Taren Grom

# Time for **A CHANGE**

*Disruptive innovation, a term coined by Clayton Christensen, describes a process by which a product or service takes root initially in simple applications at the bottom of a market and then relentlessly moves up market, eventually displacing established competitors.*

Disruptive innovation typically happens in industries that are broken (too expensive or inefficient), when assets and technologies (many of which are already in existence) combine in new configurations to deliver value more efficiently. And according to EY, all of these conditions exist in today's healthcare industry. The system is broken, with the cost of healthcare rapidly becoming unsustainable across major markets. The focus on outcomes is providing the catalyst for disruptive innovation and giving nontraditional players an opening.

According to PwC, major scientific and technological advances, coupled with sociodemographic changes, increasing demand for medicines and trade liberalization, will revive pharma's fortunes in another 10 years and deliver dramatic improvements in patient care. But pharma companies will need to make some tough decision now if they want to be viable in 2020.

PwC says the industry faces three fundamental challenges:

» **Cultural sclerosis.** The prevailing management culture, mental models, and strategies on which the industry relies are the same ones it's traditionally relied on, even though they've been eclipsed by new ways of doing business.

» **Poor scientific productivity.** Pharma's output has flatlined for the past decade. Yet the process it uses to discover and develop new products remain much the same, so there's little reason to think its productivity will suddenly soar.

» **Rising customer expectations.** The commercial environment is getting harsher, as healthcare payers impose new cost constraints on healthcare providers and scrutinize the value medicines offer much more carefully. They want new therapies that are clinically and economically better than the existing alternatives, together with hard, real-world outcomes data to back any claims about a medicine's superiority.

Melonie Warfel, business line leader, life sciences, at Pegasystems, says disruptive innovation should provide process and efficiency improvements within a life-sciences organization.

"Many pharmaceutical companies are starting to divest their core businesses and increase their focus around leveraging outside expertise and engaging with new partners," she says. "This is causing disruption in the industry as new outsourcing players enter the market and begin collaborating."

Carolyn Buck Luce, co-founder and managing partner Imaginal Labs, says companies that really want to innovate need to be connected to the patient, the payer, the scientific community, as well as nontraditional players, and this requires a lot of outside-in thinking and learning.

"But this is not the way companies are set up now," she says. "They are very siloed and nervous about sharing information."

Within this special issue we will look at what's needed to drive innovation from the boardroom to the clinic to the market and beyond.

One resounding theme is clear: innovation — disruptive or not — needs to focus on the patient — be it better outcomes, access, or adherence. The patient experience — from molecule to the market — will be the driving force for years to come.

**DR. DEBORAH DUNSIRE** ▪ *Millennium: The Takeda Oncology Company*

***"Innovation, to be truly meaningful, has to change outcomes for patients because we're looking to deliver better health not just new classes of therapy."***

## FAST FACT

IN THE U.S. ALONE, ALMOST $210 BILLION A YEAR IS WASTED ON OVERUSE OR MISUSE OF MEDICINES AND PROCEDURES. CARE FOR CONDITIONS THAT COULD BE CORRECTED THROUGH LIFESTYLE CHANGES COSTS ANOTHER $303 BILLION TO $493 BILLION A YEAR.

Source: PwC

## Change Starts at the Top

Disruption across the board is clearly needed if pharma is to be successful, and innovation starts with corporate leadership.

PwC analysts accurately point out that the values, beliefs, habits, and management style that determine how people in an organization think and behave have a profound bearing on its decision-making processes. Yet, most pharma companies still rely on a corporate culture that prevailed 20 years ago.

CAROLYN BUCK LUCE ▪ *Imaginal Labs*

***"Ten years from now I don't think this industry is going to be called the pharmaceutical research and manufacturing industry, which is clearly focused on the product."***

Some say the homogenized corporate culture of pharma is slowly changing as the need for diversity of thought and leadership necessary for innovation becomes more pervasive, yet according to PwC only 10.5% of the 3,933 pharma and biotech directors in the BoardEx global leadership database are women. Similarly, only 10.2% of the 1,500 who disclose their nationality come from countries outside of North America and Europe.

In addition, today's C-Suite faces increasing turnover, which in turn impacts strategy and process.

