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To make the career switch to pharmacology, Dr. Verst had to become an undergrad again and get a pharmacy degree. "I graduated on a Saturday night with my doctorate in pharmacy and actually began Monday morning with an industry career at Procter & Gamble Pharmaceuticals," she says.

For DeSimone, the decision to become a pharmacist came when she went to college – at a time when there were very few women in that field. But her switch to the pharmaceutical industry came after she observed the pharmaceutical reps at the pharmacy she worked at after graduating.

"I thought that would be a way to take the reasons why I went into pharmacy – healthcare, helping people, and counseling people, educating people – and I thought I could take those priorities into the pharmaceutical industry," DeSimone says. "I didn't understand much more than that they were sales reps who went into doctors offices and pharmacies. I didn't understand the marketing piece at the time and everything else that went into it." DeSimone worked for ER Squibb, and then Genentech, and then went back to ER Squibb when it became Bristol-Myers Squibb.

Dr. Horobin was a working physician when she had the encounter 30 years ago that spurred her to go into the pharmaceutical industry.

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September 25, 2013 12:00 pm ET

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IN THIS ISSUE:

4 women, 4 paths, 1 goal

Four high-level female executives with different scientific backgrounds wound up in the pharmaceutical industry for the same reason – the patients; and as each achieved her career goals because of strong mentors, they mentor in return.

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

Although the four women interviewed for this article – Anna Protopapas, president and CEO of Millennium Pharmaceuticals; Jill DeSimone, senior VP and general manager of Teva Global Women's Health; Dr. Joanna Horobin, chief medical officer of Verastem; and Dr. Cynthia Verst, head of the global Phase IIIb/IV for Quintiles – have taken different paths to the heights of their careers, they all have scientific backgrounds. But all got into their chosen fields for one reason – the patients – and they are taking the time to mentor the next generation of leaders in the industry.

For Protopapas, her involvement in the pharmaceutical industry came because of her experience with biotech. And her path to biotech was directly because of her science background.

"I was trained in science and engineering, I'm a chemical/biochemical engineer, when early on in my career I decided to switch to the business side," Protopapas says. "I was really looking for an environment where I could combine the business and the science, and biotech was quite an exciting opportunity. You could definitely combine the science, and very cutting-edge science, that coupled with my background, with the business side. And the mission of the industry, to really bring new science and turn it into new medicines that help patients, was a very exciting one. And it's been just as exciting if not more exciting since then. There's really been an explosion in our understanding of human biology and that really has unearthed huge opportunities to use that information to improve human health."

Protopapas started with Millennium in 1997, three years after the company started, and became senior VP of corporate development in 2005, and then executive VP, Global Business Development at Takeda Pharmaceuticals International Inc. in 2011, a position that she still retains.

"It's been a change, there are also new dimensions, there are additional dimensions to my expanded role," she says. "But it's not like I am walking into a completely new organization. I know Millennium well, I know Takeda well, and hopefully I can help bridge the gap during this time of transition as we look at Millennium and aligning it more closely with the rest of Takeda."

Both Dr. Verst and DeSimone have backgrounds in pharmacy – DeSimone was a pharmacist, and Dr. Verst eventually received her doctorate in pharmacy after a realization.

"I actually began with a career interest in quite frankly the research sector, and I was bound to get my Ph.D. in biochemistry and in particular structural and cellular biology," she says. "And it was there that I was actually getting my master's when I realized that benchtop research was probably not for me. Serendipitously, my advisor had collaborated in research with one of the faculty members who happened to be a pharmacologist. One day in the lab, he looked at me and said, 'Hey Cindy, what do you want to do when you grow up?' And I said, 'I don't know. I love science, and I love research, but I have to say, benchtop, probably not for me. But I guess maybe I'll have to continue on the trajectory of trying to figure out what research has more readily acceptable applications.' The short answer here is, he was a pharmacologist involved in industry research in the pharmaceutical sector, and that's what changed my life."

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By Christiane Truelove chris.truelove@ubm.com

Not quite there yet

This is the third year I've been doing interviews of women executives in the pharma industry and have shared their experiences and their perspectives on what it takes to rise. While it's clear that there are many women who have risen to upper-level positions, there is still some way to go. There are still no female CEOs among the top 15 pharmaceutical and biotech companies, even though at many of these companies, women comprise about half the management.

Then again, the presence of so many women in pharma executive management bodes well for a future in which we'll see a female CEO of a Pfizer, a J&J, a GlaxoSmithKline, or a Sanofi. Women are already running divisions of these companies, and there has been a concerted effort among the top pharmas to build a deep bench of women with C-suite leadership potential. A woman pharma CEO among the top 15 or 20 is not a possibility; it's an inevitability. There is already a woman CEO in the top 50 pharmaceutical companies: Heather Bresch of Mylan, the 25th highest-ranking pharma company in terms of healthcare income, generating $6.19 billion in 2011.

Bloomberg notes that Bresch was paid $9.96 million in 2012, 33 percent less than the average chief of a pharmaceutical, biotechnology, or life sciences company.

But an article from Bloomberg News last month has given me pause. According to Carol Hymowitz and Cécile Daurat, who looked at the payment of CEOs at the S&P 500 companies and how many women were among them, they found that about 20 of the 500 CEOs were women, just 8 percent of the total."Those high-achievers on average earned $5.3 million, 18 percent less than men," the writers say.

"Even after graduating from the same business schools, women tend to start out at lower salaries than men, and many don't catch up later in their careers. Female executives say they can be less demanding than men when it comes to pay, partly out of fear of being labeled as overly aggressive and self-centered," the writers say.

And what is more, women CEOs are lagging behind their male counterparts in certain industries. Bloomberg notes that Bresch was paid $9.96 million in 2012, 33 percent less than the average chief of a pharmaceutical, biotechnology, and life sciences company.

So how do you develop the strength to lean in and become a leader in the first place? All of the women I have spoken with over the years had parents and mentors who encouraged them to rise above restrictive gender roles. From playing sports not previously open to girls to entering fields of work dominated by men, these women did not take, "But girls don't do that," as an answer.

The female chief executives and upper-level executives I spoke with did not discuss their compensation, but they did say that for a woman to succeed, she needs to acquire champions and mentors in the workplace. Looking at the stats gathered by Bloomberg, women are certainly leaning in – but maybe not quite hard enough.

Unfortunately, the drumbeat of negative messages girls and young women are receiving has become even more relentless and inescapable in our social media-connected world. For example, many girls and women who like to participate in multiplayer online video games have reported being harassed. In February, Emily Matthew on the Pricecharting blog found that 80 percent of 874 respondents polled believe sexism is rampant in the gaming community, and 35 percent have been on the receiving end of sexual harassment while playing online. As VG24/7 reported the study, "63 percent of women reported being called a 'c*nt, bitch, slut, and whore." Others reported they were threatened with sexual assault, or asked for sexual favors, and stereotypical comments regarding female gender roles were prevalent as well. We're assuming these comments include, but were not limited to: "Go make me a sandwich," or, "Get back in the kitchen and make me some pie." Sexual harassment, because of the Internet and social media, is no longer something that is just experienced in the workplace. For today's young women and girls, it's everywhere. What's not helping is the continued tendency to blame the victim.

So who honestly wants to try and "lean in" in such an atmosphere? Probably a lot fewer than before; and if we don't look at the whole system, from top to bottom, the gains made over the decades will disappear.

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ON THE COVER

INSIDE

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SEPTEMBER 25, 2013

TIME: 12:00 PM ET

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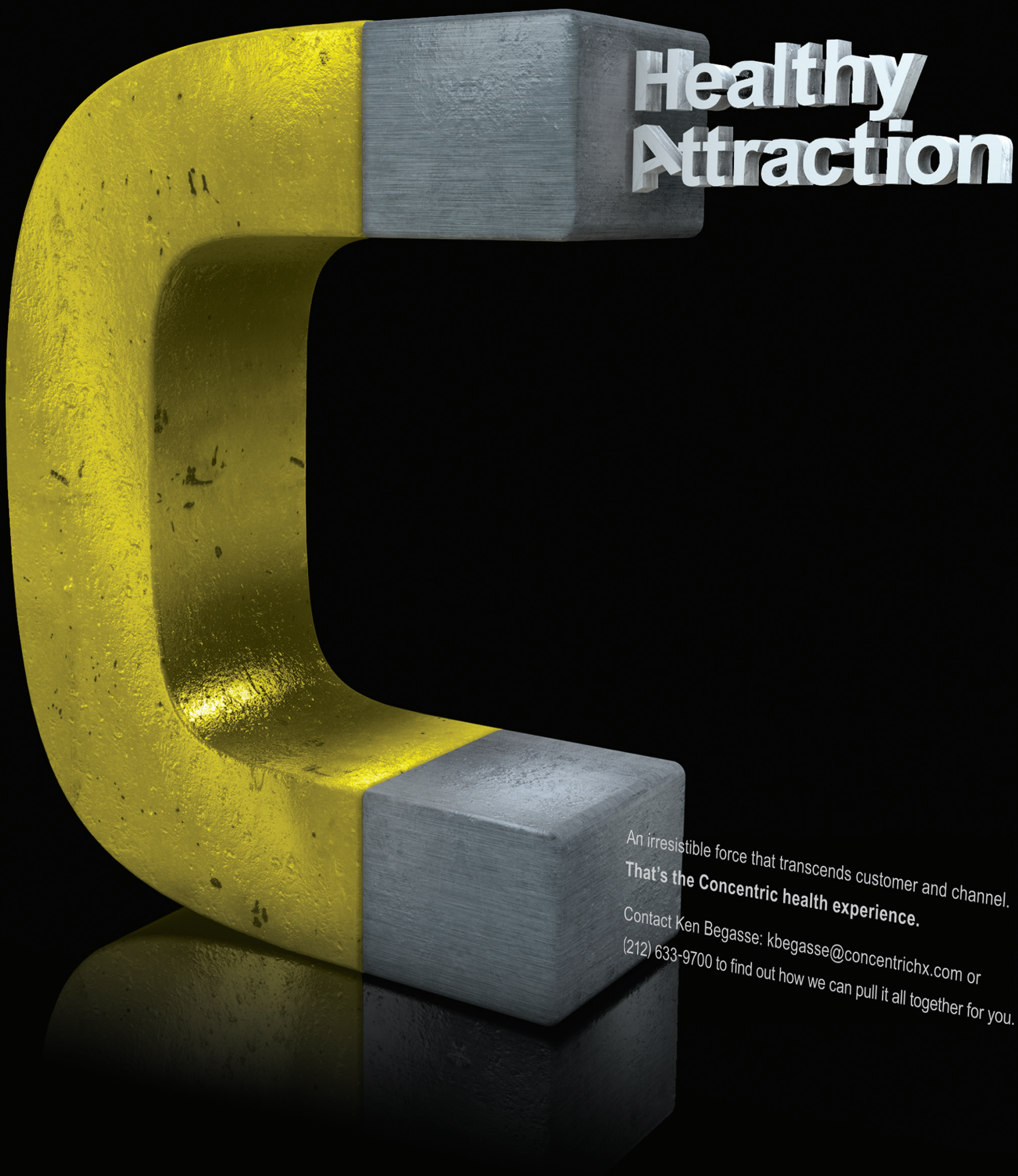

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"I was doing a research project concerning antibiotic abuse and use, and I contacted Beecham as it was in those days, and Glaxo, as it was in those days, to find out more information about antibiotic development and prescribing and all that good stuff," Dr. Horobin says. "And I was actually amazed to find that there were physicians working in the industry, and that they had an interesting and completely different career track than anything I'd ever heard about. It seemed rather exciting, this idea that you could affect the lives potentially of hundreds of thousands of patients, was rather appealing. And so frankly, I joined Beecham. And then within the first five years of Beecham, I had the opportunity help drive the approval of four antibiotics and a nonsteroidal, which all reinforced what I thought in the first place, that pharma was going to be a great place to be as a physician."

Dr. Horobin, in her time at Beecham, helped develop and launch the antibiotics Augmentin, Bactroban, and Timentin, and the nonsteroidal anti-inflammatory Relafen.

"It was a golden era for Beecham at the time, and I just happened to drop into it and grow with it," she says.

After Beecham, Dr. Horobin worked for Rorer, which became part of Rhone-Poulenc Rorer, which itself eventually became part of Aventis, and then Sanofi. It was at Rorer that she discovered her true research and development passion, oncology.

"I was completely hooked. I was never going to do anything else again except drug development, and I was never going to do anything else except oncology," she says.

During the time she was VP of oncology at Rhone-Poulenc Rorer, Dr. Horobin worked on the development and launch of the breast cancer drug Taxotere, and the colon cancer drug Camptosar/Campto. She also ran the joint venture between Chugai and Rhone-Poulenc Rorer to develop and market the white blood cell stimulator Granocyte.

The joint venture reinforced her love of small company culture and gave her the experience of leadership. "That was just an extraordinary opportunity to be running a cross-cultural organization," Dr. Horobin says.

"That gave me a taste of what it would be like in an entrepreneurial role," she says. "That was a very small company, but of course the backers were two large ones, so it had tremendous financial stability if you like but it had all of the aspects of a startup that I've come to love. It was a wonderful opportunity and I was given a great break."

When she left Rhone-Poulenc Rorer, Dr. Horobin became chief operating officer of CombinatoRx and executive VP of EntreMed. As CEO of Syndax, an independent biotechnology company, she designed and implemented the Phase II clinical development of entinostat in metastatic breast and lung cancer.

Dr. Horobin's move to small biotech companies was driven by the need to better serve patients in the oncology arena.

"One of the things that's been really interesting to me, first and foremost, I am still an M.D., that's the moniker I wear and am proud of it," she says. "So that means what I really want to do is bring new options to patients. That's why I get up in the morning. In oncology, the needs have always been obvious, but the challenge we have there, particularly in the last few years where we have had lots of new drugs coming into oncology and yet we haven't really moved the needle on survival. And so as I left large pharma and jumped into these smaller companies, I was really interested in trying to take on new targets and new ideas because it seemed to me to keep on doing the same old, same old, to try and solve the same old problem, you never get anywhere. You needed to have new ideas and new approaches if we were ever going to make a difference.

"So I spent time with antigenesis inhibitors and I then spent time thinking about combination drug strategies, I was working with epigenetics in my last company, and here I am working against cancer stem cells. So really, all of those are new approaches to try and change the way we treat patients with cancer – not just about bringing new drugs, but new ideas and new paradigms of treatment."

Dr. Horobin's love of entrepreneurial companies is shared by DeSimone, who had left Bristol-Myers Squibb last year "to pursue other areas in terms of wanting to take all of my commercial experience and go to startup-type of organizations," she says.

DeSimone found just that situation with Teva, which wanted to establish a women's health division. "I was able to take my focus on helping women develop, and being a mentor, and developing people as a passion, and creating the new, to Teva as they were creating the women's health business," she says.

Like the rest of the women interviewed, Dr. Verst wanted to see the results of her work translated into immediate gains for patients. "I knew industry research was the best of both worlds – research prevalent, but yet immediacy in terms of the application of that research," Dr. Verst says. "I have to say, it was the right place at the right time, but never without the sole focus of wanting to be involved in clinical research but having some immediacy in terms of the application."

Making the decision not to seek her doctorate in cellular biology was difficult but the lack of immediate applications for her research helped guide her, Dr. Verst says.

"I probably didn't choose the best of all topics for my thesis," she admits. "It was cellular regeneration, and I was working with a regeneration model of a Mexican lizard, genus and species, *Ambistoma mexicana*, an axolotl, and trying to find relative homology between that little critter and the human genome, and regeneration. And let's face it, there's not a lot of immediacy there, right?"

As head of the Phase IIIb/IV unit, Dr, Verst has responsibility and oversight of the late-phase clinical trials as well as the observational side. "This is the real world evidence side," she says. "And so here I am responsible for that business unit, responsible for the oversight, the top and bottom line, of the interventional and the observational side of the house, and growing that business, ensuring that business is delivered with high-quality approaches output and ensuring as well that we've got a business strategy to be delivered for our continued growth in the sector.

"In addition, I have the overall growth of the top line, so I have all of the business development team members as well as the operational team members under that remit."

> "I was able to take my focus on helping women develop, and being a mentor, and developing people as a passion, and creating the new, to Teva as they were creating the women's health business." – Jill DeSimone

Women in the sciences

All of the executives interviewed for this article had a different path into the pharma industry than their counterparts who went the marketing/business route. When it comes to women's presence in the sciences, with master's level or higher degrees, the number of women obtaining these degrees remains lower.

According to statistics from the National Academy of Sciences' Committee on Women in Science, Engineering, and Medicine, in 2002, 3,669 U.S. women earned degrees in biological sciences, compared with 6,334 U.S. men.

When it came to those earning doctoral degrees in 2002 for biological sciences, the numbers were slightly more equal: 2,549 women, compared with 3,133 men.

There has actually been a decrease in the number of women earning master's degrees in biological sciences – in 1983, 3,236 women graduated with these degrees. However, the number of women earning their doctorates has jumped tremendously. Only 787 women were recorded as earning their doctorates in biological sciences in 1983.

The number of medical degrees awarded to women by U.S. medical schools continues to increase as well, though continues to be less than half of the total degrees earned. According to the American Association of Medical Colleges, in 1980-1981, 3,898 degrees were awarded to women, 24.9 percent of all the degrees awarded. In 2011-2012, 8,285 medical degrees were awarded, 47.8 percent of the total.

Scientific American reported in May 2013 that during 2008, for the first time, U.S. women earned more doctorates in biology than men did (a breakdown of numbers was not provided).

There have been concerted efforts by U.S. schools to interest more girls and young women in careers in science and technology, though the going remains tough and perhaps colored by perceived gender roles in society. The clothing store chain The Children's Place came under fire recently for carrying a girl's T-shirt listing "My Best Subjects" as "Shopping," "Music," and "Dancing" checked off. Not checked off, however, was "Math," with the tagline, "Nobody's perfect." (In response to public complaints, the offending T-shirt was removed from stores and is no longer available.)

For Dr. Verst, parental support, particularly from her mother, was important in overcoming gender biases in many ways and never making her doubt she wanted science as a career.

"I'm reminded as a small girl where I came home one day in middle school and I said, 'Hey Mom, sign this release form, I need to turn that in tomorrow,'" she says. "And she said, 'Sweetie, I think you picked up the wrong form, this is not your softball parent signature form, you picked up the baseball form for the boys. Boys play baseball, you play softball.' And I said, 'No, I want to play baseball!' I had thought softball was way too slow. My brothers had played baseball, and I had said, 'I want to play like my big brother on a baseball team.'"

Her mother could have easily discouraged her, but instead decided to support her. "Long story short, I was the first girl to play Knothole baseball in my area," Dr. Verst says. "I had said that I have to challenge that, I can play as well as the boys. … . My mom could have easily put the kibosh on that, but rather said, 'OK, well, if you're up for that, let's challenge that!'"

As it was, she never doubted that a career in science was what she wanted, Dr. Verst says.

"It was really my love, I knew I wanted to be in the healthcare arena, wasn't quite sure where," she says. "I was always asking the question, 'Why?' And biochemistry was the first real subject area that began to answer

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those questions of the why. Like blood clots, why does blood clot? Well, because prothrombin goes to thrombin, fibrinogen goes to fibrin, you know these cascades… but why? Why the cascade? And I think that my love and quest for the understanding in the scientific arena was what ultimately led me to a career on the pharmacology side. Understanding the human pathways, the biological pathways, how drugs impact the mechanisms of action, it was the first time gratifying and I really found that love here in the clinical/pharmacology side of things."

> "Long story short, I was the first girl to play Knothole baseball in my area. I had said that I have to challenge that, I can play as well as the boys. … "

DeSimone says when she shared her decision that she wanted to become a pharmacist, her father had questions. "Going into college in the '70s I came home and told my dad I was going to be a pharmacist, and right away he wanted to go to, why did I not want to be a nurse or a teacher," she says. "We had those early conversations, and after that, he was always in my court, he was always an encourager. And my aunt was a successful businesswoman, in the '60s and '70s, growing up and watching her I had a great role model in her in those important formative years."

According to Dr. Horobin her decision to go into medical school had to be made early, when she was in high school.

