chronic phase, accelerated phase, or blast phase chronic myeloid leukemia that is resistant or intolerant to prior tyrosine kinase inhibitor therapy.	Dec. 14	Ariad Pharmaceuticals
Ilevro	Nepafenac	Ilevro is indicated for the treatment of pain and inflammation associated with cataract surgery.	Oct. 16	Alcon
Inlyta	Axitinib	Inlyta is indicated for the treatment of advanced renal cell carcinoma after failure of one prior systemic therapy.	Jan. 27	Pfizer
Janumet XR	Sitagliptin phosphate and metformin hydrochloride	Janumet XR is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus when treatment with both sitagliptin and metformin extended-release is appropriate.	Feb. 2	Merck & Co.
Jentadueto	Linagliptin and metformin hydrochloride	Jentadueto is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus when treatment with both linagliptin and metformin is appropriate.	Jan. 30	Boehringer Ingelheim Pharmaceuticals and Eli Lilly
Jetrea	Ocriplasmin	Jetrea is indicated for the treatment of symptomatic vitreomacular adhesion.	Oct. 17	ThromboGenics
Juxtapid	Lomitapide	Juxtapid is indicated as an adjunct to a low-fat diet and other lipid-lowering treatments, including low-density lipoprotein apheresis where available, to reduce low-density lipoprotein cholesterol, total cholesterol, apolipoprotein B, and non-high density lipoprotein cholesterol in patients with homozygous familial hypercholesterolemia.	Dec. 21	Aegerion Pharmaceuticals
Kalydeco	Ivacaftor	Kalydeco is indicated for the treatment of cystic fibrosis in patients 6 years old or older with the G551D mutation in the CFTR gene.	Jan. 31	Vertex Pharmaceuticals
Korlym	Mifepristone	Korlym is indicated to control hyperglycemia secondary to hypercortisolism in adult patients with endogenous Cushing's syndrome who have type 2 diabetes mellitus or glucose intolerance and have failed surgery or are not candidates for surgery.	Feb. 17	Corcept Therapeutics
Kyprolis	Carfilzomib	Kyprolis is indicated for the treatment of patients with multiple myeloma who have received at least two prior therapies including bortezomib and an immunomodulatory agent and have demonstrated disease progression on or within 60 days of completion of the last therapy.	July 20	Onyx Pharmaceuticals
Linzess	Linaclotide	Linzess is indicated for the treatment of irritable bowel syndrome with constipation and for the treatment of chronic idiopathic constipation.	Aug. 30	Ironwood Pharmaceuticals and Forest Laboratories

2012'S NEW MEDICINE APPROVALS BY THE U.S. FOOD AND DRUG ADMINISTRATION

Product Name	Active Chemical	Approved Indication(s)	2012 FDA Approval Date	U.S. Developer/Marketer
Lotemax Gel	Loteprednol etabonate	Lotemax Gel is indicated for the treatment of postoperative inflammation and pain following ocular surgery.	Sept. 28	Bausch & Lomb Pharmaceuticals
Lupaneta Pack	Leuprolide acetate and norethindrone acetate	Lupaneta Pack is indicated for initial management of the painful symptoms of endometriosis and for the management of recurrence of symptoms..	Dec. 14	Abbott Laboratories
Marqibo	Vincristine sulfate	Marqibo is indicated for the treatment of adult patients with Philadelphia chromosome-negative acute lymphoblastic leukemia in second or greater relapse or whose disease has progressed following two or more anti-leukemia therapies.	Aug. 9	Talon Therapeutics
MenHibrix	Meningococcal Groups C and Y and Haemophilus b Tetanus Toxoid Conjugate Vaccine	MenHibrix is indicated for the active immunization for the prevention of invasive diseases caused by *Neisseria meningitidis* serogroups C and Y and *Haemophilus influenzae* type b in children aged 6 weeks through 18 months old.	June 14	GlaxoSmithKline
Minivelle	Estradiol	Minivelle is indicated for the treatment of moderate-to-severe vasomotor symptoms due to menopause.	Oct. 29	Noven Pharmaceuticals
Mitosol	Mitomycin	Mitosol is indicated for use as an adjunct to ab externo glaucoma surgery.	Feb. 7	Mobius Therapeutics
Myrbetriq	Mirabegron	Myrbetriq is indicated for the treatment of overactive bladder with symptoms of urge urinary incontinence, urgency, and urinary frequency.	June 28	Astellas Pharma US
Nucynta Oral Solution	Tapentadol hydrochloride	Nucynta Oral Solution is indicated for the management of moderate-to-severe acute pain in adults.	Oct. 15	Developers: Johnson & Johnson Pharmaceutical Research & Development and Grunenthal Marketer: Janssen Pharmaceuticals
Omontys	Peginesatide	Omontys is indicated for the treatment of anemia associated with chronic renal failure in adult patients on dialysis.	March 27	Affymax and Takeda Pharmaceuticals America
Onfi Oral Suspension	Clobazam	Onfi Oral Suspension is indicated for the adjunctive treatment of seizures associated with Lennox-Gastaut syndrome in patients aged 2 years old or older.	Dec. 14	Lundbeck
Oxtellar XR	Oxcarbazepine	Oxtellar XR is indicated as adjunctive therapy for the treatment of partial onset seizures in children 6 years to 17 years old.	Oct. 19	Supernus Pharmaceuticals
Oxycodone Hydrochloride Oral Solution USP 5 mg/5 mL	Oxycodone hydrochloride	Oxycodone Hydrochloride Oral Solution USP 5 mg/5 mL is indicated for the management of moderate-to-severe acute and chronic pain where the use of an opioid analgesic is appropriate.	Jan. 12	VistaPharm
Perjeta	Pertuzumab	Perjeta, in combination with trastuzumab and docetaxel, is indicated for the treatment of patients with HER2-positive metastatic breast cancer who have not received prior anti-HER2 therapy or chemotherapy for metastatic disease.	June 8	Genentech
Pertzye	Pancrelipase	Pertzye is indicated for the treatment of exocrine pancreatic insufficiency due to cystic fibrosis or other conditions.	May 17	Digestive Care
Phenylephrine Hydrochloride	Phenylephrine hydrochloride	Phenylephrine Hydrochloride is indicated for increasing blood pressure in adults with clinically important hypotension resulting primarily from vasodilation, in such settings as septic shock or anesthesia.	Dec. 20	West-Ward Pharmaceuticals
Picato	Ingenol mebutate	Picato is indicated for the topical treatment of actinic keratosis.	Jan. 23	Leo Pharma
Prepopik	Sodium picosulfate, magnesium oxide and citric acid	Prepopik is indicated for cleansing of the colon as a preparation for colonoscopy in adults.	July 16	Ferring Pharmaceuticals
Qnasl	Beclomethasone diproprionate hydrofluroalkane	Qnasl is indicated for the treatment of nasal symptoms associated with seasonal allergic rhinitis in adults and adolescents 12 years old or older; and for the treatment of nasal symptoms associated with perennial allergic rhinitis in adults and adolescents 12 years old or older.	March 23	Teva Respiratory
Qsymia	Phentermine and topiramate	Qsymia is indicated as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adults with an initial body mass index (BMI) of 30 kg/m2 or greater (obese) or 27 kg/m2 or greater (overweight) when accompanied by weight-related co-morbidities such as hypertension, type 2 diabetes mellitus, or dyslipidemia.	July 17	Vivus
Quillivant XR	Methylphenidate hydrochoride	Quillivant XR is indicated for the treatment of attention deficit hyperactivity disorder.	Sept. 27	Developers: NextWave Pharmaceuticals and Tris Pharma Marketer: Pfizer
Raxibacumab	Raxibacumab	Raxibacumab is indicated for the treatment of adult and pediatric patients with inhalational anthrax due to *Bacillus anthracis* in combination with appropriate antibacterial drugs; and for the prophylaxis of inhalational anthrax when alternative therapies are not available or are not appropriate.	Dec. 14	GlaxoSmithKline
Rayos	Prednisone	Rayos is indicated for the control of severe or incapacitating allergic conditions intractable to adequate trials of conventional treatment in adults and pediatric populations with atopic dermatitis, drug hypersensitivity reactions, seasonal or perennial allergic rhinitis, and serum sickness; for the treatment of dermatologic diseases: bullous dermatitis herpetiformis, contact dermatitis, exfoliative erythroderma, mycosis fungoides, pemphigus, and severe erythema multiforme (Stevens-Johnson syndrome); for the treatment of endocrine conditions: congenital adrenal hyperplasia, hypercalcemia of malignancy, nonsuppurative thyroiditis, and primary or secondary adrenocortical insufficiency – hydrocortisone or cortisone is the first choice – synthetic analogs may be used in conjunction with mineralocorticoids where applicable; for the treatment of gastrointestinal diseases during acute episodes in Crohn's disease and ulcerative colitis; for the treatment of hematologic diseases: acquired (autoimmune) hemolytic anemia, Diamond-Blackfan anemia, idiopathic thrombocytopenic purpura in adults, pure red cell aplasia, and secondary thrombocytopenia in adults; for the treatment of neoplastic conditions: acute leukemia and aggressive lymphomas; for the treatment of nervous system conditions: acute exacerbations of multiple sclerosis and cerebral edema associated with primary or metastatic brain tumor, craniotomy or head injury; for the treatment of ophthalmic conditions: sympathetic ophthalmia, and uveitis and ocular inflammatory conditions unresponsive to topical steroids; for the treatment of conditions related to organ transplantation: acute or chronic solid organ rejection; for the treatment of pulmonary diseases: acute exacerbations of chronic obstructive pulmonary disease (COPD), allergic bronchopulmonary aspergillosis, aspiration pneumonitis, asthma, fulminating or disseminated pulmonary tuberculosis when used concurrently with appropriate chemotherapy, hypersensitivity pneumonitis, idiopathic bronchiolitis obliterans with organizing pneumonia, idiopathic eosinophilic pneumonias, idiopathic pulmonary fibrosis, *Pneumocystis carinii* pneumonia (PCP) associated with hypoxemia occurring in an HIV(+) individual who is also under treatment with appropriate anti-PCP antibiotics, and symptomatic sarcoidosis; for the treatment of renal conditions to induce a diuresis or remission of proteinuria in nephrotic syndrome – without uremia – of the idiopathic type or that due to lupus erythematosus; for the treatment of rheumatologic conditions as adjunctive therapy for short-term administration (to tide the patient over an acute episode or exacerbation) in acute gouty arthritis, and during an exacerbation or as maintenance therapy in selected cases of ankylosing spondylitis, dermatomyositis/polymyositis, polymyalgia rheumatica, psoriatic arthritis, relapsing polychondritis, rheumatoid arthritis – including juvenile rheumatoid arthritis (selected cases may require low-dose maintenance therapy), Sjogren's syndrome, systemic lupus erythematosus, and vasculitis; and for the treatment of specific infectious diseases: trichinosis with neurologic or myocardial involvement and tuberculous meningitis with subarachnoid block or impending block used concurrently with appropriate antituberculous chemotherapy.	July 26	Horizon Pharma
Revatio Oral Suspension	Sildenafil citrate	Revatio Oral Suspension is indicated for the treatment of pulmonary arterial hypertension (WHO Group 1) in adults to improve exercise ability and delay clinical worsening.	Aug. 30	Pfizer

