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Connections

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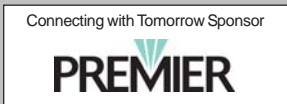
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Summer Thoughts **Kaizen and Gardening**

By Jon Roberts

As a healthcare consultant, I spend a lot of time in hospitals teaching people new ways to approach the challenges they face. When I'm not "on-site," I work from home and find that I like nothing more than tinkering around the house and yard, as I'm not able to do when I travel. I often wonder if I employ the framework that I teach when it comes to my life, outside of work. My name is Jon Roberts, I am a consultant and yard work enthusiast and this is my story.

Last spring my wife and I moved from the northeast to Portland, Oregon. We bought a house that, like many homes in the moist and temperate Pacific Northwest, has a bountiful yard and garden. We were excited to begin creating our own outdoor paradise. We had family and friends give us their thoughts and spent countless hours exploring the neighborhood for ideas of what we wanted.

We had an 800 square foot "patch" of ivy that ran from the sidewalk to the top of our sloped front and over a chain-linked fence. I was told that the ivy was likely to take over the yard, as it was already beginning to do, and kill everything in its path. We wanted it gone. Because of the sloped yard, we would need to plant some things to hold the soil down; that appealed to us. Also in the front, we have a large Cedar tree that is surrounded by a rock wall and about 500 square feet of soil and pine needles. It needed to be spruced up with a few strategically placed plants. In the back, we had a forest of running bamboo, which has grown up to 30 feet tall, that was sprouting in unwanted places. At the advice of nearly everyone, we decided it would be best to remove the bamboo and replace it with something that was a little more respectful of its neighbors.

Lastly, we had a few lilac bushes that were suffocating the back yard and we decided that removing them would really open things up.

Armed with a vision, we had a landscaper come by to give us a bid on what the heavy lifting would cost. When I received the estimate, I felt ridiculous for having asked him to come by. I would need another loan to get this stuff done. We would have to take on the yard the old-fashioned way, getting our hands dirty, bound by a budget, and slowly, over time.

Since that time, we've learned a lot about how we function in our space and what we prefer. We've also had an opportunity to save some money. First, after an initial day of hacking, we found that "evil" ivy is actually fairly easy to maintain and truly lovely when the new leaves come in. We wouldn't trade it for anything. The area around the cedar tree gets great afternoon sun and my wife and I love having dinner there. Also, we have a wiener dog, "Pants," who loves chasing squirrels around the tree. We've had to build steps that travel up the rock wall so that the dog will stop leaping from it.

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Kaizen and Gardening (Continued...)

(Dachshunds are known to often injure their backs.) We've also found that having that area as a functional space for people to gather has been great for when we're entertaining. Had we jumped right in and added some plants, this might not have worked so well. With the help of someone at a local bamboo supplier, I was able to contain the sprouts and we love the privacy. Now, when I look at the tallest sprouts, I'm excited! Lastly, we received a notice from the city of Portland that we could save \$20 a month by reducing our input into the city water drains. I simply removed a spout and fed the lilacs. I've trimmed the plants back and the back yard looks great.

If you've made it this far in the column, you might be wondering, "what in the world does this have to do with the challenges that a healthcare administrator faces?" I realized this winter, when I finally had some time to relax, that my approach towards improving our yard had changed, and I was lucky for it. Rather than make a huge, and impossible, capital investment, I had to make small improvements over time. I think there's something valuable here for healthcare.

Consider that an overgrown yard, and how a family uses it, is similar to the organization you work for. There are probably many things about your organization that you'd be happy to change once and for all. Unfortunately, it is incredibly expensive to do that and, more importantly, you probably wouldn't be happy with the results.

Lesson: Your needs will change

Getting a dog was something my wife had talked about for a while, but when it happened it was largely unexpected. I think this is similar to the way an organization grows. You could guess that it will happen, but you don't necessarily know when or how. Also, you don't know how this will change the organization. Had Betsy and I gone ahead with the "vision" we had of our perfect yard, we would have wasted some of that initial investment and probably had to spend even more money when we learned that the dog will do what he wants when it comes to chasing squirrels. So, we would have squandered a lot of money and created an environment that was inflexible to a real safety issue.