PwC statistics find that in 2000, the average tenure of a chief executive was 8.1 years; by 2010, it was down to 6.6 years. Within the pharma industry, C-suite retention is even more tenuous. PwC reports the typical tenure of 4.8 years for the chief executive and just 3.6 years for the head of R&D. This is particularly vexing for an industry whose product development cycle is at least a decade, which leaves decisions to senior managers who won't be around to see it through to the end.

Without a robust talent pipeline of innovative people who have consistent levels of investment, there is diminished probability of enhanced productivity and sucess.

"In large companies, the discovery, development, and life-cycle management of the best talent has taken a back seat to the 'engineering' focus on product development," she says. "For example, in the world today more than 80% of the college graduates are women and people of color. In the United States alone, more than 60% of the graduates with advanced degrees are women. There is a need for different metrics, a different culture, and different skills to develop an entrepreneurial, learning culture that is a precondition for sustained innovation. I tell clients: you can't pull the carrot out to see if it's growing. You can measure success, but you've got to be clear on what the timeframe for success is and what are the qualitative and quantitative measures that are going to be used.

"Ten years from now I don't think this industry is going to be called the pharmaceutical research and manufacturing industry, which is clearly focused on the product; it's an engineering industry model," Ms. Buck Luce says. "Think about it, where's the patient in there? Where's health in there? Where's outcomes in there? Where's health delivery efficiency in there? Where's wellness? There's a lot of experimentation around changing the margins, but the real challenge for companies is to understand what's required to change the business, because the business is no longer about just making medicines. It's about improving consumer's outcomes at an economic benefit to health systems."

**(To read more, see Disruptive Innovation: Courageous Leadership)**

## Changing the Clinical Landscape

The scientific foundation on which pharma rests is improving exponentially, thanks to massive increases in processing power; advances in genetics and genomics; and new data management tools.

Technological developments have also paved the way for electronic medical record (EMR) systems that capture vast quantities of outcomes data.

Despite these advances, PwC analysts say there is still a productivity crisis based on two aspects — one is scientific, the other managerial.

Between 2002 and 2011, they say the pharma and biotech sectors spent almost $1.1 trillion on R&D, yet the FDA approved just 308 new molecules and biologics, which means the annual average cost per approved molecule during that time ranged between $2.3 billion and $4 billion.

This is not a sustainable trend, and companies have already begun to cut their R&D budgets, reduce staff, re-engineer around underlying causes rather than disease areas, and enter into nontraditional alliances.

Research from KMR Group shows that the number of NMEs required to achieve one new drug approval is increasing in every stage of development. From 2007 to 2011, it took an average of 30.4 NMEs in preclinical development to secure one approval compared with 12.4 NMEs in the time frame between 2003 and 2007.

This is a clinical development stage model that some say is outdated and is in need of disruption.

"There are no regulatory requirements to run three phases of clinical studies," says Nick Davies, Ph.D., U.S. pharmaceutical and life sciences advisory services, PwC. "Yet, this is a model that the industry has developed using statistical models to create larger and larger studies to prove efficacy and safety endpoints. We advocate moving, in a safe way, into the clinic with a much smaller and targeted population using biomarkers or genetic indicators of who would be the best population to study. And we advocate the use of an in-live trial model, almost the equivalent of a Phase III trial. Most of the monitoring would

### Innovation — Upcoming Events

**APR 16** April 16-18
**Telehealthcare Leaders Forum**
**Newport Hyatt, Newport, RI**
Tunstall Americas
The conference addresses the dramatic changes that are reshaping the healthcare system and telehealth's role in the evolving business model. For more information, contact Sarah.Turner@tunstall.com

**JUNE 26** June 26-28
**3rd Annual: Alliance Management for Open Innovation in Pharma Revealing the Secrets of Sustainable Collaboration**
**Munich, Germany**
Marcus Evans
The conference focus is on the secrets of sustainable collaborations to embrace the new business model with a competitve edge. Fore more information, visit marcusevans-conferences-paneuropean.com/marcusevans-conferences-event-details.asp?EventID=19729

**SEPT 19** September 19-20
**Disruptive Innovations 2013**
**The Fairmont Copley Plaza, Boston**
The Conference Forum
This conference is designed for drug development innovative thinkers who are determined to reinvent clinical trials. It is an outcomes-focused program that delves deeply into the key strategic factors impeding clinical trial productivity and connects change makers who can share current solutions, propose new solutions, and commit to testing them and sharing the results.
For more information, visit theconferenceforum.org/conferences/disruptive-innovations/overview/

be done in an in-live situation, where the patient is taking the medication at home but being monitored remotely through various devices that are now available."