"The big decision for me was actually during my high school career, where do I want to go," says. "And it was in the days of Watson and Crick and things were looking extremely exciting, and I felt I wanted to be part of that. For me, I think it wasn't so much the bench science that I found interesting, it was the opportunity to take that science as it was translated into treatments for patients and then be able to translate it for patients. It's interesting, because I've not really done a lot of bench science at all, didn't do that much at medical school. In those days, it was really purely a clinical training. But I do think that one of the strengths I've been able to bring to my career is taking complex scientific ideas, distill them down to something relatively simple, that I can then translate into an actionable development plan, or I can communicate to an investor, or to a potential investigator. To me, I think that's been an ability of mine. It's always been less about the ability to do the science, than the ability to talk about the science and make it intelligible to other people."

Protopapas says for those girls who want to go into science, they should pursue their dreams and not worry about the ultimate job goal.

"I'm a big believer, and I say this to my children, that ultimately everyone needs to follow their passion," she says. "And I think for anyone who finds science exciting, anyone who gets excited with hearing about sequencing the rabbit genome and what it means, or the president's new initiative around mapping the human brain, I would say to anyone who finds that exciting, 'You should pursue your passion and learn about it.' I would encourage them, and I don't think that closes the door ultimately to a career that is not in the lab, but in a business career where the background you have in science helps you be better at your job. But you have to be excited about the science, if you are, then I don't think whatever the ultimate goal is should stop you from pursuing scientific studies."

Entering pharma and developing confidence

For women who want a career in the pharma industry, the executives interviewed have a lot of advice.

Dr. Verst says to build a career, a person must overall pursue their heart's desire and set goals extremely high.

"Also one factor that's paid off for me in my career is always trying to have that prospective viewpoint of being two to three years, with foresight, where I should be – what do I want to aspire to be, two to three years from now, and always beginning with the end in mind, and having short-term increments, as well as the 10-year plan," she says. "And thinking about the steps, the bridges, the necessary places one needs to be, the educational endeavors one needs to acquire, in order to get to that next step, and having that vision

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along the way is incredibly important."

Collaboration is also very important, Dr. Verst says – not only with peers, but those in adjacent positions.

"While you may be in a particular business unit, understanding those adjacencies and connections along the way, in the spirit of collaboration not only for your own business unit, but also where you can help others along the way," she says.

Protopapas advises that to plan a career, focus on the things that you can control.

"It's always been less about the ability to do the science, than the ability to talk about the science and make it intelligible to other people."

"You can't really map out in detail a career path for years to come, but there are a lot of things that do influence one's career path that you can control," she says. "It's usually doing things around following your passion, pick a path that you are good at and you like doing, focus on delivering quality results, collaborate, and indeed where it's appropriate and just be yourself, and the rest is really outside your control. And if you do all those other things, I am optimistic that the right career path will emerge for you."

DeSimone says women need to find their voice to succeed, recommending Sheryl Sanberg's book, "Lean In: Women, Work, and the Will to Lead." Sandberg, the chief operating officer of Facebook, examines why women's progress in achieving leadership roles has stalled, explains the root causes, and offers compelling, commonsense solutions that can empower women to achieve their full potential.

"That book, when I read it, I was so reminded that we need to find our voice," she says. "We need to lean in, we need to make sure that we're confident and courageous. Women have a tendency to say, 'Well, if there are 10 skills that are needed for a job, I need to have nine of them, or I'm not going to apply.' Be confident in your abilities and your skills, go for it, put yourself in uncomfortable situations, that's the best way to grow.

"Think about when you have gone skiing, and I used this story with one of my sales teams once, and I thought about it as I read Cheryl's book. I was going skiing, and was so happy that I was not falling as I'm skiing. And then I realized what that really meant was that I wasn't stretching myself, maybe I needed to go down a harder run and challenge myself. Sometimes, we need to push ourselves. Lean in, be confident, be courageous, and push yourself. You've got it, you know you've got it, so put yourself in those uncomfortable situations, because that's the way you grow."

Dr. Horobin also says it's important for women to have that confidence. "If they believe they've got the skills, they've got to find a way to develop the self-confidence to go for it," she says. "Women can sometimes come over as not having confidence in themselves."

She was particularly struck by this trait after spending a year at MPM Capital "where there were very few women coming into the venture capital firm to present their ideas."

"Sadly, more often than not, they didn't inspire confidence," Dr. Horobin says. "And I used to talk to these women afterwards sometimes, when they got the bad news that we weren't going to invest in them. They'd say, 'What can I do differently next time?' And I would always say to them, 'You've got to have more confidence in yourself, because unless you've got confidence in yourself, how on earth can you expect other people to have confidence in you?'"

According to Dr. Horobin, a lot of this still has to do with stereotypes and how children are still raised to meet them. "There was a wonderful book a few years ago, called, 'Brag is Not a Four-Letter Word,' it's essentially about the fact that most women are not prepared to self-promote," she says. "And unfortunately we live in a world where there is a lot of self-promotion. And so women put themselves at an immediate disadvantage if they're not prepared to advocate for themselves. So one of the things I've often said to young women, particularly those early in their careers, is 'If you don't feel comfortable doing it yourself, identify somebody who's a real supporter of yours. Get them to first of all help develop those skills in you, but also get them to advocate on your behalf, it's fine to do that.' So I think this is a skillset that actually needs to be taught

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to girls in school, actually how to brag, it doesn't sound very ladylike, but it's probably what they need to do."

DeSimone says early in her career, she did encounter some indication of different treatment because she is a woman.

"When I was first promoted, I was told it was because I was a woman," she says. "I was fortunate to become a sales trainer, we were hiring more women at the company and they needed a woman trainer. My response was, 'I don't care why I'm getting the job, you'll forget that I am a woman and just remember I'm the best trainer.' And that has always stuck with me, because that was the first time something had been called out so directly. But it also made me recognize that there were those thoughts that were thought, but not verbalized. I was not going to let being a woman, or any of that, get in my way if they would just remember I was a good trainer."

In the end, Protopapas says, there is one thing that truly will lead to a great career. "I am a believer that it's the quality of the work that you do and how you do it, the way you interface with your colleagues, with your management, with the people you manage and lead, that it's going to drive your career success," she says.

> "What is unique about Takeda is that although it's a 232-year-old company, it is also a very young company at the same time. It's a company in the midst of a major transformation."

The roles of mentoring and networking

Besides advocating for themselves, women also need to find mentors and sponsors, and when they get ahead, offer to mentor others Dr. Horobin says.

"The idea is if I work harder and put in a few more hours, or I park another A-plus paper, to get that, is unfortunately, not the reality of life," she says. "You could argue that instead of working harder to get a better grade, you actually might be better off going out and talking to people who could make a difference in the next promotion. ... And I think that one of the most important things that we who have managed to get to senior level in our careers can do is mentor other women. I think that's really important and to make sure other women who have the potential are, not necessarily by a woman, but are mentored in how to make this happen. So that's something else I try to do."

Protopapas says she tries to give advice when she is sought for it. "I have to say I've had people from inside and outside the company who come and ask for advice and I always enjoy doing it," she says. "Various people have helped me along the way with good advice and I am always glad to give my advice for whatever it's worth."

DeSimone says everyone needs mentors for a successful career, and she makes it a point of being a mentor.

"If I was going to write my tombstone today, it would have something about developing people and mentoring," she says. "I take great pride in that. I think that's really important. For me, successful mentoring was about taking on people who were not like me. It's great to have a couple of people and they're exactly like you, you're asking them for advice, they're giving you back exactly what you would have done. You need to, again, push yourself, get mentors that can help you stretch. If you're not strong in a certain area, that's probably the right mentor for you."

Successful women also need to be sponsors as well as mentors, DeSimone says. "Mentoring is there providing counsel, feedback, helping to advise, having tough conversations," she says. "Sponsorship is something different, and I think women need to think about sponsoring people. Sponsoring folks that they mentor, sponsoring folks that they see that are very talented and speaking up on their behalf. So mentoring and sponsorship, obviously very different and something that we as women leaders need to think about. I do see that is very strong with my male colleagues and I think we all need to give that shoutout to folks that we see are those future leaders in organizations."

She and Dr. Horobin point out that while it's important for women to mentor, a good mentor can be a man or a woman.

"I had one mentor who I worked with over the years, he's no longer with us," DeSimone says. "His name was Mike Iafolla, and he was there to be an encourager and to have tough conversations and to be a sounding board, and he took risks with me. He was also in a hiring position, not all mentors are in that position, but that goes back to that sponsorship. Sometimes you just have to take a risk, and believe in the person, and he did that with me. But he helped me as well. He was very key in helping me get through many steps over time."

Dr. Horobin says she encountered similar supporters at Rhone-Poulenc Rorer.

"I was very lucky early on in my career to just have a couple of fantastic mentors," she says. "I didn't go out seeking them, I was lucky enough to, I really can't remember quite how I found myself paired up with such great people. They happened to be men, by the way, but they were people who were really gunning for me and my prospects."

And women should join professional networks. All of the executives interviewed had been HBA members at one point or another.

DeSimone says she is trying to get Teva to be an HBA sponsor. "We've recently hired a head of inclusion and diversity, and she's helping us gain those contacts, also with organizations such as the National Organization for Female Executives, again, places where we can highlight opportunities for Teva to take on that leadership role," she says.

Quintiles has its own internal network for women, Women Inspired Network, or WIN. According to Mari Mansfield, a spokeswoman for Quintiles, the WIN coaching program is designed to support the professional development of its members with strategies and actions focused on increasing the number of women in leadership positions and expanding their leadership competencies. Additionally, Quintiles has been a partner with HBA for 22 years.

Dr. Horobin had been head of HBA's Boston chapter but says "I'm not sure it matters too much what the organization is, I think it's more important that we encourage young women to actually join that sort of group, that they're not sort of thinking about this in isolation, that they're actively seeking out others in a relatively protected environment and they can talk about things.

"This would be my advice – join any of the many excellent professional women's organizations around and be an active member and take part. You'll increase your confidence and learn how to network and that will stand you in good stead."

Encouraging diversity in the upper levels

To ensure that more future pharma CEOs and upper-level executives are women, these future executives need to be developed now, DeSimone says.

"The way to change it quite frankly is to make sure with our bench strength today, we're focused on developing the right talent to take on that P&L responsibility," she says. "If you have a P&L mindset, that you're going to develop people to really have diversity at that C-suite level, that's important, in terms of how you think about it. If you want a diverse workforce, if you want a match to the customers you're marketing to and selling to, if you want to have different kinds of thinking, then you have to have diversity at the C-suite level and at every level. We all have a responsibility that we're developing that bench and a very junior point. You don't show up one day and say, 'I can take P&L responsibility.'"

According to DeSimone, it's important for companies to be very clear as to why certain skills are needed for certain jobs.

"When I've taken on more senior assignments, I'm ready to jump in if my head of marketing was on sabbatical, or if we walked into a business development opportunity," she says. "We want to make sure you have all of those skills and your career is a lattice, not a ladder. That's really important, to consolidate those skills and get those experiences. A lot of times, people don't fully appreciate that, and that's our responsibility to make sure that folks understand what they're going to get from each assignment. And if you have a good plan in place and you can articulate the benefits of each assignment, what you're going to gain from it, that makes it much clearer for the individual to have a development plan and discussion. And ultimately, you're going to get people to leadership roles."

DeSimone saw the results of these diversity-encouraging plans take effect at Bristol-Myers Squibb.

"I know that when I was at Bristol a few years ago, in the U.S. organization, half the folks that were sitting around the table that were owning the P&L were women," she says. "And that's because if I looked around at the folks at the table, they had been developed over the years. All of us, not just women – we had great development opportunities along the years to get us ready for those assignments. So I think you need to make that conscious effort early in the game to say, 'Hey, you know what, we value diversity and inclusion, and we need to put plans in place to make sure we have the right folks at the table.'"

Verst says there has been progress at Quintiles and throughout the pharma industry in developing women for higher-level, P&L roles.

"I have seen terrific, speaking of statistics, terrific progress in the way of a greater distribution of females in that late-phase arena, in the marketing, the commercial, the sales, the commercial arena as a whole, and I've seen that at Quintiles as well, representing a big share of our CRO industry," she says. "So I'm very uplifted, very motivated to see that distribution increasing with regard to women in that sector of our marketplace. So progress is being made."

Protopapas says while some would perceive Millennium's corporate parent, Takeda, as innately conservative with women's careers because it is a Japanese company, that is not true.

"What is unique about Takeda is that although it's a 232-year-old company, it is also a very young company at the same time," she says. "It's a company in the midst of a major transformation. We have a CEO who's had a vision to fully globalize the company in a way that is unprecedented for a Japanese pharmaceutical company. He's grown operations significantly in the US and the world through acquisition, and with that has come diversity in the employee base. And I think there's a real understanding among the Takeda senior management that diversity is a strength and has really tried to advocate for that diversity.

"In addition to myself and previously Deborah [Dunsire, former president and CEO of Millennium], there are other senior women in the organization, It's been tougher in Japan, although the company has put in place development programs to help overcome the challenges for women there, and it is a priority for the organization. But I would say that Takeda really has been approaching this in kind of a unique way."

In the end, for there to be more upper-level, C-suite women executives, there have to be women who want those positions, Dr. Horobin says.

She adds that she took positions based on what made her feel fulfilled, not for the title.

"I honestly do think that it's largely up to us," she says. "We need to have the drive to move into those positions and really make the case for why we deserve those positions. I don't think, at the end of the day, some sort of external legislation is going to make this happen."

"I think there's another piece to it as well, and that while I think it's a good thing for corporate culture to have a more diverse group for leadership, I think there is also perhaps a bit of a stereotype about the fact that everyone needs to aspire to a senior position. Some of that is maybe a more male way of looking at things. I do think that there are quite a lot of women who are very happy not to necessarily be in the most senior position. We need to factor that into our thinking as well. I don't think we necessarily need to mandate 50/50 or something like that." ■ MEDADNEWS

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Most Admired Companies

Johnson & Johnson, Amgen, and Allergan headline the category winners for 2013.

by Andrew Humphreys andrew.humphreys@ubm.com

The most admired pharma, biotech/biopharma, and specialty company recipients of 2013 – as voted on by the *Med Ad News* audience – are each former winners whom have reclaimed their respective crowns. After capturing the pharmaceutical category four straight years, **Novartis** has been usurped by **Johnson & Johnson**. J&J was the last company to win this award before Novartis, back in 2008. The health-care giant has been dealing with the impact of various OTC product and medical device recalls in recent years. A new corporate brand campaign launched during 2013 and strong revenue growth across its pharma and device/diagnostics businesses has helped J&J weather the product-recall storm. Falling to runner-up in the 2013 pharmaceutical voting was Novartis, followed by third-place **Roche**, dual-category eligible **Amgen** at No. 4, and fifth-place **Abbott/AbbVie**.

Amgen returns as the champion of the biotech category after holding the title belt during 2010 and 2011, and finishing third in 2012. The world's largest independent biotechnology company is reaping the benefits of a variety of billion-dollar brands not yet exposed to biosimilar competition. Amgen also recently agreed to acquire **Onyx** Pharmaceuticals in one of the largest biotech-biotech company deals of all-time, a move that will bolster its long-term growth prospects. Last year's top vote getter in this category, **Biogen Idec**, dropped down the third place in the 2013 polls. Roche, a strong player in the biotech and pharma fields, was selected No. 2 in this year's biotech voting. **Novo Nordisk** finished in fourth place and **Gilead** Sciences rounded out the top five companies in the Most Admired Biotech/Biopharma setting. Novo and Gilead represent some of the fastest-growing entities in the health-care space, and a collection of future blockbuster drugs emerging from their pipelines have them poised to continue their strong revenue production into the next decade.

Gaining top honors in the specialty pharma category for 2013 is **Allergan**, which was also the leading vote receiver from 2008-2011 and came in second place in 2012. Last year's champ in this category, **Shire**, came in at No. 3 in this year's voting. **Teva** Pharmaceutical Industries moved up from the third spot for the 2012 polls to second place in the 2013 results. **Valeant** Pharmaceuticals International and **Mylan** finished No. 4 and No. 5 in the 2013 elections.

The following pages detail the three victors of the Most Admired Company categories. Also, more information about J&J, Amgen and Allergan as well as many other top vote getters in this year's elections will be provided in the October 2013 issue of *Med Ad News*, which analyzes the world's top 50 pharmaceutical/biotechnology/biopharma/specialty pharma companies.

MOST ADMIRED PHARMA COMPANY: JOHNSON & JOHNSON

Johnson & Johnson is one of the world's leading health-care entities. With headquarters in New Brunswick, N.J., J&J operates as a holding company for more than 275 operating companies in 60-plus countries. Incorporated during 1887, J&J has about 128,000 employees engaged in the R&D, manufacture, and sale of a diverse array of products in the health-care arena. The company consists of three business segments: Consumer, Pharmaceutical, and Medical Devices and Diagnostics.

The Consumer business covers a wide range of products used in the baby care, skin care, oral care, wound care and women's health-care areas, as well as nutritional and OTC pharma products, and wellness and prevention platforms. The Pharmaceutical business includes products in areas such as anti-infective, antipsychotic, contraceptive, gastrointestinal, hematology, immunology, infectious diseases, neurology, oncology, pain management, thrombosis and vaccines. J&J's Medical Devices and Diagnostics segment includes a diverse range of products used to treat cardiovascular disease; orthopedic and neurological products; blood glucose monitoring and insulin delivery products; general surgery, biosurgical, and energy products; professional diagnostic products; infection prevention products; and disposable contact lenses.

Amongst the J&J family member are the world's sixth-largest consumer health company; the largest and most diverse medical devices and diagnostics player; the fifth-largest biologics entity; and the eighth-largest pharma company.

Johnson & Johnson is led by Alex Gorsky, the seventh CEO in the company's 126-year history. J&J manages within a strategic framework geared toward generating sustainable growth. To accomplish this, management operates the business consistent with particular strategic principles that have proven successful over time. To this end, J&J participates in growth areas in human health care and is dedicated to attaining leadership positions in these growth areas via the development of high-quality, innovative products and services. New products launched during the past five years represented 25 percent of the company's 2012 sales. For 2012, $7.7 billion – 11.4 percent of sales – was invested in R&D. This investment reflects management's dedication to the significance of continuing development of new and differentiated products and services to sustain long-term growth.

Johnson & Johnson views its principle of decentralized management as an asset and fundamental to the success of a broadly based business. The company also fosters an entrepreneurial spirit, uniting the extensive resources of a large organization with the ability to anticipate and react quickly to local market changes and challenges, its leadership says. J&J is committed to developing worldwide business leaders who can attain growth objectives. According to executives, J&J businesses are managed for the long term in order to sustain leadership positions and achieve growth that provides an enduring source of value to the company's shareholders.

Financial and business performance

Johnson & Johnson was the leading health-care revenue generator during 2012 at $67.22 billion, more than $8 billion ahead of No. 2 **Pfizer**. J&J has produced annual revenue increases in each of the past three calendar terms, with global sales rising 3.4 percent for 2012, 5.6 percent during 2011, and 0.5 percent in 2010. Sales by U.S. companies totaled $29.8 billion during 2012, up 3.2 percent over 2011. Sales accounted for by international companies reached $37.4 billion in 2012, up 3.5 percent. The acquisition of **Synthes**, net of the related divestiture, increased total global sales growth and operational growth by 3.1 percent.

Consumer segment sales for 2012 totaled $14.4 billion, down 2.9 percent versus 2011, including 0.5 percent operational growth offset by a negative currency impact of 3.4 percent. The leading Consumer business segment for J&J in 2012 was OTC Pharmaceuticals and Nutritionals with sales of $4.4 billion, decreasing 1.1 percent.

J&J's Pharmaceutical segment produced 2012 sales of $25.4 billion, rising 4.0 percent versus 2011, with operational growth of 6.8 percent and a negative currency impact of 2.8 percent. According to IMS, J&J had the fastest-growing Top 10 pharmaceutical business in the United States, Europe and Japan during 2012.

The company's best-selling prescription medicine in 2012 was **Remicade** (infliximab), a treatment for a variety of immune-mediated inflammatory diseases. The biologic therapy accounted for 2012 sales of $6.14 billion for J&J, representing growth of 11.8 percent versus the drug's 2011 performance for the company.

The Medical Devices and Diagnostics segment generated sales of $27.4 billion in 2012, up 6.4 percent over 2011, with operational growth of 8.7 percent and a negative currency impact of 2.3 percent. The Synthes acquisition, net of the related divestiture, increased total sales and operational growth for the Medical Devices and Diagnostics business by 7.9 percent. Leading this segment's 2012 sales was the Orthopedics franchise at $7.8 billion, up 34.3 percent.