Lesson: Flexibility is worth money

Receiving the letter from the city about our drainage and a welcomed way to save money was also unexpected. I would have kicked myself had I removed the lilac and then considered planting it over again to "drink" the run-off. Can you think of any large scale changes that have prevented your organization from saving money in a way that was unexpected? I bet you can.

Lesson: "Problems" today may not be problems tomorrow

Lastly, consider the bamboo and the ivy. My own reaction, along with "informed" others, was that both would be a real problem and needed to be removed. With a little information, and a much smaller investment, I was able to actually appreciate these things. They are no longer a problem and actually enhance the space. Has your organization ever made a big investment only to find that it was a bad idea? Think large-scale technology adoption.

The key here is seeing the challenges that your organization faces, breaking them into small pieces, and learning to embrace change. Rather than trying to create perfection all at once, understand that the environment will always be changing and so will the needs of your organization. Adopting a systematic form of Kaizen, or continuous improvement, is the key to avoiding the pitfalls of large scale investments. I can hear what you're thinking, "Some big investments are unavoidable!" You're right, but armed with the skills that come with constantly making small improvements, you're sure to make big changes with an eye for flexibility.

Consider all this the next time you have an expensive proposal in front of you. The only thing I can guarantee about the future of your organization is that it will not look the way that you expect it to right now. Knowing that, what are you going to do about it?

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No Constituency for Quality?

By Rick Kneipper, Chief Administrative Officer and Co-Founder of PHNS

Healthcare has been the red-hot subject "Inside the Beltway" during the past few months, both regarding healthcare reform and regarding the use of stimulus monies to improve healthcare.

During recent weeks many voices, including this one, have spoken out strongly to urge leaders in Washington, DC, to ensure that the federal stimulus monies are only spent for technologies that improve patient care and quality, as specifically mandated in the American Recovery and Reinvestment Act, and not merely to continue the current transactional focus of healthcare information technology.

In addition to commentaries in *For Your Advantage* and in other publications, I also had the opportunity to make my plea to the Congressional Health Care Caucus, which is led by Congressman Burgess, R-TX, and to numerous Congressional leaders.

Other strong and powerful voices have been persistently advocating that result for a long time, including Carol Diamond of the Markle Foundation, Mark McClellan of the Engelberg Center for Health Care Reform at The Brookings Institution and Todd Park of the Center for American Progress.

The principal counter-arguments to these views do not oppose the objective of using stimulus dollars to improve patient care and quality (it would be hard to oppose that publicly, especially in light of the clear Congressional mandate), but advocate a much slower pace for improvement of patient care and quality.

But the most mind-boggling comment during all of these discussions on the Hill came from a very highly regarded Congressional expert on healthcare. She said that while improving patient care and quality were extremely important objectives, the political reality is that "there is no constituency for patient care

quality" and thus it will be hard to keep everyone focused on improving patient care and quality. After initial reactions of shock, protest, outrage and confusion, I began to think about the validity of her comment.

The Institute of Medicine shocked the public when it announced in 1999 that approximately 100,000 people were needlessly dying in hospitals each year. Since then, there have been only small percentage points of improvement in our healthcare quality. The number of approximately one million unnecessary deaths during the last 10 years is difficult to grasp.

So where's the loud public outcry about these deaths that we hear when way smaller numbers of soldiers and civilians were killed in Iraq or Afghanistan (a total of 4,299 and 686 have died thus far in these wars, respectively) or when H1N1 (aka. Swine Flu) killed 761, or when an Airbus A330 crashed and killed 228 off the coast of Brazil?

Is there really no constituency for improved patient quality and care? I don't think so (or at least I hope it's not so). Or is it that the public isn't getting bombarded with regular news reports regarding the unnecessary deaths and unnecessary errors in our healthcare system, and so they don't know about the quality problem? Whatever the case, I think that legions of U.S. hospitals, physicians, nurses and caregivers have been and continue to be powerful advocates for improved patient care and quality, but apparently they need to be a more vocal constituency so that our leaders in Washington can hear them.

You can be a voice for quality patient care – Congress needs to hear from you.

I would like to hear your comments.