Analysts say it is critical for companies to focus on understanding the mechanism of disease as much as possible before starting a research program. This means a greater focus on translational medicine to validate targets and small, fast clinical studies designed using sensitive endpoint biomarkers.

PwC analysts say in short, investing more money early on in understanding the molecular basis of a disease and the role a particular mechanism plays reduces the risk of losing a lot more money further down the line. And they say research should be on human studies, not animal studies. On average, pharma companies spend only 7% of their R&D budgets on target/mechanism selection and validation, a fraction of what they spend on clinical trials.

Open innovation is changing the way pharma conducts research, albeit gradually.

## FAST FACT

THE MARKET FOR MEDICINES COULD BE WORTH ALMOST $1.6 TRILLION BY 2020. IN 2010, THERE WERE AN ESTIMATED 6.9 BILLION PEOPLE. BY 2020, THERE WILL BE MORE THAN 7.6 BILLION. AND, IF PRESENT TRENDS ARE ANY GUIDE, MANY OF THEM WILL HAVE HEALTH PROBLEMS.

Source: PwC

### Paramount Change

In its Vision to Decision Pharma 2020 report, analysts at PwC focus on how companies can reach 2020 in a position to better deliver outcomes and derive profit from the changes that lie ahead.

They say the paramount challenge is to create more value for patients, providers, and payers, and thus for shareholders. They acknowledge there is no one right answer and each company's journey is individual, but there are a number of common imperatives.

- Every company will have to **provide real-world data on the outcomes** its medicines deliver, and that will entail setting up a suitable infrastructure to capture such data.
- Every company will have to **decide how much (if anything) to invest in the growth markets**, where to invest, and what strategies to pursue in the countries it targets. The biggest markets might not be the most profitable ones, for example, and the costs of setting up a local manufacturing arm might outweigh the additional custom.
- Every company will have to **be more selective about the diseases it addresses**. Many will also have to consider the implications of investing in new treatment types, such as vaccines and regenerative medicine.
- Every company will have to **invest more in genetics and genomics**, and revise its R&D processes to improve its scientific productivity. This will involve sifting through a plethora of new technologies, singling out the best and making sure they're properly integrated.
- Every company will have to **collaborate with academia, governmental, and nongovernmental organizations** and other life-sciences companies to get access to the best science and eliminate waste.
- Every company will have to **be more discriminating about the candidates** it advances through the pipeline and courageous enough to dump the junk before racking up the bills.
- Every company will have to **behave ethically at all times** and be an organization others want to associate with. That means being open and honest rather than treating compliance as a cost of doing business.
- Every company will have to transform its corporate culture to foster innovation and address the needs of patients, payers, and providers in the 21st century.

Source: PwC: From Vision to Decision Pharma 2020.

**LYNN O'CONNOR VOS** ▪ *ghg group*

***"An exciting disruptive innovation is in the area of client services in healthcare."***

Many of the major pharmaceutical companies are connecting with universities, while others are joining precompetitive discovery federations, where public and private institutions pool resources to overcome shared scientific breakthroughs.

According to Dr. Davies, the other advances are in the use of social media and crowd sourcing to solve certain problems.

"This approach, which has been used for a reasonable amount of time, particularly around chemistry, solving structures, and other ways, is now being used on a much larger scale," he says. "It ranges all the way from the early parts of R&D through to developing and running clinical trials differently. There are definitely new and different models of partnerships emerging."

**(For more information, see R&D Innovation: A Common Goal)**

## The DNA of Research

As genetics and genomics come into their own, diseases can be examined as never before. PwC says by the end of 2011, there were 1,068 published genome-wide associated studies.

PwC has identified the discipline of epigenetics, which allows researchers to understand the impact of heritable biological elements that aren't directly encoded in our DNA as one of the innovations that is driving research forward. In addition, concepts of network medicine, they say provide an understanding between distinct "pathophenotypes." Network medicine allows research to create wiring diagrams of the cells whose breakdown causes a particular disease. They say such diagrams will ultimately help pharma companies develop treatments that

TODD EVANS ▪ *PwC*

***"The channels in the marketplace are blurring and merging, which is a benefit. There's an opportunity to use these new tools to release imprisoned value and discover new value."***

can fix the underlying components of disease, as distinct from its symptoms.