For the first half of 2013, J&J worldwide sales reached $35.38 billion, increasing 8.5 percent compared to the corresponding 2012 period. During January-June 2013, U.S. sales rose 9.5 percent to $15.97 billion and international sales grew 7.6 percent to $19.41 billion. Consumer segment sales in first-half 2013 improved 1.6 percent to $7.33 billion. Global Pharmaceutical sales increased 11 percent over first-half 2012 to $13.79 billion. In the Med Devices & Diagnostics area, global sales during the first six months of 2013 improved 9.9 percent to $14.26 billion.

Remicade remained Johnson & Johnson's best-selling prescription product during the first half of 2013, with global sales improving 7.5 percent year over year to $3.27 billion.

"Our strong second-quarter results reflect the progress we've made against our near-term priorities of delivering on our financial commitments, restoring a reliable supply of over-the-counter products to consumers, continuing the successful integration of Synthes and building on the momentum in our pharmaceutical business," Mr. Gorsky noted. "Our talented colleagues at Johnson & Johnson continue to bring meaningful innovations to patients and consumers around the world and have positioned us well to deliver sustainable growth."

Acquisitions, collaborations, and alliances

The Synthes transaction for a purchase price of $20.2 billion in cash and stock represents the largest one ever for Johnson & Johnson. The net acquisition cost of the deal was $17.5 billion based on cash on hand at closing of $2.7 billion. Through this transaction – completed during June 2012 – the combination of Synthes and J&J's **DePuy** Companies constitutes the largest business within the Medical Devices and Diagnostics segment of J&J. DePuy provides one of the most diverse orthopedics portfolios in the industry. Synthes is an innovator in trauma, spine, cranio-maxillofacial and power tools.

Top 10 Most Admired Pharmaceutical Companies

1. Johnson & Johnson
2. Novartis
3. Roche
4. Amgen
5. Abbott Laboratories/AbbVie
6. Pfizer
7. Bristol-Myers Squibb
8. Eli Lilly
9. Merck & Co.
10. Boehringer Ingelheim

During 2013, J&J acquired **Aragon** Pharmaceuticals. The privately held, pharma discovery and development company concentrated on drugs to treat hormonally driven cancers. The transaction included Aragon's androgen receptor antagonist program and lead product candidate **ARN-509**. The second-generation androgen receptor signaling inhibitor is undergoing Phase II development for castration resistant prostate cancer. The deal, valued potentially at up to $1 billion, was closed in August 2013.

J&J's **Cordis** completed the acquisition of **Flexible Stenting Solutions** in March 2013. FSS is a top developer of innovative flexible peripheral arterial, venous and biliary stents. The company's **FlexStent Self Expanding Stent System** provides Cordis with the opportunity to evolve its **S.M.A.R.T. Stent** platform to address unmet needs for peripheral artery disease. The S.M.A.R.T. Stent is the only one FDA-approved for iliac, superficial femoral artery and proximal popliteal artery vascular indications.

Janssen Biotech and Johnson & Johnson Innovation announced in June 2013 the establishment of a research alliance with the **Icahn School of Medicine at Mount Sinai**. The purpose of the alliance is to advance the scientific understanding of inflammatory bowel disease and the discovery of next-generation therapeutic solutions. Scientists from the Janssen Immunology Therapeutic Area and researchers from Mount Sinai are working together to investigate disease triggers, identify new opportunities for therapeutic interventions and establish diagnostics to facilitate precision medicine and predictive biomarkers. This first-of-its-kind industry and academic partnership unites Janssen R&D capabilities with an early-stage life-science investment via the Johnson & Johnson Innovation Center in Boston and Mount Sinai's exper-

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Janssen Research & Development – a division of Janssen Pharmaceutica – and Johnson & Johnson Innovation announced in May 2013 the introduction of a collaborative initiative with scientists from three prominent Belgian academic institutions and research centers. The project is anticipated to drive discoveries to improve the prevention, diagnosis and treatment of neurodegenerative diseases. Janssen Research & Development and Johnson & Johnson Innovation are dedicating up to 5 million Euros for this project for a five-year period. The initiative intends to attract top researchers in the Benelux scientific community to submit proposals for cutting-edge research in neurodegenerative disorders. This effort advances the Janssen and Johnson & Johnson Healthy Minds initiative, which strives to accelerate progress in the battle versus neurologic and brain disorders as well as to build on the companies' long-standing dedication to neuroscience and mental health.

R&D and innovation

J&J is dedicated to investing in R&D with the aim of delivering high quality and innovative products. Global costs of R&D activities for 2012 rose 1.6 percent versus the prior calendar term, reaching $7.67 billion. The Pharmaceutical business accounted for 2012 R&D of $5.36 billion, Medical Devices and Diagnostics represented $1.68 billion, and the Consumer segment expenditure was $622 million.

As of May 2013, the Johnson & Johnson Pharmaceuticals segment was well-positioned to continue driving growth with more than 10 potential new product submissions and 25-plus significant brand line extensions by 2017. J&J managers plan for new products to represent nearly half of the overall sales in the Pharmaceuticals segment by 2017. J&J intends to continue its dedication to addressing the most serious worldwide unmet medical needs to help transform the lives of patients. The research and development strategy builds on strong internal research and external innovation. The late-stage pipeline is lead by potential breakthrough therapies that will help transform patient care and sustain future growth.

Aided by a unique model of innovation, J&J's Pharmaceuticals segment has built an industry-leading pipeline that produced 11 new drug launches since 2009 through May 2013, more than doubling its productivity during the past four years. These new products, along with core growth brands, spurred 12 consecutive quarters of operational sales growth in the segment and contributed significantly to J&J's recent earnings growth.

According to Joaquin Duato, worldwide chairman of the Pharmaceuticals Group, "We've spent the past five years transforming our business, and the growth we're seeing today is the direct impact of that effort. The innovative new therapies in our pipeline will drive our next wave of growth. With strong momentum across our global Pharmaceuticals segment, we are executing well against our commercial strategy to gain market share and ensure greater access to our medicines. We're also strengthening our presence in critical geographies and have nearly doubled our footprint in emerging markets during the last five years."

J&J's approach to innovation has led to a revitalized product portfolio for the Janssen Pharmaceutical Companies. Near-term and long-term compounds are being developed in the fields of immunology, neuroscience, infectious diseases and vaccines, cardiovascular and metabolism, and oncology.

Late-stage products Janssen intends to submit for marketing clearance by 2017 are directed at addressing serious unmet needs. Examples include **simeprevir** for hepatitis C, which is awaiting approval in United States, Europe and Japan; **ibrutinib** and **daratumumab** for treating hematologic malignancies, which both have received a record number of Breakthrough Therapy Designations by U.S. regulators according to J&J; **sirukumab** and **gusellkumab** for significant immune mediated diseases; a three-month formulation of **Invega Sustenna/Xeplion**, with a potential to change the treatment paradigm for schizophrenia; and novel vaccines for treating influenza, rabies and polio.

The pharma pipeline includes a host of potential first-in-class medicines. For instance, ibrutinib is awaiting FDA approval for two B-cell malignancies. The drug is intended for treating previously treated patients with chronic lymphocytic leukemia/small lymphocytic lymphoma, and previously treated patients with mantle cell lymphoma. If cleared for approval, ibrutinib would be the first in a class of oral BTK inhibitors and is one of the first medicines to be submitted for approval via FDA's Breakthrough Therapy Designation pathway. Ibrutinib would be jointly marketed in the United States by Janssen Biotech and **Pharmacyclics**.

With substantial growth in the Asia-Pacific pipeline, Janssen intends to continue accelerating its development-stage pipeline in Japan and China. Three new molecular entities and three brand-line extensions are in registration in Japan as of May 2013, and Janssen expects to submit two additional NMEs and six brand-line extensions by 2017. In China, four new molecular entities and four line extensions are in registration, and Janssen plans to submit nine NMEs and six brand-line extensions by 2017.

With a concentration on precision medicine, the company has additionally invested best-in-class research capabilities in genomics, biotechnology, biomarkers, companion diagnostics and vaccine platforms, and in accessing early-stage breakthrough innovation from the leading innovation hotspots globally. New products introduced since 2009 constituted 17 percent of total pharma sales in 2012, up from 9 percent for 2011. Fueled by new indications, label extensions and additional country launches of these products, as well as the potential new products expected to emerge from its pipeline, products launched since 2009 are anticipated to account for nearly half of the total sales in the segment by 2017.

These products include Invega Sustenna/Xeplion (paliperidone palmitate), a once-monthly, long-acting, injectable atypical antipsychotic for the acute and maintenance treatment of schizophrenia in adults; **Simponi** (golimumab), a biologic approved to treat adults with moderate to severe rheumatoid arthritis, psoriatic arthritis and ankylosing spondylitis; **Stelara** (ustekinumab), a biologic approved for treating moderate to severe plaque psoriasis; **Zytiga** (abiraterone acetate), an oral, once-daily medication for use in combination with prednisone for treating metastatic, castration-resistant prostate cancer; the oral anticoagulant **Xarelto** (rivaroxaban); **Incivo** (telaprevir), a direct acting antiviral protease inhibitor for treating genotype-1 chronic hepatitis C virus; **Invokana** (canagliflozin), Janssen's first pharma product for treating adults with type 2 diabetes, launched in March 2013; and **Sirturo** (bedaquiline) for the treatment of pulmonary multi-drug resistant tuberculosis, the first new mechanism of action against tuberculosis in more than 40 years.

On the new device front, **Ethicon Endo-Surgery** during 2013 introduced the **Harmonic Ace+ Shears** with Adaptive Tissue Technology. This next-generation product in the best-in-class Harmonic portfolio of ultrasonic surgical devices can handle multiple surgical jobs such as dissection, sealing, transection and otomy creation. With Adaptive Tissue Technology, Harmonic Ace+ Shears responds intelligently to different tissue conditions by regulating energy delivery and providing surgeons with enhanced audible feedback. This allows the Harmonic Ace+ Shears to exhibit 23 percent less thermal spread while delivering 21 percent shorter transection times versus Harmonic Ace without Adaptive Tissue Technology. With a refined blade design, the tapered, coated blade is designed for multi-functionality with precise grasping and dissection.

Corporate citizenship

J&J's long history includes a strong track record in the areas of citizenship and sustainability. Management says the company's Healthy Future 2015 Goals are tracking well toward their targeted impacts, including advancing global health; safeguarding the planet; encouraging sustainability among J&J's suppliers and throughout its supply chain; fostering the most engaged, health-conscious and safe employees; advancing community wellness; measuring the impact of philanthropy; and fostering transparency and collaboration.

Johnson & Johnson is in the midst of a five-year comprehensive pledge to the United Nations' Millennium Development Goals. J&J is one of the largest corporate donors, having provided $966 million in cash and products to 600 programs in 50 countries during 2012. The company's diverse partners are aligned with J&J's goal of making life-changing, long-term differences in human health.

J&J has teamed up with 12 other companies to combat neglected tropical diseases in developing countries, having enabled generic entities to make and distribute copies of its HIV medicine **Prezista** (darunavir) in sub-Saharan Africa. As mentioned earlier, accelerated marketing clearance was granted by FDA for Sirturo.

Janssen is the first pharma company to fund a Point Scholarship, the largest scholarship-granting organization in the United States for lesbian, gay, bisexual and transgender (LGBT) students of merit. The scholarship is for LGBT students whose area of study is concentrated on HIV/AIDS, or who have chosen to attend business school. The scholarship is awarded for a four-year period to graduating high school seniors and college students. During July 2013, Janssen announced the recipient of the second scholarship the company is supporting via the Point Foundation.

David Julius, Ph.D., was recognized by J&J in June as the winner of the 2013 Dr. Paul Janssen Award for Biomedical Research. Dr. Julius is chair of the Department of Physiology at the University of California, San Francisco. He was selected for his discovery of the molecular mechanism that controls thermosensation (sensory perception of temperature) and elucidation of the role this mechanism plays in the sensation of acute and inflammatory pain. By providing a mechanistic view of how stimuli are detected in the body, Dr. Julius' discovery significantly advanced the study of pain and may result in new pain therapies.

MOST ADMIRED BIOTECH/BIOPHARMA COMPANY: AMGEN

Established during 1980, the worldwide biotechnology pioneer Amgen discovers, develops, manufactures and delivers innovative human therapeutics. Based in Thousand Oaks, Calif., the company's medicines help millions of patients to combat cancer, kidney disease, rheumatoid arthritis, bone disease, and other serious illnesses. Amgen ranks as the world's second-largest biotechnology entity after Roche.

Amgen's best-selling product is **Enbrel** (etanercept), an inhibitor of tumor necrosis factor, a substance that plays a role in inflammatory diseases. Another multibillion-dollar franchise for the company is **Neulasta** (pegfilgrastim), a pegylated protein based on the Filgrastim molecule, and **Neupogen** (Filgrastim), a recombinant-methionyl human granulocyte colony-stimulating factor; those two drugs stimulate the production of neutrophils, a type of white blood cell that helps the body fight infection. The blockbuster brands **Aranesp** (darbepoetin alfa) and **Epogen** (epoetin alfa) are erythropoiesis-stimulating agents that stimulate the production of red blood cells. **Xgeva** and **Prolia** (denosumab) consist of the same main ingredient but are approved for different indications, patient populations, doses, and frequencies of administration. Denosumab is a human monoclonal antibody that specifically targets RANKL, an essential regulator of osteoclasts (the cells that break down bone). Those seven products represented 89 percent, 90 percent and 92 percent of Amgen's global sales during 2012, 2011 and 2010.

The company's other marketed medicines include **Sensipar/Mimpara** (cinacalcet), a small molecule calcimimetic that lowers serum calcium levels; **Vectibix** (panitumumab), a monoclonal antibody that binds specifically to the epidermal growth factor receptor; and **Nplate** (romiplostim), a thrombopoietin receptor agonist that mimics endogenous TPO, which is the primary driver of platelet production.

Financial and business performance

2012 marked a record year for Amgen in terms of revenue, totaling $17.27 billion, which was a $1.68 billion improvement over the 2011 figure. The 11 percent increase was aided by 9 percent product sales growth driven by strong performance across the portfolio. Generating billion dollar sales in 2012 were Enbrel ($4.24 billion), Neulasta ($4.09 billion), Aranesp ($2.04 billion), Epogen ($1.94 billion), and Neupogen ($1.26 billion). Amgen's adjusted EPS rose 22 percent to $6.51 due to 15 percent adjusted operating income growth and lower shares outstanding.

Amgen anticipates 2013 will be a stronger year for the company on the revenue front, as demonstrated during the first six months. First-half 2013 global revenue totaled $8.92 billion compared to the January-June 2012 amount of $8.53 billion. Amgen's second-quarter 2013 revenue reached $4.68 billion versus the April-June 2012 total of $4.48 billion. According to company management, 9 percent product sales growth in 2Q 2013 was driven by Enbrel ($1.16 billion, up 9 percent versus 2Q 2012), Neulasta ($1.12 billion, +10 percent), Xgeva ($249 million, +39 percent), and Prolia ($188 million, +57 percent).

"We saw solid product trends during the second quarter and are carrying good momentum into the second half," said Robert A. Bradway, Amgen's chairman and CEO. "We continue to make excellent progress with our pipeline of innovative molecules and look forward to multiple data readouts in 2014, including pivotal Phase 3 data for our cholesterol-lowering agent, **AMG 145**, in the first quarter."

In the pipeline

Amgen spent $3.38 billion on research and development in 2012 compared to $3.17 billion for 2011. The total for first-half 2013 amount-

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ed to $1.85 billion versus $1.56 billion during January-June 2012. R&D expenses rose 17 percent to $944 million for second-quarter 2013, mainly in support of Amgen's later-stage clinical programs, including AMG 145.

In November 2012, Amgen presented data from four Phase II trials evaluating AMG 145 as monotherapy, in combination with statin therapy, in heterozygous familial hypercholesterolemia, and in statin-intolerant subjects. In each of those trials, treatment with AMG 145 resulted in statistically significant reductions in low-density lipoprotein cholesterol versus the control arms at 12 weeks. The Phase II program enrolled 2,000-plus patients across seven studies to evaluate the effects of AMG 145 across multiple patient populations who may benefit from additional cholesterol-lowering treatment options. Based on the results, Amgen proceeded with Phase III enrollment in those populations.

Developed by Amgen scientists, the human monoclonal antibody AMG 145 inhibits Proprotein Convertase Subtilisin/Kexin Type 9. PCSK9 is a protein that reduces the liver's ability to remove LDL-C, or "bad" cholesterol, from the blood. As a result, bad cholesterol increases. AMG 145 binds to PCSK9 circulating in the blood and prevents it from binding to LDL receptors in the liver. Without PCSK9 bound to them, LDL receptors can take up and remove bad cholesterol from the blood, recycle and remain available for binding additional LDL-C.

Other Amgen new drug compounds that advanced to Phase III development during 2012 were **brodalumab**, **romosozumab** and **rilotumumab**. Brodalumab (product code AMG 827) is one of five inflammation monoclonal antibodies being co-developed in a collaboration with **AstraZeneca**. During October 2012, Amgen announced the beginning of Phase III studies in moderate-to-severe psoriasis. The studies include three Phase III trials with ustekinumab and/or placebo controls. Amgen completed a Phase II study for brodalumab in psoriatic arthritis in 2012. Brodalumab is additionally being evaluated for treating asthma.

As a highly selective human monoclonal antibody, brodalumab binds to and blocks signaling through the IL-17 receptor. The IL-17 pathway plays a significant role in inducing and promoting inflammatory disease processes. Brodalumab may be the only investigational treatment in development that blocks the IL-17 receptor, thereby blocking several of the IL-17 ligands at once from sending signals to the body.

Top 10 Most Admired Biotech/ Biopharma Companies

1. Amgen
2. Roche
3. Biogen Idec
4. Novo Nordisk
5. Gilead Sciences
6. Celgene
7. Vertex Pharmaceuticals
8. Regeneron Pharmaceuticals
9. Shire
10. Actelion

By halting IL-17 ligands from binding with the receptor, brodalumab prevents the body from receiving signals that may result in inflammation and other conditions.

The humanized monoclonal antibody romosozumab (product code AMG 785) inhibits the action of sclerostin. Amgen in April 2012 began two Phase III studies for treating postmenopausal osteoporosis in women. The registrational study is a placebo-controlled trial evaluating incidence of new vertebral fractures at 12 and 24 months in 6,000 patients. The active-controlled trial versus alendronate is evaluating the incidence of clinical fracture and new vertebral fracture at 12 and 24 months in 4,000 patients.

The new drug candidate romosozumab is being developed in collaboration with **UCB**. Amgen holds the rights to commercialize romosozumab for all indications in the United States, Canada, Mexico and Japan.

Rilotumumab (product code AMG 785) is a human monoclonal antibody that inhibits the action of hepatocyte growth factor/scatter factor. Rilotumumab is being studied as a cancer treatment. Amgen launched a Phase III trial for treating gastric cancer during November 2012.

Acquisitions and collaborations

Amgen entered 2013 with various opportunities to continue growing its business. Management believes that the currently approved indications for Xgeva and Prolia represent significant commercial opportunities. Longer-term growth may additionally be attained by the successful development of the company's later-stage pipeline, by expansion into emerging markets and Japan, and via strategic business development opportunities. Those opportunities include Amgen's acquisitions of **Micromet** and **Mustafa Nevzat** Pharmaceuticals during 2012.

Micromet was acquired by Amgen during March 2012 for about $1.15 billion. The publicly held biotech company has concentrated on the discovery, development and commercialization of innovative antibody-based therapies for treating cancer. Now a wholly owned subsidiary, Micromet has provided an opportunity for Amgen to further expand its oncology pipeline. Micromet's bi-specific T-cell engager technology platform has produced various drug candidates that are being developed as cancer treatments.

Amgen acquired substantially all outstanding stock of Mustafa Nevzat in June 2012 for $677 million in cash. The privately held company has been a top supplier of pharmaceuticals to the hospital sector and a major supplier of injectable medicines in Turkey. The acquisition has provided Amgen with an expanded presence in Turkey and the surrounding region.

Amgen has had a collaboration deal with AstraZeneca since March 2012 to jointly develop and commercialize certain monoclonal antibodies. The new drug candidates stem from Amgen's clinical inflammation portfolio and include brodalumab, **AMG 139**, **AMG 157**, **AMG 181** and **AMG 557**. The pact covers global development and commercialization except for certain Asian countries for brodalumab and Japan for AMG 557, which are licensed to other third parties.