2012'S NEW MEDICINE APPROVALS BY THE U.S. FOOD AND DRUG ADMINISTRATION

Product Name	Active Chemical	Approved Indication(s)	2012 FDA Approval Date	U.S. Developer/Marketer
Signifor	Pasireotide diaspartate	Signifor is indicated for the treatment of adult patients with Cushing's disease for whom pituitary surgery is not an option or has not been curative.	Dec. 14	Novartis Pharmaceuticals
Sirturo	Bedaquiline	Sirturo is indicated as part of combination therapy in adults 18 years old or older for the treatment of pulmonary, multi-drug resistant tuberculosis.	Dec. 28	Janssen Therapeutics
Sklice	Ivermectin	Sklice is indicated for the topical treatment of head lice infestations in patients 6 months old or older.	Feb. 7	Developer: Topaz Pharmaceuticals Marketer: Sanofi Pasteur
Sodium Chloride Injection USP 0.9%	Sodium chloride	Sodium Chloride Injection USP 0.9% is indicated for the dilution or dissolving of drugs for intravenous, intramuscular, or subcutaneous injections.	Jan. 6	Medefil
Sodium Nitrite Injection	Sodium nitrite	Sodium Nitrite Injection is indicated for sequential use with Sodium Thiosulfate Injection for the treatment of acute cyanide poisoning that is judged to be life-threatening.	Feb. 14	Hope Pharmaceuticals
Sodium Thiosulfate Injection	Sodium thiosulfate	Sodium Thiosulfate Injection is indicated for sequential use with Sodium Nitrite Injection for the treatment of acute cyanide poisoning that is judged to be life-threatening.	Feb. 14	Hope Pharmaceuticals
Stendra	Avanafil	Stendra is indicated for the treatment of erectile dysfunction.	April 27	Vivus
Stivarga	Regorafenib	Stivarga is indicated for the treatment of patients with metastatic colorectal cancer who have been previously treated with fluoropyrimidine-based, oxaliplatin-based and irinotecan-based chemotherapy, an anti-VEGF therapy, and – if KRAS wild type – an anti-EGFR therapy.	Sept. 27	Developer: Bayer HealthCare Pharmaceuticals Marketers: Bayer HealthCare Pharmaceuticals and Onyx Pharmaceuticals
Stribild	Elvitegravir, cobicistat, emtricitabine, and tenofovir disoproxil fumarate	Stribild is indicated as a complete regimen for the treatment of HIV-1 infection in adults who are antiretroviral treatment-naïve.	Aug. 27	Gilead Sciences
Subsys	Fentanyl	Subsys is indicated for the management of breakthrough pain in cancer patients 18 years old or older who are already receiving and who are tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain.	Jan. 4	Insys Therapeutics
Suprenza ODT	Phentermine HCl	Suprenza ODT is indicated as a short-term (a few weeks) adjunct in a regimen of weight reduction based on exercise, behavioral modification, and caloric restriction in 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).	March 27	Developer: Citius Pharmaceuticals Marketer: Akrimax Pharmaceuticals
Suprax Capsule	Cefixime	Suprax Capsule is indicated for the treatment of uncomplicated urinary tract infections; for the treatment of acute exacerbations of chronic bronchitis; for the treatment of pharyngitis and tonsillitis; and for the treatment of uncomplicated gonorrhea (cervical/urethral).	June 1	Lupin Pharmaceuticals
Surfaxin	Lucinactant	Surfaxin is indicated for the prevention of respiratory distress syndrome in premature infants at high risk for respiratory distress syndrome.	March 6	Discovery Laboratories
Synribo	Omacetaxine mepesuccinate	Synribo is indicated for the treatment of adult patients with chronic or accelerated phase chronic myeloid leukemia with resistance and/or intolerance to two or more tyrosine kinase inhibitors.	Oct. 26	Teva Pharmaceuticals USA
Tbo-filgrastim	Tbo-filgrastim	Tbo-filgrastim is indicated for the reduction in the duration of severe neutropenia in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia.	Aug. 29	Developer: Sicor Biotech Marketer: Teva Pharmaceuticals USA
Topotecan Injection 4 mg/4 mL	Topotecan hydrochloride	Topotecan Injection 4 mg/4 mL is indicated for the treatment of small cell lung cancers in patients with chemotherapy-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.	Dec. 20	Teva Pharmaceuticals USA
Tudorza Pressair	Aclidinium bromide	Tudorza Pressair is indicated for the long-term maintenance treatment of bronchospasm associated with chronic obstructive pulmonary disease, including chronic bronchitis and emphysema.	July 23	Developers: Laboratorios Almirall and Forest Laboratories Marketer: Forest Laboratories
Ultresa	Pancrelipase	Ultresa is indicated for the treatment of exocrine pancreatic insufficiency due to cystic fibrosis or other conditions.	March 1	Aptalis Pharma
Vascepa	Icosapent ethyl	Vascepa is indicated as an adjunct to diet to reduce triglyceride levels in adult patients with severe (≥ 500 mg/dL) hypertriglyceridemia.	July 26	Amarin Pharma
Viokace	Pancrelipase	Viokace, in combination with a proton-pump inhibitor, is indicated for the treatment of exocrine pancreatic insufficiency in adults due to chronic pancreatitis or pancreatectomy.	March 1	Aptalis Pharma
Viread Oral Powder	Tenofovir disoproxil fumarate	Viread Oral Powder is indicated in combination with other antiretroviral agents for the treatment of HIV-1 infection in adults and pediatric patients 2 years old or older (FDA approval = Jan. 18); and for the treatment of chronic hepatitis B in adults and pediatric patients 12 years of age and older (FDA approval = Aug. 16).	Jan. 18; Aug. 16	Gilead Sciences
Voraxaze	Glucarpidase	Voraxaze is indicated for the treatment of toxic plasma methotrexate concentrations in patients with delayed methotrexate clearance due to impaired renal function.	Jan. 17	BTG International
Xeljanz	Tofacitinib	Xeljanz is indicated for the treatment of moderately to severely active rheumatoid arthritis in patients who had an inadequate response or intolerance to methotrexate. It may be used as monotherapy or in combination with methotrexate or other nonbiologic disease-modifying antirheumatic drugs.	Nov. 6	Pfizer
Ximino	Minocycline hydrochloride	Ximino is indicated for the treatment of only inflammatory lesions of non-nodular moderate-to-severe acne vulgaris in patients 12 years old or older.	July 11	Ranbaxy Laboratories
Xtandi	Enzalutamide	Xtandi is indicated for the treatment of patients with metastatic castration-resistant prostate cancer who have previously received docetaxel.	Aug. 31	Medivation and Astellas Pharma US
Zaltrap	Ziv-aflibercept	Zaltrap, in combination with 5-fluorouracil, leucovorin, and irinotecan (FOLFIRI), is indicated for patients with metastatic colorectal cancer that is resistant to or has progressed following an oxaliplatin-containing regimen.	Aug. 3	Regeneron Pharmaceuticals and Sanofi US
Zetonna	Ciclesonide	Zetonna is indicated for the treatment of seasonal allergic rhinitis in adult and adolescent patients 12 years old or older.	Jan. 20	Sunovion Pharmaceuticals
Zioptan	Tafluprost	Zioptan is indicated for the treatment of ocular hypertension; and for the reduction of elevated intraocular pressure in patients with open-angle glaucoma.	Feb. 10	Merck & Co.

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STOPPING THE BLEEDING

Partner marketers Bristol-Myers Squibb and Pfizer are hoping to recover from major patent losses with the help of the Factor Xa inhibitor Eliquis, *Med Ad News*' Best New Medicine of the Year.

By Joshua Slatko joshua.slatko@ubm.com

Christmas came a few days late in 2012 for two of the pharmaceutical industry's biggest players. On Dec. 28th, Bristol-Myers Squibb and Pfizer finally got the good news from FDA about a compound in which both companies had placed their hopes for many years – the Factor Xa inhibitor Eliquis was approved to reduce the risk of stroke and systemic embolism in patients with nonvalvular atrial fibrillation.

Eliquis is a good example of the long-time horizon of drug development for pharmaceutical companies, and how crediting present leadership for today's successes and failures may be misleading. The compound was acquired as a Phase I asset when Bristol-Myers Squibb purchased DuPont Pharmaceuticals in 2001. In 2007, with the compound finally in Phase III trials, BMS and Pfizer launched a worldwide collaboration to develop and market the drug. Now, a half-dozen years later, analysts at EvaluatePharma have projected that Eliquis will be the No. 14 pharmaceutical product in the world and No. 11 in the United States by 2018, with worldwide sales of $4.71 billion and U.S. sales of $2.7 billion between the two marketing partners. By comparison, Eliquis' competitor Factor Xa inhibitor, Xarelto, is projected at $3.36 billion in sales worldwide and $1.67 billion in the United States in 2018.

Eliquis' approval could not have come at a better time for its developers. Plavix, responsible for a third of Bristol-Myers Squibb's revenue in 2011, lost its patent protection in May of 2012, while Pfizer's longstanding top seller Lipitor, responsible for about a seventh of the company's revenue, lost protection in December 2011.

By coincidence or not, the two companies' stock prices have grown significantly in the past 18 months as their hopes for Eliquis began to come to fruition – from $16.66 in August 2011 to just north of $28 in early March 2013 for Pfizer, and from $26.38 to over $37.50 for Bristol-Myers Squibb in the same time frame.

Last year didn't seem to start so well for Eliquis' developers, though. March 1st, 2012, Bristol-Myers Squibb and Pfizer announced that FDA had extended the action date by three months the Eliquis new drug application for the prevention of stroke and systemic embolism in patients with atrial fibrillation, to June 28. Subsequent to the filing of the NDA, the companies submitted additional information about the Eliquis clinical program to FDA, which agency regulators decided constituted a major amendment to the application requiring additional time for review.

Four months later, at the end of June, FDA issued a complete response letter on Eliquis for the prevention of stroke and systemic embolism in patients with nonvalvular atrial fibrillation. FDA requested additional information on data management and verification from the ARISTOTLE trial but did not require any new studies.

Three months after the complete response letter, in late September, FDA acknowledged receiving the two companies' resubmission of the Eliquis new drug application, assigning it a PDUFA date of March 17, 2013. A few days later, the companies announced the publication of trial results showing that the reductions in stroke or systemic embolism, major bleeding, and mortality demonstrated with Eliquis compared to warfarin in the ARISTOTLE trial were consistent across a wide range of stroke and bleeding risk scores in patients with nonvalvular atrial fibrillation.

Nov. 1, Bristol-Myers Squibb, Pfizer, and Portola Pharmaceuticals Inc. launched a clinical collaboration agreement to conduct a proof-of-concept study of PRT4445 and Eliquis. PRT4445 is a universal Factor Xa inhibitor antidote in clinical development designed to reverse the anticoagulant activity of any Factor Xa inhibitor. No agents are approved to reverse the activity of Factor Xa inhibitors.

The collaboration will be in effect during the clinical proof-of-concept study, which was projected to start by the end of 2012. The study is designed to demonstrate the safety of PRT4445 and its ability to reverse the anticoagulation activity of Eliquis and other Factor Xa inhibitors, including betrixaban, Portola's Phase III oral Factor Xa inhibitor. Bristol-Myers Squibb and Pfizer agreed to make an undisclosed cash payment to Portola upon initiation of the proof-of-concept study with Eliquis and will provide development and regulatory guidance for the study. Portola retains 100 percent global development and commercialization rights for PRT4445.

"Patient safety and improved patient outcomes have guided our clinical development program for Eliquis, including our efforts to identify a reversal agent for urgent clinical situations," says Brian Daniels, senior VP, Global Development and Medical Affairs, Bristol-Myers Squibb. "With our partner Pfizer, we look forward to working with Portola to advance the scientific understanding of the role of PRT4445 as a potential antidote for Eliquis."

Major bleeding events occur infrequently in patients taking Factor Xa inhibitors (1 percent to 4 percent per year in clinical studies) and standard measures are employed to manage these events. An agent specifically designed to reverse the activity of Factor Xa inhibitors may provide an antidote for patients who, in rare instances, experience an uncontrolled major bleeding event or require emergency surgery.

Late November began a run of major market approvals for Eliquis. Nov. 20, the European Commission approved the product for prevention of stroke and systemic embolism in adult patients with nonvalvular atrial fibrillation (NVAF) with one or more risk factors. This was the first regulatory approval in any market for Eliquis for stroke prevention in patients with nonvalvular atrial fibrillation.

The marketing authorization for Eliquis was supported by the pivotal Phase III trials ARISTOTLE and AVERROES, which

The Factor Xa inhibitor Eliquis is projected to generate $4.71 billion in worldwide sales by 2018.

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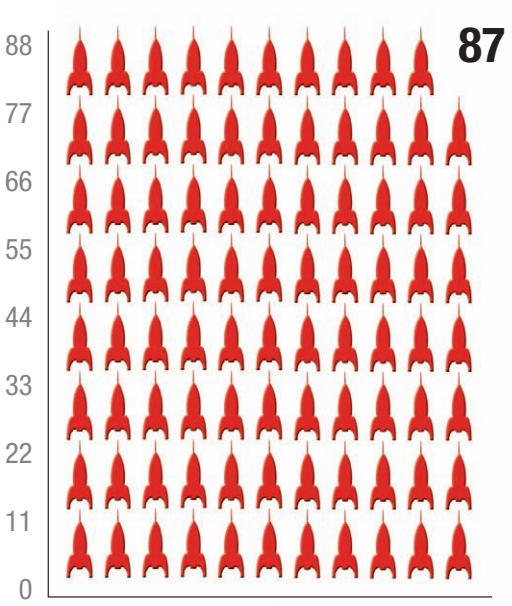

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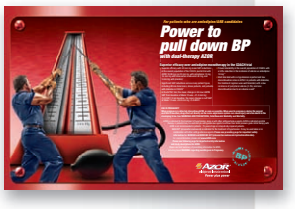

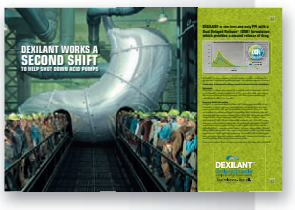

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Eliquis was approved by FDA on December 28th, 2012.

evaluated about 24,000 patients with non-valvular atrial fibrillation in the largest completed clinical trial program conducted to date in this patient population. The Eliquis clinical program is the only Phase III clinical program among the new oral anticoagulants to evaluate the safety and efficacy of Eliquis versus aspirin in patients who were unsuitable for vitamin K antagonist therapy.

"Today's approval of Eliquis in the EU is the result of a strong collaboration between Bristol-Myers Squibb and Pfizer to help address the unmet need for improved treatment options versus warfarin to reduce the burden of stroke in patients with nonvalvular atrial fibrillation," said Lamberto Andreotti, CEO of Bristol-Myers Squibb, on the announcement. "With its compelling clinical profile, Eliquis represents the commitment of our partnership with Pfizer to scientific innovation and our shared vision of bringing innovative and meaningful medicines to patients."

On Dec. 6, Health Canada approved Eliquis for the prevention of stroke and systemic embolism in adult patients with nonvalvular atrial fibrillation. Then, on Dec. 8, the two companies announced the results of the Phase III AMPLIFY-EXT trial, which evaluated treatment with Eliquis over a one-year period compared to placebo for the prevention of recurrent venous thromboembolism in 2,486 patients who had already completed six to 12 months of anticoagulation treatment for the condition, including deep-vein thrombosis or pulmonary embolism. In the trial, extended treatment with Eliquis 2.5 milligrams and 5 milligrams twice daily, demonstrated superiority versus placebo in the reduction of the composite endpoint of symptomatic, recurrent venous thromboembolism and death from any cause (11.6 percent in the placebo group, compared with 3.8 percent and 4.2 percent in the Eliquis 2.5 milligram and 5 milligram groups, respectively).