In 2001, it cost $95 million to read an entire human genome. Today, two manufacturers are developing machines that can do so for as little as $1,000 — in a matter of hours.

According to PwC, the industry spends just $6 billion a year, less than 7% of its total R&D budget, on genomics research. They predict that by 2020 pharma could be investing as much as 20% of its R&D budget in genetics and genomics for discovering and commercializing new drugs.

The prospect of personalizing medicine — in and of itself a disruptive innovation — based on genomic insights is closer to becoming a reality. For example, according to sources one genomic research firm CardioDX, has analyzed more than 100 million gene samples to identify the 23 primary predictive genes for coronary artery disease and has developed a test that can identify coronary artery disease at its earliest stages.

**(For more information, see Disruptive Innovation: Genomics)**

## The New Value Prop

For several years now, various industry experts have identified outcomes data as the driving force behind change in the industry.

PwC analysts say rather than creating awareness through marketing and sales, companies can demonstrate the worth their products with real-world evidence of lower mortality and morbidity rates or savings in total healthcare costs.

But using outcomes data requires changes to three major functions — R&D, health economics, and marketing sales.

For example, PwC analysts say R&D will have to focus on creating value for customers when it decides which medicines to bring through the pipeline. R&D will also have to collect proof of that value, using real-world outcomes data.

Furthermore, rather than using unit prices and sales volumes to produce budgets and forecasts, the health economics function will have to use outcomes-based modeling and make sure that investors understand the new model, a system capable of managing a network of continency payments and rebates.

The marketing and sales function will have to make even bigger adjustments, PwC says. Companies will need to grapple with rigorous scientific data and complex economic studies, as well as developing the skills to negotiate with healthcare payers equipped to perform their own analysis.

Deborah Dunsire, M.D., president and CEO of Millennium: The Takeda Oncology Company, says in recent conversations with a number of payers there is agreement that innovation is not just a new class of therapy.

"Innovation, to be truly meaningful, has to change outcomes for patients because we're looking to deliver better health not just new classes of therapy," she says. "Hopefully, new classes of therapies do deliver better health outcomes, which is why we're working on them, but that's not always the case."

As healthcare reform places a stronger emphasis on not only patient outcomes, but the cost of care as well, sees opportunities for technological innovation that can lessen the costs associated with patient care and pharmaceutical development. Interestingly, he looks to the industry, not the consumer, to generate the demand for this change.

"Change is usually created from the result of consumer demand," he says. "However, healthcare is different. Most people have no idea what their treatments and drugs cost, so there isn't direct consumer demand for better value in healthcare. People with insurance mostly care about their co-pay and their annual healthcare insurance premiums, and even that is only once a year. So the real competitive pressure isn't on the product, i.e. healthcare, it's on the insurance company."

He sees data standardization and process repeatability as crucial to achieving the goal of lowered healthcare delivery costs.

"We all know that patient outcomes, hospital companies, and big insurance companies are related, but currently there is nothing tying all of the parts together," he says. "Each hospital system has a different technology infrastructure and environment. There's no common universal standard of data or data models to tie it all together. There's a government mandate to automate processes electronically, but there's no mandate for a common platform. Without a common platform, the real value of electronic medical records will not be realized for many years to come."

## Beyond the Pill

Maximizing the molecule is one way PwC analysts say pharma can create value for consumers. Along the way there are plenty of opportunities for innovation to disrupt the status quo. For example, Porteus Digital Health's chips, ingestible microchips embedded in drugs, allow doctors to tell whether patients are taking their medicines as prescribed.

Other devices in the pipeline include implants that wirelessly inject drugs at prespecified times and sensors that send a patient's electrocardiogram to a smartphone.

Mobile health applications also hold huge potential. PwC cites Happtique as one example in that it launched a pilot program that lets doctors prescribe apps as part of an overall healthcare package.

Experts predict that mHealth will cause disruptive innovation in that it will encourage patients to take responsibility for their own health and provide a means for measuring key health parameters.

Smartphones and video streaming facilities, especially in emerging markets, will open the doors to other health services. By 2020, patients will be able to consult a doctor remotely and send information about their symptoms during the consultation itself.