Send them to:

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Reform Takes the Next Step in Congress

It happened last week. It was a milestone. A Senate panel became the first congressional committee this year to approve major healthcare legislation. Now we move on from there.

The Senate Health, Education, Labor and Pensions Committee bill would create a controversial government-run health insurance plan and require employers to provide health coverage for workers or face stiff financial penalties. The bill has gotten heavy criticism from business groups and Republicans, who say it would come at too high a cost to taxpayers and the private sector.

The bill was approved along party lines in a 13-10 vote.

The bill's prospects are unclear, reports *The Wall Street Journal*. Senate Democrats plan to combine it with another measure being negotiated by members of the Senate Finance Committee, which may exclude elements such as a government-run health plan in order to gain the support of moderate Democrats and Republicans.

Because of the tenuous negotiations on the Finance panel, Democratic boosters of healthcare legislation concede that it will be difficult to pass a bill in the Senate before a month-long congressional recess in August, their stated target.

The Health Committee has labored for nearly a month on the bill – an unusually long period of time. Sen. Christopher Dodd, D-CT, acting chairman of the committee, allowed consideration of dozens of Republican amendments to a bill with a liberal orientation.

Many of the amendments were adopted, including several aimed at stemming healthcare and Medicare fraud, and one sponsored by Sen. Tom Coburn, R-OK, that would require members of Congress to enroll in the new public plan. But Republicans complain that any of their amendments that would change the basic outline of the bill were rejected.

While Sen. Dodd frequently mentions conversations he

has with the committee's chairman, Sen. Edward Kennedy, D., MA, nearly every hearing and meeting on the bill this year occurred in the absence of the ailing Sen. Kennedy. Still, the bill bears his imprint; Sen. Kennedy has been a vigorous supporter of extending health insurance coverage to the over 40 million Americans who currently lack it.

As written, the bill would add 21 million people to the ranks of the insured at a cost of \$611.4 billion over 10 years, according to the nonpartisan Congressional Budget Office. But committee staff said that once the Finance Committee approves legislation that would expand eligibility for the low-income Medicaid program, 97 percent of Americans would carry insurance.

Under the employer mandate proposal, firms with 25 or more employees that don't offer coverage would face fees of \$750-per-year for full-time workers and \$375-per-year for part-time workers. Individuals who chose not to carry insurance would face a penalty of up to \$750 a year as well.

The bill would create health insurance "gateways," in which individuals who do not qualify for Medicaid and do not receive employer-based health coverage could purchase insurance. One of their options would be the public plan, which would be run by the Department of Health and Human Services.

Families and individuals at up to four times the federal poverty level – \$88,000 for a family of four – would receive federal subsidies to purchase insurance.

The committee approved an amendment that would protect makers of biologic drugs from competition from generic drug manufacturers for 12 years.

The drugs – which are manufactured using living cells – represent a growing segment of the pharmaceuticals industry. The committee vote on the amendment, sponsored by Sen. Orrin Hatch of Utah, and Sen. Mike Enzi, R-WY, gave the biotechnology industry a major victory.

About



PHNS provides IT services for hospitals, other healthcare providers and businesses. PHNS' IT services include application hosting, co-location and managed services; electronic off-site data back-up and data vaulting; business continuity solutions; disaster recovery services; and systems integration services. PHNS also provides comprehensive business process

solutions for hospitals including admitting, HIM (including medical record management and storage, transcription, coding, release of information and electronic medical record services) and revenue cycle services. PHNS creates business-healthy hospitals by improving operations, enhancing technology and increasing cash on hand, which allows hospitals to focus on their core competency--patient care. PHNS has approximately 1,670 customers, including approximately 400 hospital IT and business process customers and approximately 1,270 IT customers. PHNS is headquartered in Dallas, Texas. See www.phns.com for additional information about PHNS.

Purchasers Beware: Better Oversight of Foreign Pharma Plants Just the First Step

By Mike Alkire

In 2008, the Food and Drug Administration estimates that as many as 146 patients died in the U.S. after receiving heparin manufactured using counterfeit raw materials in China. The contaminated heparin contained oversulfated chondroitin sulfate, which costs \$9 a pound compared with \$900 a pound for heparin.