Eliquis also was superior to placebo for the predefined secondary efficacy outcome of recurrent VTE and VTE-related death (8.8 percent in the placebo group, compared with 1.7 percent in both the Eliquis 2.5 milligrams and 5 milligrams groups). Both of these endpoints, the primary and secondary efficacy outcomes, were statistically significant.

"Up to 10 percent of patients will experience a recurrent venous thromboembolism event after completing the currently recommended six-to-12-month treatment period, suggesting the need for additional prophylaxis," says Dr. Giancarlo Agnelli, professor of internal medicine, University of Perugia, Italy; director of the Department of Internal and Cardiovascular Medicine and Stroke-Unit, University Hospital, Perugia, Italy; and lead investigator of the study. "In the AMPLIFY-EXT trial, which added an additional year of treatment, Eliquis reduced the composite risk of recurrent venous thromboembolism and total mortality without an increase in major bleeding versus placebo."

The day after Christmas, regulators in Japan approved Eliquis for the prevention of ischemic stroke and systemic embolism in patients with nonvalvular atrial fibrillation.

"The approval in Japan marks the third regulatory approval for Eliquis within six weeks," said John Young, president and managing director, Pfizer Primary Care Business Unit, on the annoucement. "We are excited by this momentum and confident that our combined cardiovascular leadership and expertise with BMS will lead to a successful introduction of this important medicine to patients and physicians in Japan."

Then, just two days later, the two companies got the best news of all when FDA approved Eliquis to reduce the risk of stroke and systemic embolism in patients with nonvalvular atrial fibrillation.

"The approval of Eliquis offers patients with nonvalvular atrial fibrillation a novel treatment option for reducing the risk of stroke," said Mr. Andreotti. "Eliquis is the result of leading scientific innovation and the shared vision of our alliance to introduce a new oral anticoagulant for patients with nonvalvular atrial fibrillation in the United States." ■ MEDADNEWS

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Future blockbusters

An upswing in NME approvals is an encouraging sign for an industry trying to overcome mega-brand patent expirations and a lag in research and development productivity.

By Andrew Humphreys (andrew.humphreys@ubm.com)

R&D expenditure growth for the industry as a whole has reached a stagnant state, though many companies remain dedicated to innovation and improving pipeline productivity. For the first time in many years, there was an annual drop-off in the combined R&D expenditure of the leading pharmaceutical/biopharma companies. From 2011 to 2012, a 2.7 percent decrease in R&D spending was produced by the top 10 pharma/biopharmaceutical companies. From 2012 to 2013, the R&D expenditure total for those industry leaders is expected to remain about flat year over year. The longer-term outlook for that group is forecasted to be more positive though when compared to the 2012 R&D spend, with a predicted 3.8 percent increase for the 2014-2016 period average and a significant 9.2 rise for the 2017-2020 period average.

Industry trackers contend that the ultimate measure of R&D productivity is the amount of new regulatory approvals as well as the commercial value of new molecular entities. The total amount of approved new molecular entities (NMEs) submitted under new drug applications and therapeutic biologics submitted through original biologic license applications (BLAs) to FDA increased from 21 in 2010 to 30 during 2011 to 39 for 2012. The 2012 tally was the highest since 39 new molecular entities were approved during 1997, which followed a one-year record of 53 in 1996.

The recent two-year increase in NME approvals is a positive trend for the industry during a time in which patent-expiration losses of some of the best-selling prescription medicines of all-time have occurred. The pharmaceutical arena's total U.S. prescription drug sales reportedly are undergoing an annual decrease as of 2012 as generic competition continues to grow and the average internal rate of return from pharma leaders' R&D has declined in recent years.

The 39 NME/BLA approvals of 2012 included about a dozen oncology-related products. Oncology will continue to be the most heavily targeted therapeutic field by the industry for years to come due in part to the scientific advances being accomplished for such a vast unmet medical need. Drug makers will also continue to shift R&D more towards biologics based on their higher pricing and lower commercial infrastructure needs, as well as because of less exposure to generic competition. Additionally, pipeline success rates for biologic drugs are much higher than those for small-molecule medicines.

Following is an overview of select new molecular entities expected to be approved by the U.S. Food and Drug Administration during the next 12 months or so that have the potential to generate more than $1 billion in peak annual sales.

DOLUTEGRAVIR

The investigational integrase inhibitor dolutegravir (product code S/GSK1349572) represents another advance in the fight against HIV/AIDS. The product candidate is being evaluated for safety and efficacy without another 'booster' drug being added to the regimen. Integrase inhibitors block HIV replication by the prevention of viral DNA from integrating into the genetic make-up of human immune cells (T cells). This process is essential in the HIV replication cycle and is responsible for establishing chronic infection.

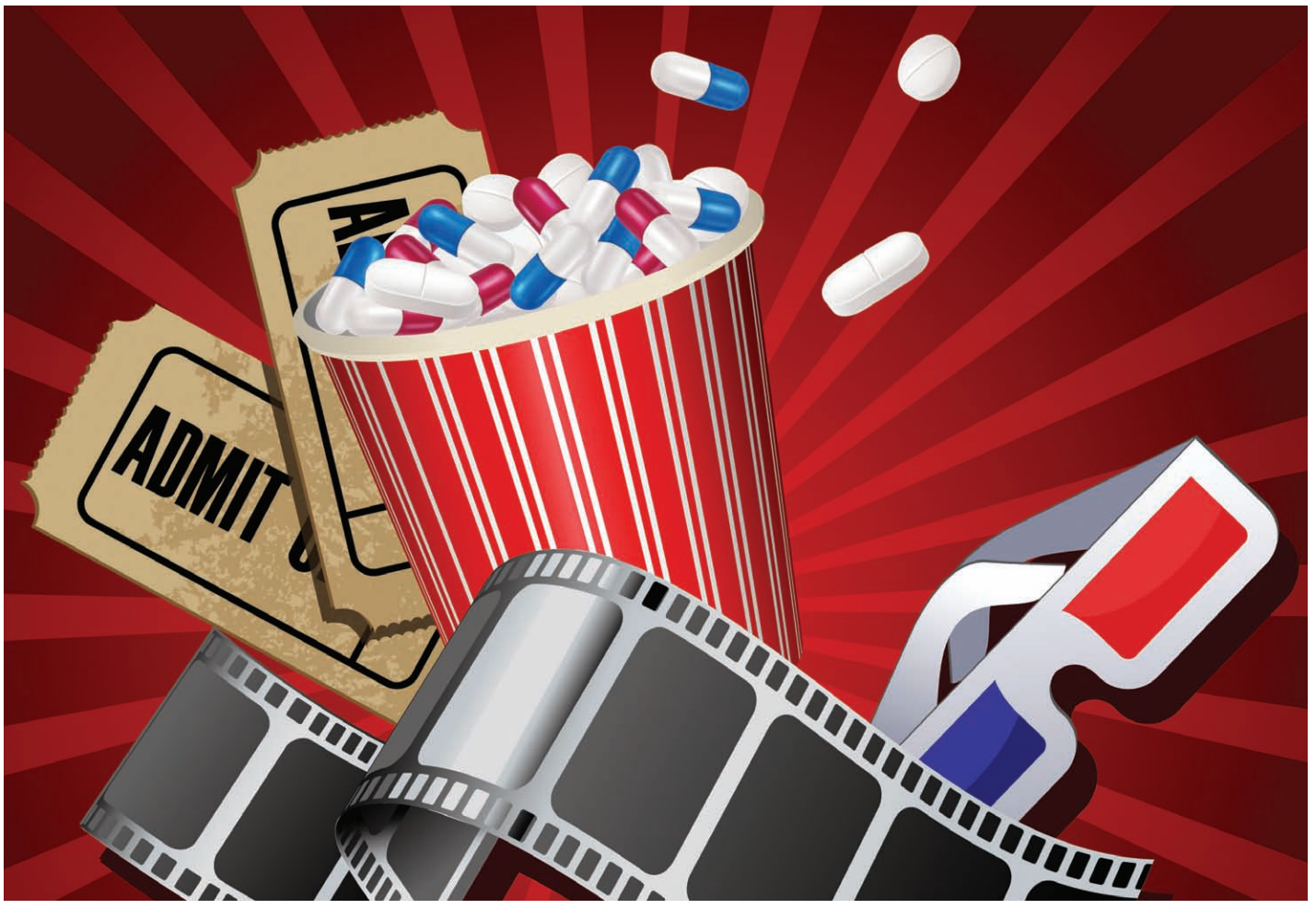
Dolutegravir is being developed for treating HIV for use in combination with other human immunodeficiency virus drugs. The compound is intended for HIV infection treatment in adults and children aged 12 years and older. Regulatory applications were announced as filed for the new product candidate during December 2012 in the United States, European Union, and Canada. Dolutegravir has been granted FDA priority-review status and U.S. marketing clearance is expected by Aug. 17, 2013.

The regulatory submissions for dolutegravir were based on Phase III clinical data from the VIKING-3, SAILING, SPRING-2 and SINGLE studies. VIKING-3 (ING112574) is a Phase III, multicenter, open-label, single arm trial to assess the antiviral activity and safety of dolutegravir 50mg twice-daily in treatment-experienced adults with HIV-1 and historical or current evidence of resistance to raltegravir or elvitegravir. SAILING (ING111762) is a multicenter, double blind, double dummy study comparing the efficacy and safety of dolutegravir 50mg once-daily to raltegravir 400mg twice-daily in treatment-experienced, integrase inhibitor-naive adults with HIV-1.

SPRING-2 (ING113086) is a multicenter, double blind, double dummy trial comparing the efficacy and safety of dolutegravir 50mg once-daily to raltegravir 400mg twice-daily in treatment-naïve adults with HIV-1. SINGLE (ING114467) is a multicenter, double blind, double dummy trial to compare the efficacy and safety of once-daily dolutegravir 50mg plus abacavir/lamivudine versus **Atripla** (tenofovir/emtricitabine/efavirenz). Along with data from a bioequivalence study (ING114580), SINGLE is designed to support additional regulatory submissions for a fixed-dose combination of dolutegravir/abacavir/lamivudine.

Discovered by Japanese pharma company **Shionogi**, dolutegravir was licensed to pharmaceutical giant **GlaxoSmithKline** during 2003. The product was eventually transferred to **ViiV** Healthcare, a worldwide company with a sole concentration on HIV that was established during 2009 by GlaxoSmithKline and **Pfizer**. Shionogi joined ViiV Healthcare during 2012, resulting in the **Shionogi-ViiV** Healthcare joint venture. In October 2012, ViiV and Shionogi announced a deal revamping their integrase inhibitor relationship. Through the updated pact, ViiV Healthcare acquired the exclusive worldwide rights to Shionogi-ViiV. The assets include dolutegravir and other early-stage integrase inhibitor compounds.

Sanford Bernstein analysts in a March 2013 report projected that total dolutegravir global sales will amount to £1.05 billion ($1.62 billion) in 2020, based on regulatory approval during 2013. Dolutegravir's competition will include the biopharma company **Gilead** Sciences' various once-daily fixed-dose combo drugs such as Atripla and the quad pill **Stribild**. Launched in the United States during July 2006, Atripla generated worldwide 2012 sales of $3.57 billion. Stribild (elvitegravir, cobicistat, emtricitabine, and tenofovir disoproxil fumarate) was introduced to the U.S. market in August 2012 and has annual multi-billion sales potential.



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SOFOSBUVIR

Gilead also has a potential yearly billion-dollar sales generator in the form of the nucleotide NS5B inhibitor sofosbuvir (product code GS-7977). Sofosbuvir is being developed in Phase III studies for treating hepatitis C. The drug candidate is on track to become the first purely oral treatment available for hepatitis C.

Top-line results were announced by Gilead in February 2013 from the Phase III FUSION study evaluating 12-week and 16-week courses of therapy with once-daily sofosbuvir plus ribavirin (RBV) in treatment-experienced patients with genotype 2 or 3 chronic hepatitis C virus (HCV) infection who failed prior treatment. The study met its primary efficacy endpoint of superiority versus a predefined historic control sustained virologic response rate of 25 percent. In FUSION, half of the patients (n=50/100) in the 12-week arm and 73 percent of patients (n=69/95) in the 16-week arm attained SVR12 ($p<0.001$ for both arms).

"This study demonstrates that all-oral therapy with sofosbuvir provides significant

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efficacy among difficult-to-treat hepatitis C patients who could not be cured by prior regimens containing pegylated interferon and now have limited treatment options," noted Norbert Bischofberger, Ph.D., executive VP of R&D and chief scientific officer at Foster City, Calif.-based Gilead. "With positive results from all four Phase III trials now in hand, Gilead is on track to meet its goal of filing regulatory applications in the United States and Europe in the second quarter."

Results from each of sofosbuvir's four pivotal Phase III trials – FUSION, POSITRON, FISSION and NEUTRINO – will support the initial regulatory submission for sofosbuvir. The regulatory filings are intended for sofosbuvir as part of an all-oral therapy with RBV among genotype 2 and 3 treatment-naïve, treatment-experienced and interferon-intolerant HCV patients, and in combination with RBV and pegylated interferon among treatment-naïve patients with genotypes 1, 4, 5 and 6.