Hospitals in major cities will also be outfitted with interactive holograms that can answer basic health questions, eliminating the need to talk to a doctor at all in some cases.

Gamification **(see the February issue of PharmaVOICE)** and health video games are making their way into the healthcare space.

PwC analysts say biosensors will eventually be able to record everything we eat and drink as well as the amount of exercise we undertake.

These examples, according to PwC, demonstrate how some companies are creating new businesses and business models, not just new products or services.

All of these market disrupters will help to improve compliance and plug the leak in the system that PwC analysts say costs upward of $493 billion a year.

Many of the innovations that are in the works are reminiscent of what used to be referred to as science fiction or bionics. Technol-

ogy is rapidly advancing to produce biosensors that can monitor health and vital signs remotely.

PwC says the race is on to develop a Star Trek-style medical tricoder, which can be used to diagnose a patient's condition simply by scanning his body.

"We are also starting to see technologies that enable us to generate 3-D structures, such as trachea, capillaries, and arteries," Dr. Davies says. "It doesn't seem like a giant leap of faith or imagination to predict that in the future we could be manufacturing organs. The unmet medical need there is huge. These are not things of science fiction; there are already treatments available today on the marketplace."

Other new technologies, such as those in the audio field, will transform the way in which patient data are recorded, captured, and reported.

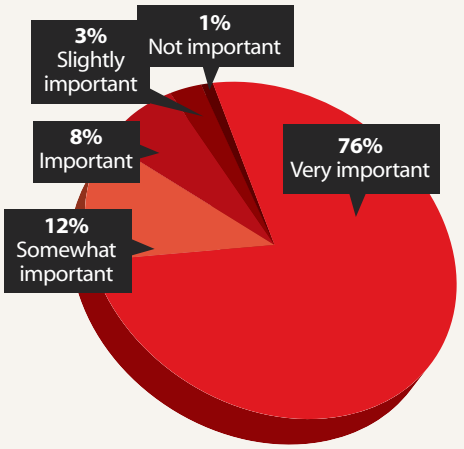
Still other examples include a smart tattoo in development at MIT. Using nanoparticle ink, glucose levels can be tracked in patients with diabetes.

**(For more information, see the exclusive bonus digital article: Patient Adherence Tools Get Personal)**

## Innovation For Competitive Advantage Leads The Way

At the beginning of 2012, Insigniam sought out the forward-facing sentiments of executives among Global 1000 companies. The results show sentiments across four dimensions critical to organizational transformation and lasting change: elevating performance, accountability, employee engagement, and innovation.

**What is the importance of innovation in your organization's ability to succeed and strengthen competitive advantage in the next 12-36 months?'**




Insigniam's study revealed that 76% of executives feel that innovation is very important to their ability to succeed and strengthen competitive advantage in the next one to three years.

Executives want results and they want them quickly, and innovation is clearly a priority for any organization that wants to be competitive in its industry and successful both on a micro and macro level. Innovation that is executed with speed is how organizations see the most favorable results, and an underlying correlation in this survey points to the frustration executives share with the biggest enemy to innovation — complacency embedded in organizational culture. Overcoming this obstacle requires leaders to become aligned through challenging conversations to create breakthrough results, further supported by the previous insights on concerns with people and managing change.

Responses from executives showed they believe innovation means:

- Bringing new value to their customers that makes their lives better
- Being the first in the market to be different.
- Creating new ideas and ways of working.

Based on their comments, respondents see innovation as a way to create new perspectives throughout their organizations, take risks, and transform business from the old to the new, creating lasting change, unprecedented growth, and breakthrough results.

Insigniam also asked executives to define innovation. Their answers fell within six categories:

- **Process:** internal processes, procedures, and practices
- **Offerings:** products or services offered in the market
- **Strategy:** business model, funding, or partnerships with other firms
- **Marketing:** manner of delivering value message in the market
- **Ideas:** related to the concept of new ideas, irrespective of domain
- **Change:** using the word "change" or referring to the concept

Source: Insigniam. For more information, about the survey, contact Alexes Fath at afath@insigniam.com.

## The Patient at the Center

Driven by payers that are looking for more value for their money, innovation will continue to redefine how pharma companies address patient needs.

According to PwC, the pharmaceutical industry has focused on about 15% of the health budget that goes on medicines, which leaves another 85% from which it can generate revenue by reducing consumption of more costly medical services.