Amgen revealed in August 2013 its acquisition of Onyx, cited as the fifth-largest biotech-biotech company deal in history. Amgen is expected to acquire all outstanding shares of Onyx for $10.4 billion, or $9.7 billion net of estimated Onyx cash. Onyx is engaged in the development and commercialization of innovative cancer therapies.

Onyx's significant and growing multiple myeloma franchise includes **Kyprolis** (carfilzomib) for Injection, FDA-approved during 2012 and projected by some industry analysts to have multi-billion annual sales potential. Onyx has three partnered oncology assets: **Nexavar** (sorafenib) in partnership with **Bayer** HealthCare Pharmaceuticals, which is on the market for unresectable hepatocellular carcinoma and advanced renal cell carcinoma and generated more than $1 billion in 2012 sales; the Bayer compound **Stivarga** (regorafenib) tablet, which is FDA-approved for metastatic colorectal cancer; and the Pfizer drug candidate **palbociclib** in Phase III for advanced breast cancer. Onyx also has multiple oncology compounds in various stages of clinical development.

Through this deal, Amgen is anticipating the benefits from the worldwide rights to Onyx's innovative oncology portfolio and pipeline. Amgen plans to leverage its oncology capabilities and experience to support Onyx's clinical-development programs and maximize Kyprolis' global potential. The acquisition additionally adds to Amgen's robust late-stage pipeline, which includes nine innovative products for which registration-enabling data are expected by 2016; four of these are regarded as innovative, first-in class oncology products.

Corporate citizenship

Amgen annually commits significant financial support and product donations to assist in making a difference in people's lives. Company staff members dedicate thousands of hours volunteering their time and talent to stheir communities. Amgen's corporate giving initiatives are quite diverse: research grants and fellowships; medical education grants; donations of cash, product and equipment; community involvement via corporate sponsorships; and cash donations and volunteerism by staff members. The Amgen Foundation provides grants and matches staff donations to eligible non-profits.

The Amgen Foundation is an integral component of Amgen's dedication to dramatically improve people's lives. The foundation has donated more than $200 million to nonprofit organizations across the United States, Puerto Rico and Europe supporting its areas of concentration. The foundation seeks to advance science education, advance quality of care and access for patients, and support resources that create sound communities where Amgen staff members live and work. Nearly $20 million was invested during 2012 to 170-plus organizations that reflect Amgen's core values and complement the company's dedication to impacting lives in inspiring and innovative ways.

Amgen donates to qualified charitable organizations for the support of science, technology, medicine, healthcare or education; public education of disease states, medical conditions, science, or technology; and genuine philanthropic and charitable causes consistent with the company's scientific and medical interests. Donation types include endowed professorships, fellowships, fundraising events, patient advocacy programs, public education programs, and scholarships.

The company makes charitable donations and sponsorships concentrated on humanitarian, social, education and community programs to qualified organizations outside the U.S. healthcare community. Donations and sponsorships include support for fundraising events. Amgen provides its medicines at no cost to uninsured American patients with no or restricted drug coverage who could otherwise not afford treatment via two foundations. These foundations have supported hundreds of thousands of patients throughout the years. The nonprofit Safety Net Foundation supported by Amgen provides company products at no cost to qualifying people with no or limited drug coverage. The Safety Net Foundation covers Aranesp, Epogen, Neulasta, Neupogen, Nplate, Prolia, Sensipar, Vectibix, and Xgeva. The nonprofit ENcourage Foundation supported by Amgen and Pfizer provides Enbrel at no cost to qualifying people with no or limited drug coverage.

MOST ADMIRED SPECIALTY PHARMA COMPANY: ALLERGAN

The multi-specialty health-care company Allergan was established in 1950 with a dedication to uncover the best of science as well as develop and deliver innovative and meaningful treatments to help people reach their life's potential. Allergan has 11,200 employees and a presence in 100-plus countries, a rich and ever-evolving portfolio of pharmaceuticals, biologics, medical devices and OTC consumer products, and state-of-the-art resources in R&D, manufacturing and safety. Allergan employs more than 50 percent of its work force in research and development or sales to ensure the company's focus on innovation and its customers.

Allergan started as an eye-care company and remains a global leader in that field. In time, the company's focus has transformed to include neurosciences, medical aesthetics, medical dermatology, breast aesthetics, obesity intervention, and urologics. The flagship franchises – eye care, neurosciences, medical dermatology and urologics – fall under Allergan Pharmaceuticals.

The corporation added breast aesthetics and dermal fillers to its business arsenal via the acquisition of **Inamed** during 2006, thus creating a world-leading medical aesthetics franchise. Through Inamed, Allergan additionally acquired a leading product portfolio in obesity intervention that offers minimally invasive devices to help patients obtain sustained weight loss and reduce health risks associated with obesity. Each of these products are represented via the Allergan Medical corporate division.

Top 10 Most Admired Specialty Pharma Companies

1. Allergan
2. Teva Pharmaceutical Industries
3. Shire
4. Valeant Pharmaceuticals International
5. Mylan
6. Actavis/Warner Chilcott (in the process of merging)
7. Salix Pharmaceuticals
8. Jazz Pharmaceuticals
9. Hospira
10. Endo Health Solutions

"With specialty product lines focused on high-growth markets, Allergan represents a new multi-specialty health care model for the future, where diversification and focus live together to offer physicians and patients best-in-class treatments and a robust pipeline for continuous innovation," according to the company. "Bolstered by an integrated R&D organization and global infrastructure, characteristics of some of the industry's largest pharmaceutical companies, Allergan also maintains a lean and efficient operation with solid growth prospects, like many smaller and more specialized organizations in the health-care field. Allergan is large enough to command sufficient resources to address significant patient needs yet small enough for nimble execution. As we look to the future, we will continue to follow our R&D technologies into additional specialty areas and build a leadership presence of relevance to the doctors and patients we serve."

Allergan develops, manufactures and markets a wide array of prescription and OTC products designed to treat eye diseases and disorders. These include dry eye, glaucoma, inflammation, infection, allergy and retinal disease. **Restasis** (cyclosporine ophthalmic emulsion) 0.05 percent is the company's best-selling eye-care product and the largest prescription ophthalmic pharmaceutical by sales value in the U.S. Restasis is the first prescription eye drop to help increase tear production in instances where tear production may be reduced by inflammation because of chronic dry eye. Chronic dry eye is a painful and irritating condition involving ab-

INDICATION

This advertisement is indicated for the commending of our friends and colleagues at Johnson & Johnson.

IMPORTANT CONGRATULATORY INFORMATION

Johnson & Johnson was recently recognized by *Med Ad News* as the Most Admired Pharmaceutical Company of 2013. On behalf of all of us at Wx, we would like to congratulate everyone at J&J for all the extraordinary work you do. It's a privilege and an honor to call you our partners.

Please see yourselves as the wonderfully talented people that you are.

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normalities and deficiencies in the tear film due to various causes. The incidence of chronic dry eye rises with age, after menopause in women and in people with systemic diseases. Allergan introduced Restasis in the United States during 2003 and the drug is sold in 40 countries.

Allergan's best-selling product is the multi-functional **Botox**, which is available in about 88 countries. The blockbuster brand treats 26 different conditions including spasticities, dystonias, chronic migraine and the urological conditions of neurogenic detrusor overactivity and idiopathic overactive bladder. Botox (onabotulinumtoxinA) was first given the green light by U.S. regulators in 1989 for treating two eye muscle disorders: strabismus and blepharospasm. Botox was the first botulinum toxin type A product approved anywhere globally.

The company's diversified business model includes products for which patients may be eligible for reimbursement and cash pay products that consumers pay for directly out-of-pocket. For fiscal-year 2012, an estimated 62 percent of Allergan's product net sales were derived from reimbursable products and 38 percent stemmed from cash pay products.

Allergan announced a new president on June 24, 2013: Douglas S. Ingram. Mr. Ingram heads the company's global commercial operations, with responsibility for Allergan's broad portfolio of pharmaceutical, consumer and medical device products. For the previous three years, he was executive VP and president of Europe, Africa and Middle East. Mr. Ingram has been with Allergan since 1996.

Financial and business performance

Allergan's total revenue amounted to $5.81 billion for 2012, $5.42 billion during 2011, and $4.92 billion in 2010. For Allergan during 2012, the eye-care pharma business led the way in terms of the company's product lines with sales of $2.69 billion ($2.52 billion for 2011). Botox was the No. 2 product line for Allergan in 2012 at $1.77 billion ($1.59 billion in 2011), accounting for 31 percent of Allergan's consolidated product net sales. Therapeutic uses accounted for 52 percent of Botox total sales and aesthetic uses represented the other 48 percent.

Allergan reported first-half 2013 total revenue of $3.06 billion, compared to $2.8 billion during the first six months of the previous calendar term. The company reported $1.58 billion in total product net sales for second-quarter 2013, up 10.6 percent versus April-June 2012.

"In the second quarter, double digit sales and earnings growth is in line with our long term growth aspirations," stated David E.I. Pyott, Allergan chairman and CEO. "We are also pleased with further R&D progress with the FDA Advisory Committee's unanimous recommendation for **Juvederm Voluma XC** and with the filing of **Ozurdex** for diabetic macular edema in both the United States and Europe."

Based on the first-half results, Amgen expected full-year 2013 total product net sales of between $6.05 billion and $6.2 billion, excluding the obesity intervention business. For full-year 2013, total specialty pharmaceuticals net sales are projected between $5.23 billion and $5.34 billion, and medical devices net sales are predicted to fall between $820 million and $860 million. Botox net sales for 2013 are estimated between $1.94 billion and $2 billion; Restasis net sales are predicted to range from $870 million to $900 million; **Lumigan** franchise net sales are estimated between $620 million and $640 million; **Alphagan** franchise net sales are expected to be $450 million to $480 million; and **Latisse** net sales are estimated at $110 million. Breast aesthetics product net sales for full-year 2013 are expected to fall between $380 million and $400 million, and facial aesthetics product net sales are projected between $440 million and $460 million.

Product and pipeline updates

Allergan is regarded as a pioneer in specialty pharmaceutical, biologic and medical device research and development. The company's R&D efforts are concentrated on products and technologies related to the many specialty areas in which Allergan operates as well as new specialty areas. Allergan's R&D budget for 2012 totaled $989.6 million, representing 17.3 percent of its product net sales. The company supplements its R&D with a dedication to identify and obtain new technologies via in-licensing, research collaborations, joint ventures and acquisitions.

Allergan announced in May 2013 an FDA advisory committee's unanimous vote that the benefits of Juvederm Voluma XC outweigh the risks. The injectable hyaluronic acid dermal filler is for cheek augmentation to correct age-related volume deficit in the mid-face. If approved (potentially by late 2013), it would be the first dermal filler in the U.S. with that indication.

Allergan submitted a supplemental new drug application in second-quarter 2013 for U.S. clearance of Ozurdex (dexamethasone intravitreal implant) 0.7 mg to treat diabetic macular edema. Also during this period, the company filed a Type II variation to the Marketing Authorisation Application with the EMA for approval of Ozurdex 700 micrograms intravitreal implant in applicator to treat adult patients with diabetic macular edema.

FDA regulators issued a complete response letter to its new drug application for **Levadex** (dihydroergotamine) inhalation aerosol for the acute treatment of migraine in adults, as announced by Allergan on April 16, 2013. The company intends to file an amended application by year-end 2013 and anticipates marketing clearance during second-quarter 2014.

Botox was approved by FDA during January 2013 for a new indication. U.S. health authorities cleared Botox for treating overactive bladder with symptoms of urge urinary incontinence, urgency and frequency in adults who have had an inadequate response to or are intolerant of an anticholinergic medication. An estimated 14.7 million adults experience overactive bladder symptoms with urinary incontinence.

Natrelle 410 Highly Cohesive Anatomically Shaped Silicone-Filled Breast Implants for use in breast reconstruction, augmentation and revision surgery were FDA-approved in February 2013. The implants are designed to mimic the slope of the breast to deliver a subtle, non-augmented look while remaining soft to the touch. U.S. approval was based in part on Allergan's 10-year prospective, multi-center pivotal study including nearly 1,000 women who have undergone breast reconstruction, augmentation or revision surgery.

M&A and deals

Allergan has been active on the acquisition and deal front during 2012 and 2013. In fourth-quarter 2012, the company acquired **SkinMedica** for $348.3 million. The acquisition consists of various aesthetic skin-care products but did not include the SkinMedica Colorescience aesthetic make-up business.

The SkinMedica family consists of physician-dispensed, non-prescription aesthetic skin care products such as **Lytera**, **TNS** (Tissue Nutrient Solution) and **Vaniqa**. Lytera is an over-the-counter, non-hydroquinone skin-brightening product that minimizes the appearance of skin discoloration and dark spots. The TNS anti-aging OTC product line includes **NouriCel**, a patented biotech-derived enriched nutrient solution, and also consists of cleansing, toning, moisturizing, sun protection, acne, visible redness, lightening products and peels. Vaniqa (eflornithine HCl) is a topical prescription cream used to reduce the growth of facial hair in women, and was FDA-cleared during 2000.

MAP Pharmaceuticals was acquired by Allergan for $25 per share. The deal, first announced Jan. 22, 2013, was completed on March 1. MAP is a biopharma company developing and commercializing new neurology therapies.

Allergan entered into a collaboration with MAP in January 2011 to jointly promote Levadex to neurologists and pain specialists in United States and Canada upon regulatory approval in those countries. MAP initially filed a New Drug Application for Levadex with U.S. health authorities in May 2011. MAP refiled the NDA in October 2012 with additional data and provided responses to FDA comments. During the following month, MAP announced that its NDA refiling was accepted for FDA review as a complete Class 2 response, with a Prescription Drug User Fee Act goal date of April 15, 2013.

Allergan announced in first-quarter 2013 the completion of the company's previously disclosed review of strategic options for maximizing the value of its obesity intervention business. Allergan is formally dedicated to pursue a sale of that business unit. Management intended to execute a signed deal to sell the obesity intervention business in first-half 2013, but no announcement had been made as of August 2013.

The obesity intervention business include the **Lap-Band** and **Orbera** Systems. Lap-Band is designed to provide minimally invasive long-term treatment of severe obesity and is used as an alternative to more invasive procedures including gastric bypass or sleeve gastrectomy. U.S. regulators cleared for marketing Lap-Band during 2001 to treat severe obesity in adults who have failed more conservative weight reduction choices. Lap-Band is the first FDA-approved device for bariatric surgery in patients with a BMI of 30-35 with one or more obesity related comorbidities. The Orbera Intragastric Balloon System is a non-surgical option for treating overweight and obese adults in 60-plus countries, but it is not available in the United States.

"Evidenced by our recent acquisitions of SkinMedica and MAP Pharmaceuticals and our decision to declare our obesity intervention assets as a discontinued business, we are dynamically managing our portfolio to drive long-term sales growth," Mr. Pyott stated.

Corporate citizenship

The Allergan Foundation was established in 1998 as a U.S.-based, private charitable foundation with a mission to make a positive and lasting impact on the community. According to Allergan, the foundation lends philanthropic support and involvement to organizations working hard to make the lives of individuals healthier and happier and to make their communities better places to live.

The Allergan Foundation has made grants totaling more than $33 million. Support is concentrated in four philanthropic areas: the arts, civic programs, education, and health and human services. As part of the foundation's dedication to health and human services, it supports selected initiatives known as "Focus Grants." Those grants improve patient diagnosis, treatment, care and quality of life, and promote access to quality health care. Each organization receiving support from the foundation is committed to addressing unmet community needs.

Allergan funds educational activities via an extensive unrestricted educational grant program. By doing this, Allergan fosters increased understanding of scientific, clinical, and healthcare issues. The company also seeks to provide an efficient and effective grant review process to help facilitate grant requests for quality independent education. ■ MEDADNEWS

Notes & Methodology

The editors of *Med Ad News* polled the healthcare industry to determine the Most Admired Company in three categories: pharmaceutical, biotechnology/biopharma, and specialty pharma. Respondents were asked to complete a ballot, selecting their top three choices for Most Admired Company in each category. The editors of *Med Ad News* selected the nominees in each category based on their ranking by 2012 revenue. For all three categories only parent companies are listed, and subsidiaries and divisions are excluded from the lists unless there are special circumstances.

The pharmaceutical category poll represented the top half from *Med Ad News*' Top 50 Companies report featured in the October 2013 issue. This grouping included crossover from the biotechnology and specialty company listings. The biotechnology/biopharmaceutical category voting represented the top quarter of *Med Ad News*' Top 100 Biotechnology Companies report as published in the June 2013 magazine. To be included in the specialty pharma category, companies must develop and/or market prescription drugs and/or generic drugs. The specialty company category includes generic, drug-delivery, and drug-development companies. Companies that develop and/or market only OTC products are excluded.

Previous Most Admired Company Winners

PHARMACEUTICAL
2012: Novartis
2011: Novartis
2010: Novartis
2009: Novartis
2008: Johnson & Johnson
2007: Novartis
2006: Novartis
2005: Pfizer
2004: Pfizer
2003: Pfizer
2002: Pfizer
2001: Pfizer

BIOTECHNOLOGY
2012: Biogen Idec
2011: Amgen
2010: Amgen
2009: Genentech
2008: Genentech
2007: Genentech
2006: Genentech
2005: Genentech
2004: Genentech
2003: Amgen
2002: Amgen
2001: Amgen

SPECIALTY
2012: Shire
2011: Allergan
2010: Allergan
2009: Allergan
2008: Allergan
2007: Teva Pharmaceutical Industries
2006: Teva Pharmaceutical Industries
2005: Teva Pharmaceutical Industries
2004: Allergan
2003: Allergan

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All around the world

This year's *Med Ad News* Executives on the Rise share diverse resumes that cross geographic and industry lines.

By Joshua Slatko joshua.slatko@ubm.com

As the world grows smaller and pharmaceutical companies attempt to reach outside the industry's traditional geographic and philosophical boundaries, the demand for creativity in leadership has grown exponentially. The leader who grows up in a single division, company, or country is at a disadvantage; a diverse background across business areas and geographies has become nearly a requirement for the industry's top executives. This year's *Med Ad News* Executives on the Rise, nominated by a group of executive search firms focused on the healthcare industry, reflect this trend. Of the five individuals profiled, four are either based outside the United States or focused on international matters; four came to pharma from entirely different industries, including finance, law, engineering, and retail; four have spent time at at least two different pharma companies (with one working at four different pharmas in less than 20 years); and all have worked across multiple business disciplines. These profilees come from all over the map of pharma, from small companies to large, but they all share multidimensional and diverse backgrounds that have stood them in good stead as they rise to the top of the industry.

Sheelagh Cawley

Sheelagh Cawley is VP Strategy International for **Baxter**. She joined the company recently after spending nearly ten years working her way up the ladder at **Novartis**, first as a corporate IT project consultant and program manager, then as VP of innovation, quality, and productivity, and finally as a part of the company's Executive Commercial Leadership Development Program. She made her bones at Novartis as a cost-cutter; as global IT program manager she was responsible for $100 million in infrastructure savings, and her Global LEAN and Six Sigma group drove initiatives that reduced Novartis US headquarters costs by $60 million and increased the savings of the company's Pharma Global Productivity Program from $500 million to $612 million. In the district sales management portion of her time in the Novartis leadership development program, her district was the top performer in its region.

"Whether serving as a consultant or in a role within a company, the common thread [in my career] has been looking at how to drive operational efficiency and effectiveness and create growth," Ms. Cawley says. "The principle remains the same: how can you drive 'waste' or 'non-value'-added activities out of core processes and ensure that you are delivering on the 'voice of the customer.' This is key in the pharmaceutical industry as we continually look at ways to accelerate the drug development process in a dynamic industry with a heightened focus on cost containment."

Ms. Cawley has taken a winding path to the top of the pharma industry. After finishing degrees in economics and politics, she started her professional career in finance, as a business analyst at Allied Irish Corporate Bank. But she quickly realized that the world of banking wasn't for her; after less than two years, she moved on to a consulting position at PA Consulting Group, and then a role as senior management consultant at Cap Gemini Ernst & Young in France, where she worked on a long-term assignment for General Electric Energy Products Europe. It was at GE where her skills at business economy were first tested on a large scale; her management of the company's Six Sigma IT Infrastructure program led to $5 million in annual cost savings.

After seven years in consulting, though, Ms. Cawley came to a decision point. So when presented with the chance to move to Novartis, she took it. "I believe in every consultant's life there comes a point in time where one is presented with the choice to either remain on the consulting path longer term or move within industry," she says.