Gilead is also evaluating a once-daily fixed-dose combo tablet containing sofosbuvir and the NS5A inhibitor ledipasvir (product code GS-5885) in several Phase II and III studies. The studies are evaluating sofosbuvir/GS-5885 with and without ribavirin among a range of genotype 1 HCV patient populations. Interim data from the Phase II ELECTRON study were revealed by Gilead in November 2012. The study is examining a 12-week course of therapy with sofosbuvir, ledipasvir, and ribavirin in patients with genotype 1 chronic hepatitis C virus infection. Among treatment-naïve patients receiving this combo therapy, every one (n=25/25) remained HCV RNA undetectable four weeks after completing therapy.

"Since the acquisition of Pharmasset only a year ago, we have fully enrolled four Phase III studies of sofosbuvir and during the first quarter of this year we will have initiated two Phase III studies of the sofosbuvir and GS-5885 fixed-dose combination," commented Bischofberger during January 2013. "We are on track to submit the initial regulatory filing for sofosbuvir by mid-2013 and to file for approval of the fixed-dose combination of sofosbuvir and GS-5885 in 2014."

Gilead agreed to buy Pharmasset during November 2011 in a $11 billion cash transaction. The agreement was designed to diversify Gilead away from HIV medicines and give the company a boost in the fast-growing hepatitis C drug arena. Included in the deal was the hepatitis C polymerase inhibitor sofosbuvir. Some industry analysts have projected sofosbuvir franchise global sales of more than $5 billion in 2018.

ALPHARADIN

Bayer is awaiting FDA approval of a new medicine for prostate cancer, which is the second most common cancer among American men after skin cancer. The investigational compound radium Ra 223 dichloride is intended for treating castration-resistant prostate cancer (CRPC) patients with bone metastases. Radium Ra 223 dichloride is an alpha particle emitting pharmaceutical.

Expected to be branded as Alpharadin, Bayer submitted the NDA for the product as announced during December 2012. Radium-223 was granted fast-track designation by the U.S. regulatory agency.

The regulatory filing was based on data from the ALSYMPCA (ALpharadin in SYMptomatic Prostate CAncer) study. The Phase III, randomized, double-blind, placebo-controlled international trial compared radium-223 with best standard of care (BSC) versus placebo with BSC in symptomatic CRPC patients with bone metastases. The clinical trial enrolled 921 patients in 100-plus centers in 19 countries. The study treatment contained up to six intravenous administrations of radium-223 or placebo, each separated by a four-week interval.

The study's primary endpoint was overall survival. Secondary endpoints consisted of time to occurrence of skeletal-related events (SRE), time to total alkaline phosphatase (ALP) and prostate-specific antigen (PSA) progression, total ALP response and normalization, safety, and quality of life.

Sixteen percent of prostate cancer cases are considered regional or distant, which means that the cancer has spread beyond the prostate to nearby or distant regions of the body (metastasis). A majority of men with castration-resistant prostate cancer have radiological evidence of bone metastases. Bone metastases secondary to prostate cancer generally target the lumbar spine, vertebrae and pelvis. Bone metastases are the primary cause of morbidity and death in patients with CRPC.

"If approved, radium-223 has the potential to play a key role in the treatment of men with CRPC that has metastasized to the bone," commented Pamela A. Cyrus, M.D., VP and head of U.S. medical affairs for Bayer HealthCare Pharmaceuticals. "The development of a compound like radium-223 is an example of Bayer's commitment to investing in approaches to treat hard-to-treat cancers."

Bayer inked a deal during September 2009 with **Algeta** of Oslo, Norway, for the development and commercialization of radium-223. Bayer is developing, applying for health authority approvals globally, and will commercialize the radiotherapy agent worldwide. Bayer and Algeta will jointly promote radium-223 in the United States.

Industry analysts have projected Alpharadin global sales of more than $1 billion for 2018.

DIMETHYL

The immunomodulator dimethyl fumarate (product code BG-12) is a promising treatment for multiple sclerosis and an anticipated mega-brand for **Biogen Idec**. The drug is awaiting approval in the United States, European Union, Australia, Canada, and Switzerland for treating relapsing-remitting multiple sclerosis (RRMS). Dimethyl fumarate is the only known investigational compound for treating RRMS that has experimentally shown activation of the Nrf-2 pathway.

Biogen Idec announced in October 2012 that the Food and Drug Administration extended the initial Prescription Drug User Fee Act (PDUFA) date for its review of the new drug application for dimethyl fumarate. The three-month extension – a standard extension time line – was needed to allow extra time for review of the application. The updated PDUFA date is reportedly set for late March 2013.

A pre-specified analysis of integrated data from the Phase III DEFINE and CONFIRM trials for dimethyl fumarate demonstrated statistically significant and clinically relevant effects in reducing MS relapses and progression of disability, as well as reductions in MRI measures of disease activity as announced by Biogen Idec in October 2012. Interim safety data from a Phase III extension trial indicate that continued exposure to dimethyl fumarate did not lead to any new or worsening safety signals, and that the drug's safety and tolerability profiles were consistent with previous studies.

In a June 2012 report, EvaluatePharma cited BG-12 as the second most valuable R&D project in the industry at that time with a net present value of $9.08 billion. In that report, the analysts projected global 2018 sales of $3.4 billion for the drug.

ANORO AND BREO/RELVAR

GlaxoSmithKline is awaiting the market arrival of two new-generation COPD treatments to eventually replace its long-time best-seller **Advair/Seretide**. The London-based company is developing two investigational bronchodilator molecules: the long-acting muscarinic antagonist (LAMA) GSK573719/umeclidinium bromide (UMEC), and the long-acting beta2 agonist (LABA) vilanterol (VI). Intended to be branded as Anoro, the product is administered via the **Ellipta** inhaler.

A New Drug Application for 62.5/25mcg and 125/25mcg doses of UMEC/VI was submitted to U.S. regulators on Dec. 18, 2012. The NDA is for the long-term once-daily maintenance bronchodilator treatment of airflow obstruction in patients with COPD, including chronic bronchitis and emphysema. The PDUFA goal date is set for Dec. 18, 2013.

An EU submission for UMEC/VI was filed on Jan. 8, 2013. The Marketing Authorisation Application was submitted for 55/22mcg and 113/22mcg doses of UMEC/VI with the proposed proprietary name Anoro. The product also was filed with the European Medicines Agency as a maintenance bronchodilator treatment to relieve symptoms in adult patients with COPD. The UMEC/VI doses of 55/22mcg and 113/22mcg are specified as the delivered doses (emitted from the inhaler) that are equivalent to the 62.5/25mcg and 125/25mcg pre-dispensed doses (contained inside the inhaler) filed for FDA approval.

Filings for UMEC/VI will take place in other countries during 2013. Additionally, GlaxoSmithKline plans to commence worldwide regulatory submissions for UMEC monotherapy in the Ellipta inhaler for COPD patients during 2013. UMEC/VI and UMEC monotherapy are two of several late-stage assets in GlaxoSmithKline's respiratory development arsenal. The portfolio also includes fluticasone furoate/vilanterol (FF/VI), vilanterol monotherapy, MABA (GSK961081), FF monotherapy, and the anti-IL5 MAb mepolizumab.

The once-daily investigational medicine FF/VI is administered by the new dry-powder inhaler Ellipta. The product candidate has the proposed trade names Breo in the United States, and Relvar in Europe and Japan.

GSK and **Theravance** announced during September 2012 that the NDA for FF/VI for COPD patients had been accepted for FDA review. The PDUFA goal date is scheduled for May 12, 2013. The companies announced on July 13, 2012, the filing of U.S. and EU regulatory applications for COPD patients, and a EU regulatory application for asthma. The MAA for FF/VI for COPD and asthma was validated by the European Medicines Agency. GSK additionally filed a Japanese New Drug Application for FF/VI for COPD and asthma patients on Sept. 25, 2012. Breo is undergoing U.S. Phase III trials for asthma treatment.

Anoro, Breo/Relvar, and MABA (GSK961081) are being developed in collaboration with Theravance. The biopharma company is concentrated on the discovery, development and commercialization of small-molecule medicines across various therapeutic fields such as respiratory disease, bacterial infections, and CNS/pain. GSK holds a reported 27 percent stake in the South San Francisco, Calif.-based company.

Assuming U.S. and EU regulatory clearance during 2013, Sanford Bernstein analysts have projected total Anoro 2020 global sales of £1.37 billion ($2.19 billion). Through Anoro, GSK and Theravance are expected to have the first LABA/LAMA combination product to reach the market. **Novartis** also has one in the works via **QVA149**, which combines the long-acting beta2-adrenergic agonist indacaterol with the long-acting muscarinic antagonist NVA237. That combo medicine and projected blockbuster may not be submitted for FDA approval until late 2014 due to the necessity of another study to determine the lowest effective dose and support once-a-day administration.

Based on regulatory approval during 2013, Sanford Bernstein analysts have forecasted Breo/Relvar worldwide sales of £949 million ($1.52 billion) for GSK in 2020. Theravance is reportedly entitled to a 15 percent royalty on the first $3 billion in yearly Breo/Relvar sales and 5 percent thereafter. ■ MEDADNEWS

POTENTIAL FUTURE BLOCKBUSTERS EXPECTED TO RECEIVE FDA APPROVAL DURING 2013/2014

Product	Class of drug	U.S. pipeline status (latest stage only)	Companies
Alpharadin (radium-223 dichloride)	Alpha-pharmaceutical	Awaiting approval for the treatment of hormone-refractory prostate cancer in patients with skeletal metastases.	Bayer HealthCare Pharmaceuticals and Algeta
Anoro (umeclidinium bromide and vilanterol)	Muscarinic acetylcholine antagonist and long-acting beta2 agonist	Awaiting approval for the treatment of chronic obstructive pulmonary disease.	GlaxoSmithKline and Theravance
Breo (fluticasone and vilanterol)	Glucocorticoid agonist and long-acting beta2 agonist	Awaiting approval for the treatment of chronic obstructive pulmonary disease.	GlaxoSmithKline and Theravance
Dimethyl/BG-12	Immunomodulator	Phase III for the treatment of relapsing-remitting multiple sclerosis.	Biogen Idec
Dolutegravir/ S/GSK1349572	HIV integrase inhibitor	Awaiting approval for the treatment of HIV infection in adults and children aged 12 years and older.	ViiV Healthcare
Sofosbuvir/GS-7977	Nucleotide NS5B inhibitor	Phase III for the treatment of hepatitis C.	Gilead Sciences

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IN THE TWILIGHT ZONE

The Caronia decision was excitedly hailed as a breakthrough for pharmaceutical marketing, but industry observers say as FDA continues business as usual, pharma companies are not changing their tactics – though the ruling could open the way for the industry to engage in online conversations.

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

When the U.S. Court of Appeals for the Second Circuit ruled that the off-label statements made by pharmaceutical marketing representative Alfred Caronia about the drug Xyrem were protected free speech, there was an excited flurry of commentary, for and against the pharma industry, and experts predicted that the decision was a game changer for pharma companies' promotional efforts. Almost three months after the decision was handed down, however, healthcare ad agency leaders say they and their clients are still trying to figure out what the ruling means – and no one is doing anything differently in their marketing campaigns. With FDA officials publicly stating that the agency will continue to go after companies for what it believes is misbranding, it looks like things won't be changing for quite some time.

Meanwhile, with healthcare organizations generating their own data about the effectiveness of drugs on the market, often establishing standards of care based on off-label use, the pharma industry has to remain silent even as debate about off-label uses expands online – another tricky area of involvement for pharma companies, with its corresponding lack of FDA guidelines.

CAUTIOUS AND QUIET

Nick Colucci, president and CEO of Publicis Healthcare Communications Group and head of the board for the industry group the Coalition for Healthcare Communication, says the atmosphere in the wake of the Caronia decision is "complicated."

"There are some that I actually don't think know how to take it right now, and there are some that believe that very little will change in terms of how they act and in enforcement, and I guess that there are combinations of both, in that they are a little confused by it," Colucci told *Med Ad News*.

Matt Giegerich, chairman and CEO of Ogilvy CommonHealth Worldwide, says the decision is massively important, and was surprising when it came out. However, "then you start to ponder what does it mean and what happens next, and it becomes a hell of a lot less clear than the decision itself," he says. "The decision sounded emphatically clear, but it's only a district that only affects legally those states in the district, and what will happen next is an open debate.

"The question of whether or not there will be an appeal, will it go to the Supreme Court, with the FDA eventually modifying their guidelines, and would their power be disintermediated because of the decision, all of those things are left completely unanswered, although as we understand it the FDA is letting it sit and not responding and letting it fade into the background while they keep doing what they're doing. It is a very strange, uncertain moment considering how momentous it was when it was first announced and decided."

Colucci believes that the decision will have an impact – eventually. "I think like always, when these things happen, there's a heightened reaction that there's a whole lot of 'this can change and is unprecedented,' and then people start to think about it and pull it apart piece by piece, and not, in the way that they act, see a huge impact on their day-to-day life until something profound in the marketplace beyond this happens, or whether someone will take the initiative at OPDP and places like that, where they'll need to interact," he says.

"From the 30,000 foot vantage, this decision creates potential risk for our industry," says Jay Carter, VP of strategy, AbelsonTaylor. "The key to the credibility of our industry's claims to both healthcare provider and consumer stems from the legitimacy offered by the FDA's imprimatur. Reducing that credibility in any way opens up the potential for our credibility to be undermined. The reason for this is that claims not supported by a label can be perceived as misleading, something that is both illegal and bad for patient outcomes. I'll refer you to PhRMA's statement on Caronia: 'truthful and nonmisleading' – my emphasis – 'communication between biopharmaceutical companies and health care professionals is good for patients, because it facilitates the exchange of up-to-date and scientifically accurate information about new treatments.'"