Companies need to focus on treatments that prevent disease, reduce the overall use of resources and let patients stay as productive as possible for as long as possible. These are the types of medicines, PwC analysts say, that governments and health insurers in mature markets will buy.

"To really be innovative, I think we as leaders need to be absolutely focused on whatever scientific advance we can capitalize on to bring forward new therapies that truly change outcomes," Dr. Dunsire says. "The question that needs to be very firmly at the front of one's mind is: what will this deliver to patients that is not available to them today? Keeping the patient central to the equation creates challenges and pushes us to solve problems."

Beyond the clinic, an exciting disruptive innovation is in the area of client services in healthcare, says Lynn O'Connor Vos, president, ghg group.

"Improving the customer experience in healthcare is very exciting," she says. "This is an area where many consumer companies, such as the airline industry, are excelling. Recently, I was on a plane and I found out that the flight was delayed via text before an on-board announcement was even made. Airlines are trying to improve their customer service by making it easy for consumers. The healthcare industry is pretty far behind in terms of consistency and touch points to make it easier for the patient and consumer to interact. There is no other industry in which a consumer would tolerate having to call on a phone to make an appointment, wait three weeks to see someone, drive to an office, sit for another 45 minutes, see someone for five minutes, and walk out with a piece of paper. There will be disruption."

Ms. Warfel agrees that the same level of customer service and experience that people get from their bank or from their mobile services provider should be provided by the healthcare industry.

"We're starting to see the industry evaluating what the financial services industry is doing, what the communications industry is doing, and looking to these industries for guidance," she says.

On another note, Ms. Vos says because of the predicted shortage of physicians worldwide, much more treatment will be driven at the allied health professional level.

"This is the next level of disruption and an opportunity for pharma to understand how to empower and harness the influence of the allied health professional, whether she is an optometrist, a veterinary assistant, a dental hygienist, a pharmacist, and so on," she says.

David Zaritsky, president, Roska Healthcare, believes the big winners will be those companies that focus on two things: strategy and good old-fashioned storytelling.

"The reason people engage in a really good traditional story is because they can recognize themselves," he says. "They aspire to be somebody they're emotionally caught up with. The real winners moving ahead will start strategically with a great story, understand the protagonists, who are the physicians and the caregivers, and tie it all together seamlessly."

**(For more information, see Disruptive Innovation: The Patient-Centric Business Model)**

## Innovation Ahead

Todd Evans, director, PwC pharmaceutical and life sciences advisory services, says in comparison with financial services, high technology, even the automotive industry — where there's been substantial change on a near continuous basis for quite some time — the pharmaceutical and life-sciences industry has been relatively stable over the last three or four decades.

"Yes, we've seen some changes but not of the titanic structural nature that other industries have already gone through," he says. "We're now facing that as an industry ourselves. We're seeing a compression in the life cycle of benefits delivered. This is not necessarily about patent life or exclusivity, it's more a statement on how a solution is regarded and the fast moving nature, both structurally and of metrics, that are being used to measure value. This is a major challenge for the industry and it requires a degree of flexibility to receive new sensors of innovation and incorporate them into solutions.

"The channels in the marketplace are blurring and merging, which is a benefit," Mr. Evans continues. "There's an opportunity to use these new tools to release imprisoned value and discover new value. Our value as an industry has been trapped in a price and that price has gone through a bidding process that establishes where a product is on a formulary, which may or may not have a correlation to its true therapeutic value or its broad value within an episode of care. We're moving from a unit transaction view of value to an episode of care value, which allows tangible products to become combined with other aspects or solutions, be they technology-driven, information-driven, or services-driven. And when a pharmaceutical or device is combined with one of these tangible products, it creates a whole new level of discussion, impact on metrics, and frankly, value within an entire episode of care."

PwC analysts say any company that wants to reach 2020 will either have to offer more value without charging more or prove unequivocally that it can remove costs from another part of the healthcare system to make room for the higher prices being charged.

"When we talk about outcomes and all of the market dynamics in that space, I just don't think it fully translates back to the pharmaceutical industry," Mr. Benton says. "We've got to find a way to bring new therapies to market faster and cheaper over time. We need to continue to drive innovation, drive better ways of doing business, and be ready for when pressures really start to come about." PV