After nearly a decade at Novartis came another decision point – the chance to go leaner at Baxter.

"Baxter has a very interesting mix of capabilities and businesses and is at a very exciting point in its evolution with an acceleration of business development activity including the pending acquisition of Gambro, the largest acquisition in the history of the company," Ms. Cawley told *Med Ad News*. "The company has a strong portfolio that spans biotechnology, pharmaceuticals, and medical devices, and a longstanding and well-regarded global footprint. While it is so diversified, it also has retained a strong focus on innovation that saves and sustains lives – critical therapies that have tremendous impact on patients and public health globally. The increased investments the company has made in research and development, both in-house and through collaborations, have yielded numerous products in late-stage development or nearing launch. I feel privileged to be part of this journey at such an exciting time in the history of the company."

Looking beyond Baxter, Ms. Cawley sees the pharmaceutical industry moving away from the world of big blockbuster launches and products that maintain a "buoyant" P&L to more specialized therapies and orphan drugs with smaller niche patient populations. "This, coupled with increasing access and reimbursement restrictions across both emerging and established markets are driving key players in the industry to not only re-think their go-to market strategies but also to embed continuous improvement and operational effectiveness into all elements of the value chain," she says. "This environment provides interesting opportunities for companies like Baxter, which can bring more pragmatic, sustainable solutions and approaches toward helping governments deliver quality, cost-effective healthcare to their populations."

When asked to offer advice to individuals starting their careers, Ms. Cawley emphasizes the importance of valuing the team.

"We are nothing without the people that surround us," she says. "Starting out in our careers, we are always so focused on the 'I,' and it is only when you really start to make it about others that you can truly succeed. I recall my mother's words of wisdom as I was growing up in Dublin; 'Do onto others as you would have done onto you.' Now I see every day how important, relevant, and true those words are – so elemental to mentoring/coaching, collaboration, trust and leadership."

John Crowley

John Crowley, chairman and CEO of **Amicus** Therapeutics, has one of the more remarkable stories in the annals of pharmaceutical executives. After attending the U.S. Naval Academy and earning a degree in foreign service at Georgetown, he went to law school and practiced as a litigation associate for several years before going back to school and getting an MBA at Harvard Business School. He was working at a management consulting company in 1998 when two of his children, Megan and Patrick, were diagnosed with Pompe disease, a severe and often fatal neuromuscular disorder. Soon afterwards, he took a position at **Bristol-Myers Squibb**. But he only stayed at Squibb for two years; in an attempt to find a cure for his children, he left his position there to co-found **Novazyme** Pharmaceuticals, a biotech start-up conducting research on a new experimental treatment for Pompe disease, which he credits as ultimately saving his children's lives. In 2001, Novazyme was acquired by **Genzyme** Corp.; Mr. Crowley continued to play a lead role in the development of a drug for Pompe disease as senior VP, Genzyme Therapeutics. In 2003 he became president and CEO of **Orexigen** Therapeutics; then, in 2005, he was named president and CEO of Amicus, where he has remained since then, continuing to advocate for pediatric rare disease research. His time at Amicus also offers another unique distinction; he is perhaps the only pharma CEO to have taken a leave of absence from his position to serve in a combat zone, deploying to Afghanistan with the U.S. Navy.

The story of Mr. Crowley's efforts on behalf of his children has captured the attention of many. He and his family have been profiled in *The Wall Street Journal* and are the subjects of a book by journalist Geeta Anand, "The Cure." Additionally, the movie *Extraordinary Measures*, starring Brendan Fraser and Harrison Ford, is inspired by the Crowley family story. Mr. Crowley himself is the author of a personal memoir, "Chasing Miracles: The Crowley Family Journey of Strength, Hope and Joy."

"[Pharma] is the best business that you can be in when it works," Mr. Crowley says. "You can do good and do well and build great companies and people's careers and provide a measure of financial security for people who took enormous risks in coming to build the business. But you also, even more importantly, are able to fundamentally change people's lives. For me it's all the more personal, of course. It's a hard business too because almost everything we put into the clinic doesn't work. You can raise enormous amounts of money and bring the best and brightest people to an organization, build beautiful facilities, but still it is wholly dependent on some very complicated technologies, especially the most innovative piece of it."

The first major turning point in Mr. Crowley's professional journey was when he decided to end a promising legal career to go back to school and earn a business degree.

"Working with a lot of our clients in business, I realized that I liked the challenges that you can get in a business that you might not necessarily get in the law," he explains. "The law is still rooted in precedent and it was tremendous training for how to think, how to negotiate, how to work through a lot of different scenarios. But the scenarios we were always trying to solve for were generally business problems and business strategies, and I thought that maybe that would be something I might find more interesting. I didn't have any formal training and thought one way to jumpstart a career in business would be to get an MBA, and was fortunate enough to get in to Harvard and pack up a really nice house in Indianapolis and trade it in for a tiny, very expensive apartment in Boston and $100,000.00 in student loans!"

Mr. Crowley's later move from consulting to pharma, a few months after his children were diagnosed, was not necessarily the *Lorenzo's Oil*-style leap that a screenwriter might prefer. But in the end, the transition to pharma was what led to his pursuit of a cure for Pompe.

"Going into Bristol-Myers in 1998 about three months after Megan and Patrick were diagnosed, I really didn't do it to get training, to go out and start my own biopharmaceutical company," Mr. Crowley told *Med Ad News*. "I did it because it was a good job and good health insurance and it seemed like a reasonable career path for a while. Then it just kind of morphed from there, to become an entrepreneur and then to work within the biotech industry."

As CEO at Amicus, Mr. Crowley tries to divide his time into thirds: one-third on the company's operational programs, one-third outside as the company's public face, and one third thinking about strategic planning and issues. This final third, he believes, is what distinguishes great companies and business leaders.

"Thinking about long-term strategy is critically important, because otherwise you run full stream day to day, month to month, year to year, and look back and think, 'What did we do and remind me why did we do it?'" he says. "Those aren't the questions you want to be asking. You ought to be thinking, 'Okay, I know what I did, and I know why we did it even if it didn't work.' What I want to figure out is where we want to be five or 10 years from now and what actions to take today to make those options a reality and to give then the highest chance of success in an inherently risky business. Ultimately, strategy is about choice, and that's where I try to spend a good amount of my time, understanding the choices we have in front of us or how can I help to reset the chess game and move the pieces so that we have different or potentially better choices."

When asked to offer advice to those at the beginning of their careers, Mr. Crowley suggests that too much planning may not be the best approach.

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ABOVE AND WAY BEYOND

"Don't plan your life like you're building a resume," he says. "Plan it like you're building a set of experiences. That may take you to very different places in your life and in your career but at the end you will be happier and you will very likely be much more effective in whatever career you choose, because you never know where fate is going to take you in your career."

Sue Foelix

Sue Foelix is one of two of the executives profiled to have spent nearly her entire professional career in the pharmaceutical industry. Currently the head of **Sanofi**'s U.S. Oncology Patient Centered Unit, she was appointed to this position in May after leading Sanofi's U.S. Renal PCU, previously Genzyme Renal, serving patients with chronic kidney disease bone and mineral disorder. Before that Ms. Foelix had spent nearly four years at Genzyme as VP marketing, and three and a half years in the same role at MedPointe Pharmaceuticals. Her presence today at Sanofi actually represents a return to the company, as she spent nearly ten years at the Sanofi predecessor companies Rhone-Poulenc Rorer and Aventis, first as an area sales manager, then a senior manager of sales training, then a product manager, then director of marketing for DTC, and finally director of marketing for oncology.

"One thing that I know about myself is that I like to see growth and am unafraid to work through change," Ms. Foelix told *Med Ad News*. "Curiosity and desire to learn have been the drivers for each new opportunity. Integrity and commitment to the patient, customers and coworkers has been constant. From sales, I wanted to learn how to lead a team as a manager. Sales training afforded the opportunity to understand how adults learn and how to effectively help people master new material. Marketing allowed the exercise of strategic, organizational behavior, creative, and project management skills."

Despite her long pharma resume, Ms. Foelix actually started somewhere quite different; her undergraduate degree was in computer science, and her first job was as an engineer at Lockheed.

"Entering Saint Anselm College, I had no clear idea of what career to pursue," she says. "Fainting while dissecting critters in biology suggested that medicine was not the right path. My parents had chemistry and engineering backgrounds and suggested that engineering would likely yield a paying job at the end of undergraduate work. They were right on that account! I knew early on that while I *could* do this work, I did not love it."

After reaching this conclusion, Ms. Foelix got an MBA at Boston University, which led to her first position in sales at Rhone-Poulenc Rorer. But her computer science and engineering background hasn't quite left her.

"The training in logical thinking through engineering and balancing perspectives refined by four years of college debate still helps me to assimilate information and drive to decisions," she says.

In her current role, Ms. Foelix's primary responsibility is for stewardship of Sanofi's various marketed cancer products in the United States. Her appointment to the position is a clear reflection of upper management's faith in her; while oncology offers perhaps the greatest opportunities for growth of any disease category, Sanofi's cancer drugs have been lagging, with its top brand **Eloxatin** falling 10.7 percent to $1.23 billion in sales in 2012, just 94th in revenue among all pharma brands. But Ms. Foelix has high hopes for the future of oncology at Sanofi.

"We created a global hub for oncology in the Cambridge area a few years ago," she says. "Today we are bringing the U.S. medical affairs and commercial oncology teams from New Jersey to Cambridge. While this creates short term challenges, the opportunity to work in close proximity with the larger oncology-focused team will strengthen our work. People choose to work in the field of oncology. It is complicated, ever changing, and yet critically important and rewarding. I am privileged to be part of this team and my priorities are to strengthen our U.S. teams; listen to and collaborate with our customers; and to return the business to growth."

When asked what suggestions she would offer to individuals beginning their careers, Ms. Foelix actually wants to go back even further, to the beginning of undergraduate studies.

"First, learn how to learn, because that is the skill that will endure for life," she says. "Second, pay attention to the subject matter that you really thrive in and seek to understand why you find it interesting, intellectually stimulating, or even fun. Finally, be open to opportunity and unafraid to try new things. Shakespeare had it right when he wrote the words of Polonius in *Hamlet*: 'This above all: to thine own self be true, And it must follow, as the night the day, Thou canst not then be false to any man.'"

Jeff George

The youngest of the *Med Ad News* rising executives at just 40 years old, Jeff George has been the global head of the **Novartis** subsidiary Sandoz, the second-largest generic pharmaceutical company in the world, for the past five years. Before being elevated to his current position, Mr. George was head of Western and Eastern Europe for Novartis Vaccines and then head of emerging markets for the Middle East, Africa, Southeast Asia, and CIS for the whole company – two positions he held for a total of less than two years. He came to Novartis from the world of retail, having served as senior director of strategic planning and business development for Gap Inc. Before that he was an engagement manager at McKinsey and Co., and worked in emerging markets private equity in Johannesburg and Washington, D.C. Mr. George was named one of *Fortune* magazine's "Top 40 under 40" up-and-coming global leaders in both 2011 and 2012.

"I had always been attracted to healthcare because it's a field that really makes a difference in people's lives," Mr. George says. "Whether it's the way new medicines are discovered and developed on the innovator side of Novartis in order to address serious unmet needs in diseases like cancer, multiple sclerosis, or immunology, or the way in which high-quality, affordable generic medicines from Sandoz reached over 400 million people in 2012, the work we do in healthcare makes a big difference."

Unlike most of our other executives, who spread their studies out with career moves in between, Mr. George spent nearly a decade straight in various universities before moving into consulting at McKinsey. After earning his undergraduate degree in international relations in 1996, he went to the Johns Hopkins School of Advanced International Studies, where he earned a Masters degree in 1999, and then to Harvard Business School, where he earned an MBA in 2001. All this, plus his diverse experience pre-Novartis, has been crucial to his development as a leader.

"I've always felt it was important to get experience in several fields before choosing the one in which I wanted to spend my career," he says. "Strategy consulting and private equity were attractive to me because of the breadth of industries in which you have the opportunity to gain exposure. And both fields gave me a chance to strengthen my problem-solving, project management, financial, and communications skills, which are all valuable in general management."

At McKinsey Mr. George often worked at the nexus of retail/consumer goods and health, in sectors like retail pharmacy and consumer healthcare. "In 2004, I had opportunities to go into either pharma or retail, and I chose retail because it allowed my wife and me to stay in San Francisco and gave me the opportunity to work with a close mentor who was the most inspirational leader I worked with in consulting," he says. "I ended up becoming his successor leading strategic planning and business development for a division of Gap Inc., which I enjoyed a great deal. But I always knew I was a line executive at heart, so when Novartis reached out to me in late 2006, I was intrigued by the opportunity to transition into general management with a more global company – and in a more global industry."

Though retail experience is probably unusual among pharmaceutical executives, Mr. George believes that his time at Gap provided a valuable perspective – and one that will become more valuable as pharmaceutical companies move closer to the patient.

"Retail is a very fast-moving industry, and this has certainly been something I've leveraged in my time in generics, emerging markets pharma, and vaccines during the past seven years with Novartis," Mr. George told *Med Ad News*. "In addition, it's really important to understand the customer -- mindset, beliefs, behaviors -- in retail and fast-moving consumer goods, which I think is becoming increasingly important in healthcare as well."

When asked to offer advice to those at the beginning of their careers, Mr. George offers three simple but crucial tips.

"One, know yourself; without self-awareness, you can't lead yourself, and without this, how can you expect to lead others? Two, stay focused on the job at hand: don't look past your current job. By doing the best possible job in your current role, others will ultimately take notice – if you spend too much time looking past the job you are in, you won't do as well in your current job, which will limit your career growth. Third, be kind to others – never underestimate the simple power of saying 'thank you.'"

Charl van Zyl

Charl van Zyl, the second *Med Ad News* profilee to spend nearly his entire career in pharma, has spent the last four and a half years as executive VP and president EMEA at **Bausch & Lomb**. During his time at Bausch, he's helped drive his division to 10 percent revenue growth, completed the acquisition of an Italian company, concluded two major in-licensing deals, and created new regional and country footprint structures as well as new go-to market commercial models within high growth markets, such as Russia, Turkey, Central and Eastern Europe, and Africa.

Before joining Bausch in 2009, Mr. Van Zyl built a remarkably diverse pharmaceutical resume with stops all over the world. He started out in 1996 as a Diabetes Care product manager in South Africa for Eli **Lilly** and Co. A year later he was promoted to sales manager, primary care in South Africa, with responsibility for three product lines; his sales team was ranked No. 1 in the country, and he received the affiliate Manager of the Year award. Then came another promotion, to business unit manager for diabetes care of the **Roche**/Lilly alliance in South Africa. In just under two years in this position, Mr. van Zyl launched Lilly's innovative insulin range and pushed market share from 8 percent to 28 percent.

After that Mr. van Zyl's international adventures really began – marketing manager in Japan, marketing manager for diabetes care and neurosciences in Latin America and Canada, and then business unit manager of a Lilly/**Boehringer Ingelheim** strategic alliance in the UK. In the second role, he led the launch of **Actos** in the United States, Mexico, and Canada, where its market share passed competitor **Avandia**'s in 12 months; in the third, he was responsible for the launch of **Cialis** in the UK, exceeding sales performance targets by 30 percent.

After nearly 10 years at Lilly, in 2004 Mr. van Zyl moved to **Novartis**, becoming head of global marketing for the company's ophthalmics division and then head of marketing and sales for Europe, where he was responsible for the successful European launches of **Exforge**, **Rasilez**, and **Lucentis**. Then, in 2007, he stepped away from big pharma, serving as CEO of the biotech company **Jado** Technologies for a year and a half before moving into his current role at Bausch.

"I have been fortunate to have roles which allowed me to build a a very broad and diverse set of experiences, from specialty areas to primary care, to OTC and medical devices across many different cultures and countries," Mr. van Zyl told *Med Ad News*. "This very broad experience in both large matrixed organisations as well as small start-ups, in a relatively short period of time, has helped me develop strong leadership and a diverse set of experiences needed for the fast-changing pharma environment."

Like the other profilees, Mr. van Zyl's move into pharma came as much by chance as design.

"I started my academic career without a clear goal to join the pharma industry; I was more interested in progress in academics," he says. However, a chance meeting with some pharma executives triggered my interest to join. It was the best thing I could have done. It was a perfect fit for my interest but also my strong orientation to work with people and teams and develop results."

From his perch near the top of one of the world's best-known specialty pharma companies, Mr. van Zyl has a bird's-eye view of the issues facing the modern specialty operation. The biggest challenge, he feels, are reimbursement levels of specialty products balanced against emerging opportunities in OTC. But there are many others as well.

"The major structural challenge is how to rapidly gain scale and coverage in key markets as a specialty player when competing against the larger consolidated companies," Mr. van Zyl says. "Further challenges relate on the ability of companies and healthcare insurers to mobilize consumers to seek treatment earlier and on a regular basis for eye health rather than wait until the condition has advanced."

When asked what advice he would give to individuals starting out in their careers, Mr. van Zyl is brief and to the point.

"Work hard and be committed in every role you have," he says. "The career will take care of itself." ■ MEDADNEWS

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4th annual report:

Pharma employment snapshot

For the fourth year, *Med Ad News* has surveyed its readership to develop a picture of the current working environment for companies in and around the pharmaceutical space.

By *Med Ad News* staff

THE WORK EXPERIENCE

How many years have you worked in your current position?

Answer	2013	2012	2011
0 to 3 years	39.7%	34.9%	30.5%
4 to 6 years	21.8%	24.0%	29.9%
7 to 9 years	15.6%	11.1%	11.0%
10 to 12 years	4.7%	7.9%	6.1%
> 12 years	18.1%	22.0%	22.4%

How many years have you worked within your current industry?

Answer	2013	2012	2011
0 to 3 years	6.0%	6.4%	2.9%
4 to 6 years	6.0%	9.5%	7.8%
7 to 9 years	7.3%	7.5%	7.6%
10 to 12 years	6.3%	10.9%	10.5%
> 12 years	74.4%	65.7%	71.2%

How many hours do you work per week?

Answer	2013	2012	2011
< 19	3.6%	1.8%	1.5%
20 to 29	2.5%	1.4%	1.2%
30 to 39	6.1%	7.1%	4.4%
40 to 49	41.1%	50.3%	47.4%
50 to 59	31.5%	29.8%	31.7%
> 60	15.2%	9.6%	14.0%

STAFFING AND BUDGET

How many direct reports do you have?

Answer	2013	2012	2011
1 to 5	78.3%	79.7%	74.1%
6 to 10	13.6%	13.3%	16.0%
11 to 15	3.6%	3.3%	5.5%
16 to 20	1.0%	1.4%	1.7%
> 20	3.6%	2.3%	2.6%

What is the staff level of your overall organization?

Answer	2013	2012	2011
1 to 25	28.4%	18.8%	23.3%
26 to 50	11.6%	10.3%	7.3%
51 to 75	6.2%	6.3%	5.5%
76 to 100	2.6%	4.5%	7.3%
> 100	51.3%	60.1%	56.7%

What is the staff level of your division/group?

Answer	2013	2012	2011
1 to 25	55.2%	47.5%	48.5%
26 to 50	13.0%	11.1%	14.0%
51 to 75	8.1%	6.4%	6.4%
76 to 100	3.1%	5.6%	4.9%
> 100	20.6%	29.4%	26.2%

Has the staff level of your division/group changed in the past year?

Answer	2013	2012	2011
Yes	63.7%	66.0%	61.3%
No	30.0%	28.7%	34.3%
Not sure/not applicable	6.3%	5.2%	4.4%

Has it increased or decreased?

Answer	2013	2012	2011
Increased	36.6%	34.3%	29.1%
Decreased	27.1%	31.7%	32.3%

Do you expect the staff level of your division/group to change within the next year?

Answer	2013	2012	2011
Yes	53.1%	51.4%	54.4%
No	29.7%	28.0%	29.4%
Not sure/not applicable	17.2%	20.5%	16.3%

How would you rate the staff level of your division/group?

Answer	2013	2012	2011
Over staffed	3.2%	3.7%	3.5%
Adequately staffed	42.4%	39.8%	39.2%
Under staffed	49.9%	52.7%	54.1%
Not sure/not applicable	4.5%	3.9%	3.2%

Does your division/group have open positions?

Answer	2013	2012	2011
Yes	42.7%	39.0%	45.3%
No	50.9%	54.4%	49.4%
Not sure/not applicable	6.4%	6.6%	5.2%

Has the budget allotment of your division/group changed in the past year?