However, these three leaders are not seeing their clients doing anything differently.

"On a day-to-day practical level, I believe it is business as usual," Carter says. "Communications to physicians and to patients rely heavily upon making relevant and believable claims about our brands, and the package insert is, and will remain, the core source for those claims. I believe that my clients will continue to base formal promotion to healthcare professionals and consumers on the package insert. I don't believe that there is an appetite for very much risk in pharma today."

"It will be interesting to see how it plays out, but for the moment, we don't have a single client who has changed their belief set or approach or direction as a result of this ruling, not a single change," Giegerich told *Med Ad News*. "And if you think about big pharma in total, many of them are operating under corporate integrity agreements in the U.S. as it is, so no one is gong to step out of line, they're just going to have to wait until it plays out and try to keep themselves clear and clean in the process."

Colucci agreed that companies will not want to stick their necks out, and agencies will not be leading the way. "Agencies have to follow along how their clients are going to approach," he says. "Some clients who are already under these corporate integrity agreements, they're going to be very cautious, no matter what."

Carter theorizes that a certain kind of company may test the waters. "I think if anyone does stick their neck out, it will be a new company, with a single brand, who decides to try it because they have a lot less to lose," he says. "You're not going to see a major pharma do it."

A quick poll of the agency's account directors showed that none of AbelsonTaylor's clients are moving to take advantage of the implications offered by the ruling, Carter says. "None of our clients are even remotely considering anything other than sticking to the label, sticking to the package insert, because that's where there's great confidence that you're not going to misbrand," he told *Med Ad News*. "I felt that way anyway. This is a very conservative business, it's become even more conservative, and in some ways I think this is a little uncomfortable."

Still, Colucci believes something will happen. "There will be something, there always is, with a ruling like this, once there's a wedge, there's going to be a couple of little taps on that wedge over time and the log will split," he says. "I'm not so sure what that means, whether it will split for the positive or the negative, and I'm not so sure what the positive or the negative is, based on what your perspective is. But I do think the feeling many of the thought leaders in this industry have is something different has happened with this ruling, we're just not sure what it is."

FDA STILL HOLDS THE HAMMER

The problem right now for any company wanting to test the strength of the ruling is that FDA, for all intents and purposes, is steadfastly ignoring the decision. At a conference last month, Tom Abrams, director of FDA's Office of Prescription Drug Promotion, told the audience that the ruling does not challenge the agency's enforcement ability. FDA has declined to appeal the case, and the ruling technically applies to just the states that the Second Circuit covers.

John Kamp, executive director of the Coalition for Healthcare Communication, fervently believes that something will happen to shake FDA into action to put together new standards on what can be discussed off label, but still be considered truthful and not misbranding or misleading. "It's going to be multiple petitions to FDA to do something, they're going to stay in the denial stage, and then it will probably have to take some court action to get them to do something. To them, the label is the label is the label, and anything that's off the label is, in their perspective, false and misleading. But virtually no one else in the industry believes that, because many times off label use is the standard of care in a lot of areas."

In a Webinar held by the CHC in January, Bert Rein, managing partner of the law firm Wiley Rein; Alan Bennett, managing partner of the law firm Ropes and Gray; and Mit Spears, general counsel of PhRMA, stated their beliefs that FDA will have to move to a system that will have to acknowledge that many unapproved uses have become the standard of care, and any companies truthfully talking about those uses should not be penalized for doing so.

Spears is "very anxious" to reach out and work directly with FDA on creating new standards for the industry, Kamp says.

Colucci and Giegerich believe that FDA will have to consider new standards because so many discussions about off-label use are happening online and so much data that will drive treatment decisions is being amassed.

"There's so much data out there now, people pull it together, they are in many respects contextually ignorant about what the different pieces can mean," Colucci says. "If they engage a company in a conversation about trying to better understand it, it's almost irresponsible for a company to not respond or to say, I can't respond."

According to Colucci, it's better for the consumer to have someone – either the company, or a physician going on the most recent information supplied by a knowledgable rep – to help them understand the data that they find.

As accountable care organizations and insurers start to compile usage and effectiveness data for marketed drugs, and the data direct more prescribing decisions and formulary coverage, pharma should not be barred from the discussions, so long as the data being discussed was generated in scientific, rigorous ways.

"You've got integrated health systems and large group practices coming together, and more and more powered by their own data," Giegerich says. "Their future is not dependent on the clinical trial data, like the pharma companies. Their future is going to be dependent on their experiential data and their own outcomes data. They, for example, could amass their own formularies and protocols that say product X is good for this condition even though it's not approved for that condition, because of their experience with thousands of patients, it is the appropriate first-line choice for the treatment of this disorder. And that is data invalidating some clinical pathway, but it has almost nothing to do with what the pharmaceutical companies are doing. This again begs the question of who regulates what? Are you allowed to do anything you want if you're not a pharmaceutical company? That's a very strange position to take."

Meanwhile, "The only one with a gag order is the one with the actual information" – the pharma companies that conducted the approval studies, Giegerich says.

Carter says discussing off-label use, even if the company is conducting its own studies and has good data and the best intentions, can be a pitfall. "For instance – say you have a great drug, with killer Phase II studies – how confident are you to have a rep have a conversation with a physician about that?" he says. "You don't know if the dose is exactly right, and you don't have Phase III powered support to know if it's going to work or not. So what truth are you going to make that's not misleading?"

Until everything is figured out, agencies will continue to do what they have been doing for years – getting the best messages possible out of the label data for promotion, he says.

"It's gotten tighter, year after year, with CIA after CIA, but it's still about looking at the label and figuring out what to say that is responsible to patients," Carter says. "The good news for me is that 15 years ago I figured out that I felt a lot better when it was about patients. The people who are happiest in our industry focus on what's good for patients. If you use that as your metric, you're a lot better off." ■ MEDADNEWS

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UBM Canon

By *Med Ad News* staff

Minority patients harder for "health extenders" to reach

By Mia Burns

Among the many challenges that healthcare stakeholders face are language and cultural barriers, as well as finding ways to make a difference within the healthcare setting. The healthcare marketing agency HealthEd has issued a new report, *Engaging Patients from Multicultural Backgrounds*, to explore answers to these questions. The convergence of three factors – ongoing demographic change, persistent healthcare disparities, and sweeping healthcare transformation – make it all the more necessary for healthcare organizations to provide better support within these patient populations.

In developing the report, HealthEd surveyed 192 healthcare extenders – non-M.D. healthcare professionals who work directly with and on behalf of patients. Healthcare extenders use a wide variety of strategies to reach patients from diverse cultural backgrounds, with the aim of helping patients feel comfortable in the healthcare setting. These strategies include hiring culturally diverse staff, training staff on cultural competence, offering flexible hours, and providing programs and services tailored to health problems that disproportionately affect minority groups.

The findings reveal that healthcare extenders are treating an increasingly diverse patient population whose members speak a wide variety of languages. Twenty-nine percent of respondents reported that communication and language barriers presented challenges.

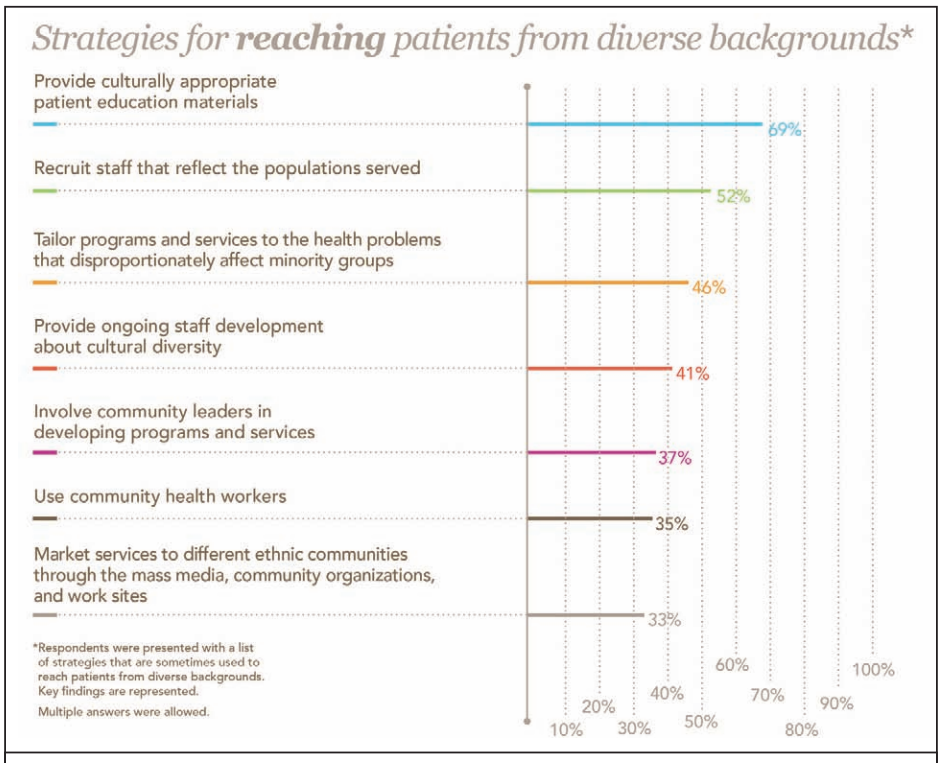
"I think that the key to keep in mind with that is that the language and the bilingual aspect are reflective of the patient population being served," says Susan Collins, senior VP, health education research and development at HealthEd. "It's not just a matter of language and background that's similar to the patients being served and also recognizing that cultural competence diversity comes not only from the language that people speak, but also from the beliefs that people have, and the values that they share, and their social norms."

When Collins and her team asked about languages, English came in at 95 percent, followed by Spanish at 94 percent. "What that said to us when we looked at that result is that Spanish is equally as important; it really emphasizes to us that marketers as well as others organizations that are creating programs for patients that they need to be thinking of Spanish at the beginning of the project just as they are in terms of English," she says. "It definitely shouldn't be an afterthought."

Patients also said they needed educational materials in Chinese, Southeastern Asian languages, and Creole.

Respondents are also concerned about gaps in how well patients and providers can understand each other. Almost half of respondents say that they often or sometimes experience situations in which language differences prevent effective communication between them and their patients or caregivers. Also, 44 percent of respondents were often or sometimes uncertain how to best educate a patient or family member because of cultural differences.

The involvement of community members in outreach and education efforts could assist healthcare extenders overcome challenges to reaching culturally diverse audiences. These challenges include a lack of appropriate resources for marketing, outreach, and patient education, a lack of familiarity with cultural beliefs and lifestyles, and communication and language barriers.



SOURCE: "ENGAGING PATIENTS FROM MULTICULTURAL BACKGROUNDS," HEALTHED

"The reason that we brought up community health workers within the report is that one of the keys that the extenders cited to being able to reach culturally diverse patients is that 36 percent of them said they had challenges related to helping patients feel comfortable within the healthcare setting," Collins said. "They're really lay people who come from the community and they're being used to help service this bridge between patients within the community and the healthcare system. And there's definitely been research done in diabetes, hypertension, and HIV where community lay workers are really effective in helping support follow up visits for patients."

FACTS & FIGURES

Seventy-seven percent of consumers who have seen a physician in the last year value the information that they receive, according to research by Kantar Media Healthcare Research. For marketers and ad professionals, reaching patients right before they speak with their physicians can have a huge impact on the conversation. Patients are exposed to a brochures, pamphlets, posters, TV, and waiting room magazines as they wait their turn.

According to Kantar Media's research, **41 percent** of consumers who have seen a doctor during the last year valued brochures and other literature that can be easily viewed or picked up at the office. A bit less than **one in three** value magazines at doctors' offices, and **20 percent** value the TV programs. The physician's specialty is an important factor in consumer perceptions of point-of-care media value. When compared to other patient groups, rheumatology patients are more likely to prefer magazines whereas endocrinology and neurology patients index very high on television programs.

Many other differences between patient groups appeared in the Kantar study. For example, **35 percent** of neurology patients are more likely to value TV programming in the doctor's office; **8 percent** of oncology patients are more likely to value their doctor; psychiatric patients are more likely to value all available information sources at the doctor's office – **25 percent** magazines, **27 percent** ads/brochures, and **15 percent** TV; and endocrinology patients are **14 percent** less likely to value their physician, but **26 percent** more likely to value TV programs.

The way that physicians use digital devices and consume online media has changed significantly since 2009. Only half of doctors used a personal digital assistant for professional purposes three years ago, but now, almost **three in four** use a smartphone. A majority of physicians use a smartphone professionally. **One third** have already incorporated a tablet into their professional routine. Accessing the Internet and checking email are the top two activities of doctors on these devices. Additionally, **40 percent** of physicians are starting to use their smartphones to reference drug data, while **36 percent** find and perform clinical calculations, **30 percent** make prescribing decisions, and **24 percent** research general medical issues. For the tablet users, reading articles from medical journals and researching general medical topics top the list of other activities.

In the first three quarters of 2012, consumer health ad dollars surpassed **$2.6 billion**, according to Kantar Media Intelligence. The top direct-to-consumer categories regarding advertising spend were **antidepressants**, **impotence drugs**, **chronic obstructive pulmonary disease medications**, **arthritis medications**, and **lower back pain and osteoarthritis drugs**.