Sadly, this is not an isolated incident. The World Health Organization says up to 10 percent of the world's medicines are fakes; in China and India, that's true for up to a third of medicines sold. Even so, U.S. drug companies purchase 40 percent of their active pharmaceutical ingredients, or API, from the counterfeiting hotbeds of India and China – with some estimating this may reach 80 percent within 15 years.

Chinese authorities are weak enforcers of drug regulations, mostly because corruption and bribery have allowed counterfeiters to thrive. Moreover, the Chinese government has a record of obscuring health scandals to avoid embarrassment. In the case of API, the Chinese say that they aren't responsible for ingredients used outside the country, so they aren't regulated. The problem isn't better in India, where there is no drug regulatory agency.

Although the U.S. Food and Drug Administration is supposed to conduct regular inspections of overseas facilities, the agency has just eight inspectors for all device and pharmaceutical manufacturing in China. Considering the volume of overseas production, these facilities may get inspected every 13 years compared with every 2.7 years in America.

Meanwhile, the FDA does not even have a

comprehensive list of foreign API suppliers, so there may be more facilities that have never been inspected. I hope a reinvigorated FDA under Margaret Hamburg and a new Congress with a stated commitment to drug safety will do more.

We need government action to ensure rigorous oversight of the supply chain – from chemicals to finished products. Leading experts agree that U.S. authorities can't be everywhere, so some of the responsibility for registering and inspecting facilities must be led by foreign regulators. In most nations, oversight can be trusted. In nations like China and India, regulators must get serious about preventing counterfeiting, and U.S. trade authorities must work to ensure adequate oversight is in place.

Second, the U.S. government needs to pressure foreign nations to regulate API the same way they do finished pharmaceuticals, and ensure those laws are *enforced*.

Lastly, criminal penalties for counterfeiting must be strengthened. Even in the U.S., counterfeiting a drug label is punishable by up to 10 years in prison, while counterfeiting the drug gets only three years. To fix the problem, we need the same enforcement and interagency coordination that we devote to other global organized crimes. These increased penalties need to be included as part of trade agreements and enforced via cooperative coordination among law enforcement.

Knowing the challenges of regulating API from regions with poor safety records, manufacturers should exert more control by requiring that suppliers meet distribution and safety standards.

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Purchasers Beware: Better Oversight of Foreign Pharma Plants (Continued...)

Manufacturers can reduce risks by obtaining intelligence about the distribution chains for imports, establishing procedures to qualify suppliers and ensuring the purity of ingredients.

Manufacturers should inspect suppliers rigorously and repeatedly and have a traceable supply chain to identify raw materials to the lot level. Each lot should be inspected by quality control to ensure purity, in compliance with good manufacturing practices. Suppliers should provide audits and drug master files as evidence that materials are from safe sources.

Manufacturers have most of these measures in place today, but compliance abroad is inconsistent. Manufacturers may want to revisit their policies and do further due diligence to address new safety threats. In every case, manufacturers sourcing abroad must be vigilant and design quality controls that set the highest bar for safety.

For purchasers, protecting patients requires factoring in safety before buying. Do you know where the pharmaceuticals in your facility are made? Does the manufacturer have in place adequate controls to ensure the safety of their API? These are not questions typically asked, but the risk of not knowing could mean putting lives in jeopardy.

One way for hospitals to get answers on safety

is to assign the task to their group purchasing organization. GPOs develop contract terms with hundreds of manufacturers, and can insist on transparency – that drug manufacturers disclose where the medicine was made, the safety and quality measures in place and whether additional steps have been taken, such as working with an accreditation or third-party auditor to ensure safety.

Armed with this information, hospitals can choose products based on the protections in place, and take significant steps to improve safety while creating a competitive incentive for manufacturers to continually enhance safety protocols.

According to former FDA associate commissioner Peter Pitts, pharmaceutical counterfeiters are committing nothing short of healthcare terrorism. There are serious risks affecting patients, and we have a moral imperative to ensure safety and punish those who would put lives in jeopardy. We all have a role to play and a responsibility to get it right. Anything short of that is unacceptable.

Mike Alkire is president of Premier Purchasing Partners, part of the Premier healthcare alliance.



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