Answer	2013	2012	2011
Yes	52.9%	60.7%	57.8%
No	28.7%	24.9%	27.9%
Not sure/not applicable	18.4%	14.3%	14.2%

Has it increased or decreased?

Answer	2013	2012	2011
Increased	27.0%	25.5%	22.4%
Decreased	25.9%	35.2%	35.5%

Do you expect the budget allotment of your division/group to change within the next year?

Answer	2013	2012	2011
Yes	50.0%	57.2%	51.5%
No	26.6%	22.3%	27.6%
Not sure/not applicable	23.4%	20.5%	20.9%

Do you expect an increase or decrease?

Answer	2013	2012	2011
Increase	32.7%	26.8%	28.5%
Decrease	17.3%	30.4%	23.5%

Do you have confidence in your superiors?

Answer	2013	2012	2011
Yes	57.8%	60.4%	61.3%
No	23.1%	25.3%	25.0%
No opinion/not applicable	19.1%	14.3%	13.7%

Do you have confidence in your direct reports?

Answer	2013	2012	2011
Yes	75.8%	78.5%	77.9%
No	6.5%	5.1%	5.5%
No opinion/not applicable	17.7%	16.4%	16.6%

BENEFITS

What employment benefits do you receive?

Answer	2013	2012	2011
Medical	80.7%	87.4%	86.3%
Dental	67.6%	74.1%	72.7%
Retirement	62.4%	68.2%	70.3%
Stock	34.6%	43.1%	48.5%
Signing bonus	14.2%	14.6%	15.4%
Car	17.4%	16.2%	18.9%
Family leave	40.1%	44.9%	41.9%
Child-care services	10.1%	10.8%	10.8%
Technology (laptop, iPad, Blackberry, iPhone, phone, etc.)	67.0%	61.8%	64.0%
Product discounts/ free products	23.4%	31.3%	29.9%
Other	17.4%	12.1%	16.0%

Has a change to your employment benefits been made in the past year?

Answer	2013	2012	2011
Yes	26.4%	43.7%	39.2%
No	63.5%	51.4%	55.2%
Not sure/not applicable	10.1%	4.9%	5.5%

THE WORK PLACE

How would you rate the working conditions/ amenities of your organization?

Answer	2013	2012	2011
Excellent	23.2%	23.8%	22.4%
Good	47.4%	45.8%	48.8%
Fair	19.3%	23.8%	21.2%
Poor	8.2%	5.6%	7.0%
Do not know/not applicable	1.9%	1.1%	0.6%

Does your organization provide mentoring opportunities?

Answer	2013	2012	2011
Yes	43.1%	45.9%	47.7%
No	42.0%	42.2%	42.4%
Not sure/not applicable	15.0%	11.9%	9.9%

Does your organization encourage volunteerism/ philanthropic work outside the company?

Answer	2013	2012	2011
Yes	55.9%	60.4%	64.0%
No	32.2%	28.2%	27.6%
Not sure/not applicable	12.0%	11.4%	8.4%

Does your organization offer opportunities to work abroad?

Answer	2013	2012	2011
Yes	36.8%	41.2%	45.6%
No	51.2%	46.3%	43.0%
Not sure/not applicable	12.0%	12.5%	11.3%

Does your organization offer work-from-home opportunities?

Answer	2013	2012	2011
Yes	61.2%	57.2%	52.3%
No	33.3%	38.6%	38.7%
Not sure/not applicable	5.5%	4.3%	9.0%

How would you rate the technology level provided by your organization in-office (as in DSL, phones, computers, etc.) or provided individually (as in Blackberry, handhelds, laptops, iPads, etc.)?

Answer	2013	2012	2011
Excellent	24.5%	18.9%	18.0%
Good	44.0%	45.6%	43.9%
Fair	23.9%	27.5%	30.2%
Poor	5.5%	6.4%	5.2%
Do not know/not applicable	2.2%	1.6%	2.6%

DEMOGRAPHICS

Company type

Answer	2013	2012	2011
Pharmaceutical manufacturer	28.1%	42.5%	40.1%
Biotechnology company	7.7%	15.2%	13.1%
Generic pharmaceutical manufacturer	2.9%	2.4%	2.0%
Medical equipment manufacturer	6.3%	25.5%	28.8%
Contract research organization	5.2%	2.7%	1.5%
Clinical study site/SMO	1.1%	0.0%	0.0%
Clinical lab	0.3%	0.0%	0.9%
Healthcare communications company	12.9%	0.0%	1.2%
Marketing services company	8.0%	1.1%	2.0%
General business services company	1.1%	0.0%	0.0%
Hospital	2.0%	0.3%	1.2%
Academic/ university research institution	2.9%	1.4%	0.6%


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Government agency	1.1%	0.3%	0.3%
Data management company	1.4%	0.0%	0.0%
Packaging company	0.6%	0.5%	1.5%
Executive recruitment agency	0.6%	0.3%	0.3%
Venture capital/ financial investment firm	0.3%	0.3%	0.3%
Consulting firm	9.2%	2.2%	2.9%

Media company	1.7%	0.5%	0.0%
Legal firm	0.0%	0.0%	0.0%
Other support or service company	6.6%	4.9%	3.5%
Job function			
Answer	**2013**	**2012**	**2011**
R&D management	6.9%	13.3%	14.2%
Senior management	26.1%	15.7%	11.6%
Product management	3.2%	7.6%	5.5%

Sales management	9.5%	6.2%	4.4%
Agency account management	3.7%	0.0%	0.0%
Marketing services	4.6%	3.0%	4.4%
Media management (incl. directors/ planners)	0.6%	0.5%	0.3%
Quality control	1.7%	7.9%	7.6%

Marketing, advertising, or promotion management	8.3%	4.9%	8.1%
Medical director/ associate medical director	3.2%	1.4%	3.2%
Clinical trials management	1.4%	2.7%	1.7%
Clinical/drug research	1.1%	1.6%	4.4%
Regulatory affairs	2.9%	6.0%	4.9%
Clinical monitoring/ CRC/CRA	1.1%	0.5%	0.3%
Academic research or professor	0.6%	1.1%	0.9%
Data management or analysis	1.1%	0.8%	0.9%
Clinical document preparation	0.6%	0.3%	1.2%
Project management	2.6%	3.5%	3.5%
Drug safety	1.4%	1.1%	0.6%
Finance management	0.6%	1.1%	0.3%
Licensing	1.1%	1.9%	1.2%
Manufacturing	1.7%	3.8%	6.1%
IT management	0.9%	0.0%	0.3%
Business Strategy	2.6%	4.3%	5.5%
Legal professional	0.3%	1.4%	0.3%
Other functions	12.3%	9.5%	8.7%
Gender			
Answer	**2013**	**2012**	**2011**
Male	62.2%	64.8%	74.1%
Female	37.8%	35.2%	25.9%
Age			
Answer	**2013**	**2012**	**2011**
20 to 30	4.9%	4.1%	1.2%
31 to 40	14.3%	17.3%	14.5%
41 to 50	28.7%	32.2%	33.1%
51 to 60	40.1%	34.7%	39.8%
61 to 70	12.0%	11.7%	11.3%
Annual salary			
Answer	**2013**	**2012**	**2011**
< $25,000	5.2%	4.9%	4.1%
$25,000 to $50,000	6.9%	5.7%	6.1%
$51,000 to $75,000	12.6%	12.2%	8.7%
$76,000 to $100,000	9.5%	18.2%	23.3%
$101,000 to $150,000	25.2%	30.9%	29.4%
$151,000 to $200,000	18.6%	16.3%	19.2%
> $200,000	22.1%	11.9%	9.3%
Employer's gross U.S. revenue			
Answer	**2013**	**2012**	**2011**
Less than $5 million	28.2%	18.0%	18.3%
$5 million to $10 million	8.1%	4.4%	5.8%
$11 million to $25 million	9.6%	6.4%	4.4%
$26 million to $50 million	5.8%	5.5%	5.5%
$51 million to $75 million	4.1%	1.4%	5.5%
$76 million to $100 million	2.0%	3.0%	2.6%
$101 million to $150 million	2.9%	4.4%	10.5%
> $150 million	39.2%	56.8%	47.4%


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By Joshua Slatko joshua.slatko@ubm.com

Entrepreneurial regulation

By Peter Pitts

Having just returned from meetings with regulatory authorities in Kenya, Jordan, and Saudi Arabia, I am energized that higher levels of pharmaceutical quality and pharmacovigilance are possible.

But it won't be easy.

Enhanced levels of excellence will require, if not global harmonization, more aggressive partnerships between agencies around the world.

In other words, it's time to plan and execute a regulatory Marshall Plan to help build, nation-by-nation, global systems for both quality and safety. Working together to raise the regulatory performance of all nations will help all nations (even the 20 percent deemed "capable" by the WHO) to create sound foundations to address a multitude of quality and safety dilemmas such the manufacturing of biosimilars, the control of API and excipient quality, pharmacovigilance and, yes, even counterfeiting.

But drug regulation has to go beyond safety and quality and pharmacovigilance. It's got to embrace innovation. What we need here at home and around the world is a hunger for entrepreneurial regulation.

Entrepreneurial Regulation is a philosophy that allows agencies such as the FDA to be both regulator of and colleague to industry. Expedited pathways are Entrepreneurial Regulation. Special Medical Use is Entrepreneurial Regulation. REMS are Entrepreneurial Regulation. The exercise of enforcement discretion is Entrepreneurial Regulation. More aggressive use of the Reagan/Udall Foundation is Entrepreneurial Regulation. A more central role for the patient voice is Entrepreneurial Regulation.

Entrepreneurial Regulation makes bodies such as the FDA enablers rather than roadblocks to innovation.

One of the key conundrums of Entrepreneurial Regulation is that there is an inherent tension between predictability and innovation.

The foundational principle of PDUFA is predictability – not speed. And that's been the focus of the conversation: ambiguity vs. predictability. But, when it comes to innovation, ambiguity is inherent. The pathways to innovation are always ambiguous. Innovation is risky – and not only to investors.

And Entrepreneurial Regulation is likewise risky. But as with all matters regulatory, risk must be viewed alongside benefit – to the public health.

Another level of tension is the relationship between research (R) and development (D). Specifically, the lack of respect between the two. Beyond the disproportionate levels of government funding (when's the last time you heard anyone talk about "doubling" the FDA budget), nascent relationships between academia ("R") and industry ("D") are struggling.

The issue of out-sourcing basic research isn't new – but it's mighty contentious. And it's the new reality of drug development. But, if we are to learn any lesson from the CRO experience, it's that while we say "partnership," the danger is that it devolves into a vendor-like relationship. It's the Golden Rule. He who has the gold makes the rules. Will that be acceptable to high-level, big ego Ivy Hall-ers?

And then there's the issue of academic priorities, specifically tenure. Does industry funding carry the same weight as NIH grants when it comes to advancing a university career? Not at present. That will have to change.

Need drives change. Just as CROs are finally really partnering with pharma to drive the development of personalized medicine, so too must academe and industry collaborate on the continued evolution of pharmaceutical innovation. It will take discipline and focus. It will be risky. And it will take will. There is a confluence of interest.

When it comes to global safety, quality, and pharmacovigilance standards, there's a general consensus that a high tide floats all boats. When it comes to Entrepreneurial Regulation demands that we honestly address a tough but fundamental question, how can regulatory agencies around the world (FDA-led by both word and deed) focus on what they can do to facilitate collaboration that results in innovation?

Step One is focus.

In the words of entrepreneur extraordinaire Steve Jobs, "I'm convinced that about half of what separates the successful entrepreneurs from the non-successful ones is pure perseverance."

And, in the case of Entrepreneurial Regulation, failure is not an option.

Peter Pitts is president and co-founder of the Center for Medicine in the Public Interest.

FACTS & FIGURES

The total market value for orphan drugs is expected to hit **$112 billion** in 2017 after increasing at a five-year compound annual growth rate of **5.4 percent**, according to a new report from BCC Research. The global market for orphan drugs was valued at **$82.6 billion** in 2011 and nearly **$86 billion** in 2012.

Orphan drugs treat diseases that do not receive significant investment, research, or attention from the medical and pharmaceutical industries. These diseases tend to be rare and are defined by using a ratio of incidence to population in the United States, the European Union, Japan, and other developed countries. In addition, an orphan disease can be a tropical disease whose typical sufferers cannot afford access to pharmaceutical treatment options.

"Some of the key factors included in study are the growth of orphan drugs market which includes exclusivity options for multiple orphan indications, off-label usage, expansion of orphan indications, and freedom from generic competition," market research analyst Shalini Shahani Dewan told *Med Ad News*. "Market exclusivity has played a crucial role in the success of the orphan drug market. Currently, as Asian pharmaceutical markets are growing, the opportunities for orphan drugs in Asia are also growing. In next five years, the orphan drugs market will experience steady growth in emerging markets, mostly Asia. The increase is a pro for global orphan drugs market as it is encouraging manufacturers to invest in the research and development of new orphan drugs."

According to the BCC Research report, for biological orphan drugs, oncology was highest among the nephrology, infectious diseases, and neurology segments. For non-biological orphan drugs, oncology was highest among blood disorders, neurology, and fibrosis. About **282 companies** plus partners are developing **361 orphan drugs** in oncology drugs, and about **40 percent** of today's orphan drugs are used to treat cancer.

Cancer products tops in journal advertising: study

Cancer products remain tops in advertising in professional health journals, according to the latest research from Kantar Media Healthcare Research. In the first half of 2013, advertisers in professional health journals purchased about 45,829 total pages, and total print advertising dollars in professional health journals reached more than $288 million. Cancer therapies were the top drug class in advertising by both pages and dollars, with 4,546 pages and $23 million in spend in professional health journals. The class also held the top spot at the mid-year point in both 2011 and 2012. The diabetes oral category has made a significant jump since 2012, rising 163 percent in page count to 842 and from 21st to 3rd among all drug categories. Anticoagulants, the second-ranked class, increased page count by 18 percent to 2,115.

"The increase in media spend within oncology is an indicator of how active this field is with introducing new, innovative products," says Jennifer Oleski VP, account director, GSW. "As more products enter the market, they will continue to compete for valuable share of voice and mind space. That clearly represents an exciting opportunity for an advertising agency to help clients achieve their business goals."

Oleski did not find the study results exceptionally surprising. "Overall, the increase in media spend is not surprising because of the changing dynamics within oncology – new products entering the market, innovations in treating some of the more complex tumor types, environmental factors impacting the cost of care, and additional guidelines regulating the interactions between pharma and healthcare providers," she says. "All of these factors have created a need for more information yet less access to it. The question for many brand managers will be how to determine the ROI on their media spend vs. the other non-personal channels that may afford them the opportunity to provide deeper brand engagement."

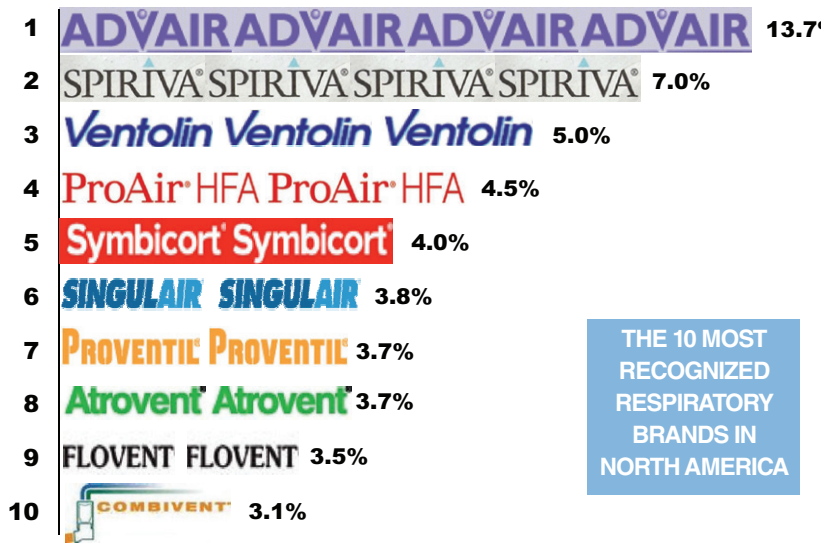
Matt McNally, president, Publicis Health Media also says that the Kantar Media study results were not shocking. "We are also seeing an overall increase in ad spend across all channels for oncology therapy products," he told *Med Ad News*. "The oncology treatment landscape has been evolving over the past few years. For example, with combination therapies and the launch of more niche targeted oncology treatment agents, there is a need for marketers to ensure their products remain top of mind in a rapidly changing therapeutic landscape. Furthermore, journal and digital programs are utilized to compliment efforts of oncology sales forces. We are also seeing significant increases in digital investment in oncology. Marketers are able to precision-target and create customized experiences both online and via mobile for their healthcare professional audiences."

Regarding individual pharma companies, **Johnson & Johnson** has maintained its spot at the top pharma company advertising in professional health journals by dollars. The company spent $20 million advertising in professional health journals through the second quarter of this year, about 7 percent of the total advertising share. **Forest** Laboratories placed second, with $9 million in spend, while **Pfizer** spent $8 million and **Novartis** spent $6 million.

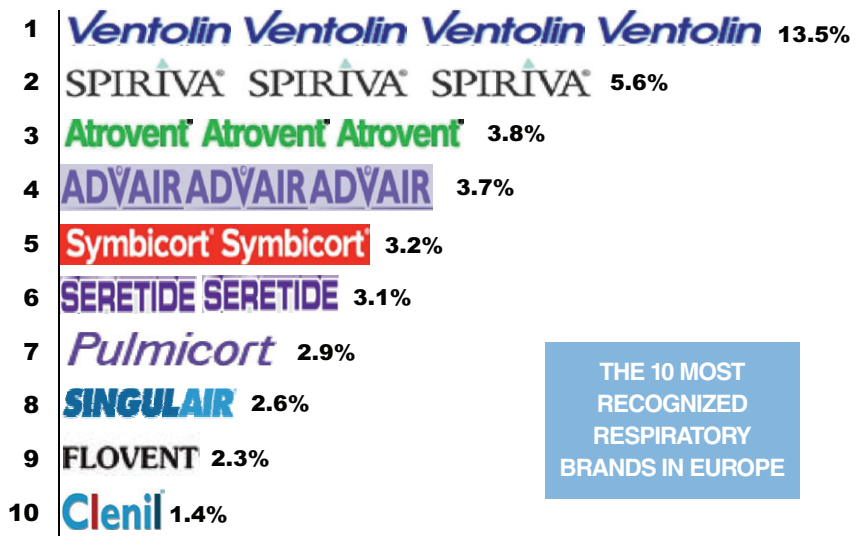
As for brands, the oral anticoagulant **Xarelto** was the top drug product being advertised in professional health journals through the second quarter of 2013 by both pages and dollars, according to Kantar Media. In the first half of the year 1,221 pages appeared in journals with advertising for Xarelto, costing about $9 million, an increase of 32 percent from this period last year. Xarelto, marketed by **Bayer**, was the second-ranked product by dollars last year at this time. Three products finished tied for second in dollars: **Linzess** Capsules, an experimental drug for irritable bowel syndrome being developed by **Ironwood** Pharmaceuticals; **Tudorza Pressair** Inhalation powder, a chronic obstructive pulmonary disease brand approved by FDA in July 2012 and marketed by Forest; and **Invokana**, a first-in-class treatment for type 2 diabetes approved by FDA in March and marketed by Janssen. Each of these brands spent about $5 million on journal ads in the first half of 2013. Placing fifth with $3 million in spend, an increase of 51 percent, was the prostate cancer drug **Zytiga**, marketed by Centocor Ortho Biotech. The Forest antidepressant **Viibryd**, which took the top spot for the first half a year ago, fell all the way to 15th this year with an 81 percent decrease year-over-year.

MOST-RECOGNIZED BRANDS

RESPIRATORY



THE 10 MOST RECOGNIZED RESPIRATORY BRANDS IN NORTH AMERICA



THE 10 MOST RECOGNIZED RESPIRATORY BRANDS IN EUROPE

The most-recognized respiratory brand in North America is **Advair**. The brand was most recognized by 13.7 percent of physicians in a survey conducted by **Brand Institute** Inc. in first-quarter 2013. Advair, comprising fluticasone propionate and salmeterol xinafoate, is marketed by **GlaxoSmithKline** (gsk.com). Since its initial approval by FDA in 2000, Advair's various formulations have earned indications for long-term, twice-daily, maintenance treatment of asthma in patients 12 years old or older and for the maintenance treatment of airflow obstruction and reducing exacerbations in patients with chronic obstructive pulmonary disease, including chronic bronchitis and emphysema.