MOST-RECOGNIZED BRANDS

FEMALE HEALTHCARE

The most recognized female healthcare brand in North America is **Premarin**. The brand was most-recognized by 8.6 percent of physicians in a survey conducted by **Brand Institute** Inc. during the third quarter of 2012. 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 3.8 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 **Ortho Tri-Cyclen**. About 3.5 percent of physicians recognize this brand the most. Ortho Tri-Cyclen, comprising ethinyl estradiol and norgestimate, is marketed by Janssen Pharmaceuticals, a division of Johnson & Johnson. The product is indicated as a contraceptive for prevention of pregnancy.

The most-recognized female healthcare brand in Europe is Premarin. About 3.9 percent of physicians recognize this brand the most.

Canesten is the second most-recognized female healthcare brand in Europe. About 3.1 percent of physicians recognize this brand the most. Canesten, comprising clotrimazole, is marketed by **Bayer** Healthcare (bayerhealthcare.com) for the treatment of vaginal yeast infections and other fungal infections.

The third most-recognized female healthcare brand in Europe is **Yasmin**. About 2.9 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.

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.

Sex, lies, and DTC: Advertising for impotence pills

By Ed Silverman

Several years ago, the drugmakers that sell impotence pills convinced Congress that federal regulations were not required to ensure objectionable ads would not be seen by children. However, a new study charges that industry efforts to regulate direct-to-consumer advertising have been a "ruse" designed to deflect criticism and block Congress from intervening.

From 2006 to 2010, when DTC advertising for erectile dysfunction pills rose 62 percent to $324.3 million, the study found a "consistent pattern" in which drugmakers failed to comply with guiding principles that were propagated by the Pharmaceutical Research and Manufacturers of America, the industry trade group.

PhRMA instituted 15 principles for DTC advertising in 2006 and revised and expanded them three years later. The principles include accuracy, patient education, readability, availability of treatment options, assistance for uninsured or underinsured patients, and avoiding audiences for which messages may be inappropriate. Both times, PhRMA cited its principles as reasons that Congress should not pass a law that would have restricted the time of day that TV ads for impotence pills could be aired. Drugmakers said such a move would be unnecessary because they complied with industry principles which, after the revision, said that at least 90 percent of the audience for the ads would be 18 years or older.

But the study says that did not happen. Instead, consumers were exposed to approximately 500 billion TV ad impressions for impotence pills since 2006, and more than 100 billion were seen by children – those under the age of 18, which violated the guiding principles. And the study found the 90 percent goal was not met for any quarter during the years that TV ad materials were studied.

The researchers found that ads for **Cialis**, which is sold by Eli **Lilly** and Co., consistently violated six principles, partially complied with two principles, and fully complied with one principle. **Pfizer**'s **Viagra** DTC campaign consistently violated five principles, partially complied with one principle, and fully complied with two principles. **GlaxoSmithKline**'s **Levitra** ads consistently violated five principles, partially complied with three principles, and fully complied with one principle. GSK is responsible for U.S. Levitra marketing. Glaxo halted Levitra TV ads in fall 2009 and, in 2011, stopped running TV ads for the drug.

At no point did the drugs comply with the guideline at a rate better than 50 percent for the total category. Cialis was the most consistently compliant, with violation rates ranging from 33.7 percent to 55.7 percent. Viagra's rates ranged from 56.9 percent to 64.4 percent, and Levitra's from 56.6 percent to 72.2 percent.

"Our conclusions provide evidence to support the idea that self-regulation can be utilized as a way to prevent new governmental regulations while allowing companies to engage in practices consonant with their independent strategic aims through a collective blocking strategy," wrote the researchers in the *Journal of Health Politics, Policy and Law*.

"Cumulatively, our data shows that ED marketing campaigns fail to responsibly educate consumers about health conditions and appropriate treatments," says lead author Denis Arnold, an associate professor of management in the Belk College of Business at UNC Charlotte. "Instead of facilitating a balancing of interests between company profits and public health, the illusion of industry self-regulation is primarily serving the interest of pharmaceutical companies at the expense of the public's interest in genuine health education and welfare." The study notes that PhRMA has played the role of facilitator. (The researchers examined nine of the 18 principles, since they believed they could not independently verify all of them).

The researchers suggest more regulation is in order. These might include restrictions on ads that can reach children; requiring ads to address treatment options other than medicines along with comparative costs; requiring FDA approval of ads before being broadcast for the first time, and assessing fees for each ad that is broadcast, which would provide funding for the National Library of Medicine to distribute simple information about benefits, harms and costs.

Lilly responded: "We're actually looking into this study and checking with our media buyers regarding the violations mentioned in the article. Lilly takes this very seriously. The main goal of all of our direct-to-consumer ads is to educate and inform, and we have been able to do that in a responsible and thoughtful way with the Cialis ads through the years. As with all of our direct-to-consumer materials, these commercials are straightforward and sincere and the content is open and honest about ED, which is in line with our corporate brand. Also, the ads provide men with important benefit and risk information, consistent with FDA guidelines, allowing men to make a decision about whether to consult with their physician about Cialis."

Pfizer says: "We have not reviewed the analysis, but we take great care in choosing when and where we advertise because we want the right message to reach the right person at the right time. Viagra ads air only during programs that have greater than 90 percent adult viewership. We believe that both healthcare providers and patients need information about the benefits and risks of available treatment options. We believe it is our responsibility to communicate clear information about medical conditions and treatments so patients can work with their healthcare professionals to make informed decisions about their health and get appropriate prevention, diagnosis, treatment and wellness information. DTC advertising is one way of communicating information to patients."

PhRMA says: "The *Journal of Health Politics, Policy and Law* study fundamentally ignores the health benefits of direct-to-consumer advertising, including raising awareness of diseases and treatment options and empowering patients to communicate with their physicians about medical problems and potential treatments. DTC communications about prescription medicines can not only increase awareness about diseases, but can motivate patients to engage with their physicians.

"...Since 2009, PhRMA member companies complying with PhRMA's Guiding Principles on DTC Advertising have voluntarily exceeded the legal requirements regarding submitting advertisements to FDA for review. The principles are intended to help improve the ways that our companies communicate with patients about medicines that, if prescribed by their physicians and used appropriately, can improve and save lives. PhRMA is especially encouraged that the *Journal of Health Politics, Policy and Law* study found high compliance by biopharmaceutical companies in describing safety information about medicines, which is an important feature of the PhRMA Guiding Principles."

Interactive&DigitalMarketing

By Joshua Slatko joshua.slatko@ubm.com

CIOs see mobility as primary channel for customer engagement

Demonstrating the growing importance of incorporating mobility into enterprises, CIO respondents to an Accenture survey believe mobility will generate significant sources of new revenue for their businesses, and most will invest between 31 and 40 percent of their discretionary budgets to achieve that goal, compared with just 19 percent of CIOs surveyed last year.

In The Accenture 2013 CIO Mobility Survey, the overwhelming majority of respondents (79 percent) cited mobility as a revenue generator and said it would significantly improve customer interactions (84 percent) as well as significantly affect their business (83 percent). The survey also found that mobility is a top priority in the coming year for more than one-third (34 percent) of CIOs; and 42 percent of CIOs ranked mobility as one of their top five priorities. Anecdotal data from interviews also suggests that many CIOs approach new IT projects with a "mobile first" thinking.

Regarding specific mobile capabilities, survey respondents indicated that improving field and customer service with instant data access, capture, and processing topped the list of needs (43 percent), followed by engaging customers via mobile devices (36 percent), especially with transactions on mobile devices (34 percent). Twenty-nine percent of all respondents said they plan to design, develop, and/or distribute connected devices to support B2B applications.

Over the next year, nearly half (46 percent) of CIOs said they plan to make workflow changes to better incorporate mobility into their business. Additionally, 73 percent believe mobility will impact their business as much or more than the web revolution of the late 90s, compared to 67 percent who felt this way in a similar Accenture survey conducted last year.

"It's encouraging that companies are embracing the importance of mobility but they need to go further by identifying the top areas for mobile deployment," says Jin Lee, senior managing director, Accenture Mobility. "In particular they should look at areas that will grow, such as connected devices, and conduct a 'gap analysis' to determine how to catch up, or even better, get ahead of the curve. Other critical considerations include investments, budget allocation, re-training staff, hiring mobile expertise, and leveraging external experts to help develop or implement mobility strategies."

Progress in mobile strategy varies

More than half of the companies surveyed (58 percent) have a moderately developed formal mobile strategy, and about one-quarter (23 percent) have an extensively-developed formal mobile strategy, down from 31 percent from last year. This suggests that the velocity of the uptake of mobile technology is accelerating to the extent that companies are being pushed to take action before they can get a well-defined strategy in place.

China (50 percent), Italy (47 percent), and Brazil (37 percent) lead the way globally with extensively-developed mobile strategies. Despite varied progress in strategy development, half (50 percent) of the companies surveyed said they would identify prioritized mobility initiatives over the next year, an increase over last year (41 percent).

Nearly all said their mobile strategies must support smartphones (85 percent) and tablets (78 percent), a nod to the increase in employees' use of their own tablets for work, and companies' deployment of tablets as work devices. The survey further found that mobile device management (27 percent), collaboration (25 percent), and knowledge sharing (23 percent) are the top three most important features to a developed mobile strategy. When participants were asked about their top two priorities, China (53 percent), Italy (53 percent), and India (50 percent) tagged mobility as one of their top two focus areas. The United Kingdom (67 percent), Japan (57 percent), and France (52 percent) ranked mobility as one of their top five IT priorities.

Most respondents in India (77 percent), and almost half (47 percent) of respondents in Japan, Mexico, and the United Kingdom plan to focus their enterprise efforts on improving field and customer service delivery with instant data access, capture and processing. In consumer-related mobility priorities, 63 percent of respondents in India and the United Kingdom cited driving revenue through transactions on mobile devices within their top priorities, followed by the United States (36 percent).

Staffing, security, interoperability, BYOD continue as challenges

Fifty-two percent of companies said they would retrain existing staff to enable their mobile strategies, and 37 percent will hire full-time mobile expertise into their organization, indicating a high demand in the market for mobility talent. The survey also found that more projects are being staffed internally (76 percent in 2013, versus 63 percent in 2012) to support the development of mobile applications. Surprisingly, while 2012 may be remembered as the year HTML5 took the Internet by storm – the catch-all term used for the latest protocols that define the content, layout, and navigation of Webpages through web browsers – almost half (49 percent) of respondent companies' mobile application approaches relied on both native and web apps.

Accenture's analysts say that security is still a significant concern, and interoperability has risen as an issue, indicating that existing systems were not all built for mobile and must be transformed for adoption to continue. The study found that security (45 percent), budget concerns (41 percent), and lack of interoperability with legacy systems (31 percent) are still the main barriers cited by companies as impacting their mobile priorities.

Another area related to mobile adoption is "Bring your own device," or BYOD. However, more than half of the enterprises surveyed (59 percent) provide only limited support to their employees while about one-quarter (28 percent) offer full support.

"CIOs must find ways to support the myriad of mobile devices entering the work environment," Mr. Lee says. "They should also address the need to focus intensely on people and expertise. Almost twice as many companies – 40 percent in 2013, versus 27 percent in 2012 – plan to leverage external experts to develop and refine their strategy, indicating that mobile usage is growing faster than the market can provide in terms of skilled and available talent."

All (100 percent) of survey respondents in the healthcare sector plan to reach their top mobile priorities within the next year. Healthcare respondents cited location-based services (46 percent) as most important. Among communications companies citing M2M as a mobile priority, sixty-seven percent said they would execute M2M communications in their organization within the next year.

FACTS & FIGURES

According to a survey by Nuance Communications, **80 percent** of physicians believe that within five years, virtual assistants will drastically change how they interact and use electronic health records and other healthcare apps, making them more efficient and freeing up time to spend on patients.

Survey respondents stated that mobile virtual assistants could impact healthcare most by helping them access information in EHRs, and navigate through the process using conversational commands. **One out of three doctors spends 30 percent or more of their day on administrative duties** — activities that could be redirected or removed using voice-enabled virtual assistants.

65 percent of respondents to the Nuance survey say that the top role for a virtual assistant would be more accurate, timely information to support care or alert them to missing information in records. **73 percent** expect virtual assistants could improve healthcare and patient engagement by helping to coordinate care between multiple caregivers. And **80 percent** believe virtual assistants will benefit patients most by engaging them in the process, prompting them to adhere to health advice and modifying behaviors.

"Mobile virtual assistants have the potential to reinvent the way we deliver patient care," says Dr. Alireza Shafaie, Palo Alto Medical Foundation. "As a consumer, I already experience the value of mobile assistants, and would love to bring that natural, intelligence-based dialogue to my work as a primary care physician. For every one patient I see I have to communicate my recommendations in three different places. A mobile advisor that could do that on my behalf in one shot would give me back more time in what truly matters – time with my patients."

One area of interest with physicians is intelligent, voice-driven, computerized physician order entry (CPOE) that uses more sophisticated reasoning for ordering medications, labs and radiology exams beyond mere speech. Healthcare developers can embed virtual assistants — ones that conduct meaningful conversations, interpret physician requests, ask for clarification and seamlessly manage changes in course of action much like their human equivalents — directly into any clinical app to enhance a variety of new and existing workflows, including CPOE.

ACOs on the rise

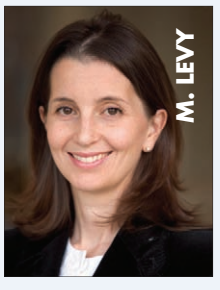
By Monique Levy

Healthcare moves fast when it has to.

According to HealthLeaders-InterStudy, there are currently 500 accountable care organizations either in development or in operation in the United States, about half of which have contracted with the Centers for Medicare & Medicaid Services since the Affordable Care Act passed. Moreover, another 150 ACOs, by conservative estimates, are expected to form by yearend.

All of this implies added challenges to pharma's already rapidly evolving sales and marketing landscape. To adapt to ACO environments, pharma will have to look for ways to align with the ACOs' strategic goals, namely helping lower risk by driving patient behaviors and treatments that reduce cost and improve outcomes. Some leading pharmas are certainly ready to pursue new partnerships. Novartis CEO Joseph Jimenez went on record in an interview in the *Wall Street Journal* on New Year's Day discussing the company's growing focus on patient outcomes, a hallmark of ACOs.

Key findings from our recent physician and consumer U.S. studies indicate several opportunities pharma sales organizations and brand marketing teams can explore:



Watch for opportunities on Electronic Health Records (EHR). According to Manhattan Research's Taking the Pulse U.S. 2012 study, more than two-thirds of physicians said they are interested in accessing resources from pharma via the EHR. Patient education materials, samples (or vouchers for samples), financial assistance resources, and product information are most popular. Pharma should look for innovative EHR vendors and publishers that are integrating third-party content via the EHR platform. PDR Network, for example, has a growing EHR partner network and the acquisition of Epocrates by Athenahealth is likely to lead to products leveraging the EHR platform.

Explore Patient Support Programs. Getting patients to adhere to new behaviors and treatments is notoriously challenging; however, consumers' overall digital sophistication (from device ownership to proficiency managing digital media) and growing knowledge around gaming and behavioral modification could usher in a new era of more engaging patient support programs. More than 3 in 10 online consumers say they are interested in using a registration-required online patient support program from pharma.

Think of what you can do in the office for patients. More than half of online consumers said they are interested in receiving resources from pharma via the doctor or nurse in the office. Resources shared via email and the patient portal garnered especially high interest.

It remains to be seen whether ACOs and payers will be interested in partnering with pharma. Intense pressure to succeed and scarce resources might well drive ACOs to welcome value-added services from pharma that drive desired outcomes just the way many payers have. According to Manhattan Research's Taking the Pulse Formulary Decision Makers 2012 study, about half of Hospital, PBM, and MCOs surveyed reported using patient education resources provided by pharma and more than one-quarter have used financial assistance resources.

Buckle up for more big moves in this space in the next 18 months.

Monique Levy is VP of research for Manhattan Research.

AdAgencyUpdate

By Joshua Slatko joshua.slatko@ubm.com

Havas taps WebMD veteran to lead New York agency

Former WebMD executive Dorothy Gemmell has joined Havas Health as leader of the network's Havas Life New York office.

The agency network Havas Health has named Dorothy Gemmell, a long-time WebMD executive, to lead the network's **Havas Life New York** office. According to network leaders, Ms. Gemmell, who has never worked for an agency before, will bring a fresh leadership perspective to one of Havas Health's most significant unified health and wellness agency brands.

Ms. Gemmell brings an impressive track record to her new job at Havas. She has more than 20 years of healthcare experience spanning biopharmaceuticals, medical education, and digital healthcare. At WebMD, her most recent role was senior VP, sales and sales operations, and she sat on the company's executive leadership committee, which set the strategic priorities for the company and was directly responsible for leading WebMD's Global Biopharmaceutical and Medical Device businesses, WebMD The Magazine and its sales, revenue and advertising operations groups. In her tenure at WebMD, she was responsible for creating new revenue streams, developing go-to-market strategies for new products and acquisitions, building specialized sales organizations, and leading the operations groups to support sales operations. She grew WebMD's sales organization from 20 to more than 130 people and its sales from $20 million to $400 million.

"Dorothy has really been a pioneer and a star," says Doug Burcin, co-global CEO of Havas Health. "She's a great leader and a business builder. Our clients are looking toward technology in the digital era for ways to drive their business, so we were thrilled to be able to get Dorothy to consider us. She's coming from the new market; she's worked with digital content, connecting with payers and providers, so having that skill set will enable the agency to continue to accelerate its growth trajectory for today's clients."

The need for a new leader at Havas Life New York arose when one of the agency's executives, Laurel Rossi, moved back to her original bailiwick of consumer work and another, Marc Porter, had to take a leave of absence for personal reasons. "Laurel Rossi came to us two years ago when we acquired her agency, Strategy Farm," Mr. Burcin says. "She came from the consumer space, so when we bought her agency it was for her to take that piece of business and grow it. We persuaded her to step into running the New York agency in addition to what she was doing and help bring in that consumer perspective, which she did. She was doing double duty, and now this enables her to go back to what we actually acquired her for, to continue to grow the consumer business."

Mr. Burcin and Donna Murphy, the other Havas Health co-CEO, knew exactly who they wanted for the new job. They both had a long track record of working with Ms. Gemmell and had already built a strong relationship with her, in part through the joint development of a proprietary virtual product by Havas Drive and WebMD. So the two CEOs began scheming ways to bring Ms. Gemmell in-house.

"We actually texted her and said, 'Where are you, we have an opportunity, and we want to talk with you about it,'" Ms. Murphy says. "She was actually in Italy on holiday. She texted back, 'I'm on holiday,' and I said, 'When do you arrive?' We texted her the day she landed and said, 'Okay did you land? Let's talk.'"

As Mr. Burcin tells it, their target had never even considered moving to an agency. "We'd worked with Dorothy in the past and have a lot of respect for her; I think what initially enticed her was her familiarity with us and our culture," he says. "That at least got her to respond while she was on holiday. When we met to discuss it, she said, 'You know, I never even considered this path, but I'm interested,' and that led to more discussion. From a culture perspective it is an absolute hand in glove fit."

One of the benefits of bringing Ms. Gemmell to the agency, aside from her experience and skill set, is that many Havas clients already know her name. "All our clients think very highly of her because they've worked with her at WebMD and they really view her as an innovator," Ms. Murphy says.

According to Mr. Burcin, leading an agency in today's healthcare marketplace requires a new perspective, which is why Havas looked outside of what might be considered the usual suspects.

"To lead an agency today requires a superior skill set, to work with people and keep a culture moving in the right direction for the business," he says. "Our clients are very demanding, and times are tough. So we've been looking for talent in unexpected areas, because expected areas were just more of the same. Having uncovered someone in an unexpected area, someone like Dorothy – we're just so excited."

Pacific named AoR for Natrelle

Allergan Inc., a multi-specialty health care company, has selected **Pacific Communications** to assist in the promotion of Natrelle silicone and saline breast implants and tissue expanders. Pacific Communications will also support the U.S. launch of Natrelle 410, a highly cohesive anatomically shaped silicone-filled breast implant.

"The innovative design of Natrelle 410 is designed to help prevent upper pole deformities, thus holding its shape over time and giving women a shape that mirrors a woman's real curves," says Karen Melanson, senior VP, director of client services. "Already a preferred product in Europe and Canada, the launch of Natrelle 410 in the U.S. will offer patients and surgeons a highly sought after product with demonstrated benefits."

Pacific Communications will manage the professional and in-office patient marketing communications for Natrelle reconstruction and augmentation products.

PITCH THERARY

Average teams lose every time

By Mark Schnurman

My basic understanding of statistics says that if four teams are pitching, an average team will win one out of four pitches. The flaw in the logic is that usually one out of the four teams is above average and they are the ones that go home with the prize. As a result, the average team wins infrequently.

No one likes to admit when they have an average pitch team but let's take a look at what average means in the new business pitch world by describing below-average, average and above average presenters.

Starting with below-average presenters. They get nervous to the point where it gets in the way of the presentation. I know many nervous presenters that do a terrific job presenting. They don't enjoy it, but they have found coping mechanisms that help them to do a good job in spite of a flock of butterflies in their stomach.

Below average presenters frequently have difficulty with the content on the slides. To make matters worse, they are practicing the words on the slide without paying much attention to the intent of the slide. The end result is that they come across as as distant, nervous, bored, disinterested, smug…any one of a number of adjectives that jump out and say "I am not terribly interested in your business."

The last characteristic that would put someone in the below average category is that they make it difficult for the client to select the agency. Usually this comes from acting as if they invented advertising. Working on a recent consumer pitch on the West Coast, I ran into a gentleman that managed to combine know-it-all and laid back into one, interesting presentation. He spent his eight minutes describing how much better his 50 person agency was than Goodby and a slew of other top agencies. As an audience member I could not help but think, "If you are so great, why are you only 50 people?" A common thread of this type of presenter is that they make the audience either feel uncomfortable or belittled with unsupported sales puffery.

The bulk of presenters at a new business pitch are average. They can deliver slides without much of an issue. A little practice and they can do a good job getting through what in our industry can be some pretty difficult bullets. There are two areas where the presentations fall short.

The first thing that makes presenters average is that they focus on the content and themselves and rarely concentrate on connecting with the audience. This becomes very important because the person that is most likely trying to connect with the audience is the managing director, who will probably not be spending much time with the client. The people that need to make an attempt to connect are the more day to day people. They are the ones that the client needs to like. Give them a little more time to practice their section so that they can stop focusing on the bullets and have time to focus on the audience.

The other area where presenters become average is that the presenter is so busy presenting bullets they forget why they are presenting in the first place. Don't just tell me the bullets, tell me why they are important. What is the story behind that data? What insight does that data reveal? An average presenter feels that it is their job to deliver the points on the slide. Typically, all slides or bullets are presented with equal emphasis. The fact of the matter is that in a typical presentation, a few slides or points are much more important than the balance of the presentation. Those points need to be sold, not just presented. By delivering everything with equal emphasis, often times the important points get lost in a sea of less important slides.

The very best presenters basically do two things well. They sell the important stuff much harder than the less important stuff and they connect with the audience. These are the people that clients say "that person is smart and I can work with them." The smart part of presenting is taking data and research and turning it into actionable opportunities.

Connecting with the audience can be a learned skill. Mentoring, training, rehearsal can all lead to a more compelling presentation. How much of your time as a manager are you dedicating to mentoring or training? The more time you invest in these areas the more likely you are to put an above average team on the pitch field.

Take a critical eye to your team. Who on the team is average? Who is above average? Remember, we only have 90 minutes. Don't make excuses like, "Once they get to know Bob, they love him." If Bob can't bring it on game day, you are in trouble. If all you have are people delivering bullets, you are in trouble. Get people to understand why they are presenting a particular slide instead of just what to present and it will be a far better pitch. All of this is an investment on your part, but winning agencies make the investment.

Mark Schnurman is the managing partner of Filament Inc., a new business pitch consulting company.

AGENCY PEOPLE ON THE MOVE

AbelsonTaylor

Jeff Berg is promoted to senior VP and director of client services, AbelsonTaylor (abelsontaylor.com). Mr. Berg is replacing **Nancy Drescher**, who is leaving to be a full-time mom for her two young daughters. **Carrie Hixson** is promoted to senior account supervisor. Ms. Hixson joined the agency in 2010 as an account supervisor. **Bill Morley** is promoted to account executive. Mr. Morley, who joined AbelsonTaylor in 2011, was an account coordinator. **William Shea** is promoted to senior account executive. Mr. Shea was an account executive and joined the agency in 2009. **Alexa Stuart** is promoted from account coordinator to account executive. Ms. Stuart joined AbelsonTaylor in 2011.

Centron

Kelly Lupton joins Centron (centroncom.com) as VP, account director. Ms. Lupton was business development manager, LehmanMillet. **Merry Lampi** becomes creative supervisor. Ms. Lampi has many years of experience as an art director in graphic design, digital design, and print production. **Joe Macera** joins the agency as an account coordinator from Cucina Antica Foods Corp., where he was a marketing and social media coordinator. **Helen An** is named senior VP, associate creative director. Ms. An was VP, associate creative director, H4B Chelsea.

Fingerpaint

Elizabeth Rizzo joins the account service team at Fingerpaint (fingerpaintmarketing.com). Ms. Rizzo was marketing manager

at MAC Source Communications. **Bruce Robinson** joins the agency's medical strategy team. Mr. Robinson was senior medical copywriter at the CDM Group and Ignite Health.

Natrel Communications

Jamie Babbitt is promoted to copy supervisor, Natrel Communications (natrelusa.com). Ms. Babbitt was senior copywriter. **Meghan Byers** is promoted to junior editor. Ms. Byers was administrative assistant. **Marie Fitzsimmons** is promoted to assistant account executive. Ms. Fitzsimmons was traffic coordinator. **Susan LaPenta** is promoted to senior traffic manager. Ms. LaPenta was traffic manager. **Jason Mills** is promoted to senior art director/studio manager. Mr. Mills was art director/studio manager. **Cathy Orsi** is promoted to office manager. Ms. Orsi was assistant office manager. **Bradley Turner** is promoted to assistant account executive. Mr. Turner was traffic coordinator. **Laura Wisniewski** is promoted to account group supervisor. Ms. Wisniewski was account supervisor.

Rosetta

Kim Corrigan joins Rosetta (rosetta.com) as a partner in the healthcare vertical. Ms. Corrigan was executive VP, group management director, Draftfcb New York.

PeopleontheMove

By Joshua Slatko joshua.slatko@ubm.com

Ariad names new leaders for European market

The oncology company Ariad Pharmaceuticals Inc. has named a number of new executives to its European leadership team in anticipation of the approval of a new product and expansion in the region. Most prominently, the company has appointed **Jonathan E. Dickinson** to the position of general manager, Ariad Pharmaceuticals (Europe), Sàrl. Mr. Dickinson, company leaders say, is a seasoned commercial executive bringing more than 20 years of pharmaceutical-industry experience to Ariad, with special emphasis on global and pan-European leadership of several important cancer medicines. He will be responsible for leading Ariad's European commercialization initiatives, focused first on the anticipated European approval and launch of Iclusig (ponatinib) in the third quarter of 2013, and subsequently on Ariad's other cancer medicines in development.