Spiriva is the second most-recognized respiratory brand in North America. About 7 percent of physicians recognize this brand the most. Spiriva, comprising tiotropium, is marketed by **Boehringer Ingelheim** (boehringer-ingelheim.com) and **Pfizer** Inc. (pfizer.com). The product was first approved by FDA in January 2004 for the long-term once-daily maintenance treatment of bronchospasm associated with chronic obstructive pulmonary disease, and for reducing COPD exacerbations.

The third most-recognized respiratory brand in North America is **Ventolin**. About 5 percent of physicians recognize this brand the most. Ventolin is GlaxoSmithKline's brand name for albuterol, which was first marketed by Allen and Hanburys (now part of GlaxoSmithKline) in 1968 and is sold by several companies under a number of brand names for the relief of bronchospasm in asthma and chronic obstructive pulmonary disease.

The most-recognized respiratory brand in Europe is Ventolin. About 13.5 percent of physicians recognize this brand the most.

Spiriva is the second most-recognized respiratory brand in Europe. About 5.6 percent of physicians recognize this brand the most.

The third most-recognized pain and inflammation brand in Europe is **Atrovent**. About 3.8 percent of physicians recognize this brand the most. Atrovent, comprising ipratropium, is marketed by Boehringer Ingelheim. The product in its various formulations is indicated as a bronchodilator for maintenance treatment of bronchospasm associated with chronic obstructive pulmonary disease, including chronic bronchitis and emphysema; and for symptomatic relief of rhinorrhea associated with the common cold and allergic and nonallergic rhinitis.

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 respiratory. Brandpoll is the company's marketing tool and is designed to help clients monitor the competitive marketplace and identify the potential strengths and weaknesses of their brands.

A Pfizer whistleblower, Lipitor marketing, and free speech rights

By Ed Silverman

Will free speech rights factor into a long-running dispute between **Pfizer** and a former executive over guidelines used to market its **Lipitor** cholesterol pill?

The issue is being raised by Jesse Polansky, who filed a whistleblower lawsuit accusing the drugmaker of illegally scheming to boost Lipitor sales by misrepresenting product labeling and federal cholesterol guidelines. He also charged Pfizer paid kickbacks that resulted in off-label marketing that allegedly defrauded Medicaid and Medicare. A federal judge dismissed his case last fall and he is now appealing.

In his legal brief, the former director of outcomes management cites a controversial court ruling last winter about off-label marketing and the First Amendment rights that allow drugmakers to promote their products, so long as they do not make false or misleading statements. The ruling questioned a fundamental premise long asserted by FDA that off-label promotion is prohibited by law.

In that case, a panel of the U.S. Court of Appeals for the Second Circuit overturned the conviction of Alfred Caronia, a former sales rep for **Jazz** Pharmaceutical, who allegedly encouraged doctors to prescribe a drug on an off-label basis. He argued that the government is not permitted to criminalize truthful promotion and the court ruled that his conviction violated his First Amendment rights.

Polansky points to this ruling to underscore the contention that Pfizer improperly promoted Liptor. He charged that Pfizer wanted to extend Lipitor use beyond the indication found on the labeling by targeting people at moderate risk of developing heart disease or having a heart attack. Specifically, he claims the drugmaker used false and misleading statements by allegedly disregarding distinctions in the National Cholesterol Education Program guidelines.

The NCEP guidelines approved drug therapy for about 36.5 million Americans, although the largest subset of the population was "moderate risk" patients, those with two or more risk factors and less than 10 percent risk of heart attack. At the time he filed his lawsuit, there were an estimated 14.6 million people who needed only therapeutic lifestyle changes, while drugs were recommended for only 2.8 million people.

By off-label marketing to the rest of the population, he charged, Pfizer recognized an opportunity to increase revenues by billions of dollars, his lawsuit stated. And Polanksy reiterates this point as part of a broader argument that payment claims submitted to federal healthcare programs, such as Medicare and Medicaid, are considered false, or fraudulent, if a drug was promoted on an off-label basis.

There is an interesting wrinkle, though. To what extent, if any, the issue is considered by the court remains to be seen. But Polansky, who claims he was fired for objecting to the Lipitor marketing, has appealed to the same court that ruled in favor of Caronia, suggesting his appeal may generate more than a passing interest in any discussion about off-label promotion and false and misleading statements.

For its part, Pfizer did not raise the Caronia case – and the notion that truthful off-label promotion can be considered protected speech – as part of its defense. A source familiar with the Polansky case explained, however, that the free speech issue was not among the key points cited by the lower court judge in ruling against Polansky and, therefore, there was no reason to raise a new issue.

As reported previously on Pharmalot, U.S. District Court Judge Brian Cogan maintained that the NCEP guidelines are nothing more than guidelines. In his view, there was nothing that mandated Pfizer to market Lipitor only for people whose cholesterol levels fell within the ranges stated by the NCEP and FDA had every opportunity to require such language in the labeling. He also ruled that Polansky had not sufficiently demonstrated evidence that Pfizer caused false claims to be submitted to federal healthcare programs.

Opportunity in antibiotics

Rising demand for antibiotics to counter increasing cases of drug-resistant infections, combined with decreasing research and development costs, is presenting an ideal opportunity for pharmaceutical manufacturers to launch novel products into the marketplace, according to a new report from the research and consulting company GlobalData.

The company's latest report, "PharmaFocus: Market Access Strategies for Antibiotics Targeting Multidrug-Resistant Gram-Negative Bacteria," concludes that over the coming years, the growing level of threat posed by multidrug-resistant bacteria, particularly Gram-negative organisms, will be a key driver behind the growth of the antibiotics market in the United States, France, Italy, Germany, Spain, and the UK.

A stagnant antibiotic pipeline has escalated medical concerns caused by MDR bacteria in these countries, and a significant unmet need exists for novel antibiotics to counter the problem.

However, low returns on investment, primarily caused by expensive R&D processes and convoluted regulatory requirements, have been deterring drug manufacturers from developing new products, according to the report.

"Many large pharmaceutical companies have previously abandoned antibiotics due to the drugs' risky and prolonged R&D processes," says Christopher Pace, Ph.D., GlobalData's analyst covering infectious disease. "However, we can now expect to see upcoming regulatory reform on clinical trial design, led by guidance from the Food and Drug Administration and the European Medicines Agency, which will facilitate more efficient clinical development programs and reduce a number of barriers to market entry."

As a result, regulators, pharmaceutical companies and physicians are now working more closely than ever to remove a number of obstacles for keen developers.

"Future financial backing from governments will also play a key role in all stages of the R&D process, helping to decrease the cost of antibiotic development and therefore better enabling more companies to launch new products that address the current unmet clinical need," says Brad Tebbets, Ph.D., GlobalData's infectious disease analyst. "More specifically, public-private partnerships, represent an alternative business model that effectively aligns clinical and commercial needs."

Interactive&DigitalMarketing

Med Ad News staff

Crowdsourcing in life sciences: On the cusp of major change

By Dan Goldsmith

Crowdsourcing – the generation of data or insights through the contribution of many individual sources, often online – has been revolutionary for consumers, and is beginning to transform business. The advent of social media enables this powerful new way to collaboratively build information sets and harness the power of collective insights across multiple domains in the cloud (i.e., Wikipedia). Despite the industry's cautious approach so far, crowdsourcing holds great promise for the life sciences industry for consumer engagement, conducting research, database management, and even developing products. This is especially true as bodies of collective knowledge become pervasive resources for patients, sometimes even replacing physician recommendations signifying today's dramatic shift in influence.

Today, with the proliferation of information, most health consumers are better informed than in previous times. Crowdsourcing not only facilitates this change but makes it easy. Consequently, influence is shifting away from physicians to the networked masses sharing their collective knowledge online. Pharmaceutical companies have been creating forums that bring together patients for discussion, but this is just the tip of the iceberg. Companies that find ways to capitalize on the information gained from the masses in online communities will have a competitive advantage. Enter crowdsourcing – today's most efficient way to reach bright minds on a global scale.

The primary concern for pharmaceutical companies considering crowdsourcing is that this is a legislative minefield. How do you control such a public forum that, by definition, becomes more influential the wider the net? But new technologies may offer ways to limit the risk. Advanced cloud technology is creating new avenues to bring together crowdsourced data in a responsible, validated way by enabling semi-private crowds to collaborate in controlled domains. For example, multiple companies in the life sciences industry can use crowdsourcing or even different teams or geographic regions within a single company.

Early success can be seen in research environments where there's an enormous benefit to short-cutting some of the basic molecular research through collaboration. Lilly Ventures, for example, manages an open marketplace for transacting molecules. Also, Kaggle, with its cloud-based platform that connects companies to a community of more than 95,000 data scientists from more than 100 countries and 200 universities, provides a potential new model for molecular development using crowdsourcing. Last year, Boehringer Ingelheim partnered with Kaggle to use the knowledge from its online scientific community to help its scientists predict biological molecular response.

In another promising pharmaceutical research example, the NIH's National Center for Advancing Translational Sciences created the Therapeutics Discovery pilot program this past March to bring life sciences companies together to reduce inefficiencies and drive innovation by re-engineering the research pipeline. By crowdsourcing compounds that have already cleared several key steps in the development process, including safety testing in humans, scientists nationwide can contribute their expertise to advancing these resources for new disease therapies. Abbott, Bristol-Myers Squibb, GlaxoSmithKline, Janssen Pharmaceutical Research & Development, Sanofi, Pfizer, AstraZeneca, and Eli Lilly and Co. have joined the program.

"If a compound made available through the New Therapeutic Uses pilot program had five or more applications, we saw three or more different ideas for new indications," says Dr. Christine Colvis, director of the NIH program. "Though we will not know the veracity of these predicted indications for another year or two, these early results suggest that crowdsourcing will be an effective complement to other means of identifying new indications for pharmaceutical compounds."

Life sciences crowdsourcing is also making waves in the area of market research with help from cloud-based technologies. In 2010, InCrowd – a tech start-up headquartered in Boston – launched an on-demand platform that enables pharmaceutical companies to survey a growing database of pre-screened healthcare professionals across all therapeutic areas. Companies can conduct specialized micro-surveys that target specific segments of the database in real-time, with results delivered in days or even minutes via mobile device. The idea has taken off; InCrowd's customers include more than 50 life sciences companies ranging from small biotechs to global pharmaceutical organizations.

"Crowdsourcing for market research is interesting by itself, but the real value added here is in being able to integrate the primary data garnered from highly targeted groups with how business decisions get made on a daily basis," says Janet Kosloff, CEO and co-founder of InCrowd. "We use crowdsourcing techniques to provide life sciences companies with real-time actionable insights about their target markets rather than having to wait for a report from a lengthy market research project."

The commercial space is the last frontier to adopt crowdsourcing methods in the industry, due to HIPAA and privacy concerns. "Privacy concerns and fear of an uncontrolled forum are both perceived roadblocks to crowdsourcing that can be overcome with the right combination of technology and services," says Eric Newmark, program director, Business Systems Strategies for IDC Health Insights. "Multitenant cloud applications offer the potential to address these challenges and harness the 'network effect' of life sciences companies electing to work together."

Fortunately, the technology is here. Each day, field teams are capturing the most current information available on healthcare practitioners and organizations within their customer relationship management systems. By using this continuous, real-time data stream to create a shared network accessible in the cloud, life sciences companies have the opportunity to create a single customer master reference data set that's always more current, more accurate, and more complete than a static customer master database any one company can stitch together on its own. A multitenant technology platform enables the sharing of resources, and the cloud allows for continuous input to the data with easy access worldwide. The result is a "network effect," or the crowdsourcing of commercial life sciences without the risks of uncontrolled social media feedback.

"Crowdsourcing is an incredibly useful approach to anything that isn't your 'secret sauce' like physician names and addresses," says Ian Elverson, manager of IT for Accera Pharmaceuticals. "Why should every pharmaceutical company on the planet expend massive energy just to compile basically the same exact list of doctors? As the guy responsible for keeping that database clean, I would value any shared, crowdsourced physician data so I could alternatively spend more of my time making the database more useful to our team in other ways."

But the success of a crowdsourced database would hinge on the controls in place. "A totally freeform framework wouldn't work simply because the data might be suspect," Elverson says. "This was the initial problem with Wikipedia, but now Wikipedia has clear controls and more structure so companies have faith in the information published on the site. It's all about building trust in the integrity of the data – with that, a network of basic physician data could alleviate many time-consuming, expensive data problems for pharmaceutical companies of all sizes."

The life sciences industry has historically been slow to move on many of the great advances in the consumer world. Many organizations are recognizing that they can't afford to be laggards anymore. The network effect brings together valuable, crowdsourced information in a responsible, validated way to meet the best interests of all pharmaceutical enterprises.

"If crowdsourcing techniques can help life sciences companies like ours better understand customers so that we can start to see trends on how patient care is evolving amidst changing government directives, then what are we waiting for?" asks Tom Helmstetter, director of information technology for Janssen. "This collective knowledge might show us how to adapt our business model to handle future challenges and help improve patient care – and that's what is most important."

Dan Goldsmith is general manager of the Veeva Network for Veeva Systems.

FACTS & FIGURES

Almost half of the physicians surveyed in the Kantar Media Sources & Interactions Study, March 2013 – Medical/Surgical Edition say they have participated in a pharmaceutical manufacturer e-detail presentation, and trending data indicates that more physicians are participating in e-detailing. In 2009, less than **one in four** doctors admitted to participating in an e-detailing presentation. According to this year's study, the figure has more than doubled.

"While the percentage of doctors who have participated in e-detailing has shown an increase since 2011, the majority (**53 percent**) of doctors still haven't ever participated in a pharmaceutical manufacturer e-detail presentation," says Kantar Media's Healthcare Research Team. "Further, only **27 percent** of those that have ever participated in e-detailing did so within the past six months."

Of the 47 percent of doctors that have participated in an e-detailing presentation, **8 percent** participated within the past month, **13 percent** participated one to three months ago, **6 percent** participated four to six months ago, and **21 percent** participated more than six months ago.

Among the physicians who have participated in e-detailing before, **78 percent** reported that they would participate again. Regarding the physicians who have never participated in an e-detail presentation, **42 percent** reported that they would consider participating in the future. Physicians spend an average of **10.3 minutes** during an e-detail presentation, with **one quarter** averaging less than **five minutes** per presentation.

During the past two years, social media use in healthcare has increased **21 percent**, according to Kantar Media's 2013 Online Behavior Study. The most significant jump was in health video, but health blogs also experienced substantial growth.

"A driver for this increase in social media is the increase in mobile devices ownership," the report says. "Between 2012 and 2013, the portion of adults owning a smartphone or tablet increased from **42 percent** to **55 percent**. **Two thirds** of smartphone or tablet owners report that social networking is a reason they access the Internet."

According to Kantar Media's Healthcare Research Team, consumers who go online to research certain health conditions and use social media may be looking for different types of information based on the stage of the condition. "Those recently diagnosed are more likely to visit or post comments to online message boards or forums," the researchers told *Med Ad News*. "Those experiencing symptoms or preparing for their first medical appointment are more likely to read blogs about a particular health topic or participate in online support groups. Those recovering, undergoing treatment, or have an ongoing condition are more likely to visit or join health support groups."

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AdAgencyUpdate

By Joshua Slatko joshua.slatko@ubm.com

GSW report explores healthcare sales trends

Outcomes-based reimbursement and high no-see rates are among 11 healthcare trends that are changing the world of pharma sales, according to new research sponsored by GSW. The new report was lauched by GSW's Health Experience Project, also known as HxP. To develop the report, Leigh Householder, who edits HxP and is also a member of GSW's innovation strategy team, got together with a team to answer the question, "If we really got close to the trends changing the salesforce, what new experiences and new best practices could we uncover?"

The team worked with colleagues from around the world to address the trends that are leading to change within the realm of pharma sales. These trends include physicians becoming less central to healthcare to a new global center of opportunity in Asia-Pac to evolving multi-media expectations from doctors.

"The challenge in Asia-Pac is the deep discounts that some governments are requiring of pharma innovators who sell in the region," Householder told *Med Ad News*. "In China, for example, the government imposes a 90 percent discount on some products through a tendering process. According to Yahoo! Finance's industry summary, the largest average profit margin for major drug manufacturers is at 18.4 percent. This group includes Pfizer, AstraZeneca and Bristol-Myers Squibb. For the 'other drug manufacturers' category, which includes Teva Pharmaceutical Industries and Allergan, the average margin drops to 12.2 percent. Although the margin required will vary by company, few or none could reasonably make it work in the long term in an environment of such deep discounting. Marketers around the world are testing remote marketing solutions that pair doctors with dedicated reps and key opinion leaders through texting, video conferencing, and online events. As these tools mature, they may become the go-to in price sensitive markets like those in Asia-Pac."

According to the report, the next three years are considered the perfect payer storm. "The biggest U.S. trend that is factored into that perfect storm payer story is the big shift to outcomes-based reimbursement, which has its roots in the Affordable Care Act," Householder says. "Pharma companies can do two things immediately to help navigate the new landscape: Create greater transparency so that there's never a surprise at the pharmacy and demonstrate why these products are worth fighting for by helping doctors share data across diverse care teams, use predictive modeling to figure out which patients are at higher risk for adherence or tolerance challenges, and generally get smarter about how the specific Rx impacts personal outcomes."

Pharma sales are vulnerable to big innovation from outsiders, but that is not necessarily something to curtail, Householder told *Med Ad News*. "For a whole range of good and bad reasons, healthcare in general – and pharma in particular – have made incredible, life-changing strides in our labs (for our products), but innovated only incrementally in the experience around them," she says. "It's possible that innovation from outsiders will challenge us in ways that help us all achieve more – for both the people we serve and the brands we represent. I say, don't fight it, learn from it."

High no-see rates have made reps cautious about protecting the access that they have; however, this course of action limits how aggressively they pitch existing contacts and how often they knock on new doors, according to the report. To tackle this, reps can "change who's knocking through a return to more expert (veteran HCP) sales teams and new kinds of KOL initiatives that leverage our medical teams to start new conversations," Householder says. "Group learning opportunities seem to make an impact, too, in Europe particularly."

To prepare for selling within this new paradigm, reps need to become experts. "Be the person the doctor looks forward to talking to because you know so much about the trends and context changing the industry, about the debates that divide physicians, and ultimately about the examples and stories that make the case in a much more personal way," Householder told *Med Ad News*.

In some cases, doctors have literally taken iPads away from reps during detailing. "Initially it was reps in our Rep Lab who told us that doctors would literally take the iPad out of their hands to look more closely at a topic that intrigued them," Householder says. "The latest Manhattan numbers confirmed the trend – a full 50 percent of doctor's report holding the iPad at some point during the call."

In addition, reps will need to foster into real world behavior by not only asking physicians to write prescriptions, but helping ensure that it is filled. "Reps can help by creating transparency to real-world behavior," Householder told *Med Ad News*. "Remember, many of our doctors still believe that patients do what they say. If we can show them the percent of their patients who aren't even making it to that initial fill, we can also credibly offer them programs, tools, and advice on how to improve that conversion they prescribed."

As reps learn to adapt to new physician preferences and implement flexible communication, this means that they will need to think about communication in three ways, according to Householder. "How could it be delivered in person – by a rep, by a peer, by a patient?" she says. "How could someone use it to learn on their own – by reading, watching or trying? How could it be used in the practice – with a care team, at the point of care, in their daily workflow?"

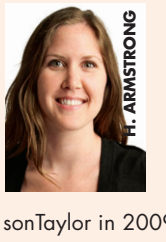
The report mentions that sales and marketing need to reconnect, but this is not exactly the same as a lack of understanding the difference between the two. "A bigger challenge could be that we haven't learned enough from the broader world of B2B marketing," Householder says. "We're lobbing tools to reps and they're pitching data back, but we're not making it all work together to create something bigger and more powerful. These tactics are table stakes for people selling hard drives, but we don't put them to work to sell life-changing medication. Why?"