Mr. Dickinson joined Ariad from Bristol-Myers Squibb, where he served for the past three years as the European brand lead for ipilimumab, responsible for the product's European launch and commercialization in 29 countries. Previously, during his 13-year tenure at Hoffmann-La Roche, Mr. Dickinson held several key leadership positions, including lifecycle leader for capecitabine, where he managed global marketing, clinical development, regulatory affairs and manufacturing activities for the brand. At Roche, he had assignments both in the United States and Switzerland that included leadership roles of Roche's three leading oncology medicines – trastuzumab, rituximab, and capecitabine. Mr. Dickinson began his career at Novartis, where he held commercial roles in its oncology and endocrinology businesses, including medical sales, product manager and business director in the United Kingdom.


J. DICKINSON

Mr. Dickinson received his B.Sc. degree in Genetics and his M.B.A. degree from the University of Nottingham. He is based at Ariad's European headquarters in Lausanne, Switzerland and reports to Marty J. Duvall, senior VP, commercial operations, Ariad.

"Jonathan is a proven leader with broad commercial and general management experience promoting several of the most highly regarded oncology medicines available today," says Harvey J. Berger, M.D., chairman and CEO of Ariad (ariad.com). "His knowledge of the evolving European market and his success in commercializing important cancer medicines throughout Europe and globally will serve us well as we prepare for anticipated approval and commercialization of Iclusig in the EU this year."

Anna Casse is named head, marketing and sales. Ms. Casse joins Ariad from Novartis, where she served as head of the nephrology business unit in Germany. Prior to this, as head of oncology marketing in Germany, she led the country launches of nilotinib and everolimus. Ms. Casse also served as head of the Novartis oncology business in Finland and oversaw global business development and licensing for Novartis Ophthalmics. Prior to her eight-year tenure at Novartis, she spent four years in business development and strategic planning at Amgen Europe. She also worked as a consultant at Arthur Little in the Benelux countries. Ms. Casse has a B.S. from the University of Birmingham and an M.B.A. at the INSEAD, Fontainebleau, France.

Anant Murthy, Ph.D., becomes head, pricing, reimbursement, and access. Dr. Murthy joins Ariad from Celgene, where he was most recently the executive director and head of global pricing and market access for hematology and oncology. Previously, he expanded and led Celgene's European pricing team to support the launches of lenalidomide, azacitidine, and nab-paclitaxel across the EMEA region. Prior to Celgene, Dr. Murthy worked in the reimbursement and health economics team for the CRDM business of Medtronic, Inc. Dr. Murthy has a B.A. from the University of Rochester, an M.S. in international health economics from the London School of Economics, and a Ph.D. in international health systems from the Johns Hopkins Bloomberg School of Public Health.

Kai C. Chan, M.D., is named head, medical affairs. Dr. Chan joins Ariad from Genzyme (Sanofi), where he was European head of medical affairs for transplant oncology. Previously, Dr. Chan was with Johnson & Johnson as global medical lead for bortezomib lung cancer development, and with AstraZeneca in oncology clinical research. He is a practicing surgeon at Wycombe Hospital in High Wycombe, U.K. Dr. Chan has a M.B., Ch.B., M.D., and M.Sc. in Oncology from the University of Manchester, a F.R.C.S. from the Royal College of Surgeons of Edinburgh, and a Diploma in Pharmaceutical Medicine from the University of Wales.

Thierry Bataillard is named head, regulatory affairs. Mr. Bataillard joins Ariad from Merck Serono, where he held leadership positions in regulatory affairs within the oncology, endocrinology and diabetes businesses. He has a M.Sc. from the Institute of Industrial Pharmacy at the University of Bordeaux and a Pharm.D. from Claude Bernard University.

Ariad has also hired the country managers for France, Germany, Italy, and the United Kingdom. Each of them brings more than a decade of experience commercializing cancer medicines.

"As we build an integrated global oncology company, the recruitment of this outstanding European team clearly demonstrates our commitment to success," Mr. Duvall says. "Led by Jonathan Dickinson, Ariad will be fully prepared for the anticipated EU approval and launch of Iclusig later this year."

PHARMA

■ **Rajiv De Silva** becomes president and CEO, Endo Health Solutions Inc. Mr. De Silva was president of Valeant Pharmaceuticals. Endo (endo.com) is a diversified healthcare company that finds solutions for the unmet needs of patients along care pathways for pain management, pelvic health, urology, endocrinology, and oncology.

■ **Ann Powell Judge** is named senior VP, human resources, Bristol-Myers Squibb (bms.com). Ms. Judge was chief human resources officer at Shire Pharmaceuticals.

BIOTECH/BIOPHARMA

■ **Sean P. Nolan** joins InterMune Inc. as executive VP and chief business officer. Mr. Nolan was VP and chief commercial officer, Reata Pharmaceuticals. InterMune (intermune.com) is a biotechnology company focused on the research, development and commercialization of innovative therapies in pulmonology and orphan fibrotic diseases.

■ **Gary J. Bridger**, Ph.D., becomes executive VP, research and development, Xenon Pharmaceuticals Inc. Dr. Bridger was a partner with Ventures West Capital Management. Xenon (xenon-pharma.com) is a privately owned, clinical genetics-based drug discovery and development company engaged in developing novel therapies for rare diseases.

■ **Jane Henderson** is named senior VP and chief business officer, Kolltan Pharmaceuticals. Ms. Henderson was VP, business development at ISTA Pharmaceuticals Inc. Kolltan's (kolltan.com) primary focus is to create novel biologic agents that can modulate the function of receptor tyrosine kinases.

■ **Larry Bell**, M.D., is appointed VP of regulatory affairs, Prosensa Therapeutics. Dr. Bell was VP and global head of regulatory affairs at GE Healthcare. Prosensa (prosensa.com) is a biopharmaceutical company focused on the discovery, development and commercialization of RNA-modulating therapeutics correcting gene expression in diseases with significant unmet need, in particular neuromuscular disorders.

SPECIALTY

■ **Adrian Adams** is named chairman of the board of directors, AcelRx Pharmaceuticals Inc. Mr. Adams is CEO and president of Auxilium Pharmaceuticals. **Thomas Schreck**, co-founder of AcelRx and board member, departed from the board Feb. 11. AcelRx (acelrx.com) is a specialty pharmaceutical company focused on the development and commercialization of innovative therapies for the treatment of acute and breakthrough pain.

■ **Charles Walker** is appointed CEO, Alchemia Ltd. Mr. Walker had been the company's chief financial officer for the past two years. Alchemia (alchemia.com.au) is a drug development company with a late stage oncology product pipeline and an FDA-approved drug, Fondaparinux.

■ Aqua Pharmaceuticals co-founder **Jay Gooding** has retired from the company. Fellow co-founder **Craig Ballaron** will continue in the role of CEO. Mr. Gooding and Mr. Ballaron founded Aqua in 2004. **Ted White** is promoted to chief operating officer. Mr. White was previously the company's VP of sales. **Mark Boyer** becomes director of finance. Mr. Boyer was controller. Aqua (aquapharm.com) is a specialty pharmaceuticals company focusing on acquiring, developing and marketing prescription dermatology products.

■ **Cécile Miles** is appointed chief business officer, Prosonix. Ms. Miles was commercial director EU at the Watson group. Prosonix (prosonix.co.uk) is a specialty pharmaceutical company developing a portfolio of inhaled respiratory medicines enabled by its unique particle engineering technology.

■ **Graham Cooper** is named chief financial officer, Receptos Inc. Mr. Cooper previously served as chief financial officer for Geron Corp. and Orexigen Therapeutics Inc. Receptos (receptos.com) is a biopharmaceutical company developing therapeutic candidates for the treatment of immune and metabolic diseases.

■ **Jim Hartman** is promoted to VP of the U.S. aesthetics business unit of Merz North America. Mr. Hartman was hired in June 2012 to lead the company's U.S. dermatology business unit. Merz North America (merzusa.com) is a specialty healthcare company that develops and commercializes innovative treatment solutions in aesthetics, dermatology and neurology in the United States and Canada.

■ **Gilles Della Corte**, M.D., becomes director of clinical development, Anergis. Dr. Della Corte has worked for a number of pharmaceutical companies, including Rhone-Poulenc Rorer, Servier, Solvay, Serono, and Merck Serono. **Eva Castagnetti**, Ph.D., is named director of product development. Dr. Castagnetti previously worked for Lonza, Senn Chemicals, and Rapid Pharmaceuticals. Anergis (anergis.ch) is a Swiss-based biopharmaceutical company specializing in the discovery and development of novel allergy vaccines targeting the most frequent allergies.

SERVICE SUPPLIERS

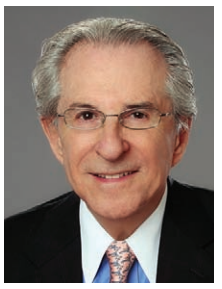
■ **Soumya Roy**, Ph.D., is promoted to managing partner of the U.S. Health practice, Hall & Partners Health. Dr. Roy joined the agency in 2010. Hall & Partners Health is the specialist division of Hall & Partners (hallandpartners.com) dedicated to healthcare and pharmaceutical marketing research.

■ **Beth Thompson** is appointed VP, qualitative research, CMI. Ms. Thompson previously managed her own qualitative consultancy for a number of years and has held senior positions at Genactis, AlphaDetail, and GfK. CMI (cmiresearch.com) is a full-service marketing research company that combines comprehensive market research expertise with marketing insight to provide clients with a deep understanding of their customers by identifying the choices they make and why.

RETIREMENTS/RESIGNATIONS

■ **Georgina Kilfoil**, former senior VP of product development, has left Anthera Pharmaceuticals Inc. to pursue other opportunities. Dr. **Colin Hislop**, the company's senior VP and chief medical officer, will continue to oversee all product development-related activities for Anthera's developmental compound blisibimod. Anthera (anthera.com) is a biopharmaceutical company focused on developing and commercializing products to treat serious diseases associated with inflammation and autoimmune diseases.

Lessons of Lincoln … What happened to doing the right thing?



By Sander A. Flaum

I've loved Abraham Lincoln (happy 204th birthday, Mr. President) for as long as I can remember.

If you look for an example of an exemplary life, I can't think of a better role model. He showed it all. *Determination*. Who suffered more setbacks on his way to the presidency? *Focus*. What politician has spoken more succinctly and honestly? *Courage*. Who would be willing to risk withering attacks from both enemies and supporters alike and keep moving forward?

For me, the attribute I admire the most – and I confess I'm at a loss for a single word to capture it – was his willingness to do the right thing. And let's put capitals on those words: "Do The Right Thing." By this I mean a commitment to the greater good that eclipses one's own needs and even the needs of one's supporters. The biographies of Lincoln make it clear that while his foes loathed his determination to end slavery, his allies were maddened by his deliberation and patience.

I'm going to assume you've all seen the film *Lincoln* (if not, please do), and so I won't deliver a history lesson about the battle to pass the 13th Amendment through an intransigent Congress. It's enough to say that while Lincoln's methods in capturing the votes he needed were not always aboveboard, his aim was always on the broader goal. For Lincoln, the essential task – really the only task – was not a victory, but to Do The Right Thing – and more exactly, to *get the right thing done*.

A curious aspect of the "Right Thing" is that although to many it seems obvious, to another faction it is often abhorrent. Today, it's hard to believe that once in America, humans could be bought and sold like cattle. Yet in the 1860s, as nations around the world were abolishing slavery, many Americans considered the institution woven into the Constitution itself, right up there with apple pie. To them, ending slavery was certainly not a "Right Thing To Do," but a deadly threat to their way of life that ultimately prompted armed – and futile – insurrection. Today, we look at the roughly 700,000 soldiers who died in the Civil War and can only scratch your head wondering … why?

Hold that thought. Let's look at another issue we face today, which for many is clearly a Right Thing to Do, yet which is seen by others as an another unconstitutional abomination that engenders talk of armed resistance – guns.

Like so many, I am appalled by the ongoing use of assault weapons to kill innocent people. I am equally repulsed when the NRA leadership opposes mandatory background checks on gun purchasers and rails against restrictions on military-style weapons. I'm also painfully aware that U.S. Supreme Court has decided that the Second Amendment confers an unfettered right to bear arms – just as in Lincoln's time, slavery was protected by the U.S. Supreme Court and the Constitution.

Surely it is time for those in positions of leadership – and for we who support them with our votes and contributions – to say to the Gun Lobby: "You will help us end this madness or we will amend the Constitution so that we can enact effective gun control legislation. Because your further irresponsible obstruction will forfeit the so-called absolute right to possess firearms."

Could the Second Amendment be modified or even repealed? Of course it could! Right now, 90 percent of people agree that mandatory background checks are a good idea, and many of those people are NRA members. We need a leader, with the stature and the courage of a Lincoln, to take on the Second Amendment, and it can be done. I can't think of such a person right now, but perhaps someone's waiting in the wings.

Let's step back again. Away from national issues and political causes. Take a moment and look closely at your business unit or company. Are there situations that trouble you? Things that are unfair and need fixing? We all have chances every day to take a lesson from Lincoln and consider for the greater good. You can start tomorrow. Or you can take your time and do it with all due deliberation. But do it. Do the Right Thing. ■ MEDADNEWS

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

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