Reps will need to consider every healthcare professional within the mix. "We've definitely seen that non-physician prescribers aren't always following the lead of the physicians in the practice – they're writing their own way," Householder told *Med Ad News*. "So, detailing them could actually create an opportunity for connection. Reps learn what's working for non-physician prescribers and can share that knowledge with non-physician prescribers outside the practice or other healthcare providers within, bridging critical gaps and connections and conversations. If sales teams aren't already detailing non-physician prescribers, they're missing out an important pre-

AGENCY PEOPLE ON THE MOVE

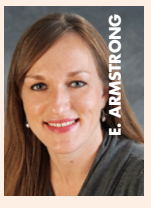
AbelsonTaylor

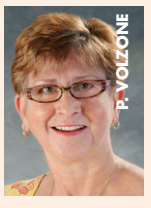
Noah Lowenthal is promoted to VP, group creative director, AbelsonTaylor (abelsontaylor.com). Mr. Lowenthal, a 13-year veteran of the agency, was creative director. **Hillary Armstrong** is promoted to senior account supervisor. Ms. Armstrong was a senior account manager; she joined the agency in 2011 after working at Discovery Chicago. **Craig Taylor** is promoted to senior account executive. Mr. Taylor was an account executive; he joined AbelsonTaylor in 2009.



Fingerpaint

Jessica Lafave joins Fingerpaint's (fingerpaintmarketing.com) account service team. Ms. Lafave was a marketing specialist at HCPRO Health Leaders Media. **Erin Armstrong** also joins the account service team. Ms. Armstrong was a sales representative for Lilly USA's Cardiovascular Health Specialty Division. **Pam Volzone** joins the medical strategy team. Ms. Volzone has more than 30 years of experience in medical communications, pharmaceutical/medical sales, and health education at companies including AXIOM Professional Health Learning, Evolution Medical Communications, and Excerpta Medica. **Alexandra Roth** joins Fingerpaint's operations team. Ms. Roth was fundraising coordinator for the Muscular Dystrophy Association's Albany office. **Danielle Saladino-Evans** joins the corporate communications team. Ms. Saladino-Evans was account manager and social media strategist for Baker Public Relations.





Natrel Communications

Rick Kelly is named VP, account group supervisor, Natrel Communications (natrelusa.com). Mr. Kelly was VP and account management supervisor in payer marketing at Ogilvy CommonHealth Worldwide. **Howard Kanter** becomes account group supervisor. Mr. Kanter is a 20-year industry veteran with experience as an account director at agencies including ICC and BIG Communications. **Kristen Seraphine** is named account executive. Ms. Seraphine joins Natrel from Fougera Pharmaceuticals, where she was a business development associate.

Marie Fitzsimmons is promoted from assistant account executive to account executive. Ms. Fitzsimmons, a three-year employee of the agency, joined Natrel after graduating from Marywood University with a degree in advertising/public relations. **Cassandra Hartline** is promoted from traffic coordinator to assistant account executive. Prior to joining Natrel in 2012, Ms. Hartline was an account coordinator for The Macaluso Group Inc. **Emil Vernarec** becomes senior copywriter. Mr. Vernarec was articles editor at RN Magazine and copy supervisor at Torre Lazur Healthcare Group. **Heather Maher** becomes copywriter. Ms. Maher joins the agency from Beacon Healthcare Communications. **John Duff** is named group art supervisor. Mr. Duff was VP, group art supervisor at Harrison and Star and Bozell Global Healthcare. **Laura Klein** becomes senior editor. Ms. Klein previously worked at Strategic Healthcare Alliance and Advogent. **Joann Busciglio** is named traffic coordinator. Ms. Busciglio was a selling supervisor for PPR/Gucci America at Saks Fifth Avenue. **Ron Harris** becomes traffic manager. Mr. Harris was a project manager for The Access Group. **Rose Dattler** is promoted from receptionist to assistant traffic coordinator. Ms. Dattler joined Natrel in 2012 from The Heritage Guild, where she managed consumer social media programs. **Courtney Bailey** becomes receptionist. Ms. Bailey recently graduated from Temple University with a bachelor's degree in advertising.

scriber population plus this ability to create connection."

As the shift to more outcomes-driven reimbursement changes the type of data that doctors seek, there is no guarantee that the skills to use it or challenge it will be present, according to the report. One way in which reps can navigate new data is finding a new kind of key opinion leader who is becoming empowered and driven by numbers that are relevant to small groups of peers, in addition to being connected across digital networks. "In the case of real world data, the No. 1 advantage is uncovering a second tier of key opinion leaders who are likely making digital connections, such as Doximity, with other people in practices very similar to theirs," Householder says. "You can understand what data or population characteristics influenced their decisions and know who their influencing – potentially helping elevate their voice, the way we do with traditional key opinion leaders."

Siren leaders tops in orphan drugs social media influence

A list of the top 50 social media influencers in orphan drugs and rare disease, recently released by the World Orphan Drug Congress, recognized two Siren Interactive team members for their social media activity, engagement, and reach within the rare disease community.

Wendy White, founder and president of Siren Interactive, tweets on clinical trials, patient advocacy issues, legislation, and orphan drug approvals. **Frieda Hernandez**, VP of strategic initiatives for Siren, tweets on social media in pharma, the e-patient, and issues in the rare disease community.

The fact that two of the top 50 social media influencers are affiliated with Siren Interactive "goes to show how clued in they are on the value of social media in the rare disease space," says Caroline Hornby, marketing director for the World Orphan Drug Congress USA.

The list of social media influencers was developed in response to the high level of activity on Twitter Facebook, LinkedIn and other online communities surrounding the 2013 World Orphan Drug Congress USA. "Patients who suffer with rare diseases can often feel isolated and alone in their path to finding diagnosis, treatment, and hopefully a cure," Hornby says. "What better way to find other patients to empathize and share experiences with than through social media?"

Siren Interactive is a digital relationship marketing agency focused exclusively on addressing the challenges and unmet needs of patients, caregivers and physicians dealing with chronic rare disorders.

PeopleontheMove

By Joshua Slatko joshua.slatko@ubm.com

Novo names new North America leader


J. HØILAND

Novo Nordisk has announced that **Jesper Høiland** has been appointed president of Novo Nordisk Inc., the company's North American affiliate. The appointment became effective August 1, 2013. Mr. Høiland was previously Novo Nordisk's head of International Operations, where he oversaw all of the company's operations outside Europe, China, Japan, Korea, and North America. He replaces **Jerzy Gruhn**, who served in the role since 2008. Mr. Gruhn has been appointed to lead the company's European business. In the first six months of 2013, the North American region accounted for 46 percent of total Novo Nordisk reported sales.

Mr. Høiland joined Novo Nordisk in 1987 as assistant area manager in Denmark. He moved to marketing positions in Canada, Belgium, and France before being promoted to general manager of Novo Nordisk Australia in 1998. In 2000, he was promoted to senior VP of international marketing, and in 2004, senior VP of international operations. Under his leadership, the company's international operations region has grown its business and organization significantly, leading to the successful spinoff of China as a new, separate region in 2011, among many other achievements.

"This position is a great opportunity to lead an organization that is both driving the growth of our business and helping solve one of the most pressing health challenges facing the United States," Mr. Høiland says. "Novo Nordisk must play a vital role in addressing America's diabetes crisis not only through the treatments we develop, but also by engaging with patients, caregivers, physicians, policy makers and communities to help prevent diabetes and improve treatment across the board."

The changes in leadership have been triggered by the retirement of some of the company's most experienced and successful leaders, including **Martin Soeters**, former head of the Europe region. Successors were identified through Novo Nordisk's succession management process, part of the company's annual organization review.

PHARMA

■ Dr. **Sripada Chandrasekhar** is appointed president and global head of human resources, Dr. Reddy's. Dr. Chandrasekhar was VP and head of human resources for the India/South Asia region, IBM. Dr. Reddy's (drreddys.com) is an integrated global pharmaceutical company, committed to providing affordable and innovative medicines for healthier lives.

■ Dr. **Michael Hall** is named senior VP of clinical development, Ironwood Pharmaceuticals. Dr. Hall was chief medical officer and senior VP at Repligen Corp. Ironwood (ironwoodpharma.com) is committed to the art and science of making medicines, from discovery through commercialization.

BIOPHARMA

■ **Daniel J. O'Connor** is promoted to president and CEO, Advaxis Inc. Mr. O'Connor was executive VP. Dr. **James Patton** is elected non-executive chairman of the board. Dr. Patton is a founding member of the Advaxis board and VP of Millennium Oncology Management Inc. The two will replace **Thomas A. Moore**, formerly chairman and CEO, who will continue to serve on the board and as a consultant to the company. Advaxis (advaxis.com) is a clinical stage biotechnology company developing the next generation of immunotherapies for cancer and infectious diseases.

■ **Peter Kiener, Ph.D.**, is appointed chief scientific officer, Ambrx. Dr. Kiener was a cofounder of Zyngenia. Ambrx (ambrx.com) is a clinical stage biopharmaceutical company using an expanded genetic code to create best-in-class biotherapeutics, including ADCs, bispecific antibodies and proteins with improved pharmacologic properties.

■ **Douglas W. Losordo**, M.D., is named chief medical officer, NeoStem Inc. Dr. Losordo was VP, new therapies development, regenerative medicine, and Baxter Ventures at Baxter International. **Andrew L. Pecora**, M.D., the company's outgoing chief medical officer, will assume the role of chief visionary officer. **Robert Dickey IV** becomes chief financial officer. Mr. Dickey joins the company from Hemispherx Biopharma Inc., where he was senior VP. **Larry May**, NeoStem's former chief financial officer, is assuming the newly-created position of VP, strategic initiatives. NeoStem (neostem.com) develops novel proprietary cell therapy products.

■ **Gregory D. Perry** has resigned as executive VP and chief financial officer, ImmunoGen Inc. Mr. Perry joined the company in January 2009 and was promoted to executive VP in March 2011. **Daniel M. Junius**, ImmunoGen's president and CEO, will serve as acting chief financial officer while the company searches for Mr. Perry's permanent replacement. ImmunoGen (immunogen.com) is a biotechnology company that develops novel anticancer therapeutics using its proprietary antibody-drug conjugate technology.

■ **David Smith** is appointed CEO of the service division of Galapagos NV. Mr. Smith was director of finance at the Cambridge University Hospitals; he had previously been chief financial officer of Galapagos for two years. Galapagos (glpg.com) is a clinical stage biotech company focused on developing novel medicines.

■ **Lewis Barrett** is named senior VP, commercial strategy, Synthetic Biologics Inc. Mr. Barrett was assistant VP, established products at Pfizer. Synthetic Biologics (syntheticbiologics.com) is a biotechnology company focused on the development of biologics for the prevention and treatment of serious infectious diseases.

■ **Stephen Kennedy** becomes senior VP of manufacturing, operations, and supply chain, Histogenics Corp. Mr. Kennedy was executive VP of research and development at Mascoma Corp. **Vladimir Scerbin** is appointed VP of clinical affairs. Mr. Scerbin was VP of international clinical affairs at Covidien. Histogenics (histogenics.com) is a late-stage company developing novel tissue repair solutions initially targeting orthopedics using the latest advances in molecular biology, materials sciences, and tissue engineering.

SPECIALTY

■ **Jeffrey Jonas**, M.D., is appointed CEO of Sage Therapeutics. Dr. Jonas was president of regenerative medicine at Shire Plc. He succeeds **Kevin Starr**, who has served as interim CEO since the company's founding. **Stephen Kanes**, M.D., Ph.D., is named chief medical officer. Dr. Kanes was executive director/therapeutic area clinical director for the inflammation, neuroscience, and respiratory GMED division of AstraZeneca. **Kimi Iguchi** becomes chief financial officer. Ms. Iguchi was chief operating officer, North America, for Santhera Pharmaceuticals. Sage (sagerx.com) is a neuroscience-focused company developing therapeutics to treat CNS specialty and orphan diseases.

■ **Arthur Tzianabos**, Ph.D., becomes chief scientific officer, OvaScience. Dr. Tzianabos was senior VP and head, research and early development, Shire. OvaScience (ovascience.com) is a life sciences company focused on the discovery, development, and commercialization of new treatments for infertility.

■ Dr. **Andreas Menrad** is appointed chief scientific officer, Algeta ASA. Dr. Menrad was chief scientific officer at Ablynx NV. Dr. **Thomas Ramdahl** is promoted to chief operating officer, from executive VP. Algeta (algeta.com) is focused on the development of novel targeted cancer therapeutics.

■ **André C. Muller** is named chief financial officer, Actelion Ltd. Mr. Muller was chief financial officer, Pierre Fabre SA. He succeeds Andrew J. Oakley, who leaves to focus on outside opportunities. Actelion (actelion.com) is a biopharmaceutical company specializing in in innovative science related to the endothelium - the single layer of cells separating every blood vessel from the blood stream.

■ **Terrence Moore** becomes executive VP and chief commercial officer, Acadia Pharmaceuticals Inc. Mr. Moore was a principal of Cook-Moore-Consulting. Acadia (acadia-pharm.com) is a biopharmaceutical company focused on innovative treatments that address unmet medical needs in neurological and related central nervous system disorders.

■ **Jaye Viner**, M.D., is named chief medical officer and executive VP, Curis Inc. Dr. Viner was medical director at Millennium: The Takeda Oncology Company. She replaces **Maurizio Voi**, M.D., who has left the company to pursue other opportunities. **Tania Chander** becomes VP of product development. Ms. Chander was associate director, product development team lead at MedImmune LLC. Curis (curis.com) is an oncology-focused drug development company seeking to develop novel drug candidates for the treatment of human cancers.

■ **Jonathan Rubin, M.D.**, becomes chief medical officer, Alcobra Ltd. Dr. Rubin was medical director in global medical affairs, Shire Pharmaceuticals. Alcobra (alcobra-pharma.com) is an emerging biopharmaceutical company primarily focused on the development and commercialization of a proprietary drug, MG01CI, to treat ADHD.

■ **James D'Arecca** is named chief accounting officer, Actavis Inc. Mr. D'Arecca previously served in a similar role at Bausch & Lomb. Actavis (actavis.com) is a global, integrated specialty pharmaceutical company focused on developing, manufacturing and distributing generic, brand, and biosimilar products.

■ **Barry Labinger** is appointed executive VP and president, Biosciences Division, Emergent BioSolutions Inc. Mr. Labinger was executive VP and chief commercial officer at Human Genome Sciences Inc. Emergent BioSolutions (emergentbiosolutions.com) is a specialty pharmaceutical company seeking to protect and enhance life by offering specialized products to healthcare providers and governments to address medical needs and emerging health threats.

■ **Doug Plassche** becomes executive VP of operations, Elite Pharmaceuticals Inc. Mr. Plassche was managing director of the New Jersey Solid Oral Dose Operations at Actavis. Elite (elitepharma.com) develops oral sustained and controlled release products.

■ **Michael Dunn** is appointed senior VP, corporate development, CalciMedica. Mr. Dunn was senior VP, corporate development at Biocept Inc. CalciMedica (calcimedica.com) is dedicated to the discovery and development of novel drugs for the treatment of autoimmune and inflammatory diseases.

■ **Deborah DuFresne** is named VP, strategic portfolio selection and management, InnoPharma Inc. Ms. DuFresne was senior director, project management, product identification and development at Impax Laboratories. InnoPharma (innopharmainc.com) is a sterile product development company focused on developing complex generic and innovative specialty pharmaceutical products in injectable and ophthalmic dosage forms.

■ **Larry J. Singer** is appointed VP, manufacturing, Hyperion Therapeutics. Mr. Singer was president of NexGen Consulting Group LLC. Hyperion (hyperiontx.com) is a commercial stage biopharmaceutical company committed to developing and delivering life-changing treatments for orphan diseases and hepatology.

SERVICE SUPPLIERS

■ **Stephen R. Sun**, M.D., is named chief medical officer, ParagonRx. Dr. Sun was a medical officer at FDA. ParagonRx (paragonrx.com), an inVentiv Health company, is a provider of risk and benefit consulting services to the pharmaceutical and medical device industries.

■ **Chris Schneider** becomes senior VP, commercial strategy and forecasting, Ipsos Healthcare. Mr. Schneider led market research teams at another healthcare market research agency. Ipsos (ipsos.com) is an independent market research company controlled and managed by research professionals.

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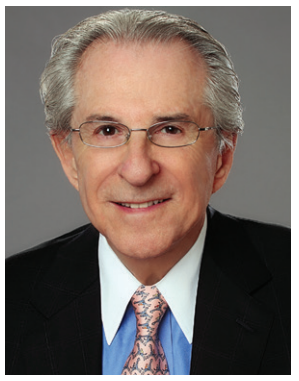
THELASTWORD

Forget the bathwater and save the baby

By Sander A. Flaum



I'M NOT THE KIND OF person who wishes ill on others; but when I read the latest bashing of pharma and the Orphan Drug Act, I'm tempted to wonder what tune the authors would sing if they were diagnosed with a rare disease. Consider a recent piece in the *New York Times* by Steven Rattner, "An Orphan Jackpot." Instead of marveling at the amazing job pharma has done in developing life-enhancing drugs for uncommon conditions, Mr. Rattner complains that the industry is making a profit.

You'd think that pharma was the only industry that has the gall to want to be paid for its products. And not just that – it even has the nerve to hire accountants to study the IRS codes and lower its taxes. It actually hires lobbyists!

Pharma detractors like Mr. Rattner not only dwell on what they hate about our industry, but they also suffer collective amnesia about the good. How else can you explain why they never mention that 20th and 21st century medicine has extended our collective lifespans by decades?

And why in heaven's name would anyone disparage the Orphan Drug Act, arguably one of the best pieces of pharmaceutical legislation ever enacted? Passed by Congress and signed by Ronald Reagan in 1983, the Orphan Drug Act has been copied around the world, with one nation after another passing its own version tailored to its individual needs and population. As you probably know, the impetus behind the ODA was not because pharma was "ignoring" rare diseases (as some suggest), but because Federal regulations and patent laws had made the development of drugs for uncommon conditions financially unfeasible.

Pharma opponents like Mr. Rattner point out that some orphan drugs generate large profits because the company has an exclusive right to the indication and can therefore charge whatever they wish. To this I'm tempted to say, so what? But even if you agree, this "problem" is easily addressed.

For example, some countries have enacted a provision that if an orphan drug earns a defined level of profits after a certain number of years, the exclusivity period or financial incentives are adjusted. No big deal. In fact, the U.S. Congress passed such an amendment to the Orphan Drug Act a few years ago; but President George W. Bush cast a veto. Was he right or wrong? I'm sure there were merits on both sides of the case, but the important fact is that whatever glitches you can identify in the Orphan Drug Act, they are fixable and zilch compared with the overall value it adds to society.

Perhaps the bashers' most shameful tactic is how they belittle the drugs themselves. For example, Mr. Rattner mentions Xyrem, which he calls a "good drug," but then delivers a backhand slap, noting that it "doesn't cure any deadly disease or even directly prolong life." No, Xyrem only treats narcolepsy – which merely compromises a patient's ability to drive a car, hold a job, or function in society. No big deal!

And for that, Mr. Rattner complains, the manufacturer, Jazz Pharmaceuticals, charges a whopping $65,000 a year! Who can afford that? Think of all those people who are deprived of the drug! But as Mr. Rattner eventually admits: "Nearly every patient gets the drug pretty cheaply – Jazz subsidizes co-payments above $35 per month – so few users care what Jazz charges."

What's that? Well, if the patients aren't upset, the insurance companies must be up in arms. But it turns out, they aren't either. The cost of orphan drugs may seem exorbitant to the indignant press, but to most payers, they're manageable because of the small sizes of the patient population (not to mention the benefit they deliver.)

So who's really angry about Xyrem? Mr. Rattner.

But forget about Xyrem – many of the orphan drugs in the "orphan jackpot" actually do prolong life. Do you know anyone with MS? Or leukemia? How about multiple myeloma? You've certainly heard the names. Geraldine Ferraro courageously fought multiple myeloma for years with the aid of orphan drugs like thalidomide. Montel Williams and others with MS have used injectable orphan drugs like Avonex, Rebif, and Tysabri to slow disease progress and control symptoms. And now a new generation of oral MS drugs may bring even more hope.

These drugs would never have been possible without the Orphan Drug Act. Mindless criticism of this legislation is not only unfair but reckless. Despite popular belief, legislators do read the papers. In the last few years, complaints about government waste led to the gutting of the NIH and a massive shutdown in scientific research. Tomorrow, orphan drug development could face the same fate. I wish that Mr. Rattner and his colleagues would take a few moments to realize that someday they, or a loved one, may be facing a rare disease – and that it may be their turn to pray that pharma can come through with a treatment in time. So, please just dial down the dialogue a bit. Let's save the baby.

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